Submitter : Mr. David Gross **Date:** 10/10/2006

Organization : Surgery Center of Duncanville

Category : Ambulatory Surgical Center

Issue Areas/Comments

Medicare Contracting Reform Impact

Medicare Contracting Reform Impact

see Attached comments

CMS-1506-P-420-Attach-1.DOC

#1120

October 10, 2006

Mark B. McClellan, M.D., Ph.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1506-P - Medicare Program; CY 2007 Update to the Ambulatory Surgical Center Covered Procedures List

Dear Dr. McClellan:

I am the Administrator of the Surgery Center of Duncanville in Duncanville, Texas. Each year, our surgery center provides 2500 procedures to 1200 Medicare beneficiaries. Medicare patients represent 30% percent of our business and ensuring appropriate payment for their services is vital to our ability to serve our community. Please accept the following comments regarding Section XVII of the proposed rule, which would make revisions to policies affecting ambulatory surgical centers for CY 2007. 71 Fed. Reg. 49505 (August 23, 2006).

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

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

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

1. The inclusionary ASC list should be abandoned.

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

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

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

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

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

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

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

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

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

developed predominately in an outpatient setting and are performed safely and cost-effectively on thousands of commercial insurance and self-pay patients each year.

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

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

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

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

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

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

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

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

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

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

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

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

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

c. Operating and recovery time limits are unnecessary.

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

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

B. Procedures Proposed for Addition to the ASC List

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

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

We are concerned about the payment group assignment for CPT code 22522, which describes percutaneous vertebroplasty performed at additional levels. The proposed payment group assignment is a Group 1 ($333.00). The cost of the kit used at each level varies from $700 to $1400, depending on the supplier (Stryker, Arthrocare). Therefore, the proposed level of reimbursement would not be sufficient to cover supply costs for the procedure. In light of this, we recommend revising the payment group assignment to a Group 9 ($1339.00). Because this particular code is an add-on code, and therefore will always be subject to multiple procedure payment reduction, even assignment to payment Group 9 will only cover supply costs. Further, using the median cost information supplied in the HOPD, CMS has established the APC payment for this service at $1542.47. **We** believe the HOPD data is a more reliable proxy for the cost of providing this service.

We are also concerned about CPT codes 37205 and 37206, which describe transcatheter placement of an intravascular stent. The proposed payment group assignments are Group 9 ($1339.00) and Group 1 ($333.00), respectively. The cost of the intravascular stent averages $1725 (see CMS's 2005 file which calculates device related percentages for APC 0229), which

exceeds the current maximum Group 9 reimbursement level. Therefore, no level of reimbursement currently available to ASCs would be sufficient to cover the device costs for these procedures. Unfortunately, there is no real opportunity for ASCs to receive separate reimbursement for the stent. Because there is no specific Level II HCPCS code that describes this stent, this device would have to be reported using L8699. ASCs experience considerable difficulty securing reimbursement from Medicare carriers for devices reported using L8699. In light of this, we believe ASCs will not be able to cover the costs of performing these procedures under the current reimbursement methodology. However, we still believe CMS should add the procedures to the list because they are clinically appropriate services and doing so will allow those patients whose private health plans look to CMS's ASC list for coverage decisions to access these procedures in the ASC setting.

C. Suggested Additions Not Accepted

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

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

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

Most of the procedures CMS has indicated it will not add to the ASC list are typically performed as secondary procedures for non-Medicare beneficiaries. Failure to add the requested procedures because they are commonly performed in the office setting deprives both the Medicare program and its beneficiaries of the efficiencies of care and added affordability that other patients enjoy as a result of use of the ASC setting.

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

both procedures performed concurrently as an outpatient, the Medicare beneficiary must been seen at the HOPD.

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

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

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

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

a. Osteochondral arthroscopic grafting

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

b. Laparoscopic cholecystectomy

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

volume data shows these procedures We re being performed on an outpatient basis 51%, 48% and 24% of the time, respectively.

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

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

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

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

Finally, it is important to note that if the laparoscopic approach is unsuccessful in the ASC setting, the patient does not have to be transported to the hospital for the open procedure. Generally, the laparoscopic procedure can be converted to an open procedure and completed at the ASC. The patient is then transported to the hospital following completion of the procedure and postoperative stabilization. Again, the application of patient selection criteria would make such conversions a rare occurrence.

c. Lumbar disc decompression

CPT code 63030 describes lumbar disc decompression. As a result of today's minimally invasive approaches, more of these procedures are being safely and successfully performed in the outpatient setting. Anesthesia and operating times are less than 90 minutes. Though recovery

times can extend beyond four hours, these procedures can be performed without an overnight stay. As we noted above, we believe the continued imposition of specific operating and recovery time limits is unduly restrictive, a point which has been recognized by MedPAC and CMS itself in the past. Patients with private insurance routinely have these procedures performed in the ASC setting and therefore we urge CMS to allow Medicare patients to access these procedures in the ASC setting as Well.

D. Other Appropriate Additions Not Addressed in the Proposed Rule

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

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

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

CPT Code	Descriptor
20610	Arthrocentesis, aspiration and/or injection; major joint or bursa
27096	Injection procedure for sacroiliac joint, arthrography and/or anesthetic/steroid
43257	Upper gastrointestinal endoscopy with delivery of thermal energy to the loWe r esophageal sphincter
62290	Injection procedure for diskography, each level; lumbar
62291	Injection procedure for diskography, each level; cervical or thoracic
62368	Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion with programming
63655	Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural
64402	Injection, anesthetic agent; facial nerve

64405	Injection, anesthetic agent; greater occipital nerve
64408	Injection, anesthetic agent; vagus nerve
64412	Injection, anesthetic agent; spinal accessory nerve
64413	Injection, anesthetic agent; cervical plexus
64418	Injection, anesthetic agent; suprascapular nerve
64425	Injection, anesthetic agent; ilioinguinal, iliohypogastric nerves
64435	Injection, anesthetic agent; paracervical (uterine) nerve
64445	Injection, anesthetic agent; sciatic nerve, single
64448	Injection, anesthetic agent; femoral nerve, continuous infusion by catheter
64449	Injection, anesthetic agent; lumbar plexus, posterior approach, continuous infusion by catheter
64505	Injection, anesthetic agent; sphenopalatine ganglion
64508	Injection, anesthetic agent; carotid sinus (separate procedure)
64555	Percutaneous implantation of neurostimulator electrodes; peripheral nerve (excludes sacral nerve)
64612	Chemodenervation of muscle(s); muscle(s) innervated by facial nerve (e.g. for blepharospasm, hemifacial spasm)

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

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

While we also generally agree with the list of examples of superior outcomes provided by CMS, we believe any revision of §416.195 should make it clear that these are strictly examples. Given the rapid pace of technological advances, it would be unfortunate if the revised language did not provide sufficient flexibility to accommodate future innovations because they are not specifically outlined as a superior outcome. Specifically, we suggest §416.195(a)(4) be modified to read, "Evidence demonstrated that use of the IOL results in measurable, clinically meaningful, improved outcomes in comparison with use of currently available IOLs. Examples of superior outcomes include, but are not limited to:".

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

* * * * *

Thank you for considering our comments. If you have any questions or need additional information, please do not hesitate to call me at 972.296.6912.

Sincerely,

David Gross
Administrator
Surgery Center of Duncanville
1018 East Wheatland Road
Duncanville, Texas 75116

Submitter : Mrs. Lisa Arington **Date:** 10/10/2006

Organization : Northern Shared Medical Services, Inc.

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1506-P-421-Attach-1.DOC

#1121

October 10, 2006

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

ATTN: FILE CODE CMS-1506-P

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

Dear Administrator McClellan:

I am writing on behalf of Northern Shared Medical Services, Inc. to address an issue of great importance to Medicare beneficiaries with cancer. Northern Shared Medical Services, Inc. is a mobile provider and an independent diagnostic testing facility (IDTF), which provides PET/CT, among other imaging services. We serve approximately 25,000 cancer patients annually, many of whom we serve in outlying rural areas and Critical Care Hospitals. Without our mobile units they would have to travel significant distances to receive the needed diagnostic imaging care. I am very concerned that the substantial cuts in the payment rate for positron emission tomography with computed tomography (PET/CT) set forth both in the proposed physician fee schedule and the proposed hospital outpatient rule will seriously underpay hospitals and IDTFs, which could compromise beneficiary access to this vital technology, especially in the rural areas.

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

The hospital outpatient proposal does not recognize the important clinical and technological distinctions between PET/CT and conventional PET. In fact, the costs to Northern Shared Medical Services, Inc. of acquiring, maintaining, and operating a PET/CT scanner is substantially higher than those for a conventional PET scanner. When PET technology became commercially available in the mobile environment about five years ago we, like other mobile providers, purchased the technology and began to service our facilities, most of which are in the rural areas of the Midwest, and only two years after purchasing the technology it was no longer viewed as state-of-art or even acceptable to most oncology physicians as the "gold standard" for care so we were forced to retire that technology and repurchase the new PET/CT technology, which was a significant financial burden that we continue to carry the debt on. Today, the fair market value for a PET system is $100,000 to $200,000 and a PET/CT is $2,000,000, the significant cost difference in the systems alone as well as the annual premium paid for preventative maintenance should be reflected in the reimbursement rate.

Medicare payment rates for PET/CT performed by free standing facilities traditionally have been determined by regional carriers. Under the Deficit Reduction Act Medicare payments for the technical component of PET/CT would be capped at the hospital outpatient rate. CMS has proposed to reduce the hospital outpatient rate for PET/CT to $865—the same rate proposed for conventional PET—from its current rate of $1,250. For IDTFs that represents a cut up to 30% to 50% in one year from current carrier based prices.

The proposed payment rate reduction for PET/CT would seriously underpay hospitals and IDTFs, and risk limiting beneficiary access to this vital technology. I respectfully request that CMS maintain the current hospital outpatient PET/CT payment rate of $1,250 and also maintain the IDTF reimbursement rate of $1,750. If there is a need to lower the reimbursement rate for PET only studies based on the researched cost data and equipment costs, PET and PET/CT should be given their own independent reimbursement codes and their reimbursements established independently of one another.

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

Sincerely,

Lisa Arington
President/CEO
Northern Shared Medical Services, Inc
4253 Argosy Court
Madison, WI 53714
608-663-6080

Submitter : **Mr. David Gross** **Date: 10/10/2006**

Organization : **Surgery Center of Duncanville**

Category : **Ambulatory Surgical Center**

Issue Areas/Comments

Impact

Impact

I am representing the Surgery Center of Duncanville, in Duncanville, TX. Our center currently serves 1,200 Medicare beneficiaries annually. 50% of our patients receive highly complex pain management service often including high cost implants. By setting payment rates at the proposed low level we will have difficulty in meeting this need and will result in surgeons utilizing the more expensive hospital setting for Medicare. We are also concerned with the lack of increases in payment since 2003 while our costs have increased; such as our nursing labor cost have increased 16% since 2003. I believe ASCs should receive the same increases as hospitals instead or a different lower rate calculation as our costs for salaries and supplies face the same pressures.

Submitter : **Mr. Michael Pelc** **Date: 10/10/2006**

Organization : **Detroit Medical Center**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

SEE ATTACHMENT

CMS-1506-P-423-Attach-1.DOC

#123

October 6, 2006

Mark McClellan, M.D., Ph.D.

Administrator, Centers for Medicare & Medicaid Services

Attn: CMS–1540–P

Room 445-G

Hubert H. Humphrey Building

200 Independence Avenue, S.W.

Washington, DC 20201

RE: Medicare Program; Outpatient Prospective Payment System Rule for 2007; Proposed Rule.

Dear Dr. McClellan:

On behalf of the Detroit Medical Center's (DMC)six member hospitals- Children's Hospital of Michigan, Detroit Receiving Hospital, Harper-Hutzel Hospital, Huron Valley Hospital, Rehabilitation Institute of Michigan and Sinai-Grace Hospital- the DMC appreciates the opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS) regarding the 2007 proposed rule to update the Medicare outpatient prospective payment system (OPPS).

HOSPITAL QUALITY DATA

The CMS proposes to require compliance with the inpatient prospective payment system (IPPS) Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program in order for hospitals to receive a full payment outpatient update in 2007. Under the IPPS, the annual payment update is linked to the collection of quality measures and hospitals that fail to comply with the program requirements receive a marketbasket update that is 2 percent less than the full update. Beginning in 2007, the CMS indicates it has the authority and proposes to also reduce the outpatient PPS conversion factor update by 2 percent

for hospitals that are required to report quality data under the IPPS RHQDAPU. In addition, hospitals not submitting all of the inpatient measures required for 2008 would have their outpatient payment update for FY 2008 reduced by 2percent. The CMS asserts that it is appropriate to link full payment for outpatient services to the submission of these inpatient measures because several of the measures assess care that is often provided in the emergency department (e.g., aspirin and beta blockers for those thought to be experiencing a heart attack), and therefore if the hospital improves the system for delivering these medications, quality improvement to other emergency and other ambulatory services have likely occurred as well.

The DMC strongly disagrees with the CMS' proposed linkage of the reporting of the inpatient measures to payments under the OPPS for the following reasons:

• Congress has already determined the inpatient penalty for hospitals that do not submit the inpatient data. In the Deficit Reduction Act (DRA), Congress specified that the penalty would be a 2 percent reduction in the IPPS market basket update. It did not authorize additional penalties for outpatient services. If Congress had intended to authorize outpatient penalties, it would have specified those in the DRA. We conclude that Congress did not intend additional penalties for hospital outpatient services.

• The CMS' proposed rule asserts that the authority for adding the penalty to the outpatient payment comes from its "equitable payment authority". The equitable payment provision in the Social Security Act was intended to enable the CMS to eliminate inequitable impact on a particular provider or group of providers. Implementation of the equitable payment provision must be done in a budget neutral manner. For OPPS, there are no inequities in outpatient payment. Rather, application of this requirement may result in less payment to OPPS providers

• The CMS states that inpatient measures provide insight into the clinical care in the ambulatory setting. There is no relationship between the measures being used to assess the adequacy of inpatient heart attack, heart failure, pneumonia and surgical care and the care of patients receiving diagnostic, radiological, pharmaceutical and other procedures covered under OPPS.

Prior to linking any set of measures to the payment for outpatient care, there should be clear evidence that the measures specifically have an impact on the quality and outcome of patients who are treated in hospital outpatient settings. Many measures that can provide insights into the quality in outpatient care settings are being reviewed by the Hospital Quality Alliance and the AQA (formerly known as the Ambulatory Quality Alliance). **The DMC urges the CMS to continue working with the HQA and the AQA to identify and implement measures that truly assess important aspects of outpatient care quality**. Once appropriate measures have been identified, the CMS should work with Congress to consider how the payment system should be modified to support the provision of high quality care in the outpatient setting. Since appropriate outpatient care measures have

not been identified, **the CMS should remove any link between quality measures and outpatient care payments in this rule.**

NEW TECHNOLOGY APCS

The CMS proposes to assign 23 services from new technology APCs to clinically appropriate APCs. The CMS generally retains a service within a New Technology APC group for at least two years, unless the agency believes it has collected sufficient claims data before that time. In the proposed rule, the CMS proposes to assign some services that have been paid under the New Technology APCs for less than two years to clinically appropriate APCs. An example is as Positron Emission Tomography (PET)/Computed Tomography (CT) Scans, which were assigned to New Technology APC 1514 in 2005. Once approved by the CMS, there may be a delay in providing the services, resulting in less than 12 months full utilization in the first year of the CMS data files. **As a result, the DMC recommends that when the CMS assigns a new service to a new technology APC, the service should remain there for at least 2 years until sufficient claims data are collected.**

While new technology may increase outpatient cost, it frequently eliminates more invasive inpatient procedures that are most costly for Medicare. While this means that Medicare may be paying somewhat more for new technologies in hospital outpatient settings, in the end these costs are likely to be less than the cost of caring for such patient in an inpatient setting or using more invasive, but traditional, outpatient procedures.

Proposed Payment for Specified Covered Outpatient Drugs (SCODs). The DMC is concerned about the CMS's proposal to reduce payments for specified covered outpatient drugs (SCODs) to ASP plus 5 percent in 2007. This represents a one percent reduction from the ASP plus 6 percent rate in 2006. This payment reduction means that drugs and biologicals provided in hospital outpatient departments would be reimbursed for the same drug paid in physician office settings. **The DMC believes that consistency in payment for drugs and biologicals across settings is important and recommends that the CMS maintain the payment rates for drugs at the rate of ASP plus 6 percent for 2007.**

Payment Policy for Radiopharmaceuticals. The CMS proposes to no longer pay for radiopharmaceutical agents at hospital charge reduced to cost but instead pay for them at aggregate hospital mean costs as derived from the 2005 claims data. For brachytherapy sources, the CMS proposes to pay on the basis of claims-based median cost per source for each brachytherapy device. Due to concerns that the claims data may be incomplete due to frequent code and descriptor changes for radiopharmaceuticals, we believe that it is too soon to end the current policy of paying at hospital costs. **As a result, the DMC recommends that for 2007, the CMS continue using the current methodology of payment at charges reduced to costs for radiopharmaceuticals and brachytherapy sources.**

EVALUATION & MANAGEMENT (E/M) CODES

Despite the CMS's previous assurances that they would not create new codes to replace existing CPT E/M codes until national guidelines were developed, for 2007, the CMS proposes to establish new Health Care Procedure Coding System (HCPCS) level II G codes to describe hospital clinic visits, emergency department (ED) visits and critical care services. The CMS proposes five levels of clinic visit G codes, five levels of ED visit G codes for two different types of EDs, and two critical care G codes. Until national guidelines are formally proposed and finalized, the CMS states that hospitals may continue to utilize their existing internal guidelines for determining the visit levels to be reported with the new G codes, or they can adjust their guidelines to reflect the new codes and policies.

The DMC continues to believe that the CMS should not implement new codes for hospital clinic and ED visits in the absence of accompanying national code definitions and national guidelines for their application. **The DMC recommends that the CMS support the continued use of the current five level CPT codes, which would be assigned to the three existing APCs for hospital clinic and ED services until such a time as national coding definitions and guidelines are formally proposed, subjected to stakeholder review and finalized.** Creating temporary G-codes without a fully developed set of national guidelines will increase confusion and add a new administrative burden requiring hospitals to manage two sets of codes - G-codes for Medicare and CPT codes for non-Medicare payers - without the benefit of a standardized methodology or better claims data. Instead, our approach would provide for stability for hospitals in terms of coding and payment policy and would allow the CMS and stakeholders to focus instead on the development and fine-tuning of a set of national hospital visit guidelines that could be applied to a new set of E/M codes in the future.

