Submitter : Mrs. Sandra Aardsma **Date:** 10/09/2006

Organization : Advocate Christ Medical Center

Category : Nurse Practitioner

Issue Areas/Comments

GENERAL

GENERAL

Please consider reversing your proposal and continue current payment codes and rates. Your proposals are based on insufficient data from only a few centers located in only a few settings. Many centers are just getting under way such as our facility which just went up July 2006 in the Chicagoland area. This would greatly affect us and limit our ability to care for the many patients who would benefit from CyberKnife treatment because of these posposed fee reductions. Feel free to contact me as needed regarding my comments. Sincerely, Sandra Aardsma RN, BSN, OCN Coordinator, Chicago CyberKnife Radiosuregy Center - 1-866-684-2923

Submitter : Mrs. Cheryl Rice **Date:** 10/09/2006

Organization : Catholic Healthcare Partners

Category : Hospital

Issue Areas/Comments

APC Relative Weights

APC Relative Weights

The annual APC coding recalibrations and reassignments are necessary to account for differences in clinical proccesses, resource utilization, and technological advances. We support the proposed APC recalibrations and new APC reassignments for ongoing refinement of Fractures/Dislocations, Myocardial and Non-myocardial PET, Therapeutic Radiologic Procedures, Drug Administration Services, and Facility Evaluation and Management Services (Clinics, ER Type A Levels, ER Type B Levels, Critical Care).

CAHs: Emergency Medical Screening

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. Catholic Healthcare Partners supports this proposal which will provide CAHS with staffing flexibility needed to maintain access and provide efficient emergency and urgent care services. Currently hospitals have two separate documents that are used to outline care roles and responsibilities: the medical staff bylaws and the rules and regulations. Both documents have different review and approval processes. Similar changes to roles and responsiblities for EMTALA false labor certifications were recently made under the 2007 Inpatient IPPS rulemaking process. However is was noted that under the proposed inpatient rule the roles were to be documented in the "medical staff bylaws or rules and regulations" but in the final rule the roles appeared to limit documentation to the "medical staff bylaws" only. This wording has created some concern that CMS is requiring a more restrictive policy on "where" the roles and responsibilities are documented. We request that CMS clarify whether the designation as a "qualified medical personnel for emergency medical screening" is required to be outlined in the facility medical staff bylaws and/or hospital rules and regulations in order to meet Condition of Participation requirements.

Device-Dependent APCs

Device-Dependent APCs

CMS proposed 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 and added administrative fees for billing. 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 some cases the hospital will be responsible for paying the price difference between the upgraded device to be implanted and the replaced device that is being removed. The proposed rule did not provide guidance on how this situation should be addressed for billing purposes. Onc possible way to differentiate an upgraded device could be through the addition of another G code or application of an unique modifier, similar to the historic DME modifiers used to designate an upgraded or modified supply. We recommend that CMS should differentiate between replacements with an equivalent device and replacements with an upgraded higher functioning device.

GENERAL

GENERAL

On behalf of Catholic Healthcare Partners(CHP)and our affiliated twenty-nine acute care hospitals including our three Critical Access Hospitals, we appreciate the opportunity to comment on the proposed rule for the 2007 Medicare Hospital Outpatient Prospective Payment System (OPPS) policy and payment changes. This year's proposed rule contains several policy changes that not only have immediate impact on our hospitals' clinical and financial opertations, but also impact future initiatives with respect to the continued evolution and implementation of Health Quality Initiatives, Hospital and Clinic Evaluation and Management Visit coding, and our interactions with community free-standing Ambulatory Surgery Centers under new procedure and payment policies in 2008 and beyond. We appreciate CMS willingness to provide clarifications to existing definitions and policies that have been problematic for hospitals in general. Specifically we want to comment regarding the following proposed changes: (1) Health Quality Measures, (2) Healthcare Information Technology, (3) Special Packaged Services, (4) Cost to Charge Ratio (CCR) and Outlier Payments, (5) Observation, (6) APC Recalibration and APC Reassignments, (7) Facility Evaluation and Management Services, (8) Non-Pass Through Drugs, Biologicals, and Radiopharmaceuticals, (9) Device-Dependent APCs and Recalled Devices (10) CAH: Emergency Medical Screening and (11) Medication Therapy Managment Services. Attached you will find our specific comments and recommendations on the topics contained within the proposed rule. A second separate comment was filed regarding Visits as noted. Catholic Healthcare Partners appreciates the opportunity to submit comments for CMS considcration in effort to cooperatively work towards improved access, consistency in care, and quality in health services. If staff has any questions regarding these commcnts, please feel free to contact Cheryl Rice, Catholic Healthcare Partners Corporate Director of Corporate Responsibility at 513-639-0116 or clrice@health-partners.org.

Health Information Technology

Health Information Technology

Increasingly healthcare information technology is intertwined with clinical instrumentation, diagnostic interpretative services, and health information storage and retrieval. Hospitals are constantly challenged to balance the need for timely exchange of information between patient-physician-providers and the need for complete documentation to meet regulatory requirements under the Conditions of Participation (CoP), national and local medical necessity coverage policies, as well as other State and Federal laws. In particular, hospitals are challenged with finding health information systems that consistently incorporate automatic date-time technology, procedure start-stop time tracking, and electronic authentication to all clinician medical record entries (e.g. nursing assessments, physician progress notes, therapist notes). Under existing provisions within CoP and State laws, healthcare professionals are required to date, time, and authenticate entries to ensure professional accountability for the information. As healthcare facilities move away from paper-based documentation towards electronic media, providers are increasingly frustrated in determining how to meet the CoP documentation standards without having to supplement electronic media with additional paper-based

supporting documentation. Two issues continue to complicate implementation of healthcare information technology within the hospital setting: (1) the existing Conditions of Participation have conflicting requirements regarding the content and extent of documentation required for specific types of entries (i.e. surgical notes, History & Physicals, Nursing Assessments, interpretations) relative to date, time, and signatures, and (2) the lack of software HIT standards for documentation. We recommend CMS consider developing Conditions of Participation for use of HIT that is supportive of either existing CoP documentation requirements or consider revising current CoP documentation provisions based on prior rulemaking commentary that are still under consideration.

Hospital Quality Data

Hospital Quality Data

Our system and affiliated hospitals have voluntarily participated in the original CMS Health Quality Initiatives and continue to participate in the mandatory reporting now required under the Deficit Reduction Act Public Law 109-171. Catholic Healthcare Partners supports the development of national quality care standards and the need for pay-for-performance compensation for those healthcare facilities committed to providing quality care to all patients. Inpatient care often begins in an outpatient setting (e.g. Emergency Room services and or outpatient surgery); therefore, quality care should not be limited to inpatient care. We support the proposed policy to extend pay-for-performance incentives to outpatient services meeting specified national quality standards. Ambulatory surgical services are one subset of outpatient services impacted by quality standard changes as outlined in the 2007 OPPS Proposed Rule. Specifically, CMS is considering the adoption of three new measures in FY 2008 including the Surgical Care Improvement Project (SCIP) which monitors the prophylactic use of venous thromboembolism (VTE) and antibiotics for surgical patients. Under the current proposed OPPS policy, hospital-based ambulatory surgical services paid under APCs would be subject to a 2% reduction if national quality standards are not met. However, free-standing Ambulatory Surgery Center services are not currently being held to that same surgical quality reporting standard even though future payment may be based on the same OPPS APC payment used for hospital-based surgical services. If free-standing ASCs are not held to the same level of accountability and standards of care as hospital-based outpatient surgical services, CMS may be unintentionally re-establishing a two-tiered system of compensation for the same surgical procedure. We recommend that CMS consider requiring both hospital-based and free-standing Ambulatory Surgery Centers to be subject to the same surgical quality of care standards under the RHQDAPU program for OPPS in FY2008 and the same APC payment reduction if they fail to meet the applicable outpatient quality measures or fail to pass the 80% validation threshold. CMS' commitment to patient safety and quality must equally incentivize all providers, hospitals, ASCs, and physicians to report quality measures.

Medication Therapy Management Services

Medication Therapy Management Services

With the development of the new codes for Medication Therapy Management Services (MTMS), it is our understanding that these codes are to be used when the hospital-employed pharmacist has a face-to-face encounter with the patient for MTMS services. Quoting from an article from the American Society of Health-System Pharmacist: ' MTMS performed by a pharmacist are broadly defined and may include the following: providing education and training; monitoring medication compliance: modifying therapy; administering medication; formulating a treatment and/or follow-up plan; management of medication problems or complications; providing recommendations for disease prevention; and/or evaluating the patient's knowledge of medication and willingness to implement recommendations. MTM services may be initiated at the request of the patient and/or caregiver, payor, pharmacist, and/or other healthcare provider.' The question facing hospitals is whether a hospital pharmacist can bill Medicare Part B for these types of services. We have found conflicting information in our research between our Fiscal Intermediaries, CMS FAQs, Local Coverage determinations for specifie drug coverage, and the CMS manuals related to 'incident to' services within the hospital setting. State law in several of the states where our hospitals are located, permit pharmacist medication management if service agreements are obtained from the outside physician who refers the patient to the pharmacist. Our pharmacists have been in contact with colleagues who are either operating or considering operating outpatient specialized drug management clinics such as Coumadin Clinics. One of the options being considered is for the pharmacist to provide the MTMS services and bill using the existing facility low-level visit code 99211 as an evaluation and managment service. It is our understanding that at this time the 0115T code is not payable under Outpatient OPPS. The definition of 99211 includes the phrase, 'under physician supervision'. The pharmacists providing this service would be hospital employees and physician supervision in a hospital is often assumed. Patients in hospital-based outpatient clinics are typically referred to the clinic by their private physician. The hospital pharmacist would communicate any issues or problems to the patient's physician for proper management of the drug therapy. The pharmicists are in a unique position to provide this service because of their background in pharmaceuticals and extensive knowledge of drug interactions. Pharmacists often spend more time with the patients than the patient's physician to discuss the drug therapy, to review the patient's drug history and to check for drug interactions, and to explain the importance of drug compliance relative to the prescribe treatment regimen. We request that CMS clarify if this setup would meet the 'incident to' requirements in the hospital setting or would more stringent requirements have to be met under 'incident to' (e.g. similar to Cardiac Rehabiliation incident to clarifications). Previously on the CMS website under the Medicare Coverage Database, there was an article entitled 'Article for Documentation of Medical Management Services Billed Using CPT Code 99211 for Outpatient Hospital Clinics (A16427)'. This article is no longer on the website. Providers are unsure if the article was officially withdrawn due to a policy change, due to an oversight in the web conversion or due to other clarification. We request that CMS clarify if it has officially withdrawn the article and the previous instruction on billing pharmacist medication therapy management services under the facility visit code 99211. We also request that CMS elaborate further the options available for hospitals to account of pharmacist medication management, particularly when performed on an outpatient basis, from a billing and Cost Report perspective.

OPPS

OPPS

We support the existing Observation policy provisions and the new proposed APC designation for G0379 Direct admission by hospital for observation. However we are concerned that providers continue to struggle with denials under Medicare and Medicaid for Observation versus One Day Stay cases. The recently published 2007 OIG Workplan the QIO Ninth Scope of Work Special Projects also reiterate the concern for inappropriate use of Observation and One Day Stays despite the presence of a fairly stable and detailed Observation payment policy. Unlike past years, providers no longer are struggling with how to bill for the observation service itself. Instead the current issue facing providers is how to determine who should qualify for Observation versus an inpatient Admission. This dilemma is compounded by the fact that some providers are required to use different sets of clinical criteria depending on the payer. The lack of a single set of clinical criteria for patient placement complicates patient care, charting and documentation, clinical review and auditing. Physicians, Case Managers and Utilization Reivew must work twice as hard to ensure staff is properly educated on both sets of criteria and internal forms and documentation can accomodate the reporting of required elements. We recognize that commercial insurer policy is outside of CMS authority. However, CMS should be able to ensure uniformity in the criteria used to review cases billed under governmental Medicare and Medicaid programs. Presently hospitals and physicians in Ohio (including 23 of our 29 CHP-affilitated hospitals) are subject to two separate sets of proprietary clinical criteria in order to maked appropriate clinical placement determinations which include Observation.

The Ohio Medicare program requires the use of Milliman & Roberts Criteria, whereas, the Ohio Medicare Fiscal Intermediary QIO requires the use of Interqual criteria. Unlike other "required" CMS program elements such as the Conditions of Participation that are available online to Medicare and Medicaid provider for "free", both sets of proprietary criterion (i.e. Interqual and Milliman & Roberts) represent significant cost to hospitals to purchase and update. States like Ohio which are subject to two different clinical criteria are subject to unnecessary and costly operational redundancy. We do not believe it is the intent of CMS to support policies or practices that differentiate clinical and administrative care based on patient insurance or the lack thereof. This persistent dichotomoy within federally funded health coverage violates the spirit, if not the letter, of the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act (HIPAA) of 1996, and continues to drive up avoidable, administrative costs of healthcare that are unrelated to, and often in direct opposition to, safe, efficient, high quality medical care for all. We request that CMS consider the following policy alternatives: (1) migrate towards a national set of clinical criteria for all patient placement to Observation and Inpatient admission; (2) consider contracting with the proprietary vendors (e.g. Interqual and Milliman & Roberts) in order to secure "free" access to both sets of criteria for use by all Medicare and Medicaid providers; or (3) consider requiring future MACs and QIOs to provide as part of their oversight and review functions "free access" to both sets of criteria and therefore eliminating any undo financial burden for providers in states that require use of two standards.

