CMS-1427-P-164

Submitter : Mr. Mark Walters **Date & Time:** 10/07/2004 01:10:12

Organization : Adventist Health Systems' Florida Hospital

Category : Hospital

Issue Areas/Comments

Issues 21-30

Payment Rate for APCs

Please accept my comments and concerns regarding the Department of Health and Human Services Centers for Medicare & Medicaid Services' 2005 Hospital Outpatient Prospective Payment System proposed rule (Proposed Rule) that sets forth new reimbursement rates for hyperbaric oxygen therapy treatment (HBOT), 69 Fed. Reg. 50448 (Aug. 16, 2004). The new rate is excessively low and has negative ramifications for patients and providers.

For perspective, Adventist Health System (AHS) is part of a tradition that began promoting the benefits of good health more than a century ago. In 1866, the Seventh-day Adventist Church opened its first healthcare center in Battle Creek, Michigan. It was a special place where scientific treatment of disease was combined with education in the prevention of disease--a tradition that continues in Adventist healthcare today. Around the world, the church sponsors more than 500 healthcare facilities dedicated to helping people achieve physical, mental and spiritual wholeness. These include approximately 160 hospitals in addition to nursing homes, dispensaries and clinics.

Adventist Health System's flagship organization is Florida Hospital, a 1,793-bed tertiary care center with seven campuses in Central Florida. Established in 1908, Florida Hospital is now the largest healthcare provider in Central Florida and is the nation's leader in cardiac care. It is also an established leader in cancer care, neuroscience, orthopedics, organ transplantation, limb replantation, sports medicine, rehabilitation and women's medicine. The Hyperbaric Medicine Unit has the area?s only multiplace chamber to treat critically ill patients suffering from life threatening diseases such as gas gangrene, carbon monoxide, and cerebral air embolism.

The danger in reducing the APC rate is that hyperbaric units may not recoup enough revenue to offset the expenses of staffing, supplies, and overhead allocations. The resultant course of action may be a reduction services offered to the community and the subsequent decrease in quality of care provided. My request is that CMS recognize and implement the Hyperbaric Oxygen Therapy Association (HOTA) position and the Lewin Group's findings. Please consider the following four items.

1. Leave the HBOT reimbursement rate at CY 2004 levels until CMS has an opportunity to develop and perform a calculation that will accurately detail HBOT costs and cost-to-charge ratios.
2. Due to the differences in which the hospitals have reported costs, adopt the overall cost to charge ratio (CCR) of .47
3. Apply the Lewin Group methodology to the 389 hospitals that reported hyperbaric claims for the year 2003.
4. Adopt the Lewin Group approach at $118.21 per 30 minute increment.

Thank you in advance for your action to assure hyperbaric oxygen therapy remains available to patients across the USA.

Respectfully submitted by,
Mark Walters, Administrative Director
Adventist Health System's Florida Hospital: Hyperbaric Medicine Unit
601 East Rollins Street
Orlando, FL 32803
407 - 303 - 5720

CMS-1427-P-165

Submitter : Mr. Glenn Hackbarth **Date & Time:** 10/07/2004 03:10:45

Organization : Medicare Payment Advisory Commission

Category : Congressional

Issue Areas/Comments

GENERAL

GENERAL

See attached PDF file.

CMS-1427-P-165-Attach-1.pdf

MEDPAC Medicare Payment Advisory Commission

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Glenn M. Hackbarth, J.D., Chairman
Robert D. Reischauer, Ph.D., Vice Chairman
Mark E. Miller, Ph.D., Executive Director

October 7, 2004

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

Re: File code CMS-1427-P

Submitted electronically

Dear Dr. McClellan:

The Medicare Payment Advisory Commission (MedPAC) welcomes the opportunity to comment on the notice of proposed rulemaking (NPRM) entitled *Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates* (August 16, 2004). We appreciate the ongoing efforts of the CMS staff to administer and improve the outpatient prospective payment system (PPS), particularly considering competing demands on the agency.

As you know, services provided in the hospital outpatient department are classified into ambulatory payment classification (APC) groups for payment. Each APC group is given a relative weight. Payment is determined by multiplying the relative weight by a conversion factor. The proposed rule documents changes in the composition of some APC groups and proposes changes to the relative weights based on analysis of claims and cost report data. The NPRM discusses new policies required by the Medicare Prescription Drug and Modernization Act (MMA), payment for drugs, parameters for outlier payments, and the movement of some services from new technology APCs to clinical APCs. Finally, the rule estimates the calendar year 2005 update to the conversion factor.

Our comments on the proposed rule center on three issues: changes to the outlier policy; payment for drugs; and movement of items from new technology APCs to clinical APCs.

Outlier payments

Based on MedPAC analysis, CMS proposes to add a fixed dollar threshold to the outlier policy. Previously, the only threshold was relative to each APC's payment rate. Under the new proposal, in order for a hospital service to qualify for outlier payments in 2005, it must both cost more than 1.5 times

the APC payment amount AND cost more than the sum of the APC rate plus $625. The outlier payment will cover 50 percent of the costs above the threshold. Although MedPAC recommended eliminating the outlier policy, we appreciate that implementing a dollar threshold is the only regulatory action CMS can take. We agree with CMS's conclusion that the dollar threshold will allow for better targeting of outlier payments to the most expensive services.

Payments for drugs (drugs, biologicals, and radiopharmaceuticals non-pass-throughs)

The MMA required CMS to pay separately for all drugs costing $50 or more per administration. It set specific payment levels based on a reference average wholesale price (AWP) for most, but not all, drugs. Given the MMA provisions and other considerations, the proposed payment rates for drugs are more complex than ever. Payments for drugs are determined many different ways, depending on their cost, their treatment under the MMA, and their newness. One indicator of complexity is the number of APC codes for separately paid drugs: of a total of about 780 APCs, just under 40 percent are for separately paid drugs. MedPAC has concerns about the threshold for separate payment, payment methods for drugs not covered by the MMA, the proposed treatment of Aranesp and Procrit, and the implications of payments for new drugs for the pass-through provision.

We continue to be concerned about the use of an arbitrary cut-off ($50 per administration) for separate payment of drugs. The difficulties of this standard are highlighted in the proposed rule, where a class of drugs, anti-emetics, had some drugs fall above the threshold while others fell below. To ensure that payment rules do not impede access to a particular anti-emetic, CMS is proposing an exception to the packaging rules that would provide separate payment for all anti-emetics, including those falling below the threshold. While treating all anti-emetics similarly probably makes sense, the policy giving rise to this situation is problematic. MedPAC is concerned that separate payment for some, more expensive, drugs gives hospitals an incentive to use those drugs rather than those that are packaged into the payment rate for related services. The threshold also gives manufacturers an incentive to price their drugs to ensure that they are above $50 per administration. CMS should carefully analyze alternative thresholds or the creation of larger bundles to allow for alternative approaches once the MMA provision requiring a $50 threshold expires in 2007.

The MMA established payment methods for several categories of separately paid drugs. For two groups of drugs, CMS had discretion in how to set payment: those coming off the pass-through list this year; and the 41 drugs that have never been eligible for the pass-through, or that were historically packaged, but are now above the threshold for separately payment. The agency proposes to treat these groups differently, with the drugs coming off pass-through paid as if they were covered by the MMA (based on a reference AWP), and the older drugs paid based on the median cost data from claims. Given that one purpose of the pass-through payments is to allow time to accumulate data on costs, there seems to be no reason to believe that claims data are more accurate for one category of drugs than the other. The drugs coming off pass-through and the older drugs should be paid consistently. To help inform the decision of which approach to take, and to better understand the impact of the MMA, it would be useful to have a comparison of what the rates for separately paid drugs would be using the claims data with the rates in the proposed rule.

The MMA requires CMS to pay 95 percent of AWP for newly approved drugs and biologicals that do not have a HCPCS code. CMS also proposes to pay 106 percent of the average sales price (ASP) (as determined under the physician fee schedule) for drugs and biologicals newly approved by the FDA that have a HCPCS code. This class of drugs was not mentioned in the MMA. This proposal represents a

change in policy; previously, drugs of this nature were packaged until sufficient claims data were accumulated to calculate payment rates, unless they received pass-through status via an application process. With the change in policy, all newly approved drugs and biologicals with a HCPCS code will be paid the same, whether or not they meet the pass-through criteria of newness and costliness (MedPAC has recommended that clinical benefit also be a criterion). In addition, those newly approved drugs and biologicals that do not go through the pass-through payment mechanism will be added to the fee schedule without any control on spending. While the pass-through payments have a budget neutrality provision, the new policy does not. Given that the pass-through policy exists as a controlled mechanism for introducing new drugs into the PPS, these drugs should either be treated through the pass-through process or continue under the previous policy.

We note that the proposed rule sets payment for both Aranesp and Procrit according to the formulas in the MMA. Previously, functional equivalence was used to justify equivalent payment. As costs to the Medicare program continue to grow, the program will need to examine tools for obtaining value in its purchasing. We believe that, absent evidence that the previous policy denied beneficiaries' access to needed treatments, CMS should pursue value-based purchasing where possible.

Movement of items from new technology APCs

The outpatient PPS puts certain new technologies into separate APCs with payment based only on costs, as reported by those applying for new technology status. CMS proposes to move 24 services (as denoted by HCPCS codes) from new technology APCs to clinical APCs because the agency feels it has adequate claims experience on which to estimate costs. A number of PET scans are included in the services to be moved in 2005, for which the claims data indicate a significant reduction in payment. CMS is considering three approaches to setting payment for these services: a) use the claims data; b) keep the services in a new technology APC; or c) base payment on a blend of these two approaches. For example, payment for a PET scan used in diagnosing lung cancer (e.g., HCPCS G0210) would decline from $1,450 in 2004 to $899 in 2005, if payment were based on the hospital cost data. The blended payment approach would result in a payment of $1,150.

Services are placed in the new technology APCs based on data submitted by the applicant. One goal of the new technology APCs is to allow sufficient time for data on costs to accumulate. Barring convincing evidence that the cost data from hospitals are flawed and the resulting payment rates would limit beneficiary access to care, CMS should use hospital cost data to set payment rates for services moving from the new technology APCs. In this way, the same methodology will be used to set payment rates for services already in a clinical APC and those moving from a new technology APC to a clinical APC. MedPAC appreciates your consideration of our comments. If you have any questions, feel free to contact me or Mark Miller, Executive Director.

Sincerely,

Glenn M. Hackbarth, J.D.
Chairman

Submitter : Nancy Payne **Date & Time:** 10/07/2004 04:10:39

Organization : Allina Hospitals and Clinics

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

Please review attached document with all of our comments. Thank you.

CMS-1427-P-166-Attach-1.doc

ALLINA
HOSPITALS AND CLINICS

October 7, 2004

Mark B. McClellan, M.D., Ph. D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1427-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: File Code CMS – 1427-P, Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Program System and Calendar Year 2005 Payment Rates; Proposed Rule", August 16, 2004, Federal Register.

Dear Dr. McClellan;

I appreciate the opportunity to comment on the proposed rule concerning the hospital outpatient prospective payment system on behalf of Allina Hospitals & Clinics. Allina Hospitals & Clinics 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, pharmacy and hospice services. Allina serves communities throughout Minnesota and western Wisconsin.

Thank you for the comprehensive rule. 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.

General Comments

The purpose of commenting on rules and regulations is to help CMS identify issues and errors in your proposals. The short timeline between the comment date and the effective date of the final rule does not allow adequate time for system/software changes. We encourage you to change your proposed rule publication date to July 1, with the final rule to be published on October 1. We would appreciate one additional month to plan and implement the final OPPS rule. This is especially important with the elimination of the HCPCS grace period and requires that all of our systems and our vendor systems are all up to date within the 2 month period. We understand that this timeline would create issue with the inpatient rule; however the inpatient rule is not nearly as complex to administer. We would support the publication of the proposed outpatient rule prior to the publication of the final inpatient rule.

Inpatient List
We continue to support the Advisory Panel's recommendation to eliminate the Inpatient Only Procedure List and support any movement of procedures off of the list.

New Technology APC's
PET Scans
We have evaluated the financial impact of all 3 options and would support Option 1. By keeping PET scans in the new technology APC 1516, CMS can continue to gather data and build a better decision making foundation. We suggest that CMS consider the wide variation in costs of PET Scans and look at integrating this technology into a number of APC's in order to capture that variation in the future.

Unlisted HCPCS Codes
We do not support the movement of any more of the unlisted HCPCS codes to the lowest level APC. We have processes in place to assure that we are not using the unlisted codes inappropriately and feel that this proposed change penalizes good coding practices with lower payment. New HCPCS codes are not assigned on a timely basis and we are forced to use unlisted codes where we have no specific code. The new procedures may be very costly and with reimbursement at the lowest level because we don't have a specific HCPCS code may impact access.

Physical Examinations
We appreciate the government's recognition of the importance of preventative services and hope to see additional coverage in the future. While the new beneficiary physical examination is a great first step, we have some concerns for the limited extent of coverage it provides. Screening laboratory tests such as cholesterol and hemoglobin should be considered standard in order to establish a baseline for future follow up and treatment. The EKG should not be packaged as part of the physical but paid for separately as it may be completed by a different billing entity than the physical.

Mammography
We support the change of screening and diagnostic mammography in being moved from the OPPS structure to the physician fee schedule.

Multiple Procedure Claims
Although we support the work that CMS has done to try and factor in a portion of the multiple procedure claims with the pseudo claim data, we continue to have concerns that you do not have a representative sample of claims when so many of our claims are for multiple procedures. The overall integrity of data used to set rates for the OPPS program is questionable. We understand the complexity in getting at this data and support any efforts on the part of CMS to factor in a greater percentage if not all of the multiple procedure claims. It is only in looking at all claims that CMS will be able to accurately apply the calculations and establish rates that reflect hospital costs.

Calculation of Median Cost
Due to the elimination of 'C' codes for 2003 and the option to use them in 2004, CMS must recognize that the cost data is understated. We support making the "C" codes mandatory for 2005 but have concerns for the lack of good data to set rates in 2005 and 2006.

APC 0651 Complex Interstitial Radiation Application
Please develop separate codes for the placement of needles and catheters for brachytherapy application. These services should not be bundled as they are in G0256 and G0266 as they may be performed in two different hospital departments.

Devices
CMS has the option to support pass through payments up to 3 years. Please consider giving the full benefit of this payment structure to those devices that are noted to expire within a shorter period of time such as C1819 which went on pass through 1/1/04 and is proposed to go off 12/31/05.

Drugs, Biologicals and Radiopharmaceuticals Non Pass-throughs
Again, we have concerns about the lack of data in rate setting for these drugs for 2005. The proposed payment rates do not include many of the specific drug costs due to the coding methodology used in 2003. Many of these drugs were packaged and due to CMS dropping the use of the 'C' codes, the actual drug cost was not captured in the 2003 data. We strongly oppose these rates due to major issues with the lack of data and request that CMS retain the rates from 2004 until you have enough data to accurately and legitimately determine the appropriate level of reimbursement.

It would be very beneficial if you would show 3 separate tables for the non pass through drugs; one for sole source, one for innovator multi source and a separate table for non innovator multi source drugs. With the two tables presented, it is impossible to identify the specific innovator versus non innovator multi source drugs.

We appreciate the proposal to bill for oral anti-emetics associated with chemotherapy, however have significant concerns from an operations perspective. It will be extremely difficult to bill for these drugs when we use the same code for use in nausea <u>not</u> associated with chemotherapy. Please consider establishing a separate HCPCS code or an edit that will only allow payment when a cancer diagnosis is on the claim.

Observation Services
We support the changes in observation time tracking to end with the actual time of discharge. We appreciate the elimination of the specific diagnostic testing requirements, however, we continue to be challenged in operationalizing the seven criteria for the separate payment for observation for these patients in particular.

Brachytherapy
<u>APC 0651 Complex Interstitial Radiation Application (page 50495)</u>

Please develop separate codes for the placement of needles and catheters for brachytherapy application. These services should not be bundled as they are in G0256 and G0266 as they may be performed in two different hospital departments.

Payment for Brachytherapy Sources

We do not understand the rationale in setting up codes that reflect radioactive intensity due to the uncertainty which radioactive substance will be available at a given time. The proposed payment structure appears complex and necessitates that providers distinguish between low and high activity without giving definition to what is high activity. We ask that you do not add the two new brachytherapy source codes as proposed and continue with the current code and payment structure.

Allina appreciates the opportunity to provide comments on the Proposed Rule on Changes to the Medicare Outpatient Prospective Payment System and Payment Rates for Calendar Year 2005. We hope that CMS will consider our recommendations. If you have any questions, please feel free to contact me at 612-775-9744. We look forward to seeing the final rule.

Sincerely,

Nancy Payne, RN, MA
Director of Regulatory Affairs

Submitter : Ms. Wendy Resnick **Date & Time:** 10/07/2004 04:10:47

Organization : Shands HealthCare

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

This comment letter covers a variety of areas.

CMS-1427-P-168

Submitter : Valerie Rinkle **Date & Time:** 10/07/2004 04:10:11

Organization : Provider Round Table

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1427-P-168-Attach-2.doc

CMS-1427-P-168-Attach-1.doc

Department of Health and Human Services
Centers for Medicare and Medicaid Services (CMS)
Offices of Strategic Operations and Regulatory Affairs

The attachment to this document is not provided because:

1. The document was improperly formatted.
2. The submitter intended to attach more than one document, but not all attachments were received.
3. The document received was a protected file and can not be released to the public.
4. The document is not available electronically at this time. If you like to view any of the documents that are not posted, please contact CMS at 1-800-743-3951 to schedule an appointment.

Submitter : Valerie Rinkle **Date & Time:** 10/07/2004 04:10:00

Organization : Provider Round Table

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Attachment

CMS-1427-P-169-Attach-1.doc

Department of Health and Human Services
Centers for Medicare and Medicaid Services (CMS)
Offices of Strategic Operations and Regulatory Affairs

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1. The document was improperly formatted.
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4. The document is not available electronically at this time. If you like to view any of the documents that are not posted, please contact CMS at 1-800-743-3951 to schedule an appointment.

CMS-1427-P-170

Submitter : Mr. Michael Sengewalt **Date & Time:** 10/07/2004 04:10:08

Organization : Fairmont General Hospital, Inc.

Category : Hospital

Issue Areas/Comments

Issues 21-30

Payment Rate for APCs

Dear Tommy G. Thompson:

Fairmont General Hospital. Inc. is pleased to have this opportunity to comment on proposed rule 69 Fed. Reg. 50448, Aug. 16, 2004. Specifically the median cost for APC 0659, hyperbaric oxygen therapy (HBOT) treatment, which is proposed dropping to $82.91 from the CY 2004 payment of $164.93.

We are a 123 bed acute care hospital located in rural Marion County, West Virginia. We have been providing HBOT for over 2 ? years and are the only provider of HBOT in Marion County. For fiscal year 2003, the Hospital performed 3,366 ? hour treatments, of which 1,865 were for Medicare patients. This huge drop in the payment rate will not cover the cost of providing this service and will threaten patient?s access to this proven method for treating wounds that are both painful and otherwise expensive.

The Hyperbaric Oxygen Therapy Association?s (HOTA) position is reasonable given the report by The Lewin Group. The Lewin Group?s proposals for fixing this appear very reasonable: Leave the HBOT reimbursement rate at CY 2004 levels until CMS has an opportunity to perform a corrected calculation; or Apply the Lewin Group?s methodology to all hospitals; or Adopt the Lewin Group?s proposed reimbursement rate of $118.21 for a half-hour of treatment; or Calculate the reimbursement rate for HBOT using each hospital?s overall cost-to-charge ratio. CMS?s rules for calculating the median cost indicate if the cost-to-charge ratio cannot be calculated, the overall hospital cost-to-charge ratio is to be used.

Correcting this calculation would have a significant impact on our Hospital, even though using the Lewin Group?s estimate of $118.21 per half-hour would only change HBOT payments by $17 million.

Thank you in advance for you consideration in this matter and the Hospital is looking forward to your revision of the HBOT APC.

Gratefully,

Michael J. Sengewalt
Senior VP / CFO

CMS-1427-P-171

Submitter : **Date & Time:** **10/07/2004 05:10:18**

Organization : **PBI Regional Medical Center**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

PBI Regional Medical Center appreciates and welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services(CMS) proposed rule entitled Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment Systems and Calendar Year (CY) 2005 Payment Rates; Proposed Rule, 69 Fed. Reg. 50448 (August 16, 2004).

Our comments relate to the Wage Index section of the proposed rule.

Please be advised that PBI Regional Medical Center generally supports the CMS final rulemaking related to 'Special Circumstances of Hospitals in All-Urban States' contained in the Federal Fiscal Year (FFY) 2005 final inpatient rule published in the August 11, 2004 Federal Register. The FFY 2005 final inpatient rule adopted a methodology that imputes a wage index floor for those states that are deemed to be 'All-Urban States'. It is clear that the absence of a floor for the Medicare wage index calculation creates an uneven playing field between the All-Urban States (currently three under the final inpatient rule) and the remaining forty-seven states. Imputing a wage index floor for the All Urban State adds symmetry, equity and consistency to the reimbursement methodology.

PBI Regional strongly supports the contention that the imputed wage index floor should also apply to outpatient hospital services effective with CY 2005. Unfortunately, the proposed outpatient rule does not recognize this contention since the proposed inpatient wage index amounts (that is, the wage indexes that CMS proposed for the hospital inpatient PPS rules as published in the May 18, 2004 Federal Register) are currently scheduled to be implemented for outpatient services beginning with CY 2005. Utilizing the proposed inpatient wage index amounts circumvents the implementation of the 'Special Circumstances of Hospitals in All-Urban States' for outpatient purposes for CY 2005 since this provision was not adopted until the final inpatient rulemaking.

It should be noted that since the inception of the outpatient prospective payment system (OP PPS) in August 2000, final inpatient wage index amounts consistently have been implemented by CMS in the final OP PPS rulemaking. This provision is in accordance with 42 CFR/419.43(c). The proposed outpatient rule for CY 2005 deviates from prior established methodology with regard to wage index implementation.

PBI Regional strongly urges CMS to adopt the methodology of implementing final inpatient wage index amounts for outpatient wage index purposes for CY 2005, which is consistent with prior year OP PPS implementation and which promotes equity and consistency in this area.

Thank you for considering these important comments and we look forward to your response.

CMS-1427-P-172

Submitter : Mr. Carlo Medici **Date & Time:** 10/07/2004 05:10:47

Organization : Bracco Diagnostics

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

see attached word document

CMS-1427-P-172-Attach-1.doc

CMS-1427-P-172-Attach-2.doc

October 7, 2004

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

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

ATTN: FILE CODE CMS-1427-P

Re: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates; Proposed Rule

Dear Administrator McClellan:

Bracco Diagnostics Inc. (Bracco) offers a full line of diagnostic imaging products including contrast agents, drugs, and radiopharmaceuticals. We employ more than 400 people in the United States. Bracco provides a select line of quality radiopharmaceuticals that assist in the diagnosis and treatment of disease for Medicare beneficiaries. Bracco's featured product line for nuclear medicine departments includes: Choletec®, the undisputed market leader in hepatobiliary imaging; Iodotope® diagnostic and therapeutic capsules for thyroid diseases, offered in potencies up to 130 mCi with low volatility and the smallest capsule commercially available; MDP-Bracco, an exceptional bone imaging agent; Rubratope®, the only nuclear medicine test available for the diagnosis of pernicious anemia; and ***CardioGen-82®, the only generator-based Positron Emission Tomography (PET) Agent*** and the primary focus of our comments to you today.

We are writing in response to the Proposed 2005 Hospital Outpatient Prospective Payment System (HOPPS) rule published in the August 16, 2004 (69 Fed. Reg. 50447). Our comments for the 2005 NPRM will focus on two sections as identified by CMS in the proposed rule: ***Radiopharmaceuticals*** and the ***2 Times Rule***.

I. Radiopharmaceuticals

PET Radiopharmaceutical CMS Proposed Payment Policy Change

In the proposed rule on page 50507 CMS states, "We note that there are three radiopharmaceutical products for which we are proposing a different payment policy in CY 2005. These products are represented by HCPCS codes A9526 (Ammonia N-13, per dose), C1775 (FDG, per dose (4-40 mCi/ml), and Q3000 (Rubidium-Rb-82). Radiopharmaceuticals are classified as a "specified covered outpatient drug" according to section 1833(t)(14)(B)(i)(I) of the Act; and their payment is dependent on their classification as a single source, innovator multiple source, or noninnovator multiple source product as defined by sections 1927(k)(7)(A)(iv), (ii), and (iii) of the Act. Upon further analysis of these items, we determined that these three products do not meet the statutory definition of a sole source item or a multiple source item."

CMS continues, "Pub. L. 108-173 requires us to pay for "specified covered outpatient drugs" using specific payment methodologies based on their classification and does not address how payment should be made for items that do not meet the definition of a sole source or multiple source item. Therefore, we are proposing to set the CY 2005 payment rates for these three products based on median costs derived from CY 2003 hospital outpatient claims data, which would reflect hospital costs associated with these products. With regard to HCPCS code A9526, we have no hospital outpatient cost data for this HCPCS code. We received correspondence from an outside source stating that Rubidium-Rb-82 (HCPCS code Q3000) is an alternative product used for procedures for which Ammonia N-13 is also used and these two products are similar in cost. Therefore, we are proposing to establish a payment rate for Ammonia N-13 that is equivalent to the payment rate for Rubidium Rb-82. We request comments on the proposed CY 2005 payment rates for these three items and invite commenters to submit external data if they believe the proposed CY 2005 payment rates for these items do not adequately represent actual hospital costs."

Bracco appreciates the openness of CMS and applauds the decision to solicit specific comments regarding this new proposed payment policy for PET radiopharmaceuticals. We respectfully disagree with CMS regarding two major points; ***CardioGen-82® referred to above as Rubidium Rb-82 (HCPCS code Q3000) does meet the classification as a single source drug as defined by the MMA 2003*** and second Ammonia (A9526 Ammonia N-13 per dose) and CardioGen-82® (Q3000 Rubidium Rb-82 per dose) ***are NOT similar in cost, clinical composition or utilization.***

We do agree with CMS that CardioGen-82® does yield a PET radiopharmaceutical. However, CardioGen-82® significantly differs from the other listed PET radiopharmaceuticals as it is produced by a radionuclide generator system compared to FDG F-18 and N-13 which are cyclotron-produced PET radiopharmaceuticals. CardioGen-82® is a convenient[1] radiotracer as compared to N-13 as is does not require an on-site cyclotron. It is true that Rb-82 and N-13 are both radiopharmaceuticals which are used with the same series of G HCPCS codes G0030 – G0047; however, the similarity ends there. There are many other situations in nuclear medicine in which different radiopharmaceuticals are used with the same set of procedures and CMS currently sets individual payment rates for each radiopharmaceutical, (e.g. SPECT and Planar myocardial perfusion imaging agents.) ***CMS should NOT use the criteria of "an alternative product used for procedures" for establishing payment policy for Ammonia N-13. CMS should obtain AWP and cost information for each product individually to set payment rates.***

CardioGen-82® qualifies as a "Single Source Drug"

The MMA 2003, Section 1927(k)(7)(A)(iv) of the Act defines the term "single source drug" to mean a covered outpatient drug which is produced or distributed under an original new drug application (NDA) approved by the Food and Drug Administration (FDA), including a drug product marketed by any cross-licensed producers or distributors operating under the NDA. Bracco has obtained an approval from the FDA under an NDA and is currently the only manufacturer of CardioGen-82® generators used to produce Rubidium Chloride Rb-82. Attached at the end of this letter are supporting documents for CardioGen-82® including the FDA approval letter, the electronic Orange Book reference and the 2004 Redbook AWP. ***We urge CMS to recognize CardioGen-82® as a single source drug as defined by the MMA 2003 and set payment at 83% of the published AWP.***

Bracco recognizes the difficulties and challenges CMS might have in establishing a payment rate based on 83% of an AWP for a generator when the HCPCS code describes the product per dose. Transitioning an AWP listed for a generator into a single administered unit dose payment requires CMS to have additional information which may not be readily available. We offer CMS the following formula and external data supplied by IMV. Additionally, we offer our expert staff to meet with CMS officials to review any of the information supplied in our comments.

[1] Myocardial Perfusion Imaging with PET, Journal of Nuclear Medicine Vol. 35 No. 4. April 1994 p 694

AWP for CardioGen-82® Generator	/ divided by	Average # of doses per generator*	=	AWP per Average Dose
$34,375.00 (See Redbook)	/	7042/54=130	=	$264.42
2005 HOPPS Payment Rate Q3000 per dose 83% AWP per dose			=	**$219.47**

*See IMV CardioGen-82® report attached.

Bracco has contracted with an external party, IMV Medical Information Division, to conduct a survey of our hospital sites to obtain data reflective of "true" hospital costs. This IMV report is attached at the end of our comments and includes methodology and response rate information. This report identifies the median cost (from a CardioGen-82® generator) as reported by hospitals in this survey as $244.73 per dose for Q3000 Rubidium Rb-82.

Bracco has reviewed the median cost data published by CMS listing Q3000 Rubidium Rb-82 per dose mean $99.59 and median $113.80 as represented by the 2003 hospital claims data. Based on our experience and the IMV survey attached, Bracco believes that this CMS hospital cost data are flawed and do not represent "true" hospital costs. **CMS should not use 2003 hospital claims cost data to set the 2005 HOPPS payment rate for Rubidium Rb-82 Q3000.**

CardioGen-82® and Ammonia N-13 are NOT similar in cost, clinical composition or utilization

As mentioned earlier in our comments, rubidium Rb-82 and ammonia N-13 are produced by very different methods: a generator versus a cyclotron. The IMV survey attached demonstrates the current unit dose costs for Rb-82, excluding the fixed equipment costs.

We do not intend to supply the specific costs for ammonia; we will leave these specifics to those who produce ammonia. We would however, like to point out several major differences for CMS to consider when comparing costs. The fixed costs associated with an on-site cyclotron would be significantly greater than the fixed equipment costs for Rubidium (i.e., infusion system). However, it is our understanding that these fixed costs do not factor into the cost calculations for CMS

to use in setting hospital payments for drugs or radiopharmaceuticals. We are aware of efficiencies and inefficiencies by having an on-site cyclotron such as the ability to produce different radiopharmaceuticals, (e.g. FDG and Ammonia) or the limitations regarding how many runs can be performed to produce product.

Other characteristics demonstrate product difference of a clinical nature: PET images with Rb-82 demonstrate homogeneous distribution; N-13 ammonia distribution is slightly nonhomogeneous, with reduced radiotracer activity in the lateral wall making interpretation in this area difficult. The low uptake of ammonia in the lateral wall is a reproducible finding in both rest and stress images. Although the mechanism is unknown, it appears to be a regional metabolic alteration in N-13 tissue retention[2]. Rubidium is a potassium analog with a physical half-life of only 75 seconds. This short ½ life allows rapid reimaging without technical problems. In contrast to Rb-82, N-13 has a much longer ½ life of 10 minutes and has a worse signal-to-noise ratio. The kinetics of Rb-82 show high extraction at high flow rates.[3] ***We URGE CMS to recognize these differences in the two products and to investigate and obtain accurate hospital cost data independently for each PET radiopharmaceutical.***

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CMS requested information regarding C9013, cobaltous chloride. This is a radiopharmaceutical solely manufactured for and distributed by Bracco Diagnostics, Inc. It is used in conjunction with Schillings tests to diagnose patients with pernicious anemia. Over the past two years, Bracco has experienced problems with the production of cobaltous chloride, which has resulted in a temporary market suspension of the product. However, this product will be commercially available in November of 2004. Therefore, we respectfully request that C9013 remain in effect. Cobaltous chloride is an FDA-approved radiopharmaceutical which was assigned an APC before December 31, 2002. Therefore, C9013 should be paid as a "specified covered outpatient drug" and we urge CMS to establish payment for C9013 cobaltous chloride consistent with other specified covered outpatient drugs at 83% of AWP. Bracco is working with Redbook staff regarding published product information and will forward confirmation from Redbook to the CMS staff as it becomes available.

[2] Schwaiger, Markus, "Myocardial Perfusion Imaging with PET" J Nucl Med 1994: 35: 693-698.
[3] Cerqueira, Manuel, "A symposium: New Directions in Adenosine Pharmacologic Stress Imaging" Supplement to Volume 94, Number 2A, American Journal of Cardiology July 22, 2004: 19D-25D.

II. 2 Times Rule

Myocardial Positron Emission Tomography (PET) APC 0285

We understand detailed comments will be supplied by the Nuclear Medicine APC Task Force (TF) and other nuclear medicine professional societies regarding APC 0285**. We agree with the TF and do not support a CMS exception to break the 2 Times Rule for this APC.** We are concerned that CMS is using an inadequate number of claims to set payment rates and we support the TF efforts and recommendations to move these codes into New Technology APCs until an adequate number of claims are available to set payments. Additionally, splitting these codes into two levels of APCs one for single studies MPI (G0030, G0032, G0034, G0036, G0038, G0040, G0042, G0046) and another for multiple studies MPI (G0031, G0033, G0035, G0037, G0039, G0041, G0043, G0045, G0047) would be appropriate and consistent with other nuclear medicine APCs.

Again, Bracco appreciates the opportunity to comment on this proposed rule to CMS. If you have any further questions or would like to set up a meeting, please contact Gail Rodriguez at 800-631-5245 ext. 2304.

Respectfully submitted,

Signed copying arriving via Federal Express
Tracking #848962640282

Carlo Medici
President, Bracco Diagnostics, Inc.