OBSERVATION SERVICES

For 2007, the CMS proposes to continue applying the criteria for separate payment for observation services and the coding and payment methodology for observation services that were implemented in 2006. The DMC continues to support the CMS's concept of allowing the outpatient code editor (OCE) logic todetermine whether observation services are separately payable. This has resulted in a simpler and less burdensome process for ensuring payment for covered outpatient observation services.

In addition, since the process for determining whether observation is separately payable is largely "automated", the DMC believes the CMS should consider expanding diagnoses for which observation may be separately paid. As a result, the DMC supports the APC Panel's recommendation that the CMS consider adding syncope and dehydration as diagnoses for which observation services qualify for separate payment

OUTLIER PAYMENTS

Outlier payments are additional payments to the APC amount to mitigate hospital losses when treating high-cost cases. For 2007, the CMS proposes to retain the outlier pool at 1 percent of total outpatient PPS payments. Further, the CMS proposes to increase the fixed-dollar threshold to $1,875 - $625, or 50 percent, more than in 2006 - to ensure that outlier spending does not exceed the reduced outlier target. This increase in the fixed-dollar threshold is largely due to the projected overpayment of outliers resulting from the change in the CCR methodology. To qualify for an outlier payment, the cost of a service would have to be more than 1.75 times the APC payment rate and at least $1,875 more than the APC rate.

While the DMC supports the continued need for an outlier policy in all prospective payment systems, including the outpatient PPS, the CMS proposed outlier threshold is too high. With the significant changes to outlier policies, including the methodology for calculating the hospital-specific CCR proposed for 2007, the DMC is concerned that Medicare may not actually spend the outlier target set-aside. **The CMS should publish the annual outlier payments as a percent of total expenditures for 2005 and prior. The outlier threshold increase should be limited to the increase in APC rates, or 3.4 percent, unless clear evidence exists that proves the outlier payments exceed the allocated pool.**

Proposed Critical Care Coding. The DMC is opposed to the proposed structuring of critical care coding on the basis of time. Tracking and documenting time for critical care services would pose a significant burden to hospitals and could be subject to gaming. Time has never been incorporated as a component of critical care coding and billing instructions for hospitals since the inception of the OPPS. In fact, the April 7, 2000 final rule establishing the OPPS clearly states, "In addition, we believe it would be burdensome for hospitals to keep track of minutes for billing purposes. Therefore we will pay for critical care as the most resource intensive visit possible as defined by CPT code 99291."

While the 30-minute threshold has applied to physician professional service billing, it has long been understood that hospital resources for critical care are not linked to time, but rather reflect the immediate intensity of care provided to patients receiving these services. The goal of the ED is to stabilize the patient as quickly as possible, which involves multiple hospital staff to be simultaneously present, and may even require a multidisciplinary team. It would be extremely burdensome and confusing to track time for different individuals involved in providing critical care services. **The DMC recommends that the CMS eliminate the reference to time in the definition of the new critical care codes and instead continue with its long-standing OPPS policy concerning coding and billing for critical care services.**

PROPOSED PROCEDURES THAT WILL BE PAID ONLY AS INPATIENT PROCEDURES

CMS proposes to remove 8 codes from the inpatient list, which identifies services that are unable to receive payment if they are performed in an outpatient setting and then assigns them to clinically appropriate APCs.

The DMC remains concerned about the inconsistency between Medicare payment policy for physicians and for hospitals with regard to procedures that are on the inpatient list. It is our understanding that while Medicare will not pay hospitals if procedures on the inpatient list are performed in outpatient settings, that physicians would be paid their professional fee in such circumstances. There are a variety of circumstances that may result in such services being performed without an inpatient admission. For instance, because the inpatient list changes annually, physicians may not always be aware of that a procedure they have scheduled for performance in an outpatient department is on the inpatient list. There may also be other reasonable, but rare, clinical circumstances that may result in these procedures taking place in the absence of an inpatient admission.

The DMC again recommends that the CMS consider developing an appeals process to address those circumstances in which payment for a service provided on an outpatient basis is denied because it is on the inpatient list. This would give the provider an opportunity to submit documentation to appeal the denial, such as physician's intent, patient's clinical condition, and the circumstances that allow this patient to be sent home safely without a more costly inpatient admission.

MEDICARE CONTRACTING REFORM MANDATE

In the rule, the CMS proposes conforming changes to the regulations in order to implement the Medicare contracting reform provisions of the Medicare Modernization Act (MMA). Hospitals will be integral customers of the Medicare Administrative Contractors (MAC), and a significant proportion of hospital revenue will depend on appropriate contractor's performance.

The MMA requires that the Secretary of the Department of Health and Human Services consult with providers of services on the MAC performance requirements and standards, and the DMC appreciates the many opportunities that hospitals and other providers have had in contributing to this process. With the advent of competitive procedures for the selection of MACs, the DMC believes that such provider input is critical.

However, we encourage the CMS to further include providers in the contractor selection and renewal process. Furthermore, to address any serious problems with the selected MACs, providers also should be permitted to provide formal mid-contract reviews of their performance. We are concerned that with the

introduction of competitive procedures for the selection of the MACs, it is likely that some contractors may bid so low that they may not be able to adequately perform at the level that HHS and providers require. Hospitals have had first-hand experience with contractors who submit "low-ball" bids and then cannot do their job adequately in the Medicaid program, where competitive bidding is often used to select contractors. Therefore, hospitals should have input on both the selection and termination of MACs.

The DMC also requests that the CMS to do everything within its authority to ensure that MACs are accountable to the agency and providers for the services they provide. It is critical that the selected contractors understand how hospitals and health care systems function, and that MAC staff have the necessary technical expertise to efficiently and correctly process hospital claims.

In addition, given that each defined A/B MAC jurisdiction will include several states, the CMS must ensure that the chosen contractor is able to maintain a significant local presence. This includes the ability to work within different time zones, availability and accessibility within typical hospital administrative hours of operation, and the ability to conduct face-to-face meetings and teleconferences with individual hospitals or groups of hospitals on a regular basis.

FY 2008 IPPS RHQDAPU

In the proposed rule, the CMS announces the measures hospitals paid under the Medicare acute care hospital inpatient PPS must submit in order to get the full inpatient payment to which they would otherwise be entitled in FY 2008. Under the DRA, hospitals that fail to submit these measures and the other quality measures that are currently required would suffer a penalty of having their FY 2008 inpatient payments reduced by two percent.

The DMC is supportive of the CMS utilizing quality measures that have already been adopted as part of the Hospital Quality Alliance's efforts to promote public reporting of hospital quality data. These are well-designed measures chosen because they represent aspects of care that are important to patients, and that provide insights into the safety, efficiency, effectiveness and patient-centeredness of care. **We strongly urge the CMS to continue to align its choices of measures to link to payment with the measures chosen by the HQA to provide a public accountability for quality.** This alignment will reinforce the importance of the public transparency on quality and help to focus quality improvement efforts on the chosen high priority areas of care.

We also support the CMS for publishing information on what measures hospitals will be expected to report to continue to receive their full inpatient payments

early enough for them to put the proper data collection processes in place. As we said in our earlier comments on the Inpatient Prospective Payment System rule, if hospitals are not told until August what quality data they will be expected to report, they are unable to put the proper data collection processes in place quickly enough to ensure reliable abstraction of the information from patient records.

HEALTH INFORMATION TECHNOLOGY (HIT)

The proposed rule states that it "supports the adoption of health IT as a normal cost of doing business to ensure patients receive high quality care." It also notes that the quality and efficiency benefits of health IT may provide a policy rationale for promoting the use of health IT through the Medicare program.

The DMC strongly believes that health IT is a very important tool for improving the safety and quality of health care, and our members are committed to adopting IT as part of their quality improvement strategies. They also view IT as a public good that requires a **shared investment between the providers and purchasers of care.**

Health IT is a very costly tool, requiring both upfront and ongoing spending. A 2005 American Hospital Association (AHA) survey noted that the median amount hospitals invested annually on health IT was greater than $700,000, 15 percent of total capital expenses. Hospitals spent even greater amounts - a median of $1.7 million or 2 percent of all operating expenses - on operating costs related to IT.' Survey respondents identified the upfront and ongoing costs of IT as the greatest barriers to further adoption. The survey also found that hospitals with negative margins and those with lower revenues use less IT.1

The proposed rule highlights the anticipated benefits of health IT as laid out by the RAND Corporation. **However, it overlooks another of the study's major findings - that the financial benefits of IT investments accrue more to the payers and purchasers of care than the hospitals and health systems that pay for them.2**

Simply put, our members have not seen financial returns greater than the costs of implementing clinical IT systems, particularly in the short term. They adopt clinical IT because it is the right thing to do for improving patient safety and quality of care, not because it saves them money. Thus, while IT may be a "normal cost of doing business," it systematically raises those costs. **Given that they reap many of the financial benefits of IT, the DMC believes that the payers and purchasers of care should share in the costs of IT.**

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1. Forward Momentum:Hospital use of Information Technology. Washington, DC: MHA (2005)
2. R. Hillestad, J. Bigelow, A. Bower, F. Girosi, R. Meili, R. Scoville, and R. Taylor. Can Electronic Medical Record Systems Transform Health Care? Potential Health Benefits, Savings, and Costs.
Health Aff., September 1, 2005; 24(5): 1103-1117.

Finally, we learned through the HIPAA process that efficient health information exchange requires all parties to upgrade their systems and work from a common set of standards. As we moved toward implementation of health IT in hospitals, payers - including the federal government - must modify their own systems to accept electronic data.

Statutory Authority. The broad question of whether the CMS has statutory authority to encourage adoption and use of health IT will depend on the specific mechanisms it selects. For example, the CMS has some authority to pursue demonstration projects. However, more systematic approaches, such as value-based purchasing or payment adjustments, would require legislative action.

Value-based Purchasing. The DMC believes that any value-based purchasing program should not be punitive. **With regard to IT, only programs that add funds to the inpatient PPS should be pursued because IT is costly, requiring both upfront and ongoing expenditures.** Decreasing payments to those that have not been able to afford IT further limits their ability to invest. A budget-neutral approach also ignores the reality that health IT systematically increases hospitals' costs.

The DMC also believes that value-based purchasing programs should build off the consensus measures endorsed by the broad spectrum of organizations - including the CMS - that participate in the HQA. In general, the HQA favors measures that address quality outcomes, rather than the tools used to get there.

Health IT can play a role in reducing the burden of quality reporting. Presently, electronic health records (EHRs) and other clinical IT systems do not automatically generate quality measures. Most hospitals still require special calculations - including expensive manual chart abstraction and use of third-party contractors - to submit quality data. The CMS could advance the quality agenda by investing in the development of algorithms for the calculation of the quality measures it wants reported from EHRs and encouraging vendors to include them in their products.

Rather than including health IT in a value-based purchasing program, **the CMS could support adoption of health IT through a payment adjustment funded with new money.** For example, it could increase payments to hospitals that use health IT that improves the safety and quality of care by 1 percent. This kind of payment adjustment represents Medicare's share of the necessary investment to achieve this goal and would recognize the greater costs of a "wired" health care system. The DMC will pursue legislation authorizing such a payment adjustment. Other mechanisms, such as loan guarantees and grant funds, are needed to help hospitals finance the upfront costs of implementing health IT.

Conditions of Participation. **The DMC firmly believes that the CMS should not include health IT in the Medicare conditions of participation (COP) for hospitals.** The COPs address the basic, essential infrastructure needed to ensure patient safety and must be clearly understood. Successful implementation of quality-enhancing IT requires careful planning and changes to work processes. The hospital field is still developing its understanding of how to implement these systems correctly. In addition, the commercial health IT applications available do not always meet hospitals' needs. The evidence on health IT does

not yet support this level of requirement and would amount to an unfunded mandate. A recent report supported by the AHRQ found that the existing research on the quality benefits of health IT is limited to a handful of leadership institutions that generally developed their own systems. And, while promising, the results are not yet generalizable to the average community hospital using the vendor systems currently on the market.3

While the DMC appreciates the efforts of the Certification Commission on Health Information Technology (CCHIT) to provide the market with better confidence in vendor product, we do not believe those efforts are sufficiently advanced to warrant inclusion in any adoption incentives the CMS might pursue. CCHIT is only at the beginning stages of looking into certification of hospital inpatient products. CCHIT's work on ambulatory products is more advanced but, while it shows promise, has not yet proven itself in the marketplace.

HEALTH CARE INFORMATION TRANSPARENCY INITIATIVE

In 2006, the Department of Health and Human Services (HHS) proposes to undertake a new effort to expand the availability of information on health care quality and pricing. The HHS intends to identify several regions in the United States with high health care costs and use its leadership role in health care policy to help lead change in those areas.

While progress has been made in quality transparency, similar information on hospital pricing is less accessible. The proposed rule discusses the CMS perspective on the difficulties in providing information for health care consumers and offers several options to consider.

Providing meaningful information to consumers about the price of their hospital care is the most significant challenge hospitals, and the CMS, face in increasing transparency of hospital pricing information. Objectives for improving pricing transparency should include:

• Presenting information in a way that is easy for consumers to understand and use;

• Making information easy for consumers to access;

• Using common definitions and language to describe pricing information for consumers;

• Explaining to consumers how and why the price of their care can vary; and

• Encouraging consumers to include price information as just one of several considerations in making health care decisions.

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3 "Costs and Benefits of Health Information Technology." Agency for Healthcare Research and Quality Publication
No 06-E006 (April 2006).

The DMC recommends that the CMS convene a workgroup comprised of representatives from hospitals, the DMC and state associations, and Medicare beneficiaries to identify the core issue to be resolved by the transparency initiative. Once that is identified, the hospital industry can provide valuable input toward resolution.

Another option the CMS offered is establishing a Medicare condition of participation to post prices on assistance programs for uninsured. While many hospitals are moving toward transparency in this area, including this as a condition of participation seems punitive and will not resolve the CMS core issue of what hospitals are doing to assist the uninsured. It is important for the CMS to understand that the income level of the uninsured varies by community and charity care policies will also vary. **Therefore, the DMC objects to the CMS expanding the conditions of participation to include posting of prices on assistance programs to the uninsured.**

Although we have learned much about the type of information consumers want about the quality of their health care, we know significantly less about what they want in regard to pricing information. Depending upon whether and how they are insured, consumers need different types of price information as illustrated below:

• **Traditional Insurance**. Because traditional insurance typically covers nearly all of the cost of hospital care, individuals with this type of coverage are likely to want information about what their personal out-of-pocket cost would be if they receive care at one hospital versus another.

• **Health Maintenance Organization (HMO) Insurance**. Individuals who have HMO coverage will have more specific price information needs since they typically face no additional cost for care beyond their premium and applicable deductibles and co-payments. Persons covered by an HMO must agree to use physicians and hospitals that are participating in that HMO plan. As a result, these individuals likely have little, if any need for specific price information.

• **High-Deductible or Health Savings Account (HSA) Insurance**. Individuals with HSAs have more interest regarding price information compare to a typically-insured person since these plans are designed to make consumers more price-sensitive and encourage consumers to be prudent "shoppers" for the care they need. Since a typical plan of this type has a deductible of $2,500, consumers with HSA coverage are likely to be more interested in price information for physician and ambulatory care than for inpatient hospital care.

• **Uninsured Individuals of Limited Means**. Uninsured individuals have limited means to pay for the health care services they receive and need to know how much of their hospital or physician bill they may be responsible for paying. In the case of hospital care, the information these patients need must be provided directly by the hospital, after the hospital can ascertain whether the individual is eligible for state insurance programs of which they were unaware, charity care provided by the hospital, or other financial assistance.

Again, the DMC appreciates this opportunity to provide input to the CMS and urge you to modify the OPPS proposed rule based on our comments above. If you have questions or require additional information, please contact me at (313) 578-2820 or mpelc@dmc.org

Sincerely,

Michael A.Pelc
Vice President, Finance

Submitter : **Dr. Frederick Blum** **Date: 10/10/2006**

Organization : **American College of Emergency Physicians**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1506-P-424-Attach-1.DOC

CMS-1506-P-424-Attach-2.DOC

#1211

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October 9, 2006 **Attention: CMS-1506-P**

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

RE: CMS-1506-P: Medicare Program: Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates

Dear Dr. McClellan:

On behalf of the American College of Emergency Physicians (ACEP), I am pleased to submit comments on the proposed rule for the Hospital Outpatient Prospective Payment System for Calendar Year 2007, published in the Federal Register on August 23, 2006. ACEP is a national medical specialty society with more than 25,000 members, dedicated to improving the quality of emergency care through continuing education, research, and public education. We appreciate the opportunity to provide the Centers for Medicare & Medicaid Services (CMS) with our comments on outpatient hospital payment policy and its effects on the delivery of emergency medicine services.

ACEP's comments focus on the OPPS rather than the Ambulatory Surgical Center (ASC) proposal. While we support CMS' continuing efforts to create payment incentives to provide medical services in the most appropriate and efficient settings, we note that payment policies which encourage the shifting of services from hospital outpatient departments to ASCs to physicians' offices will result in additional cuts in the physician updates under the current SGR formula.

Emergency Department Visits

Since the OPPS was first implemented, CMS has paid for hospital ED visits using the five levels of CPT codes (99281-99285). These five codes have been mapped to only three levels of payment (APCs 0610, 0611, and 0612). This year, CMS proposes to replace the 5 levels of CPT codes with temporary HCPCS codes (Gyyy1-Gyyy5) that will be mapped to five new APCs (0609 and 0613-0616). ACEP strongly supports the proposal for five levels of payment which will allow for more accurate reporting of services and a more appropriate distribution of payments across the range of ED visits. However, we object to the proposal to switch to new HCPCS codes which will create unnecessary complications in reporting and payment since not all payers recognize Medicare's "temporary" codes. We urge CMS to continue the use of the existing CPT codes and to work with the AMA and other stakeholders to develop the necessary codes. In any event, new HCPCS codes should not be implemented until the necessary coding guidelines have been developed, tested and implemented.

Proposed ED Coding

For the first time, CMS is proposing to differentiate EDs that are open 24/7, meeting the CPT definition of an ED (as well as EMTALA requirements), from those that meet the EMTALA definition of a "dedicated emergency department" but are not open 24/7. The proposal will require that five separate HCPCS "G" codes be used for billing purposes by both the 24/7 (Type A) EDs and those that are open less than 24/7 (Type B) EDs to allow CMS to collect data over the next year or two. In the proposal, CMS states that "the fact they (Type B) facilities do not operate with all the capabilities full-time suggests that hospital resources associated with EDs or facilities that operate less than 24/7 may not be as great as resources associated with EDs that .....meet CPT definitions." The ostensible result of CMS' analyses will be to establish a separate payment rate for the Type B ED. In the meantime, CMS states that these EDs must bill at clinic rates.