OPPS: Cost-to-Charge Ratios

OPPS: Cost-to-Charge Ratios

We support CMS' decision to enforce a standard CCR calculation for both modeling and payment of outliers under OPPS. However, we are concerned that the proposed increase in the fixed Outlier Threshold from $1250 to $1825 will significantly reduce the number of outpatient cases that would qualify for outlier payment in 2007. The proposed $575 increase to the fixed outlier threshold is an offset due to an internal error found by CMS. In this instance, healthcare providers were not the source of the error; however, providers will be bearing the brunt of the penalty for the mistakes of the Fiscal Intermediary if the proposed Outlier Threshold of $1825 is approved. We request CMS reconsider the increase in the fixed Outlier Threshold amount proposed for 2007, and instead, consider offsetting the CCR calculation error by reducing administrative contract payments made to Fiscal Intermediaries by the error amount. In this manner, the Fiscal Intermediaries are held to the "same level" of financial accountability as providers are for their financial mistakes. In the alternative, if the outlier threshold must be adjusted to compensate for the error, a 46% one-year increase unfairly penalizes hospitals and should be phased in over three years to enable hospitals to plan for this significant reduction in payment for the sickest patients who cost hospitals significantly more than the nationally based average APC payment amount.

Packaged Services

Packaged Services

We appreciate CMS' willingness to review some of the coding challenges associated with packaged clinical procedures and to consider a packaged policy change to account for those procedures with dual use. We support CMS' review and determination to allow separate payment under a new proposed "special packaging" provision for codes 36540, 36600, 38792, 75803, 94762, and 96523. This policy will improve hospital reimbursement for legitimate services that are medically necessary, but were previously denied separate payment consideration when performed alone on a given date of service. We also support efforts to develop automatic payments via claim processing OCE logic edits rather than require manual intervention on the part of providers. We recommend that CMS issue a separate and more focused communication beyond the Federal Register notice to explain how the new OCE edit will function, what codes are subject to "special packaging", and most importantly, the specific rationale behind why other codes discussed in the August 23, 2006 Federal Register were not approved. The majority of incorrect, stand-alone coding identified by CMS included "guidance" codes typically associated with imaging procedures or surgery. Providers struggle with "guidance coding" because there are multiple "guidance" coding policies. Presently, "guidance" can be coded separately under its own CPT (ex. 75998, 76000), included in the overall CPT/HCPC procedure description (ex. 31622-31646, 43752, 62318, 62319, 62263, 62264, 70332, 70340, 73085, 73115, 73525, 73580, 73615, 74320, 74350, 74355, 74445, 74470, 74475, 75809) or reported separately if other combinations of procedures are reported (76003, 76005) on the same claim for the same date of service. Guidance is used not only as part of the diagnostic imaging or surgical intervention procedures, but also used for stand alone pre- or post- procedure planning (i.e. to verify placement or positioning, to check for patency). Providers need additional clarification on guidance coding (i.e Ultrasound, fluoroscopy) since current CPT and HCPC coding policy is not consistent and guidance technology is being used in new ways not currently captured by CPT/HCPC codes. We recommend that CMS and CPT/HCPC coding authorities review current "guidance" coding policy and consider future CPT/HCPC changes that will simplify guidance coding and improve overall coding compliance.

Policy and Payment Recommendations

Policy and Payment Recommendations

The Medicare Modernization Act required that payment for specified covered outpatient drugs (SCOD) be equal to the average acquisition cost for the drug 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 sales price (ASP) plus 6%. This payment was adopted by Medicare to standardize payments between physician offices and hospitals for like services, thus eliminating any potential for "site of service" selection based solely on which setting paid more for the drugs and biologicals. The underlying principle for the payment reform was to direct patients to the appopriate setting based on medical need not on payment. 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 serves as the best proxy for the combined acquisition and overhead costs of separately payable drugs and biologicals in CY 2007. However, this proposed rate eliminates the uniformity between physician office and hospital payments and re-establishes a payment differential based on the "setting of the service". This 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 hosptial 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.

Visits

Visits

Catholic Healthcare Partners strongly supports the development of national guidelines to help hospitals properly code for emergency room and clinic evaluation management services. We support the development of new temporary G codes to differentiate facility EM services and the phased implementation of multi-level Evaluation and Management (EM) services reflective of four types of patient care visits typically treated within hospitals and provider-based facilities: routine clinic services, urgent care, emergent care, and critical care. The four types of patient care represent different levels of clinical resource utilization, staffing, and

facility setup that are associated with the hospital "technical" charge. Based upon the clarifications provided in the August 23, 2006 Federal Register, it is necessary to distinguish between EM visits that are provided on a "scheduled routine" versus "unscheduled" basis and EM services rendered in a provider-based location to address life-threatening "emergent" care available on a 24/7 basis (Type A Emergency Room) versus acute but non-life-threatening "urgent" care (Type B Dedicated Emergency Department available during limited hours of operation) on a less than 24/7 basis. We agree with CMS' decision to eliminate the "new" versus "established" patient designation from the new EM level definition. We also agree with the proposed policy to create five separate levels within clinic visits, urgent care, and emergent care, but disagree with the proposed policy to only maintain three separate payment APC groupings. If it is necessary to differentiate resource levels into five categories, then it should be reasonable to have five different payment amounts commensurate with the incremental intensity of service and resource consumption. Critical Care services are readily identifiable but have been problematic to bill historically due to a variety of technical issues. As mentioned previously, hospital information systems do not typically record start-stop times automatically for procedures or nursing interventions. Without an automated process for tracking time, staff would have to revert to manual documentation in order to ensure compliance with the proposed minimum 30-minute threshold for Critical Care. In reality, the nature of Critical Care cases often preclude accurate time tracking because the cases often involve fast-paced activity, split-second decision-making processes, punctuated by specialized care procedures performed concurrently or sequentially by various team members. Documentation of Critical Care activities often is completed "after the crisis period" and when the patient is stable enough for staff to focus on other activities. Furthermore, most Critical Care cases typically result in the patient being admitted as an inpatient which "negates" the separate APC payment and replaces outpatient payment with an overall inpatient case DRG paymnet. Another complicating factor is that several states', including Ohio where several of our hospitals are located, Medicaid plans do not recognize Critical Care as a payable EM service for the hospital. Under the current Medicaid policy, the hospital is only paid a level 5 Emergency Room service even though the more intensive level of service is provided. We encourage CMS to standardize its policy across both Medicare and Medicaid programs to allow for payment of a single Critical Care level regardless of the time spent with the patient that is sufficiently reimbursed to reflect the high-intensity of activity by multiple care givers and prolonged one-on-one direct patient care. [A second separate comment will be filed on behalf by Catholic Healthcare Partners regarding additional commentary on Visit coding concerns]

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

Organization : Archbold Medical Center

Category : Hospital

Issue Areas/Comments

CAHs: Emergency Medical Screening

CAHs: Emergency Medical Screening

A revision of regulation 485.618 allowing CAHs to use qualified RNs to perform EMTALA compliant screenings the same as PPS hospitals is an efficient use of professional health resources. EMTALA standards should not be applied differently to CAH hospitals because emergency departments in both settings are fundamentally the same. CAH emergency departments treat proportionally high numbers of non-emergent patients as do PPS hospitals, thus have an equal nced to reserve finite physician services for emergency patients.

OPPS: Drug Administration

OPPS: Drug Administration

We bring before you this letter to once again comment and express our concerns to CMS the continuation into 2007 their decision to allow hospitals to bill only one IV push per drug administered per encounter. In 2006, during a Medicare teleconference, it was noted taht CMS did not intend to impose a reduction in reimbursement on the hospitals; however, significant reduction in Medicare reimbursement took place in 2006 and will continue into 2007. Since it is hard to bill one way for MC patients and another for other payers, there will be a significant reimbursement reduction across the board. CMS stated on pg 68677 of the 2005 OPPS Final Rule Fed. REg. that it "is not our intent to change the drug administration payment policies in place in 2005." Page 68679 states: "Thc CY 2006 CPT drug administration codes that we weill NOT be using in the OPPS for CY 2006 are codes taht require determiniation of initial, sequential, and concurrent infusions or IV pushes. The C codes will permit straight forward billing of types of infusions and IV pushes for the first hour and then each additional hour of infusion, or for each intravenous push, an approach to coding that commenters indicated was consistent with current patterns of delivery and billing of drug administration services in the hospital setting." Questions and concerns continued to be brought forth to CMS well after the comment period ended about these concerns through lctter, phone calls, telnets, etc. Despite repeated efforts, CMS did not change it's policy on IV pushes in 2006. Looking forward to 2007 it appears that IV pushes will remain the saem as 2006 as little mention to these eodes appears in the 2007 Proposed Rule. It's important to note that the cost and skill for administering the first dose of a medication is the same as administering subsequent doses of the same medication. CMS seems to suggest that the cost, skill, and training needed to administer and monitor for these subsequent doses is somehow less. For ER and Observation patients, it is common practice to administer multiple doses of a single drug during a patien's stay and we had been previously able to bill and receive reimbursement for each IV push, regardless of the medication type up until 2006. This change represents a requriement on hospital providers that is not administrable. Prior to 2006 the CPT code for IV injection was 90784, defined by CMS in 2005 as "an intravenous push injection in which the healtheare professional administers a substance/drug and is continuously present to administer the injection and observe the patient; or an infusion of 15 minutes or less." HCPCS code C8952 was created for 2006 to replace CPT code 90784,but new regulations were attached to C8952. Hospitals are now being restricted from billing multiples units of IV injections which had a negative impact in 2006 on our revenues, yet the description of the C code did not make any reference to a different drug/substance. This negative impact will continue to be detrimental to hospitals in 2007. CMS continues to instruct hospitals to code and bill for all medically necessary services that are provided to our patients. With so many services being provided on an outpatient basis, it becomes even more important to capture and charge for these services and to receive APC payments from Medicare. Over the last several years the trend has moved from Inpatient to Outpatient services, and these outpatient encounters can extend anywhere from one to 48 hours. During that period of time, the patient may require medication administration services, many of which may be the same substance. Prior years we had been coding and charging for each of these injections regardless of the substance/drug administered. Time taken to administer the same drug is not different from the time spent administering a different drug. The requirement to bill only one IV push per drug in each encounter is complex as the patient's care involves multiple settings

CMS-1506-P-364-Attach-1.DOC

CMS-1506-P-364-Attach-2.DOC

We bring before you this letter to once again comment and express our concern to CMS the continuation into 2007 the decision to allow hospitals to bill only one IV push per drug administered per encounter. In 2006, during a Medicare teleconference, it was noted that CMS did not intend to impose a reduction in reimbursement on the hospitals; however, significant reduction in Medicare reimbursement took place in 2006 and will continue into 2007. Since it is so hard to bill one way for Medicare patients and another way for other payers, there will be a significant reimbursement reduction across the board.

CMS stated on page 68677 of the 2005 OPPS Final Rule Federal Register that it is "not our intent to change the drug administration payment policies in place in 2005." Page 68679 states: "The CY 2006 CPT drug administration codes that we will NOT be using in the OPPS for CY 2006 are codes that require the determination of initial, sequential, and concurrent infusions or IV pushes. The C codes will permit **straight forward billing of types of infusions and IV pushes** for the first hour and then each additional hour of infusion, or for each intravenous push, an approach to coding that commenters indicated **was consistent with current patterns of delivery and billing of drug administration services in the hospital outpatient setting**."

Questions and concerns continued to be brought forth to CMS well after the comment period had ended about these issues through letters, phone calls, telnets, etc. Despite repeated efforts, CMS did not change it's policy on IV pushes in 2006 Looking forward to 2007 it appears that IV pushes will remain the same as 2006 as little mention to these codes appears in the 2007 Proposed Rule.

It is important to note that the cost and skill for administering the first dose of a medication is the same as administering subsequent doses of the same medication. CMS seems to suggest that the cost, skill, and training needed to administer and monitor for these subsequent doses is somehow less. For ER and Observation patients (which can be up to a 48 hour stay), it is common practice to administer multiple doses of a single drug during a patient's stay and we had been previously been able to bill and receive reimbursement for each IV push, regardless of the medication type up until 2006. This change represents a requirement on hospital providers that is not administrable.

Prior to 2006 the CPT code for IV injection was 90784. Defined by CMS in 2005 as "*an intravenous push injection in which the healthcare professional administers a substance/drug and is continuously present to administer the injection and observe the patient; or an infusion of 15 minutes or less.*" HCPCS code C8952 was created for 2006 to replace CPT code 90784, but new regulations were attached to C8952. Hospitals are now being restricted from billing multiple units of IV injections which had a negative impact in 2006 on our revenues, yet the description of the C code did not make any reference to a different drug/substance. This negative impact will continue to be detrimental to hospitals in 2007.

In 2006, CPT code 90784 was replaced with two codes: 90774 (for the initial push) and 90775 (for subsequent pushes). The definition for 90774 is "*intravenous push, single or*

initial substance/drug" and for 90775 it is, *"each additional sequential intravenous push of a new substance/drug*." This terminology references a "new substance" not a "different substance." We continue to believe the following statement from the AMA speaks clearly to the substance issue: According to the AMA, "*In the instances where the service consists of administration of only one syringe containing three non-chemotherapy drugs over 15 minutes, the single injection/substance IV push code 90774 would be reported one time only*." We are agreement that if multiple substances are injected in one push, we would only charge one initial push; however, we feel strongly that we need to report the exact number of IV pushes given during the patient's encounter.

CMS continues to instruct hospitals to code and bill for all medically necessary services that are provided to our patients. With so many services being provided on an outpatient basis, it becomes even more important to capture and charge for these services and to receive APC payments from Medicare. Over the last several years the trend has moved from Inpatient services to the Outpatient setting, and these outpatient encounters can extend anywhere from one to 48 hours. During that period of time, the patient may require medication administration services, many of which may be the same substance. In prior years we had been coding and charging for each of these injections (IV push) regardless of the substance/drug that was administered. The time taken to administer the same drug is not different from the time spent administering a different drug. Also, the requirement to bill only one IV push per drug or substance in "each encounter" becomes complex when one applies various clinical scenarios to the equation. As the patient is cared for in multiple settings within the hospital stay, it becomes very difficult to continue implementing these rules.

As we do appreciate the decision to reimburse for additional hours of IV infusion and hope the proposed APC changes will relax the CCI edit requirements; we must respectfully comment once again, and request that CMS reconsider the decision NOT to change the requirements and reimbursement for IV push administration. We have attached multiple scenarios for you to review so you can better understand the impact these issues have on our health care systems. We appreciate your continued review and consideration of this request.