Cc: Kenneth Simon
Edith Hambrick
Joan Sanow
Cindy Read
Sabrina Ahmed

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-414

JAN 05 1990

L. BAUM

DEC 29 1989

Squibb Diagnostics
P.O. Box 4500
Princeton, New Jersey 08543-4500

Attention: Leonard M. Baum
Worldwide Regulatory Affairs
Director

Dear Mr. Baum:

Reference is made to your new drug application dated December 27, 1984 submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act for the diagnostic radiopharmaceutical, Cardiogen-82 (rubidium Rb 82 generator for elution of rubidium chloride Rb 82 injection). Reference is also made to our letter of December 14, 1989 informing you that your application was regarded as approvable by the Agency and informing you of labeling and other deficiencies requiring resolution prior to approval of the application.

We acknowledge the receipt of your amendments dated December 20 and 29, 1989 addressing those deficiencies. The amendments also provide your commitments to revise the established name for the generator to "strontium Sr 82 - rubidium Rb 82 generator" within 6-months from the date USAN accepts the revised name; to submit the advertising copy which you intend to use in your proposed promotional and/or advertising campaign and to work with the Agency to resolve any differences as a result of FDA's review of the advertising copy; and, to market only generators manufactured with raw material (strontium Sr 82) obtained from Brookhaven National Laboratories.

We have completed our review of this application as amended, including the submitted draft labeling, and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the draft labeling submitted on December 20, 1989 as amended on December 29, 1989. Accordingly, the application is approved effective on the date of this letter.

While all other aspects of this application have been found to be approvable, the required validation of the analytical methods has not been completed. In such a case, the policy of the Center for Drug Evaluation and Research is to proceed with approval. We note your December 20, 1989 agreement to cooperate in the resolution of any problems that may occur with respect to validation.

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Should additional information relating to the safety and effectiveness of this drug product become available prior to our receipt of the final printed labeling, revision of that labeling may be required.

Please submit one market package of the generator when available.

We remind you that you must comply with the requirements set forth under 21 CFR 314.80 and 314.81 for an approved NDA.

Sincerely yours,

BRACCO

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Proprietary Name Search Results from "OB_Rx" table for query on "cardioGen-82."

Appl No	TE Code	RLD	Active Ingredient	Dosage Form; Route	Strength	Proprietary Name	Applicant
019414		No	RUBIDIUM CHLORIDE RB-82	INJECTABLE; INJECTION	N/A	CARDIOGEN-82	BRACCO

ELECTRONIC ORANGE BOOK

Search results from the "OB_Rx" table for query on "019414."

Active Ingredient:	RUBIDIUM CHLORIDE RB-82
Dosage Form;Route:	INJECTABLE; INJECTION
Proprietary Name:	CARDIOGEN-82
Applicant:	BRACCO
Strength:	N/A
Application Number:	019414
Product Number:	001
Approval Date:	Dec 29, 1989
Reference Listed Drug	No
RX/OTC/DISCN:	RX
TE Code:	
Patent and Exclusivity Info for this product:	View

Patent Data

Appl No	Prod No	Patent No	Patent Expiration	Drug Substance Claim	Drug Product Claim	Patent Use Code
019414	001	4562829	MAY 01,2004			U-503

Exclusivity Data

There is no unexpired exclusivity for this product.

Additional information:
1. Patents are published upon receipt by the Orange Book Staff and may not reflect the official receipt date as described in 21 CFR 314.53(c)(3)(5).
2. Patents submitted on FDA Form 3542 and listed after August 18, 2003 will have one to three patent codes indicating specific patent claims as submitted by the sponsor and are detailed in the above table.
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Patent Use Codes

This page defines the patent use codes.

Code	Definition
U-503	GENERATOR MUST BE USED WITH INFUSION SYSTEM SPECIFICALLY LABELED FOR USE WITH GENERATOR

FDA/Center for Drug Evaluation and Research
Office of Generic Drugs
Division of Labeling and Program Support
Update Frequency:
Orange Book Data - **Monthly**
Orange Book Data Updated Through July, 2004

METHODOLOGY

Introduction

This study summarizes the results of the IMV Medical Information Division's survey of sites performing PET procedures with Rubidium^{82}.

The objective was to calculate the average cost per dose paid by facilities using Rubidium 82 generators, using utilization data provided by the sites and generator cost data provider by Bracco.

Initial candidate sites were identified using a customer list provided by Bracco. Twenty four sites were identified using this list. In addition, contact was made with Eastern Isotopes, a radiopharmacy that purchases Rubidium generators from Bracco and facilitates sharing of these generators among Eastern's customers.

Data Acquisition and Entry

The twenty-four sites were contacted and recruited using the recruiting script shown in Exhibit A. Contacts willing to participate in the study were faxed or emailed a copy of the letter in Exhibit B along with the questionnaire labeled Exhibit C. All questionnaires were returned by FAX.

Respondents were instructed to include only those doses used for imaging, and NOT to include doses used for positioning and gating. They were also asked only to report data for fully utilized generators.

Nineteen sites returned twenty questionnaires. One facility with 2 PET scanners, that purchases 2 generators each month, provided data for each of the two generators used each month with each of their PET scanners. Data was entered into an Excel spreadsheet.

In addition, Eastern isotopes provided average cost per dose data for 4 of their sites. Since this did not include the entire customer base for the generators purchased by Eastern, and since the basis for their calculation was not fully explained, it was decided not to include this information in the calculations. Using the data provided by Eastern Isotopes the average cost per dose across these sites was $ 269.73.

Quality Control

The quality of data was checked by visual inspection, by comparing dose to patient ratios, and by comparing cost per dose. High and low outliers in all comparisons were contacted to make sure their data was accurate and did not include doses used for positioning or gating and that they were reporting fully utilized generators.

One site received 3 generators to test the procedure with their PET scanner. The performed the procedures under the assumption that their scanner vendor would be paying for the generators. Their average calculated cost per dose of $4,875.88 and the 3 generators used for these patients were excluded from this analysis.

Estimation of Cost per Dose

The total *cost per generator*, was calculated by adding the generator cost ($27,500 in all cases) plus the shipping cost ($ 130 in all cases) plus $8.40 for each patient after the 25th patient imaged with that generator. The additional per patient charges cover the ancillary tubing and supplies required to connect the patient to the generator. Tubing for 25 patients is supplied with the purchase of a single generator.

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imv
Medical Information Division

The *cost per dose per generator* was calculated for each generator by dividing the total cost for that generator by the total number of imaging doses drawn. The *cost per dose per site/scanner* was calculated by dividing the total costs for all generators reported by a site divided by the total imaging doses drawn at that site. One site had only fully utilized one generator at the time of the survey, and another site had only used 2 generators at the time of survey. All other sites reported data for the 3 most recently used generators.

Adding the total costs for each generator and dividing that total by the total number of imaging doses drawn calculated the *average cost per dose for the entire sample*. This number is the key Finding reported on the next page.

The average cost per dose based on data from 19 sites and 54 generators is $214.67.

Total Sites Surveyed:	19
Total Generators Reported:	54
Total Doses Reported:	7,042
Total Costs	$ 1,511,689.12
Cost per Dose	**$ 214.67**
Per Generator:	
Maximum Cost per Dose:	$ 6,907.50
Minimum Cost per Dose:	$ 102.00
Median Cost per Dose:	$ 244.73
Per PET Scanner/Site:	
Maximum Cost per Dose:	$ 2,181.32
Minimum Cost per Dose:	$ 110.29
Median Cost per Dose:	$ 248.49

At the facility with 2 PET scanners, each PET scanner is counted as a separate site.

107 College Road East • Princeton, New Jersey 08540

October 7, 2004

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

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

ATTN: FILE CODE CMS-1427-P

Re: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates; Proposed Rule

Dear Administrator McClellan:

Bracco Diagnostics Inc. (Bracco) offers a full line of diagnostic imaging products including contrast agents, drugs, and radiopharmaceuticals. We employ more than 400 people in the United States. Bracco provides a select line of quality radiopharmaceuticals that assist in the diagnosis and treatment of disease for Medicare beneficiaries. Bracco's featured product line for nuclear medicine departments includes: Choletec®, the undisputed market leader in hepatobiliary imaging; Iodotope® diagnostic and therapeutic capsules for thyroid diseases, offered in potencies up to 130 mCi with low volatility and the smallest capsule commercially available; MDP-Bracco, an exceptional bone imaging agent; Rubratope®, the only nuclear medicine test available for the diagnosis of pernicious anemia; and ***CardioGen-82®, the only generator-based Positron Emission Tomography (PET) Agent*** and the primary focus of our comments to you today.

We are writing in response to the Proposed 2005 Hospital Outpatient Prospective Payment System (HOPPS) rule published in the August 16, 2004 (69 Fed. Reg. 50447). Our comments for the 2005 NPRM will focus on two sections as identified by CMS in the proposed rule: ***Radiopharmaceuticals*** and the ***2 Times Rule***.

I. Radiopharmaceuticals

PET Radiopharmaceutical CMS Proposed Payment Policy Change

In the proposed rule on page 50507 CMS states, "We note that there are three radiopharmaceutical products for which we are proposing a different payment policy in CY 2005. These products are represented by HCPCS codes A9526 (Ammonia N-13, per dose), C1775 (FDG, per dose (4-40 mCi/ml), and Q3000 (Rubidium-Rb-82). Radiopharmaceuticals are classified as a "specified covered outpatient drug" according to section 1833(t)(14)(B)(i)(I) of the Act; and their payment is dependent on their classification as a single source, innovator multiple source, or noninnovator multiple source product as defined by sections 1927(k)(7)(A)(iv), (ii), and (iii) of the Act. Upon further analysis of these items, we determined that these three products do not meet the statutory definition of a sole source item or a multiple source item."

CMS continues, "Pub. L. 108-173 requires us to pay for "specified covered outpatient drugs" using specific payment methodologies based on their classification and does not address how payment should be made for items that do not meet the definition of a sole source or multiple source item. Therefore, we are proposing to set the CY 2005 payment rates for these three products based on median costs derived from CY 2003 hospital outpatient claims data, which would reflect hospital costs associated with these products. With regard to HCPCS code A9526, we have no hospital outpatient cost data for this HCPCS code. We received correspondence from an outside source stating that Rubidium-Rb-82 (HCPCS code Q3000) is an alternative product used for procedures for which Ammonia N-13 is also used and these two products are similar in cost. Therefore, we are proposing to establish a payment rate for Ammonia N-13 that is equivalent to the payment rate for Rubidium Rb-82. We request comments on the proposed CY 2005 payment rates for these three items and invite commenters to submit external data if they believe the proposed CY 2005 payment rates for these items do not adequately represent actual hospital costs."

Bracco appreciates the openness of CMS and applauds the decision to solicit specific comments regarding this new proposed payment policy for PET radiopharmaceuticals. We respectfully disagree with CMS regarding two major points; ***CardioGen-82® referred to above as Rubidium Rb-82 (HCPCS code Q3000) does meet the classification as a single source drug as defined by the MMA 2003*** and second Ammonia (A9526 Ammonia N-13 per dose) and CardioGen-82® (Q3000 Rubidium Rb-82 per dose) ***are NOT similar in cost, clinical composition or utilization.***

We do agree with CMS that CardioGen-82® does yield a PET radiopharmaceutical. However, CardioGen-82® significantly differs from the other listed PET radiopharmaceuticals as it is produced by a radionuclide generator system compared to FDG F-18 and N-13 which are cyclotron-produced PET radiopharmaceuticals. CardioGen-82® is a convenient[1] radiotracer as compared to N-13 as is does not require an on-site cyclotron. It is true that Rb-82 and N-13 are both radiopharmaceuticals which are used with the same series of G HCPCS codes G0030 – G0047; however, the similarity ends there. There are many other situations in nuclear medicine in which different radiopharmaceuticals are used with the same set of procedures and CMS currently sets individual payment rates for each radiopharmaceutical, (e.g. SPECT and Planar myocardial perfusion imaging agents.) ***CMS should NOT use the criteria of "an alternative product used for procedures" for establishing payment policy for Ammonia N-13. CMS should obtain AWP and cost information for each product individually to set payment rates.***

CardioGen-82® qualifies as a "Single Source Drug"

The MMA 2003, Section 1927(k)(7)(A)(iv) of the Act defines the term "single source drug" to mean a covered outpatient drug which is produced or distributed under an original new drug application (NDA) approved by the Food and Drug Administration (FDA), including a drug product marketed by any cross-licensed producers or distributors operating under the NDA. Bracco has obtained an approval from the FDA under an NDA and is currently the only manufacturer of CardioGen-82® generators used to produce Rubidium Chloride Rb-82. Attached at the end of this letter are supporting documents for CardioGen-82® including the FDA approval letter, the electronic Orange Book reference and the 2004 Redbook AWP. ***We urge CMS to recognize CardioGen-82® as a single source drug as defined by the MMA 2003 and set payment at 83% of the published AWP.***

Bracco recognizes the difficulties and challenges CMS might have in establishing a payment rate based on 83% of an AWP for a generator when the HCPCS code describes the product per dose. Transitioning an AWP listed for a generator into a single administered unit dose payment requires CMS to have additional information which may not be readily available. We offer CMS the following formula and external data supplied by IMV. Additionally, we offer our expert staff to meet with CMS officials to review any of the information supplied in our comments.

[1] Myocardial Perfusion Imaging with PET, Journal of Nuclear Medicine Vol. 35 No. 4. April 1994 p 694

AWP for CardioGen-82® Generator	/ divided by	Average # of doses per generator*	=	AWP per Average Dose
$34,375.00 (See Redbook)	/	7042/54=130	=	$264.42
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Tracking #848962640282

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President, Bracco Diagnostics, Inc.

Cc: Kenneth Simon
Edith Hambrick
Joan Sanow
Cindy Read
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-414

JAN 05 1990

L. BAUM

DEC 29 1989

Squibb Diagnostics
P.O. Box 4500
Princeton, New Jersey 08543-4500

Attention: Leonard M. Baum
Worldwide Regulatory Affairs
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ELECTRONIC ORANGE BOOK

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Proprietary Name:	CARDIOGEN-82
Applicant:	BRACCO
Strength:	N/A
Application Number:	019414
Product Number:	001
Approval Date:	Dec 29, 1989
Reference Listed Drug	No
RX/OTC/DISCN:	RX
TE Code:	
Patent and Exclusivity Info for this product:	View

Patent Data

Appl No	Prod No	Patent No	Patent Expiration	Drug Substance Claim	Drug Product Claim	Patent Use Code
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Division of Labeling and Program Support
Update Frequency:
Orange Book Data - **Monthly**
Orange Book Data Updated Through July, 2004

METHODOLOGY

Introduction

This study summarizes the results of the IMV Medical Information Division's survey of sites performing PET procedures with Rubidium^{82}.

The objective was to calculate the average cost per dose paid by facilities using Rubidium 82 generators, using utilization data provided by the sites and generator cost data provider by Bracco.

Initial candidate sites were identified using a customer list provided by Bracco. Twenty four sites were identified using this list. In addition, contact was made with Eastern Isotopes, a radiopharmacy that purchases Rubidium generators from Bracco and facilitates sharing of these generators among Eastern's customers.

Data Acquisition and Entry

The twenty-four sites were contacted and recruited using the recruiting script shown in Exhibit A. Contacts willing to participate in the study were faxed or emailed a copy of the letter in Exhibit B along with the questionnaire labeled Exhibit C. All questionnaires were returned by FAX.

Respondents were instructed to include only those doses used for imaging, and NOT to include doses used for positioning and gating. They were also asked only to report data for fully utilized generators.

Nineteen sites returned twenty questionnaires. One facility with 2 PET scanners, that purchases 2 generators each month, provided data for each of the two generators used each month with each of their PET scanners. Data was entered into an Excel spreadsheet.

In addition, Eastern isotopes provided average cost per dose data for 4 of their sites. Since this did not include the entire customer base for the generators purchased by Eastern, and since the basis for their calculation was not fully explained, it was decided not to include this information in the calculations. Using the data provided by Eastern Isotopes the average cost per dose across these sites was $ 269.73.

Quality Control

The quality of data was checked by visual inspection, by comparing dose to patient ratios, and by comparing cost per dose. High and low outliers in all comparisons were contacted to make sure their data was accurate and did not include doses used for positioning or gating and that they were reporting fully utilized generators.

One site received 3 generators to test the procedure with their PET scanner. The performed the procedures under the assumption that their scanner vendor would be paying for the generators. Their average calculated cost per dose of $4,875.88 and the 3 generators used for these patients were excluded from this analysis.

Estimation of Cost per Dose

The total *cost per generator*, was calculated by adding the generator cost ($27,500 in all cases) plus the shipping cost ($ 130 in all cases) plus $8.40 for each patient after the 25th patient imaged with that generator. The additional per patient charges cover the ancillary tubing and supplies required to connect the patient to the generator. Tubing for 25 patients is supplied with the purchase of a single generator.

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imv
Medical Information Division

The *cost per dose per generator* was calculated for each generator by dividing the total cost for that generator by the total number of imaging doses drawn. The *cost per dose per site/scanner* was calculated by dividing the total costs for all generators reported by a site divided by the total imaging doses drawn at that site. One site had only fully utilized one generator at the time of the survey, and another site had only used 2 generators at the time of survey. All other sites reported data for the 3 most recently used generators.

Adding the total costs for each generator and dividing that total by the total number of imaging doses drawn calculated the *average cost per dose for the entire sample*. This number is the key Finding reported on the next page.

The average cost per dose based on data from 19 sites and 54 generators is $214.67.

Total Sites Surveyed:	19
Total Generators Reported:	54
Total Doses Reported:	7,042
Total Costs	$ 1,511,689.12
Cost per Dose	**$ 214.67**
Per Generator:	
Maximum Cost per Dose:	$ 6,907.50
Minimum Cost per Dose:	$ 102.00
Median Cost per Dose:	$ 244.73
Per PET Scanner/Site:	
Maximum Cost per Dose:	$ 2,181.32
Minimum Cost per Dose:	$ 110.29
Median Cost per Dose:	$ 248.49

At the facility with 2 PET scanners, each PET scanner is counted as a separate site.

107 College Road East • Princeton, New Jersey 08540

Submitter : Mr. Joseph Zuraw **Date & Time:** 10/07/2004 05:10:05

Organization : Bayer Biological Products

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

October 6, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1427-P
P.O. Box 8010
Baltimore, MD 21244-8018

CMS FILE CODE 1427-P Orphan Drugs

Bayer HealthCare Biological Products Division (?Bayer?) appreciates the opportunity to submit these comments to the Proposed Rule for the calendar year 2005 Prospective Payment System for Outpatient Hospital Services, appearing at 69 FR 50447 et. seq. on August 16, 2004.

Our comments are limited to the Proposed Changes in Payment for Single Indication Orphan Drugs found on pages 50517-50518.

Alpha 1- proteinase inhibitor (A1-PI) is one of the single indication orphan drugs covered by the proposed payment rule. Bayer manufactures and distributes Prolastin? Alpha 1 ? Proteinase Inhibitor (Human). According to Bayer market research, Prolastin has the largest share of the U.S. A1-PI market, which includes two other products, Aralast? distributed by Baxter Healthcare Corporation and Zemaira? distributed by ZLB Behring.

Proposed A1-PI Payment Seems Incorrect Under Formula

We applaud your efforts to ensure beneficiary access to A1-PI by reimbursing health care providers according to the following formula: the higher of 88 percent of average wholesale price (AWP) or 106 percent of average sales price (ASP), but not to exceed 95 percent of AWP. However, the payment rate of $2.46 per 10 mg. ($.246 per mg.) you propose for A1-PI (J0256, APC 901) on page 50785 seems incorrect by our estimate.

Prolastin has the lowest AWP of the three products -- $0.31 per mg. Aralast has a Red Book? AWP of $0.41 per mg.; Zemaira?s is $0.43. Under the Orphan drug formula, if Prolastin were the only product in J0256, the payment rate should be no lower than $0.273 ($0.31 x .88) and could be as high as $0.295 ($0.31 x .95) depending upon the Prolastin ASP reported by Bayer.

Aralast?s and Zemaira?s AWP, when blended into the calculation for the payment rate for J0256 will, by definition, raise the minimum payment to something higher than $0.273 based upon their portion of total A1-PI units sold. The actual payment rate, which requires input of their ASPs and units sold, may raise that rate substantially higher.

Because the Aralast and Zemaira ASP and sales data are not available to us, and the 88 percent minimum payment rate calculation seems incorrect on its face, we request that you recheck all relevant prices and sales data and recalculate the payment rate for J0256 when publishing the Final Rule.

Respectfully submitted,

Joe Zuraw
Director- Bayer BP
400 Morgan Lane
West Haven, CT
203-812-6493

CMS-1427-P-173-Attach-1.doc

Bayer HealthCare
Biological Products Division

October 6, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1427-P
P.O. Box 8010
Baltimore, MD 21244-8018

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Respectfully submitted,

Joe Zuraw
Director- Bayer BP
400 Morgan Lane
West Haven, CT
203-812-6493

Submitter : Ms. MarciA Nusgart **Date & Time:** 10/07/2004 05:10:11

Organization : Alliance of Wound Care Stakeholders

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 21-30

E/M Services Guidelines

October 3, 2004

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8010
Baltimore, MD 21244-8012

Attn: CMS-1427-P ? Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates; 69 Federal Register (August 16, 2004) ?E/M Services Guidelines?

Dear Dr. McClellan;

On behalf of the Alliance of Wound Care Stakeholders, we are submitting comments in regards to the ?E/M Services Guidelines?. The Alliance is an organization of 18 physician, clinical, provider, manufacturer and patient organizations that have an interest in wound care and represents over 1600 wound care clinics. Our mission is to create an alliance of organizations to promote quality care and patient access to wound care products and services. This is accomplished by focusing on compelling issues of commonality to the organizations in reimbursement, government and public affairs affecting wound care.

In page 50538, CMS noted that ?we discussed our primary concerns and direction for developing the proposed coding guidelines for emergency department and clinic visits and indicated our plans to make available for public comment the proposed coding guidelines that we are considering through the CMS OPPS website as soon as we have completed them. We will notify the public through our `listserve? when the proposed guidelines will become available.?

While there is nothing in the proposed rule to comment on, we wanted to be on the record to note that we would like to serve as a resource to CMS to assist them in identifying variables useful to determine E/M levels for wound care. We understand that since the panel was unable to address all the concerns surrounding wound care, wound size has been selected as a determinant for E/M level assignment as it relates to specialized wound care departments.

The specialty wound care departments represented by the Alliance of Wound Care Stakeholders have concerns with this and have contacted CMS staff Debbie Hunter to make her aware that we will be submitting under separate cover a list of services that wound care clinics currently perform that should be considered under the E/M code. We will be submitting these in the upcoming months.

We appreciate the opportunity to work with CMS in this endeavor.

Sincerely,

Marcia Nusgart R.Ph.
Executive Director

CMS-1427-P-174-Attach-1.rtf

ALLIANCE OF

Wound Care Stakeholders

October 3, 2004

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8010
Baltimore, MD 21244-8012

Attn: CMS-1427-P – Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates; 69 Federal Register (August 16, 2004) "E/M Services Guidelines"

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We appreciate the opportunity to work with CMS in this endeavor.

Sincerely,

Marcia Nusgart R.Ph.

Marcia Nusgart R.Ph.
Executive Director

CMS-1427-P-175

Submitter : Ms. Denise Merlino **Date & Time:** 10/07/2004 05:10:02

Organization : Nuclear Medicine APC Task Force

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

Please see the attached detailed Nuclear Medicine APC Task Force comments.
Regards,
Denise Merlino

CMS-1427-P-175-Attach-1.doc

NUCLEAR MEDICINE APC TASK FORCE

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Academy of Molecular Imaging
American College of Nuclear Physicians
American College of Radiology
American Society of Nuclear Cardiology
Council on Radionuclides and Radiopharmaceuticals, Inc.
National Electrical Manufacturers Association
Society of Nuclear Medicine
Society of Nuclear Medicine - Technologist Section

October 8, 2004

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

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

ATTN: FILE CODE CMS-1427-P

Re: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates; Proposed Rule

Dear Administrator McClellan:

We are writing in response to the Proposed 2005 Hospital Outpatient Prospective Payment System (HOPPS) Rule, 69 Fed. Reg. 50447, August 16, 2004. The Nuclear Medicine APC Task Force (NMTF) is pleased to submit these comments and recommendations to assist the Centers for Medicare and Medicaid Services (CMS) in refining the HOPPS.

The Nuclear Medicine APCs underwent a major restructuring in 2004. This resulted in newly proposed organ-based Nuclear Medicine APCs. We believe this refined structure is more clinically homogeneous, is consistent with guiding legislation, and will allow improved access to quality care for Medicare recipients through more accurate cost accounting for individual procedures. We continue to analyze the impact of that restructuring, as discussed below in our specific recommendations.

(I) TWO TIMES RULE

APC 0285 Myocardial Positron Emission Tomography (PET)
Issues: frequency of service & resource homogeneity

APC 0285 contains the HCPCS codes G0030-G0047 for Myocardial PET studies. This APC is listed in Table 13 Proposed APC Exceptions to the 2 Times Rule. The small volume of these

procedures, when paired with the complex G codes (lumped into one APC group) that were created seven years ago to describe only two myocardial perfusion imaging procedures, has led to the generation of inadequate and confusing cost data.

The payment rate for this APC in CY 2003 was $945.47. The final CY2004 payment was $772.08. The current proposed payment of $690.61 is an 11% drop from 2004, and a 37% reduction from 2003.

In December 2003, *The NM Task Force recommended that CMS restore APC 0285 to the proposed published rate of $1,058.87, utilizing a New Technology APC at or close to the level of the proposed rate until a time at which CMS has adequate data to set appropriate payment rates which will not adversely affect access to care*.

There are 14 G codes used to report two basic procedures:

- a single rest or stress Myocardial Perfusion Imaging (MPI) PET study and
- a multiple stress and/or rest MPI PET studies.

CMS's calculated costs for these G coded studies in APC 0285, ranged from $3 to $2,700 dollars; the median cost data ranged from a low of $356 to a high of $2,140. There were no more than 454 studies for any one G code, and less than 1400 studies for the entire APC. The complexity of multiple G codes describing both single and multiple imaging sessions precludes reasonable conclusions about the cost of providing these services. Further, other than the radiopharmaceuticals, the resources required to perform PET myocardial perfusion imaging studies do not differ significantly from many of the PET tumor imaging procedures contained in APC 1516.

NM TF Recommendations

1. **We recommend that the payment for APC 0285 be increased to reflect the known resources, required to perform those studies, which are similar to several PET tumor imaging studies. At this time the studies should be placed in APC 1516**

2. **CMS should consider separating these procedures based on resources for single and multiple studies (Table 1 attached.)**

The use of G codes for these procedures began in 1995, apparently as a way to track the utilization of PET for assessing myocardial perfusion in coronary artery disease. We are unaware of any analysis of this utilization. We do not expect that meaningful information could be obtained from an analysis today.

3. **We recommend that G0030-G0047 be replaced by the two CPT codes:**

   78491 ***Myocardial imaging, positron emission tomography (PET), perfusion; single study at rest or stress*** **and**

78492 ***Myocardial imaging, positron emission tomography (PET), perfusion; multiple studies at rest and/or stress***

Additionally, we would like to bring to your attention a **PET coding issue that requires clarification**. Both last year and again in this current Rule, CMS published the following information in Addendum B: CPT® code 78459 *Myocardial imaging, positron emission tomography (PET), metabolic evaluation* (APC 0285), and G0230 *PET myocardial viability* (APC 1516). These two codes describe the same PET imaging procedure which is done using F18-FDG. It was our understanding that providers should use the CPT code, and that the G0230 code would be discontinued***.*** We urge CMS to clarify proper choice of code, and to place 78459 into the current APC 1516.

Radionuclide Therapy APC 0407

We note the inclusion of the nuclear medicine therapy APC 0407 on the exception to the two times rule. In January 2005 there will be new and revised nuclear medicine therapy CPT codes. We withhold comments on this section until publication by CMS of the final rule, which we assume will assign the new and revised CPT codes to the appropriate APC. We would be pleased to discuss this issue with CMS prior to publication at your convenience.

(II) NEW TECHNOLOGY APCs

Technical Component for Oncology PET APC 1516

The Task Force appreciates the hard work and careful consideration CMS has put into developing the three options for the payment of PET scans. We believe that another reduction in 2005 may limit access to this new technology for those Medicare patients served by rural and hospitals that perform less than 4 PET tumor studies daily, and that reducing the payment for tumor PET imaging would restrict the adoption and/or continuation of PET imaging in many hospitals.

We also note that the current APC 1516 contains G codes for imaging of one area such as heart or brain or lung, other G codes for greater body area such as for colon and lung tumors or for the whole body such as for melanoma imaging.

We further note that effective January 2005 there will be three new CPT codes for tumor PET imaging to replace CPT 78810 *Tumor imaging, positron emission tomography (PET), metabolic evaluation;* these will reflect three extents of body tumor imaging from limited to torso to whole body*.* There will also be CPT codes for PET with concurrent CT for anatomical localization. We strongly recommend that CMS utilize the new CPT codes for PET and PET/ CT in place of these innumerable G codes. CMS should assign the new PET/CT CPT codes to a New Technology APC in the Final Rule. **Table 2 (attached)** is a proposed APC placement for all PET procedures as described in CPT 2005. To maintain clinical homogeneity we suggest that there be APCs for Level I and II Cardiac PET, a single Level I Brain PET, Levels I -III Tumor PET, and that PET/CT be placed into three different New Technology APCs. We would be pleased to discuss this further with CMS.

NM TF Recommendations

4. **Because of these confounding factors, we recommend that CMS make no substantial change in reimbursement for Tumor PET Imaging at this time, and thus we support Option One.**

5. **The Task Force recommends that CMS eliminate all PET G codes and adopt the current and new CPT codes that will be effective January 1, 2005.**

(III) BRANDED VS. GENERIC RADIOPHARMACEUTICALS:

CMS proposes to add the following HCPCS codes describing some branded radiopharmaceuticals as listed in CMS Table 16 and noted below:

CMS Table 16

CPT/HCPCS	***Descriptions***
C9400	Thallous chloride, brand
C9401	Strontium-89 chloride, brand
C9402	Th I131 so iodine cap, brand
C9403	Dx I131 so iodine cap, brand
C9404	Dx I131 so iodine sol, brand
C9405	Th I131 so iodine sol, brand

MMA requires CMS to determine different payment if a drug is a sole source, innovator or non-innovator multiple source drug. These conventional FDA/Medicaid distinctions do not apply for many radiopharmaceuticals. In fact, CMS deleted a code it had created for Gallium with the recognition that it was not a multiple source drug. See CMS Manual System, Pub. 100-04 Medicare Claims processing, trans. 290 (Aug. 27, 2004) see table B2.

We urge CMS to delete the newly created C codes noted above because all radiopharmaceuticals are better characterized as either sole source or innovator multiple source drugs. Deletion of these codes should result in payment for the corresponding radiopharmaceuticals based on their status as a sole source or innovator multi-source drug. The APC Advisory Panel recommended that such an approach was preferred and would significantly lessen hospital administrative burden and confusion.

NM TF Recommendation

6. **The Task Force recommends that CMS delete the new C codes for "apparent" brand radiopharmaceuticals.**

(IV) APC RELATIVE WEIGHT

Radiopharmaceutical Revenue Codes & Revision to 0636 Description

Effective October 1, 2004, there are two new radiopharmaceutical revenue codes, 0343 and 0344. CMS in its August 27, 2004 PM (Transmittal 290) said that the new radiopharmaceutical revenue codes are "N", which is for packaged items or services. This is clearly not the case for many radiopharmaceuticals. CMS should correct the status indicator for these revenue codes to "K" -- *Non-pass through drugs, biologics and radiopharmaceuticals*.

Hospitals are preparing their charge description masters for this change. Current CMS policy Pub 100-04 Transmittal 112 February 27, 2003 (attached) states that hospitals should use revenue code 0636 for status "K" indicator drugs and radiopharmaceuticals. We are not aware of any published policy from CMS which addresses the new radiopharmaceutical codes or the revised language for 0636.

The revised and new nuclear medicine revenue codes effective October 1, 2004 were referenced in CMS transmittal 81, February 6, 2004, NUBC UB-92 Medicare Claims Processing (http://www.cms.hhs.gov/manuals/pm_trans/R81CP.pdf and portions attached.)

The description and instruction change for revenue code 0636 specifically excludes the use of that code for radiopharmaceuticals, and directs hospitals to use the two new radiopharmaceutical revenue codes 0343 and 0344. These new radiopharmaceutical revenue codes were created to allow hospitals to track and capture the unique costs associated with radiopharmaceuticals. Many providers believe that mixing radiopharmaceutical costs in with traditional drug revenue codes led to charge compression, and under represented the reasonable costs of radiopharmaceuticals. We believe that these new radiopharmaceutical revenue codes will lead to claims and cost data that more accurately portrays the unique features and costs associated with radiopharmaceuticals.

The creation of new revenue codes is not the complete answer for accurate hospital and department specific costs. Universal implementation of these revenue codes with changes in the cost report will be required. Specifically, hospitals will subscript the nuclear medicine cost report line (line 43 on Worksheet A, the Trial Balance of Expenses) to report expenses. For example Diagnostic Radiopharmaceuticals would be on line 43.01 and Therapeutic Radiopharmaceuticals would be on line 43.02. In Worksheet C, line 43 would need to be subscripted in the same manner to record the revenue. **Moving forward, it will be important for CMS to recognize this subscripting and NOT roll up these costs into line item 43**. Line item 43 would hold all costs for the nuclear medicine department outside of the separate and subscript radiopharmaceutical line items. This will give CMS and hospitals a separate CCR for both diagnostic and therapeutic radiopharmaceuticals that is separate from the CCR for the nuclear medicine department and other traditional drugs.