ACEP has long supported full-service 24/7 EDs that provide safety net medical care to anyone and everyone. We are very concerned that unfettered proliferation of less than full-service EDs could reduce access for many individuals who need emergency care after hours when Type B EDs are closed. We do not want these facilities to have financial incentives to locate in areas where the population is more affluent and largely insured, leaving full-service hospital EDs with an even larger financial burden to care for the uninsured and underinsured after hours. In some regions of the country however, EDs that are open less than 24 hours provide invaluable access to emergency care that would not be otherwise available.

Most free-standing EDs that are owned and operated by hospitals provide comprehensive emergency services with the exception of operating rooms and have available the backup capacity of the full service ED on the hospital's main campus. Many of these facilities are provider-based by CMS definitions and billing for both EDs is often combined under the hospital's provider number. This practice will make reporting separate G codes somewhat burdensome. At the same time we believe that the proposed use of the CPT 24/7 definition as a "placeholder" makes sense for the purposes of data collection to differentiate costs of each facility. While the costs of operating an ED less than 24/7 are probably less, they are certainly much closer to a 24/7 facility than a clinic.

Therefore, ACEP supports the CMS' efforts to differentiate costs between Type A and Type B EDs. We note however, that CMS does not provide any information on how many hospital-based Type B EDs exist and how many of those are currently billing at ED versus clinic rates. Further, it's not clear whether this proposal will cause significant financial hardships to some of these EDs and actually reduce patient access to emergency care.

Going forward, CMS must balance the need to address serious ED crowding and access issues while maintaining a high and explicit threshold to qualify as a dedicated ED. In the longer term, a dedicated ED should continue to meet the current EMTALA definitions, regardless of whether it is open 24/7 or not:

- It is licensed by the state in which it is located as an emergency department;
- It is held out to the public by name, posted signs, advertising, or other means as a place that provides care for emergency medical conditions on an urgent basis without requiring a previously scheduled appointment; and
- At least one-third of the patient visits were for treatment of emergency medical conditions in the past year.

ACEP recommends adding the following requirements for stand-alone dedicated EDs and dedicated EDs not open 24/7:

- Has transfer agreements with local and/or regional full service hospitals, and
- Presence of a "qualified medical person" (as defined by EMTALA) during operating hours.

E/M Services Guidelines

After five years of study, CMS has not yet finalized its ED visit facility guidelines. After expressing concerns with ACEP's guidelines' accuracy at documenting hospital resources during an ED visit, the American Hospital Association and the American Health Information Management Association joined to develop a draft set of guidelines and submitted them to CMS in 2003. CMS has not found these guidelines totally satisfactory either. A recent CMS contractor study to test the AHA/AHIMA guidelines was halted before completion as the reviewers found them confusing which greatly limited their reliability. AHA/AHIMA panel has begun to review its work and the need to clarify definitions and make the guidelines more precise.

ACEP is prepared to work with CMS and the AHA/AHIMA panel in the development of guidelines that will lead to accurate and reliable coding for ED visits. Before new guidelines are implemented it is critical that they be tested. We continue to urge CMS to carefully select a coding system that will accurately reflect resource use by hospitals in the provision of emergency department services, while minimizing subjectivity and potential gaming in coding levels of service.

Observation Services - APC 0339

For CY 2007, CMS is proposing to continue applying the CY 2005 criteria that determine when a hospital may receive separate payment for medically necessary observation care provided to a patient with congestive heart failure, chest pain, or asthma. ACEP continues to urge CMS to review yet another year of claims and rescind the limits altogether as the APC Advisory Committee proposed in February 2004, allowing physicians to make clinical judgments based on medical necessity. This view is supported by the IOM in its recent report on *The Future of Emergency Care.* Recommendation # 4.2 states "The Centers for Medicare and Medicaid Services should remove the current restrictions on the medical conditions that are eligible for separate clinical decision unit payment." ACEP urges CMS to review and adopt this recommendation. At a minimum, CMS should incorporate the APC Advisory Committee's August 2006 recommendation to add syncope and dehydration as separately payable conditions under APC 0339.

We appreciate the opportunity to offer these comments and we look forward to continuing to work cooperatively with CMS in order to address these important issues. If you have any questions about our comments and recommendations, please contact Barbara Marone, ACEP's Federal Affairs Director at (202) 728-0610, ext. 3017.

Sincerely,

Frederick C. Blum, MD, FACEP, FAAP
President

Submitter : **Dr. Michael Repka** **Date: 10/10/2006**

Organization : **American Academy of Ophthalmology**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-425-Attach-1.PDF

#125

AMERICAN ACADEMY OF OPHTHALMOLOGY
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via Electronic Mail

October 10, 2006

Mark McClellan, M.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1478-P
P.O. Box 8013
Baltimore, MD 21244-8012

RE: CMS-1506-P; CMS-4125-P (Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; Ambulatory Surgical Center List of Covered Procedures; Ambulatory Surgical Center Payments System and CY2008 Payment Rates; Medicare Administrative Contractors; and Reporting Hospital Quality Data for FY 2008 Inpatient PPS Annual Payment Update Program—HCAHPS Survey, SCIP, and Mortality)

Dear Dr. McClellan:

On behalf of the American Academy of Ophthalmology (Academy) I am writing to comment on the 2007 proposed Ambulatory Surgical Center Covered Procedures list rule as well as the OPPS CY2007 Payment Rate rule. The Academy is the world's largest organization of eye physicians and surgeons, with more than 27,500 members. Over 16,000 of our members are in active practice in the United States. We appreciate the opportunity to comment on the proposed rule. Additionally, we will comment under separate cover on the new proposed payment system for ASC CY2008 Payment rates.

Our comments focus on the following points in the Outpatient Prospective Payment System:

1) Medicare Payment for Keratoprosethesis
2) Medicare Payment Policy for Ocular Tissue Processing
3) APC Relative weight adjustments

The Academy will also address the following points in the CY2007 Payment Rates for ASCs:

1) ASC list of covered services
2) New Technology Intraocular Lenses (NTIOL)

AMERICAN ACADEMY OF OPHTHALMOLOGY
The Eye M.D. Association

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Federal Affairs Department

- **Outpatient Patient Prospective Payment System**

1) Medicare Payment for Keratoprosthesis

The Academy would like to commend and support the CMS decision to place the code for keratoprosthesis (CPT 65770) in a new APC—Level V Anterior Segment Eye Procedures. We agree that the cost for the device used with this implantation procedure was not appropriately reimbursed under the previous APC category and appreciate the CMS correction. We would encourage the close monitoring of the cost data associated with the procedure to ensure that this is the appropriate level of payment.

2) Medicare Payment Policy for Ocular Tissue Processing Should be Consistent with HOPPS Payment for V2785, Corneal Tissue

Currently, there are two HCPCS codes used to report services related to corneal tissue and amniotic membrane transplantation under HOPPS—V2785 (processing, preserving and transporting corneal tissue) and V2790 (amniotic membrane for surgical reconstruction, per procedure). There is a discrepancy in payment policy and status indicators for these two types of tissue. Both types of tissue are used for ocular surface reconstruction procedures. As a result, hospitals are paid separately—in addition to the APC rate—for costs associated with corneal tissue transplantation, but not for costs associated with processing preserved amniotic membrane tissue for ocular surface transplants.

The Academy is concerned that this inequitable payment classification creates a financial disincentive for hospitals to promote the treatment of ocular surface diseases using amniotic membrane tissue, and impedes beneficiary access to this unique ocular reconstructive procedure.

We respectfully request that CMS revise the current HOPPS payment policy for amniotic membrane transplant procedures so that it is consistent with the policy to reimburse hospitals for costs associated with V2785 (processing, preserving and transporting corneal tissue). This should include a change in the status indicator for V2790 (amniotic membrane for surgical reconstruction, per procedure) from an "N" (bundled in APC rate) to an "F" (payment based on acquisition costs).

3) APC Relative Weights: Concerns regarding decreased payments for 2 Ophthalmologic APC categories

CMS indicates that it is using the same methodology to review and revise the APC relative payment weights as has been used since the new reweighting began in August of 2000. The Academy is not aware of substantial decreases in the cost of providing services for the procedures that are included in APCs 0241 and 0232 and therefore believes that there is no justification for these decreases.

According to Addendum B in CMS 1506-P the following notable decreases occurs for those APCs:

APC Code	APC Description	2006 OPPS	2007 NPRM OPPS	% Change in OPPS Rate
241	Level IV Repair and Plastic Eye Procedures	$1,806.03	$1,529.55	-15.31%
232	Level I Anterior Segment Eye Procedures	$411.84	$368.07	-10.63%

While the Academy does not have access to the cost data utilized by CMS, we have checked with members familiar with the procedures associated with these APCs and were unable to verify any cost reductions that would have facilitated such decreases for these categories. If such declines are not reflective of true cost reductions, facilities will be unable to continue to provide these procedures in the more convenient and cost-effective outpatient setting. Further, because ASCs will be subject to an even smaller percentage of the rates afforded hospital outpatient departments once the new ASCP payment systems is implemented in 2008, we are concerned that these reductions will compromise surgery center services to Medicare beneficiaries.

- **CY 2007 Update to the list of covered procedures under the Ambulatory Surgical Center Payment System and Comments on NTIOL**

1) The Academy's June 2005 comment letter to CMS regarding the interim final ASC list the Academy respectfully disagreed with the CMS decision to keep the code 66990 (use of ophthalmic endoscope) from the list of approved procedures. We respectfully disagree with the decision to not add 66990 to the ASC list. This newest proposed rule updating the ASC list for 2007 again mistakenly indicates that code 66990 is not a separate surgical procedure, and we do not believe it is an appropriate addition to the ASC list." **CPT code 66990 code is an add-on code for a specific endoscopic surgical approach and therefore represents the surgical work of the surgereon.** It is reported in conjunction with many ophthalmic surgical services which are allowed in the ASC setting. Exclusion of this code from the approved procedures list will prevent many ophthalmic surgical services from being performed in the ASC setting, necessitating their being performed in either the hospital outpatient department or inpatient setting at substantially greater cost to the Medicare program. The Academy strongly urges CMS to reconsider adding procedure code 66990 to the list of ASC approved procedures.

2) New Technology Intraocular Lenses (NTIOL): Modification of the current ASC process for adjusting payments

The Academy appreciates the opportunity to comment on CMS' proposal to streamline and update the process for adjusting payments for NTIOLs. While we agree that incorporating this process into the annual notice and comment for proposed rulemaking will help ensure a more regular process that simplifies monitoring and coordination, we are concerned that this timeframe may not be adequate to ensure speedy access to the newest technologies. If such review creates a backlog of requests for updates, then the agency will need to reconsider a more timely approach to updating NTIOLs. We have previously suggested that CMS adopt a process similar to that of new technology/pass through status.

To answer CMS' thoughtful question on the best interpretation of "currently available" when CMS is considering and comparing new IOLs we hope that CMS bears in mind that these technologies change and advance rapidly. This must be accounted for in this process. One suggestion on what would be considered "currently available" would be to establish a threshold of sales in the market.

We also agree with CMS when it states that the new process *should* support the development and dissemination of new IOL technology that continues to improve clinical outcomes for Medicare beneficiaries. In fact, the Academy would state that payments ***must*** be adequate in order to ensure Medicare patients who undergo cataract extraction with corrective IOL insertion achieve the best possible outcomes. We have noted previously in our May 30, 2006 comments on NTIOLs that the $50 payment had not been adjusted enough to keep up with inflation or the rising costs of innovative research.

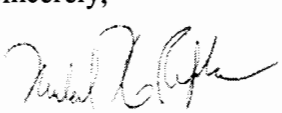
We note that CMS is proposing to assess the clinical outcomes from the use of new candidate lenses. The Academy has long supported improving clinical outcomes and works vigorously to create and update our Preferred Practice Patterns documents. If the information CMS uses to make outcomes assessments is being collected, maintained and analyzed by ophthalmologists, the Academy would request that CMS also ensure that the costs associated with such data collection are adequately reimbursed and that the standards for collection are uniform and that results are measured consistently, statistically relevant and are independently verifiable.

Finally, the best approach to answering the questions posed by the agency may be to hold a town hall meeting or other means by which to bring together stakeholders and CMS staff further to deliberate on this important process.

Conclusion:

The Academy would like to thank CMS for providing us with the opportunity to comment on the proposed rule regarding the CY 2007 OPPS proposed payment update and the ASC covered procedures list. And, we especially welcome the CMS decision to upgrade the APC category for keratoprosthesis in order to ensure that the device cost is adequately covered. We are hopeful that CMS will give immediate consideration to and act on the changes we have recommended regarding rectifying the inequitable treatment of amniotic tissue versus corneal tissue in the outpatient setting. Further, we strongly encourage the agency to add CPT procedure code 66990 to the list of covered procedures for 2007. Finally, we hope that our comments regarding NTIOL guides the agency's decision for their new update process and we stand ready to provide further assistance or input in a meeting of stakeholders convened by the agency.

Sincerely,



Michael X. Repka, M.D.
Secretary of Federal Affairs

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

Organization :

Category : **Other Health Care Provider**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-426-Attach-1.PDF

#426

CATHOLIC HEALTH EAST

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October 5, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P or CMS-4125-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: CMS-1506-P; CMS-4125-P – The Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; CY 2007 Update to the Ambulatory Surgical Center Covered Procedures List; the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates; Medicare Administrative Contractors; and Reporting Hospital Quality Data for FY 2008 Inpatient Prospective Payment System Annual Payment Update Program – HCAHPS® Survey, SCIP and Mortality *(71 Federal Register 49505).*

Dear Dr. McClellan:

On behalf of Catholic Health East (CHE), I would like to thank you for the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule regarding the Hospital Outpatient Prospective Payment System (OPPS) and CY 2007 Payment Rates published on August 23, 2006 in the *Federal Register*. Catholic Health East (CHE) is a multi-institutional, Catholic health system located in 11 eastern states from Maine to Florida, including 33 acute care facilities.

Hospital Quality Data

CMS is proposing to initiate a Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program under the OPPS for Calendar Year 2007. Until CMS develops a set of quality measures designed to specifically measure the quality of patient care given in the outpatient setting, CMS is proposing to structure the OPPS RHQDAPU by tying the outpatient annual payment update to compliance with the Inpatient Prospective Payments System (IPPS) RHQDAPU. Hospitals that don't report their IPPS RHQDAPU data will receive a 2 percent reduction in their OPPS market basket update

for CY 2007. Hospitals which are paid under the OPPS, but which are exempt from the IPPS would not be required to submit data under the IPPS RHQDAPU and would automatically receive the full OPPS market basket update for CY 2007.

Catholic Health East, in general, is supportive of the reporting and transparency of hospital quality information. However, CHE is concerned this proposal would not satisfy CMS' stated goal of promoting value based purchasing in outpatient payments as inpatient quality measures are not appropriate clinical indicators of outpatient quality, and because not all hospitals paid under the OPPS would be required to comply with CMS' proposal. CHE also has concerns regarding CMS's statutory authority to implement this regulatory proposal.

In the Inpatient Prospective Payment System Final Rule, CMS adopted 21 measures to assess the quality of inpatient care provided by hospitals paid under the IPPS. Those evidenced-based measures assess the quality of care provided to patients suffering heart attack, heart failure, pneumonia and undergoing surgery in the inpatient setting. CMS suggests that the inpatient measures will serve as an adequate proxy of the quality of care provided in the outpatient setting because hospitals function as integrated systems that provide health care services to patients in both the inpatient and outpatient settings for many of the same clinical conditions. However, CMS offers no clinical or research based evidence to support its assertion that measures specifically developed to assess the quality of inpatient care can serve as a proxy for outpatient quality. Without such clinical support, it is difficult to understand how reporting quality data on inpatient care would "provide a strong incentive to encourage hospital accountability in general and quality improvement in particular," or further CMS's goal of value based purchasing in the outpatient setting.

Under this proposed provision, to receive a full market basket update for CY 2007, a hospital must comply with the FY 2007 IPPS RHQDAPU reporting requirement. CMS will make the determination whether hospitals have met the IPPS RHQDAPU reporting requirement for the IPPS and the proposed OPPS market basket updates on or about September 1, 2006. Those determinations will already be made by the time the Outpatient Prospective Payment System Final Rule has been published. If CMS implements this provision, by the time the final rule is announced hospitals will be bound by CMS' determination of whether they met the inpatient reporting criteria and will be unable to make any changes to save their outpatient market basket increase should it be in jeopardy as a result of prior noncompliance with the IPPS RHQDAPU. CHE agrees with the American Hospital Association (AHA) when it likens this proposal to retroactive rulemaking. Its retroactive nature provides no opportunity or incentive for hospitals to make any alterations to achieve the full market basket update for OPPS in CY 2007.

Because CMS is proposing that hospitals reimbursed under the OPPS submit data collected and reported under the IPPS RHQDAPUA, CMS had to contend with those hospitals that are subject to the OPPS but are exempt from the IPPS. For these hospitals, CMS proposes to exempt them from the quality reporting requirement and give them the full market basket update for OPPS reimbursements. While it is understandable that

those hospitals exempt from the IPPS RHQDAPU would find it extremely difficult to comply with the proposed RHQDAPU reporting requirement, exempting these hospitals creates an unlevel playing field and does not further CMS's goal of promoting value based purchasing in the outpatient setting because it wouldn't apply to all hospitals paid under the OPPS. In crafting a quality data reporting proposal that will significantly impact market basket updates, CMS should ensure parity across the hospital community, and therefore should not implement the proposed OPPS RHQDAPU until quality measures specific to the outpatient setting are developed and all hospitals reimbursed under the OPPS will have to comply with reporting on those quality measures.

CMS had specific statutory authority to develop and expand the IPPS RHQDAPU from Section 501(b) of Public Law 108-173 (the Medicare Modernization Act of 2003) and Section 5001(a) of Public Law 109-171 (the Deficit Reduction Act of 2005) respectively. In the absence of similar statutory authority, CMS claims its authority to implement the OPPS RHQDAPU proposal originates from Section 1833 (t)(2)(E) of the Social Security Act, which reads, "the Secretary shall establish, in a budget neutral manner, outlier adjustments under paragraph (5) and transitional pass-through payments under paragraph (6) and *other adjustments as determined to be necessary to ensure equitable payments, such as adjustments for certain classes of hospitals.*" That this statutory language, which appears to focus on reimbursing hospitals for services that would not be appropriately reimbursed under the prospective payment system, would provide the appropriate authority to institute an outpatient quality program seems tenuous at best. CHE would be more comfortable with CMS moving forward on this proposal if, as in the case of the IPPS RHQDAPU, CMS had specific statutory authority granted by Congress to implement an outpatient quality reporting program.