#361

IV SCENARIOS

1. Patient is scheduled for a hernia procedure. Before the procedure is actually started she becomes tachycardic and receives 3 mg propranolol hydrochloride by IV push at **08:33**. Procedure is cancelled and patient receives another IV push of propranolol hydrochloride at **08:40** in recovery. With patient having Type 1 DM and complication of tachycardia patient is admitted to observation. Patient receives IV push of propranolol hydrochloride one last time 4 hours later at **12:40**.

Potential reimbursement 2005 - 3 IV pushes - $135.18	2005 - $135.18
2006 - 1 IV push - $43.19	2007 - $48.99
Loss – 2006 - $91.99	Loss - 2007 - $86.19

2. Patient is involved in a MVC and is brought to the ED. Patient complains of back and leg pain and has an obvious deformity to the right lower extremity. Labs and x-rays are ordered and an IV is started. An IV injection of Demerol and Phenergan is given at **15:00** for relief of pain and nausea after patient gets a good look at his leg. Labs and x-ray of back are negative, but obvious fracture of lower leg is noted. The ED physician contacts Ortho and patient is sent for surgery. The procedure goes well but patient continues to complain of nausea and pain. Another IV injection of Demerol and Phenergan is administered at **19:00** in recovery. Patient becomes hypertensive and vomits prompting admission to observation overnight. Observation orders include orders for Demerol and Phenergan to be administered by IV Q4 hours starting at **23:00** and given again at **03:00**, **07:00**, and **11:00**. An IV infusion of Labetalol is also started at admission to observation. The patient is discharged home the following afternoon. Demerol and Phenergan administered a total of 6 times.

Potential reimbursement 2005 - 6 IV pushes - $270.36	2005 - $270.36
2006 – 1 IV push - $43.19	2007 - $48.99
Loss – 2006 - $227.17	Loss - 2007 - $221.37

3. Patient comes to the ED with chest pain. An EKG, chest x-ray and lab work is ordered. Patient is hypertensive and continues with pain. Patient is given an IV injection of enalapril maleate at **12:00** and an IV injection of oxymorphone hydrochloride at **12:05** in the ED. Patient is admitted to observation with Unstable Angina. IV injections are to be continued Q6 hours, labs and EKGs are to be repeated as well. IV injection of enalapril maleate is given again at **18:00** and **24:00** and then discontinued when the hypertension becomes controlled. Oxymorphone hydrochloride is administered at **18:02, 24:00,** and **05:55**. Lab work is negative, but the patient has a questionable EKG and is scheduled for cardiac cath at 11:30. The cardiac cath is negative but patient still receives an IV injection of oxymorphone hydrochloride for pain in the cath lab at **12:03**. Patient is returned to the observation room and receives another IV injection of oxmorphone hydrochloride at **17:58** and is discharged later that evening. Enalapril Maleate is administered 3 times, Oxymorphone hydrochloride 6 times.

Potential reimbursement 2005 - 9 IV pushes - $405.54	2005 - $405.54
2006 – 2 IV pushes - $86.38	2007 - $97.98
Loss – 2006 - $319.18	Loss - 2007 - $307.56

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

Organization :

Category : **Congressional**

Issue Areas/Comments

Medicare Contracting Reform
Impact

Medicare Contracting Reform Impact

I am a LMHC currently working in a Partial Hospitalization Program, but I have also worked in an outpatient and residential setting. I have been in the field for over 6 years and have experienced the positive impact therapy can provide. I have also seen the negative impact denied coverage and reduced benefits can reap on a individual and a community. What saddens me is that my government continues to cut funding and help to individuals who do not have a voice in their government. Many people who receive Medicare are mentally ill, have limited income and therefore have limited resources to lobby their government and speak up for their issues. Therefore they rely on their congressmen to fight for them and be their voice. Unfortunately, it seems our government is more interested in special interests and issues where lobbyists have money to influence their government. It is short sighted of our government to cut funding for Medicare reimbursement. The government may feel they are saving money but in the long run more money will be spend on hospitalizations and incarcerations when people relapse, cannot afford their medications or experience a relapse in their mental illness. We need to be more preventative in our treatment of mental health issues and not wait until people suffer and become ill before we take care of our citizens.

A366

THE PINNACLE HEALTH GROUP
301 Oxford Valley Road, Suite 601B
Yardley, Pennsylvania 19067
215 369 9290 • 866 369 9290
www.thepinnaclehealthgroup.com

October 5, 2006

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

Re: Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates

Dear Dr. McClellan:

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

The Pinnacle Health Group provides coding and reimbursement support for hospitals and physicians across the country. This comment letter specifically addresses the proposed payment for hyperthermia therapy (CPT 77600-77620) in the proposed hospital outpatient rule for calendar year 2007.

Executive Summary

Hyperthermia is a type of treatment in which body tissue is targeted and exposed to high temperatures in order to damage and to kill cancer cells, or to increase the sensitivity of cancer cells to the effects of radiation and certain chemotherapy drugs. Hyperthermia may be induced by a variety of energy sources including microwave, ultrasound, radiofrequency or probes. Hyperthermia therapy is almost always used in conjunction with other forms of therapy (radiation therapy, chemotherapy, and biological therapy) to increase their effectiveness. With hyperthermia therapy the area may be heated externally with high-frequency waves aimed at a tumor from a device outside the body. To achieve internal heating, one of several types of sterile probes are inserted to the target site which facilitate the heating via thin, heated wires; hollow tubes filled with warm water; implanted microwave antennae; or radiofrequency electrodes. For therapy to be effective, the appropriate amount of heat must be applied to a specific area over a defined period of time. By controlling the heated volume, cancer cells are targeted while sparing the surrounding cells from becoming damaged.

Hyperthermia treatments include external (superficial and deep), interstitial, and intracavitary. Radiation therapy, chemotherapy or brachytherapy concurrently provided during cancer treatment are reported separately.

The following codes are reported by hospitals for hyperthermia treatment:

CPT	Description
77600	Hyperthermia, externally generated; superficial (ie. heating to a depth of 4cm or less)
77605	Hyperthermia, externally generated; deep (ie. heating to a depths greater than 4cm)
77610	Hyperthermia generated by interstitial probe(s); 5 or fewer interstitial applicators
77615	Hyperthermia generated by interstitial probe(s); more than 5 interstitial applicators
77620	Hyperthermia generated by intercavitary probe(s)

Claims Data Issues

Hyperthermia treatments (CPT 77600-77620) have mapped to APC 314 since 2002 with a history of very unstable median cost due to low procedure volume. For example, in the table below, the median costs for 77605 increased significantly from 2003 to 2004, yet dropped each year from 2005 and 2006. In addition, CMS reports no single claims (and hence no median cost values) for this code in 2007. As the second highest utilized code in the series, we are perplexed why no claims were reported for this period.

The Pinnacle Health Group contacted four hospitals to confirm that deep hyperthermia procedures (CPT 77605) were performed at their facility during 2005. Physicians from these facilities confirmed that the technology was utilized and the procedures were performed during this period of time. Although we could not confirm that the procedures were billed to CMS by these hospitals, it is most likely that the hospitals did not permit these procedures to be performed without reporting them to Medicare. These hospitals have owned and used this technology for over five years. It is perplexing that CPT 77605 does not appear in the CMS claims data system for 2007, but has appeared in each of the prior years.

Medians from Year to Year										
CPT	2003		2004		2005		2006		2007	
	Single Claims	Median Cost	Single Claims	Median Cost	Single Claims	Median Cost	Single Claims	Median Cost	Single Claims	Median Cost
77600	255	$229.37	227	$190.53	395	$200.17	264	$224.34	163	$164.06
77605	175	$392.39	114	$624.09	118	$540.00	131	$460.49	NA	NA
77610	14	$186.79	5	$211.89	1	$231.07	7	$328.06	4	$308.95
77615	4	$273.81	5	$490.67	34	$233.96	5	$365.80	25	$488.55
77620	0	0	0	0	0	0	1	$137.18	0	0

The percentage change in medians from year to year is significant due to low volume and the small number of facilities reporting procedures. For example, the percent change for this set of codes over the reporting period of 2003-2007 was substantial and seemingly unrelated. 77600 showed modest increase in 2004-2006, but dropped precipitously in the proposed 2006-2007 (-27%) while the medians for 77615 decreased substantially in 2004-2005 but increased the next two years.

Percent Change in Medians				
CPT	2003-2004	2004-2005	2005-2006	2006-2007
77600	-17%	5%	12%	-27%
77605	59%	-13%	-15%	-100%
77610	13%	9%	42%	-6%
77615	79%	-52%	56%	34%
TOTAL		-6%	33%	-32%

The payment rates for APC 314 have increased steadily from 2003-2006 (see table below) to fairly reasonable levels compared to the costs for the various hyperthermia procedures, (77600-77620). However, the proposed payment rate for 2007 is significantly lower than 2006 and is substantially lower than the median costs for this sequence of codes for hyperthermia.

APC 314 Payment Rates				
2003	2004	2005	2006	Proposed 2007
$199.54	$217.80	$251.20	$332.31	$225.17

CPT 77605 (Hyperthermia, externally generated; deep) is the second most performed hyperthermia procedure by hospitals. The CMS data indicate that NO procedures, single or multiple claims were reported that contained CPT 77605. This raises significant questions about the accuracy of the data. The table below outlines the rank order of each CPT in APC 314. From year to year 77600 has been reported with the largest number of procedure, followed by 77605. Clearly, the lack of any claims in 2007 raises the question of the accuracy of the claims data used to establish the median payment level for 2007.

CPT 77605 (Hyperthermia, deep) Single Claims					
CPT	**2003**	**2004**	**2005**	**2006**	**2007**
77600	255	227	395	264	163
77605	175	114	118	131	0
77610	14	5	1	7	4
77615	4	5	34	5	25

Data reported to CMS to establish the median costs for 77600-77620 originates from very few hospitals, most likely contributing to the unstable medians. The table below lists the number of hospitals reporting 77600-77620 for 2004 vs 2005.

Number of Hospitals Billing Hyperthermia Codes					
Year	**77600**	**77605**	**77610**	**77615**	**77620**
2004	16	8	5	5	1
2005	16	0	0	8	0

A maximum of 16 hospitals across the US reported hyperthermia codes (77600-77620) under APC 314. This is an extremely low number of institutions to provide reliable data on median costs for CPT 77600-77620.

Hospital Cost to Charge Ratio (CCR) Issues

There appear to be significant variances in hospitals cost to charge ratio (CCR) within the hospitals reporting costs for Hyperthermia. The Hospital CCRs for hospitals reporting Hyperthermia procedures range from 14% to 50%. The top five hospitals reporting Hyperthermia procedures in the CMS database have very different CCRs as indicated below.

2005 Imputed Hospital CCR			
Hospital	**Charge per line**	**Cost per line**	**Imputed CCR**
Hospital 1	$1,005	$136	14%
Hospital 2	$1,800	$525	29%
Hospital 3	$1,337	$183	14%
Hospital 4	$3,747	$878	23%
Hospital 5	$1,588	$641	40%

In July 2006 the GAO published a report titled "*CMS's Proposed Approach to Set Hospital Inpatient Payments Appears Promising*". This report discussed the use of overall hospital CCR use on the hospital outpatient rate setting process. The GAO report stated that *"hospitals vary in how they allocate revenue center charges to cost centers on their Medicare cost reports. When estimating costs for purposes of weighting APCs, however, CMS uses its own system of mapping the hospitals' revenue center charges to cost center CCRs in order to convert the charges to an estimate of cost. This can be problematic since hospitals may allocate their revenue centers to cost centers in a different manner from CMS."*

The GAO sited that "some hospitals allocate charges from the same revenue center to separate cost centers; others allocate charges from several revenue centers to a single cost center. CMS's use of a single method in mapping charges to costs and then applying that methodology across all hospitals for purposes of cost estimation does not recognize the differences in hospital allocation decisions when estimating costs. As a result, some service costs are "*systematically overestimated and some are underestimated.*" Further, the report states that *"The differences between aggregate estimates using the OPPS method and hospitals reported costs indicate that a single approach to mapping cost center CCRs to revenue center charges is problematic because CCRs are applied to certain charges that do not capture the cost-to-charge relationship for those charges."*

We believe that in the situation of hyperthermia codes (77600-77620), the combination of low utilization among few institutions, hospitals cost allocation methodology and CMS's application of hospital specific CCRs leads to the fluctuations in median costs of APC over the past five years and has resulted in a payment structure which does not support the use of the technology to help cancer patients who need this therapy.

Procedure Cost

An analysis of hospital costs required to perform Hyperthermia reveal that the actual cost to perform the procedure significantly exceeds the APC value proposed by CMS. Members of the Society for Thermal Medicine (STM) were surveyed for three levels of hyperthermia treatment. The average costs for the facilities responding to the survey, regarding time and cost were as indicated on the table below.

CPT	Description	Estimated Hospital Cost
77600	Hyperthermia, externally generated; superficial (ie. heating to a depth of 4cm or less)	$885.00
77605	Hyperthermia, externally generated; deep (ie. heating to a depths greater than 4cm)	$1,205.00
77610	Hyperthermia generated by interstitial probe(s); 5 or fewer interstitial applicators	$1,005.00
77615	Hyperthermia generated by interstitial probe(s); more than 5 interstitial applicators	$1,005.00
77620	Hyperthermia generated by intercavitary probe(s)	$1,005.00

The detail for each of the hyperthermia treatment types are outlined in the following tables.