We are pleased that CMS is continuing to refine claim capture methodology. CMS has indicated they are including detailed analysis of the CCR. **We urge CMS to begin to clarify and identify issues regarding the CCR and hospital cost report.** We support CMS efforts to retain sufficient line item and cost report details to get accurate radiopharmaceutical cost data.

NM TF Recommendations

7. **CMS should publish a clarification and correction regarding the new diagnostic and therapeutic radiopharmaceutical revenue codes as follows:**

   Hospitals should be reminded to use revenue code 0636 when billing for items with a status indicator = K, with the exception of radiopharmaceuticals. Effective October 1, 2004, hospitals should use revenue code 0343 for Diagnostic Radiopharmaceuticals and 0344 for Therapeutic Radiopharmaceuticals. These specific radiopharmaceutical revenue codes should be used regardless of status indicator K or N.

8. **CMS should correct the status indicator for the new radiopharmaceutical revenue codes from N to K.**

(V) DRUGS BIOLOGICALS, and RADIOPHARMACEUTICALS NON-PASS THROUGHS

Payment for Specified Covered Outpatient Drugs

We commend highly CMS for implementing the MMA provisions that clarify that radiopharmaceuticals are drugs and must be treated as specified covered outpatient drugs. As radiopharmaceuticals have unique clinical, coding, and payment features, the new MMA drug payment provisions must be adapted to address those distinct considerations.

We appreciate that CMS has given the hospital community better insight into hospital reported data by publishing median cost data for certain drugs. The data for radiopharmaceuticals, however, has been significantly distorted and tends to under report their actual costs. There are reasons for this including changes in HCPCS descriptors and lag time in hospitals updating their charge masters to reflect revised code descriptors. The GAO is conducting a study which holds the promise to capture more accurate acquisition costs which will be an important factor in determining payment in the future. However, we are concerned that existing hospital cost data reporting is inadequate. CMS in the past has allowed external data to clarify and confirm payment levels and we urge CMS to continue that policy.

<u>Qualify for Status K</u>

CMS has recognized separate payment for a number of radiopharmaceuticals. We believe CMS should add to the list of separately payable drugs A9524 *I-131 Albumin* and *Q3010 labeled red blood cells (RBCs) per mCi*. We believe, as does CORAR, that hospital coders were confused by the code description changes and unit measurements. The translation of actual hospital cost per

administered dose into the charge masters may not have been reflective of the description per mCi or uCi.

NM TF Recommendations

9. **We recommend CMS add - A9524 I-131 albumin and Q3010 Tc99m labeled red blood cells to the list of separately payable radiopharmaceuticals.**

10. **We also recommend that CMS should use external data and or AWP to set payment rates in 2005 for these radiopharmaceuticals.**

C9013 Cobaltous Chloride

CMS requested information regarding HCPCS C9013 cobaltous chloride. It is our understanding that this product also called Rubratope, has periodically experienced issues with raw materials and production. We also understand that this product will become available again in November 2004.

11. **We request CMS maintain C9013 and set payment at a % of AWP consistent with the MMA.**

A9600 Strontium-89

In our comparison of available CMS hospital drug and radiopharmaceutical median cost data with the SNM survey cost data (**Table 3 attached)** we have identified several other radiopharmaceuticals and nuclear medicine related drugs which we believe CMS would underpay due to flawed CMS median cost data.

Specifically, HCPCS A9600 Strontium-89 per mCi is proposed to be paid at $410.45 per mCi. SNM data show a median cost of $800 per mCi.

12. **We believe hospital costs for A9600 are approximately $800 per mCi and request CMS adjust payment accordingly.**

Diagnostic and Therapeutic Iodine

HCPCS codes C1064, C1065, C1188, C1348, A9528, A9529, A9530, A9531, A9517 and A9518 all describe in various years and forms diagnostic and therapeutic Iodine 131. These codes have had varying descriptions that have resulted in flawed cost data. It would be difficult to crosswalk the SNM data to the current HCPCS code descriptions as these codes and descriptions contain too many differing variables to achieve an accurate crosswalk. We would like to point out that the SNM data does support that the cost for I-131 in the capsule form is higher than for solution.

NM TF Recommendations

13. **CMS should use external data to restore and correct payment rates for Iodine so that the payment more accurately reflects hospital costs.**

Adenosine

HCPCS code J0150, J0151 and J0152 all describe Adenosine in various sizes, respectively per 6 mg, 90 mg and 30 mg. We point to our SNM survey data which shows a median cost per 6 mg at $32.81 versus CMS data $12.63, and J0151 converted to J0152 CMS median data $62.39/$20.80 compared to SNM median data $185.00/$61.67. We again believe CMS claims data are under estimating true hospital costs. We request CMS to use external data when available such as the SNM Survey to assist in assigning an accurate payment rate for drugs and radiopharmaceuticals.

14. **CMS should use external data to restore and correct payment rates to an appropriate rate for Adenosine to more accurately reflect hospital acquisition costs or payment based on the applicable MMA standard.**

PET Radiopharmaceutical Payment Policy Change

CMS is proposing major reductions in payment for PET radiopharmaceuticals: F18FDG (C1775), N13 ammonia (A9526), and Rb82 rubidium (Q3000). It appears this is based in part on CMS' perception that these products do not fit the category of sole source or innovator multiple source drugs, and thus must default to a payment based on median costs. CMS states that it has no data for A9526. It also suggests that it has data stating that costs for Rb82 and N13ammonia are similar.

CMS's proposal would drop FDG payment from $324.48 to $220.50 and Rubidium payment from $162.63 to $111.91. We believe PET radiopharmaceuticals are best categorized as innovator multi-source or sole source specified covered outpatient drugs as detailed in the CORAR comments and we urge CMS to treat them as such.

The NM APC Task Force would like to express strong concern that the median cost data used by CMS for FDG and Rubidium payment under report the actual and reasonable hospital costs needed to safely prepare, store, administer and dispose of the products. **Table 3 (attached)** contains an SNM 2003 survey of 2002 nuclear medicine cost data, as reported by 82 facilities, which showed a hospital median cost of $425 per dose of FDG.

Moreover, we believe that CMS is using a presumptive functional equivalence in using the same payment for ammonia and rubidium. MMA clearly precludes such an approach.

15. **CMS should establish payment for PET radiopharmaceuticals using the appropriate percentage of AWP (83% for sole source or 68% for innovator multi-source of AWP for these products in 2005.**

Radiolabeled (Radioimmune) Antibody Therapy

Radiolabeled antibody therapy is a major step in the management of patients with non-Hodgkins lymphoma, specifically for those who have become refractory to other treatment. Two products, Zevalin and Bexxar have been available for less than three years, and although they are of a similar class they differ in composition. There may be clinical reasons to administer one product rather than the other depending upon the unique characteristics of a particular patient. However, even modest differences in reimbursement between these products, may preclude hospitals from providing what may be clinically appropriate.

The proposed reimbursement for Bexxar in 2005 is less than the product costs the hospital to purchase. and to formulate. **Table 4 (attached)** summarizes Reimbursement for Zevalin and Bexxar from 2003, and **Tables 5 and 6 (attached)** define the basis for those totals. The coding algorithms differ for the two products because the antibody used in Zevalin therapy is also approved as a therapy itself, and dosimetry is required prior to treatment with Bexxar. Further there is a compounding fee for the hospital to label Bexxar, which is not reflected in either the coding algorithm or the reimbursement for C1080 or C1081 (*Supply of radiopharmaceutical diagnostic imaging agent I-131 tositumomab* and *Supply of radiopharmaceutical therapeutic imaging agent I-131 tositumomab,* respectively.*)*

What we are requesting is reimbursement that allows treatment decisions to be made on the basis of patient condition and clinical characteristics of the potential therapies -- and not on the basis of reimbursement alone. It is our understanding that survey data are being provided to CMS on the cost of compounding and purchase of Bexxar.

16. **We recommend that CMS use external source data and the MMA statutory standards in setting reimbursement for radiolabeled antibody therapy, and**

17. **That CMS consider the cost of compounding Bexxar in the reimbursement for the product, and place C1080 - 1081 in a New Technology APC to reflect that total cost.**

(VI) APC GROUPS

CMS is proposing to move CPT 78730 *Urinary bladder residual study* from APC404 to APC 0340 ("minor ancillary procedures"). This is an imaging study. The proposed change results in a payment rate change of $203.53 to $36.85, or an 82% reduction. We reviewed the utilization of CPT 78730 in BMAD 2003 and note that of the total of 16,191 procedures, 13,512 were done by urologists, 494 by internists, and only 586 by radiologists. This code is being misused to report other than urinary bladder residual imaging as described by this nuclear medicine CPT code. Again, it is an imaging study performed following administration of a radioactive drug, using the

resources of other Level I Renal and GU studies. This imaging study is not an ancillary study. The resources used are comparable to other studies in APC 0404.

NM TF Recommendation

18. **We recommend CMS keep CPT 78730 in APC 0404.**

We thank you for your attention and consideration of these recommendations and comments. We look forward to continue working with CMS as we refine the Nuclear Medicine and Radiopharmaceutical APCs. If you need additional information please contact the NM APC TF staff, Denise Merlino at 781-435-1124 or dmerlino@snm.org.

Sincerely,

Kenneth A. McKusick, MD
Chair, Nuclear Medicine APC Task Force

Ken Simon. MD
Edith Hembrick, MD
Cindy Read
Joan Sanow
Cindy Hake
Denise Merlino
Nuclear Medicine APC Task Force
Gary Dillehay, MD

Table 1 (Reference to Section I) Cardiac G and CPT Codes

CPT or HCPCS Single Study	CPT or HCPCS Multiple Studies	Description
G0030	**G0031**	PET myocardial perfusion imaging, (following previous PET, G0030-G0047); rest or stress (exercise and/or pharmacologic)
G0032	**G0033**	PET myocardial perfusion imaging, (following rest SPECT, 78464); rest or stress (exercise and/or pharmacologic)
G0034	**G0035**	PET myocardial perfusion imaging, (following stress SPECT, 78465);rest or stress (exercise and/or pharmacologic)
G0036	**G0037**	PET myocardial perfusion imaging, (following coronary angiography, 93510-93529);rest or stress (exercise and/or pharmacologic)
G0038	**G0039**	PET myocardial perfusion imaging, (following stress planar myocardial perfusion, 78460);rest or stress (exercise and/or pharmacologic)
G0040	**G0041**	PET myocardial perfusion imaging, (following stress echocardiogram, 93350);rest or stress (exercise and/or pharmacologic)
G0042	**G0043**	PET myocardial perfusion imaging, (following stress nuclear ventriculogram 78481 or 78483);rest or stress (exercise and/or pharmacologic)
G0044	**G0045**	PET myocardial perfusion imaging, (following rest ECG, 93000); rest or stress (exercise and/or pharmacologic)
G0046	**G0047**	PET myocardial perfusion imaging, (following stress ECG, 93015); rest or stress exercise and/or pharmacologic)
78491	**78492**	Myocardial Imaging, positron emission tomography (PET), perfusion; at rest and or stress

Table 2 (Reference to Section II)
Proposed APCs for PET procedures by CPT® Code

Reimbursement Grouping	*Cardiac*	*Brain*	*Oncology*
Level 1	CPT **78459**	CPT **78608**	CPT **78811**
	CPT **78491**	CPT **78609**	
Level 2	CPT **78492**		CPT **78812**
Level 3			CPT **78813**
New Technology Category I			CPT **78814**
New Technology Category II			CPT **78815**
New Technology Category III			CPT **78816**

CPT 78811, 78812, and 78813 are new CPT codes for 2005. They reflect PET tumor imaging studies that are for a limited body area, an area equivalent to the torso and the whole body respectively. We recommend that CPT 78814-16, which are codes defining limited body, torso and whole body PET/CT be placed into three New Technology APCs.

CPT® Code	Long Description
78459	*Myocardial imaging, positron emission tomography (PET), metabolic evaluation*
78491	*Myocardial imaging, positron emission tomography (PET), perfusion; single study at rest or stress*
78492	*Myocardial imaging, positron emission tomography (PET), perfusion; multiple studies at rest and/or stress*
78608	*Brain imaging, positron emission tomography (PET), metabolic evaluation*
78609	*Brain imaging, positron emission tomography (PET), perfusion evaluation*
78811	*Tumor imaging, positron emission tomography (PET); limited area (eg, chest, head/neck)*
78812	*Tumor imaging, positron emission tomography (PET); skull base to mid-thigh*
78813	*Tumor imaging, positron emission tomography (PET); whole body*
78814	*Tumor imaging, positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization; limited area (eg, chest, head/neck)*
78815	*Tumor imaging, positron emission tomography (PET with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization); skull base to mid-thigh*
78816	*Tumor imaging, positron emission tomography (PET with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization); whole body*

Table 3 (Reference to Section V)
Society of Nuclear Medicine (SNM) 2003 Utilization Survey* reporting 2002 Cost Data

HCPCS 2002 Code & Description	*CMS Median*	*SNM Median*	*SNM Survey Number of Facilities Reporting*	*Comments or HCPCS Code Crosswalk to 2004*
A9600 Strontium-89 per mCi	$417.39	$800.00	**47**	Some facilities may have reported per dose and not per mCi no more than 5 sites may have done this currently all data is included in SNM median
C1775 FDG per dose	$224.23	$425.00	**82**	
J0150 Adenosine per 6 mg	$12.63	$32.81	53	
J0151 Adenosine per 90 mg	$62.39	$185.00	202	
	$62.39/3 = $20.80	$185.00/3 = $61.67		J0152 code changed to per 30 mg
C1064 I-131 cap each add mCi	Dx solution 0.01 per mCi & TX caps 6.71 per mCi	14.00	202 sites reported caps and 21-25 reported solution	A9528, A9529, A9530, A9531, A9517, A9518 are new and revised codes used to report I-131. Due to the numerous code and description changes we believe that CMS does not have adequate cost information on I-131 capsules or solution.
C1065 I-131 sol each add mCi		7.00		
C1188 I-131 cap per 1-5 mCi		66.00		
C1348 I-131 sol per 1-6 mCi		51.60		

*The SNM survey numbers are provided from a comprehensive SNM and SNM TS joint survey (survey tool attached) conducted in the fall of 2003 to obtain the current (2003) NM workforce demographics and 2002 facility cost and utilization patterns. 4,425 NM facilities in the US were sent this survey identifying the Chief Nuclear Medicine Technologist as the contact person. 983 surveys were returned with a 22% response rate in total. The data was first divided into Hospital versus Non-Hospital with 58% of the responses coming from hospitals. Not all facilities reported all procedures and radiopharmaceuticals cost information, this was expected since not all nuclear medicine departments perform all procedures, additionally we expected differences based on the facility choice of radiopharmaceuticals. In the median cost reported in the above table are the Hospital ONLY cost and frequency data as reported for 2002 in our survey.

Table 4 (Reference to Section V)

Summary of Bexxar and Zevalin OPPS Payments: 2003-2005		
	Total Payment	
CMS Federal Register Notice	**Bexxar**	**Zevalin**
2003 Final Rule	$27,152.39	$25,991.16
2004 Final Rule, Pre-MMA	$27,616.35	$26,420.30
2004 Final Rule, Post-MMA	$30,567.09	$30,949.04
2005 Proposed Rule	$27,461.27	$29,277.48

Table 5 (Reference to Section V)

Total Payments for Bexxar Therapy under the 2005 OPPS Proposed Rule					
	Code	**Description**	**Units**	**2005 Proposed APC Payment**	**Total Payment**
Dosimetric Step	G3001	Administration and supply of tositumomab, 450mg	1	$2,250.00	$2,250.00
	C1080	Supply of radiopharmaceutical diagnostic imaging agent, I-131 tositumomab, per dose	1	$2,241.00	$2,241.00
	78804	Radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s); whole body, requiring two or more days imaging	1	$650.00	$650.00
	77300	Basic radiation dosimetry calculation	1	$98.27	$98.27
Therapeutic Step	G3001	Administration and supply of tositumomab, 450mg	1	$2,250.00	$2,250.00
	C1081	Supply of radiopharmaceutical therapeutic imaging agent, I-131 tositumomab, per dose	1	$19,422.00	$19,422.00
	79403	Radiopharmaceutical therapy, radiolabeled monoclonal antibody by intravenous infusion	1	$550.00	$550.00
Grand total					**$27,461.27**

Table 6 (Reference to Section V)

Total Payments for Zevalin™ Therapy under the 2005 OPPS Proposed Rule					
	Code	**Description**	**Units**	**2005 Proposed APC Payment**	**Total Payment**
Pre-treatment planning step	J9310	Rituximab, 100 mg	5	$437.83	$2,189.15
	Q0084	Chemotherapy by infusion	1	$165.60	$165.60
	78804	Radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s); whole body, requiring two or more days imaging	1	$650.00	$650.00
	C1082	Supply of radiopharmaceutical diagnostic imaging agent, indium-111 ibritumomab tiuxetan, per dose	1	$2,419.78	$2,419.78
Therapeutic step	J9310	Rituximab, 100 mg	5	$437.83	$2,189.15
	Q0084	Chemotherapy by infusion	1	$165.60	$165.60
	79403	Radiopharmaceutical therapy, radiolabeled monoclonal antibody by intravenous infusion	1	$550.00	$550.00
	C1083	Supply of radiopharmaceutical therapeutic imaging agent, yttrium 90 ibritumomab tiuxetan, per dose	1	$20,948.20	$20,948.20
Grand total					**$29,277.48**

(Reference to Section IV)

CMS Manual System Pub. 100-04 Medicare Claims Processing	Department of Health & Human Services (DHHS) Centers for Medicare & Medicaid Services (CMS)
Transmittal 112	Date: FEBRUARY 27, 2004
	CHANGE REQUEST 3144

13. Hospitals should be reminded to use revenue code 636 when billing for items with a status indicator = K.

C. **Provider Education:** A provider education article related to this instruction will be available at www.cms.hhs.gov/medlearn/matters shortly after the CR is released. You will receive notification of the article release via the established "medlearn matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article must be included in your next regularly scheduled bulletin.

The revised and new nuclear medicine revenue codes effective October 1, 2004 CMS transmittal 81 published on February 6, 2004 titled, NUBC UB-92 Medicare Claims Processing (available at http://www.cms.hhs.gov/manuals/pm_trans/R81CP.pdf)

This is a long transmittal and to assist you, we have extracted the items pertaining to the nuclear medicine section and radiopharmaceuticals, as well as highlighted the changes underlined.

034X Nuclear Medicine
Subcategory Standard Abbreviations
0 - General Classification NUCLEAR MEDICINE or (NUC MED)
1 - Diagnostic Procedures NUC MED/DX
2 - Therapeutic Procedures NUC MED/RX
3 - Diagnostic Radiopharmaceuticals NUC MED/DX RADIOPHARM Effective 10/1/04
4 - Therapeutic Radiopharmaceuticals NUC MED/RX RADIOPHARM Effective 10/1/04
9 - Other NUC MED/OTHER

063X Code indicates charges for drugs and biologicals requiring specific identification as required by the payer. If HCPCS is used to describe the drug, enter the HCPCS code in FL 44.
6 - Drugs Requiring Detailed Coding (a) DRUGS/DETAIL CODE

NOTE: (a) Charges for drugs and biologicals (with the exception of radiopharmaceuticals, which are reported under Revenue Codes 0343 and 0344) requiring specific identifications as required by the payer (effective 10/1/04). If HCPCS are used to describe the drug, enter the HCPCS code in Form Locator 44. [The specified units of service to be reported are to be in hundreds (100s) rounded to the nearest hundred (no decimal).]

Nuclear Medicine APC Task Force October 8, 2004

Society of Nuclear Medicine Staff Utilization Survey

Facility Demographics

1. Type of Facility *(Check one.)*
A definition of "Facility" and other guidance can be located on the back of the cover letter which arrived with this survey or on the SNM website at http://www.snm.org/survey_def.html.

a. ____ Hospital
b. ____ Non-hospital

2a. If hospital, what type? *(Please check all that apply.)*

a. ____ Private
b. ____ Community
c. ____ Government
d. ____ University

2b. If hospital, how many licensed hospital beds does your facility have? _____

3a. If non-hospital, what specialties are practiced at your facility? *(Please check all that apply.)*

a. ____ Nuclear Medicine (non-PET)
b. ____ PET
c. ____ Cardiology
d. ____ Oncology
e. ____ Endocrinology
f. ____ General Internal Medicine
g. ____ Neurology
h. ____ Radiology (other than Nuc. Med/PET)
i. ____ Other primary care
j. ____ Other medical subspecialties
k. ____ Other surgical subspecialties

3b. If non-hospital, what type? *(Please check all that apply.)*

a. ____ Imaging Center (multiple imaging modalities)
b. ____ Multi-Specialty Physician Office
c. ____ Single-Specialty Physician Office
d. ____ Other _____

4a. Please identify the organizations that have awarded accreditation to your nuclear medicine (NM) facility: *(Please circle "yes" or "no" for each one.)*

a. ICANL Yes No
b. ACR Yes No
c. JCAHO Yes No N/A
d. Other: _____

4b. Do you use Phantoms to test proficiency at your NM facility? *(Circle one.)* Yes No
If yes, do you use the following phantom programs?

a. SNM Quality Assurance phantom program Yes No
b. ACR NM Accreditation program Yes No
c. Other phantom program used_____

5. Number of days per week this facility routinely provides nuclear medicine patient services: *(Please check only one.)*

a. ___ 1 day/week b. ___ 2 days/week c. ___ 3-4 days/week d. ___ 5 days/week e. ___ 6-7 days/week

6. Total hours this facility is open per week for routine nuclear medicine patient services: *(Please check only one.)*

a. ___ 45 hours or less/week b. ___ 46 – 55 hours/week c. ___ 56 - 65 hours/week d. ___ 66 - 79 hours/week e. ___ 80 hours/week or more

Staffing Information

7. Does your NM facility require certification or licensure for NM technologists? *(Circle one.)* Yes No

8. Please indicate the number of Full-Time Equivalents (FTEs) and pay rates for the following NM technologists at your facility:
(Please write in the number of FTEs and their average hourly rate. If there are none, please put a "0" in the space provided.)

	Number of current FTEs	Average hourly rate
a. Nuc. Med. Chief Technologist/Supervisor	_____	_____
b. Nuc. Med. Administrator (if not a Chief Tech)	_____	_____
c. New graduates (Less than 1 year of experience)	_____	_____
d. Technologists (1 – 5 years experience in the field)	_____	_____
e. Technologists (6 – 10 years experience in the field)	_____	_____
f. Technologists (More than 10 years experience)	_____	_____

9. Do you use any special incentives, such as sign-on bonuses, to recruit nuclear medicine technologists? Yes No
If yes, what are the incentives that you use?_____

10. Do you use any special incentives, such as monetary incentives or vesting schedules, to retain NM technologists? Yes No
If yes, what are the incentives that you use?_____

11. How many NM technologists at your NM facility have the following types of degrees or certificates:
(If a technologist has more than one degree, please only include them in the category for their highest level of degree received.)

a. No degree _____ b. Certificate only _____ c. 2-year degree _____ d. 4-year degree _____ e. Post-graduate degree _____

11a. How many NM technologists at your NM facility are certified by:

a. NMTCB _____ b. ARRT(N) _____ c. Other_____

12. How many FTEs (not number of employees) are employed by your NM facility? *(If there are none, please put a "0" in the space.)*

	Number of FTEs
a. Nurses?	_____ FTEs
b. Physician Assistants?	_____ FTEs
c. Technologist Assistants?	_____ FTEs

13. Do you have a NM medical director at your facility? *(Circle one.)* Yes No **(If No, skip to Q14)**
If Yes, what percent of their time is spent on administrative duties/research?_____
If Yes, what percent of their time is spent on clinical activities? _____

14. Do you have NM technologists on-call at your facility in the following areas: *(Please circle "yes," "no," or "not applicable". If your facility does not do procedures in any of the following areas, please circle "not applicable".)*

a. General Nuclear Medicine?	Yes	No	Not applicable (N/A)
b. Nuclear Cardiology?	Yes	No	N/A
c. PET?	Yes	No	N/A

15. Do you have open NM Technologist positions in the following areas at your facility: *(Please circle "yes," "no," or "not applicable".)*

a. General Nuclear Medicine?	Yes	No	N/A	If Yes, how many open FTE positions? _____
b. Nuclear Cardiology?	Yes	No	N/A	If Yes, how many open FTE positions? _____
c. PET?	Yes	No	N/A	If Yes, how many open FTE positions? _____

16. Do you have open NM Physician positions in the following areas at your facility: *(Please circle "yes," "no," or "not applicable".)*

a. General Nuclear Medicine?	Yes	No	N/A	If Yes, how many open FTE positions? _____
b. Nuclear Cardiology?	Yes	No	N/A	If Yes, how many open FTE positions? _____
c. PET?	Yes	No	N/A	If Yes, how many open FTE positions? _____

17. Please indicate the board certifications of physicians who read nuclear medicine studies at your NM facility (for up to 12 physicians). *Please use the following codes to identify each certification. Next to each physician, write in the code numbers of his/her certifications. If they are certified in more than one, separate them with a comma. For example, if a physician is ASNC and Cardiology certified, then write in "4, 6".*

1 = ABNM 2 = ABR 3 = ABR with CAQ in NM 4 = ASNC 5 = ABIM 6 = Cardiology 7 = Endocrinology 8 = Pathology 9 = Surgery 10 = Other

Certifications		Certifications		Certifications		Certifications	
Physician 1	_____	Physician 4	_____	Physician 7	_____	Physician 10	_____
Physician 2	_____	Physician 5	_____	Physician 8	_____	Physician 11	_____
Physician 3	_____	Physician 6	_____	Physician 9	_____	Physician 12	_____

17a. Are any physicians considering obtaining additional credentials within the next two years? *(Check one response.)*
a. ____Yes b. ____No c. ____Don't know
If yes, how many are planning to obtain additional credentials? _____
If yes, which credentials are they considering obtaining? *(Use same codes as in question 17 above.)* _____

Operation/Utilization

18. What is the average wait time for the following types of non-urgent nuclear medicine procedures at your NM facility? *(Please check one for each type of procedure. If your facility does not do procedures in any of the following areas, please check "not applicable".)*

a. Nuclear cardiology:	____2 days or less	____3-4 days	____1 week	____2-3 weeks	____more than 3 weeks	____N/A
b. PET:	____2 days or less	____3-4 days	____1 week	____2-3 weeks	____more than 3 weeks	____N/A
c. All other NM procedures:	____2 days or less	____3-4 days	____1 week	____2-3 weeks	____more than 3 weeks	____N/A

19. Do you have a computerized radiology information system (RIS) at your NM facility? *(Circle one.)* Yes No
If Yes, what functions are being used on the RIS? *(Check all that apply.)*
a. ____Registration b. ____Scheduling c. ____Film-Tracking d. ____Transportation e. Other_____

20. Do you have an image archiving system (e.g., PAC) at your NM facility? *(Circle one.)* Yes No
If yes, is it operational in nuclear medicine? *(Circle one.)* Yes No
If yes, are the nuclear medicine images readable by referring physicians? *(Circle one.)* Yes No

21. How many total Gamma/PET and PET/CT imaging systems does your facility have? _____

22. Please answer the following questions for your facility's four (4) newest Gamma/PET or PET/CT imaging systems.

	Manufacturer/ Brand Name?	Year purchased?	Is it a Gamma Camera or a dedicated PET scanner?	If Gamma Camera:			If PET:	
				# of detector heads?	SPECT capable?	Coincidence imaging capable?	PET/CT?	Full ring?
Camera 1			Gamma PET	1 2 3	Yes No	Yes No	Yes No	Yes No
Camera 2			Gamma PET	1 2 3	Yes No	Yes No	Yes No	Yes No
Camera 3			Gamma PET	1 2 3	Yes No	Yes No	Yes No	Yes No

Camera 4			Gamma PET	1 2 3	Yes No	Yes No	Yes No	Yes No

23. Does your NM facility plan on upgrading or purchasing nuclear medicine equipment in the next year? Yes No
If yes, please indicate the type of upgrade or purchase you are planning: *(Check all that apply.)*

a. _____ SPECT b._____ PET c._____ PET/CT d. _____ Other _____

24. What percentage of your radiopharmaceuticals are prepared in the following ways: *(The percentages should add up to 100%.)*

a. ____% Commercially prepared Unit Dose b.____% Commercially prepared Multidose Vial (Kits) c.____% In-house preparation

For the remaining questions in the survey, we are trying to learn information regarding the volume of NM procedures performed at your facility. Please answer the remaining questions for the 2002 fiscal year at your facility.

25. Do you perform cardiac nuclear medicine procedures in your facility/hospital? *(Choose one.)*

a. ____Yes b. ____ No **(If No, Skip to Question 26)**

25a. How many of the following cardiac nuclear medicine procedures were performed in 2002? Please put the combined total number of procedures performed for each category of CPT codes.

CPT or G Code	Procedure Description	Number of Procedures
a. 78465	SPECT Myocardial Perfusion Imaging (MPI) Multiple	_____
b. 78464	SPECT Myocardial Perfusion Imaging (MPI) Single	_____
c. 78461	Planar Myocardial Perfusion Imaging (MPI) Multiple	_____
d. 78460	Planar Myocardial Perfusion Imaging (MPI) Single	_____
e. 78478	Wall Motion Add On	_____
f. 78480	Ejection Fraction Add On	_____
g. 78494	Cardiac Blood Pool (SPECT)	_____
h. 78496, 78473	Gated Blood Pool (MUGA,RVG) Multiple	_____
i. 78472	Gated Blood Pool Single (RVEF)	_____
j. _____	Cardiac Stress Test	_____

(Please write in code used for Cardiac Stress Test.)

25b. How many of the following radiopharmaceuticals and drugs were used in 2002 cardiac nuclear medicine procedures, what was the average cost, and what was the average dose?

Radiopharmaceutical	Number Used in 2002	Average Cost	Average Dose
a. A9500 Tc 99m Sestamibi per dose	_____	$_____ per dose	_____mCi
b. A9502 Tc 99m Tetrofosmin per dose	_____	$_____ per dose	_____mCi
c. A9505 TL 201 Thallium per mCi	_____	$_____ per mCi	_____mCi
d. Q3010 Tc 99m RBC per dose	_____	$_____ per dose	_____mCi
e. J1245 Dipyridamole per 10 mg	_____	$_____ per 10 mg	_____mg
f. J0150 Adenosine per 6 mg	_____	$_____ per 6 mg	_____mg
g. J0151 Adenosine per 90 mg	_____	$_____ per 90 mg	_____mg
h. Other _____	_____	$_____ per unit	_____unit
i. Other _____	_____	$_____ per unit	_____unit

26. Do you perform therapeutic nuclear medicine procedures in your facility/hospital? *(Choose one.)*

a. ____Yes b. ____ No **(If No, Skip to Question 27)**

26a. How many of the following therapeutic procedures were performed in 2002? Please put the combined total number of procedures performed for each category of CPT codes.

CPT or G Code	Procedure Description	Number of Procedures
a. 79000 – 79020	Thyroid non-cancer	_____
b. 79030, 79035	Thyroid Carcinoma	_____
c. 79100	Polycythemia Vera, Chronic Leukemia	_____
d. 79200 - 79440	Miscellaneous	_____
e. Other _____		_____

26b. How many of the following radiopharmaceuticals and drugs were used in 2002 therapeutic nuclear medicine procedures, what was the average cost, and what was the average dose?

Radiopharmaceutical	Number Used in 2002	Average Cost	Average Dose
a. A9600 Strontium-89 Chloride, per mCi	_____	$_____ per mCi	_____mCi
b. A9605 Samarium-153 lexidronamm, 50 mCi	_____	$_____ per mCi	_____mCi
c. C1064 I-131 Cap, each additional mCi	_____	$_____ per mCi	_____mCi
d. C1065 I-131 Sol, each additional mCi	_____	$_____ per mCi	_____mCi
e. C1188 Iodine I-131 CAP, per 1-5 mCi	_____	$_____ per mCi	_____mCi
f. C1348 I-131 Solution, per 1-6 mCi	_____	$_____ per mCi	_____mCi
g. Q3007 Sodium Phosphate P-32, per mCi	_____	$_____ per mCi	_____mCi
h. Q3011 Chromic Phosphate P-32, per mCi	_____	$_____ per mCi	_____mCi
i. Other _____	_____	$_____ per unit	_____unit
j. Other _____	_____	$_____ per unit	_____unit

27. Do you perform PET nuclear medicine procedures in your facility/hospital? *(Choose one.)*

a. ____Yes b. ____ No **(If No, Skip to Question 28)**

27a. How many of the following PET procedures were performed in 2002? Please put the combined total number of procedures performed for each category of CPT codes.