In summary, given the fact that the inpatient quality measures do not directly measure the quality of services provided in the outpatient setting and the retroactive nature of the proposal, CHE does not believe that CMS's OPPS RQHDAPU proposal satisfies CMS's stated goal of instituting value based purchasing within the outpatient setting, nor does it "provide a strong incentive to encourage hospital accountability in general and quality improvement in particular." Therefore, it does not follow to predicate the receipt of something as significant as full market basket updates for outpatient reimbursements on the submission of inpatient quality data when the inpatient data does not directly measure outpatient quality. **CHE requests the CMS postpone implementation of an OPPS RQHDAPU until specific evidenced based outpatient quality measures have been developed and Congress has given the appropriate statutory authority for such a program.**

Inpatient Only Procedures

CMS is proposing to remove eight procedures from the inpatient list thereby allowing for reimbursements for these procedures under the OPPS when they are performed in an outpatient setting. CHE shares the AHA's concern on this issue regarding the inconsistency between Medicare payment policy for physicians and hospitals with regard to procedures on the inpatient-only list. While Medicare would refuse to reimburse hospitals if procedures on the inpatient list were performed in an outpatient setting, the

physician would still be reimbursed for his fee. Whether the procedure will be performed in an inpatient or outpatient setting is usually decided by the physician and physicians are not always aware of what procedures are on the inpatient only list.

CHE joins the AHA in requesting that CMS consider developing an appeals process to address those circumstances in which payment for a service is provided on an outpatient basis is denied because it is on the inpatient-only list. This would give the provider an opportunity to submit documentation to appeal the denial, such as physician's intent, patient's clinical condition and the circumstances that allow this patient to be sent home safely without an inpatient admission.

Volatility of APC Relative Weights

Current law requires CMS to review and revise the relative payment weights for APCs at least annually. CHE remains concerned about the volatility of the APC weights from year to year. The swings in the APC weights, which can be significant, make it challenging for hospitals to adequately plan and budget for future years. **CHE requests that CMS take appropriate steps to ensure the stability of the APC weights.**

Thank you for your review and consideration of these comments. If you have any questions, please feel free to contact me at (610) 355-2121.

Sincerely,

Kenneth A. Becker
Vice President, Advocacy & Government Relations

Submitter : **Dr. Frederick Cahn** **Date: 10/10/2006**

Organization : **BioMedical Strategies LLC**

Category : **Device Industry**

Issue Areas/Comments

Skin Replacement Surgery and Skin Substitutes

Skin Replacement Surgery and Skin Substitutes

Please see attached letter.

CMS-1506-P-427-Attach-1.PDF

#127

October 10, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
C5-01-17
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore MD 21244

Via: CMS e-rulemaking web site

Re: CMS-1506-P,
Skin Replacement Surgery and Skin Substitutes

Dear Dr. McClellan:

I wish to comment on section III.D.1 of CMS-1506-P ("Proposed Changes to the Hospital Outpatient PPS and CY 2007 Rates") titled "Skin Replacement Surgery and Skin Substitutes (APCs 0024, 0025, 0027)." I am concerned that the APC classifications of several CPT codes, including 15170, 15171, 15175, and 15176, for CY 2007 may be based on an underestimation of the hospital resources required for these procedures.

My company, BioMedical Strategies LLC provides consulting services in medical economics, statistics, coding and other issues regarding the introduction of new technology into medical practice. We have extensive experience in tissue engineering products, especially skin substitutes, and one of our clients, Integra Lifesciences Corporation, manufactures and markets acellular dermal replacement products; the procedures to apply these products are affected by the payment for these CPT codes. In addition, I am chairman of ASTM International subcommittee F04.41, "Terminology and Classification of Tissue Engineered Medical Products." My subcommittee developed and published ASTM International standard F2311-06, "Standard Guide for Classification of Therapeutic Skin Substitutes," which presents definitions and classification of procedures utilizing skin substitutes. ASTM Standard F2311 was one of the resources used by the American Medical Association (AMA) in the creation of the 2006 CPT codes, and I also am now advising the workgroup of the AMA's CPT Editorial Panel that is responsible for the supporting documentation and future modifications to these codes.

Background

As you know, effective in 2006, the CPT codes regarding skin grafts and related procedures were updated. Codes 15342 and 15343 that described skin substitutes as well as codes 15350 and 15351 that described allograft were deleted. Codes15300 and 15320 now describe application of allograft skin for temporary wound closure for the first 100 sq cm or less, and add-on codes 15301 and 15321 describe allograft skin for temporary wound closure for each additional 100 sq cm at these anatomic locations. New codes15170 and 15175 describe acellular dermal replacement for the first 100 sq cm or less, and new add-on codes15171 and 15176 describe acellular dermal replacement for each additional 100 sq cm.

In the final rule for CY 2006, CPT 15300 was assigned to APC 27, but the very similar CPT 15320 was assigned to APC 25. Moreover, CPT codes 15170 and 15175, add-on codes 15171 and 15176, and all of the new codes for all skin substitutes were assigned only to APC 24.

In a comments letter to CMS dated January 10, 2006 and in a presentation to the APC Panel on March 2, 2006, I pointed out that the hospital resources required to perform the allograft and acellular dermal replacement procedures are similar, irrespective of the anatomic location. The clinical utilities of these procedures are also similar since they are used in skin replacement surgery and both accomplish immediate wound closure. Thus, logically, CPT 15320, 15170 and 15175 should all be assigned to the same APC group as 15300, which was APC 27.

The American Burn Association (ABA) also sent a comments letter and made a presentation to the APC Panel. ABA recommended that CPT 15170, 15175, 15300, and 15320 as well as all other procedures using skin substitutes (CPT 15340, 15360, 15365, 15420, and 15430) be placed in APC 27. The ABA recommended that the add-on procedures for these codes be placed in APC 25. These recommendations of the ABA were accepted by the APC Panel in their Final Report, dated March 1-2, 2006.

Proposed Rule for FY 2007

In the proposed rule, CMS accepted most of the logic of the ABA and of the APC Panel concerning the equivalence of allograft procedures to skin replacements:

> "We reviewed the presentations to the APC Panel; the APC Panel's recommendations; the CPT code descriptors, introductory explanations, cross-references, and parenthetical notes; the clinical characteristic of the procedures; and the code-specific median costs for all related CPT codes available from our CY 2005 claims data. While we agree with the APC Panel that the codes currently placed in APC 0024 (Level I Skin Repair) should be assigned to an APC with a higher median cost for CY 2007, we disagree that these procedures should be placed in APC 0027 (Level IV Skin Repair). APC Panel presenters reasoned that some of the codes (CPT 15170, 15175, 15320, 15340, 15360, 15365, 15420, and 15430) for the first increment of body surface area treated should be placed in APC 0027 because they are similar to CPT code 15300 (Allograft skin for temporary wound closure, trunk, arms, legs; first 100 sq cm or less, or one percent of body area of infants and children). Upon further review of the clinical and expected hospital resource characteristics of CPT code 15300, we believe that this procedure is not appropriately placed in APC 0027. Split-thickness and full thickness skin autograft procedures currently assigned to APC 0027 are likely to require greater hospital resources, including additional operating room time and special equipment, in comparison to application of a separately paid allograft skin product. Instead, for CY 2007 we are proposing to reassign CPT code 15300 to APC 0025 (Level II Skin Repair), with an APC median cost of $314.58. We agree, in principle that other CPT codes for the first increment of body surface area treated with a skin replacement or skin substitute are similar clinically and from a hospital resource perspective to CPT code 15300 and are, therefore, proposing to assign these procedures to APC 0025 as well for CY 2007."

I agree with the conclusion of CMS that application allograft requires less resources than application of autograft, since the time and material resources required to harvest the autograft are not required for allograft. Similarly, the procedure to apply "acellular dermal replacement" is very similar in resources to the procedure to apply allograft. A review of "Skin Replacement Surgery and Skin Substitutes" published by the AMA in the September issue of the "CPT Assistant" supports the equivalence of skin allograft procedures to acellular dermal replacement. For allograft:

"Description of Procedure (15300)

"After the induction of anesthesia, hemostasis of the graft site is obtained with epinephrine-soaked laparotomy pads and/or a topical hemostatic agent. Human allograft skin is obtained from the skin bank. A total of 100 sq cm is applied to the leg and secured to the excised wound with interrupted sutures or surgical staples. The wound is covered with gauze dressings and secured with a bulky dressing to prevent mechanical shear."

For acellular dermal replacement:

"Description of Procedure (15170)

"After the induction of anesthesia, hemostasis of the graft site is obtained with epinephrine-soaked laparotomy pads and/or a topical hemostatic agent. The acellular dermal replacement is removed from the rinsing solution and a total of 100 sq cm is applied to the trunk and secured to the excised wound with interrupted sutures or surgical staples. A net dressing is applied and expanded over the graft site and secured with staples to prevent mechanical shear. The wound is covered with gauze dressings and secured with a bulky dressing to further prevent mechanical shear."

Underestimation of resources required for CPT 15170 to 15176

I agree with the conclusion by CMS that allograft and acellular skin replacement procedures require similar resources. I also agree that the resources required for these procedures are less than those required for split thickness autograft (which requires an additional procedural step to harvest the autograft tissue). However, the new APC assignments for these procedures appear to greatly exaggerate the differences between autograft and the allograft or acellular dermal replacement procedures: APC 27 (autograft) has an OPPS payment rate of $1,308.85, whereas APC 25 (allograft, acellular dermal replacement) has an OPPS payment rate of $313.49, which is only 24% of the autograft payment. I believe it is unreasonable to presume that the grafting procedures for allograft or acellular dermal replacement require only 1/4 of the resources required for an autograft. Anesthesia requirements, procedure room facilities and time, sterility requirements, and supplies are very similar, as are the recipient site preparation (excision, separately paid under OPPS), the need to cut to fit the wound edges, suturing or stapling, and dressings. APC 686, with an OPPS payment rate of $821.29 (63% of autograft) would be a more appropriate approximation of resource requirements.

Differentiation of resources required for skin replacement surgery from other procedures using skin substitutes

This similarity in resources to allograft also applies to some, but not all, of the procedures used to apply skin substitutes. Although both the ABA and the APC panel made the suggestion that the all of the new APC codes be placed in the same APC classification as allograft, and the proposed rule places all of the skin replacement and skin substitutes in APC 25, I suggest that these placements deserves further examination.

A review of procedures for skin replacements and skin substitutes described in the recently published CPT Assistant article shows that not all of the new CPT codes describe procedures that require hospital resources equivalent to those of allograft. For example, the procedure to apply tissue cultured allogeneic skin substitute shows substantial differences, especially, that only 25 sq cm is treated:

"Description of Procedure (15340)

"The wound is debrided and, after adequate hemostasis has been achieved and administration of anesthesia has occurred, graft materials were obtained. The wound was measured. Approximately 25 sq cm of tissue-cultured allogeneic skin substitute was fenestrated, grafted to the excised surface, and secured with interrupted sutures."

ASTM standard F2311 explains a fundamental distinction between skin replacement surgery, (skin autograft, acellular skin replacement, allograft, and other procedures in the range of CPT 15040 to 15321), and procedures that support healing by second intention (such as CPT 15340-1). The resources required for skin replacement surgery may be significantly greater than those for procedures for healing by second intention. For example, wound preparation for skin replacement surgery should be more meticulous (excision) and the requirements for sterility and fixation to the wound bed are much higher, to avoid loss of the graft. However, procedures for healing by second intention may have less stringent procedure requirements and it is likely that these differences result in significant decreases in the hospital resources required.

(Other skin substitute products have utility both for healing by first and second intention, and the CPT Assistant article generally describes only the procedure for healing by first intention. For example, a product comprised of allogeneic fibroblasts cultured on a silicone membrane can be used as a substitute for allograft for a temporary wound closure of excised wounds, but it can also be used to enhance healing of second degree burns that are not excised. It is difficult to generalize the appropriate APC classification for these, since while the procedure for healing by first intention may have similar resource requirements to allograft, the procedure for healing by second intention may require substantially less resources.)

Recommendation

I believe that these comments justify the need for a higher payment classification for acellular dermal replacement (CPT 15170-6) and for temporary wound closure by allograft (CPT 15300-15321). I recommend that these procedures be placed in APC 686.

Sincerely yours,

Frederick Cahn, Ph.D.
CEO

Submitter : **Dr. Michael Marks** **Date: 10/10/2006**

Organization : **Coastal Orthopaedics**

Category : **Physician**

Issue Areas/Comments

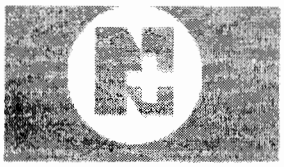
Policy and Payment Recommendations

Policy and Payment Recommendations

Please see the attached comment letter. Thank you for your consideration.

CMS-1506-P-428-Attach-1.DOC

#1128



NORWALK HOSPITAL

Michael R. Marks, M.D. MBA
Coastal Orthopaedics, 40 Cross St #300, Norwalk, CT 06851
Direct Line: 203-845-2200 Email mmarks1988@aol.com

October 6, 2006

Filed Electronically

Mark B. McClellan, M.D., Ph.D.
Administrator, Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attn: CMS-1506-P
7500 Security Boulevard
Baltimore, Maryland 21244

Re: CMS-1506-P -- Changes to Hospital Outpatient Payment System for 2007
Support Proposed Increased Payment for Kyphoplasty Procedures – APC 052

Dear Dr. McClellan:

I am pleased to submit comments on the Centers for Medicare & Medicaid Services' (CMS) Medicare hospital outpatient prospective payment system (HOPPS) proposed rule for calendar year 2007 which was published in the Federal Register on August 23, 2006.

I am an orthopedic surgeon, the Immediate Past President of the Connecticut State Orthopaedic Society and the Chief of Staff at Norwalk Hospital in Connecticut. I have been performing kyphoplasty procedures since June 2001. In my leadership role with the Orthopaedic Society, I was pleased to work with CMS staff as they moved forward and established new C-codes for the kyphoplasty procedures in 2005. More recently, I have worn my "hospital administrator" chief of staff hat when communicating and working with CMS staff on payment and coding related matters for kyphoplasty. Because of my involvement with the coding process and my role as a hospital administrator, I am keenly interested in CMS proposed changes to the Hospital Outpatient PPS for 2007.

In brief, I recommend CMS finalize (or increase) the Medicare hospital outpatient payment rates ($4,055) for kyphoplasty procedures in the final 2007 HOPPS rule.

By way of background, balloon kyphoplasty is a minimally invasive surgical treatment which restores the height of pathologically fractured vertebrae whether by osteoporosis or cancer. Using specialized equipment and devices we can stabilize the fracture and correct the spinal deformity. As a result, patients generally report a significant reduction in pain as well as improved mobility. In turn, this reduces (1) the number of days they spend in bed (bedrest), (2) the amount of pain medication they need, and (3) potential complications related to bedrest and inactivity. Overall, patients report an increase in their quality of life following kyphoplasty. Most patients who need kyphoplasty are over 65 so Medicare is the primary payer and appropriate Medicare reimbursement is important to ensure that Medicare patients have full access to this procedure.

For 2007, CMS has proposed increasing the payment to $4,055 for kyphoplasty procedures described by CPT codes 22523, 22524, and 22525. These three kyphoplasty CPT codes became effective on January 1, 2006. In the 2006 final HOPPS rule, CMS considered comments and moved the kyphoplasty procedures to APC 052 because APC 052 was a better fit and maintained the clinical and resource homogeneity of the APC procedure groupings. At that time, CMS also indicated that they would review claims data and evaluate the APC assignment again for 2007. I appreciate the attention

that Ken Simon and the staff in CMS's Outpatient Care Division have given to kyphoplasty procedures to ensure that the procedures are assigned to the correct APC both from a clinical perspective and a resource consumption standpoint. They have carefully reviewed and examined the hospital charge data that I provided for kyphoplasty procedures and I am pleased that, as a result of the coding changes, CMS now has charge data for kyphoplasty in their hospital claim file.

In closing, addressing reimbursement, including payment and coding for kyphoplasty to ensure that Medicare patients have access to this important procedure in all practice settings, is one of my primary goals, and achieving this goal involves a concerted effort on the part of all interested parties, especially CMS staff and the CMS medical officers. I sincerely appreciate CMS's efforts and look forward to continuing to work with CMS on this important matter.

Thank you for your time, attention, and consideration. If you have any questions or need additional information, please feel free to contact me.

Sincerely,

Michael Marks MD MBA

Michael R. Marks, M.D., MBA
Norwalk Hospital

cc: Carol Bazell, M.D., CMS
Edith Hambrick, M.D., J.D., CMS
Ken Simon, M.D. CMS
Gail Daubert, R.N., Esq.

Submitter : Ms. PATRICIA ANDERSEN **Date:** 10/10/2006

Organization : OKLAHOMA HOSPITAL ASSOCIATION

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

SEE ATTACHMENT OHA COMMENT LETTER ON OPPS CY 2006

CMS-1506-P-429-Attach-1.DOC

#4

October 10, 2006

Patricia D. Andersen, Vice-President
Oklahoma Hospital Association
4000 Lincoln blvd
Oklahoma City, OK 73105

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

Ref: [CMS-1506-P and CMS-4125-P] Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; Medicare Administrative Contractors; and Reporting Hospital Quality Data for FY 2008 Inpatient Prospective Payment System Annual Payment Update Program – HCAHPS Survey, SCIP, and Mortality (71 Federal Register 49506), August 23, 2006.

Dear Dr. McClellan:

The Oklahoma Hospital Association (OHA), on behalf of our more than 140 hospital members welcomes the opportunity to comment on the proposed rule related to the Medicare Prospective Payment System (PPS) for outpatient services. Of great concern to OHA and our member hospitals are the continued significant fluctuations in APC payment rates. We believe it is reasonable to expect that after four years of experience these significant changes would no longer occur; that the payment rates and the associated payment-to-cost ratios would be more stable. Such wide swings are very difficult for hospitals to deal with. In addition, even after the CY 2007 update, CMS will be paying less than the cost of the care provided to Medicare patients served in the outpatient hospital setting. Our comments follow:

OPPS: LINKING INPATIENT HOSPITAL QUALITY DATA REPORTING TO OUTPATIENT PPS UPDATE RATES

CMS Proposes to require compliance with the inpatient PPS Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program to receive a full payment update in the outpatient setting for calendar year (CY) 2007. Under the inpatient PPS, the annual payment update is linked to the collection of inpatient quality measures and hospitals that do not comply with the program requirements receive a reduction to the inpatient PPS update. The CMS proposal would reduce the outpatient PPS conversion factor update by 2% in CY 2007 for those hospitals that are required to report quality data under the inpatient PPS RHQDAPU program in order to receive the federal fiscal year (FFY) 2007 update, and fail to meet the requirements for receiving the full FFY 2007 inpatient PPS payment update.