Hyperthermia Treatment Delivery, Superficial	
Procedure	**Average Cost**
Treatment suite, 2-4 hours	$180
Required treatment hardware and software/per treatment	$60
Engineer/Physicist (2 hours)	$130
Technician (2 hours)	$80
Nursing Staff (3 hours) patient preparation and monitoring	$135
Medical Supplies/Disposables	$280
Administrative Staff/Secretary (0.5 hour)	$20
TOTAL COST	**$885**

Hyperthermia Treatment Delivery, Deep	
Procedure	**Average Cost**
Treatment suite, 4-6 hours	$300
Required treatment hardware and software/per treatment	$260
Engineer/Physicist (2 hours)	$130
Technician (2 hours)	$80
Nursing Staff (3 hours) patient preparation and monitoring	$135
Medical Supplies/Disposables	$280
Administrative Staff/Secretary (0.5 hour)	$20
TOTAL COST	**$1,205**

Hyperthermia Treatment Delivery, Interstitial/Intracavitary	
Procedure	**Average Cost**
Treatment suite, 3-5 hours	$240
Required treatment hardware and software/per treatment	$120
Engineer/Physicist (2 hours)	$130
Technician (2 hours)	$80
Nursing Staff (3 hours) patient preparation and monitoring	$135
Medical Supplies/Disposables	$280
Administrative Staff/Secretary (0.5 hour)	$20
TOTAL COST	**$1005**

Recommendations
Based upon the unstable medians, low utilization, seemingly lack of claims data for 77605, application of overall hospital CCR and actual hospital cost survey results, we believe that it is necessary to establish an exception to the median claims application for APC 314.

We recommend that CMS consider the one of the following options as an alternative to the proposed payment for APC 314.

OPTION 1
CMS use external hospital survey data provided above to establish a more appropriate median payment rate of $1,005 for APC 314.

OPTION 2
CMS consider applying an average cost for 77605 from 2004-2006 to the 2007 medians for other procedures in APC 314 to establish a more appropriate payment rate for 2007 of $398.75. The average cost for 77605 for 2007 is the average of the median cost from 2004-2006.

HCPCS	Description	Median Cost			
		2004	2005	2006	Proposed 2007
77600	Hyperthermia	190.53	200.17	224.34	164.06
77605	Hyperthermia	624.09	540.00	460.49	**541.53**
77610	Hyperthermia	211.89	231.07	328.06	308.95
77615	Hyperthermia	490.67	233.96	365.80	488.55
				Computed Median	**$398.75**

OPTION 3
Hold the payment rate for APC 314 at the current 2006 payment of $332.31 while more accurate claims data can be evaluated for 2008.

Hyperthermia therapy offers a cancer treatment option to patients with recurrence faced with no other option for treatment. Appropriate payment for hyperthermia treatment is required to ensure that hospitals can continue to offer Medicare beneficiaries the highest quality of cancer care.

Thank you for your consideration of these important issues.

Sincerely,
THE PINNACLE HEALTH GROUP, INC.

Kathy A. Francisco
Principal
kfrancisco@thepinnaclehealthgroup.com

Submitter : Mrs. Carolyn Scanlan **Date:** 10/09/2006

Organization : HAP

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachmcnt

CMS-1506-P-367-Attach-1.DOC

CMS-1506-P-367-Attach-2.DOC

#361

HAP

THE HOSPITAL & HEALTHSYSTEM ASSOCIATION OF PENNSYLVANIA

October 9, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1506-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

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

Dear Dr. McClellan:

On behalf of our more than 225 member hospitals and health care systems, The Hospital & Healthsystem Association of Pennsylvania (HAP) welcomes this opportunity to comment on the proposed rule, **"Medicare: Hospital Outpatient Prospective Payment System (OPPS) and Calendar Year 2007 Payment Rates; Proposed Rule"** as published in the August 23, 2006, *Federal Register.*

The Centers for Medicare & Medicaid Services (CMS) has proposed significant changes to the Medicare OPPS and, while the proposed rule has many components, there are three key areas within the rule that significantly will impact Pennsylvania hospitals and health systems:

- Hospital Coding for Emergency Departments
- Ambulatory Surgical Centers
- Hospital Quality of Care

HAP commends CMS for working toward the refinement of the OPPS to ensure equal opportunity for return across the areas of reimbursement, as well as to afford equal incentive to treat all types of patients and conditions.

The following are summary comments on the key issues mentioned above.

Reporting of Hospital Quality Data

We disagree with CMS' proposed linkage of the reporting of the inpatient measures to payments under the (OPPS) and would like CMS to delay this rule until it has developed a program that would assess the quality of services provided to Medicare beneficiaries receiving outpatient services.

4750 Lindle Road
P.O. Box 8600
Harrisburg, PA 17105-8600
717.561.9200 Phone
717.561.5334 Fax
www.haponline.org

Hospital Coding for Emergency Departments

We continue to believe that CMS should not implement new codes for hospital clinic and emergency department visits in the absence of accompanying national code definitions and national guidelines for their application. We also oppose CMS' proposal to create temporary Level II G-codes, but instead recommend that CMS support the continued use of the current five level CPT codes, which would be assigned to the three existing ambulatory payment classifications (APC) for hospital clinic and emergency department services until such a time as national coding definitions and guidelines formally are proposed, subjected to stakeholder review, and finalized.

Ambulatory Surgery Centers

We are concerned that potential weakening of the standards that determine which services may be performed in an ambulatory surgery center (ASC) could jeopardize patient safety and quality of care. This is an issue because regulations and facility standards to which ASCs are subject fall far short of the requirements that hospitals and their outpatient departments must meet in areas such as patient safety, patient rights, quality assurance, and operating (e.g., facility, equipment, staffing, etc.) standards.

HAP has enclosed more detailed comments on other sections of the proposed rule, which further delineate our concerns and recommendations.

Finally, given the regulatory process, HAP does not believe there has been adequate time for Pennsylvania hospitals to thoroughly analyze the proposed changes and assess impact to their individual facilities. Preliminary analysis has shown that even the slightest of changes in the proposed payment method results in potentially large changes to a hospital outpatient payment.

Again, HAP appreciates the opportunity to submit these comments and recommendations. If you have any questions regarding our comments, please contact me or Michael Lane, HAP's director, health care finance, at (717) 561-5317 or mlane@haponline.org; or Lynn Gurski-Leighton, HAP's vice president, professional and clinical affairs, at (717) 561-5308 or lgleighton@haponline.org.

Sincerely,

Carolyn F. Scanlan

CAROLYN F. SCANLAN
President and Chief Executive Officer

Attachment

THE HOSPITAL & HEALTHSYSTEM
ASSOCIATION OF PENNSYLVANIA

Detailed Comments on the CY 2007 Outpatient Prospective Payment System Proposed Rule

Proposed Changes on:

REPORTING ON HOSPITAL QUALITY DATA AND OTHER QUALITY INITIATIVES

In the proposed Outpatient Prospective Payment System (OPPS) rule, the Centers for Medicare & Medicaid Services (CMS) proposes that eligible inpatient prospective payment system (IPPS) hospitals must comply with the IPPS Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program in order to qualify and receive the full market basket update for outpatient services effective in CY 2007.

Second, CMS has outlined the proposed IPPS RHQDAPU measures for FY 2008, the time frames related to data collection for each of the measures, and when the data would need to be reported to the Quality Improvement Organization (QIO) Clinical Warehouse to qualify for the annual payment update in FY 2008.

With respect to these the two proposals, HAP offers the following comments and recommendations for consideration by CMS:

Hospital Quality Data/Equity Payment Authority

CMS' proposal would require compliance with the IPPS RHQDAPU program for hospitals to receive a full payment update for outpatient services in CY 2007. The proposed provision does not apply to hospitals and hospital units excluded from the IPPS, including critical access, psychiatric, rehabilitation, long-term care, children's and cancer hospitals, or hospital units. For the initial stage of implementation of the OPPS RHQDAPU in CY 2007, hospitals that are paid under the OPPS but that do not qualify as "subsection (d)" hospitals will continue to receive the full update to the OPPS conversion factor. CMS plans to expand the OPPS RHQDAPU program in the future by requiring all hospitals that receive payment under the OPPS to participate in the program in order to receive a full market basket update.

CMS asserts that it has the authority to adapt the quality improvement mechanism provided by the IPPS RHQDAPU program for use in OPPS. CMS also outlines why it believes that the quality measures under the IPPS RHQDAPU program reasonably represent the quality of care provided in the outpatient setting, particularly in hospital emergency departments. CMS has indicated that hospitals function as integrated systems that provide care to patients in both inpatient and outpatient settings for many of the same clinical conditions, and that quality improvement in a hospital inpatient department is likely to correlate with and promote similar quality improvement in the hospital's outpatient departments and other sectors of the institution. CMS also walks through each of the IPPS measures for acute myocardial infarction, heart failure, pneumonia, and surgical infection prevention to demonstrate how the various measures relate to care provided in hospital outpatient settings. Consequently, CMS believes it is appropriate to use the IPPS quality measures as proxies for the quality of outpatient care as an interim step while actual performance measures for the outpatient setting are being developed and refined.

HAP strongly disagrees with CMS' proposed linkage of the reporting of the inpatient measures to payments under the outpatient prospective payment system for several reasons:

- Congress already has determined, in the Deficit Reduction Act of 2005 (DRA), that hospitals reporting certain quality measures would receive a full market basket update under the IPPS. Hospitals not reporting would receive an update equal to the market basket minus two percentage points. The DRA did not authorize additional requirements

4750 Lindle Road
P.O. Box 8600
Harrisburg, PA 17105-8600
717.561.9200 Phone
717.561.5334 Fax
www.haponline.org

to be applied at the discretion of the Department of Health and Human Services (HHS). HAP believes that if Congress had wanted to authorize additional penalties, it could either have identified those penalties itself, or given the Secretary the authority to add penalties, but it did not. Therefore, HAP asserts that Congress did not intend additional penalties be associated with the non-submission of these data.

- 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 CMS to modulate the effect of a provision when it determined that implementation of a particular payment provision would put a particular provider or group of providers in an inequitable position. Implementation of the equitable payment provision must be done in a budget neutral manner to eliminate the inequities that are observed. In this instance, there are no inequities in outpatient payment that have been observed; thus CMS' assertion that it can make this change under the "equitable payment authority" is a misapplication of that provision.

- Finally, CMS tries to argue that there are reasons to assume that the measures included in the inpatient care arena are appropriate for providing insight into the clinical care in the ambulatory setting. However, these measures are specified in such a way that they apply only to patients that are admitted to the hospital. There is little or 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 in the outpatient setting. While it is the goal of many quality improvement efforts to create systemic changes, which in turn positively affect the care of many patients, there is little to no evidence of such systemic change resulting from the inpatient quality measures.

Alternatives to Managing Outpatient Expenditures

In the proposed rule, CMS describes its concerns about the rapid growth in the use of physician-related and hospital outpatient services in the Medicare program. Anticipated expenditures under OPPS in CY 2007 will be more than $32.5 billion. This represents a 9.2 percent increase over estimated expenditures of $28.8 billion in CY 2006. CMS specifically notes that implementation of OPPS has not slowed outpatient spending growth. In fact, double-digit spending growth has been occurring. Furthermore, the growth in spending is related to the intensity and utilization of services rather than price or enrollment increases. CMS further states that the rapid growth in utilization of OPPS services demonstrates that Medicare is paying mainly for more services each year, regardless of their quality or impact on beneficiary health.

HAP is supportive of the development of a program that would assess the quality of services provided to Medicare beneficiaries receiving outpatient services; however, HAP believes that focusing on and/or paying for quality will not solve the problem that Medicare has with the escalation of expenditures for outpatient services. In fact, it is well established that the patients with chronic illness, such as diabetes and heart failure, often don't receive evidence-based care such as hemoglobin A1C testing, eye examinations, and nutritional counseling. In fact, focusing

on improving the care delivered to patients with chronic illness in ambulatory settings, whether that be in hospital outpatient clinics or private physician practices, might actually increase the number of visits and services provided to Medicare beneficiaries. It also is not clear how better provision of care, whether through disease management and/or case management programs, impacts hospital inpatient utilization. The sad truth is that most of the chronic diseases are progressive in nature, and at some point, many of these patients will require hospitalization. Obviously, there is a sense that better overall medical management should delay the need for hospitalization and/or frequency of hospitalization.

In fact, CMS recently announced a three-year demonstration that will assess whether health risk reduction programs developed in the private sector could be adapted to improve health for Medicare beneficiaries and reduce the need for medical care. The demonstration program also seeks to encourage Medicare beneficiaries to use the preventive services that have been included in Medicare coverage during the last several years. Roughly 85,000 fee-for-service beneficiaries will be invited to participate in the Medicare demonstration, which will target health risks such as physical inactivity, obesity, smoking, depression, high blood pressure, and underuse of preventive benefits. Participants will receive a health risk assessment, information about disease prevention, and referrals to help them address their particular risk factors. HAP believes that this demonstration project is a good start to understanding better how outpatient care can be delivered and what impact it might have on inpatient hospital expenditures.

As CMS recognizes, most of the increased cost is associated with the increasing number of services being provided in the outpatient setting, new technologies that allow for more non-invasive diagnostic testing, and higher utilization of laboratory, pharmacy, and imaging services. There has been a rapid growth in Pennsylvania of for-profit, freestanding ambulatory surgery centers, many physician-owned, from 50 in 1997 to 177 in 2005. According to the Pennsylvania Health Care Cost Containment Council, in FY 2003, the operating margin for these centers averaged 12.2 percent, whereas acute care hospital operating margins averaged 2.2 percent. In FY 2004, ambulatory surgery center margins grew to 18.6 percent, and hospital operating margins decreased slightly to 2.10. There also has been significant growth in freestanding imaging centers, again, many owned by physicians. States across the country have been confronted with similar issues of increasing expenditures in the outpatient setting, most typically related to increases in utilization of services.