CPT or G Code	Procedure Description	Number of Procedures
a. G0125, G0210 – G0212, G0234	Lung	_____
b. G0213 – G0215, G0231	Colorectal	_____
c. G0216 – G0218, G0233	Melanoma	_____
d. G0220 – G0222, G0232	Lymphoma	_____
e. G0223 – G0225	Head and Neck Cancers	_____
f. G0226 – G0228	Esophageal	_____
g. 78810	Tumor	_____
h. G0252 – G0254	Breast	_____
i. G0219	Non-covered indications	_____
j. G0229 – 78608, 78609	Brain	_____
k. G0230, 78459, 78491, 78492	Cardiac	_____
l. G0032 – G0047		_____
m. G0030 – G0031		_____

(Turn page

27b. How many doses of the following radiopharmaceuticals were used in 2002 PET nuclear medicine procedures, what was the average cost per dose, and what was the average dose?

Radiopharmaceuticals	Number of Doses	Average Cost	Average Dose
a. C1775 FDG per dose	_____ doses	$_____ per dose	_____ mCi
b. Q3000 Rubidium 82 per dose	_____ doses	$_____ per dose	_____ mCi
c. Other _____	_____	$_____ per unit	_____ unit

28. Do you perform any other nuclear medicine procedures in your facility/hospital? *(Choose one.)*

a. ____Yes b. ____ No **(If No, Skip to Question 29)**

28a. How many of the following other nuclear medicine procedures were performed in 2002? Please put the combined total number of procedures performed for each category of CPT codes.

CPT or G Code	Procedure Description	Number of Procedures
a. 78000 - 78011	Thyroid Imaging and Uptake	_____
b. 78015, 78020	Thyroid Carcinoma Metastases Imaging	_____
c. 78070, 78075	Parathyroid & Adrenal	_____
d. 78195	Lymphatics and Lymph Node	_____
e. 78185, 78201 - 78220	Liver and Spleen	_____
f. 78223	Hepatobiliary	_____
g. 78300 - 78320	Bone Scan	_____
h. 78580 - 78596	Ventilation and Perfusion Scans	_____
i. 78600 - 78615	Brain Imaging including SPECT	_____
j. 78700 - 78725	Renal Imaging	_____
k. 78730 - 78740	Ureteral Reflux & Retention Study	_____
l. 78760 - 78761	Testicular Imaging	_____
m. 78800 - 78803	Localization of Tumor	_____
n. 78805 - 78807	Localization of Abscess	_____
o. Other _____	_____	_____
p. Other _____	_____	_____

28b. How many of the following radiopharmaceuticals were used in the other 2002 nuclear medicine procedures, what was the average cost, and what was the average dose?

Radiopharmaceutical	Number Used in 2002	Average Cost	Average Dose
a. A4642 Satumomab penedetide per dose	_____	$_____ per dose	_____ mCi
b. A9500 Technetium TC 99m sestamibi per dose	_____	$_____ per dose	_____ mCi
c. A9503 Technetium TC 99m medronate per dose	_____	$_____ per dose	_____ mCi
d. A9504 Technetium TC 99m apcitide per dose	_____	$_____ per dose	_____ mCi
e. A9505 Thallous chloride TL 201 per mCi	_____	$_____ per mCi	_____ mCi
f. A9507 Indium/111 capromab pendetid per dose	_____	$_____ per dose	_____ mCi
g. A9510 Technetium Tc-99m Disofenin per dose	_____	$_____ per dose	_____ mCi
h. A9511 Technetium 99m Depreotide per mCi	_____	$_____ per mCi	_____ mCi
i. C1058 Technetium 99m Oxidronate per vial	_____	$_____ per vial	_____ mCi
j. C1066 In111 Satumomab Pendetide per dose	_____	$_____ per dose	_____ mCi
k. C1087 Iodine I-123 (capsule), per 100 uCi	_____	$_____ per uCi	_____ uCi

l.	C1092 IN-111 Pentetate, per 0.5 mCi	_____	$_____ per mCi	_____ mCi
m.	C1094 Tc99m Album Aggregate, 1.0 mCi	_____	$_____ per mCi	_____ mCi
n.	C1095 Tc99m Depreotide, per dose	_____	$_____ per dose	_____ mCi
o.	C1096 Tc99m Exametazime, per dose	_____	$_____ per dose	_____ mCi
p.	C1097 Tc99m Mebrofenin, per dose	_____	$_____ per dose	_____ mCi
q.	C1098 Tc99m Pentetate, per dose	_____	$_____ per dose	_____ mCi
r.	C1122 Tc99m Arcitumomab, per dose	_____	$_____ per dose	_____ mCi
s.	Q3006, C1200 Tc99m Glucoheptonate per dose	_____	$_____ per dose	_____ mCi
t.	C1201 Tc99m Succimer, per dose	_____	$_____ per dose	_____ mCi
u.	C1202 Tc99m Sulfur Colloid, per dose	_____	$_____ per dose	_____ mCi
v.	Q3002 Gallium Ga-67, per mCi	_____	$_____ per mCi	_____ mCi
w.	Q3003Tc99m Biscate, per dose	_____	$_____ per dose	_____ mCi
x.	Q3004 Xenon XE 133 per 10 mCi	_____	$_____ per mCi	_____ mCi
y.	Q3005 Tc99m Mertiatide per dose	_____	$_____ per dose	_____ mCi
z.	Q3008 In 111 Pentetreotide per dose	_____	$_____ per dose	_____ mCi
aa.	Q3009 Tc99m oxidronate per dose	_____	$_____ per dose	_____ mCi
bb.	Other _____	_____	$_____ per unit	_____ unit
cc.	Other _____	_____	$_____ per unit	_____ unit

29. How many total in-patient NM procedures were performed at your facility in 2002? _____

30. How many total out-patient NM procedures were performed at your facility in 2002? _____

Submitter : Mr. Robert Ragona **Date & Time:** 10/07/2004 06:10:24

Organization : Newton Memorial Hospital

Category : Hospital

Issue Areas/Comments

Issues 21-30

Wage Index

October 7, 2004

Dr. Mark McClellan
CMS Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1427-P
P.O. Box 8010
Baltimore, MD 21244-8018

Re: File Code CMS-1427-P

Dear Dr. McClellan:

Newton Memorial Hospital welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services? (CMS) proposed rule entitled Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment Systems and Calendar Year (CY) 2005 Payment Rates; Proposed Rule, 69 Fed. Reg. 50448 (August 16, 2004).

Our comments relate to the ?Wage Index?section of the proposed rule.

Please be advised that Newton Memorial Hospital generally supports the CMS final rulemaking related to ?Special Circumstances of Hospitals in All-Urban States? contained in the Federal Fiscal Year (FFY) 2005 final inpatient rule published in the August 11, 2004 Federal Register. The FFY 2005 final inpatient rule adopted a methodology that imputes a wage index floor for those states that are deemed to be ?All-Urban States.? It is clear that the absence of a floor for the Medicare wage index calculation creates an uneven playing field between the All-Urban States (currently three under the final inpatient rule) and the remaining forty-seven states. Imputing a wage index floor for the All Urban State adds symmetry, equity and consistency to the reimbursement methodology.

Newton Memorial Hospital strongly supports the contention that the imputed wage index floor should also apply to outpatient hospital services effective with CY 2005. Unfortunately, the proposed outpatient rule does not recognize this contention since the proposed inpatient wage index amounts (that is, the wage indexes that CMS proposed for the hospital inpatient PPS rules as published in the May 18, 2004 Federal

Register) are currently scheduled to be implemented for outpatient services beginning with CY 2005. Utilizing the proposed inpatient wage index amounts circumvents the implementation of the ?Special Circumstances of Hospitals in All-Urban States? for outpatient purposes for CY 2005 since this provision was not adopted until the final inpatient rulemaking.

It should be noted that since the inception of the outpatient prospective payment system (OP PPS) in August 2000, final inpatient wage index

amounts consistently have been implemented by CMS in the final OP PPS rulemaking. This provision is in accordance with 42 CFR ? 419.43(c). The proposed outpatient rule for CY 2005 deviates from prior established methodology with regard to wage index implementation.

Newton Memorial Hospital strongly urges CMS to adopt the methodology of implementing final inpatient wage index amounts for outpatient wage index purposes for CY 2005, which is consistent with prior year OP PPS implementation and which promotes equity and consistency in this area.

Thank you for considering these important comments and we look forward to your response.

Respectfully submitted,

Robert A. Ragona
Vice President, Finance

/ds

Submitter : Mr. Jeffrey Steiner **Date & Time:** 10/07/2004 07:10:19

Organization : Memorial Hospital

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 21-30

Payment Rate for APCs

Please see letter attached

Department of Health and Human Services
Centers for Medicare and Medicaid Services (CMS)
Offices of Strategic Operations and Regulatory Affairs

The attachment to this document is not provided because:

1. The document was improperly formatted.
2. The submitter intended to attach more than one document, but not all attachments were received.
3. The document received was a protected file and can not be released to the public.
4. The document is not available electronically at this time. If you like to view any of the documents that are not posted, please contact CMS at 1-800-743-3951 to schedule an appointment.

Submitter : Dr. Emmet Keeffe **Date & Time:** 10/07/2004 07:10:34

Organization : American Gastroenterological Association

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

see attached comment letter

CMS-1427-P-178-Attach-1.doc

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October 4, 2004

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1427-P
P.O. Box 8010
Baltimore, MD 21244-8018

Re: Medicare Program; Revisions to Payment Policies Under the Hospital Outpatient Prospective Payment System for Calendar Year 2005; Proposed Rule; 69 *Fed. Reg*. 47,969 *et seq.* (Aug. 12, 2004); CMS-1427-P.

Dear Sir or Madam:

The American Gastroenterological Association (AGA) appreciates the opportunity to comment on the proposed revisions to payment policies under the Medicare Hospital Outpatient Prospective Payment System for Calendar Year ("CY") 2005. 69 *Fed. Reg*. 47,969 *et seq.* (August 12, 2004).

The AGA is the nation's oldest not-for-profit medical specialty society, and the largest society of gastroenterologists, representing more than 14,000 physicians and scientists who are involved in research, clinical practice, and education on disorders of the digestive system. In light of the implications of the proposed changes on AGA members, and AGA's ongoing interest in the matters discussed therein, AGA is providing comments on the following topics:

- Capsule endoscopy (APC 1508),
- Stretta procedure (APC 1557); and
- Endocinch procedure (APC 1555).

A. Capsule endoscopy (APC 1508)

AGA believes that CMS may not have accurate cost data for the Capsule endoscopy procedure. Since being introduced in 2001, Capsule endoscopy has been defined by several different codes and assigned to two different APC payment categories. Moreover, coding instructions from Medicare contractors have varied. Prior to the establishment of the temporary code, G0262, in 2003, some contractors required hospitals to use single codes; others advised hospitals to use unlisted codes; others instructed hospitals to use combinations of multiple codes with and without modifiers. Keeping up with the changes has been difficult and resulted in confusion among hospitals, physicians and even some

Medicare contractors. As a result of this confusion, CMS cannot have uniform and accurate cost information.

Currently, CPT code 91110, Capsule endoscopy, is assigned to APC 1508, which pays $650.00. Under the proposed rule, this service would be moved to APC 141, Upper GI endoscopy, with a payment level of $464.52.

Capsule endoscopy is a fundamentally different gastrointestinal procedure from upper gastrointestinal endoscopy. It is not clinically homogeneous, nor is it comparable in terms of resource use to the other procedures listed within the existing Gastroenterology APC categories. Furthermore, the existing gastrointestinal APC's were not established with the additional costs associated with single use disposable devices in mind. The cost of each single use capsule required to perform code 91110 is $450.00. If this procedure is mapped into APC 141, this means there would remain only an additional $14.00 to all remaining costs associated with performing this procedure. We have grave concerns that this reclassification will restrict Medicare beneficiary access to this procedure. AGA asks that CMS retain the current New Technology APC 1508 for at least one more year to obtain more accurate hospital cost data.

B. Stretta procedure (APC 1557)

The AGA also is concerned about CMS' proposal to reassign the Stretta procedure (C9701), currently assigned to APC 1557 with a payment rate of $1,850.00, to APC 422 with a payment rate of $1,274.51. It appears that CMS has not adequately accounted for all of the components associated with the performance of this procedure. For example, the disposable supplies necessary to perform this procedure, which include a single-use Stretta catheter costing approximately $1,030.00, a guidewire costing approximately $60.00, and a pressure relief pack valve valued at approximately $22.00, the procedure cost far exceeds the proposed reimbursement. CMS also seems to be forgetting that hospitals incur the cost of the specialized Stretta generator equipment, which costs in excess of $33,000. AGA is likewise concerned that inadequate Medicare reimbursement will discourage hospitals from embracing this new technology during its introductory years, and beneficiaries will not have adequate access to this procedureIn light of these concerns, AGA recommends that CMS keep the Stretta procedure in APC 1557 until the agency can acquire more accurate billing data.

C. Endocinch procedure (APC 1555)

The AGA also is concerned about CMS' proposal to reclassify the Endocinch procedure (C9703). This procedure is currently assigned to APC classification 1555 with a payment of $1,650.00. Medicare is proposing to reassign this procedure to APC 422, with a payment rate of $1,274.51. This drastic reduction does not account for all the components associated with the performance of this procedure. The proposed reimbursement amount would not adequately cover even the disposable supplies necessary to perform this procedure. AGA is likewise concerned that inadequate Medicare reimbursement will discourage hospitals from embracing this new technology during its introductory years, and beneficiaries will not have adequate access to this procedure. We ask that CMS continue to assign this procedure to APC 1555 until the agency can acquire more accurate billing data.

D. Esophagoscopy

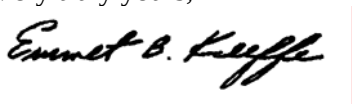
AGA commends CMS for reclassifying codes 43228, esophagoscopy with ablation of tumor(s), polyp(s), or other lesion(s), not amenable to removal by hot biopsy forceps, bipolar cautery or snare technique from APC 0141 to 0422, and codes 45005, incision and drainage of submucosal abscess, rectum and 45020, incisions and drainage of deep supralevator, pelvirectal, or rectrorectal abscess from APC 0148 to 0155.

AGA supports these welcome changes towards improving the fairness of the formula in view of the costs involved with providing these services.

* * * * *

We appreciate your consideration of these comments. If you have any questions, please call AGA's Vice President of Public Policy and Government Affairs, Michael Roberts, at (301) 654-2055.

Very truly yours,



Emmet B. Keeffe, MD
President

cc: Michael Roberts, Vice President of Public Policy and Government Affairs

CMS-1427-P-179

Submitter : Dr. Jon Shallop **Date & Time:** 10/07/2004 08:10:13

Organization : Dr. Jon Shallop

Category : Other Practitioner

Issue Areas/Comments

Issues 1-10

APC Relative Weights

I am the audiology consultant supervising the Cochlear Implant Program at Mayo Clinic in Rochester, Minnesota. I am pleased to add the following comments to CMS-1427, published in the Public Registrar on August 16, 2004. We are pleased to see this proposed increase in payment for Cochlear Implants (APC25969930) and recognize the progress that this change would represent. However, the proposed payment under the Outpatient Prospective Payment System (OPSPS) is less than our hospital costs to acquire the cochlear implant device itself, let alone provide the associated surgical services. We would like to see this payment for cochlear implantation calculated more accurately on the basis of data from 2003 that has been analyzed by CMS. We feel that the current proposal is not representative of the costs of the device and the procedure.

Our practice in the cochlear implant program consists of about two-thirds adults and one-third children in approximately 60 implants per year. A significant number of these adult patients, at least 50%, are Medicare patients. Since the cost of surgery and the device exceeds the reimbursement under Medicare, our hospital incurs a loss every year from implanting these Medicare patients.

I also wanted to express concern about billing and coding errors that may occur in hospitals. While there has been some improvement, we would urge CMS to accelerate its efforts to educate hospitals on the importance of accurate coding for cochlear implant devices and other technology. In addition to using L8614, hospitals also need to be educated on how to report these charges for cochlear implants. Especially those utilized in the outpatient department.

As you know, the advisory panel on ambulatory classifications groups has recommended a 5% cap rather than the increase proposed by CMS. Cochlear implantation is significantly underpaid relative to the actual cost. Therefore, we disagree with the advisory panels? recommendation because it is arbitrary and it hinders the goal of CMS to ultimately rely on accurate claims data to establish these rates.

In summary, the proposed increase in payment for APC0259 is based on available data. Based on the proposed rate of this we anticipate that our hospital would lose approximately $25,000 per Medicare cochlear implant surgery in 2005. We ask CMS to improve the educational outreach programs to hospitals. In addition we oppose the arbitrary measures such as APC panels? 5% recommendation as the cap increase.

The cochlear implant program at Mayo Clinic appreciates the agencies recognition of the potential impact on payment rates and access to care and we hope that you will consider careful our comments as well as those of the others who will submit them for review. I would be pleased to answer any further question or provide any information and you can contact me as follows.

Sincerely yours,

Jon K. Shallop, Ph.D.
Director, Cochlear Implant Facility
Mayo Clinic
200 First Street, SW
Rochester, MN 55905

CMS-1427-P-180

Submitter : **Date & Time:** **10/07/2004 08:10:18**

Organization :

Category : **Health Care Provider/Association**

Issue Areas/Comments

Issues 1-10

APC Relative Weights

THE UNIVERSITY OF CHICAGO
Otolaryngology ? Head And Neck Surgery
5841 S. Maryland Avenue, MC 1035 ? Chicago, IL 60637
Phone: (773) 702-1865 Fax: (773) 702-6809

4 October 2004

Mark McClellan, MD, PhD, Administrator
Centers for Medicare and Medicaid Services
Dept. of Health and Human Services
Attn: CMS-1427-P
PO BOX 8010
Baltimore, MD 21244-8018

RE: Medicare Program?Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year (CY) 2005 Payment Rates; CMS-1427-P; Proposed Recalibration of APC Weights for CY 2005

Dear Dr. McClellan:

On behalf of The University of Chicago Hospitals Otolaryngology/Head and Neck Surgery and Audiology Department, we are pleased to submit the following comments on the proposed rule CMS-1427-P published in the Federal Register on August 16, 2004. We are pleased to see the proposed increase in payment for cochlear implantation (APC 259, 69930) and recognize the progress this represents. However, the 2005 proposed payment under the outpatient prospective payment system (OPPS) is less than our hospital?s cost to acquire the cochlear implant device and provide associated surgical services. We are concerned that payment for cochlear implantation has not been accurately calculated because the 2003 data analyzed by CMS is not representative of the costs of the device and procedure.

Here at The University of Chicago Hospitals, we have offered the cochlear implant surgery and related follow-up support since 1997. To date, we have 50 cochlear implant patients, and we estimate increasing this number by 10 patients per year. Approximately one-third of all cochlear implant patients at The University of Chicago Hospitals rely on Medicare. We have had to discontinue accepting public aid patients for this procedure due to lack of appropriate reimbursement.

In addition, the Advisory Panel on Ambulatory Classification Groups has recommended a 5% cap rather than the increase proposed by CMS. It is well established that cochlear implantation has been significantly underpaid relative to the actual costs for the device and procedure.

Therefore, we disagree with the Advisory Panel?s recommendation because it is arbitrary and a hindrance to CMS? goal to ultimately rely on accurate claims data to establish rates for device-dependent APCs. We ask CMS to improve educational outreach programs to hospitals. Similarly, we oppose arbitrary measures such as the APC Panel?s recommendation to cap increases at 5%.

The University of Chicago Hospitals appreciates the agency?s recognition of the potential impact of payment rates on access to care, and we hope that you will consider carefully the comments and recommendations that we have submitted. If you require further information, please do not hesitate to contact Rebecca Blankenhorn at 773-834-2548 or Rebecca.blankenhorn@uchospitals.edu.

Sincerely,

Dr. Miriam Redleaf

Jeanne Perkins, Audiologist

Erin Lawley, Audiologist

Rebecca Blankenhorn, Audiologist

Thomas Wardzala, Audiologist

CMS-1427-P-180-Attach-1.doc

THE UNIVERSITY OF CHICAGO
Otolaryngology — Head And Neck Surgery
5841 S. Maryland Avenue, MC 1035 • Chicago, IL 60637
Phone: (773) 702-1865 Fax: (773) 702-6809

4 October 2004

Mark McClellan, MD, PhD, Administrator
Centers for Medicare and Medicaid Services
Dept. of Health and Human Services
Attn: CMS-1427-P
PO BOX 8010
Baltimore, MD 21244-8018

RE: Medicare Program—Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year (CY) 2005 Payment Rates; CMS-1427-P; Proposed Recalibration of APC Weights for CY 2005

Dear Dr. McClellan:

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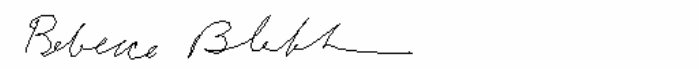
The University of Chicago Hospitals appreciates the agency's recognition of the potential impact of payment rates on access to care, and we hope that you will consider carefully the comments and recommendations that we have submitted. If you require further information, please do not hesitate to contact Rebecca Blankenhorn at 773-834-2548 or Rebecca.blankenhorn@uchospitals.edu.

Sincerely,

Dr. Miriam Redleaf

Jeanne Perkins, Audiologist

Erin Lawley, Audiologist



Rebecca Blankenhorn, Audiologist

Thomas Wardzala, Audiologist

CMS-1427-P-181

Submitter : Ms. Abbey Meyers **Date & Time:** 10/07/2004 08:10:30

Organization : National Organization of Rare Disorders

Category : Consumer Group

Issue Areas/Comments

Issues 11-20

Orphan Drugs

Please see PDF file attached.

CMS-1427-P-181-Attach-1.pdf

October 8, 2004

Via electronic submission at http://www.cms.hhs.gov/regulations/ecomments

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

RE: CMS–1427–P
Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates; Proposed Rule
Comments on Orphan Drugs

Dear Dr. McClellan:

On behalf of the National Organization for Rare Disorders (NORD), we are pleased to provide comments on this Proposed Rule. Our guiding principle is that Section 621 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (the MMA), along with the section 303 (Part B drugs provided outside the hospital) and the new Part D (outpatient prescription drug benefit), are implemented to:

- expand access where there was no coverage, and
- maintain access where there has been coverage.

Specifically, we are concerned about the access of rare disease patients (estimated to be at least 10 percent of the overall Medicare population) to orphan drugs and biologicals provided in the hospital outpatient setting under the Outpatient Prospective Payment System (OPPS).

NORD is a federation of approximately 130 voluntary health organizations and approximately 60,000 individual patients, healthcare providers and clinical researchers. We are all committed to the identification, treatment, and cure of rare disorders through programs of education, advocacy, research and service.

Unique Needs of Rare Disease Patients; Unique Role of Orphan Drugs In Filling this Need

Although rare diseases affect 25 million Americans—none of the 6,000 rare diseases has a service population exceeding 200,000 individuals. Most rare disease populations are much smaller, often

numbered in dozens or only hundreds of patients. For many of these diseases, Medicare elderly and adult disabled are a significant portion of those affected by the rare disease.

Orphan drugs are of little value to Medicare beneficiaries—both elderly and adult disabled with rare diseases—if they are not covered by CMS and reimbursed at levels sufficient to insure that providers will stock them. We are committed to doing everything possible to assure that Medicare beneficiaries with rare diseases have and maintain access to orphan drugs and biologicals, which they need to sustain and improve the quality of their lives.

Incentives Seriously Diminished if Access is Limited

The Orphan Drug Act (passed in 1983, amended several times since) represents Congress' continuing support for the development and accessibility of orphan drugs for rare diseases. Incentives under the Act have been enormously effective in stimulating research and development. Only 10 orphan drugs were developed in the 10 years prior to 1983; 259 orphan drugs, and biologicals have been approved for marketing by the FDA since enactment, and approximately 1,000 experimental orphan drugs are in various stages of research.

Given a choice, hospitals will usually stock lower cost, widely used therapies and ignore the few patients who have a rare disease and need an expensive medication—unless they are encouraged to do otherwise. The incentives under the Act intended to foster new orphan drug development are likely to be much less effective if a company believes that the Medicare marketplace is relatively closed to them. Since most rare diseases do not yet have a therapy, this is a critical consideration for the future of our constituents.

We are pleased that Congress took action to increase access to orphan drugs and biologicals by making certain changes to payment for drugs and biologicals in the hospital outpatient setting as well as the physician office setting and by creating the new Part D drug benefit However, the follow-through in regulations needs to be equally sensitive to the vulnerable position of Medicare beneficiaries with a rare disease, and a need for orphan drugs.

2005 Proposed Rates May be Adequate, but There is a Continuing Need to Monitor Access

For the past three years, we have submitted comments to CMS and we have met with you, your staff and the former Administrator to explain the serious concerns we have had with payment for orphan drugs and biologicals under OPPS. The claims-based cost methodology—although it may be improving—remains seriously flawed. The claims-based imputed costs (hospital charges multiplied by departmental cost-to-charge ratios) do not reflect actual hospital acquisition costs for most orphan drugs and biologicals. For many orphan drugs, at least one-quarter to one-third of the claims are useless—the units reported are clinically impossible.

Even those claims that are "clean" seriously underestimate costs. Comparison of actual acquisition costs to claims and review of hospital charging practices confirm that hospitals do not uniformly mark-up the charges for all drugs and biologicals—mark-ups are much lower for higher cost

products. Why is this general methodological problem particularly critical for orphan drugs and biologicals? First, because many orphan drugs and biologicals are relatively high cost products. Second, because the averaging principle inherent in OPPS does not work for drugs that are offered by only a small subset of hospitals and used by only a small number of patients in those institutions. Third, as noted above, when payments for drugs fall substantially below hospital costs, hospitals are likely to drop rare disease therapies from their formularies before they discontinue providing drugs that are more commonly ordered.

We were very pleased that Congress enacted Section 621 of the MMA to raise payments for most OPPS drugs in 2004 from the drastically reduced rates that were put into effect in 2003. Although most orphan drugs and biologicals would experience decreased payments in 2005 (compared to 2004) under the proposed rules, most of the decreases are consistent with what was expected under the MMA. We believe that, in the main, the proposed 2005 payments will be adequate to avoid problems with access to the orphan drugs and biologicals that patients with rare diseases need. However, we do think it important to continue to monitor the effect of changes in payment rate on access to orphan drugs and biologicals and to consider new orphan drugs and biologicals that have been introduced. We offer specific the following specific recommendations:

CMS should:

- Actively monitor the effect on access of changes in reimbursement for orphan drugs and biologicals.

- Review the claims databases on a regular basis to see if utilization of orphan drugs and biologicals falls below historical levels (adjusting for expected increases in utilization due to changes in the size of the Medicare population, and in methods for detection of specific conditions).

- Actively seek input from beneficiaries with rare diseases about any problems they experience with access to orphan drugs and biologicals, such as hospitals no longer offering these drugs or referring their Medicare patients to other settings to receive the drugs they need.

- Inform beneficiaries about changes in payments to health care providers for certain drugs and biologics and alert them to the potential impact on access. Beneficiaries should have convenient methods to report any problems with access.

Congress has repeatedly voiced concern about the impact of Medicare payment policies on access to orphan drugs and biologicals by rare disease patients. Just this past month, the following concern about access to orphan drugs and biologicals was raised in the Labor, Health and Human Services and Education and related agencies appropriations bill—

> *The Committee is concerned that Medicare patients with rare diseases may have difficulties accessing care that involves orphan drugs. The Committee encourages CMS to carefully*

> *consider the impact on this population in proposing regulations. The Committee encourages the Administrator to solicit the views of the FDA Office of Orphan Products Development and the NIH Office of Rare Diseases, as well as stakeholder groups, before determining whether an access problem exists or would be made worse by proposed regulations. (HR Report 108-636)*

Designation of Only 12 Orphan Drugs for Payment Protection is Insufficient to Meet the Needs of the Rare Disease Population

We were quite pleased that CMS and Congress both acknowledge the vulnerability of the rare disease population and the need for special payment policy to protect orphan drugs and biologicals under OPPS. We agree completely with CMS's statement in the Proposed Rule:

> *We recognize that orphan drugs that are used solely for an orphan condition or conditions are generally expensive and, by definition, are rarely used. We believe that if the cost of these drugs were packaged into the payment for an associated procedure or visit, the payment for the procedure might be insufficient to compensate a hospital for the typically high cost of this special type of drug. Therefore, we are proposing to continue making separate payments for orphan drugs based on their currently assigned APCs.*

We applaud CMS for setting the payment for designated orphan drugs and biologicals at the higher of 88-percent of average wholesale price or 106-percent of average sales price (not to exceed 95-percent of AWP). This special payment policy will help assure that patients who require the designated orphan drugs and biologicals will not be turned away for treatment by hospitals. We agree with you when you said:

> *If we had not classified these drugs as single indication orphan drugs for payment under the OPPS, they would have met the definition and been paid as single source specified covered outpatient drugs, resulting in lower payments which could impede beneficiary access to these unique drugs dedicated to the treatment of rare diseases.*

Nevertheless, we are deeply disappointed that CMS is proposing to limit the class of designated orphan drugs and biologicals to 12 drugs. Has CMS determined that the rare disease patients who require the other nearly 90 orphan drugs and biologicals paid under OPPS are not worthy of the same protection? CMS has made the flawed assumption that its criteria for designating "single indication orphan drugs" identifies the pool of orphan drugs for which access may become a problem if payment rates are inadequate to cover hospital costs. The "single indication orphan drug" criteria are not adequate to identify those orphan drugs for which rare disease patients may experience access problems due to inadequate reimbursement levels.

As we outlined in our August 23 letter following up on our July meeting with the you, when CMS adopts specific payment policies that affect access to orphan drugs and biologicals, like the OPPS policy on orphan drugs, CMS should take the following steps—

- For the purposes of identifying drugs and biologicals that are treatments for rare diseases, CMS will adopt the definition of "orphan drugs" used in the Food, Drug and Cosmetics Act;

- For the purpose of determining whether rare disease patients utilizing specific orphan drugs are subject to access problems, CMS will:

  - accept orphan products designated by FDA as a valid class,

  - develop prospective criteria to determine which orphan drugs should not be part of this class because patients with rare diseases do not experience problems with access to these orphan drugs,

  - work with stakeholder organizations, such as the National Organization for Rare Disorders, to identify any access problems that may occur or are likely to occur in the near future and

  - provide patients and pharmaceutical companies an opportunity to present data and receive a written explanation with examples before making a final decision that an orphan drug is not subject to access problems.

With all due respect, CMS has never developed prospective criteria for designating orphan drugs and biologicals that were based upon utilization data or review of evidence about access to orphan drugs. CMS has not worked with us or any other organization to monitor access to orphan drugs and biologicals. CMS has not provided stakeholders with a written explanation—supported by examples—of the Agency's rationale for the criteria it has used to designate orphan drugs and biologicals.

GAO Survey Provides Hope for Long-Term Fix

We agree with the conclusions reached by the US Government Accountability Office (GAO) in its report on OPPS payments for drugs, biologicals and medical devices—the payment rates determined from the APC methodology do not reflect hospital's costs. We endorse Congress's decision to ask the GAO to conduct a comprehensive survey of hospital acquisition costs for drugs and biologicals provided under OPPS. We are hopeful that the survey will provide accurate information on the cost of orphan drugs and biologicals paid under OPPS that may provide a basis for a long-term solution to setting payment rates for drugs and biologicals under OPPS.

We have been pleased with GAO's openness in seeking input from interested stakeholders, like NORD, on the survey design and the list of drugs and biologicals paid under OPPS. GAO has agreed with our recommendation to include the 12 designated orphan drugs and biologicals in its survey even though these do not meet the definition of "specified covered outpatient drugs" for 2004 and 2005.

As we look forward to 2006, we urge CMS to carefully consider the findings and recommendations that GAO will make when it concludes its survey. At the same time, we would recommend that you

accept external data, when these are provided by knowledgeable stakeholders, such as manufacturers, providers or patients, to verify the findings from the GAO study.

* * * *

We appreciate the opportunity to provide comments on this Proposed Rule and to continue our dialogue about assuring access to orphan drugs and biologicals under all parts of the Medicare program.

Sincerely,

Abbey S. Meyers, President
National Organization for Rare Disorders
55 Kenosia Avenue
Danbury, CT 06813
Phone: (203) 744-0100

MIA 288807-3.020980.0048

CMS-1427-P-182

Submitter : Mr. Stephen Webb **Date & Time:** 10/07/2004 08:10:53

Organization : ChromaVision Medical Systems, Inc.

Category : Device Industry

Issue Areas/Comments

Issues 1-10

2 Times Rule

Please see PDF file attached.

CMS-1427-P-182-Attach-1.pdf

Department of Health and Human Services
Centers for Medicare and Medicaid Services (CMS)
Offices of Strategic Operations and Regulatory Affairs

The attachment to this document is not provided because:

1. The document was improperly formatted.
2. The submitter intended to attach more than one document, but not all attachments were received.
3. The document received was a protected file and can not be released to the public.
4. The document is not available electronically at this time. If you like to view any of the documents that are not posted, please contact CMS at 1-800-743-3951 to schedule an appointment.

Submitter : Mr. Gene Meyer **Date & Time:** 10/07/2004 09:10:08

Organization : Lawrence Memorial Hospital

Category : Health Care Industry

Issue Areas/Comments

Issues 21-30

Payment Rate for APCs

Dear Tommy G. Thompson:

Lawrence Memorial Hospital is a 173-bed community hospital, an instrumentality of the City of Lawrence, Kansas. LMH receives no tax support from the city or county and serves the community?s health care needs regardless of individuals? ability to pay. Dedicated to improving the health of the community, as a not-for-profit hospital, LMH invests all excess revenues in services, equipment and facilities which further that mission. We are opposed to the proposed changes to the Medicare Hospital OPPS Payment Rates, in the 69 Fed. Reg. 50448, which have the median cost for APC 0659, hyperbaric oxygen therapy treatment declining to $82.91 from the 2004 payment of $164.93.