CMS states in the proposed rule that the statute permits the Secretary to ". . . establish, in a budget neutral manner... adjustments as determined to be necessary to ensure equitable payments" under the OPPS. CMS has indicated that they believe "the promotion of high quality care" qualifies as an issue of payment equity.

The OHA believes that this interpretation and the related use of inpatient quality reporting in lieu of outpatient quality reporting is a misapplication the Secretary's statutory authority. We believe that there is little logic in linking outpatient payments to inpatient quality. Linking a reduction in the outpatient conversion factor to inpatient quality data that have already been reported does not further the stated goals of CMS to encourage hospital accountability and quality improvement. And, finally, we believe that linking outpatient payments to submission of data that predates the outpatient PPS rule is unfair and is effectively retroactive rule-making.

While we agree that the promotion of high quality care is a necessary objective, it is not a matter of payment equity. Moreover, the quality of outpatient care will not be improved by linking the outpatient update to the submission of inpatient data on quality measures that are designed for acute inpatient care.

The OHA recommends that CMS withdraw its proposal to link inpatient quality reporting to the outpatient payment update and to rely on the efforts of the Hospital Quality Alliance (HQA) and Ambulatory Quality Alliance (AQA) to develop outpatient quality measures.

Finally, CMS should not attempt to link the outpatient update to either inpatient or outpatient quality measures without explicit legislative authority. The update has been linked to quality reporting for both the inpatient PPS and the home health PPS. However, in both cases the link was authorized by statute. This is a clear indication that Congress regards such policies as subject to determination by legislation and does not intend that such actions be undertaken administratively.

The OHA recommends that CMS seek Congressional authorization before proposing to extend the link between quality reporting and payment updates to the outpatient setting and to any other patient care settings.

IPPS: FY 2008 INPATIENT QUALITY MEASURES

In the proposed rule, CMS announces the measure that hospitals paid under the Medicare acute care hospital inpatient PPS must submit in order to receive the full inpatient payment in FY 2008. The OHA applauds CMS for adding to its requirements for the full update the quality measures that have been ado0ped by the Hospital Quality Alliance (HQA). The measures are well-designed and represent measures of effectiveness and patient-centered care. We encourage CMS to continue to align its choices of measure to link to payment with the measure chosen by the HQA. We are grateful to CMS for proposing in August the measure that hospitals will be required to report well in advance of the date reporting must begin. We hope that CMS will continue this advance decision-making and communication to the industry in the future.

OPPS: HOSPITAL EMERGENCY AND CLINIC VISITS

Currently, hospitals are instructed to use the current procedural terminology (CPT) codes used by physicians to report clinic and emergency department (ED) visits and critical care services on claims paid under the OPPS. However, CMS realizes that the CPT Evaluation and Management (E & M) codes reflect the activities of physicians but do not describe the range and mix of services provided by hospitals during visits of clinic and ED patients and critical care encounters. In addition, there is no national policy to determine the assignment of E & M codes and hospitals are instructed to develop internal hospital guidelines to determine what level of visit should be reported for each patient.

CMS proposes to replace the current E & M codes with new Health Care Procedure Coding System (HCPCS) level II G codes to describe hospital clinic visits, ED visits and critical care services for Medicare patients. *In response to concerns about implementing code definitions without national guidelines, CMS specified in an earlier outpatient PPS rule that they would not create new codes to replace the existing E & M codes until national guidelines were developed.* However, in this proposal CMS states that while they do not yet have a formal set of national guidelines to report different levels of hospital clinic and emergency department visit and to report critical care services, they "have made significant progress in developing potential guidelines and, therefore, are proposing for CY 2007 the establishment of HCPCS codes to describe hospital clinic and emergency department visits and critical care services. Prior to our implementation of national guidelines for the new hospital visit HCPCS codes, we are proposing that hospitals may continue to use their existing internal guidelines to determine the visit levels to be reported with these codes."

Implementation of new codes in CY 2007 without implementation of national guidelines will require hospitals to manage two sets of codes—G codes for Medicare and Current Procedural Terminology (CPT) codes for non-Medicare payers—without the benefit of a standardized methodology or better claims data. This will cause an unnecessary burden and possible confusion for hospitals.

The OHA joins the American Hospital Association (AHA) in opposing the proposed creation of temporary level II G-codes while continuing to allow hospitals to apply their own internal guidelines to these codes. Instead of implementing a temporary system, the OHA recommends that CMS defer creation of new evaluation and management (E & M) codes until such a time as national coding definitions and guidelines are formally proposed, subjected to stakeholder review, approved and published.

OPPS: Partial Hospitalization

The OHA recommends that in the final rule for 2007, CMS freeze payment rates for partial hospitalization services at the 2006 level of $245.65. This approach will provide payment stability for these services and protect beneficiary access while allowing CMS adequate time to address the instability in the CMHC data.

OPPS: Rural SCH Payments

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) required that CMS conduct a study to determine if the cost of providing outpatient care in rural hospitals exceeded that of urban hospitals. The CMS analysis showed that rural Sole Community Hospitals (SCH) demonstrated significantly higher cost per unit than urban hospitals. CMS stated that its analysis showed that other rural hospitals did show some levels of higher cost per unit; however, CMS did not believe it was significant enough to justify an adjustment for other rural hospitals. Therefore, in CY 2006 provided an adjustment of 7.1% for SCHs but provided no adjustment for other rural hospitals. CMS proposes to continue this policy in CY 2007.

The MMA mandated report was intended to coincide with the scheduled expiration of hold-harmless payments for small rural hospitals on December 31, 2005. The payments were subsequently extended through December 31, 2008 with a gradual phase-down of the payment amount.

The OHA supports the continuation of the 7.1% adjustment for rural SCHs. However, given the phase-down and eventual elimination of rural hold-harmless payments, we urge CMS to revisit their analysis of the cost of providing outpatient care in rural hospitals and to propose an adjustment for other rural hospitals in CY 2008 or CY 2009 if justified by the analysis.

OPPS: Rural Hospital Hold Harmless Transitional Payments

The OHA is concerned about the impact that the phase-out of the transitional corridor hold harmless payments will have on small rural hospitals. These are vulnerable facilities that provide important access to care in their communities. The OHA supports S. 3606, *Save Our Safety (SOS) Net Act of 2006*, which would permanently extend hold harmless payments to small rural hospitals and sole community hospitals, as is currently the case for cancer hospitals and children's hospitals.

OPPS: Outlier Payments

Outlier payments are added to the APC amount to mitigate hospital losses when treating high-cost cases. For 2007, CMS proposes to retain the outlier pool at 1 percent of total outpatient PPS payments. Further, CMS proposes to raise the fixed-dollar threshold to $1,875 – $625 more than in 2006 – to ensure that outlier spending does not exceed the reduced outlier target. This increase in the fixed-dollar threshold is largely due to the projected overpayment of outliers resulting from the change in the CCR methodology. To qualify for an outlier payment, the cost of a service would have to be more than 1.75 times the APC payment amount and at least $1,875 more than the APC payment amount.

The OHA is concerned that CMS has set the threshold for outliers too high. With the significant changes to outlier policies, including the methodology for calculating the hospital-

specific CCR proposed for 2007, the OHA is concerned that Medicare may not spend the targeted outlier pool.

OPPS: NEW TECHNOLOGY APCS

The OHA recommends that when CMS assigns a new service to a new technology APC, the service should remain a new technology APC for at least two years until sufficient claims data are collected.

OPPS: RADIOLOGY PROCEDURES

In the proposed rule, CMS indicates that it will continue to defer the implementation of a multiple imaging procedure payment reduction policy pending further analyses. **The OHA supports CMS' decision not to implement this policy.**

OPPS: NONPASS-THROUGH DRUGS, BIOLOGICALS AND RADIOPHARMACEUTICALS

The OHA recommends that CMS eliminate the drug packaging threshold for all drugs, biologicals and radiopharmaceuticals with HCPCS codes.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) required that payment for specified covered outpatient drugs be equal to the average acquisition cost for the drug for that year as determined by the Secretary of Health and Human Services (HHS), subject to any adjustment for overhead costs and taking into account the hospital acquisition cost survey data collected by the General Accounting Office (GAO). For CY 2006, CMS paid for the acquisition and overhead costs of separately paid drugs and biologicals at a rate based on the average sale price (ASP) plus 6%.

For CY 2007, CMS proposes to set payment for these drugs at the ASP plus 5%. CMS states that they believe that this payment level would serve as the best proxy for the combined acquisition and overhead costs of separately payable drugs and biologicals in CY 2007.

The proposed payment reduction would result in hospital outpatient department rates that are less than the payment for the same drugs and biologicals provided in physician office settings where the rate would remain at ASP plus 6%.

The OHA believes that there is no justification for lower payments in hospital outpatient departments and we recommend that CMS maintain the payment rates for separately paid drugs and biologicals at the rate of ASP plus 6% for CY 2007.

OPPS: BRACHYTHERAPY PAYMENTS AND RADIOPHARMACEUTICALS

CMS proposes to discontinue the current policy proving payment for brachytherapy sources at hospital charges reduced to cost and instead pay for them based on aggregate hospital mean costs as derived from the 2005 claims data. CMS notes that a Government Accountability Office (GAO) on payment for radioactive sources used in brachytherapy was published in July 2006, but states that it was not available in time to review and discuss in the proposed rule.

The OHA recommends that CMS not change the current brachytherapy and

radiopharmaceuticals payment policies without taking into account the GAO recommendations. We recommend that CMS continue payment under the current policy in CY 2007 and evaluate the GAO recommendations and any related payment changes in the proposed rule for CY 2008.

Further, CMS did not provide an estimate of the effect that this change will have on payments for brachytherapy sources. We are concerned that the change could have a significant impact on hospitals that provide this service.

The OHA recommends that CMS evaluate the impact of any proposed change in payment methodology for brachytherapy and radiopharmaceuticals prior to implementing changes.

DRUG ADMINISTRATION

The OHA recommends that in 2007, CMS implement the full set of CPT drug administration codes and eliminate the six HCPCS C codes created to parallel the 13 drug administration codes that were not implemented in 2006. This policy change eliminates the burden of having to apply and maintain two sets of codes for essentially the same services.

The OHA supports CMS' proposal that hospitals apply modifier 59 to drug administration services using the same correct coding principles that they generally use for other outpatient PPS services.

CMS also proposes six new APCs in 2007 that are intended to better distinguish costs related to infusions of different types and furnished over different lengths of time. Previously, payment for additional hours of infusion has been packaged due to the inability to use claims data to distinguish costs associated with infusions of different duration. However, in 2005, codes used in the outpatient department distinguished between the first hour of infusion and additional hours of infusion. Using newly available 2005 claims data, CMS proposes to assign CPT/HCPCS codes to six new drug administration level APCs, with payment rates based on the median costs from this 2005 claims data.

The OHA supports CMS' proposal to create six new drug administration APC levels which will provide more accurate payment for complex and lengthy drug administration services.

In addition, as part of the implementation of new drug administration codes in 2006, CMS decided to no longer allow for the reporting of separate IV pushes of the same drug. This coding instruction created a situation in which no payment is made for packaged drugs that are given as separate IV pushes. The prime example is pain management where a patient may require multiple IV pushes of morphine, but only one drug administration code could be reported. Because morphine is a packaged drug, not only would the administration services involved in the subsequent IV pushes of morphine not be reimbursed, the drug itself would not be paid. We do not believe CMS' intent was to discontinue payment for this drug when it is medically necessary.

The OHA recommends that CMS make payment for a second or subsequent IV push of the same drug by instituting a modifier, developing a new HCPCS code for the

procedure, or implementing another methodology in 2007 so that an appropriate payment is made for this service.

Further, the OHA also recommends that CMS allow providers to use all available HCPCS codes for reporting drugs to reduce the administrative burden associated with reporting drugs using only HCPCS codes with the lowest increments in their descriptors.

OPPS: OBSERVATION SERVICES

For 2007, CMS proposes to continue applying the criteria for separate payment for observation services and the coding and payment methodology for observation services that were implemented in 2006. The OHA continues to support CMS' concept of allowing the Outpatient Claims Editor logic to determine whether observation services are separately payable. This has resulted in a simpler and less burdensome process for ensuring payment for covered outpatient observation services.

In addition, now that the process for determining whether observation is separately payable is largely "automated," CMS should explore a narrow expansion in the diagnoses for which observation may be separately paid.

The OHA recommends that CMS consider adding syncope and dehydration as diagnoses for which observation services qualify for separate payment. This is consistent with a recent recommendation from the Advisory Panel on APC Groups.

PROPOSED PROCEDURES THAT WILL BE PAID ONLY AS INPATIENT PROCEDURES

CMS proposes to remove eight codes from the inpatient-only list, which identifies services that are ineligible for payment if they are performed in an outpatient setting, and assign them to clinically appropriate APCs.

The OHA is very concerned about the inconsistency between Medicare payment policy for physicians and hospitals with regard to procedures on the inpatient-only list. It is our understanding that while Medicare will not pay hospitals if procedures on the inpatient-only list are performed in outpatient settings, physicians would be paid their professional fee in such circumstances. There are a variety of circumstances that may result in such services being performed without an inpatient admission. For instance, because the inpatient-only list changes annually, physicians may not always be aware that a procedure they have scheduled in an outpatient department is on the inpatient-only list. There also may be other reasonable, but rare, clinical circumstances that may result in these procedures occurring in the absence of an inpatient admission.

The OHA recommends that CMS consider developing an appeals process to address those circumstances in which payment for a service provided on an outpatient basis is denied because it is on the inpatient-only list. This would give the provider an opportunity to submit documentation to appeal the denial, such as physician's intent, patient's clinical condition, and the circumstances that allow this patient to be sent home safely without an inpatient admission.

OPPS: DEVICE-DEPENDENT APCs

CMS proposes to reduce the APC payment for selected APCs in cases in which an implanted device is replaced without cost to the hospital or with full credit for the removed device. CMS proposes to adjust the APC payment rate by the entire cost of the replaced device. However, CMS should recognize that hospitals incur administrative handling costs associated with a replacement device—both in the acquisition of the device and generally in returning the original device. In addition, frequently, a recalled device is replaced with an upgraded device. In such cases, the hospital is often responsible for paying the price difference between the upgraded device to be implanted and the replaced device that is being removed.

Therefore, we recommend that CMS evaluate the proposed percentage offsets related to recalled devices to ensure that they take into account administrative resources and associated handling costs required to provide the replacement devices. In addition, CMS should differentiate between replacements with an equivalent device and replacement with an upgraded higher functioning device and appropriately compensate hospitals based on the costs they incur.

CAHs: EMERGENCY MEDICAL SCREENING

CMS proposes to revise the CAH conditions of participation to allow registered nurses to serve as qualified medical personnel for emergency medical screenings.

The OHA supports this proposal which will provide CAHs with the staffing flexibility needed to maintain access and provide efficient emergency and urgent care services.

HEALTH INFORMATION TECHNOLOGY

Health IT is a critical tool for improving the safety and quality of health care, and the OHA's members are committed to adopting IT as part of their quality improvement strategies. They also view IT as a public good that requires a shared investment between the providers and purchasers of care.

As summarized in the final inpatient PPS rule, most commenters noted that health IT is a costly tool requiring both upfront and ongoing investment of money and human resources. While providers bear the burden of those costs, the financial benefits of having improved HIT systems often flow to the payers and purchasers of care, including Medicare. **Given that they reap many of the financial benefits of IT, the OHA believes that the payers and purchasers of care should share in its costs.** An add-on payment to Medicare is one possible mechanism for doing so.

With regard to value-based purchasing, the OHA believes that these programs should build on the consensus measures endorsed by the broad spectrum of organizations, including CMS, that participate in the Hospital Quality Alliance (HQA). In general, the HQA favors measures that address quality process and outcomes, rather than the tools used to get there. Health IT, however, can play a role in reducing the burden of quality reporting.

In the FY 2007 final inpatient PPS rule, CMS stated that it would not make use of certified, interoperable health IT a condition of participation in Medicare, but might revisit the issue in future rulemaking. **The OHA opposes including health IT in the Medicare conditions of**

payment for hospitals. The conditions of participation address the basic, essential infrastructure needed to ensure patient safety and must be clearly understood. Successful implementation of quality-enhancing IT requires careful planning and changes to work processes. The hospital field is still developing its understanding of how to implement these systems correctly. In addition, current commercial health IT applications do not always meet hospitals' needs, and certification efforts are in their infancy.

TRANSPARENCY OF HEALTH CARE INFORMATION

While progress has been made regarding quality transparency, similar information on hospital pricing is less accessible. Consumers deserve meaningful information about the price of their hospital care, and hospitals are committed to sharing information that will help consumers make important decisions about their health care.

However, sharing pricing information is more challenging because hospital care is unique. Hospital prices can vary based on patient needs and the services they use; prices reflect the added costs of hospitals' public service and most hospitals cannot yet provide prices that reflect important information from other key players, such as the price of physician care while in the hospital or how much of the bill a patient's insurance company may cover.

Providing *meaningful* information to consumers about the price of their hospital care is the most significant challenge hospitals and CMS face in increasing transparency of hospital pricing information. Objectives for improving pricing transparency should include:

We are pleased that CMS acknowledged in its FY 2007 inpatient PPS final rule the complexities involved in presenting pricing information in an accurate and useful manner, and recognized that an education effort will be required. We also are pleased that CMS plans to make pricing information available for other types of providers and services. Consumers should have information on physician services, and common procedures in hospital outpatient clinics and ambulatory surgery centers.

More can and should be done to explain pricing information to consumers clearly and consistently. Hospitals will work together to create common terms, definitions and explanations of complex pricing information. HHS should provide incentives to the states to improve transparency at the state and local level, and, through AHRQ, complete research on what consumers want and would use in purchasing health care services.

CONCLUSION

The OHA appreciates having the opportunity to comment on the proposed rule. If you have any questions regarding our comments, please contact me at

Sincerely,

THE OKLAHOMA HOSPITAL ASSOCIATION

Patricia Andersen

Patricia D. Andersen, VP-Finance & Information Services

Submitter : **Ms. Ju-Ming Chang** **Date: 10/10/2006**

Organization : **Healthcare Association of New York State**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Attached please find HANYS' comments.

CMS-1506-P-430-Attach-1.DOC

#120

Healthcare Association
of New York State

October 10, 2006

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

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

Dear Dr. McClellan:

The Healthcare Association of New York State (HANYS), on behalf of our more than 550 hospitals, nursing homes, home health agencies, and other health care providers, welcomes the opportunity to comment on the Medicare Outpatient Prospective Payment System (OPPS) proposed rule. Below are our comments, arranged by topic.