Approaches that HAP believes may be particularly relevant to CMS include:

- CMS should perform a comprehensive review of existing Medicare Condition of Participation requirements to ensure that inpatient and outpatient services are held to comparable requirements, including adherence to evidence-based practices; provision of care to the uninsured, Medicaid, and other publicly-supported patients; implementation of quality and patient safety programs; and quality/price transparency. HAP supports appropriate oversight of ambulatory health care settings either by CMS or through CMS' existing contracts with state agencies.
- The issues around physician self-referral and payment are complicated but need to be fully explored, understood, and clearly articulated. As physician payment declines, there is a strong incentive to perform more services to achieve an expected income level. CMS needs to carefully consider the issue of physician self-referral and financial structures to assure that the clinical interest of the patient remains central to what services are provided and where the care is delivered. HAP strongly suggests that there be standards at the federal and state levels to define the types of physician self-referral arrangements, including in outpatient care settings that clearly need to be prohibited. Alternatively, standards for allowable arrangements need to be defined as well to ensure that physician referral decisions are being made in the best interest of the patient and not influenced by financial interest in a facility or other financial arrangements that create conflicts of interest for physicians in making decisions regarding patient care.
- To address appropriate utilization and improve quality, CMS needs to develop programs that align hospital and physician incentives. Pennsylvania hospitals and health systems have long indicated how critical it is to align incentives to achieve improvements in quality and safety. HAP is very interested in the CMS pilot project that will allow hospitals to offer physicians a portion of the savings achieved through provider-led quality-improvement initiatives. Under the three-year Physician-Hospital Collaboration

Demonstration, up to 72 hospitals will be paid their usual inpatient rates and will be allowed to reward participating physician groups with a percentage of the savings generated through documented care quality improvements. The project will assist in determining if gainsharing can align incentives between hospitals and physicians to improve the quality and efficiency of care provided to beneficiaries over episodes of care and across settings. HAP believes that this project offers the kinds of incentives that could improve care delivered across multiple settings, improve quality, and reduce utilization of services.

HAP recognizes the challenges that CMS must deal with to manage outpatient expenditures. CMS will need to carefully examine how to ensure appropriate utilization and pricing of services while at the same time ensuring that strategies do not create unintended consequences affecting quality or unduly jeopardizing access to quality care or new technology. HAP, along with its member hospitals and health systems, would welcome more opportunity for further discussion on these issues.

Outpatient Cost and Quality Measures

CMS indicates that it will develop a specific set of measures to assess the quality of care provided to outpatients and is looking for suggestions on where and how to begin this process, including what current measures are most applicable to the outpatient setting; what measures currently are available; what privately-led organizations or alliances are best suited to develop and/or endorse outpatient quality measures; and how CMS can expand this program to all types of hospitals, including specialty hospitals that are paid under OPPS.

HAP offers the following thoughts, comments, and recommendations to CMS as follows:

- There are innumerable measures already available in the public domain that could be used to measure the quality of outpatient services provided. In fact, the Health Plan Employer Data and Information Set (HEDIS) developed and maintained by the National Committee for Quality Assurance (NCQA) uses several different measures to allow consumers to reliably compare health plan performance and spur health plans to make internal efforts at quality improvement and with its network of providers. Other appropriate measures have been included in the AHRQ National Healthcare Quality. Many measures that can provide insights into the quality in outpatient care settings currently are under review through the Hospital Quality Alliance (HQA) and the AQA (formerly known as the Ambulatory Quality Alliance).

- An HQA-AQA steering committee has been formed along with five work groups that will be considering a number of different issues of interest to the hospital and the physician community, including consideration of additional pilot projects similar to the Physician-Hospital Collaboration Demonstration Project. HAP believes that support for similar pilot projects aimed at aligning physician and hospital payment and measurement is essential in better understanding how to collect and report information on quality and price, impact utilization, improve quality, and manage expenditures.

- Given the breadth of outpatient services, CMS will need to prioritize where it wants to place its initial focus and have clear evidence that supports that the measures selected have an impact on the quality and outcomes of care that patients receive in hospital and other outpatient settings. As already outlined previously in this comment letter, measures should be appropriate to care delivered across a number of different outpatient settings. For example, measures used to assess the quality of care delivered to patients with diabetes should be applied to hospital outpatient clinics, physician offices that may be owned by the hospital or health system, and private physician offices. Additionally, given CMS' interest in impacting the delivery of care to patients with chronic illness, it would seem that measures aimed at impacting the way this care is delivered should receive the highest priority.

- A greater challenge for CMS and groups working with CMS will be to determine how to get at quality measurement in those areas that are driving utilization and ultimately outpatient expenditures such as diagnostic imaging procedures, outpatient therapy, and various ambulatory surgery procedures.

- Finally, if CMS is interested in identifying appropriate measures for specialty hospitals, such as children's and rehabilitation hospitals, these providers need to be brought into discussion at the same time as general acute care hospitals. In fact, it would be ideal to include these groups in identification and selection of appropriate outpatient quality measures, as there may very well be measures that could be identified that apply to all outpatient settings across hospitals regardless of specialty. But more importantly, it would prevent delay in identifying those measures of importance to those patient populations served in any of their outpatient settings.

HAP strongly urges CMS to continue to work with the HQA and the AQA in identifying and implementing 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. Because appropriate outpatient care measures have not been identified, CMS should eliminate any link between quality measures and outpatient care payments in this rule.

FY 2008 IPPS Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU)

Since the DRA calls for further expansion of the measures reported to the data warehouse, HAP previously recommended that CMS develop a process that affords organizations sufficient time prospectively to begin collection and reporting of any additional measures that will be considered in an annual payment update or part of a value-based purchasing program for hospitals. HAP appreciates that CMS has attempted to address this recommendation by publishing what measures CMS is considering for the hospital IPPS annual update, as well as the time frames that hospitals will be required to meet in order to qualify for the update. **However, HAP respectfully requests that in the future, CMS refrain from embedding proposed inpatient rule changes in an outpatient rule.**

HCAHPS®

In the proposed rule, CMS has reiterated that the national implementation of HCAHPS® will begin in October 2006. As a result of the consumer interest in HCAHPS®, the initial public reporting will cover nine months of discharges (October 2006 through June 2007). After initial implementation, the website will contain 12 months of HCAHPS® data and will be updated quarterly. In late June 2007, hospital results will be publicly reported on the CMS Hospital Compare website, and there will be seven composite scores and two overall ratings that are publicly reported. There will be both state and national comparisons for each of the nine areas reported. Testing is presently underway with consumers to determine how best to display the information, and hospitals will have the opportunity to view their data before it is made public.

HAP has appreciated the iterative process that CMS engaged in with the hospital field and other federal agencies such as the Agency for Healthcare Research and Quality (AHRQ) in the

development and then implementation of HCAHPS®. In previous comments shared with CMS, HAP recommended that CMS consider implementing a process similar to that used jointly by CMS and AHRQ in shaping the HCAHPS® perception of care survey/survey methodology to develop the Medicare value-based purchasing program for hospitals. This is a process that should involve multiple opportunities for public comment in order to prepare the hospital community for the value-based purchasing program and obtain consensus with regards to the value-based purchasing program that CMS selects to implement.

In the proposed rule, CMS has indicated that there will be designated HCAHPS® project teams that will review and discuss with survey vendors and self-administering hospitals their specific quality assurance plans; survey management procedures; sampling and data collection protocols; and data preparation and submission. These reviews may occur face-to-face or through other means of communication. Additionally, based on conversations with the state's Quality Improvement Organization (QIO), it does not appear that the QIO will have any involvement with HCAHPS®. Pennsylvania hospitals and health systems have expressed concern about having yet another group that they need to be familiar with, especially since they deal primarily with the QIO issues around quality measurement, submission of data to the QIO Clinical Warehouse, annual payment update, and appeals related to chart validation.

HAP recommends that CMS reconsider what role the QIOs can and should play with HCAHPS®, particularly since the staff at the QIOs are viewed as an accessible and knowledgeable resource to all hospitals and health systems in the state. This is especially the case for some of the smaller hospitals that have fewer resources available to them to meet the requirements for the full annual payment update.

Surgical Care Improvement Project

CMS has proposed the following measures be included in the IPPS RHQDAPU program in FY 2008:

- SCIP-VTE 1—venous thromboembolism prophylaxis ordered for surgery patient
- SCIP-VTE 2—prophylaxis within 24 hours pre/post surgery
- SCIP Infection 2—prophylactic antibiotic selection for surgical patients

As in the most recent IPPS proposal that CMS modified in the final IPPS rule, CMS is proposing that hospitals submit data starting with first quarter discharges in CY 2007 for this set of proposed measures. The deadline for hospitals to submit January through March 2007 discharge data to the QIO Clinical Warehouse will be August 15, 2007, in order to qualify for the full FY 2008 market basket update.

As with other process of care measures, this data will need to be abstracted from the medical record and reported to the QIO Clinical Warehouse. HAP again believes that CMS is proposing a tight time frame for hospitals to have sufficient staff on board and to make sure that they have been properly educated and trained to ensure a high degree of accuracy in the data abstraction. Otherwise, hospitals may fail to meet the chart validation requirements, which can disqualify them from receiving the full marketbasket update. Additionally, hospitals and health systems require time to work with their respective performance improvement vendors to make sure that all tools are available to allow them to do the chart abstraction. Ideally, hospitals should be given at least six months from the time that CMS finalizes its proposal to comply with a requirement that involves planning and implementation as is the case with the abstraction and reporting of additional process measures. HAP recommends that CMS require hospitals submit data for these measures beginning with discharges in the third quarter 2007 (July through September 2007).

While HAP understands the interest of Congress and CMS to make more quality data available to the public and to use that data to drive quality improvement, Pennsylvania hospitals and health systems are concerned about adding more data abstraction requirements. At the present time, additional data abstraction translates into having to hire and train more staff, and every time staff needs to be added for these functions, hospitals have fewer resources to hire staff that provides direct care to patients. HAP appreciates that CMS is considering other measures that can be derived from claims databases to alleviate additional resource requirements for hospitals, but also respectfully requests that CMS understand and consider the cumulative impact on hospitals and health systems associated with additional chart abstraction rather than looking at what the impact of adding just one or two additional measures might have on hospitals. As more opportunity to obtain data through an electronic health record becomes feasible, this may become less of a concern or different concerns may emerge. For now, though, each requirement for additional abstraction requires additional resources for hospitals and health systems.

As a final comment, HAP appreciates that CMS has proposed measures for FY 2008 that have already been adopted as part of the HQA's efforts to promote public reporting of hospital data — but with the caveats already outlined above. HAP believes that it will be vitally important for CMS to continue to work with HQA and to align its choices of measures and to link payment with the measures chosen by HQA to provide a public accountability for quality. This alignment will reinforce the importance of public transparency on quality and help to focus quality improvement efforts on identified high priority care areas.

Mortality

CMS has proposed including mortality measures as outcome measures that would be publicly reported on Hospital Compare. The mortality measures proposed by CMS are:

- AMI 30-day mortality—Medicare patients
- HF 30-day mortality—Medicare patients
- Pneumonia 30-day mortality—Medicare patients

CMS proposes to publicly report 30-day mortality rates for acute myocardial infarction and heart failure conditions for the June 2007 Update to Hospital Compare. Rates for pneumonia will be posted as soon as possible after NQF endorsement, and hospitals will have a 30-day period to preview their rates before publication.

Claims data submitted to CMS for index hospitalizations occurring from July 2005 through June 2006 (third quarter CY 2005 through second quarter CY 2006) will be used to calculate the mortality rates that will be used for FY 2008 payment determinations and will be posted on the website in June 2007.

Medicare has proposed using Medicare claims information in developing the risk adjustment methodology. The mortality risk adjustment will rely on Medicare patients' historical medical care use, including inpatient and physician office visits and outpatient care one year before their index hospitalization.

The national dry run for the acute myocardial infarction and heart failure measures will occur in late 2006 to test implementation and educate hospitals on the methodology. Hospitals will be given an opportunity to examine their rates and other data associated with the measures, provide feedback to CMS, and ask questions about the calculation of the rates. Rates used in the dry run will be used for quality improvement purposes and will not be publicly reported to Hospital Compare.

Hospital-specific patient outcomes reports have been publicly available in Pennsylvania for more than 20 years. These hospital performance reports cover more than 30-code based conditions and

19 DRGs. Outcomes included in these reports, which are updated on a quarterly basis and available to the public include: risk-adjusted in-hospital mortality; risk-adjusted length-of-stay; risk-adjusted readmissions for any reason; risk-adjusted readmissions for complications, including infections; average hospital charge; and the percent of cases transferred to another acute care facility.

As previously stated in comments submitted on the IPPS proposed rule, HAP does not believe that use of a 30-day risk-adjusted mortality for acute myocardial infarction and heart failure patients represents the best outcome measures that could be selected by Medicare to represent the quality of care delivered to patients in hospitals. **HAP would strongly suggest that Medicare identify outcome measures that better reflect the quality of hospital care. Additionally, use of the 30-day risk-adjusted mortality for acute myocardial infarction is not congruent with the in-hospital mortality measure that is part of the JCAHO core measures for acute myocardial infarction and an outcome measure that was used in the Premier Hospital Quality Incentive Demonstration project.**

Since it appears that CMS will move forward with the public release of these outcome measures, HAP recommends that CMS publicly recognize the limitations associated with the use of these measures, as every risk-adjustment methodology has limitations based on its underlying assumptions and the data that is available and used in those calculations. HAP strongly encourages CMS to be open to refining the risk adjustment methodology and/or selection of alternate outcome measures based on hospital and health system recommendations.

Proposed Changes on:
APC RELATIVE WEIGHTS

Proposed Recalibration of APC Relative Weights for CY 2007

Current law requires CMS to review and revise the relative payment weights for ambulatory payment classifications (APC) at least annually. HAP continues to support the agency's use of hospital data, rather than data from other sources, to set the payment rates, as this information more accurately reflects the costs hospitals incur to provide outpatient services. However, since the August 2000 implementation of the outpatient PPS, payment rates for specific APCs have fluctuated dramatically. For CY 2007, the proposed rates continue to show significant volatility.