The hospital recently made a significant commitment to provide hyperbaric oxygen therapy (HBOT) to our community and will be the sole provider of this service in Lawrence,KS. Hyperbaric oxygen therapy is an integral component of our newly established comprehensive program for the management of chronic wounds. The proposed lower payment will have a dramatic impact on our ability to provide this care and may threaten our patient?s access to this effective and efficient treatment.

The Lewin Group?s report indicates that Respiratory Therapy?s cost-to-charge ratio was applied in determining the proposed reimbursement. Clearly, this will not be the same situation with hyperbaric therapy provided with our wound program.

I am hopeful that CMS will reconsider their proposed rate structure revisions.

I appreciate your time in reviewing my concern.

Very Truly Yours,

Gene Meyer
President & CEO

Submitter : Dr. A. Bradley Eisenbrey **Date & Time:** 10/07/2004 09:10:07

Organization : William Beaumont Hospital, Royal Oak

Category : Physician

Issue Areas/Comments

Issues 11-20

Blood and Blood Products

7 October 2004

Center for Medicare and Medicaid Services
Department of Health and Human Services
Attention CMS-1427-P
P.O. Box 8010
Baltimore, MD 2144-8018

Commissioners,

Provision of fully disease-marker tested, safe blood products, in a medically-appropriate setting for the patient?s underlying disease is an increasingly expensive process for which current reimbursement does not cover cost. Although care can be given which does not meet community standards of care, I do not believe it is the intent of the Center for Medicare and Medicaid Services to drive patients into substandard care for the purpose of saving tax dollars. Some patients may benefit from increased use of recombinant hormones such as erythropoietin and granulocyte colony stimulating factors to improve red cell and granulocyte numbers, however, these, too, are expensive products and do not benefit patients with non-functioning bone marrow. There are no substitutes for platelets. There are no substitutes for providing fully-tested products.

The costs of providing safe blood products are multi-factorial and must be considered by CMS when determining reimbursement rates. First, the number of donors is declining due to increasingly stringent criteria and requiring more effort toward recruitment of volunteer donors by the blood suppliers. This is expensive since the recruitment effort requires competing for advertising time and space with businesses and telephone and face-to-face recruiters must themselves be paid. The quality of recruiter is, generally, proportional to the amount of money the organization is willing to pay. Low pay results in poor outcomes and high turnover rates requiring more training and more expense.

Second, there is no incentive for the government, or other regulatory agencies, to reduce the number of disease-marker tests performed on blood products. Every test has a slightly different profile for disease prevention with overlap but without being able to completely replace testing which was previously performed. The existing pressure from mandatory and voluntary regulators is to add more testing and more cost to each blood product produced. In addition, the added complexity that comes with new testing has additional cost due to the need to purchase new equipment, hire new staff and discard units of blood which were previously considered ?safe? for transfusion. There is, likewise, no move to reduce the regulatory burden on the blood suppliers, particularly the American Red Cross, despite evidence that other suppliers are just a prone to errors as the Red Cross. The costs of increasing staffing to provide audits and reports to regulatory agencies must be passed on to the payor, whether private or CMS.

Availability will be compromised and willingness to received clinically indicated transfusions will be reduced if reimbursement to hospitals does not keep up with the increasing costs of providing the service of blood transfusion to our patients. Neither the patient nor the hospital can continue to function under a system which does not adequately reimburse the cost of providing this critical, life-saving and life-prolonging service.

I can be contacted at 248-898-8013. My email is beisenbrey@beaumont.edu.

Sincerely,

//SIGNED

A. Bradley Eisenbrey, MD, PhD

Chief, Transfusion Medicine Services
William Beaumont Hospital, Royal Oak, MI 48073

CMS-1427-P-185

Submitter : Connie Melton **Date & Time:** 10/07/2004 09:10:38

Organization : Saline Memorial Hospital

Category : Hospital

Issue Areas/Comments

Issues 21-30

Payment Rate for APCs

Friday, October 01, 2004

Dear Tommy Thompson
Saline Memorial Hospital is pleased to have this opportunity to comment on the proposed changes to the Medicare Hospital OPPS and CY2005 Payment Rates set forth in the proposed rule (69 Fed. Reg. 50448, Aug. 16, 2004). Our comments related to the median cost for APC 0659, hyperbaric oxygen therapy (HBOT) treatment. In the proposed rule, median cost at $82.91 is less than half of the CY 2004 payment of $164.93. Such a decrease will cause us to seriously consider whether we can continue to provide this modality of care.

We are a 160 bed-acute care hospital located in central Arkansas. We have been providing HBOT for approximately three and one half years and are the sole provider in our primary service area. This incredible drop in the payment rate will not cover the cost of providing this service and will threaten patient?s access to this proven modality of treating painful and otherwise expensive non-healing wounds.

We support the Hyperbaric Oxygen Therapy Association?s (HOTA) position and the Lewin Group?s findings regarding the error in this calculation. We understand CMS has inappropriately applied each Hospital?s Respiratory Therapy department?s cost-to-charge ratio (CCR) to HBOT charges, regardless of the department,t which actually contains the HBOT charges. If left uncorrected, this error may prevent us from continuing to provide this service.

We support any one of the The Lewin Group?s four recommendations:
? Apply the Lewin Group?s methodology to all hospitals that submitted HBOT claims in CY2003.
? Adopt the Lewin Group?s proposed reimbursement rate of $118.21 for the APC.
? Calculate the reimbursement rate for HBOT using each hospital?s overall cost-to-charge ratio. CMS?s rules for calculating the median cost indicate if the cost-to-charge ratio cannot be calculated, the overall hospital cost-to-charge ratio is to be used.
? Leave the HBOT reimbursement rate at CY 2004 levels until CMS has an opportunity to perform a corrected calculation.
Although we understand using The Lewin Group?s median cost calculation of $118.21 would only change overall HBOT payments by approximately $17 million, this will have a significant impact on our Hospital.
In closing, we appreciate your careful review of our comments.

Respectfully Submitted,

Connie Melton MBA, CHE
VP Hospital Services
Saline Memorial Hospital
Benton, AR 72015

CMS-1427-P-186

Submitter : Ms. Erin Mass **Date & Time:** 10/07/2004 09:10:03

Organization : The Nebraska Medical Center

Category : Hospital

Issue Areas/Comments

Issues 1-10

APC Relative Weights

CMS has proposed to continue utilizing single procedure claims to set the medians on which the APC weights would be based. This is done because for claims containing more than one primary service, packaged services and their costs cannot be associated with particular primary services as the costs of a packaged service may be associated with one or a combination of primary services. CMS however has been able to convert some multiple service claims into single service or 'pseudo' single claims. The United States Government Accountability Office (GAO) recently released a report which highlighted the inadequacy of rates under OPPS. They focused on multiple service claims and their exclusion in the recalibration process as being a key issue. Their review of hospital claims used to set the 2003 rates showed that CMS excluded over 40% of all multiple service claims because they could not associate a particular packaged service with a specific primary service. Multiple service claims represent more complex, and costlier outpatient visits and excluding them underestimates the actual cost of a service. The Nebraska Medical Center proposes that CMS continue to pursue a solution for this issue. Hospitals are not currently being paid enough to cover the costs of providing outpatient care and this is one area that needs to be reviewed in depth to ensure that hospitals can continue to provide higher levels of care.

Inpatient List

The Nebraska Medical Center agrees with CMS's proposal to move procedure codes currently listed on Table 35 as inpatient procedures from this list and be assigned to an APC group for payment under OPPS.

Unlisted HCPCS Codes

CMS explains in detail the purpose and payment methodology behind the 'unlisted' HCPCS Codes. These codes have been provided so that providers are able to report services for which there is no specific HCPCS code for the furnished services. It has been CMS's intent to pay for the unlisted codes in the lowest level APC of the applicable clinical grouping. The theory behind this is that the lower payments will provide an incentive for providers to pursue assignment of new codes for these procedures. However CMS has discovered that not all HCPCS codes are being grouped to the lowest paying APC in the clinical grouping and therefore has proposed to move 22 unlisted HCPCS codes to be paid as such. The Nebraska Medical Center provides several difficult, high cost procedures that currently are unable to be matched to a specific HCPCS code and so are coded to an unlisted HPCS code. A review of our fiscal year ended June 30, 2004 unlisted procedures showed that CMS's proposed change would result in a 643% decrease in payments for unlisted procedures on the proposed list. The current APC's for these procedures do not even come close to covering the average charge on these cases. Should CMS finalize this proposal, the possibility exists that beneficiaries would have limited access to such services. The Nebraska Medical Center proposes that CMS make no further changes to the grouping of unlisted HCPCS codes.

Issues 21-30

Inpatient Procedures

The Nebraska Medical Center agrees with CMS's proposal to move procedure codes currently listed on Table 35 as inpatient procedures from this list and be assigned to an APC group for payment under OPPS.

Observation Services

The Nebraska Medical Center agrees with and is appreciative of CMS's proposal to remove the current requirements for specific diagnostic testing in order to receive payment for observation services under APC 0339. This will greatly reduce our administrative burden in eliminating the need to verify that all tests were performed and coded appropriately.

Issues 31-33

Outlier Payments

The proposed target for outlier payments is 2.0%. This is consistent with what the target has been set at in prior years, however legislation has given CMS the authority to set aside up to 3% for outlier payments of which .36% is for CMHC's. Since the inception of the Outpatient Prospective Payment System, it has been known that this payment methodology significantly underpays costs.

CMS has also proposed to adjust the outlier payment qualification thresholds to be costs exceeding 1.5 times the APC payment and a fixed dollar threshold of $625 plus the APC payment. The Nebraska Medical Center agrees with CMS this is a more equitable way of distributing outlier payments since it would redirect payments from lower cost, simple procedures to high cost, financially risky procedures. However, The Nebraska Medical Center would suggest that instead of the proposed 50% outlier payment, CMS utilize an 80% payment. This would mirror the inpatient payment methodology for outliers and improve the adequacy of payments under OPPS.

Submitter : Mr. Stephen Nierman **Date & Time:** 10/07/2004 09:10:32

Organization : Town and Country Hospital

Category : Hospital

Issue Areas/Comments

Issues 21-30

Payment Rate for APCs

Dear Mr. Tommy G. Thompson:

Town and Country Hospital is pleased to have this opportunity to comment on the proposed changes to the Medicare Hospital OPPS and CY2005 Payment Rates set forth in the proposed rule (69 Fed. Reg. 50448, Aug. 16, 2004). Our comments are specifically related to the median cost for APC 0659, hyperbaric oxygen therapy (HBOT) treatment. In the proposed rule, median cost at $82.91 is less than half of the CY 2004 payment of $164.93.

We are a 201-bed acute care hospital located in Tampa, Florida. Our hospital does provide general wound care services to patients with plans to offer HBOT treatment beginning in December, 2004. We?re nearly complete with construction of the HBOT treatment rooms and the chambers are scheduled for delivery within the next few weeks. This dramatic drop in the payment rate will not cover the cost of providing this service and as such, will threaten patient?s access to this proven modality of treating painful and otherwise expensive non-healing wounds.

We support the Hyperbaric Oxygen Therapy Association?s (HOTA) position and the Lewin Group?s findings regarding the error in this calculation. We understand CMS has inappropriately applied each Hospital?s Respiratory Therapy department?s cost-to-charge ratio (CCR) to HBOT charges, regardless of the department which actually contains the HBOT charges. If left uncorrected, this error will likely result in the cancellation of our hospital plans to add this valuable service.

We support any one of the The Lewin Group?s four recommendations:
1. If CMS has sufficient time, apply The Lewin Group methodology to all hospitals that submitted HBOT claims in CY2003.
2. Adopt The Lewin Group?s proposed reimbursement rate of $118.21 per 30-minute increment for HBOT.
3. Calculate the reimbursement rate for HBOT using each hospital?s overall cost-to-charge ratio. CMS?s rules for calculating the median cost indicate if the cost-to-charge ratio cannot be calculated, the overall hospital cost-to-charge ratio is to be used. Because there is currently no standardization as to which cost center HBOT costs and charges are located, CMS is unable to appropriately determine the correct cost-to-charge ratio to apply to claims, unless HBOT is indicated in the description of a hospital-specific subscripted cost center.
4. Leave the HBOT reimbursement rate at CY 2004 levels until CMS has an opportunity to develop and perform a calculation that will accurately reflect HBOT costs and cost-to-charge ratios.
Although we understand using The Lewin Group?s median cost calculation of $118.21 would only change overall HBOT payments by approximately $17 million, this will have a significant impact on our Hospital.
Thank you for the opportunity to comment.

Sincerely,

Steve Nierman
COO
Town and Country Hospital

Submitter : Mr. Kurt Meyer **Date & Time:** 10/07/2004 10:10:11

Organization : Rebsamen Medical Center

Category : Hospital

Issue Areas/Comments

Issues 21-30

Payment Rate for APCs

Dear Tommy Thompson:

Rebsamen is pleased to have this opportunity to comment on the proposed changes to the Medicare Hospital OPPS and CY2005 payment rates set forth in the proposed rule (69 Fed. Reg. 50448, Aug. 16, 2004). My comments relate to the median cost for APC 0659, hyperbaric oxygen therapy treatments (HBOT). As you know, in the proposed rule, the median cost of $82.91 is less than half of the CY2004 payment of $164.93.

As a 120-bed acute care hospital located in central Arkansas, we have been providing HBOT for five years by operating two hyperbaric chambers in our Wound Healing Center and we are the sole provider of this service in our service area. HBOT is a wonderful adjunctive therapy for our patients who have non-healing wounds. This incredible proposed drop in the payment rate for HBOT will not cover our cost of providing this necessary service and will threaten our patient?s ability to access this vital treatment. HBOT has been proven by research to cure expensive non-healing wounds. Patients are traveling large distances up to 200 miles to be able to receive this treatment that often is their last option before amputation.

The Hyperbaric Oxygen Therapy Association?s (HOTA) position is one we wholeheartedly support as well as the Lewin Group?s findings regarding an error in the reimbursement calculation. It is understood that CMS has inappropriately applied each hospital?s respiratory therapy department?s cost-to-charge ratio (CCR) to HBOT charges, regardless of the department that actually contains the HBOT charges. If left uncorrected, this error may prevent us from offering this vital service in the future.

Based upon the above, we support any of the following recommendations:
? Apply the Lewin Groups methodology to all hospitals that submitted HBOT claims in CY2003.
? Adopt the Lewin Groups proposed reimbursement rate of $118.21 for the APC.
? Calculate the reimbursement rate for HBOT using each hospital?s overall cost-to-charge ratio. CMS?s rules for calculating the median cost indicate if the cost-to-charge ratio cannot be calculated, the overall hospital cost ?to-charge ratio is to be used.
? Leave the HBOT reimbursement rate at CY 2004 levels until CMS has an opportunity to perform a corrected calculation.

This proposed rate reduction will have a significant impact on our hospital. In closing, I appreciate your careful review of these recommendations.

Respectfully submitted,
Kurt Meyer, CEO

CMS-1427-P-189

Submitter : Dr. Andrea Trescot **Date & Time:** 10/07/2004 10:10:18

Organization : The Pain Center

Category : Physician

Issue Areas/Comments

Issues 1-10

APC Groups

I am a pain provider experienced in endoscopic, minimally-invasive surgery for the treatment of spinal pain. I am very concerned about the proposed reassignment of CPT codes 62263.

The proposed rule does not offer any explanation as to the reasoning behind this move, although there is a lengthy discussion about the nerve injection codes, into which percutaneous lysis of epidural adhesions has always been grouped. I do not understand the intent to move percutaneous lysis of adhesions to a lower paying APC group, particularly when the claims data CMS used to determine the proposed 2005 payment rates validate that the ?true? median cost for 62263 is $574.50 and 62264 is $616.77. Moving these procedures to an APC that is scheduled to pay $335.23 does not appear to create resource homogeneity.

From a resource use perspective, CPTs 62263 & 62264 are not comparable with the rest of the procedures listed in the proposed APC 0207 configuration. The CPT code description for both procedures the CPT code includes the radiologic localization (both CPTs 76005 and 72275). This language contained within the CPT code description indicates a provider (hospital and physician) cannot code for the radiological localization aspect of the complete procedure. Due to the precise nature of adhesiolysis, the physician must know the exact location of areas of scarring, nerve constriction(s), any nerve inflammation, and if there is any fluid flow into the epidural space. This requires an epiduragraphy and as the CPT code descriptor implies, an epiduragraphy (72275) is always performed in conjunction with a percutaneous lysis of epidural adhesions (CPTs 62263 & 62264) and therefore cannot be billed separately.

Furthermore, percutaneous lysis of epidural adhesions (CPT 62264 & 62264) is the only procedure `grouped ` in APC 0207 with radiological localization language included within the context of the CPT code description. Because an epiduragram is always performed, there is a greater resource use associated with CPTs 62263 & 62264 than with the other procedures listed in APC 0207. The hospital may bill and receive reimbursement for epiduragraphy if performed in conjunction with any other procedure listed in APC 0207. For example, if an epiduragram is performed in conjunction with an epidural injection/infusion of neurolytic substance (CPT 62281), the hospital will receive $526.95 ($335.23 +$191.72); whereas, the reimbursement for a percutaneous lysis of epidural adhesions done with epiduragraphy will have a corresponding payment of $335.23. Again, this disparity is in contrast to CMS? intent to create resource homogeneity within the APCs.

I respectfully suggest it is more appropriate to leave these procedures in the APC (0203) to which they are currently assigned until a more complete assessment can be made on the procedure of percutaneous lysis of spinal adhesions.

Thank you for your attention to these comments, and I look forward to your response.

Sincerely,

Andrea M. Trescot, MD

Diplomate American Board of Anesthesiology
Special Qualifications in Pain Management
Special Qualifications in Critical Care
Diplomate American Board of Pain Medicine
Diplomate American Academy of Pain Management
Fellow, Interventional Pain Practice
President, Florida Society of Interventional Pain Physicians
Board of Directors, American Society of Interventional Pain Physicians

CMS-1427-P-189-Attach-1.doc

THE PAIN CENTER

Andrea M. Trescot, MD John B. Hunt, MD Gordon Beardwood, MD Lavida Thomas-Richardson, MD

1564 Kingsley Avenue
Orange Park, Fla. 32073

(904) 276-9311 Office
(904) 276-4462 FAX

10/7/04

The Honorable Mark McClellan, M.D., Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1427-P
P.O. Box 8010
Baltimore, MD 21244-8018

RE: Re: [CMS-1427-P] Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates
Specifically: Section II. Proposed Changes Related to Ambulatory Payment Classifications (APCs) - "APC Groups"

Dear Dr. McClellan:

I would like to support the following comments on behalf of interventional pain doctors regarding the above-referenced "proposed rule." I am a pain provider experienced in endoscopic, minimally-invasive surgery for the treatment of spinal pain. I am very concerned about the proposed reassignment of CPT codes 62263, *Percutaneous lysis of epidural adhesions using solution injection (e.g., hypertonic saline, enzyme) or mechanical means (e.g. catheter) including radiologic localization (includes contrast when administered), multiple adhesiolysis sessions 2 or more days* and 62264, *Percutaneous lysis of epidural adhesions using solution injections (eg, hypertonic saline, enzyme) or mechanical means (eg, catheter) including radiologic localization (includes contrast when administered), multiple adhesiolysis sessions; 1 day* from APC 0203 (Level IV Nerve Injections) to APCs 0207 (Level III Nerve Injections).

The proposed rule does not offer any explanation as to the reasoning behind this move, although there is a lengthy discussion about the nerve injection codes, into which percutaneous lysis of epidural adhesions has always been grouped. I understand the intent in general of making nerve block procedures clinically homologous as well as resource homogeneous. However, I do not understand the intent to move percutaneous lysis of adhesions to a lower paying APC group, particularly when the claims data CMS used to determine the proposed 2005 payment rates validate that the "true" median cost for 62263 is $574.50 and 62264 is $616.77. Moving these procedures to an APC that is scheduled to pay $335.23 does not appear to create resource homogeneity.

From a resource use perspective, CPTs 62263 & 62264 are not comparable with the rest of the procedures listed in the proposed APC 0207 configuration. The CPT code description for both procedures [percutaneous lysis of epidural adhesions using solution injection (eg, hypertonic saline, enzyme) or mechanical means (eg, catheter) including radiologic localization (includes contrast when administered), multiple adhesiolysis sessions;] indicates the CPT code includes the radiologic localization (both CPTs 76005 and 72275). This language contained within the CPT code description indicates a provider (hospital and physician) cannot code for the radiological localization aspect of the complete procedure. Due to the precise nature of adhesiolysis, the physician must know the exact location of areas of scarring,

nerve constriction(s), any nerve inflammation, and if there is any fluid flow into the epidural space. This requires an epiduragraphy and as the CPT code descriptor implies, an epiduragraphy (72275) is always performed in conjunction with a percutaneous lysis of epidural adhesions (CPTs 62263 & 62264) and therefore cannot be billed separately.

Furthermore, percutaneous lysis of epidural adhesions (CPT 62264 & 62264) is the only procedure 'grouped ' in APC 0207 with radiological localization language included within the context of the CPT code description. Because an epiduragram is always performed, there is a greater resource use associated with CPTs 62263 & 62264 than with the other procedures listed in APC 0207. The hospital may bill and receive reimbursement for epiduragraphy if performed in conjunction with any other procedure listed in APC 0207. For example, if an epiduragram is performed in conjunction with an epidural injection/infusion of neurolytic substance (CPT 62281), the hospital will receive $526.95 ($335.23 +$191.72); whereas, the reimbursement for a percutaneous lysis of epidural adhesions done with epiduragraphy will have a corresponding payment of $335.23. Again, this disparity is in contrast to CMS' intent to create resource homogeneity within the APCs.

I respectfully suggest it is more appropriate to leave these procedures in the APC (0203) to which they are currently assigned until a more complete assessment can be made on the procedure of percutaneous lysis of spinal adhesions.

Thank you for your attention to these comments, and I look forward to your response.

Sincerely,

Andrea M. Trescot, MD

Diplomate American Board of Anesthesiology
Special Qualifications in Pain Management
Special Qualifications in Critical Care
Diplomate American Board of Pain Medicine
Diplomate American Academy of Pain Management
Fellow, Interventional Pain Practice
President, Florida Society of Interventional Pain Physicians
Board of Directors, American Society of Interventional Pain Physicians

CMS-1427-P-190

Submitter : **Date & Time:** 10/07/2004 11:10:46

Organization :

Category : Other Health Care Professional

Issue Areas/Comments

Issues 21-30

Observation Services

The issue of observation versus inpatient has grown to be an all-consuming task of the utilization review department. I am the supervisor of the UR staff. We spend an enormous percentage of our day trying to sort out the "appropriate status." Of course, the MDs, who have no financial risk at all if they admit the patient to the inappropiate status, are suppose to care if the hospital is penalized. Besides, they feel and voice that this is just a bureaucratic issue imposed by the government that does not influence the care they give their patients. And Interqual criterea, which we inform them that Medicare uses, may or may not influence the reviewers decision made retrospectively.

Then we have the Medicare recipient who does not have a clue how the observation status influences their personal financial responsibility. No mention is made of observation status in their Medicare handbook. As it is not addressed, they expect that they would be an inpatient with inpatient benefits if they are in a hospital bed overnight! They do not understand "medical necessity" as being anything different than that their MD kept them in a hospital. Thus, when they are billed for their self-administered medications, they are not happy! Why isn't this education done by Medicare as we are following your rules!

It is an out of control issues! When I read the web sites, all hospital organizations are spending enormous amounts of time and resources to work on this problem, some staffing UR 24/7. This energy could be so much more useful moving the patient along the appropriate continuum.

In Oregon, Medicaid patients, reviewed by OMPRO for medical necessity, can be rebilled as observation if they do not meet criterea. Also, a large national insurance carrier has just informed us that in the absence of documented intent for in versus observation, they will apply the criterea and reimburse appropriately. These rules demonstrate much more common sense than the continuous, confusing transmittals we receive from Medicare. Please consider some of these very viable options.

CMS-1427-P-191

Submitter : Mr. Thomas Barthel **Date & Time:** 10/08/2004 12:10:20

Organization : Clarus Medical, LLC

Category : Device Industry

Issue Areas/Comments

Issues 1-10

APC Groups

See attached file.

CMS-1427-P-191-Attach-1.doc

Department of Health and Human Services
Centers for Medicare and Medicaid Services (CMS)
Offices of Strategic Operations and Regulatory Affairs

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CMS-1427-P-192

Submitter : Dr. Samuel Silver **Date & Time:** 10/08/2004 12:10:33

Organization : Dr. Samuel Silver

Category : Physician

Issue Areas/Comments

Issues 11-20

Drugs, Biologicals, and Radiopharmaceuticals NonPass-Throughs

I am Samuel M. Silver, MD, PhD, and I am a Clinical Professor of Medicine and a hematologist/medical oncologist at University of Michigan in Ann Arbor, Michigan. CMS has asked for comments on its 2005 hospital outpatient prospective payment system (OPPS) proposed rule. Specifically, CMS would like hospitals to comment on whether an ?equitable adjustment? should be made with regard to darbepoetin alfa and epoetin alfa. I am commenting on behalf of the interest of my institution?s patients and their access to the most appropriate medication based on their individual needs. At my institution, our physicians most commonly prescribe darbepoetin alfa at 200 mcgs Q2W (and epoetin alfa at 40,000 IUs QW) for the treatment of chemotherapy-induced anemia. At these doses, we see comparable clinical outcomes for our patients. At these doses, darbepoetin alfa provides a cost savings to my institution, to our patients (in terms of their coinsurance for the drug and the related services), and to the Medicare program (Proposed reimbursement rates are $4.14/mcg for Aranesp and $11.09/10,000 U for Procrit. At doses of 200 mcg Q2W and 40,000 QW, the comparative CMS costs would be $414/week for Aranesp and $443.60/week for Procrit. Aranesp is 7% less expensive to CMS). We see many rural patients at the University of Michigan. Rural patients who require burdensome travel to and from our institution benefit from darbepoetin alfa?s less-frequent dosing schedule. There is no rationale for applying an equitable adjustment to darbepoetin alfa and epoetin alfa because darbepoetin alfa is less expensive than epoetin alfa based on current dosing, and because both products are already proposed to be paid equitably using the same methodology. If an equitable adjustment is made, the result will be that hospitals will be prompted to use the more expensive product, epoetin alfa. CMS should allow both products to be reimbursed under the same methodology to ensure that patients have access to the treatment option that best meets their individual needs. Darbepoetin alfa saves my institution, its patients, and the Medicare program money; therefore, no equitable adjustment needs to be made.

Samuel M. Silver, MD, PhD
Clinical Professor, Internal Medicine
University of Michigan
Ann Arbor, MI

CMS-1427-P-193

Submitter : Mr. Philip Bruch **Date & Time:** 10/08/2004 01:10:38

Organization : University of Nebraska Medical Center

Category : Academic

Issue Areas/Comments

Issues 11-20

New Drugs, Biologicals, and Radiopharmaceuticals Pass-Throughs

I would like to comment on the Bexxar reimbursement situation that is being considered for the 2005 CMS schedule. If this payment schedule remains as per suggested, it would cause an undo hardship on these lymphoma patients who have a viable treatment option. The University of Nebraska Medical Center has worked for a number of years on a variety of clinical research projects with the I-131 Tositumomab (Bexxar) for refractory disease. We have experienced numerous remissions and have allowed these patients more time to spend with their families and loved ones. Every so often a new therapeutic regimen comes along that is very beneficial to patients...and Bexxar is one of them. Patients with CD-20 antigen positive lymphoma now have a viable option in the treatment of their disease. If I were in a situation similar to these patients, I would seek Bexxar as my main course of treatment.

I have worked in healthcare for over 24 years and I have seen and provided diagnostic testing and therapy to a lot of individuals with cancer. It is tough to not have any options for some of these patients. Therefore, I would like to recommend that this drug code reimbursement be re-evaluated to allow for the increasing volume of lymphoma patients to have a viable option without the worry of a major expense.

I do believe that individuals should be responsible for part of their financial obligations when it comes to healthcare, but we cannot and should not make it unbearable in accessing a treatment.

Please re-consider this reimbursement code and provide these lymphoma patients and the healthcare professionals with a viable option to aid in the treatment of this disease.

Thank you for your time.

Philip M. Bruch MS,CMPE
Administrator II
Department of Radiation Oncology
UNMC

Submitter : Mr. James Wallace **Date & Time:** 10/08/2004 01:10:36

Organization : Lourdes Health System

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

LOURDES HEALTH SYSTEM
1600 Haddon Avenue
Camden, New Jersey
08103

October 8, 2004

Dr. Mark McClellan
CMS Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1427-P
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: File Code CMS-1427-P

Dear Dr. McClellan:

Lourdes Health System (Our Lady of Lourdes Medical Center, Camden, NJ and Lourdes Medical Center of Burlington County, Willingboro, NJ) welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services? (CMS) proposed rule entitled Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment Systems and Calendar Year (CY) 2005 Payment Rates; Proposed Rule, 69 Fed. Reg. 50448 (August 16, 2004).

Our comments relate to the ?Wage Index?section of the proposed rule.

Please be advised that Lourdes Health System generally supports the CMS final rulemaking related to ?Special Circumstances of Hospitals in All-Urban States? contained in the Federal Fiscal Year (FFY) 2005 final inpatient rule published in the August 11, 2004 Federal Register. The FFY 2005 final inpatient rule adopted a methodology that imputes a wage index floor for those states that are deemed to be ?All-Urban States.? It is clear that the absence of a floor for the Medicare wage index calculation creates an uneven playing field between the All-Urban States (currently three under the final inpatient rule) and the remaining forty-seven states. Imputing a wage index floor for the All Urban State adds symmetry, equity and consistency to the reimbursement methodology.

Lourdes Health System strongly supports the contention that the imputed wage index floor should also apply to outpatient hospital services effective with CY 2005. Unfortunately, the proposed outpatient rule does not recognize this contention since the proposed inpatient wage index amounts (that is, the wage indexes that CMS proposed for the hospital inpatient PPS rules as published in the May 18, 2004 Federal Register) are currently scheduled to be implemented for outpatient services beginning with CY 2005. Utilizing the proposed inpatient wage index amounts circumvents the implementation of the ?Special Circumstances of Hospitals in All-Urban States? for outpatient purposes for CY 2005 since this provision was not adopted until the final inpatient rulemaking.

It should be noted that since the inception of the outpatient prospective payment system (OP PPS) in August 2000, final inpatient wage index amounts consistently have been implemented by CMS in the final OP PPS rulemaking. This provision is in accordance with 42 CFR ? 419.43(c). The proposed outpatient rule for CY 2005 deviates from prior established methodology with regard to wage index implementation.

Lourdes Health System strongly urges CMS to adopt the methodology of implementing final inpatient wage index amounts for outpatient wage index purposes for CY 2005, which is consistent with prior year OP PPS implementation and which promotes equity and consistency in this area.

Please contact Tom Regner, Chief Financial Officer, at 856-824-3088 for further discussion on this issue.

Thank you for considering these important comments and we look forward to your response.

Respectfully submitted,

James C. Wallace
Senior Vice President for
Corporate Services

CMS-1427-P-195

Submitter : **Date & Time:** **10/08/2004 02:10:35**

Organization : **Owensboro Medical Health System**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

See attached file

CMS-1427-P-195-Attach-1.doc

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Offices of Strategic Operations and Regulatory Affairs

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CMS-1427-P-196

Submitter : Dr. Harvey Neiman **Date & Time:** 10/08/2004 02:10:29

Organization : American College of Radiology

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Please see the attached comment letter from the American College of Radiology

CMS-1427-P-196-Attach-1.pdf

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CMS-1427-P-197

Submitter : Dr. Neil Giddings **Date & Time:** 10/08/2004 02:10:38

Organization : Spokane Ear Nose

Category : Physician

Issue Areas/Comments

Issues 1-10

APC Relative Weights

Please increase reimbursement rates to cover the actual cost of cochlear implants to the hospital. Continued underfunding of these devices has resulted in the past in closure of the only cochlear implant program in Eastern Washington, serving more than 2 million people.

Hospitals cannot continue to take a loss every time a patient is implanted, and low reimbursement continues to threaten the availability of this technology for severe to profound hearing loss patients in our area.
Thank you for your time and consideration
Neil Giddings, MD (neurotologist)

CMS-1427-P-198

Submitter : Ms. Bonnie Handke **Date & Time:** 10/08/2004 03:10:37

Organization : Medtronic, Inc

Category : Device Industry

Issue Areas/Comments

GENERAL

GENERAL

Comment letter and supporting documents attached

CMS-1427-P-198-Attach-1.doc

CMS-1427-P-198-Attach-6.rtf

CMS-1427-P-198-Attach-4.rtf

CMS-1427-P-198-Attach-3.rtf

CMS-1427-P-198-Attach-2.pdf

CMS-1427-P-198-Attach-5.rtf

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CMS-1427-P-199

Submitter : Ms. Barrie Strickland **Date & Time:** 10/08/2004 03:10:02

Organization : Memorial Hermann Hospital

Category : Hospital

Issue Areas/Comments

Issues 1-10

APC Relative Weights

See attached letter

CMS-1427-P-199-Attach-1.doc

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CMS-1427-P-200

Submitter : **Date & Time:** **10/08/2004 03:10:10**

Organization : **American Society of Clinical Oncology**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

October 8, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1427-P
Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: Comments on the Proposed Changes to the Medicare Hospital Outpatient Prospective Payment System

These comments are submitted by the American Society of Clinical Oncology (ASCO). ASCO is the national organization representing physicians and other healthcare professionals who specialize in the treatment of cancer. These comments are submitted in response to the proposed changes in the Medicare hospital outpatient prospective payment system published in the Federal Register on August 16, 2004.