OPPS: HOSPITAL QUALITY DATA

The Centers for Medicare and Medicaid Services (CMS) proposes to require compliance with the Inpatient PPS (IPPS) Reporting Hospital Quality Data for the Annual Payment Update (RHQDAPU) program to receive a full payment update in the outpatient setting for calendar year (CY) 2007. Under the IPPS, the annual payment update is linked to the collection of inpatient quality measures. Hospitals that do not comply with the program requirements receive a reduction to the IPPS update. The CMS proposal would reduce the OPPS conversion factor update by 2% in CY 2007 for those hospitals that are required to report quality data under the RHQDAPU program to receive the federal fiscal year (FFY) 2007 IPPS update, but fail to meet the requirements for receiving the full update.

CMS states in the proposed rule that the statute permits the Secretary of Health and Human Services to ". . . establish, in a budget neutral manner, . . . adjustments as determined to be necessary to ensure equitable payments . . ." under the OPPS. CMS holds that the promotion of high quality care qualifies as an issue of payment equity. **While we agree that the promotion of high quality care is an admirable goal, HANYS believes that this is a misapplication of the Secretary's statutory authority and that the proposal should be withdrawn.**

Moreover, the quality of outpatient care will not be improved by linking the outpatient update to the submission of inpatient data on quality measures that are designed for acute inpatient care. **CMS should not propose any outpatient reporting requirements until quality measures specific to outpatient services have been proposed and validated.**

Finally, CMS should not attempt to link the outpatient update to either inpatient or outpatient quality measures without explicit legislative authority. The update has been linked to quality reporting for both the IPPS and the Home Health PPS. However, in both cases the link was authorized by statute. This is a clear indication that Congress regards such policies as subject to determination by legislation and does not intend that such actions be undertaken administratively. **CMS should seek congressional authorization before proposing to extend the link between quality and payment updates to other settings.**

VISITS

Under the OPPS, hospitals are instructed to use the Current Procedural Terminology (CPT) codes used by physicians to report clinic and emergency department (ED) visits and critical care services. However, CMS realizes that the CPT Evaluation and Management (E/M) codes reflect the activities of physicians but do not describe the range and mix of services provided by hospitals during visits of clinic and ED patients and critical care encounters. In addition, there is no national policy to determine the assignment of E/M codes and hospitals are instructed to develop internal hospital guidelines to determine what level of visit should be reported for each patient.

CMS proposes to replace the current E/M codes with new Health Care Procedure Coding System (HCPCS) level II G-codes to describe hospital clinic visits, ED visits, and critical care services. CMS specified in an earlier OPPS rule that it would not create new codes to replace existing E/M codes until national guidelines were developed. However, in this proposal, CMS states that while it does not yet have a formal set of national guidelines to report different levels of hospital clinic and ED visits or to report critical care services, CMS has *" . . . made significant progress in developing potential guidelines and, therefore, are proposing for CY 2007 the establishment of HCPCS codes to describe hospital clinic and emergency department visits and critical care services."* Before CMS' implementation of national guidelines for the new hospital visit HCPCS codes, CMS proposed that hospitals continue to use their existing internal guidelines to determine the visit levels to be reported with these codes.

Implementation of new codes in CY 2007 without implementation of national guidelines will require hospitals to evaluate their current internal guidelines and revise them to be consistent with the new codes. Then, when national guidelines are implemented in a subsequent year, hospitals may again need to revise their coding procedures. This will cause an unnecessary burden and possible confusion for hospitals. **HANYS joins the American Hospital Association (AHA) in opposing the proposed creation of temporary level II G-codes while continuing to allow hospitals to apply their own internal guidelines to these codes. Instead, CMS should defer creation of new E/M codes until national coding definitions and guidelines are formally proposed, subjected to stakeholder review, and published.**

OPPS: RURAL SCH PAYMENTS

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) required that CMS conduct a study to determine if the cost of providing outpatient care in rural hospitals exceeded that of urban hospitals. CMS' analysis showed that rural Sole Community Hospitals (SCHs) demonstrated significantly higher cost per unit than urban hospitals. The analysis showed that other rural hospitals showed higher cost per unit; however, CMS did not believe the higher costs were significant enough to justify an adjustment for other rural hospitals. Therefore, in CY 2006, CMS provided a 7.1% adjustment for SCHs but provided no adjustment for other rural hospitals. CMS proposes to continue this policy in CY 2007.

The MMA-mandated study was intended to coincide with the scheduled expiration of "hold-harmless" payments for small rural hospitals on December 31, 2005. The payments were subsequently extended through December 31, 2008, with a gradual phase-down of the payment amount.

HANYS supports the continuation of the 7.1% adjustment for rural SCHs. However, given the phase-down and eventual elimination of rural hold-harmless payments, we urge CMS to revisit its analysis of the cost of providing outpatient care in rural hospitals and to propose an adjustment for other rural hospitals in CY 2008 or CY 2009, if justified by the analysis.

OPPS: NON PASS-THROUGH DRUGS, BIOLOGICALS, AND RADIOPHARMACEUTICALS

The MMA required that payment for specified covered outpatient drugs be equal to the average acquisition cost for the drug for that year as determined by the Secretary, subject to any adjustment for overhead costs and taking into account the hospital acquisition cost survey data collected by the General Accountability Office (GAO). For CY 2006, CMS paid for the acquisition and overhead costs of separately paid drugs and biologicals at a rate based on the average sale price (ASP) plus 6%.

For CY 2007, CMS proposes to set payment for these drugs at the ASP plus 5%. CMS believes that this payment level would serve as the best proxy for the combined acquisition and overhead costs of separately payable drugs and biologicals in CY 2007.

The proposed payment reduction would result in hospital outpatient department rates that are less than the payment for the same drugs and biologicals provided in physician office settings where the rate would remain at the ASP plus 6%. We believe that there is no justification for lower payments in hospital outpatient departments. **We recommend that CMS maintain the payment rates for separately paid drugs and biologicals at the rate of ASP plus 6% for CY 2007.**

OPPS: BRACHYTHERAPY

CMS proposes to discontinue the current policy of providing payment for radioactive sources for brachytherapy at hospital charges reduced to cost and instead pay for them based on aggregate hospital mean costs as derived from the 2005 claims data. CMS notes that a GAO report on payment for radioactive sources used in brachytherapy was published in July 2006, but states that it was not available in time to review and discuss in the proposed rule. **CMS should continue payment under the current policy in CY 2007 and evaluate the GAO recommendations and any related payment changes in the proposed rule for CY 2008.**

Further, CMS did not provide an estimate of the effect that this change would have on payments for brachytherapy sources. We are concerned that the change could have a significant impact on hospitals that provide this service. **CMS should evaluate the impact of any proposed change in brachytherapy payments before acting.**

DEVICE-DEPENDENT APCS

CMS proposes to reduce the Ambulatory Payment Classification (APC) payment for selected APCs in cases in which an implanted device is replaced without cost to the hospital or with full credit for the removed device. CMS proposes to adjust the APC payment rate by the entire cost of the replaced device. However, CMS should recognize that hospitals incur administrative handling costs associated with a replacement device. **Therefore, CMS should evaluate the proposed percentage offsets related to**

recalled devices to ensure that they take into account administrative resources and associated handling costs required to provide the replacement devices.

In addition, CMS should differentiate between replacement with an equivalent device and replacement with an upgraded, higher functioning device. In these cases, the hospital will often be responsible for paying the price difference between the upgraded device to be implanted and the replaced device that is being removed.

PARTIAL HOSPITALIZATION

HANYS is concerned that an additional proposed 15% reduction in the per diem payment rate for partial hospitalization services could harm the financial viability of partial hospitalization services in hospitals and health care systems, and could endanger Medicare beneficiary access to them. This will be the second year in a row that the per diem rate was reduced by 15%; hospitals cannot sustain further reductions in the per diem rates. These services already are quite vulnerable, with many programs in recent years closing or limiting the number of patients they can accept.

HANYS supports AHA in recommending that CMS freeze payment rates for partial hospitalization services at the 2006 level of $245.65 in the final OPPS rule for 2007. This approach will provide payment stability for these services and protect beneficiary access while allowing CMS adequate time to address the instability in the CMHC data. HANYS requests that CMS better define how it is monitoring and working with CMHCs to improve their reporting.

We understand CMS' concern about volatility of community m ental health center (CMHC) data and support the agency's intent to monitor CMHC costs and charges for these services, and work with CMHCs to improve their cost reporting so that payments can be calculated based on better empirical data.

CAHs: EMERGENCY MEDICAL SCREENING

CMS proposes to revise the CAH conditions of participation to allow registered nurses to serve as qualified medical personnel for emergency medical screenings. **HANYS supports this proposal, which will provide CAHs with the staffing flexibility needed to maintain access and provide efficient emergency and urgent care services.**

HANYS appreciates having the opportunity to comment on the proposed rule. If you have any questions regarding our comments, please contact me at (518) 431-7704 or at jchang@hanys.org, or Steve Harwell, Director, Economic Analyses, at (518) 431-7777 or at sharwell@hanys.org.

Sincerely,

Ju-Ming Chang
Vice President, Economics, Finance, and Information

JC:do

Submitter : Mr. James Hugh **Date:** 10/10/2006

Organization : AMAC

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Re: CMS 1506-P SEE ATTACHMENT

CMS-1506-P-431-Attach-1.DOC

AT131

October 9, 2006

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

Re: CMS 1506-P

Dear Dr. McClellan:

AMAC® performs billing and consulting services with more than 800 cancers center nation wide both hospital and freestanding. We work with providers and act as a liaison to third party payors.

We would like to recommend the following:

1. Leave the image guided SRS codes G0339 and G0340 in the current APC payment rate till better data is gathered. CMS has acknowledged in the past it does take considerable time for hospitals to start charging correctly for new services 1-2 years. These codes were available for use in 2004 and data in 2004 and early 2005 should not be utilized.
2. The new IGRT code 77421 should remain at the 2006 level until further data is gathered as this code is less than one year old.
3. The high activity sources, C2634 and C2635 used in eye plaques are severely undervalued and do not approach the average cost. We recommend that all sources with the exception of C1718 and C1720 continue to be paid at cost to charges until correct reimbursement can be worked out.
4. Hyperthermia charges 77600-77620 were reduced substantially and further review is needed.

Thank you for your attention to these matters.

The societies that we at AMAC® work with have sent in letters addressing a number of items in detail and we support all of those by AFROC, AAPM and ASTRO.

Sincerely yours,

James E. Hugh III, MHA, CHBME, ROCC®
Senior Vice President
AMAC®

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Submitter : **Mr. Jason Chandler** **Date: 10/10/2006**

Organization : **BrainLAB, Inc.**

Category : **Private Industry**

Issue Areas/Comments

Radiology Procedures

Radiology Procedures

Please see attached comment letter. Thank you for your consideration.

CMS-1506-P-432-Attach-1.DOC

#1132

BrainLAB

BrainLAB, Inc.
3 Westbrook Corporate Center · Suite 400
Westchester · IL 60154 · USA

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brainlab.com

October 6, 2006

Via Electronic Filing and Hand Delivery

Mark B. McClellan, M.D., Ph.D.
Administrator, Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attn: CMS-1506-P
7500 Security Boulevard
Baltimore, Maryland 21244

Re: CMS-1506-P -- Comments to the HOPPS Proposed Rule:
APC Assignment for Stereoscopic X-ray Guidance: HCPCS Code C9722 / CPT 77421

Dear Dr. McClellan:

BrainLAB appreciates this opportunity to submit comments on the proposed rule updating the Medicare hospital outpatient prospective payment system ("HOPPS") as set forth in the Proposed Changes to the Hospital Outpatient Prospective Payment System for Calendar Year 2007, 71 Fed. Reg. 49506 (August 23, 2006).

BrainLAB develops, manufactures, and markets software-driven medical equipment to provide advanced radiotherapy, radiosurgery, and neurosurgery services, among other things. Accordingly, the company is keenly interested in the impact CMS's proposed changes to HOPPS payments for 2007 would have on its products and on patient access to the medical services performed using its technologies.

Specifically, BrainLAB wishes to comment on the insufficient payment rate proposed for CPT Code 77421 Stereoscopic x-ray guidance which describes our ExacTrac x-ray guidance system. As many of the CMS medical officers may recall, BrainLAB and a distinguished group of neurosurgeons from across the country worked with the Division of Outpatient Care, Dr. Bill Rogers (Director, PRIT Team), and various staff in the Administrator's office to obtain a new code for stereoscopic Kv x-ray (C9722 Stereoscopic Kv X-ray). CMS medical officers and staff made a trip to Philadelphia to see the Stereoscopic Kv x-ray technology and how it is used to more accurately guide radiation treatment for cancer patients. Subsequently for 2005, CMS established C9722 to describe the technology. C9722 transitioned to CPT code 77421, effective January 1, 2006.

Unfortunately, this first year of claim data for C9722 is at striking odds with the reality of the hospitals' costs. For the reasons explained in greater detail below, we **respectfully request that CMS reassign CPT 77421 to APC 296 Level II Therapeutic Radiologic Procedures to more accurately reflect the true costs associated with providing this very important service to cancer patients.**

Background on Technology and Procedure

The ExacTrac stereoscopic Kv x-ray guidance system uses a combination of Kv x-ray imaging and infrared tracking to correlate the exact location of internal tumors being treated with

radiation. The ability to visualize the exact location of a moving target in real-time enables more precise, respiration-triggered dose delivery of radiation therapy. As a result, significantly more normal tissue may be spared from radiation, leading to reduced side effects and better treatment outcomes for patients. This technology also permits verification of images at any time during treatment delivery.

In the HOPPS final rule for 2005, CMS recognized the value of stereoscopic Kv x-ray guidance with infrared tracking and established a temporary C code – C9722 –which became effective on January 1, 2005. Moreover, CMS encouraged the specialty societies to establish a new CPT code for this procedure and to "evaluate the resources necessary to provide this service" (see 69 Fed. Reg. at 65,714). The medical community and the AMA CPT worked together, and effective January 1, 2006 stereoscopic Kv x-ray was assigned a new CPT code, 77421 Stereoscopic x-ray guidance.[1] As part of this process, the specialty societies surveyed physicians using the technology and gathered data on the practice expense components (costs of supplies and equipment). In turn, this data was conveyed to CMS and staff further evaluated the practice expense data for the "technical' component. After this extensive process in 2006, CMS established that the costs related to the technical component for stereoscopic x-ray guidance should be valued at about $130 per procedure. BrainLAB's technology is currently the only procedure described by CPT code 77421.

Proposed Change and New APC Assignment

Under the HOPPS proposed rule for 2007, CMS proposes to assign CPT code 77421 to APC 257 Level I Therapeutic Radiologic Procedures. The $60.14 payment rate for APC 257, however, severely under-represents the true costs associated with providing ExacTrac Kv x-ray guidance services. APC 257 is designed for much simpler and less resource-intense procedures than ExacTrac stereoscopic Kv x-ray, which is far more sophisticated and technologically complex.

As you may recall, CPT 77421 stereoscopic Kv x-ray guidance for tumor localization requires, at minimum,

- Two infrared cameras;
- Computerized data system and image analysis system;
- Two 80-100 kiloelectron volt (Kv) x-ray tubes;
- Infrared sensitive tissue markers; and
- Specialized treatment planning software.

The procedure requires a radiation technician in addition to the physician and takes at least 15 to 30 minutes, per procedure.

Under the Medicare physician fee schedule (MPFS) for calendar year 2006, the global payment rate for CPT 77421 is $151.59, of which $131.13 represents the technical component for providing the service. As you know, in establishing payment under the MPFS for the technical component, the relevant specialty societies surveyed the physicians using this technology and carefully mapped out all the practice expense inputs. This cost information was

[1] Previously, ExacTrac was assigned to HCPCS code C9722.

then closely examined and reviewed by CMS staff prior to establishing the practice expense relative value units (RVUs) for stereoscopic Kv x-ray guidance, last year.

Given the extensive research and review that went into establishing the practice expense RVUs, we believe that in this particular instance, for this new and very sophisticated technology, it would be inappropriate to ignore the MPFS practice expense cost information. Thus, rather than using the very limited hospital claim data, we recommend that CMS use the cost data developed and reviewed for the MPFS to establish (or benchmark) payment for stereoscopic Kv x-ray. CMS has implemented a variety of buffering mechanisms and/or alternate data sources when proposed changes would result in significant reductions in payment. Therefore using the MPFS practice expense data to avoid radial reductions would be consistent with CMS's overall policy to preserve access to services potentially threatened by precipitous payment decreases.

Unintended Consequences–Impact of Improper APC Assignment and DRA Cap on MPFS

In the Deficient Reduction Act of 2005, Congress mandated that the MPFS payment for certain imaging services not exceed the HOPPS payment rate. Thus, in this instance, the proposed assignment of CPT 77421 to APC 257 with a payment rate of $60.14 also would result in more than a 50% cut in payment under the MPFS for this new therapeutic imaging guidance service, if the DRA cap is applied as proposed. For this reason, it is especially important for CMS to properly assign new imaging guidance technologies such as stereoscopic Kv x-ray guidance to the most appropriate APC.[2] We also believe that when CMS has more accurate cost information, as in this case, it is appropriate to use that information to avoid precipitous reductions in payment.

Wide Variation in Median Costs Supports using Mid-Point or Other CMS Data

CMS has based the proposed 2007 HOPPS payment for CPT 77421 on a small number of single claims from a very limited number of hospitals. We understand that the proposed payment is based on the "median" costs derived from these claims. However, taking a broader perspective on the claims file one sees that CMS's calculated costs for this procedure range from $15 to $316. Thus, we believe that the APC payment could be more accurately reflected by a payment amount in the $150 range (which is closer to the cost data reviewed under the MPFS).

Reassignment to Clinically Similar APC with Similar Resources

For all the reasons discussed above, BrainLAB encourages CMS to reassign CPT code 77421 to APC 296 Level II Therapeutic Radiologic Procedures. Assignment to this APC will be more appropriate clinically and will correspond to a much greater extent to the resources hospitals use to furnish stereoscopic Kv x-ray guidance procedures. The proposed payment rate for APC 296 in 2007 is $166.84. Other procedures under APC 296 include:

- 74480 X-ray control, cath insert, and

[2] We support ACR and other specialty societies recommendations and feel that when imaging guidance is used to facilitate a surgical procedure or treatment, those codes should not be defined as diagnostic imaging nor included on the list of codes subject to the DRA provisions.

- 74485 X-ray guide, GU dilation.

Both of these procedures are similar in resource use (costs) and clinical complexity to stereoscopic Kv x-ray guidance to localize tumor/target volume.