In the proposed rule, CMS uses the most recent claims data for outpatient services to set the CY 2007 weights and rates. **HAP continues to support the use of the most recent claims and cost report data to set the CY 2007 payment weights and rates. We also continue to support the use of multi-procedure claims, as we believe these data improve hospital cost estimates. HAP also supports the expanded list of codes for bypass, as it appears unlikely that these codes would have charges that would be packaged into other services or procedures.**

Proposed Revision to the Overall Cost-to-Charge Ratio Calculation

The proposed rule includes a significant change in the way the overall hospital-specific cost-to-charge ratio (CCR) is calculated. CMS uses the overall hospital CCR to set outlier thresholds and to estimate outlier and pass-through payments and in other services paid based on charges reduced to costs. The fiscal intermediaries (FI) use overall CCRs to determine outlier payments and payments for certain other services. CMS recently discovered that it calculates the overall

hospital CCR differently than the FIs. Compared with CMS's "traditional" overall CCR calculation, the FIs' method includes allied health education costs and adds weighting by Medicare Part B charges. In the rule, CMS proposes to use features of both methods by excluding allied health education costs and adopting weighting by Medicare Part B charges. **HAP believes that having a consistent methodology for use in setting policy, modeling impacts, and for making outpatient PPS payments is important. In addition, we believe that the decisions to exclude allied health education costs and to adopt weighting by Medicare Part B charges are appropriate policy decisions. Therefore, HAP supports CMS' proposal to adopt a single overall CCR calculation that incorporates weighting by Medicare Part B charges and excludes allied health costs for modeling and payment.**

Proposed Changes to Packaged Services

HAP commends CMS and the APC Packaging Subcommittee for continuing to address provider concerns that many packaged services ("N" status code services) could be provided alone, without any other separately payable services on the claim. In the rare circumstance in which a hospital provides services described by these "N" status codes alone, there is no way for the hospital to be reimbursed for the cost of providing these services.

HAP supports the proposed designation of specific CPT codes as "special packaged codes" with status indicator "Q" that will be used for separate payment for these services when they are billed on a date of service without any other separately payable outpatient PPS service. We encourage CMS to continue to work with the APC Packaging Subcommittee to further review "N" status codes and identify those that should be paid separately.

Proposed Changes on:
OPPS: NONPASS-THROUGH DRUGS, BIOLOGICALS, AND RADIOPHARMACEUTICALS

Packaging Threshold

Due to the expiration of the MMA's $50 drug packaging threshold, in the proposed rule CMS evaluated four options related to drug packaging: (1) pay all drugs separately; (2) set a high-dollar threshold; (3) continue the $50 threshold; or (4) update the current packaging threshold for inflation. CMS settled upon the fourth option, opting to establish a $55 packaging threshold for outpatient drugs.

HAP historically has supported more extensive packaging of drugs into the services with which they are provided because integrating these costs is a fundamental principle of a PPS. More packaging eliminates financial incentives to use the more costly drugs because they are separately paid.

While there had been concern related to the coding burden for keeping track of and educating staff on the drugs, we now believe that, for a variety of reasons listed below, eliminating the drug packaging threshold may pose less of a coding and financial burden than was the case in the past.

- CMS strongly has encouraged hospitals to report charges for all drugs, biologicals, and radiopharmaceuticals, regardless of whether the items are paid separately or packaged, using the correct HCPCS codes for the items used. So, for hospitals following this advice, revising payment policy so as to now pay separately for all drugs with HCPCS codes would not pose an additional coding burden.

- Eliminating the packaging threshold for drugs also would eliminate the incentive for physicians and hospital staff to base drug choice on whether it is separately paid or not and focus exclusively on the drug's clinical value for the individual patient.

- Eliminating the threshold also would provide for equity across settings. It would make payment in the hospital outpatient department more consistent with payment in the physician office setting.

- Eliminating the threshold also would address a problem of concern related to certain drugs to many hospitals. If drugs related to a second or subsequent intravenous (IV) push were separately paid, then the hospital could charge for the drug itself and be reimbursed. The current policy does not allow for that type of reimbursement.

For all these reasons, HAP recommends that CMS eliminate the drug packaging threshold for all drugs, biologicals, and radiopharmaceuticals with HCPCS codes.

Proposed Payment for Specified Covered Outpatient Drugs

HAP is concerned about 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 at a rate less than the ASP plus 6 percent rate they are paid in physician office settings. **HAP believes that consistency in payment for drugs and biologicals across settings is important, and therefore we recommend that CMS maintain the payment rates for drugs at the rate of ASP plus 6 percent for 2007.**

Payment Policy for Radiopharmaceuticals

CMS proposes to no longer pay for radiopharmaceutical agents at the hospital charge reduced to cost and instead to pay for them at aggregate hospital mean costs as derived from the 2005 claims data. For brachytherapy 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, HAP recommends that for 2007, CMS continue using the current methodology of payment at charges reduced to costs for radiopharmaceuticals and brachytherapy sources.**

Proposed Changes on:
EVALUATION AND MANAGEMENT SERVICES AND VISITS

Since April 2000, hospitals have been using American Medical Association's (AMA) Current Procedural Terminology (CPT) evaluation and management (E/M) codes to report facility resources for clinic and emergency department (ED) visits. Recognizing that the E/M descriptors were defined to reflect the activities of physicians and did not adequately describe the range and mix of services provided by hospitals, CMS instructed hospitals to develop internal hospital guidelines to determine the level of clinic or ED services.

During the last several years, different models for national coding guidelines for reporting facility visits services have been proposed and reviewed by CMS. In 2002, CMS specified that they would not create new codes to replace existing CPT E/M codes for reporting hospital visits until national guidelines were developed, in response to comments from individuals who were concerned about implementing code definitions without national guidelines.

In January 2003, the AHA and the American Health Information Association (AHIMA) convened an Expert Panel whose goal was to deliver a recommendation to CMS in time for the 2004 OPPS rule making process. During June 2003, the AHA and AHIMA submitted recommended hospital E/M visit guidelines based on the work of this independent Expert Panel comprised of members with coding, health information management, documentation, billing, nursing, finance, auditing, and medical experience.

HAP appreciates CMS's consideration of the recommendations of the independent expert panel, and the posting of this recommendation for wider public input. **While we have eagerly awaited national guidelines for hospital visits since the implementation of OPPS, we continue to support CMS's commitment to provide a minimum of 6-12 months notice to hospitals prior to implementation of national guidelines.** Sufficient time is required for providers to make the necessary system changes and educate their staff on the new coding, as well as documentation requirements.

Proposed Codes and Coding Policy for 2007

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 (HCPCS) 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 formally are 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.

HAP continues to believe that 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. Therefore, we oppose CMS' proposal to create temporary level II G-

codes while requiring hospitals to apply their own internal guidelines to these codes. Instead, HAP recommends that 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 formally are 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.

HAP recommends that once national guidelines are developed, a formal proposal should be presented to the AMA's CPT Editorial Panel to create CPT level I codes for hospital visits. These codes could then be widely reported by hospitals to all payers. We do not support the creation of temporary G-codes as an interim step for a year or two, but would instead prefer to wait for the implementation of CPT codes.

Proposed Payment Policy for 2007

CMS proposes to assign its newly proposed G codes to APCs for payment purposes as follows:

- Five new Clinic Visit G-codes would be assigned to five new Clinic Visit APCs.
- Five new Type A (open 24 hours-a-day, seven days a week ([24/7]) ED Visit G-codes assigned to five new Type A Emergency Visit APCs.
- Five new Type B (not open 24/7) ED Visit G-codes assigned to the five new Clinic Visit APCs.
- One new Critical Care G-code (hosp critical care, 30-74 min) assigned to the new Critical Care APC. The other Critical Care G-code (hosp critical care, additional 30 min) would be packaged.

CMS asserts that paying for Type B ED visits at the clinic visit rate is consistent with the agency's current policy for services furnished in EDs that have an Emergency Medical Treatment and Labor Act (EMTALA) obligation but do not meet the CPT definition of ED to be reported using clinic codes. The agency states, *"Under the OPPS, we have restricted the billing of emergency department CPT codes to services furnished at facilities that meet this CPT definition. Facilities open less than 24 hours should not use the emergency department codes."*

In the proposed rule, CMS requests comments regarding this policy and states that it is concerned with ensuring that necessary ED services are available to rural Medicare beneficiaries, recognizing that rural EDs sometimes operate on a less than 24/7 basis. Although HAP does not collect data on the hours of operation for hospital emergency departments, we believe that there would be very few that are open less than 24/7. In fact, to the extent that many rural hospitals now are designated as critical access hospitals (CAH), the Medicare conditions of participation for CAHs at 42 CFR 485.618(a) states "Standard: Availability. Emergency services are available on a 24 hours-a-day basis." Therefore, HAP believes that there are very few facilities that currently would meet the Type B ED definition, and it is likely that most of these are remotely located EDs operated by hospitals with 24/7 on-site EDs. That said, the level of services in EDs varies based on the availability of other hospitals, general population size, and availability of physician specialists.

In addition, in the proposed rule, CMS notes that the reporting of specific G-codes for emergency visits provided in Type B EDs will permit the agency to collect and analyze the hospital resource costs of visits to these facilities in order to determine whether a proposal of an alternative payment policy may be warranted in the future. **HAP believes that CMS's proposed policy to establish different sets of ED visit codes for Type A and Type B facilities will not provide adequate data to allow a comprehensive and useful analysis of comparative cost-to-charges associated with the operation of these facilities.** This is because hospitals that have both an on-site 24/7 ED as well as one or more remote non-24/7 EDs would report costs for both types of EDs under a single services category—emergency services. Rolling costs up into the

same cost report line would make it impossible to distinguish between the services provided in the Type A versus Type B ED.

Instead, we recommend that CMS create a unique revenue code for reporting non-24/7 ED services and modify the cost report to create another service category to allow separate reporting of those costs. With this structure in place, the billed services provided in the on-site 24/7 ED could be captured using a different revenue code from the billed services provided in the satellite non-24/7 ED. This would allow the matching of costs to charges. **Using such an approach also would make it unnecessary to establish a separate set of codes for "Type B" EDs.** We are confident that over time, reviewing cost report data combined with patient level of care data will help determine whether the costs of non-24/7 EDs are more similar to those of a clinic, to 24/7 ED, or fall somewhere in-between.

We are concerned about CMS's proposed coding and payment structure. From a coding perspective, what should be taken into consideration are the services provided to individual patients. In addition to highlighting the traditional 24/7 availability of hospital EDs, we believe that the CPT description of emergency department services as requiring 24-hour services may also serve as a proxy for the level and scope of care that the facility can provide. If an ED that is open less than 24/7 can provide the same level and scope of care that an ED open 24/7 can provide, then it should be paid at the ED rate. For instance, this may be the case if the non-24/7 ED:

- Operates as a provider-based facility at a different location than its main campus hospital, but essentially is an extension of the main campus 24/7 ED.
- Complies with EMTALA by virtue of meeting the criteria as a "dedicated emergency department."
- Provides unscheduled care and maintains procedures to register and triage patients.
- Accepts patients from emergency medical services (EMS), including patients who are at risk of loss of life and/or limb and require emergency stabilization.
- Is staffed during hours of operation similar to the hospital's on-site 24/7 ED, and provides patients with access to the same type and range of services—including physician specialists, laboratory tests, imaging procedures, and other services and procedures that are typical of emergency services provided by the on-site 24/7 ED.

From a payment policy perspective assuming that the costs of these non-24/7 EDs are more similar to that of a clinic than a 24/7 ED is unfounded. After all, these are EDs that CMS has already defined as being subject to EMTALA by virtue of meeting the criteria as a "dedicated emergency department," including providing unscheduled emergency care and accepting ambulance patients. While these facilities may not bear the same staffing costs and "stand-by" expenses associated with 24-hour operation, they do bear these other costs and provide an intensity of service that make them closer to a 24/7 ED than to an outpatient clinic.

Therefore, HAP recommends, given the expected very small number of these non-24/7 EDs, and the fact that this is only an interim payment policy pending evaluation of cost data, that CMS pay for ED visit services at these facilities at either the ED APC rate or, if appropriate, at a reasonable discount from the ED rate.

Proposed Treatment of Guidelines for 2007

HAP is pleased that CMS believes that the AHA/AHIMA guidelines are the most appropriate and well-developed guidelines for use as the starting point for consideration in the OPPS. We further agree with CMS that the 2003 AHA/AHIMA guidelines require short-term refinement prior to full adoption by the OPPS, as well as continued refinement over time after their implementation.

Proposed Changes on:
OPPS: RURAL HOSPITAL HOLD HARMLESS TRANSITIONAL PAYMENTS

HAP 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. **HAP supports S. 3606, "Save Our Safety (SOS) Net Act of 2006" which permanently would extend hold harmless payments to small rural hospitals and sole community hospitals, as is currently the case for cancer hospitals and children's hospitals.**

Proposed Changes on:
OUTLIER PAYMENTS

Outlier payments are additional payments to the APC amount meant 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 rate and at least $1,875 more than the APC rate.

We are concerned that CMS has set the threshold for outliers in this rule too high. With the significant changes to outlier policies, including the methodology for calculating the hospital-specific CCR proposed for 2007, HAP is concerned that Medicare may not actually spend the outlier target set-aside.

Proposed Changes on:
NEW TECHNOLOGY APCS

CMS proposes to assign 23 services from new technology APCs to clinically appropriate APCs. 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, CMS proposes to assign some services that have been paid under the New Technology APCs for less than two years to clinically appropriate APCs. For example, Positron Emission Tomography (PET)/Computed Tomography (CT) Scans, which had been assigned to New Technology APC 1514 in 2005. Some hospitals that adopt these new technologies may not be able to quickly change their charge masters, including changing codes and setting charges that reflect actual costs of the new service. Additionally, the data that CMS obtains in the first year or two of adoption of these technologies may not appropriately reflect the use and cost of these services, because diffusion of new technologies can sometimes be slow, and waiting additional years for more hospitals to adopt and use new technology is important. **Therefore, HAP 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.**

Proposed Changes on:
RADIOLOGY PROCEDURES

In the proposed rule, CMS indicates that it will continue to defer in 2007 the implementation of a multiple imaging procedure payment reduction policy it had proposed for the OPPS last year pending results of further analyses on the topic. **HAP supports CMS's decision not to implement this policy.** We continue to believe that hospital cost data already reflect efficiencies gained when multiple images are performed, leading to lower cost estimates across all procedures.

In the proposed rule, CMS discusses an APC Panel recommendation related to hospital charging and cost reporting practices related to radiology services. CMS requests comments on ways that hospitals can uniformly and consistently report charges and costs related to all cost centers that also acknowledge the tradeoff between a greater precision in developing CCRs and the administrative burden associated with reduced flexibility in hospital accounting practices.