Payments for Anti-Emetics

For drugs that are not newly introduced drugs, the CMS policy is to pay separately for drugs that have a median cost per day that exceeds $50 and to package less expensive drugs into the related procedure without a separate payment. As an exception to this policy, CMS is proposing to establish separate payment amounts for all oral and injectable anti-emetics. If the normal rules were applied, two of the injectable anti-emetics would be packaged and one would be separately payable; two of the oral products would be separately payable, and one would be packaged. The Federal Register notice states that CMS is proposing to treat all the products the same ?to ensure that our 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.?

ASCO supports this proposal. We strongly agree that beneficiaries might face obstacles in obtaining access to particular anti-emetics if the use of some anti-emetics results in a separate payment to hospitals while the use of other anti-emetics does not.

In this connection, we urge CMS to review the proposed payment for the anti-emetic Aloxi (palonosetron), which has pass-through status in 2005. As a result of that status, it appears that hospitals may be financially disadvantaged if they use

palonosetron rather than the other anti-emetics. ASCO is concerned that this financial disparity will limit patient access to palonosetron in circumstances where it would be the most medically appropriate drug. CMS should ensure that all anti-emetics are treated similarly.

Payment for Radiopharmaceuticals

For pass-through payment purposes under the hospital outpatient prospective payment system, CMS has previously treated some radiopharmaceuticals as supplies rather than drugs. CMS is now proposing to revise that policy and to pay for radiopharmaceuticals in the same manner as other drugs.

ASCO supports this change in policy. The payment amounts for radiopharmaceuticals used in cancer treatment should be set in the same manner as the payment amounts for other types of drugs.

Thank you for the opportunity to submit these comments.
Sincerely,
Dean H. Gesme, Jr., MD

Chair, Clinical Practice Committee

CMS-1427-P-200-Attach-1.pdf

Department of Health and Human Services
Centers for Medicare and Medicaid Services (CMS)
Offices of Strategic Operations and Regulatory Affairs

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CMS-1427-P-201

Submitter : Mr. Dennis Moses **Date & Time:** 10/08/2004 03:10:34

Organization : Northwest Texas Hospital

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Secretary Tommy Thompson
Center For Medicare and Medicaid Services
Attention CMS-1427-P
RE CMS-1427-P:APC 0659 Hyperbaric Oxygen Therapy

Mr. Thompson:
On behalf of Northwest Texas Hospital in Amarillo, Texas, I would like to comment regarding our concerns with the proposed Department of Health and Human Services Centers for Medicare and Medicaid Services'2005 Hospital Outpatient Prospective Payment System proposed rule that sets forth new reimbursement rates for hyperbaric oxygen therapy treatment 69Fed.Reg50048(Aug. 16,2004) Northwest Texas Hospital is a 489 bed facility that provides services to a significant Medicare and Medicaid population in the panhandle of West Texas. This facility has three monoplace chambers and treats a daily population of 6-10 patients with Hyperbaric Oxygen Therapy. While there are other facilities that have HBO capability in this area, Northwest Texas Hospital is the only facility that coordinates care with not only the acute inpatients and outpatient populations of Northwest Texas Hospital but also with two LTAC hospitals in the area as well. A reduction in the reimbursement as proposed could jeopardize the future of this therapy at the Northwest Texas Hospital facility.

The hospital is a supporter of efforts of the Hyperbaric Oxygen Therapy Association(HOTA). The hospital administration is in support of the HOTA recommendations that follow:
1. HBOT Reimbursement rate should remain at the Current CY 2004 levels until CMS has an opportunity to develop a methodology that will accurately detail HBOT costs-to-charges ratios.
2.Recommend that the cost to charges ratio of .47 be adopted due to the differences which the hospitals have reported.
3.Apply the Lewin Group methodology to the 389 hospitals that have reported hyperbaric claims in 2003
4.Adopt the Lewin Group approach of $118.21 per 30 minute segment of HBOT.
We greatly appreciate your consideration of these comments regarding this much needed therapy for the Medicare and Medicaid patients of the Texas Panhandle.
Very respectfully
Kyle Sanders
kyle.sanders@nwths.com
Chief Operatiing Officer
Northwest Texas Hospital
1501 Coulter Ave.
Amarillo, texas 79106

CMS-1427-P-202

Submitter : Mr. Stephen Frayne **Date & Time:** 10/08/2004 03:10:10

Organization : Connecticut Hospital Association

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 21-30

Wage Index

Please see attached comments related to CMS-1427-P and the Wage Index.

CMS-1427-P-202-Attach-1.doc

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CMS-1427-P-203

Submitter : Jean Voight **Date & Time:** 10/08/2004 04:10:41

Organization : Froedtert Memorial Lutheran Hospital

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

The file I will be attaching covers a variety of issues.

CMS-1427-P-203-Attach-1.doc

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Submitter : Dr. Duane Abbey **Date & Time:** 10/08/2004 04:10:45

Organization : Abbey

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

Additional Areas of Concern -

Injections -

You (CMS) have promised comprehensive guidance in the area of coding and billing for injections and related infusion therapy. This guidance should be proposed for comments and issued as quickly as possible, certainly by January 1, 2005. Since CPT codes are used for most of these services, the CMS guidance will have to be consistent with the AMA guidelines on the CPT codes. Further guidance from the AMA may also be necessary since the AMA is the official standard code set maintainer for CPT under the HIPAA Transaction Standard/Standard Code Set rule.

Fracture Care -

As indicated elsewhere in these comments, comprehensive guidance for coding and billing in this area is desperately needed. You (CMS) have promised such guidance. This guidance should be proposed for comments and issued as quickly as possible, certainly by January 1, 2005. Since CPT codes are used for most of these services, the CMS guidance will have to be consistent with the AMA guidelines on the CPT codes. Further guidance from the AMA may also be necessary since the AMA is the official standard code set maintainer for CPT under the HIPAA Transaction Standard/Standard Code Set rule.

Blood, Blood Products, Transfusion Medicine -

You (CMS) have promised comprehensive coding and billing guidance in the area of blood, blood products and transfusion medicine for several years. Additionally, there do not appear to be any NCCI (National Correct Coding Initiative) edits for the codes in this area. For example, an irradiate blood unit should not be coded with an irradiation procedure. Likewise, the use and/or nonuse of the split blood unit code (HCPCS=P9011) in conjunction with the procedure code for splitting and/or joining blood units is unclear. Likewise, you have indicated that autologous blood collection (CPT=86890) is separately payable, but the use of this code, such as when this service can be billed, remains unclear. Questions concerning the CPT codes for preparation, freezing and thawing continue to cause concern for coding and billing. See CPT codes 86927, 86930, 86931, and 86932.

This guidance should be proposed for comments and issued as quickly as possible, certainly by January 1, 2005. Since CPT codes are used for most of these services, the CMS guidance will have to be consistent with the AMA guidelines on the CPT codes. Further guidance from the AMA may also be necessary since the AMA is the official standard code set maintainer for CPT under the HIPAA Transaction Standard/Standard Code Set rule.

Additional comments made by mail; the electronic submission system does not allow enough room to provide the needed information in making comments.

Issues 1-10

2 Times Rule

The 2-times rule is a relatively generous statistical limitation. This rule should rarely be violated. Additionally, a more normalized statistical measure should be put into place to assess variations within the costs, and thus services or items that are being mapped into a given APC. Since a lower level APC (i.e., relatively low level payment) may have variations in costs that span just a hundred dollars or so, the 2-times rule for this type of APC is vastly different from a higher paying APC in which the variation may involve thousands of dollars. A more normalized measure should be put into place.

Recommendation: The cost data for APC should include the standard deviation for the cost data along with the coefficient of variation using the geometric mean as the basis for the measure of dispersion. The coefficient of variation, which is normalized, can then be calculated for each APC and a more consistent measure can be used to judge the variation within the cost data being used. The coefficient of variation should never be allowed to exceed 50%.

Using the 2-times rule as a measure of acceptable variation, there should be very, very few APCs that are allowed to violate this rule and when violating this rule, the time period for violation should be very short. If this rule is being violated, then the given APC should be split into two or more APCs which do not violate the 2-times rule or whatever measure of variation is being used to make the APC consistent and uniform for payment based upon costs.

Comment: The proposal to have some 54 APCs violate the 2-times rule is much too large. This number should be reduced into the range of 4 or 5 APC categories. These categories should be allowed to violate the 2-times rule only for a limited period of time.

Recommendation: While cost data can certainly be the primary mechanism by which APC payments are determined, there need to be additional mechanisms developed for unusual cases. In particular, obvious clinical resource differences (possibly not reflected in cost data due to incorrect and/or inappropriate coding/billing) should be factored into the splitting and establishment of APCs.

Additional comments made by mail; electronic comment system does not provide enough room for detailed comments.

APC Relative Weights

The APC relative weight determination process is being crippled by the non-use of multiple procedure claims. CMS should take immediate steps to correct this situation. There does not appear to be a simple solution. One approach would be to return to the APG (Ambulatory Patient Groups) approach of `significant procedure consolidation?. However, this approach may introduce too much variation in the costs used for APC weight determination.

Another approach is probably what will have to occur in order to correct this situation. Hospitals will need to have delineated charges per CPT/HCPCS code, particularly in the surgical area. In other words, there must be a charge made for each groupable CPT/HCPCS code. As per regulations, the charges made must be based consistently on the hospitals? costs. If delineated charges are provided, then the multiple claims can be used as data from the development of APC weights. As with outlier payments, the ancillary charges (supplies, drugs, bundled services) can be allocated among the groupable CPT/HCPCS codes based upon the APC weights.

This change will be quite onerous for hospitals. Hospital charge master personnel along with coding and billing personnel will have to make extensive changes to the charge master and the associated charge capture processes. However, there may be no alternative to achieving the goal of having a system that is accurately based on costs.

Note: Some other third-party payers are already requiting delineated charges per CPT/HCPCS code. These are generally those third-party payers building databases of charges in order to establish payment rates for APC or APG type payment systems.

In lieu of the necessary philosophical change that must be made, there need to be immediate, interim steps to intervene in situations in which the payment for certain services is obviously incorrect. For instance, CPT=86891, `Autologous blood or component, collection processing and storage intra- or postoperative salvage?, would, by the very nature of the code, never appear as a singleton claim. Thus, the payment for this service under the current weight development algorithms (and delimitations relative to multiple service claims) needs to be made on an exceptional basis. This service currently maps to a low level Transfusion Medicine code that grossly underpays the costs for providing these services.

This is but one example. You (CMS) should be fully prepared to intervene manually in cases in which the reimbursement level for a given service is obviously well below the costs incurred by hospitals in providing the service.

Recommendation: A process should be established whereby services that are obviously being underpaid, because of any one of several reasons, are manually adjusted using other outside cost or resource utilization information.

Inpatient List

The inpatient or inpatient-only list should be limited only to those surgeries that can be performed only in the inpatient setting. Any surgery that can be performed on an outpatient basis, even if the number is quite minimal, should map to an APC. If a physician determines that a surgery can be safely performed on an outpatient basis, then the hospital should receive appropriate payment for such services as outpatient.

If the current inpatient-only list is to be continued, then provisions must be made to provide payment in those cases in which a surgery is performed on an outpatient basis for a surgery listed on the inpatient-only list. There are a number of ways in which this can be accomplished. Two approaches are outlined below.

1. Probably the easiest approach is to use a process similar to that addressed by the ?-CA? modifier and Status ?C? procedures. A default APC should be established to make payment for outpatient surgeries that are performed when the procedure is on the inpatient basis. While this will result in a single payment level for potentially highly disparate surgeries, at least there will be some payment.
2. Alternatively, hospitals can be allowed, up to the time of billing, to be allowed to change the status of the patient from outpatient to inpatient. In order for this process to work, the decision to change the status must be at the behest of the hospital with or without the concurrence of the physician.

Recommendation: While the inpatient-only list should be modified or discontinued, an interim process to make certain that hospitals receive payment for outpatient surgical procedures which are on the inpatient-only list should be immediately implemented. While there are different ways in which this can be easily accomplished, either follow the process for which the ?-CA? modifier is used or allow hospitals the option of changing the patient status from outpatient to inpatient up to the time of billing.

Physical Examinations

The language proposed and services to be offered are appropriate. It is noted that the definitions for `physician? and `non-physician practitioner? are delimited for the purposes of the CFR sections in which they are included.

Issues 11-20

Blood and Blood Products

Clearly blood and associated blood products have been grossly underpaid over the past several years, even in light of very vocal complaints from hospitals across the country. The determination of discrepancies in the use of proper cost-to-charge ratios (CCRs) is indeed a significant step forward.

Now that the inaccuracy of payments has been determined, two steps should be taken:

1. Correct the payment levels going forward, and
2. Correct the underpayments over the past several years.

The increasing proposed for CY2005 appear to be quite appropriate going forward, but the gross underpayments of the past several years should also be corrected. While there is no easy way in which to accomplish this on a hospital-by-hospital basis, an additional increase of 15%-20% for the next two to three years would be appropriate.

Recommendation: The correction and increase in blood and blood products payments for CY2005 is correct, and, additionally, an increase in the range of 15% to 20% should also be made for the next three years in order to pay hospitals for the underpayment made during the last several years.

Note: The situation uncovered in the blood and blood products area may only be an example of a much larger underlying problem with the CCRs.

Issues 21-30

Cost-to-Charge Ratios

The cost-to-charge ratios (CCRs) are used extensively by you (CMS) to convert charges made on claims to costs. While hospitals make attempts to establish their charges to meet the regulatory requirements of being consistent and based upon costs, there are two main concerns with the CCRs:

1. Timeliness of the CCRs, that is, are the CCRs up-to-date?
2. Specificity of the CCRs, that is, are the CCRs broken out finely enough to accurately represent all the pertinent area for utilization in conjunction with APCs.

The problems with CCRs has been illustrated through the incorrect use of CCRs in connection with blood and blood products. Since CCRs play such an important role in the APC weight development and overall payment process, great care should be taken to make certain the CCRs are both up-to-date and have the correct level of specificity.

Recommendation: CMS should instigate an immediate study for the improvement of the reporting of costs in conjunction with the cost-to-charge ratio development. A more timely process should be implemented so that currently accurate CCRs are being used by CMS to translate hospital?s charges to costs. Additionally, consideration should be given to greater detail in the CCRs to better reflect the full line of service areas being provided by hospitals today.

E/M Services Guidelines

The technical component E/M coding guidelines should be issued as quickly as possible, but only after thorough discussion, availability for comments and suggestions, and appropriate testing. The guidelines for the ED levels should be carefully separated from the guidelines for provider-based clinics.

Whatever guidelines are developed, one of the key attributes of the system should be simplicity. This system should be very simple and straightforward in application. This simplicity criterion is needed so that there can be some degree of consistency across a multitude of ED and provider-based settings and very different levels of service.

As noted in the April 7, 2000, Federal Register, the professional component E/M and technical component E/M levels need not match depending upon the location and type of service. This difference in E/M levels results from the difference in what the E/M levels represent. For the hospital, technical component the E/M level reflects resources utilized. For the professional, physician component the E/M level reflects what the physician actually performed and documented.

In the ED and certain provider-based clinics, there is a great deal of activity generated from services provided by hospital personnel that are coordinated but separate from the services of the physician. This is true in the ED since there are a number of non-physician providers such as ED nurses, EMTs and other qualified non-physician providers (generally technicians of various types) that provide services following various protocols. The services of these personnel, while coordinated with physician activities, are separate and distinct and may generate an E/M level that is different from the physician.

This difference may occur within certain other provider-based clinics such as wound care clinics in which services are being provided by non-physician providers that are not otherwise recognized for professional billing. For instance, specially trained nursing staff in wound care may provide extensive services for which there is no direct physician involvement and/or physician professional component billing. For those services that are not separately codeable and billable, the only recourse is to have the services map into an E/M level. Thus, even if there were some minimal involvement of the physician, the nurse is providing most of the services and thus generating an E/M level.

For most provider-based clinic situations such as family practice, dermatology, orthopedics and the like, there is a much closer correlation between the physician?s activities and the level of ancillary staff involvement which will generate the technical component E/M level. This results from the fact that ancillary personnel are directly supporting the activities of the physician for the E/M services. For instance, ancillary personnel prepare examination rooms, direct patients to examination rooms, perform preliminary assessments and then assist the physician with examinations plus providing any other necessary supporting activities. Also, major resource utilization occurs in the use of examination rooms and the level of E/M code generated by physicians correlates to the amount of time spent with a patient. If a physician spends an hour with a patient, then there is similar resource utilization on the part of the hospital (or other main provider) for the room, supplies and supporting ancillary personnel.

Recommendation: Regardless of what system is eventually developed, hospitals with provider-based clinics should be given the option of using the same E/M level as that used by the physician for those clinics in which there is generally a close correlation between the activities of the physician (or other qualified non-physician practitioner) and the resources consumed on the part of the provider-based clinic (i.e., room, supplies and support staff).

Additional commnents made by mail; electronic system does not allow space.

Inpatient Procedures

The inpatient or inpatient-only list should be limited only to those surgeries that can be performed only in the inpatient setting. Any surgery that can be performed on an outpatient basis, even if the number is quite minimal, should map to an APC. If a physician determines that a surgery can be safely performed on an outpatient basis, then the hospital should receive appropriate payment for such services as outpatient.

If the current inpatient-only list is to be continued, then provisions must be made to provide payment in those cases in which a surgery is performed on an outpatient basis for a surgery listed on the inpatient-only list. There are a number of ways in which this can be accomplished. Two approaches are outlined below.

1. Probably the easiest approach is to use a process similar to that addressed by the ?-CA? modifier and Status ?C? procedures. A default APC should be established to make payment for outpatient surgeries that are performed when the procedure is on the inpatient basis. While this will result in a single payment level for potentially highly disparate surgeries, at least there will be some payment.
2. Alternatively, hospitals can be allowed, up to the time of billing, to be allowed to change the status of the patient from outpatient to inpatient. In order for this process to work, the decision to change the status must be at the behest of the hospital with or without the concurrence of the physician.

Recommendation: While the inpatient-only list should be modified or discontinued, an interim process to make certain that hospitals receive payment for outpatient surgical procedures which are on the inpatient-only list should be immediately implemented. While there are different ways in which this can be easily accomplished, either follow the process for which the ?-CA? modifier is used or allow hospitals the option of changing the patient status from outpatient to inpatient up to the time of billing.

Observation Services

The activities surrounding separate payment for observation services needs to be expedited. We are now entering our sixth year for APCs which is ample time to develop guidelines for observation coding and billing and thus for separate payment for this relatively expensive service that is provided to patients.

One change that does need to be made immediately is to discontinue the automatic bundling of separately payable observation services when a Status=?T? service is provided. Such bundling is not appropriate in certain circumstances. See case description below.

Case Example - Patient presents to the ED with chest pains. However, upon leaving the vehicle delivering the patient to the hospital, the patient suffers a minor laceration on the hand. The laceration is treated by a single suture and is coded and billed. Since the laceration repair of this minor injury is a Status Indicator ?T? service, the otherwise separately payable observation service will be bundled into the laceration repair.

This type of situation is clearly inappropriate. If Status=?T? is to be used as a criterion for bundled the separately payable observation services, then exceptional cases should be recognized and paid separately.

This could be accomplished by allowing the ?-59?, `Separate Procedure?, modifier to be used. Guidelines for services that are `related? should be established. Thus hospitals will be able to code, bill and be properly paid.

Recommendation: CMS should develop guidance for `related? and `unrelated? services provided in conjunction with separately payable observation services. Hospitals should be allowed to use the ?-59? modifier to separate Status=?T? services from separately payable observation services.

CMS-1427-P-205

Submitter : Mrs. Lisa Potts **Date & Time:** 10/08/2004 04:10:28

Organization : Washington University School of Medicine

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

October 5, 2004

Re: Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment Systems and Calendar Year 2005 payment Rates; CMS-1427-P; Proposed Recalibration of APC Weights for CY 2005

CMS-1427-P-205-Attach-1.txt

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CMS-1427-P-206

Submitter : Mr. Gary LeRoy **Date & Time:** 10/08/2004 04:10:09

Organization : Port Huron Hospital

Category : Hospital

Issue Areas/Comments

Issues 21-30

Payment Rate for APCs

Secretary Thompson:

We are pleased to have the opportunity to comment on proposed changes to Medicare Hospital OPPS and CY 2005 Payment Rates. The proposal we object to would slash the median cost for APC 0659, hyperbaric oxygen therapy(HBOT) treatment from $164.93 to $82.91.

Port Huron Hospital is a medium sized freestanding community hospital that serves a broad geographic region covering the Thumb of Michigan. Only in July 2004 did we open the Port Huron Hospital Wound Healing Center in response to expansive community and physician demand for local wound specialty services. Our Center is the only such Center between Saginaw and the Metro Detroit area. From the outset, demand has suggested that there is a crying need for this service in our region.

Development of this Wound Center--which includes HBOT as an integrated modality--was undertaken based both on community health needs and financial viability. The proforma financials assumed the current $164.93 payment for HBOT. Those proformas--which also required some $800,000 in capital commitment--yield the Wound Center only minimal financial margin.

We feel proud to have started such a needed service-- but feel alittle like we're being smitten for our diligence in improving the health of our communities--as we consider these proposed rate reductions...Please Mr. Secretary, we ask you to maintain the full $164.93 at least until CMS has opportunity to develop and perform calculations to most appropriately reflect HBOT costs.

Thank you for your consideration.

Respectfully, Gary S. LeRoy, Vice President for Admininstration

CMS-1427-P-207

Submitter : Mr. Ross D'Emanuele **Date & Time:** 10/08/2004 04:10:13

Organization : Dorsey

Category : Attorney/Law Firm

Issue Areas/Comments

Issues 11-20

Drugs, Biologicals, and Radiopharmaceuticals NonPass-Throughs

Dorsey & Whitney respectfully submits the following comment on behalf of one of its clients, pertaining to the Proposed Rule issued by the Centers for Medicare and Medicaid Services ('CMS') on the Medicare outpatient prospective payment system for drugs. (See Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates, 69 Fed. Reg. 50,448 (Aug. 16, 2004).)

By this comment, we recommend that CMS not pay for J1260 Injection, dolasetron mesylate per 10 mg (AnzemetO Injection (dolasetron mesylate injection)) based on its reference AWP (i.e., the AWP published for this product as of May 1, 2003), because the AWP for this product was significantly reduced from $173.16 per 100 mg (as of May 1, 2003), to the current AWP of $46.80 per 100 mg (which was published in the Red Book in September 2004). If CMS were to pay for J1260 Injection, dolasetron mesylate per 10 mg in 2005 based on the 'reference AWP' for this product as defined in the Proposed Rule, it would be paying between 83% and 95% of $17.32 per 10 mg of product that could be readily acquired for less than $4.68 per 10 mg of product. We believe that such a result is not consistent with the intent of the Proposed Rule, and would not constitute responsible management of the public fisc.

Issue

In the Proposed Rule, in Calendar Year 2005, CMS would pay for J1260 Injection, dolasetron mesylate per 10 mg ('Dolasetron'), a sole source, injectable anti-emetic product, at between 83% and 95% of its 'reference average wholesale price' ('Reference AWP'), which means the AWP for Dolasetron which was published in the Red Book on May 1, 2003.

The Reference AWP for Dolasetron (NDC #0088-1206-32) published in the Red Book on May 1, 2003, was $173.16 per 100 mg (see Attachment 1). As such, under the Proposed Rule, CMS would pay for Dolasetron during Calendar Year 2005 at between 83% and 95% of this amount.

However, on June 14, 2004, the manufacturer of Dolasetron announced that it was significantly reducing the Wholesaler List Price for this product (NDC #0088-1206-32) to $39.00 per 100 mg, effective July 1, 2004 (see Attachment 2). This announced price reduction was followed by a corresponding significant reduction in the AWP for Dolasetron to the current level of $46.80 per 100 mg (NDC #0088-1206-32, published in the September 2004 Update to the Red Book, see Attachment 3). In short, if CMS were to adhere to the Proposed Rule and pay for Dolasetron based on its Reference AWP in 2005, it would be paying over $14.30 per 10 mg of product that could be readily acquired at less than $4.60 per 10 mg of product.

Conclusion

We do not believe that CMS intended this result. By submitting this comment, we hope to bring this issue to CMS' attention, and we recommend that CMS not pay for J1260 Injection, dolasetron mesylate per 10 mg, based on its May 1, 2003 Reference AWP during Calendar Year 2005. Since the AWP for this product was significantly reduced after May 1, 2003, we respectfully recommend that CMS exercise its discretion and instead pay for Dolasetron based on its current, significantly reduced AWP of $46.80 per 100 mg.

Thank you for this opportunity to comment.

Attachment 1: May 2003 Red Book dolasetron AWP
Attachment 2: June 2004 dolasetron Wholesaler List Price Reduction
Attachment 3: September 2004 Red Book dolasetron AWP

CMS-1427-P-207-Attach-2.pdf

CMS-1427-P-207-Attach-3.pdf

CMS-1427-P-207-Attach-1.pdf

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CMS-1427-P-208

Submitter : Marilyn Curtis **Date & Time:** 10/08/2004 04:10:52

Organization : Saint Francis Medical Center

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Dear Tommy G. Thompson:

I am Vice-President of Professional Services at Saint Francis Medical Center located in Cape Girardeau, Missouri. We are opposed to the proposed changes to the Medicare Hospital OPPS Payment Rates, in the 69 Fed. Reg. 50448, which will reduce the median cost for APC 0659, hyperbaric oxygen therapy treatment from the 2004 payment of $164.93 to $82.91.

Saint Francis Medical Center is a 249 bed medical center with a Wound Healing Center that offers a comprehensive program for the management of chronic wounds. Hyperbaric oxygen therapy is a highly utilized component of this program and has proven to be extremely effective in the treatment of patients in the outpatient clinic as well as emergent inpatient situations. I am concerned that the proposed lower payment may threaten our ability to provide this effective and efficient treatment to our patients.

We are in complete support of the Lewin Group?s report and are concerned that this will not be the same situation with hyperbaric therapy provided with our wound program.

It is my hope that CMS will reconsider their proposed rate structure revisions.

I appreciate the time you have taken to review my concerns.

Sincerely,

Marilyn Curtis
Vice-President of Professional Services

CMS-1427-P-209

Submitter : Mrs. Tracy Warner **Date & Time:** 10/08/2004 04:10:42

Organization : Iowa Hospital Association

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See attached comment letter from the Iowa Hospital Association.

CMS-1427-P-209-Attach-1.doc

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Submitter : Dr. Michael Cowley **Date & Time:** 10/08/2004 04:10:41

Organization : Society for Cardiovascular Angiography

Category : Physician

Issue Areas/Comments

Issues 1-10

APC Groups

October 8, 2004

The Society for Cardiovascular Angiography and Interventions (SCAI) welcomes the opportunity to comment on the proposed changes in the hospital outpatient prospective payment system for 2005. SCAI is the principal professional society for invasive and interventional cardiology representing 3,200 physicians. SCAI?s primary mission is to promote excellence in invasive and interventional cardiovascular medicine through physician education and representation, and the advancement of quality standards to enhance patient care.

We would like to first state our support for the proposed assignment of CPT codes 93571 and 93572 (intravascular distal blood flow velocity) to Ambulatory Payment Classification (?APC?) groups 0670 and 0416, respectively. Currently, these services, representing coronary flow reserve (FFR) payment procedures, are considered ?packaged? services. SCAI had previously requested that FFR be classified as separately payable procedures. SCAI also greatly appreciates CMS? responsiveness in proposing this change. We believe that the proposed APC classification is appropriate on grounds of both clinical comparability and resource homogeneity.

We would also like to comment on the proposed reassignment of CPT Code 37250, Intravascular Ultrasound (non-coronary) vessel during diagnostic and/or therapeutic intervention, from APC 0670 to APC 0416. APC 0670 has a proposed payment rate of $1,698 while APC 0416 has a proposed payment rate of $255. The median cost for Code 37250 was determined to be $363. However, this procedure involves the use of a disposable catheter costing approximately $650 and it is obvious that the proposed APC rate of $255 is grossly inadequate. The proposed APC rate does not even cover half the costs of the disposable catheter and essentially none of the other costs incurred by the hospital to perform this procedure.

Centers for Medicare & Medicaid Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Ave., SW
Washington, DC 20201

We think the problem with the proposed rate is due to substantial deficiencies in the data used by CMS in determining the median costs of this procedure. According to the database, CMS is using only 43 so-called ?single claims? for the calculation. However, there were almost 1,000 claims for this service performed in the OPD setting. We believe that the 4 percent of claims used by CMS were unrepresentative of the actual costs incurred by hospitals in performing this service. In this connection, we saw an analysis of the complete claims file provided by Boston Scientific that only considered claims which included a charge for Revenue Code 272 or 278. These are the revenue centers that most likely would be used to report a charge for an intravascular ultrasound catheter. For the 506 claims where a charge was present in one of these two revenue centers, the mean average cost was $2,061, which is much closer to what we believe the actual costs are for performing IVUS.

In light of these facts, SCAI urges CMS to (1) continue to assign Code 37250 to APC 0670 for 2005 and (2) determine what instructions need to be given to hospitals for billing this procedure in the future to assure that accurate charge data can be collected.

Thank you again for the opportunity to comment on this proposed rule.

CMS-1427-P-211

Submitter : Ms. Helen Savitzky **Date & Time:** 10/08/2004 05:10:06

Organization : Memorial Hermann Hospital System

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Please see attached document

CMS-1427-P-211-Attach-1.doc

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CMS-1427-P-212

Submitter : Dr. Stanley Satz **Date & Time:** 10/08/2004 05:10:07

Organization : Bio-Nucleonics Pharma, Inc.

Category : Drug Industry

Issue Areas/Comments

Issues 11-20

Radiopharmaceuticals

A9600 Strontium-89
In the APC Nuclear Medicine Task Force?s comparison of available CMS hospital drug and radiopharmaceutical median cost data with the Society of Nuclear Medicine?s survey of cost data, the Task Force identified several radiopharmaceuticals which it believes CMS would underpay due to flawed CMS median cost data.
Specifically HCPCS A9600 Strontium-89 per mCi is proposed to be paid at $410.45 per mCi. The APC Nuclear Medicine Task Force? and Bio-Nucleonics? data show a median cost of $800 per mCi. Bio-Nucleonics concurs with the APC Task Force that hospital costs for A9600 are approximately $800 per mCi and request CMS adjust payment accordingly. Strontium Chloride Sr-89 Injection costs much less than narcotic analgesics and has been shown in many studies to reduce the requirement for costly narcotic analgesics. Strontium Chloride Sr-89 Injection can provide rapid and significant pain relief that is long-lasting. In patients who respond, pain relief can last a median of six months and in many patients twelve months. Strontium Chloride Sr-89 Injection may be used in an outpatient setting and provides relief within one to two weeks in up to 80% of breast and prostate cancer patients with painful osteoblastic metastases, and usually results in a marked reduction in narcotic analgesic use.
This flawed CMS policy is already costing the agency and American taxpayers millions of Bio-Nucleonics concurs with the APC Task Force that hospital costs for A9600 are approximately $800 per mCi and request CMS adjust payment accordingly. Unlike conventional drugs, Strontium Chloride Sr-89 Injection is expensive to manufacture and is produced in small lots.
Distinct from non-radioactive drugs, the FDA requires that radiopharmaceuticals have traceability and intercompatibility to the NIST, a costly process. Also, unlike conventional pharmaceutical production, additional personnel are required to manufacture radiopharmaceuticals. In actual practice, this drug, in constant decay, must be used within days of manufacture, and if not sold in that ?window? is unusable and must be shipped to and disposed of at considerable expense.
The drastic decrease in the payment rate is driving the underutilization of Strontium-89 Chloride, and the CMS is using a fundamentally flawed methodology for setting a payment rate, applying the Modernization Act aimed at conventional drugs for low-volume radiopharmaceuticals a class of therapeutics that are costly and difficult to manufacture. This approach is biased against a long lasting, proven and cost-effective therapy that improves quality-of-life in patients, costing the Agency millions of dollars in reimbursements and affecting, patients with painful metastases. A flawed reimbursement policy will result in an increase in narcotic usage, a decrease in quality-of-life and a rise in the cost of health care. The reimbursement figure certainly does not accurately reflect the real acquisition cost of this drug by the hospital after passing from us to the radiopharmacy. Through the use of Strontium-89 Chloride, the CMS could achieve a substantial savings in health care treatment costs, at the same time decreasing the need for opioids and improving the quality-of-life of cancer patients suffering from metastatic bone pain. Pharmacoeconomic data, attached, supports this assumption. The decreased usage of radionuclide therapy to treat cancer bone pain may likely result in CMS paying at least $300 million more each year for opioid analgesics and tertiary care than it did in 2002 (40,000 cancer patients at a minimum $5,000 savings per patient), resulting from additional costs for analgesics, visiting nurses for outpatient administration, hospital visits and tertiary care.
Many patients with cancer do not receive adequate pain relief. Effective pain control can help patients stay involved not only in their cancer treatment but also in the activities of daily living and their quality-of-life.