Federal regulations state that APCs should include clinically similar procedures that involve similar resources. When, as with ExacTrac, hospitals are under-reimbursed because a CPT code has been incorrectly assigned, there is financial pressure not to perform the procedure. This is inconsistent with CMS' goal of ensuring access to clinically-appropriate care for all Medicare beneficiaries.

CMS can easily correct the problems caused by inadequate payment rates for ExacTrac X-ray guidance by reassigning CPT code 77421 to APC 296 or another APC which more accurately reflects the true costs associated with providing ExacTrac X-ray guidance services to cancer patients.

BrainLAB's ExacTrac X-ray product allows physicians to provide a more accurate treatment that improves medical outcomes for cancer patients undergoing radiation therapy. Therefore, we respectfully request that CMS act now to preserve patient access to this clinically valuable and economical technology by placing it into a more appropriate payment category such as APC 296 in 2007.

* * * *

We appreciate your attention to this important matter. Please contact me at 440.213.3951 or Gail Daubert at 202.414.9241 for any further information you may need.

Sincerely,

Jason Chandler

Jason Chandler
Director of Business Development, BrainLAB

cc: American College of Radiology, Pam Kassing, Director
Elizabeth Richter, Director, Hospital and Ambulatory Policy Group, CMS
Terry Kay, Deputy Director, Hospital and Ambulatory Policy Group, CMS
Carol Bazell, Director, Division of Outpatient Care, CMS
Ken Simon, M.D., Medical Officer, CMS

Submitter : **Ms. Dale Kach** **Date: 10/10/2006**

Organization : **Yale New Haven Hospital**

Category : **Hospital**

Issue Areas/Comments

OPPS Impact

OPPS Impact

October 8, 2006/Leslie Norwalk/Acting Administrator
Centers for Medicare and Medicaid ServicesDepartment of Health and Human ServicesAttn: CMS-1506-PMail Stop C4-26-057500 Security BoulevardBaltimore, MD 21244-1850
Re: Proposed Rule: Medicare Outpatient Prospective Payment System for CY 2007Dear Ms. Norwalk: On behalf of Yale New Haven Hospital, I welcome the opportunity to comment on the August 8, 2006 proposed OPPS rule. Yale New Haven Hospital is a 944 bed tertiary referral medical center and is the primary teaching hospital for the Yale Medical School.
Our emergency department cares for over 95,000 patient encounters annually.After extensive evaluation and testing of available ED facility coding methodologies, the Yale system elected to implement a problem based facility approach in 2002. We believe that this approach is superior to other available methodologies including the interventional approach suggested in the August 8, 2006 proposed rule.CMS guidelines and other CMS OPPS directives lead to our choice of the Lynx Medical Systems facility outpatient problem based approach. Our initial analysis and subsequent experience with the LYNX problem based approach illustrate that this approach has allowed the Yale system to be consistent, and complaint in our outpatient facility coding. The Lynx Medical Systems approach has allowed us to satisfy CMS OPPS guidelines.Our audits have determined that the problem based approach results in a nearly normal distribution which accurately describes resource facility use at Yale New Haven Hospital Emergency Department. The data set resulting from a consistent, measured facility coding approach allows us to better predict resource work needs and therefore accurately account and budget for these needs. This data unquestionably helps us justify facility management resources and therefore staff to insure the highest quality of care. We analyzed the August 8, 2006 CMS OPPS intervention based proposal with great care.Yale has had experience with an interventional facility coding model and found it to be insufficient in meeting CMS facility coding guidelines. We also find the facility coding model described in the August 8, 2006 proposal to be complicated and cumbersome.In particular, use of the revised AHA/AHIMA facility coding model described in the proposal leads to a distribution which does not reflect facility resources used. In fact, utilization of the proposed revised AHA/AHIMA model results in a visit distribution composed predominately of 99281 visit levels. The proposed revised AHA/AHIMA model is difficult to implement, understand, inconsistent and leads to coder confusion. Also with the overcrowding of emergency departments, especially in Connecticut the AHA/AHIMA model would require a change in nursing documentation focus. This change would adversely impact an already burdened nursing staff We are very satisfied with a problem based facility coding approach. This currently implemented problem based approach is easy to use resulting in a visit level distribution reflecting resource use. Consistent results demonstrated across our Emergency Department setting speaks to the problem based approach and standardized characteristics. We have found that our current problem based approach is easy to learn and use after completing a web based one hour educational module. The ease of use is demonstrated by the fact that the system methodology is consistently used by RN s, coder s and department clerks. In summary, Yale has experience with interventional facility coding models and our current problem based approach. Our experience indicates that our current problem based approach is the best available model allowing for consistent, compliant and standardized use for facility visit level assignment. Yale New Haven Hospital encourages CMS to reconsider its proposal to implement an interventially based coding model and consider a presenting problem based approach.

Submitter : **Mrs. Wynee Rich** **Date: 10/10/2006**

Organization : **Lexington Medical Center**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

Regarding the 2007 proposed reimbursement for Bexxar acquisition and administration to NHL patients- G3001, A9544, and A 9545 - Hospitals will not be able to financially offer this life sparing treatmnent under the proposed reimbursement. The cost to hospitals would be approximately double the reimbursed amount. Please review, and we strongly urge you to reconsider! Thank you!

Wynee Rich, RTT, Quality Reviewer

Submitter : Dr. Alfred R. Smith, Ph.D. **Date:** 10/10/2006

Organization : Particle Therapy Cooperative Group

Category : Health Care Professional or Association

Issue Areas/Comments

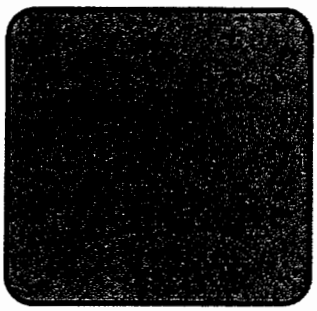
GENERAL

GENERAL

See Attachment

CMS-1506-P-435-Attach-1.PDF

#1135



September 30, 2006

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

RE: Proton Therapy Payment Rates

Dear Dr. McClellan:

We are writing to you on a matter of great importance to the proton therapy community. More than 40,000 cancer patients have been treated with proton therapy in institutions in the United States and across the world. Proton beam therapy, due to its recognized and desired physical properties, has the clinical advantage of being significantly more precise in treatment delivery. Therefore, higher radiation doses can be delivered to malignant tissues, leading to higher rates of local control. Positive clinical results achieved with proton beams have stimulated worldwide interest in the clinical applications of proton therapy and, consequently, two additional facilities opened in the United States this calendar year.

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

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

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

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

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

STATEMENTS OF CONCERN REGARDING FREESTANDING FACILITIES

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

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

Comparison of Freestanding Centers' Proton Therapy Rates by State			
	Indiana – Current	**Florida – Proposed 9/11/06**	**Texas – 9/1/06**
77520	—	$750.63	$652.75
77522	$496.83	$776.90	$653.90
77523	$811.33	$806.93	$783.79
77525	$856.12	$900.76	$954.41

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

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

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

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

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

CONCLUSIONS

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

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

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

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

Sincerely,

Alfred R. Smith

Alfred R. Smith, Ph.D.
Chairman, Particle Therapy Co-Operative Group (PTCOG)

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

Organization : **Cardiology Advocacy Alliance**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Radiology Procedures

Radiology Procedures

see attachment

CMS-1506-P-436-Attach-1.PDF

#436

CARDIOLOGY
ADVOCACY
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National leadership on issues that affect cardiovascular patients and their physicians 734.878.5449 • mburrage@cardiologycaa.com

October 10, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P
P.O. Box 8015
Baltimore, MD 21244-8015

Re: Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; CY 2007 Update to the Ambulatory Surgical Center Covered Procedures List; Ambulatory Surgical Center Payment System and CY 2008 Payment Rates;(Federal Register, August 23, 2006)

Dear Dr. McClellan:

On behalf of our 4,200 members, the Cardiology Advocacy Alliance (CAA) appreciates the opportunity to submit comments to the Centers for Medicare and Medicaid Services (CMS) regarding the above proposed rule. Specifically, we would like to comment on the proposed "**Radiology Procedures**" regarding Cardiac Computed Tomographic angiography (CTA) under the Deficit Reduction Act (DRA) implementation provisions.

Under the billing procedures set forth by the Centers for Medicare and Medicaid Services for Temporary (tracking) Codes, Category III codes are not assigned a Relative Value Unit cost. As Category III codes, they are carrier priced. The eight CTA codes (0144T-0151T) remain in the coding cycle as Category III codes and therefore should not fall under the Deficit Reduction Act implementation provisions.

The DRA crosswalks only Category I codes to the Ambulatory Surgical Center (APC) codes, not procedures designated as Category III codes (which by definition are not assigned an RVU amount). Therefore, Category III codes, specifically the eight cardiac

CTA codes, should not be considered under the DRA-mandated payment rates put forth by CMS in the above proposed rule.

In addition, the CAA disagrees with the decision of CMS to place the majority of Cardiac CTA procedures in Nuclear Medicine APCs. Cardiac CTAs are not nuclear medicine procedures, do not use the same resources and therefore should not be included in any Nuclear Medicine APC. We recommend that CMS remove all Cardiac CTA codes from the current APCs. If CMS determines the CTA codes should be crosswalked, CMS should place them in appropriate New Technology APCs. We will defer to comments being submitted by other medical specialties regarding the exact placements of those procedures.

We therefore urge CMS to either exempt the eight cardiac CTA Category III codes from the proposed rule or place them in the appropriate New Technology APC codes.

Sincerely,

Margo L. Burrage
on behalf of the members of
Cardiology Advocacy Alliance
11065 Home Shore Drive
Pinckney Michigan 48169
734.878.5449
mburrage@cardiologycaa.com

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

Organization : Accuray Incorporated

Category : Private Industry

Issue Areas/Comments

New Technology APCs

New Technology APCs

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

CMS-1506-P-437-Attach-1.PDF

#437

ACCURAY

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October 10, 2006

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

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

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

New Technology APCs

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

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

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

A detailed chronological history of SRS code development and usage since 2002 is provided in Appendix 1. The history illustrates how different types of SRS codes and descriptors have evolved over time to more accurately describe services and to more appropriately track associated claims, charges and costs. We applaud this strategy and encourage CMS to continue this process this year and in future years.

Over the years, Accuray has responsibly participated in the process by fostering relationships with providers, the CyberKnife® Coalition, and more recently with the professional associations. These efforts aim to assist appropriate and accurate comment development through providing factual information that only an equipment manufacturer can contribute to the process. It is for this reason that we join the many stakeholders who urge you to look at other information sources and external data in making classification, coding and payment rate decisions.

Proposed CY 2007 APC Changes

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

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

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

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

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

   Thus, although CMS looked at data from the years 2004 and 2005, they do not have claims data of two years' duration. It is our assertion that CMS does not in actuality

have two full years of data on which to propose revisions given that 67% and 43% of centers operated for less than the full year in 2004 and 2005, respectively. Resultingly, only the 12 centers operating in January 2004 would have been able to contribute claims data for the full 24 month period of 2004-2005. And at least 3 of those 12 centers operating since January 2004 are not included in the CY 2004 Identifiable Data Set Hospital OPPS file. We presume these centers are not included in the CY 2005 data; however, we are unable to verify this since the data is not yet available to us.

2. Further, as shared with us, the CyberKnife Coalition's analysis of the CY 2004 Identifiable Data Set Hospital OPPS file raises serious questions about the reliability of the claims as reported.

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

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

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

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

Historical Precedent – Gamma Knife New Technology Codes

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

Since the clinical process-of-care, resources utilized and related costs involved in providing intra- and extracranial image-guided robotic stereotactic radiosurgery using CyberKnife are at least as great as, if not greater than, the clinical process-of-care, resources utilized and related costs involved in the provision of intracranial radiosurgery using the Gamma Knife, the APC assignment should reflect a similar reimbursement.

Gamma Knife was maintained in temporary APC status for nearly 30 years while data was collected for review and determination of final rate setting. The proposed APC assignment for image-guided robotic radiosurgery for CY 2007 is based on less than two full years of data as well as a small number of claims (a total of 486 single billed claims for G0339 and 940 billed claims for G0340 for CY 2004). The CY 2005 Identifiable Data Set Hospital OPPS file is not yet available to us for purchase and therefore has not been analyzed. However, we expect that these trends will be evident proportionally, and possibly exclude even more centers from the "common working file".

Code Descriptors

Whereas most SRS codes are similarly worded with slight differences, the Gamma Knife codes have long included the "cobalt" terminology which, in practicality, results in codes that are vendor-specific, as there are no other cobalt-based SRS systems on the market. One byproduct of this is that practical application of the codes is very clear and there is likely very little confusion in the proper usage of the codes and the claims data are almost assuredly pure and easily interpreted.

G0339 and G0340 Code Descriptors

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

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

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

CY 2004 and CY 2005 Data Variability Summary

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

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

The 2004 Identifiable Data Set Hospital OPPS file identifies 25 centers reporting the G0339 / G0340 codes – however, at that time only 16 centers had dedicated image-guided robotic SRS equipment. As a result, the CY 2004 data are a mixture of data from all kinds of stereotactic radiosurgery procedures using various treatment modalities with vastly differing resource requirements. A clearer distinction among SRS codes through continued code descriptor refinement will help facilitate the collection of data for all types of SRS services and the eventual establishment of appropriate permanent rates for each, respectively.

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

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

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

Conclusion

The purpose of new technology HCPCS codes is to allow for collection of a comprehensive, stable data set with which to effect an analysis of the charges and costs associated with the new technology. We understand that two years is the statutory minimum amount of time for which CMS must have data before moving a covered service from a new technology code to a clinical code. In the case of CyberKnife, the minimum is insufficient. An analysis of two years of data is not enough due to the large number of new centers submitting less than a full year of data for 2004 and 2005 and the large number of centers with non-robotic equipment using the

image-guided robotic stereotactic radiosurgery codes. Thus, while G0339 and G0340 are a vast improvement over the original SRS codes, they are still unclear and potentially misleading, resulting in a lower median cost as non-robotic SRS procedures are being billed using the image-guided robotic SRS codes. There is clear precedent for maintaining new technology codes well beyond the minimum two years. Gamma Knife, for example, was maintained in temporary new technology codes for the first thirty years of its use. ***Thus the 2004 and 2005 Identifiable Data Set Hospital OPPS files result in an analysis of less than two full years of data. The data are not stable and do not accurately capture the resources used in r-SRS as is CMS's charge***.

Image-guided robotic stereotactic radiosurgery is still developing, with the CyberKnife the only dedicated r-SRS system in use to date. There is a plethora of non-claims information from a variety of non-CMS sources that may provide utility in the classification, coding and rate setting processes, particularly for newer technologies. We have shared with you the claims data analysis the CyberKnife Coalition undertook, with supplemental information that could have only been provided in a reliable fashion by the equipment manufacturer. By combining these data sources a clearer understanding of the practical usage of SRS codes was gained. We believe this presentation demonstrates the insufficiency of the CY 2004 and 2005 CMS data relative to r-SRS codes specifically. For this reason, we join the many stakeholders who urge you to look at external data in making your classification decisions.

Recommendations

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

►The code descriptor as proposed on page 4 for image-guided robotic stereotactic radiosurgery (r-SRS) could be used in a way that would promote more accurate capture of resources for all types of SRS procedures.

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

We thank you for the opportunity to review the proposed changes for 2007 and to submit comments such that there can be a greater understanding of clinical application of these new technologies resulting in appropriate payment rates for all SRS technologies.

Sincerely,

Wendy E. Wifler
Sr. Director, Health Policy & Payment
Accuray Incorporated

APPENDIX 1

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

CY 2002

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

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

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

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

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

CMS designated G0251 for treatment completed in stages, and priced the treatment using the payment for a single stage treatment (G0173), dividing the payment by 5, and allowing up to five payments. Under the payment methodology, each staged treatment was set at the national rate

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[1] Federal Register, November 30, 2001, page 59865.

[2] Federal Register, November 30, 2001, page 59866.

[3] CMS Program Memorandum A-02-026, 2002 Update of the Hospital Outpatient Prospective Payment System (OPPS), March 28, 2002.

of $1,125, which did not reflect the consistent use and cost of resources for each treatment.[4] As a result of this initial payment rate calculation methodology, CyberKnife centers continued to be underpaid for treatments 2-5.

CY 2003

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

CY 2004

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

CY 2005

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

CY 2006

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

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

Submitter : Mr. James T. Kirkpatrick **Date:** 10/10/2006

Organization : Massachusetts Hospital Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-438-Attach-1.DOC

#1128

October 10, 2006

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

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

Dear Dr. McClellan:

The Massachusetts Hospital Association (MHA), on behalf of our member hospitals and health systems, appreciates this opportunity to comment on the proposed rule for the FY 2007 Outpatient Prospective Payment System (OPPS).

HOSPITAL QUALITY DATA

In this proposed outpatient rule, CMS asserts that it is appropriate to link full payment for outpatient services to the submission of inpatient quality measures because several of the measures assess care that is often provided in the emergency department (e.g., aspirin and beta blockers for those thought to be experiencing a heart attack), and therefore if the hospital perfects the system for reliably delivering these medications, it is likely to have improved its processes to ensure a broader array of emergency and other ambulatory services are provided consistently.

However, we strongly disagree with CMS' proposed linkage of the reporting of the inpatient measures to payments under the OPPS. Many measures that can provide insights into the quality in outpatient care settings are being reviewed by the Hospital Quality Alliance and the AQA (formerly known as the Ambulatory Quality Alliance). We strongly urge CMS to continue to work with the HQA and the AQA to identify and implement measures that truly assess important aspects of outpatient care quality, and when appropriate measures have been identified, work with Congress to consider how the payment system should be altered to support the provision of high quality care in the outpatient setting. **CMS should not propose any outpatient reporting requirements until quality measures specific to outpatient services have been proposed and validated.**

In addition, CMS should not attempt to link the outpatient update to either inpatient or outpatient quality measures without explicit legislative authority. The update has been linked to quality reporting for both the inpatient PPS and the home health PPS. However, in both cases the link was authorized by statute. This is a clear indication that Congress regards such policies as subject to determination by legislation and does not intend that such actions be undertaken administratively. CMS should seek Congressional authorization before proposing to extend the link between quality and payment updates to other settings.

VISITS

Despite CMS's previous assurances that they would not create new codes to replace existing CPT E/M codes until national guidelines were developed, in 2007 CMS proposes to establish new Health Care Procedure Coding System level II G codes to describe hospital clinic visits, ED visits and critical care services. CMS proposes five levels of clinic visit G codes, five levels of ED visit G codes for two different types of EDs, and two critical care G codes. Until national guidelines are formally proposed and finalized, CMS states that hospitals may continue to use their existing internal guidelines to determine the visit levels to be reported with the new G codes, or they can adjust their guidelines to reflect the new codes and policies.