The difficulty in applying CCRs to arrive at cost is that it takes as fact that there is consistency in how HCPCS procedure codes relate to the service categories indicated on the cost report. The cost report relies on service categories that reflect the general descriptor of a provider's service departments. But other departments now can safely and effectively perform services that were once performed by a specialized departmental unit. As an example, bedside lab tests now are performed in the emergency department; procedures can be furnished in an operating room, treatment room, or outpatient surgery area; and supplies cross multiple departments. Consequently, inconsistencies occur when determining the cost of a service if the CCR assignment is made to a different cost report service category.

It is also important that CMS recognize the current limitations and inconsistencies in preparing the cost report. Today, providers must reconcile the Medicare Provider Statistical & Reimbursement (PS&R) reports to determine how intermediaries not only paid the claim but also how they recorded the units and revenue code assignment to the billed services. Often there are changes made by the FI that affect how the services and revenue matches are made. Such changes by the FI, however, fail to match the revenue as reported by the provider on the cost report.

HAP asks CMS to realize that hospitals must continue to have the flexibility to set charges and allocate costs in a way that makes the most sense for the particular mix of services offered by the hospital. In addition, even relatively small changes in practices and procedures would need to take into account the varying levels of sophistication of provider accounting systems. Allowing adequate time for dissemination of changes and for provider education on any changes would be imperative.

Proposed Changes on:
DEVICE DEPENDENT APCS

Devices Replaced without Cost or with Credit to the Hospital

CMS proposes to reduce the APC payment and beneficiary copayment 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. This is in response to device recalls and field actions involving the failure of implantable devices in which case manufacturers offer to replace devices without cost to the hospital or to offer credit for the device being replaced if the patient requires a more expensive device. CMS proposes to calculate the amount of the reduction to the APC payment rate using the same method it uses to calculate the pass-through rate for implanted pass-through devices. The adjustment would be implemented through the use of an appropriate modifier specific to a device that has been replaced.

HAP agrees that neither the Medicare program nor Medicare beneficiaries should be required to pay hospitals for devices that were provided to the hospital at no cost. In addition, while HAP agrees that there are additional burdens on hospitals associated with imposing this new policy, hospitals have been required since January 1, 2006, to use the -FB modifier with the HCPCS code for a device that was furnished to the hospital without cost to the provider. Therefore, this is not an entirely new type of policy for hospitals. **HAP requests that CMS clarify whether and how this -FB modifier would be used once the new policy goes into effect.**

Further, as CMS acknowledges in the proposed rule, the -FB modifier may not be used appropriately if the replacement device is an upgrade from the device that is being removed from the patient. In any given recall, 10 to 20 percent of replaced devices could result in upgrades, meaning the physician opts to use a higher functioning device over the one being replaced in order to meet the patient's current clinical needs. In these cases, the hospital would be responsible for paying the price difference between the upgraded device to be implanted and the replaced device that is being removed. This price difference may be significant. For instance, in the case of implantable cardiac defibrillators (ICDs), the hospital payment for the difference between the upgraded and replaced device could be in the range of $1,000 to $7,000.

HAP recommends that CMS revise its proposal to account for the additional cost that the hospital would bear in the event of a device upgrade. This could be accomplished through the use of a second modifier or through another approach to identify when the replacement procedure involves an upgraded device. The APC offset for an upgraded device replacement should be set at a lower percentage than the APC offset made for an "even" device replacement.

Proposed Changes on:
DRUG ADMINISTRATION

In 2005, CMS transitioned from using daily per-visit drug administration Q codes to using CPT codes. In the 2006 final rule, CMS implemented 20 of the 33 new 2006 CPT codes for drug administration. The 13 CPT codes that were not implemented included concepts such as initial, subsequent, and concurrent administration, which were operationally problematic for hospitals to report. CMS instead created six HCPCS C-codes that generally paralleled the 2005 CPT codes for the same services.

While hospitals were grateful for CMS's responsiveness to their concerns regarding the operational difficulties of implementing the full range of 2005 CPT codes for drug administration services, they nevertheless had to implement these CPT codes for non-Medicare payers. As such, hospitals have had to overcome the operational challenges related to concepts such as initial, subsequent, and concurrent drug administration for other payers while, at the same time, have had to implement two sets of codes for reporting certain drug administration services, depending on the payer.

HAP 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 thirty-three 2006 drug administration codes that were not implemented in 2006. We believe that this eliminates the burden of having to apply and maintain two sets of codes for essentially the same services.

In addition, in 2005 and 2006, CMS provided special instructions to hospitals for the use of modifier 59 in order to ensure proper OPPS payments, consistent with their claims processing logic. Since CMS did not expect any changes to coding structure for 2007 and because they now have updated service-specific claims data from 2005, CMS no longer has the need for specific drug administration instructions regarding modifier 59. **HAP supports CMS's proposal that hospitals apply modifier 59 to drug administration services using the same correct coding principles that they generally use for other OPPS services.**

CMS also proposes six new APCs in 2007 that are intended to better distinguish costs related to infusions of different types and be 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. **HAP supports CMS's proposal to create six new drug administration APC levels as this will provide for 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 intravenous 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 of this situation is for 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's intent was to discontinue payment for this drug when it is medically necessary. **HAP 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, and that an appropriate payment be made for this service.**

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

Proposed Changes on:

ASC PAYMENT SYSTEM—2007

While CMS is not proposing any policy changes to the criteria for adding to or deleting items from the ASC list of approved procedures, it is proposing to add 14 procedures to the ASC list in 2007. CMS also is proposing to cap payments, under a DRA provision, for ASC services at the outpatient PPS payment rate for surgical procedures performed at an ASC in 2007 when the ASC payment rate exceeds the outpatient PPS payment rate for the same procedure. HAP carefully is reviewing the proposed changes to ASC coverage and payment policy, including this broad expansion in the number and types of services that may be performed in an ASC in 2007 and 2008.

We are concerned that weakening the standards that determine which services may be performed in an ASC could jeopardize patient safety and quality of care. This is an issue because regulations and facility standards to which ASCs are subject fall far short of the requirements that hospitals and their outpatient departments must meet in areas such as patient safety, patient rights, quality assurance, and operating (e.g., facility, equipment, staffing, etc.) standards.

Proposed Changes on:
PARTIAL HOSPITALIZATION

HAP 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. 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.

We share CMS's concern about volatility of the community mental 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.

Although HAP 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, HAP 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.

Proposed Changes on:
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. **HAP continues to support CMS's concept of allowing the Outpatient Claims Editor (OCE) 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," HAP believes that the time is right to consider a narrow expansion in the diagnoses for which observation may be separately paid. **Therefore, HAP recommends that CMS consider adding syncope and dehydration as diagnoses for which observation services qualify for separate payment.**

Proposed Changes on:

PROPOSED PROCEDURES THAT WILL BE PAID ONLY AS INPATIENT PROCEDURES

CMS proposes to remove eight 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.

HAP 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, 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 that a procedure they have scheduled for performance in an outpatient department is on the inpatient list. There also may be other reasonable, but rare, clinical circumstances that may result in these procedures taking place in the absence of an inpatient admission.

HAP 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.

Proposed Changes on:

CAHS: EMERGENCY MEDICAL SCREENING

HAP supports CMS's proposal to change the CAH conditions of participation to allow registered nurses to serve as qualified medical personnel to screen individuals who present to the CAH ED, if the nature of the patient's request is within the registered nurse's scope of practice under state law and such screening is permitted by the CAH's bylaws.

This change provides hospitals with the staffing flexibility needed to maintain access and provide efficient emergency and urgent care services in CAHs. We note, however that there is an inconsistency between CMS's preamble language and the regulatory text being proposed in this section. While the preamble indicates that the CAH would have to include this change in their bylaws, the regulatory text does not mention CAH bylaws.

Proposed Changes on:
MEDICARE CONTRACTING REFORM MANDATE

In the proposed rule, CMS proposes conforming changes to the regulations in order to implement the Medicare contracting reform provisions of the MMA. Hospitals will be integral customers of the Medicare Administrative Contractors (MAC), and a significant proportion of hospital revenue will depend on these contractors operating in a timely and judicious manner.

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 HAP 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, HAP believes that such provider input is critical.

However, we encourage 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. Therefore, hospitals should have input on both the selection and termination of MACs.

In addition, given that each defined A/B MAC jurisdiction will include several states, 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.

In the proposed rule, CMS proposes to assign providers to the MAC that is contracted to administer the types of services billed by the provider within the geographic locale in which the provider is physically located. However, CMS also proposes to allow large national hospital chains that meet their criteria as "qualified chain providers" to request an opportunity to consolidate their Medicare billing activities to the MAC with jurisdiction over the geographic locale in which the chain's home office is located. In addition, qualified chain providers that were formerly granted single FI status (prior to October 1, 2005) would not need to re-request such privileges at this time.

HAP is pleased that the proposed rule will allow chain-provider organizations to receive "single MAC" status. However, we also believe that there should be a mechanism for a chain provider with facilities in many A/B MAC jurisdictions to consolidate into a smaller number of MACs instead of a single MAC in the chain's home office location. This might apply to a chain provider that has its home office and several of its facilities within the same MAC jurisdiction but other facilities located in another MAC's jurisdiction. For a chain organization that includes multiple kinds of providers—hospitals, freestanding imaging centers,

physician offices, etc. – there should be a mechanism to allow some facilities to stay with the MAC in their geographic locale while others migrate to the MAC of the chain's home office.

HAP also seeks clarification on how chain providers that currently report to a single intermediary will be managed in the coming stages of the MAC transition. If a chain hospital is in a jurisdiction that is transitioning to a MAC, but the chain's home office is not in that jurisdiction, may the chain hospital continue to report to the intermediary it has been using, or must it transition to the contracted MAC in its jurisdiction? HAP recommends that CMS expeditiously provide instructions on how a chain organization may convert to a single MAC to avoid the need for multiple transitions for chain hospitals.

Proposed Changes on:
HEALTH INFORMATION TECHNOLOGY

In the proposed rule, CMS repeats questions posed in the proposed inpatient PPS rule regarding:

- Its statutory authority to encourage adoption and use of information technology (IT).
- The appropriate role of IT in any value-based purchasing program.
- The desirability of including use of certified health IT in hospital conditions of participation.

HAP 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.

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

With regard to value-based purchasing, HAP continues to believe that these programs should build off the consensus measures endorsed by the broad spectrum of organizations, including CMS, which participate in the 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 final inpatient PPS rule, CMS stated that it would not make use of certified, interoperable health IT a condition of participation (COP) in Medicare, but might revisit the issue in future rulemaking. HAP firmly believes that **CMS should not include health IT in the Medicare COPs 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, and certification efforts are in their infancy. As noted in a recent AHRQ report, the evidence on health IT does not yet support this level of requirement.

Proposed Changes on:
TRANSPARENCY OF HEALTH CARE INFORMATION

Significant progress has been made in making quality information more transparent. The AHA, the Federation of American Hospitals, and the Association of American Medical Colleges partnered with CMS and others to form the HQA. The work of the HQA has led to the voluntary reporting and sharing with the public of 21 quality measures on the *Hospital Compare* website, and more measures of hospital quality and patient satisfaction are planned for the future. This effort has been tremendously successful, with nearly all inpatient PPS hospitals voluntarily reporting quality information. **Efforts to further expand public availability of hospital quality information must continue to be pursued through the HQA.**

While progress has been made regarding quality transparency, similar information on hospital pricing is less accessible. 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. Hospital prices can vary based on patient needs and the services they use; prices reflect the added costs of hospitals' public service role—like fire houses and police stations—serving the essential health care needs of a community 24 hours-a-day, seven days-a-week; and most hospitals cannot yet provide prices that reflect important information from other key players like the price of physician care while in the hospital or how much of the bill a patient's insurance company may cover. But more can, and should, be done to share hospital pricing information with consumers.

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:

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

We are pleased that CMS recently acknowledged in its FY 2007 Inpatient PPS Final Rule the complexities involved in presenting pricing information in an accurate and useful manner, and

the agency's recognition 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 also should have information on physician services and common procedures in hospital outpatient clinics and ambulatory surgery centers.

HAP supports a recently released position statement from AHA on hospital pricing transparency, outlining steps to be taken to improve the pricing information available to health care consumers. AHA shared this information with CMS in their comments on the FY 2007 Inpatient PPS Proposed Rule. In summary, they recommended:

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

- 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.

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

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

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 the Agency for Healthcare Research and Quality (AHRQ), complete research on what consumers want and would use in purchasing health care services.

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

Organization : Archbold Medical Center

Category : Hospital

Issue Areas/Comments

OPPS: Rural Hospitals Hold Harmless Transitional Payment

OPPS: Rural Hospitals Hold Harmless Transitional Payment

Small rural hospitals can not afford a reduction in the "hold-harmless" provision among outpatient services. Small rural hospitals are more reliant on Medicare reimbursed outpatient services than urban hospitals. A marginal reduction in this provision will have an exponential impact on small rural hospitals. Given the current cash position of most small rural hospitals, a reduction in the outpatient rate could place the hospital in a position of vulnerability.