Submitter : Dr. Stanley Satz **Date & Time:** 10/08/2004 05:10:55

Organization : Bio-Nucleonics

Category : Drug Association

Issue Areas/Comments

Issues 11-20

Estimated Transitional Pass-Through Spending

Strontium-89 Cancer Bone Pain Treatment Bibliography
Underutilization of Radionuclide Therapy in Treatment of Cancer Bone Pain

New Drugs, Biologicals, and Radiopharmaceuticals Pass-Throughs

A9600 Strontium-89
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Specifically HCPCS A9600 Strontium-89 per mCi is proposed to be paid at $410.45 per mCi. The APC Nuclear Medicine Task Force? and Bio-Nucleonics? data show a median cost of $800 per mCi. Bio-Nucleonics concurs with the APC Task Force that hospital costs for A9600 are approximately $800 per mCi and request CMS adjust payment accordingly. Strontium Chloride Sr-89 Injection costs much less than narcotic analgesics and has been shown in many studies to reduce the requirement for costly narcotic analgesics. Strontium Chloride Sr-89 Injection can provide rapid and significant pain relief that is long-lasting. In patients who respond, pain relief can last a median of six months and in many patients twelve months. Strontium Chloride Sr-89 Injection may be used in an outpatient setting and provides relief within one to two weeks in up to 80% of breast and prostate cancer patients with painful osteoblastic metastases, and usually results in a marked reduction in narcotic analgesic use.
This flawed CMS policy is already costing the agency and American taxpayers millions of Bio-Nucleonics concurs with the APC Task Force that hospital costs for A9600 are approximately $800 per mCi and request CMS adjust payment accordingly. Unlike conventional drugs, Strontium Chloride Sr-89 Injection is expensive to manufacture and is produced in small lots.
Distinct from non-radioactive drugs, the FDA requires that radiopharmaceuticals have traceability and intercompatibility to the NIST, a costly process. Also, unlike conventional pharmaceutical production, additional personnel are required to manufacture radiopharmaceuticals. In actual practice, this drug, in constant decay, must be used within days of manufacture, and if not sold in that ?window? is unusable and must be shipped to and disposed of at considerable expense.
The drastic decrease in the payment rate is driving the underutilization of Strontium-89 Chloride, and the CMS is using a fundamentally flawed methodology for setting a payment rate, applying the Modernization Act aimed at conventional drugs for low-volume radiopharmaceuticals a class of therapeutics that are costly and difficult to manufacture. This approach is biased against a long lasting, proven and cost-effective therapy that improves quality-of-life in patients, costing the Agency millions of dollars in reimbursements and affecting, patients with painful metastases. A flawed reimbursement policy will result in an increase in narcotic usage, a decrease in quality-of-life and a rise in the cost of health care. The reimbursement figure certainly does not accurately reflect the real acquisition cost of this drug by the hospital after passing from us to the radiopharmacy. Through the use of Strontium-89 Chloride, the CMS could achieve a substantial savings in health care treatment costs, at the same time decreasing the need for opioids and improving the quality-of-life of cancer patients suffering from metastatic bone pain. Pharmacoeconomic data, attached, supports this assumption. The decreased usage of radionuclide therapy to treat cancer bone pain may likely result in CMS paying at least $300 million more each year for opioid analgesics and tertiary care than it did in 2002 (40,000 cancer patients at a minimum $5,000 savings per patient), resulting from additional costs for analgesics, visiting nurses for outpatient administration, hospital visits and tertiary care.
Many patients with cancer do not receive adequate pain relief. Effective pain control can help patients stay involved not only in their cancer treatment but also in the activities of daily living and their quality-of-life.

Radiopharmaceuticals

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flawed CMS median cost data.
Specifically HCPCS A9600 Strontium-89 per mCi is proposed to be paid at $410.45 per mCi. The APC Nuclear Medicine Task Force? and Bio-Nucleonics? data show a median cost of $800 per mCi. Bio-Nucleonics concurs with the APC Task Force that hospital costs for A9600 are approximately $800 per mCi and request CMS adjust payment accordingly. Strontium Chloride Sr-89 Injection costs much less than narcotic analgesics and has been shown in many studies to reduce the requirement for costly narcotic analgesics. Strontium Chloride Sr-89 Injection can provide rapid and significant pain relief that is long-lasting. In patients who respond, pain relief can last a median of six months and in many patients twelve months. Strontium Chloride Sr-89 Injection may be used in an outpatient setting and provides relief within one to two weeks in up to 80% of breast and prostate cancer patients with painful osteoblastic metastases, and usually results in a marked reduction in narcotic analgesic use.
This flawed CMS policy is already costing the agency and American taxpayers millions of Bio-Nucleonics concurs with the APC Task Force that hospital costs for A9600 are approximately $800 per mCi and request CMS adjust payment accordingly. Unlike conventional drugs, Strontium Chloride Sr-89 Injection is expensive to manufacture and is produced in small lots.
Distinct from non-radioactive drugs, the FDA requires that radiopharmaceuticals have traceability and intercompatibility to the NIST, a costly process. Also, unlike conventional pharmaceutical production, additional personnel are required to manufacture radiopharmaceuticals. In actual practice, this drug, in constant decay, must be used within days of manufacture, and if not sold in that ?window? is unusable and must be shipped to and disposed of at considerable expense.
The drastic decrease in the payment rate is driving the underutilization of Strontium-89 Chloride, and the CMS is using a fundamentally flawed methodology for setting a payment rate, applying the Modernization Act aimed at conventional drugs for low-volume radiopharmaceuticals a class of therapeutics that are costly and difficult to manufacture. This approach is biased against a long lasting, proven and cost-effective therapy that improves quality-of-life in patients, costing the Agency millions of dollars in reimbursements and affecting, patients with painful metastases. A flawed reimbursement policy will result in an increase in narcotic usage, a decrease in quality-of-life and a rise in the cost of health care. The reimbursement figure certainly does not accurately reflect the real acquisition cost of this drug by the hospital after passing from us to the radiopharmacy. Through the use of Strontium-89 Chloride, the CMS could achieve a substantial savings in health care treatment costs, at the same time decreasing the need for opioids and improving the quality-of-life of cancer patients suffering from metastatic bone pain. Pharmacoeconomic data, attached, supports this assumption. The decreased usage of radionuclide therapy to treat cancer bone pain may likely result in CMS paying at least $300 million more each year for opioid analgesics and tertiary care than it did in 2002 (40,000 cancer patients at a minimum $5,000 savings per patient), resulting from additional costs for analgesics, visiting nurses for outpatient administration, hospital visits and tertiary care.
Many patients with cancer do not receive adequate pain relief. Effective pain control can help patients stay involved not only in their cancer treatment but also in the activities of daily living and their quality-of-life.

CMS-1427-P-214

Submitter : Ms. Jorja Sturek **Date & Time:** 10/08/2004 05:10:37

Organization : Allergan Inc.

Category : Drug Industry

Issue Areas/Comments

Issues 11-20

Drugs, Biologicals, and Radiopharmaceuticals NonPass-Throughs

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CMS-1427-P-215

Submitter : Ms. Jorja Sturek **Date & Time:** 10/08/2004 05:10:57

Organization : Allergan Inc.

Category : Drug Industry

Issue Areas/Comments

Issues 11-20

Drugs, Biologicals, and Radiopharmaceuticals NonPass-Throughs

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Submitter : Mrs. Kathy Reep **Date & Time:** 10/08/2004 05:10:50

Organization : Florida Hospital Association

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 1-10

Devices

CMS requests comments on their proposal to require the coding of C-codes for certain APCs. The use of these codes has been a roller-coaster process over the past few years. Hospitals were instructed to use the codes while the devices were paid as a pass-through, and then were told, upon the expiration of the pass-through period, that claims would be returned if they contained the C-codes. Hospitals and other commenters suggested that the Pricer should identify whether a payment was associated with an individual coded item and whether a C-code was included on the claim was inconsequential, but CMS insisted that the codes be removed from the claims. The following year, we were 'encouraged' to use the C-codes because the data were found useful; now CMS has addressed requiring the coding of certain C-codes for device-dependent APCs.

We support the use of C-codes and urge CMS to allow providers to include any valid code on their claim without fear of it being returned unprocessed. In order to ensure a smooth transition, however, CMS should allow a grace period of no less than 90 days post-implementation of the 2005 outpatient PPS to allow hospitals adequate time to make necessary system changes and to educate coders. During this period, the fiscal intermediaries should be required to accept and process these codes when submitted, but should not return the claim to the provider if the C-code is not present on the claim. In addition, we urge CMS to take one last look at the need for these codes and to announce plans for inclusion or exclusion of C-codes in the future, with a date certain.

Physical Examinations

Consistent with provisions in Sec. 611 of the Medicare Modernization Act, CMS proposes to amend regulations to provide for coverage of an initial preventive physical examination in various settings, including the hospital outpatient department, within the first 6 months after the beneficiary's first Part B coverage begins, but that coverage period may not begin before January 1, 2005. We urge CMS to work closely with hospitals, physicians, and contractors to assure that orders related to the 'Welcome to Medicare Physical' are clear and that services such as EKGs are not to be separately billed. In addition, hospitals and physicians need to be able to identify that patients are within the requisite eligibility period; whether this is something that could be queried through the common working file, eligibility shown on the enrollment card, or beneficiary notification of the benefit with an expiration date, there needs to be a method to identify the eligible 6-month window for coverage.

Issues 11-20

Blood and Blood Products

CMS proposes several changes to its payment methodology for blood and blood products. First, the agency proposes to establish new APCs as well as to reassign some of the HCPCS codes already contained in certain APCs to new APCs. Second, CMS proposes to set payment rates for all blood and blood products based on their CY 2003 claims data, utilizing an actual or simulated hospital blood-specific cost-to-charge ratio to convert charges to costs for blood and blood products. For certain low-volume products, CMS would combine claims data for CYs 2002 and 2003. While this approach results in modest payment increases for many blood and blood product-related APCs, payment rates for certain low-volume APCs will decline significantly under the propose methodology.

To ensure continued beneficiary access to low-volume blood products, the FHA recommends that CMS freeze the reimbursement rates for 2005 at the 2004 levels for those low-volume blood products whose rates would fall under the methodology of the proposed rule.

Issues 21-30

E/M Services Guidelines

The FHA encourages CMS to move ahead in issuing a proposed national, uniform evaluation and management (E&M) coding system for hospitals. It will take providers a minimum of 6 months after release of a final rule on E&M facility coding to train their staff and modify internal systems before we could move to a standard. The longer the delay in publishing even a proposed rule, however, the more concerned we are with HIPAA compliance.

While CMS can say that the coding structure that is currently in place - every hospital developing its own definition for established CPT codes - has been approved by CMS, it has not been approved by the myriad of payers that hospitals also bill. These providers are billed with the same CPT codes - with the hospital-defined matrix for placing a patient in a particular level - and this is in violation of HIPAA transactions and code set regulations that indicate use of a particular code set pertains to both the code and its definition as published by the maintainer (the AMA in the case of CPT codes).

Inpatient Procedures

CMS identifies certain procedures that are typically provided only in an inpatient setting. These procedures are assigned a status of 'C: inpatient procedure, not payable under the OPPS.' Hospitals were advised to admit these patients to receive payment. CMS rejected an APC Advisory Panel recommendation to eliminate the list of inpatient-only procedures.

The FHA joins the American Hospital Association and other state associations in recommending that the inpatient-only list be eliminated, as recommended by the APC Advisory Panel. Hospitals are unable to receive any payment for services on this list that are performed in the outpatient setting, without admission. Yet, physicians, not hospitals, determine what procedures should be performed and whether a patient's condition warrants an inpatient admission. We believe it is appropriate to leave this clinical decision making process in the hands of physicians.

Observation Services

CMS established separate payment for observation services under the OPPS for three medical conditions: chest pain, congestive heart failure, and asthma. A number of accompanying requirements were established, including provision of specific diagnostic tests to beneficiaries based on their diagnoses. CMS has responded to comments from the hospital community by proposing to eliminate the requirements for specific diagnostic tests. In addition, CMS is proposing to modify the rules so that time in observation care would end when the outpatient is actually discharged from the hospital or admitted as an inpatient. The FHA supports these changes, which will result in more accurate billing and provide payment for more clinically appropriate care.

CMS also proposes to exclude from the rate calculation any claims that report more than 48 hours of observation care. We believe that CMS should reevaluate the final payment rate for APC 0339, including those claims exceeding 48 hours of observation care. These observation service claims have been paid by Medicare and reflect services that were reviewed and determined to be medically necessary. Therefore, the costs for such covered services should be included in calculating the payment rates.

Wage Index

CMS indicates that the final inpatient wage index will be used in the outpatient final rule. However, in reference to the wage index utilized for the outpatient system, the proposed rule omits one important caveat that was included as part of the inpatient final rule. While the rule specifically mentions that various inpatient wage index adjustments such as current reclassification status, occupational mix adjustments, out-migration adjustments and one-time reclassification appeals granted under Section 508 of the Medicare Modernization Act of 2003 (MMA) will apply to the outpatient payment system, it neglects to mention the one-year temporary relief provided in the inpatient final rule for hospitals harmed by the redefinition of wage areas. Under this relief, hospitals experiencing a wage index decrease due to labor market changes receive a blend of 50% of the wage index based on the new definitions and 50% based on the old boundaries.

We urge CMS to specify that the wage index used with the outpatient prospective payment system will include the one-year temporary relief for facilities that experienced a loss caused by geographic redefinitions, which was provided under the FY 2005 inpatient system.

Issues 31-33

Outlier Payments

CMS proposes to require that costs must exceed 1.5 times the Ambulatory Payment Classification (APC) rate and also exceed a $625 fixed-dollar threshold in order to qualify for outlier payments. This would eliminate outlier payments for low-cost services and provide higher outlier payments for relatively expensive procedures. We are concerned, however, that the proposed thresholds for outlier payment may be too high. In the proposed federal FY 2005 inpatient prospective payment system rule, CMS suggested a substantial increase in the outlier threshold based on inflated charge estimates that did not take into account the charge decreases that many hospitals implemented in 2003 and 2004. In 2003, CMS issued a rule requiring the use of data that are more up-to-date when determining a hospital's cost-to-charge ratio (CCR) - specifically, a hospital's most recent final or tentative-settled cost report. It also instructed fiscal intermediaries, in certain situations, to retrospectively reconcile outlier payments when a hospital's cost report is settled. Because of these changes, many hospitals decreased their charges and the overall rate of increase declined. In response to comments, CMS lowered its charge increase assumptions substantially in the inpatient final rule.

CMS states that the new methodology will continue to pay 2% of total OPPS payments as outliers. However, CMS does not provide details of this estimate. FHA urges CMS to provide details of the assumptions used to set the outpatient outlier thresholds. CMS should review assumptions regarding charge increases to ensure that they do not inappropriately inflate charges in setting the OPPS outlier thresholds.

CMS-1427-P-216-Attach-1.doc

CMS-1427-P-216-Attach-2.doc

CMS-1427-P-216-Attach-1.doc

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Submitter : Dr. Michael Repka **Date & Time:** 10/08/2004 05:10:24

Organization : American Academy of Ophthalmology

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

see attached PDF file

CMS-1427-P-217-Attach-1.pdf

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CMS-1427-P-218

Submitter : Ms. Karen Ryan **Date & Time:** 10/08/2004 06:10:45

Organization : Geisinger Health System

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Please see attached letter from Geisinger Health System, Danville, Pa regarding comments on 1427-P: Proposed changes to Medicare outpatient payment system.

CMS-1427-P-218-Attach-1.doc

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Submitter : **Date & Time:** 10/08/2004 06:10:08

Organization : St. Joseph's Hospital

Category : Hospital

Issue Areas/Comments

Issues 1-10

Devices

Device Dependent APCs

St. Joseph's Hospital is in full support of requiring C-codes for those procedures listed in Table 20. We would also suggest C-codes should be mandated to be reported on all claims that have procedures performed where devices are needed in order to complete the operation. Without mandatory reporting requirements for C-codes, more skewed data will result from hospitals that feel it is not a needed part of their billing practice.

We also suggest that CMS research the cost of the devices to hospitals. Many of these devices are fixed prices from manufacturers. In order to provide the best quality of care, our hospital needs to provide these devices to patients, but cannot control the cost. Even if some hospitals do provide the C-code on their bills, again skewed data could result if the mark-up for staffing and other overhead are left off the final charge for the procedure and the device. For most devices, we are unable to recoup even the cost of the device with the reimbursable procedures performed with it.

For example when an ICD generator is implanted in a patient using G0298 we receive a CMS reimbursement of just over $18,000.00. This includes the procedure, EP study, and EKG that was done. We purchase the actual device from a vendor at a cost of just over $26,000.00. Even though a large loss of revenue is consumed each time this procedure is performed it is an essential service our hospital must provide.

Inpatient List

Inpatient List

St. Joseph's Hospital is in agreement with CMS to remove the four procedures of 44901, 49021, 49041, and 49061 off of the inpatient only list. Any procedure that is taken off this listing is an important step toward removing the entire inpatient only listing. We do object to the use of this listing since the status of the patient at the hospital is up to the physician and their medical decision-making regarding medical necessity. The physician, however, receives no consequence of making a decision of performing any surgery as an outpatient that is deemed inpatient only. The decision of medical necessity by the physician has always been stressed by CMS. In many cases physicians find it very difficult to justify the need for inpatient care.

Operationally the inpatient list can be very hard to implement. While in the operating room, surgeons may find other problems that may warrant performing an operation that is on the inpatient only listing. Postoperatively, the physician will feel that the patient is stable and able to be discharged home remaining in an outpatient status. At that point trying to reverse decisions is quite difficult and hard to justify. If the entire listing is not removed from the Final Rule, we suggest one modification to the proposed changes. We suggest vigorously that the procedure 58260 for Vaginal Hysterectomy be removed from the list. Our surgeons have felt that performing the procedure as an outpatient has been a standard of practice for a long time and so patients who can be safely sent home as an outpatient are made an inpatient for the simple fact that they are Medicare patients. This does not make sense to the medical field, as this is not viewed as a medically necessary inpatient admission.

New Technology APCs

New Technology APCs

St. Joseph's Hospital agrees with CMS that the Positron Emission Tomography (PET) scans are an important and valued technology. We also are concerned, as is CMS, that access to this needed diagnostic procedure could be hindered due to moving the PET scans to their own APC 0420. We are suggesting keeping PET scans in new technology APC 1516 (i.e. Option 1: Continue in CY 2005 the current assignment of the scans to New Technology APC 1516 prior to assigning to a clinical APC) for at least one more year to collect true data and to also study how the affects of moving this procedure to APC 0420 would affect the ability of hospitals to provide this service.

As with most hospitals, St. Joseph's Hospital uses a vendor to provide this service, resulting in a fixed patient charge. This fixed charge does not include the cost of the hospital providing this service, only the cost the hospital must pay to the vendor. We feel that skewed data resulting from hospitals not increasing their charge over and above the vendor cost to cover actual costs for performing the procedure show a cost that is much less than is true. Costs incurred by the hospital as a result of performing this procedure can include the cost to register the patient, transcription of reports, staff time (around 2 hours 45 minutes for technologist) in the Nuclear Medicine area, and other overhead. All of these must be considered

part of the total procedure. If APC 0420 were to be used with the current proposed reimbursement amount, many hospitals would be financially unable to provide this service because each time this service is performed a loss of revenue would result.
We are also aware that CMS has provided a new G-code for PET scans for Alzheimer's patients. This code is G0336 and will be assigned to APC 1516. We feel that to collect correct data for all PET scans, they should all remain in the same APC for 2005. By keeping all of the PET scans in the same APC for at least one more year will give more opportunity to receive correct data from hospitals for this relatively new billable procedure.

Issues 21-30

E/M Services Guidelines

E/M Services Guidelines
St. Joseph's Hospital supports the further research being addressed to find proper guidelines for E/M charges in the hospital setting. We feel that the proposed guidelines were insufficient to meet the needs of our hospital. Consideration must be taken to include specialty outpatient services that many hospitals currently have such as the Oncology, Heart Failure, and Wound Care areas. These guidelines must be concise and leave little room for interpretation, otherwise skewed data will be given from hospitals that misinterpret guidelines. Consistent data would be as hard to collect as it is now with hospitals setting their own E/M criteria.

Observation Services

Observation Services
St. Joseph's Hospital would like to thank CMS for removing the criteria for diagnostic tests and discharge time for separately payable observation. Removing the required diagnostic tests will leave the medical decision making up to the physicians and will not tie their hands into ordering an unneeded test that may have already been performed in the clinic setting.
We are very concerned, however, regarding the unclear criteria set for any observation care. Different interpretations are made by Metastar and other review organizations. Inpatient stays have been reversed to observation status that did not meet the criteria. We suggest that CMS provide concise criteria for hospitals that cannot leave room for interpretation by different groups. We also feel that if review organizations do deny payment to hospitals based on certain criteria, then physicians should also be denied payment for their services provided that day. The patient status comes directly from the physician order, so therefore the physician should also have some consequence for the incorrect decisions being made in observation/inpatient status.

Status Indicators and Comment Indicators

Payment Status Indicators
St. Joseph's Hospital feels that all procedures with a status indicator of 'N' should be reviewed, as there are some that may be performed as the only service for the day. A good example would be a vaccine administration using code 90471. The only reason the patient
may be coming in is to receive this injection, so why charge a low level E/M when the procedure is legitimate and has a code? Operationally trying to change the code to a low-level office visit E/M is very difficult as these charges are mostly charge master driven. We also believe that procedures such as pulse oximetry (94760, 94761, and 94762) should not have an 'N' status indicator, as these could also be the only reason for treatment.
A new status indicator could be formed that would allow a bill to be paid at the cost of a low level E/M if it is the only procedure on the claim. This would solve the issue of how to change the charge master driven charge code to the E/M code and would also show more consistent data by allowing our data to be uniform for each patient receiving a vaccine or any other packaged item as the only service.
Many x-ray injections also have a status indicator of 'N' which can be a problem operationally for the radiology area. For example, if a procedure is to be performed that would include the injection procedure 42550 (status indicator 'N') but a reaction happens from the injected material and the procedure is cancelled, instructions now call for hospitals to use the intended procedure with a ?52 modifier for reduced services. This results in a payment that may be higher than the actual injection procedure would be paid if it were not an 'N' indicator. Other payers feel that the hospital is incorrectly billing this when the procedure was not actually performed. Hospitals should be paid for what they perform so leaving this procedure and the other codes like it, as an 'N' status does not give correct data of actual procedures performed.
Another example is the non-selective wound care (97602). This procedure is a highly resource intensive visit in physical therapy departments where dressing changes and wound assessments occur. This is usually the only service rendered during a visit. Other payers do not want to see an E/M level charged along with this code. Operationally to make this happen on a claim is also difficult and time-consuming for staff.
Both the injections for x-rays and the non-selective wound care deserve separate payments.

CMS-1427-P-219-Attach-1.doc

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Submitter : Ms. Rebecca Emerick **Date & Time:** 10/08/2004 06:10:55

Organization : IRSA (International RadioSurgery Association

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 1-10

Stereotactic Radiosurgery

Please accept this word document Re: Stereotactic Radiosurgery.

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CMS-1427-P-221

Submitter : Mr. Matthew Warburton **Date & Time:** 10/08/2004 06:10:47

Organization : Forest Research Institute

Category : Drug Industry

Issue Areas/Comments

Issues 1-10

Physical Examinations

Thank you for the opportunity to comment on the proposed rules implementing the Medicare Part D prescription drug benefit. We are submitting for your consideration, a copy of our comments to the US Pharmacopeia regarding the model formulary guidelines. These comments are attached hereto and incorporated by reference herein.

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Submitter : Ms. Bonnie Handke **Date & Time:** 10/08/2004 06:10:18

Organization : Medtronic, Inc

Category : Device Industry

Issue Areas/Comments

Issues 1-10

Devices

Medtronic, Inc supports the proposed addition of APC 0315, Level II Implantation of Neurostimulator (Kinetra). In addition, we support mandatory device coding ("c" code) for APCs 0039 and 0315. We appreciate the effort and consideration that has gone into the review of these APCs.

CMS-1427-P-223

Submitter : Dr. Michael J. Wolk **Date & Time:** 10/08/2004 06:10:50

Organization : American College of Cardiology

Category : Other

Issue Areas/Comments

GENERAL

GENERAL

Please read the attached letter from Michael J. Wolk, MD,FACC, President of the American College of Cardiology.

Thank you.

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Centers for Medicare and Medicaid Services (CMS)
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CMS-1427-P-224

Submitter : Dr. Michael J. Wolk **Date & Time:** 10/08/2004 06:10:23

Organization : American College of Cardiology

Category : Association

Issue Areas/Comments

GENERAL

GENERAL

Please see the attached letter from Michael J. Wolk, MF, FACC, President, American College of Cardiology.

Thank you.

CMS-1427-P-224-Attach-1.doc

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Submitter : Dr. K. Todd Houston **Date & Time:** 10/08/2004 06:10:43

Organization : Alexander Graham Bell Association for the Deaf

Category : Other Association

Issue Areas/Comments

Issues 1-10

APC Relative Weights

Alexander Graham Bell Association for the Deaf and Hard of Hearing
3417 Volta Place, NW Washington, DC 20007
202-337-5220 (voice)
202-337-8314 (fax)
202-337-5221 (TTY)
www.agbell.org

October 7, 2004

Mark McClellan, MD, PhD Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1427-P
P.O. Box 8081
Baltimore, MD 21244-8018

Re: Medicare Program: Proposed Changes to the Hospital Outpatiuent Prospective Payment System and Calendar Year 2005 Payment Rates; CMS-1427-P.

Dear Dr. McClellan:

The Alexander Graham Bell Association for the Deaf and Hard of Hearing (AG Bell) welcomes the opportunity to submit comments in response to CMS? proposed rule CMS-14-P, published on August 16, 2004, to revise the outpatient prospective payment system (OPPS) for calendar year 2005.

AG Bell is the world?s oldest and largest membership organization promoting the use of spoken language by children and adults with hearing loss. Members include parents of children with hearing loss, adults who are deaf or hard of hearing, educators, audiologists, speech-language pathologists, physicians, and other professionals in fields related to hearing loss and deafness. Through advocacy, publications, financial aid and scholarships, and numerous programs and services, AG Bell promotes its mission: Advocating Independence through Listening and Talking!

AG Bell is pleased that CMS has proposed an increase in 2005 payment rates for services provided for cochlear implantation in the outpatient hospital setting. Included in that proposal is a baseline payment for cochlear implantation at $23,686.60 for device and procedure, from the 2004 baseline rate of $21,343.95. We appreciate and commend the agencies? willingness to work with the cochlear implant community to increase the payment rate, however, payment still underestimates hospital costs of cochlear implantation.

AG Bell submits the recommendation that if the OPPS rate is to better reflect actual costs, then the collection and analysis of accurate claim information must occur. One of the major barriers in reflecting actual cost may be the failure of hospitals to accurately comply with current billing guidelines. More accurate claim information can be collected when the CI device is properly coded. AG Bell urges CMS to make the C codes mandatory and not voluntary. Not using correct coding continues to confuse hospital billing and limits CMS potential to collect accurate data in

which to base future rate increases. We also urge you to continue to accelerate educational efforts to hospitals on accurate coding of CI devices and other technology.

In addition, the Advisory Panel on Ambulatory Classification Groups has recommended a 5% cap rather than the increase proposed by CMS. AG Bell disagrees with the recommendation, because it is arbitrary and a hindrance to CMS? goal to ultimately rely on accurate claims data to establish rates for device-dependent APC?s.

The proposed payment for cochlear implants in 2005 will have a notable impact on cochlear implant programs. CMS? OPPS payment decisions for cochlear implants have a wide and far-reaching influence on the following areas; providing the number of surgeries performed, access to qualified professionals and follow up services that are desperately required after implantation. If Medicare payment does not reflect the cost and value of this intervention, it is likely barriers to access will soon arise to preclude this life-altering technology.

Cochlear implants continue to provide individuals with hearing loss with increasing benefits by improving and increasing daily functioning and overall quality of life. Thank you for your attention and consideration in this matter.

Sincerely,

K. Todd Houston, Ph.D.
K. Todd Houston, Ph.D.
CEO/Executive Director

CMS-1427-P-226

Submitter : Dr. Richard Gans **Date & Time:** 10/08/2004 07:10:23

Organization : American Academy of Audiology

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment for comments on: APC Groups, APC Relative Weights, and Physical Examinations.

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Submitter : Mrs. Cathy Meeter **Date & Time:** 10/08/2004 07:10:56

Organization : Sutter Health

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Miscellaneous Issues

Re: CPT Codes 86077, 86078 and 86079
I have been instructed by the San Francisco Regional CMS office to address an unresolved issue within this format, i.e. respond to the proposed rules for OPPS for 2005. CPT codes 86077, 86078 and 86079 are currently listed with status indicator A in Addendum B posted out on the CMS website. They are also listed with status indicator A in the proposed Addendum B for 2005. This indicates that the hospital is not paid under OPPS but is paid by the intermediary under a fee schedule/payment system other than OPPS. These CPT codes were listed with status indicator X in 2003. The 2004 Clinical Lab Fee Schedule does not list these CPT codes. I contacted Captain H. Donna Dymon at the CMS San Francisco Regional Office who relayed to me that 86078 is not on the 2004 Clinical Lab Fee Schedule because it is a professional component only code and that payment will only be made to the physician. My next request to her was to then please have the status indicator changed to an E to indicate that this was not covered by Medicare when billed by entities operating under OPPS. Subsequent conversation with her indicated the following:
She relayed to me that the status indicators on Addendum B are relevant to physician billing. I disagree as the header for Addendum B clearly states that these are status indicators for the Hospital Outpatient Prospective System.
She pointed out that the current definition of this CPT code states that it is a physician service. I sent her two sources that I could find where CMS has published their comments that hospitals should ignore the verbiage of physician in the context of a descriptor in the CPT book published by the AMA.

I respectfully request that the CPT codes of 86077, 86078 and 86079 be included in the Clinical Lab Fee Schedule or change the status indicators back to an X with an associated APC payment or change the status indicators to an E.

California Medicaid
California Medicaid continues to utilize Level Three codes that are unique to the state and are not HIPAA compliant. Their continued use of their local codes creates a huge burden on hospitals. I shall site some examples below:

Drug dosages with their local codes are not the same dosage increments as CPT and HCPCS codes
They do not accept surgical CPT codes on a claim to represent the procedure. They require a Zxxxx code to be substituted for the surgical CPT code and a unique modifier to be attached to the surgical CPT code to represent the supplies used.
Use of their local codes for many services are not in the same timed increments as CPT and HCPCS codes. If you could please address when the California State Medicaid must become HIPAA compliant, it would be greatly appreciated.

Issues 11-20

Drug Administration

Sutter Health wholeheartedly supports the use of CPT codes in lieu of the Q codes (Q0081, Q0083, Q0084 and Q0085) to report administration of cancer chemotherapy drugs and infusion of other drugs. Commercial payers as well as our state Medicaid and Workers' Compensation utilize the CPT codes, hence billing the Q codes for only Medicare patients is burdensome to hospitals.

Issues 21-30

E/M Services Guidelines

Sutter Health supports the establishment of new codes to use in place of the current Evaluation and Management (E & M) codes for the Emergency Department (ED) (99281-99285, 99291/99292) and in a clinic (99201-99205, 99211-99215).

Because the codes submitted by a hospital represent labor supplied by the facility (technical component) not otherwise represented by a HCPCS code, we would respectfully request that CMS look at establishing 4 levels of care in the ED and clinic without regard to definition of critical care in the current CPT book or the proposed guidelines by AHIMA. Patients can be labor intensive without meeting the current definitions put forth by CPT or the proposed AHIMA guidelines relevant to critical care.
The AHIMA guidelines suggest collapsing the current five codes into three each for the ED and clinic services. Sutter Health would like to suggest adding a fourth level and not call it critical care.

Observation Services

Sutter Health agrees with your proposal to modify the CMS instructions for counting time in Observation care to end at the time the patient is actually discharged from the hospital or admitted as an inpatient.

Sutter Health agrees with your proposal to remove the current requirements for specific diagnostic testing, and rely on the physician's judgment to order the necessary tests applicable to the clinical situation.

In addition, Sutter Health would respectfully request that the time of admission to Observation care also be reviewed and amended. Comments made by CMS regarding the admission time on page 50532 under section D, Observation, and comments made on page 50533 seem to be at odds with each other. The first comment made on page 50532 states: ....'timing of observation beginning with the clock time on the nurse's admission note...' and the second comment on page 50533 states: 'Currently, hospitals report the time in Observation beginning with the admission of the beneficiary to observation...' The APC panel determined that using the time of a physician's order to discharge the patient from observation is problematic. There are also problems related to using the time of the nurse's first entry into the medical record. The time that the nurse makes the first entry into the medical record cannot be electronically captured. The time that the patient is admitted to Observation status can be electronically captured. We respectfully request that serious consideration be given to amending the time that observation begins to reflect the time that the patient is admitted into observation status.

CMS-1427-P-228

Submitter : Mr. George Mikitarian **Date & Time:** 10/08/2004 07:10:35

Organization : Parrish Medical Center

Category : Hospital

Issue Areas/Comments

Issues 21-30

Payment Rate for APCs

October 5, 2004

Tommy G. Thompson

Dear Mr. Thompson:

Parrish Medical Center is pleased to have this opportunity to comment on the proposed changes to the Medicare Hospital OPPS and CY 2005 Payment Rates set forth in the proposed rule (69 Fed. Reg. 50448, August 16, 2004). Our comments are specifically related to the median cost for APC 0659, hyperbaric oxygen therapy (HBOT) treatment. In the proposed rule, the median cost at $82.91 is less than half of the CY 2004 payment of $164.93.