Implementation of new codes in CY 2007 without implementation of national guidelines will require hospitals to evaluate their current internal guidelines and revise them to be consistent with the new codes. Then, when national guidelines are implemented in a subsequent year, hospitals may again need to revise their coding procedures. This will cause an unnecessary burden and possible confusion for hospitals. **MHA joins the American Hospital Association (AHA) in opposing the proposed creation of temporary level II G-codes while continuing to allow hospitals to apply their own internal guidelines to these codes. Instead, CMS should defer creation of new evaluation and management codes until such a time as national coding definitions and guidelines are formally proposed, subjected to stakeholder review and published.**

PARTIAL HOSPITALIZATION

MHA is concerned that an additional proposed 15 percent reduction in the per diem payment rate for partial hospitalization services could harm the financial viability of partial hospitalization services in hospitals and health care systems, and could endanger Medicare beneficiary access to them. This will be the second year in a row that the per diem rate was reduced by 15 percent and hospitals cannot sustain further reductions in the per diem rates. These services already are quite vulnerable, with many programs in recent years closing or limiting the number of patients they can accept.

Although MHA recognizes that CMS made the proposal to avoid an even more significant reduction in the payment rate for these services that would be derived from using the combined hospital-based and CMHC median per diem cost, we do not believe that hospitals offering partial hospitalization services should be penalized for the instability in data reporting that stems from CMHC-based services.

Instead, MHA recommends that in the final rule for 2007, CMS freeze payment rates for partial hospitalization services at the 2006 level of $245.65. This approach will provide payment stability for these services and protect beneficiary access while allowing CMS adequate time to address the instability in the CMHC data. We further request that CMS better define how it is monitoring and working with CMHCs to improve their reporting.

OPPS: NONPASS-THROUGH DRUGS, BIOLOGICALS, AND RADIOPHARMACEUTICALS

The Medicare Modernization Act required that payment for specified covered outpatient drugs be equal to the average acquisition cost for the drug for that year as determined by the Secretary of Health and Human Services, subject to any adjustment for overhead costs and taking into account the hospital acquisition cost survey data collected by the General Accounting Office. For CY 2006, CMS paid for the acquisition and overhead costs of separately paid drugs and biologicals at a rate based on the average sale price plus 6%. For CY 2007, CMS proposes to set payment for these drugs at the average sale price plus 5%. CMS states that they believe that this payment level would serve as the best proxy for the combined acquisition and overhead costs of separately payable drugs and biologicals in CY 2007.

The proposed payment reduction would result in hospital outpatient department rates that are less than the payment for the same drugs and biologicals provided in physician office settings where the rate would remain at ASP plus 6%. We believe that there is no justification for lower payments in hospital outpatient departments and **we recommend that CMS maintain the payment rates for separately paid drugs and biologicals at the rate of ASP plus 6% for CY 2007.**

In addition, MHA agrees with the MedPAC finding that handling costs for drugs and biologicals delivered in the hospital outpatient department are significant and should be reimbursed by Medicare. We remain concerned that payments for specified covered outpatient drugs at the proposed rate for 2007, or even at the 2006 rate of ASP plus 6 percent, will not adequately reimburse hospitals for drugs that have very high overhead and handling costs due to special equipment or procedures related to the drug's toxicity, or special compounding or preparation requirements. **MHA recommends that CMS work with stakeholders to better understand the costs involved in the preparation of pharmaceutical agents, particularly those drugs that have very high handling costs due to special equipment or procedures related to the drug's toxicity, or special compounding or preparation requirements, and that CMS develop a new payment methodology that acknowledges and provides appropriate payment for those costs.**

Payment Policy for Radiopharmaceuticals. CMS proposes to no longer pay for radiopharmaceutical agents at hospital charge reduced to cost and instead pay for them at aggregate hospital mean costs as derived from the 2005 claims data. For brachtherapy sources, CMS proposes to pay on the basis of claims-based median cost per source for each brachytherapy device. We believe that it is too soon to end the current policy of paying at hospital costs due to concerns that the claims data are incomplete and may be incorrect as a result of frequent code and descriptor changes for radiopharmaceuticals. **Therefore, MHA recommends that for 2007, CMS continue using the current methodology of payment at charges reduced to costs for radiopharmaceuticals and brachytherapy sources.**

PROPOSED PROCEDURES THAT WILL BE PAID ONLY AS INPATIENT PROCEDURES

CMS proposes to remove 8 codes from the inpatient list, which identifies services that are unable to receive payment if they are performed in an outpatient setting and then assigns them to clinically appropriate APCs.

MHA remains concerned about the inconsistency between Medicare payment policy for physicians and for hospitals with regard to procedures that are on the inpatient list. It is our understanding that while Medicare will not pay hospitals if procedures on the inpatient list are performed in outpatient settings, but physicians would be paid their professional fee in such circumstances. There are a variety of circumstances that may result in such services being performed without an inpatient admission. For instance, because the inpatient list changes annually, physicians may not always be aware of that a procedure they have scheduled for performance in an outpatient department is on the inpatient list. There may also be other reasonable, but rare, clinical circumstances that may result in these procedures taking place in the absence of an inpatient admission.

MHA again recommends that CMS consider developing an appeals process to address those circumstances in which payment for a service provided on an outpatient basis is denied because it is on the inpatient list. This would give the provider an opportunity to submit documentation to appeal the denial, such as physician's intent, patient's clinical condition, and the circumstances that allow this patient to be sent home safely without an inpatient admission.

DEVICE DEPENDENT APCs

CMS proposes to reduce the APC payment for selected APCs in cases in which an implanted device is replaced without cost to the hospital or with full credit for the removed device. CMS proposes to adjust the APC payment rate by the entire cost of the replaced device. However, CMS should recognize that hospitals incur administrative handling costs associated with a replacement device. **Therefore, CMS should evaluate the proposed percentage offsets related to recalled devices to ensure that they take into account administrative resources and associated handling costs required to provide the replacement devices.**

In addition, CMS should differentiate between replacements with an equivalent device and replacement with an upgraded higher functioning device. In these cases the hospital will often be responsible for paying the price difference between the upgraded device to be implanted and the replaced device that is being removed.

TRANSPARENCY OF HEALTH CARE INFORMATION

People deserve meaningful information about the price of their hospital care. Hospitals are committed to sharing information that will help people make important decisions about their health care. Sharing pricing information, however, is more challenging because hospital care is unique. Providing meaningful information to consumers about the price of their hospital care is the most significant challenge hospitals, and CMS, face in increasing transparency of hospital pricing information.

MHA supports the AHA's recently released roadmap for hospital pricing transparency which outlines steps to be taken to improve the pricing information available to health care consumers. The following four steps are included:

1) A federal requirement for states, working with state hospital associations, to expand existing efforts to make hospital charge information available to consumers.

2) A federal requirement for states, working with insurers, to make available in advance of medical visits, information about an enrollee's expected out-of-pocket costs.

3) A federal-led research effort to better understand what type of pricing information consumers want and would use in their health care decision-making.

4) A hospital-led effort to create consumer-friendly pricing "language" – common terms, definitions and explanations to help consumers better understand the information provided.

The four points of this roadmap include an appropriate role for HHS, which should provide incentives to the states to improve transparency at the state and local level. HHS, through the Agency for Healthcare Research and Quality (AHRQ), is in the best position to complete research on what consumers want and would use in purchasing health care services.

If I can provide you with any additional information regarding our comments, please do not hesitate to contact me at (781) 272-8000, ext. 173.

Sincerely,

James T. Kirkpatrick
Vice President, Health Care Finance and Managed Care

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

Organization : **Sirtex Medical**

Category : **Drug Industry**

Issue Areas/Comments

OPPS: Brachytherapy

OPPS: Brachytherapy

See attached letter

CMS-1506-P-439-Attach-1.DOC

#1129

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October 5, 2006

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

Re: CMS 1506P; CMS 4125-P (Hospital Outpatient Prospective Payment Systems and CY 2007 Payment Rates)

Dear Acting Administrator Norwalk:

Sirtex Medical Inc. ("Sirtex") appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' ("CMS") Proposed Rule regarding the Hospital Outpatient Prospective Payment System ("HOPPS") and CY 2007 payment rates. Sirtex manufactures SIR-Spheres®, which are biocompatible radioactive resin spheres that contain Yttrium-90 ("Y-90") and emit beta radiation to treat unresectable colorectal cancer metastasized to the liver. Y-90 is one of twelve radioactive brachytherapy devices paid for by Medicare. Our main points are the following:

- **CMS should base brachytherapy source payments on the mean cost per source as is proposed for radiopharmaceuticals.**
- **CMS should conduct a survey to determine an adequate payment amount for the significant costs of storing, handling and disposing of brachytherapy devices.**
- **CMS should create mandatory code edits to ensure that hospitals uniformly and consistently report charges and costs related to the procedure and source.**
- **CMS should revise the proposed definition of brachytherapy sources to include all brachytherapy sources, without limitation.**

I. Payment Methodology

The payment methodology for radioactive sources associated with brachytherapy has been altered several times since the inception of the HOPPS in 2000. This has led to some degree of instability. Beginning that year, CMS was required to make separate pass-through payments for all radioactive sources associated with brachytherapy. Most recently, as mandated by the Medicare Modernization Act of 2003 ("MMA")[1], sources and procedures have been paid for separately at rates based on individual hospital's charges adjusted to cost. Beyond 2006, the MMA required separate payment for all brachytherapy sources, but did not specify a methodology for determining the separate payment amounts. Rather, it directed the Government Accountability Office ("GAO") to conduct a study and make recommendations regarding future payment for radioactive sources.

The GAO report[2] was released in July 2006 (a year-and-a-half past the deadline set by Congress) and recommends that CMS use CY 2005 claims data to set prospective payment rates for iodine and palladium brachytherapy sources *based either on the mean—as is currently done with certain high-cost drugs—or the median.* (The GAO did not consider the seven other brachytherapy devices because there isn't sufficient data from 2003-2004.) Although CMS acknowledges that the GAO report was not available in time to "review and discuss" in the CY 2007 proposed rule[3], the agency proposes to pay separately for all brachytherapy devices on a prospective basis in CY 2007, with rates to be determined using the CY 2005 claims-based *median* cost per source for each brachytherapy device.

While Sirtex understands CMS's desire to pay for all outpatient services on a prospective basis, we feel that brachytherapy sources should be paid in the same manner in which CMS proposes to pay for radiopharmaceuticals in CY 2007 - the *mean* unit cost across hospitals. Both radiopharmaceuticals and brachytherapy devices contain radioactive material and are subject to oversight from the Nuclear Regulatory Commission. In addition, radiopharmaceuticals and brachytherapy devices have the same storage, handling and disposal requirements. The distinction is that radiopharmaceuticals are given to the patient orally, injected, or placed into the eye or the bladder and enter into the patient's bloodstream. Brachytherapy treatment involves a surgical implantation of seeds (or radioactive source) in or near a cancerous tumor. Brachytherapy is targeted at the tumor within the cancerous organ while radiopharmaceuticals operate systemically.

In developing the proposal for appropriate radiopharmaceutical payment in CY 2007, CMS compared the payment rates for drugs and biologicals using both fourth quarter CY 2005 ASP data and mean claims data. The results of the data analysis indicated that *using mean unit cost to*

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[1] Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), Pub. L. No. 108-173, § 621(b) (2003).
[2] U.S. Gov't Accountability Office, Rates for Certain Radioactive Sources Used in Brachytherapy Could Be Set Prospectively (GAO-06-635, July 2006) [hereinafter GAO Report], available at: http://www.gao.gov/new.items/d06635.pdf.
[3] 71 Fed. Reg. 49506 (Aug. 23, 2006).

set the payment rates for drug and biologicals would be equivalent to basing their payment rates, on average, at ASP+5 percent. CMS concludes that this option provides the "most consistent, accurate, and efficient methodology for prospectively establishing payment rates for separately payable radiopharmaceuticals; in addition, (it is) consistent with how payment rates for other services are determined under the OPPS."[4] By opting to base payment for brachytherapy devices on the median unit cost, CMS effectively proposes to pay for them at a lower rate than any other drug, biological or radiopharmaceutical within the entire hospital outpatient system. We are concerned about the potential negative impact on beneficiary access to the Y-90 treatment, as it can currently only be performed in a hospital outpatient facility.

There are other situations in which CMS bases payment on the mean unit cost. As stated in the GAO report,

> "In paying separately for technologies that are not new, the Centers for Medicare & Medicaid Services (CMS) generally sets prospective rates based on the average unit cost of the technologies across hospitals. For example, CMS currently pays separate prospective rates for certain high-cost drugs *based on the mean per-unit acquisition cost*, as derived by CMS from data provided by drug manufacturers."[5]

In addition, in this proposed rule, CMS proposes to use mean costs of drugs determined using the hospital claims data in determining the packaging status of drugs and biologicals. CMS states that it limited its analysis to the mean costs, *instead of median costs*, because the Medicare statute specifies only that payment for specified covered outpatient drugs in CY 2007 be equal to the "average" acquisition cost for the drug.

Sirtex asserts that CMS has the authority and ample clinical rationale to use the same payment methodology for radiopharmaceuticals and brachytherapy devices, and urges the agency to maintain patient access to these critical treatments by reimbursing both based on the mean unit cost.

II. Storage, Handing and Disposal Costs

CMS asserts in the proposed rule that payment for storing, handling and disposing of Medicare Part B drugs, biologicals, radiopharmaceuticals and brachytherapy devices is adequately covered by the proposed prospective payment rates. Sirtex, however, is concerned that given the shift in payment methodology and the likely reduction in CY 2006 payment rates that result, hospitals will be unable to cover the source acquisition costs in addition to the storage, handling and disposal costs. The Ambulatory Payment Classification ("APC") Advisory Panel, which advises CMS on hospital outpatient coding and reimbursement issues, demonstrated its shared concern for CMS's policy of paying no additional fee to the hospital to cover these costs. At its March 2006 meeting, the Panel recommended that CMS "examine pharmacy overhead costs issues and

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[4] 71 Fed. Reg. 49587 (Aug. 23, 2006).
[5] GAO Report, p. 2.

work with appropriate associations to study how to measure pharmacy overhead costs."[6] Sirtex applauds CMS's agreement, as stated in this proposed rule, to continue to "work on" issues related to pharmacy overhead costs and when establishing a future pharmacy overhead cost methodology.

III. Claims Data Accuracy

As outlined above, there have been a significant number of changes to the payment methodology used for brachytherapy sources and procedures since the inception of the OPPS in 2000. In addition, brachytherapy is an emerging field within the oncology arena, and each year there have been several new products introduced on the market. As a result, hospitals have been faced with the significant challenge of implementing the new systems and re-training coders each year. Not surprisingly, there is a high rate of incorrectly coded claims.

Brachytherapy procedures always require the use of a brachytherapy device(s). Every hospital claim for brachytherapy treatment should therefore include at least one unit of a brachytherapy source HCPCS code ("C" code). Currently, as illustrated in table 1 below, the majority of hospitals do not include a brachytherapy source code on the procedure claims.

Table 1

Brachytherapy Procedure APC	**Percentage of 2005 Hospital Claims with a Brachytherapy Source "C" Code**
312 Radioelement Applications	29.6%
313 Brachytherapy	59.6%
651 Complex Interstitial Radiation Source Application	36.4%

Sirtex is concerned about the extent of the miscoding of brachytherapy sources and procedures and respectfully requests that CMS institute mandatory reporting of all medical device "C" codes to improve the quality of the claims data. This is especially critical given the fact that payment in CY 2007 will be based on claims data averaged across all hospitals. We also recommend that CMS consider implementing device code edits for all device-related and "device-dependent" APCs. Furthermore, we encourage CMS to accelerate its efforts to educate hospitals on the importance of accurate coding for devices and other technologies.

At the August, 2006 APC Advisory Panel meeting[7], the American Hospital Association (AHA), the Provider Round Table group, and the APC Advisory Panel members agreed that requiring the appropriate device code on the claim prior to processing and paying the claim would be beneficial to hospitals and would aid in educating them about the appropriate device C-Codes, particularly those for more complex procedures.

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[6] Advisory Panel on Ambulatory Payment Classification (APC) Groups, Panel Recommendations (March 1-2, 2006), available at: http://www.cms.hhs.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp.
[7] Advisory Panel on Ambulatory Payment Classification (APC) Groups, Panel Recommendations (Aug. 23-24, 2006).

IV. Definition of Brachytherapy

CMS has proposed to define a device of brachytherapy eligible for separate payment under the HOPPS as a "seed or seeds (or radioactive source) as indicated in section 1833(t)(2)(H) of the Social Security Act which refers to sources that are themselves radioactive."
Section 1833(t)(2)(H) of the Social Security Act states, "The Secretary shall provide for an additional payment under this paragraph for any of the following that are provided as part of a covered OPD service (or group of services)." Under this section, current cancer therapy drugs and biologicals and brachytherapy are defined as follows:

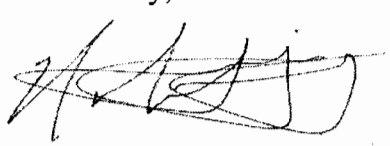
> "A drug or biological that is used in cancer therapy, including (but not limited to) a chemotherapeutic agent, an antiemetic, a hematopoietic growth factor, a colony stimulating factor, a biological response modifier, a bisphosphonate, and device of brachytherapy..."

Sirtex's understanding of the MMA legislation is that it intended to provide separate payment for all brachytherapy devices, *not* to exclude certain types of brachytherapy devices. New innovative, non-radioactive brachytherapy sources meet the criteria required by the legislation and are approved as brachytherapy devices by the Food and Drug Administration (FDA). By narrowing the definition of a brachytherapy source to a radioactive source only, CMS would not only limit access to new technology but also inadvertently eliminate Medicare beneficiary access to FDA approved cancer care.

V. Conclusion

Sirtex appreciates the opportunity to comment on the issues raised in the Proposed Rule, and looks forward to working with CMS to ensure that Medicare beneficiaries continue to have access to life-saving brachytherapy treatments such as Y-90. We sincerely hope that CMS will give thoughtful consideration to our comments and will incorporate our suggestions. Please do not hesitate to contact Nat Geissel, CEO, at 847-482-9023 or Desiree Gray, VP Marketing at 617-901-6808 if you have any questions regarding these comments. Thank you for the opportunity to comment on the proposed rule and your attention to this very important matter.

Sincerely,



Nat Geissel
CEO, Sirtex Medical Inc.

cc: Carol M. Bazell, M.D.