We are a 210-bed acute care hospital located in Titusville, Florida. We have been providing HBOT for approximately 10 months and are the sole provider of this care for our service area. This dramatic drop in the payment rate will not cover the cost of providing this service and as such, will threaten patient's access to this proven modality of treating painful and otherwise expensive non-healing wounds.

We support the Hyperbaric Oxygen Therapy Association's (HOTA) position and The Lewin Group's findings regarding the error in this calculation. We understand CMS has inappropriately applied each Hospital's Respiratory Therapy department's cost-to-charge ratio (CCR) to HBOT charges, regardless of the department that actually contains the HBOT charges. If left uncorrected, this error may prevent us from continuing to provide this service.

We support any one of The Lewin Group's four recommendations:

1. If CMS has sufficient time, apply The Lewin Group methodology to all hospitals that submitted HBOT claims in CY 2003.

2. Adopt The Lewin Group's proposed reimbursement rate of $118.21 per 30-minute increment for HBOT.

3. Calculate the reimbursement rate for HBOT using each hospital's overall cost-to-charge ratio. CMS's rules for calculating the median cost indicate if the cost-to-charge ratio cannot be calculated, the overall hospital cost-to-charge ratio is to be used. Because there is currently no standardization as to which cost center HBOT costs and charges are located, CMS is unable to appropriately determine the correct cost-to-charge ratio to apply to claims, unless HBOT is indicated in the description of a hospital-specific subscripted cost center.
4. Leave the HBOT reimbursement rate at CY 2004 levels until CMS has an opportunity to develop and perform a calculation that will accurately reflect HBOT costs and cost-to-charge ratios.

Although we understand, using The Lewin Group's median cost calculation of $118.21 would only change overall HBOT payments by approximately $17 million, this will have a significant impact on our Hospital.

We appreciate your careful review of our comments.

Respectfully Submitted,

George Mikitarian
President/CEO

CMS-1427-P-229

Submitter : Dr. Gary Stein **Date & Time:** 10/08/2004 07:10:55

Organization : American Society of Health-System Pharmacists

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See attached comment letter

CMS-1427-P-229-Attach-1.doc

CMS-1427-P-229-Attach-2.doc

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Submitter : Mr. Michael Boylan **Date & Time:** 10/08/2004 08:10:32

Organization : InSight Health Corp.

Category : Other Health Care Provider

Issue Areas/Comments

Issues 1-10

APC Groups

Please see attached file

CMS-1427-P-230-Attach-1.pdf

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CMS-1427-P-231

Submitter : **Date & Time:** **10/08/2004 08:10:06**

Organization : **NE Alabama Regional Medical Center**

Category : **Hospital**

Issue Areas/Comments

Issues 21-30

Payment Rate for APCs

Dear Tommy G. Thompson:

Northeast Alabama Regional Medical Center is a 372 bed hospital located in Anniston, AL. We are opposed to the proposed changes to the Medicare Hospital OPPS Payment Rates, in the 69 Fed. Reg. 50448, which have the median cost for APC 0659, hyperbaric oxygen therapy treatment declining to $82.91 from the 2004 payment of $164.93.

Our hospital recently made a significant commitment to provide hyperbaric oxygen therapy (HBOT) to our community. We are the sole provider of this service in Anniston as well as in our six county service area. Hyperbaric oxygen therapy is an integral component of our newly extablished comprehensive program for the management and healing of chronic wounds. The proposed lower payment will have a dramatic impact on our ability to provide this care and may threaten our patient's access to this effective and efficient treatment.

The Lewin Group's report indicates that Respiratory Therapy's cost-to-charge ratio was applied in determining the proposed reimbursement. Clearly, this will not be the same situation with hyperbaric oxygen therapy provided with our wound care program.

I am hopeful that CMS will reconsider their proposed rate structure revisions.

I appreciate your time in reviewing my concern.

Best regards,

Allen Fletcher
President
NE Alabama Regional Medical Center

Submitter : Mr. Nevin Whitelaw **Date & Time:** 10/08/2004 08:10:12

Organization : SMT

Category : Drug Industry

Issue Areas/Comments

Issues 1-10

2 Times Rule

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1429-P
P.O. Box 8012
Baltimore, MD 21244-8012

Re: II Proposed Changes Related to Ambulatory Payment Classifications (APCs)
C. Limits on Variations Within APCs: Proposed Application of 2 Times Rule
10. Immunizations

Dear Sir/Madam:

I am writing to express a concern about the proposed rule to move CPT code 90740 from APC 0356 to 0355. The CMS Drug Median file lists the median cost for 90740 at $5.55. There is simply no justification for a cost of $5.55. The only FDA approved product that meets the 90740 description is Recombivax (Generic) 40 mcg/mL. A dose less than 40 mcg/mL does not meet the criterion for 90740. From an economic standpoint, the lowest published price for Recombivax 40mcg/mL is $79.33, as published in the Federal Supply Schedule .

CPT code 90740 does not violate the 2 times rule and should not be moved to APC 0355. We would like the opportunity to discuss with CMS the awarding 90740 its own APC. You had previously asked us to collect cost data for CPT code 90740. The collected data would be the basis for discussion at the next scheduled APC Panel meeting.

Sincerely,

Nevin Whitelaw

1 We expressed concern to the APC Panel that APCs 0355 and 0356 appear to violate the 2 times rule. In order to eliminate this violation, we suggested moving CPT 90636 (Hepatitis A/Hepatitis B vaccine, adult dose, intramuscular use) from APC 0355 to APC 0356. We also suggested moving CPT codes 90375 (Rabies immune globulin, intramuscular or subcutaneous), 90740 (Hepatitis B vaccine, dialysis or immunosuppressed patient, intramuscular), 90723 (Diphtheria-pertussis-tetanus, Hepatitis.CMS-1427-P 49 B, Polio vaccine, intramuscular), and 90693 (Typhoid vaccine, AKD, subcutaneous) from APC 0356 to APC 0355.
The APC Panel recommended moving CPT 90636 from APC 0355 to APC 0356 and CPT codes 90740, 90723, and 90693 from APC 0356 to APC 0355. The APC Panel delayed making a recommendation on CPT 90375 and requested that we collect additional cost data on this procedure. The collected data would be the basis for discussion at the next scheduled APC Panel meeting.

2 Drugmedians05NPRM.08.05.04
3 Current Procedural Terminology AMA CPT, 2004
4 Department of Veterans Affairs Drug and Pharmaceutical Prices

Nevin Whitelaw
Vice President
SMT
1129 Broad Street #4
Shrewsbury, NJ 07702
(732)935-3535

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Submitter : Ms. Darralyn Alexander **Date & Time:** 10/08/2004 08:10:19

Organization : UT M.D. Anderson Cancer Center

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

October 8, 2004

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

RE: SMS-1427-P August 16, 20004 OPPS Proposed Rule
E-Mail: http://www.cms.hhs.gov/regulations/ecomments

Dear Dr. McClellan:

On behalf of MD Anderson Cancer Center, I am respectfully submitting comments to the 2005 Medicare Proposed OPPS Rule published August 16, 2005. We appreciate the opportunity to comment regarding proposed changes to payments for outpatient services. We greatly appreciate that a number of services have been incorporated in this 2005 initiative that will allow your beneficiary the ability to receive early intervention and care of disease states. We also value the fact that there is now a mechanism in place that allows hospitals to receive reimbursement for drugs as soon as they are FDA approved rather than waiting for the development of a specific and unique code.

I am commenting on behalf of our cancer center on Ambulatory Payment Classification reimbursement rates concerning the modification in payment proposed for cryosurgery of the prostate. In light of the strides made in the technology and treatment options available to men suffering from this disease, the level of reimbursement for APC 674 and HCPCS code 55873 could impact hospitals in their evaluation and more importantly, in the provision of this service.

Cryosurgery is a minimally invasive procedure that has equal to and better outcomes than radical prostatectomy and/or radiation. This procedure is more conservative and tissue-sparing than the other two and is often the first choice of many surgeons and their patients. There are usually fewer complications, the recovery time is shorter and the procedure causes the patient less physical hardship. If at a later date further surgery is warranted, patients then have the option of pursuing a more aggressive surgical approach.

The current national level of reimbursement for this procedure is $6545.86 for 2004. The cryosurgical probe kit contains six probes and list price for $8,000. In addition, but separate, are the temperature probes, which are utilized to monitor the temperature downward through the freezing phase and upward, when the thawing stage is initiated. The cost of the temperature probes is $100. The other necessary, but separate and distinct component crucial to render this service is the urethral warmer, which maintains a constant urethral temperature during all phases of the surgical procedure and prevents some other complications. The list price for the warmer is approximately $350. The total for this technology-driven surgical procedure not including any additional supplies (e.g. nitrogen, surgical supplies etc.) is over $8500.

The level of reimbursement is scheduled to decrease in 2005 to $6370. Insufficient reimbursement has led to hospitals discontinuing this service. Since the Medicare beneficiary is the primary recipient of this procedure your patients are adversely affected when hospitals limit access or eliminate the procedure. The bottom line is decreased reimbursement has led to access issues. Charge data reviewed by Medicare unfortunately does not reflect total usage because hospitals don?t always code or charge appropriately for services/devices utilized. Furthermore, in FY2003, hospitals at CMS behest had stopped utilizing ?C? codes, which further skewed your ability to do a detailed and complete analysis.

MDACC believes that APC Advisory panel?s recommendations for reimplementation of ?C? codes across all appropriate categories is appropriate

and will allow CMS to make better and more a appropriate decision when an analysis is performed this time next year. Our recommendation is to at minimum maintain the current 2004 level of reimbursement plus a 5% inflation rate.

Central Venous Access Device
For 2005,

CMS-1427-P-234

Submitter : Anwer Rizvi **Date & Time:** 10/08/2004 08:10:56

Organization : Eastern Isotopes, Inc.

Category : Drug Industry

Issue Areas/Comments

Issues 11-20

Drugs, Biologicals, and Radiopharmaceuticals NonPass-Throughs

See attached file.

CMS-1427-P-234-Attach-1.pdf

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Centers for Medicare and Medicaid Services (CMS)
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Submitter : Dr. Robert Bridges **Date & Time:** 10/09/2004 05:10:23

Organization : Alaska Open Imaging Center

Category : Radiologist

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir/Madame:

I am writing regarding the proposed changes for reimbursement of PET services under CMS-1427-P.

As one of only two providers of PET services in Alaska our present hard costs make PET services barely viable with the current CMS reimbursement. Alaska Open Imaging Center is the pioneer of PET imaging services for the state of Alaska and due to considerable logistical and financial burdens placed on us due to the distance involved in procuring and transporting the needed radio-pharmaceuticals alone to our state, we feel that our operations would be severely curtailed. The people of Alaska needing PET services prior to our company introducing PET incurred even higher costs due to the necessity of traveling outside of Alaska for this imaging service, frequently at tax payer expense. The proposed reimbursement for PET is simply much too low for the hard costs alone of this service. At the proposed rate of reimbursement we would not be able to maintain a viable operation nor would we have the opportunity to upgrade our equipment as the technology improves. Additionally we would be unable to enhance our service at a later time. If the proposed changes are enacted, the people of Alaska will suffer not just because of the lack of funding for these needed services, they will essentially be denied the same resources enjoyed by residents of the lower 48 states of the United States.

I strongly urge the CMS to postpone the proposed reimbursement change for another year to acquire more reliable information and evidence that these sweeping reimbursement changes do not compromise the health and welfare of the public, and in particular, the residents of this far flung state, effectively denying access to needed PET services.

Signed

Robert Bridges, M.D.

CMS-1427-P-236

Submitter : Ms. Sarah Wells **Date & Time:** 10/08/2004 08:10:30

Organization : Boston Scientific Corporation

Category : Device Industry

Issue Areas/Comments

Issues 1-10

APC Groups

See attached PDF file

Devices

See attached PDF

Issues 11-20

Estimated Transitional Pass-Through Spending

See attached PDF

Issues 21-30

Payment Rate for APCs

See attached PDF

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Centers for Medicare and Medicaid Services (CMS)
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Submitter : Mr. Roger Sarao **Date & Time:** 10/08/2004 08:10:55

Organization : New Jersey Hospital Association

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Dear Dr. McClellan:

The New Jersey Hospital Association (NJHA), on behalf of our 104 member hospitals and health care systems appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services? (CMS) proposed rule establishing new policies and payment rates for hospital outpatient services for calendar year 2005.

The NJHA is concerned that in the proposed 2005 OPPS, many ambulatory payment classification (APC) rates continue to fluctuate dramatically, with payments much lower or higher in 2005 than in 2004. These changes make it extremely difficult for hospitals to plan and budget from year to year. In addition, a separate payment-to-cost analysis of the OPPS that the American Hospital Association (AHA) performed using the 2003 Hospital OPPS Limited Data Set revealed troubling issues. Among them are more than 60 ?broken? APCs that resulted in hospital losses of more than $1.4 billion in payments in 2003. Even more troubling, several of the evaluation and management (E/M) services APCs ? clinic and emergency department visits ? were among the most ?broken,? resulting in losses of more than $700 million. Also, there is a tremendous degree of variation across APCs in terms of payment-to-cost ratios. We would expect that three years after the implementation of the OPPS, these payment to cost ratios would be much more stable. Such dramatic variation in payments compared to costs puts full-service hospitals and their communities at risk because limited-service, or ?niche,? providers can easily identify and redirect patients with more lucrative APCs to their facilities, leaving full-service hospitals with a disproportionate share of patients with underpaid APCs.

Further, the entire OPPS is underfunded, paying only 87 cents for every dollar of hospital outpatient care provided to Medicare beneficiaries. Hospitals must have adequate funds to address critical issues like severe worker shortages, skyrocketing liability premiums, expensive drugs and technologies, aging facilities, expensive regulatory mandates and more. The NJHA will continue to work with Congress to address inadequate payment rates and updates in order to ensure access to hospital-based outpatient services for Medicare beneficiaries.

The NJHA also continues to be concerned that the amount carved out from base OPPS rates may be greater than the funds actually spent on pass-through payments for new technologies and outlier payments. For instance, in 2004 CMS withheld 1.3 percent of total estimated OPPS payments to fund new technologies through the pass-through payment methodology. Yet it is unknown how much the agency actually spent in 2004 or in prior years for new technologies. In addition, for the past three years, CMS set aside 2 percent of total estimated OPPS payments to fund outlier payments to hospitals. However, again, there has been no data released revealing how much of this amount was actually spent. With the significant changes to outlier policies proposed for 2005, the NJHA is concerned that Medicare may not actually spend the 2 percent outlier target set-aside. The NJHA strongly urges CMS to release data on actual pass-through payments and outlier payments made in 2004 and in prior years, and to continue to report this data in the future.

CMS-1427-P-237-Attach-1.doc

CMS-1427-P-237-Attach-2.doc

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CMS-1427-P-238

Submitter : Mr. Soren Johansson **Date & Time:** 10/08/2004 08:10:16

Organization : Elekta

Category : Device Industry

Issue Areas/Comments

GENERAL

GENERAL

Please see the attached comments concerning stereotactic radiosurgery.

Thank you for the opportunity to comment.

CMS-1427-P-238-Attach-1.doc

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CMS-1427-P-239

Submitter : Dr. Kim Williams **Date & Time:** 10/08/2004 08:10:02

Organization : American Society of Nuclear Cardiology

Category : Association

Issue Areas/Comments

GENERAL

GENERAL

Please read the attached letter which comments upon the proposed HOPPS rule. Thank you.

CMS-1427-P-239-Attach-1.doc

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CMS-1427-P-240

Submitter : Dr. Richard Wahl **Date & Time:** 10/08/2004 08:10:10

Organization : Johns Hopkins University

Category : Physician

Issue Areas/Comments

Issues 11-20

Drugs, Biologicals, and Radiopharmaceuticals NonPass-Throughs

To Whom it may Concern:
I am very concerned about recent CMS rulings that may make it economically unfeasible for patients to receive Bexxar therapy, a treatment I have given to over 200 patients and for which there is substantial efficacy. It is well tolerated in the elderly and I believe cost effective.

I believe lymphoma patients should receive the most appropriate treatment based on clinical considerations. Reimbursement should not dictate whether a Medicare patient has access to the most appropriate treatment. The recent proposed Medicare rule for Hospital Outpatient reimbursement creates a reimbursement barrier that I am certain will severely limit the availability of this innovative treatment for Non-Hodgkins' Lymphoma.

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CMS-1427-P-241

Submitter : Dr. Loren Bartels **Date & Time:** 10/08/2004 08:10:01

Organization : Tampa Bay Hearing and Balance Center

Category : Physician

Issue Areas/Comments

Issues 1-10

APC Relative Weights

With respect to Cochlear implant surgery reimbursement to hospitals, my view is that even at $23300, CMS reimbursement is below cost for hospitals. Our largest provider of cochlear implant devices charges the hospital about $21,500 for each device package. We have been able to push the less frequent device providers to this price, but not lower. That leaves less than $2000 for the costs of providing out patient surgery or outpatient surgery and an occasional overnight recovery. Many of our elderly patients have problems for which overnight recovery is essential: sleep apnea, cardiac arrhythmia, nausea, dizziness, etc. The rate probably needs to be about $27000, minimum, best I can figure and more should be available for patients with comorbid conditions. The 2005 rate is a good improvement, but still results in the hospitals subsidizing Medicare cochlear implants with other revenues. I strongly encourage CMS to continue to seek accurate information so as to reimburse in a manner that makes good common sense.

CMS-1427-P-242

Submitter : Mr. Philip Besler **Date & Time:** 10/08/2004 08:10:15

Organization : BESLER Consulting

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 21-30

Wage Index

See Attached for comments

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CMS-1427-P-243

Submitter : Mr. Soren Johansson **Date & Time:** 10/08/2004 08:10:16

Organization : Elekta

Category : Device Industry

Issue Areas/Comments

Issues 1-10

Stereotactic Radiosurgery

please see attached comments

CMS-1427-P-243-Attach-1.doc

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Submitter : Mrs. Marie Hamlet **Date & Time:** 10/08/2004 09:10:22

Organization : HCA Healthcare

Category : Hospital

Issue Areas/Comments

Issues 21-30

Observation Services

"Observation Services"- Please clarify the rules surrounding the time to begin charging for observation. The three following comments have been made regarding start time of observation charging, which has resulted in confusion for the providers.

1. Previous CMS guidelines regarding APC 339 indicated that the start time for observation charging needed to match the physician order AND the observation assessment note was completed.
2.Transmittal 770 Feb. 23, 2001 states to begin charging observation hours when patient is placed in the observation bed, and round to the nearest hour.
3.CMS 1427-P status states that observation start time is to begin when the patient is admitted.

Clarification on the word ?admitted? and start time would be extremely helpful to determine the correct time to begin charging.

It would seem logical that Observation time would begin per the physician dated and signed order, or in the absence of the date and time the nurses first notation of patient care being provided.

Submitter : Mr. Frank Molinaro **Date & Time:** 10/08/2004 09:10:27

Organization : Louis A. Weiss Memorial Hospital

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 21-30

Payment Rate for APCs

Dear Tommy G. Thompson:

Weiss Memorial Hospital is pleased to have this opportunity to comment on the proposed changes to the Medicare Hospital OPPS and CY2005 Payment Rates. In the proposed rule, the median cost for APC 0659, hyperbaric oxygen therapy (HBOT) treatment dropped more than half to $82.91 from $164.93.

We have been providing HBOT for approximately 9 months. We are a 357-bed hospital in Chicago. This decrease in payment will prevent our ability to provide this proven modality for treating otherwise expensive wounds.

Weiss Memorial Hospital concurs with the Hyperbaric Oxygen Therapy Association and The Lewin Group?s understanding of how CMS has inappropriately applied cost-to-charge ratios to HBOT charges, understating median costs. We believe this needs to be corrected, as suggested by The Lewin Group, by one the following alternatives:
1. If CMS has sufficient time, apply The Lewin Group methodology to all hospitals that submitted HBOT claims in CY2003.
2. Calculate the reimbursement rate for HBOT using each hospital?s overall cost-to-charge ratio. Because there is currently no standardization for which cost center HBOT costs and charges are located, CMS will be unable to appropriately determine the correct cost-to-charge ratio to apply to claims.
3. Leave the HBOT reimbursement rate at CY 2004 levels until CMS has an opportunity to develop and perform a calculation that will appropriately reflect HBOT costs.
This issue will have a significant impact on our facility and we appreciate your time.
Warmest regards,

Frank Molinaro
Chief Operating Officer
Weiss Memorial Hospital

Submitter : Dr. Nico de Wette **Date & Time:** 10/08/2004 09:10:36

Organization : Northwest Cancer Specialists

Category : Physician

Issue Areas/Comments

Issues 21-30

Payment Rate for APCs

I work in an outpatient cancer care facility in Portland Oregon. I was attracted to this job 3 years ago because it was a new facility, and had a PET scanner on site. In my field of radiation oncology, PET scans are extremely useful tools in detecting the location of cancers, to see if they are localized or spread, in a much better fashion than CT or MRI scanners are able to do. The usefulness of PET scans is proven to me daily, as I see PET scans on patients that have proven localized disease which makes them good surgical candidates, as well as patients that have much more extensive disease seen on PET, that was not recoginized on CT or MRI scanning. These patients can thus be spared futile surgical procedures, and unnecessary hospitalizations. PET scanning can thus lead to a real savings in health care, by appropriately selecting patients for the best treatment (an often unrecognisecd and overlooked value of PET, not to mention the patient being spared the effects of futile surgery).
Our equipment was approximately $ 1.5 Million three years ago, and we have fixed costs associated with our scanner, so that we must perform 2 scans per day just to pay for the equipment. We are currently performing 3.5 scans per day which is profitable, but if the reimbursement is cut, we would not be able to make PET scanning profitable in the outpatient setting, and would have to stop providing this service. Additionally, we just upgraded to new software at a cost of $120,000, which allows us to fuse different images with PET scans (ex: PET and CT scans). This allows us to perform even better tumor localization and treatment targeting. We are offering an increased service (by obtaining CT scans that we do not charge for), and performing manual fusion of these images, all increased work and costs, that we do not even bill for. By upgrading, we have voluntarily cut into our already slim profit margin to improve the level of service. If the proposed HOPPS reimbursement cuts in CMS-1427-P (38% reduction) are inacted, we will not likely be able to provide this service in our clinic. This will ultimately be detrimental to our patient's care (how will we truly know the extent of disease?) and likely lead to more unnecessary surgical procedures, ultimately leading to more inflation of health care cost.
I request CMS to leave the reimbursement at the current rate, to continue to allow us to provide this excellent diagnostic service, which has lead to real gains in patients recieving the most approriate treatment, and best medical care.

Thank you,

CMS-1427-P-247

Submitter : Dr. Lee Adler **Date & Time:** 10/08/2004 10:10:20

Organization : Fox Chase Cancer Center

Category : Physician

Issue Areas/Comments

Issues 1-10

New Technology APCs

RE:Proposal to consider reassignment of FDG PET from APC 1516
In the proposed rule, CMS considered three options for the payment of PET scans:
? Option 1: Continue to assign FDG PET procedures to New Technology Ambulatory Payment Classification (APC) 1516.
? Option 2: Assign FDG PET procedures to a clinically appropriate APC priced according to the median costs of the scans, based on 2003 claims data.
? Option 3: Set the payment for FDG PET procedures based on a 50-50 blend of the median cost and the New Technology APC payment amount.

PET/CT, the combination of PET and CT in a single device has been shown to be significantly superior to either PET or CT and even to PET and CT performed on separate devices interpreted separately for a growing number of malignancies. Since G codes referring to PET our also used for determining the level of reimbursement of PET/CT performed for the same indication, the effect of any reduction in reimbursement for FDG PET would be a similar decrease for PET/CT. The only situation in which a facility may charge more for a PET/CT study is if a CT study was also indicated and ordered for the patient. Since CMS requires that another study, often CT, be either replaced by the PET or that the other study be considered inconclusive, the majority of PET/CT exams bill for only the PET component. Given that the cost of a PET/CT scanner is almost twice that of a PET scanner and that at current reimbursement levels, many PET centers are operating at or below break even levels, the effect of a significant decrease in PET reimbursement would be to severely limit the availability of PET/CT.
I strongly support option 1-- to continue the current assignment of FDG PET procedures in New Technology APC 1516 in CY 2005. Continuation of current payment levels for these services is essential to ensure patient access to this important technology. Currently, PET imaging is concentrated in a relatively small number of hospitals throughout the country. With Medicare representing the largest single payer of hospital services, significant payment rate reductions (as proposed in payment rate options 2 and 3) may result in these facilities abandoning or limiting PET imaging, while other facilities may fail to adopt this critical technology. In metro Philadelphia, and area of over 5,000,000 people, there are two major third party payors which together with patients with traditional indemnity Medicare cover 90% of the population. Changes in coverage rates for Medicare Part A are often reflected in both hospital and non-hospital rates from these carriers soon after. A drop in coverage rate for PET oncology procedures would have a devastating effect on the availability of PET and in particular PET/CT for patients in our region and throughout the state. Many local facilities are performing the minimum number of procedures (or fewer) to stay open. The recent approval of PET for Medicare patients with a differential diagnosis of Alzheimer's Disease and Fronto-temporal dementias is unlikely to provide the additional business necessary for these centers to continue providing care to the community.
Further, we urge CMS to carefully consider the combined impact of the PET payment options with the proposed payment rate reduction for the radiopharmaceutical FDG used with PET imaging. The FDG payment rate is proposed to decrease by more than 32%, from approximately $324 to $220.50 per dose (4-40 mCi/ml). This reduction alone will result in approximately a 6 percent reduction in the total payment for FDG PET procedures, assuming payment option 1. If combined with PET payment options 2 or 3, total payment for these procedures would decline from 23 to 37 percent. Such a change would likely close many existing facilities and severely limit the availability of this critically important and proven cost saving procedure to Medicare beneficiaries in our region.

Submitter : Ms. Frances Crunk **Date & Time:** 10/08/2004 11:10:21

Organization : Central Texas Medical Center

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

ATTN: FILE CODE CMS-1427-P
New Technology APCs
Re: Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates
Dear Administrator McClellan:
I applaud your recent efforts under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 to make new medical technologies more available to Medicare beneficiaries. I am writing to comment on the proposed payment rate for FDG positron emission tomography (PET) scans as published in Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates on August 16, 2004. PET is one of the most remarkable diagnostic imaging breakthroughs of the last two decades with tremendous benefits for patients with cardiac, cancer, and neurological disorders. I strongly support Option 1 in the proposed rule to maintain covered FDG PET procedures in New Technology APC 1516. I am greatly concerned that the other proposed options would limit beneficiary access to PET scans.
Background on Provider
I write on behalf of InSight Health Corp, which is one of the leading providers of PET services in the country. Our mobile PET services provide hospitals with a cost-effective means of providing PET services to their patients. Many healthcare providers do not have the necessary patient volume to support the purchase of a full-time dedicated PET scanner. With this in mind, InSight?s mobile PET scanners are generally scheduled among a group of hospitals and/or physicians, thereby bringing this important modality to a wider patient population. InSight?s mobile PET services provide multiple benefits to hospitals and patients, including access to state-of-the-art technology, and better control of patient disease management and early disease detection
Overview of PET
PET is a noninvasive molecular imaging procedure through which the molecular errors that cause disease can be accurately identified and understood in terms of the very nature of disease. This separates PET from conventional anatomic imaging modalities such as x-ray films, CT and MRI. PET assists physicians in the diagnosis and management of tumors, cardiac disorders and neurological disorders. PET can eliminate unnecessary surgeries, reduce the number of diagnostic procedures and otherwise demonstrate to physicians the best, most effective mode of treatment for a patient.
The key to Pet?s effectiveness is that it provides physicians with information about the body?s chemistry, cell function, and location of disease differently than anatomic imaging modalities such as CT and MRI. Certain diseases cause abnormalities of blood flow or metabolism before anatomic changes are apparent, and these diseases can be detected by PET at a time when the anatomic imaging studies are normal. Moreover, PET can evaluate tissue metabolism to determine the presence or absence of malignancy whereas anatomic imaging depends on size of lesions in certain locations to determine the likelihood of malignancy.
A Reduction in the 2005 PET Payment Rate Would Limit Beneficiary Access
I greatly appreciate the hard work and careful consideration CMS put into developing the proposed rule. In the proposed rule, CMS considered three options for the payment of PET scans. I write in strong support of Option 1 to continue the current assignment in New Technology APC 1516 in CY 2005. Adequate payment for these services is essential to ensure patient access to this important technology.
I am concerned that under proposed options 2 and 3, providers would not be able to offer PET to Medicare beneficiaries. Proposed options 2 and 3 in the hospital outpatient prospective payment system rule would drastically reduce the reimbursement rate for positron emissio

CMS-1427-P-248-Attach-1.doc

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CMS-1427-P-249

Submitter : **Date & Time:** 10/09/2004 02:10:13

Organization :

Category : Hospital

Issue Areas/Comments

Issues 21-30

Payment Rate for APCs

Dear Tommy G. Thompson:

Our hospital is it second largest Hospital provider in the East Tennessee.We are opposed to the proposed changes to the Medicare Hospital OPPS Payment Rates, in the 69 Fed. Reg. 50448, which have the median cost for APC 0659, hyperbaric oxygen therapy treatment declining to $82.91 from the 2004 payment of $164.93.

Our hospital recently made a significant commitment to provide hyperbaric oxygen therapy (HBOT) to our community.Hyperbaric oxygen therapy is an integral component of our newly established comprehensive program for the management of chronic wounds. The proposed lower payment will have a dramatic impact on our ability to provide this care and may threaten our patient?s access to this effective and efficient treatment.

The Lewin Group?s report indicates that Respiratory Therapy?s cost-to-charge ratio was applied in determining the proposed reimbursement. Clearly, this will not be the same situation with hyperbaric therapy provided with our wound program.

I am hopeful that CMS will reconsider their proposed rate structure revisions.

I appreciate your time in reviewing my concern.

Submitter : Dr. Mary Hager **Date & Time:** 10/09/2004 06:10:15

Organization : The American Dietetic Association

Category : Dietitian/Nutritionist

Issue Areas/Comments

Issues 1-10

Physical Examinations

The American Dietetic Association (ADA) is pleased to make comments about Section II.J.1.

Section II.J.1.b.(2)(9): Medical nutrition therapy (MNT) (as defined in subsection (vv) of 42 USC 1395x) is expressly listed as one of the 'other preventive services' authorized under Part B for which the physician may make referrals based on the initial preventive physician exam. There is robust literature supporting the use of MNT. Congress has responded to this body of knowledge and recognized the importance of MNT services in the MMA of 2003.

An ongoing issue is the availability of and access to MNT. MNT can control severe or disabling chronic conditions and is currently covered by Medicare for diabetes and renal disease. However, there are other chronic conditions, specifically dyslipidemia and hypertension, for which the evidence supports Medicare MNT coverage, as stated in The 2004 Report to Congress on Medical Nutrition Therapy from Secretary of Health and Human Services, Tommy Thompson. MNT is the first line therapy for controlling these conditions and, when pharmacotherapy is indicated, MNT continues to be integral to optimal disease management.

We also applaud Secretary Thompson and CMS who have recognized the value of preventive services. We urge Medicare coverage of MNT for pre-diabetes, pre-hypertension, and borderline dyslipidemias. Evidence demonstrates significant positive outcomes with nutrition and lifestyle interventions in reducing the risk of developing diabetes mellitus in pre-diabetic individuals and in reversing disease progression before life-threatening complications develop.

ADA is concerned about possible misinterpretation of the MNT benefit in the proposed regulations. 42 USC 1395x(vv)describes MNT as follows: `(vv)(1) The term 'medical nutrition therapy services' means nutritional diagnostic, therapy, and counseling services for the purpose of disease management which are furnished by a registered dietitian or nutrition professional (as defined in paragraph (2)) pursuant to a referral by a physician (as defined in subsection (r)(1)).' Therefore, the regulations must clearly state that MNT is provided upon referral to the registered dietitian or nutrition professional, and is not part of the preventive examination. MNT is a comprehensive, patient-centered service for diet behavior modification. CMS basic coverage for the first year is 3 hours of MNT and '..additional hours are considered to be medically necessary and covered if the treating physician determines there is a change in medical condition, diagnosis, or treatment regimen that requires a change in MNT and orders additional hours during that episode of care.' In each subsequent year, 2 hours of MNT are covered unless there is a change in condition or medical diagnosis requiring a change in diet.

Section II.J.1.b.(2)(11): The ADA agrees with the specific tests, definitions, and eligibility criteria proposed for pre-diabetes proposed by CMS. ADA requests that CMS state that a diagnosis of pre-diabetes warrants a physician referral for MNT and DSMT. There is evidence that lifestyle and nutrition interventions can significantly reduce the risk of developing diabetes mellitus in individuals diagnosed with pre-diabetes.

Regarding medical and social history, ADA requests CMS consider the National Screening Initiative, which suggests screening parameters for several chronic diseases specifically for older individuals (http://www.eatright.org/Public/Files/nsifinal.pdf). ADA also references the SF-36 survey instrument for consideration in assessing quality of life (http://www.golid.org/public/SF-36.html).

ADA looks forward to partnering with CMS in educating beneficiaries, physicians, and qualified non-physician practitioners about accessing and making referrals to MNT benefits covered under Medicare Part B.

Please direct questions and information requests to Pam Michael and Mary Hager, 202-775-8277

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