Submitter : Mrs. Cheryl Rice **Date:** 10/09/2006

Organization : Catholic Healthcare Partners - Supplemental

Category : Hospital

Issue Areas/Comments

Visits

Visits

As noted, a separate comment was submitted on this topic to address specific concerns for visit coding elements. Another complicating factor associated with both urgent and emergent care services is the determination of what is considered 'triage' versus completion of the 'medical screening exam' (MSE) required of every patient under federal EMTALA provisions. The proposed AHA/AHIMA guidelines do not clearly define or differentiate when the MSE obligation has been met and what MSE services, if any, can then be considered billable. We recommend that CMS include a definitive description of the Medical Screening Exam services (MSE) and the threshold of time when the MSE is considered to have 'started' and 'stopped'. Specifically, CMS should clarify what basic activities are included in the MSE and if those activities include or exclude nurse triage functions. We also recommend that CMS include clear guidance on how to assign an EM level for patients who (a) are registered and triaged but leave before the hospital completes the MSE; (b) receive MSE but leave before required stabilizing interventions are initiated; and (c) receive MSE and receive initial interventions (i.e. lab work drawn for testing) or receive initial pain management medication but elope before testing or treatment is not completed. Another problematic provision of the proposed AHA/AHIMA guidelines is the use of nursing assessment entries for EM level scoring. Although this service can be most reflective of 'intensity of facility resources', it is also the area that can be most subjective unless specific definitions are developed in terms of content, frequency, and quality. We recommend that CMS work with AHIMA and Coding Clinic to determine what is considered a 'complete' nursing assessment entry from a documentation standpoint and as presently defined by Condition of Participation standards. In addition, Catholic Healthcare Partners recommend that CMS consider limiting the definition of 'nursing assessment' to those measurable, quantitative results, (i.e. blood pressure, breath tones, heart beats, pain threshold scoring tools, neurological assessments scales) currently recognized in the clinical criterion sets (e.g. Milliman & Robert or Interqual) used by CMS Fiscal Intermediaries, Carriers, QIOs and JCAHO. In this manner, CMS would be developing definitions consistent with existing care models and would reinforce common assessment standards.

Submitter : **Dr. John Ravita** **Date: 10/09/2006**

Organization : **Lexington Medical Center**

Category : **Hospital**

Issue Areas/Comments

OPPS: Drug Administration

OPPS: Drug Administration

The proposed 2007 payment for Bexxar is 50% lower than the present alowable. The present allowable was barely adequate. The effect of this proposal will be to deny Medicare patients state of the art treatment for lymphoma. Besides being state of the art, Bexxar is also less toxic than current chemotherapy. This is yet another example of the system short-changing the patient.

Submitter : **Mrs. Martha Potter** **Date: 10/09/2006**

Organization : **Southern Delaware Surgery Center**

Category : **Ambulatory Surgical Center**

Issue Areas/Comments

Policy and Payment Recommendations

Policy and Payment Recommendations

See attachment

CMS-1506-P-371-Attach-1.DOC

#311

Southern Delaware Surgery Center
18941 John J. Williams Hwy
Rehoboth Beach, DE 19971

October 9, 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 Southern Delaware Surgery Center in Rehoboth Beach, DE. Each year, our surgery center provides approximately 1900 procedures to Medicare beneficiaries. Medicare patients represent 39 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

I 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. I 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. I recommend general standard (1) "Covered surgical procedures are those surgical and other medical procedures that are commonly performed on an inpatient basis in hospitals, but may be safely performed in an ASC" be eliminated as obsolete. This recommendation is also supported by MedPAC's 2004 report which specifically states, "it no longer makes sense to consider inpatient volume when updating the ASC list."

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

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

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

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

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

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

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

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

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

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

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

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

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

c. Operating and recovery time limits are unnecessary.

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

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

B. Procedures Proposed for Addition to the ASC List

I 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, I am 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.

I am 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, I 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. I believe the HOPD data is a more reliable proxy for the cost of providing this service.

I am 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, I believe ASCs will not be able to cover the costs of performing these procedures under the current reimbursement methodology. However, I 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, I 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 co-payment 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 co-payment 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, I urge CMS to reconsider its decision to forgo adding the services presented in Table 42 (71 Fed. Reg. at 49629) because they are predominantly performed in the physician office.

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

a. Osteochondral arthroscopic grafting

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

b. Laparoscopic cholecystectomy

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

CMS indicated it was not including these procedures on the ASC list because an overnight stay would often be required for Medicare patients. In light of the volume data presented above, I believe many Medicare beneficiaries are having laparoscopic cholecystectomies performed without an overnight stay in the HOPD. I 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. I am 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 I noted above, I 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 I 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 I urge CMS to add G0289 to the ASC list effective January 1, 2007.

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

CPT Code	Descriptor
20610	Arthrocentesis, aspiration and/or injection; major joint or bursa
27096	Injection procedure for sacroiliac joint, arthrography and/or anesthetic/steroid
43257	Upper gastrointestinal endoscopy with delivery of thermal energy to the lower

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

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

I am supportive of CMS's plans to streamline the process of recognizing intraocular lenses that qualify for a payment adjustment as a new technology intraocular lens (NTIOL). I 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 I do not believe the proposed 30 day comment period is sufficient. Given the highly technical nature of NTIOLs, I believe a 60 day comment period would be more appropriate.

While I also generally agree with the list of examples of superior outcomes provided by CMS, I 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, I 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:".

I am also concerned about CMS's proposal to revise the language at §416.190 to require that the content of each request for an IOL review include information specified on the CMS web site. It is my 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 my comments. If you have any questions or need additional information, please do not hesitate to contact me. I can be reached via phone at 302-644-6992, via fax at 302-644-6995 or via email at mpotter@bbmc.org.

Sincerely,

Martha Potter, RN, CNOR, MHCA
Administrator

Submitter : **Dr. John Ravita** **Date: 10/09/2006**

Organization : **Lex Med Ctr**

Category : **Hospital**

Issue Areas/Comments

OPPS: Brachytherapy

OPPS: Brachytherapy

The proposed 2007 payment for Bexxar is 50% lower than the present alowable. The present allowable was barely adequate. The effect of this proposal will be to deny Medicare patients state of the art treatment for lymphoma. Besides being state of the art, Bexxar is also less toxic than current chemotherapy. This is yet another example of the system short-changing the patient.

Submitter : **Dr. stanley satz** **Date: 10/09/2006**

Organization : **Bio-Nucleonics, Inc.**

Category : **Device Industry**

Issue Areas/Comments

Impact

Impact

"See Attachment".

CMS-1506-P-373-Attach-1.TXT

#313

βIO-NUCLEONICS PHARMA, INC.

Utilizing Radiation to Improve Human Health

October 6, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05; Att: CMS-1506P
7500 Security Blvd.
Baltimore, MD 21244-1850

By Fedex and e mail to: http:www.cms.hhs.gov/erulemaking

In Re: File Code CMS-1506-P, HOPPS CY 2007. Payment Rates Proposed Rule For 78492, (APC 0307), Myocardial Positron Emission Tomography (PET) Scan RHQDAPU

Dear Sir/Madam:

This is a formal submission of comments regarding a proposed payment decrease by combining single and multiple cardiac PET imaging (APC307) studies into one. Bio-Nucleonics is a small business that focuses on innovative solutions utilizing radiation to improve human health.

According to the American Heart Association, in 2006, more than 1.5 million Americans will have a first or recurrent coronary attack, and 600,000 will die. Cardiovascular disease is the nation's single largest cause of death, and more women die of the disease than of cancer. Around 7.2 million Americans age 20 and older have survived a heart attack, and 13% of middle-aged men have coronary arteriosclerosis, most of it clinically silent. Some 6.6 million have angina pectoris. Cardiac PET is a solution to the major question for cardiac care providers of how to detect and identify silent coronary artery disease in specific individuals, and how to define its severity in either the symptomatic or asymptomatic patient.

Bio-Nucleonics respectfully requests a payment rate review (Payment Rates Proposed Rule For 78492 and APC 307), myocardial PET scan, and upward readjustment for 2007 by the Centers for Medicare and Medicaid Services from the proposed cost rate of $721.26 to $2,484.88 in order to accurately reflect the real cost of providing a multiple study myocardial positron emission tomography (PET) scan. The rationale for this request follows.

A drastic decrease by more than two-thirds in the payment rate for a multiple cardiac PET procedure, caused by "bundling" single procedures and multiple procedures will serve to drive the underutilization of myocardial PET. The CMS is using a fundamentally flawed methodology for setting a payment rate, biased against a proven diagnostic tool, ultimately costing the CMS hundreds of millions of dollars of excess reimbursements for unnecessary invasive procedures. If the proposed reduced reimbursement goes into effect, CMS could see an increase in cardiac catheterizations, bypass surgery and heart transplantations resulting from false positive and false negative misdiagnosis or prognosis, leading to undesirable therapeutic approaches.

The level of reimbursement for a cardiac PET perfusion procedure was appropriately set by local Medicare providers for a rest/stress procedure. While these were acceptable payment rates, hospitals may soon experience a change in the way they are reimbursed for outpatient procedures performed on Medicare beneficiaries, and that change threatens to erode payment levels impacting the most needy of patients. The potentially negative impact on cardiovascular healthcare in America and taxpayers is all too obvious.

Bio-Nucleonics Pharma, Inc. · 1 N.E. 19th Street · Miami, Florida 33132 · Tel: 305 576-0996 · ssatz@bionucleonics.com

The Reimbursement History of Cardiac PET

Cardiac PET has been validated by the Centers for Medicare and Medicaid Services (CMS) with coverage as a primary or initial diagnostic study for determining myocardial viability in patients with ischemic heart disease, and increased PET reimbursement by the CMS and private insurers reflects a growing understanding of its clinical value. Such changes encouraged physicians to use PET imaging to detect cardiovascular disease earlier, contributing to an overall improvement in patient outcomes. For 2006, the CMS appropriately increased the reimbursement for myocardial PET perfusion imaging involving multiple studies at rest and/or stress to $2,484.88. CMS came up with the new figure by analyzing claims data and splitting the ambulatory payment classification (APC) into single studies and multiple studies, similar to how SPECT myocardial perfusion imaging procedures are handled. The Society of Nuclear Medicine, the Academy of Molecular Imaging, the American Society of Nuclear Cardiology, and the CMS APC panel were among the proponents advocating the level splitting.

Historically, the FDA approved a PET radiotracer, as a cardiac perfusion agent in 1989, and HCFA afforded coverage for Medicare patients in 1994. It was unfortunate that because of insufficient reimbursement, the diagnostic advantages of cardiac PET languished for more than a decade. Payment rate is a critical component of coverage and has been the subject of much attention. Historically, In 1998 HCFA accorded 53.96 relative value units (RVUs) for oncologic PET studies, which equated to an average payment rate of $1,980. This RVU assignment was to reflect the total technical reimbursement for the procedure, including both the actual scan fee and the radiopharmaceutical charge. It is unfortunate that cardiac PET was treated much less favorably.

While there has been exponential growth in PET camera installations in the U.S. during the past decade, and in 2005, over 1 million mostly oncological and neurological PET scans were performed, cardiac PET has languished, becoming the "orphan" brother of oncological PET because reimbursement does not economically justify the purchase of a dedicated scanner. In facilities where there is no scanner time available because of oncological, neurological and research workloads, there is no coronary PET.

For 2007, however, the CMS proposes to "bundle" single and multiple myocardial PET Scans under one code, APC 0307, (CPT Codes 78459, 78491, 78492 and under the OPPS) and to reduce the payment rate for a heart image (PET) multiple study to $721.26, a catastrophic reduction that if enacted would essentially eliminate the delivery of cardiac PET diagnostic procedures to Medicare beneficiaries.

Rationale For Not "bundling" Single and Multiple Myocardial PET Scans Under One Code

1. The CMS is proposing "bundling" lower cost single studies with multiple studies into a single new code based upon the CY 2004 claims from a single hospital (See Page 196, Line 21). Contrary what the CMS states on Page 198 of its current proposal, hospital resources to perform single and multiple studies are not similar. A multiple study takes more time, requires the multiple administration of injectable drugs and radiopharmaceuticals, takes longer to read, reduces patient throughput (adding to the amortization cost of the scanner per study), and adds to the amount of administrative time required per patient.

2. CMS stated that "we now have more data to support our proposed payment rates... based on almost 1,500 single claims for both single and multiple scans and that this should be more reflective of the hospital resources required to provide the service to beneficiaries in the outpatient setting—and that based on this data, the differential median costs of single and multiple studies procedures do not support the present 2-level APC payment structure". In fact, only a very few hospitals perform over a thousand cardiac PET studies a year (Cleveland Clinic, Brigham and Woman's and Mount Sinai of New York). Thus the CMS data relied upon was only for one or two hospitals and continues to be flawed, skewing to single scans.

3. The new rate for a multiple cardiac PET study is based on a statistically insignificant small number of claims, wherein there is confusion on the part of billing clerks between single and multiple scans. This has unfortunately resulted in a skewing; using the cost of a single scan to also cover more costly multiple scans.

4. We have surveyed the five leading hospitals performing cardiac PET and spoken to the billing clerks, administrative personnel and nuclear cardiologists. The results of these finding is that in four of these institutions the persons that enter in the data that is transmitted to CMS did not know that a multiple scan could be billed separately! Instead, in error, they were entering multiple studies as single ones. The result is that underreporting and "averaging" skews the figure that CMS has arrived at in its conclusion to eliminate reimbursement for multiple scans and pay for a multiple scan at the single scan rate.

5. For example, Brigham and Women's Hospital is participating in a multicenter clinical study to compare the diagnostic accuracy, cost-effectiveness, and prognosis of PET, and SPECT in coronary angiography. This medical center and other participants in a NIH funded study are appropriately reporting to the CMS at zero or near zero dollars because the expenses are being covered under a multi-year grant.

6. Nuclear cardiologists report that the majority of cardiac PET scans being performed are multiple studies, not single ones.

7. If enacted, the proposed cut is extreme and will unquestionably change how, where and if Medicare patients get the imaging services they need. The CMS cannot simply cut cardiac PET scan reimbursement radically without affecting patients. The cut is based upon a statistically insignificant data. A survey of reporting hospitals has shown that the persons responsible for data input confused single studies for multiple studies and, in fact, did not know how to distinguish between a single study and a multiple study.

8. CMS examined only 296 claims for single scans and 1,150 claims for multiple images. In fact, based upon a population of about sixty radionuclide generators, about 60,000 cardiac PET scans were performed in 2005 (4 scans per day X 60 sites X 250 days). Therefore, even when those scans paid for by private insurers are removed, the number of claims analyzed by CMS is simply statistically insignificant and the number of "so-called" single and multiple procedures used by CMS is unreliable and does not reflect the actual multiple studies that were performed.

9. If this proposed reimbursement elimination for multiple scans and resulting reduction is allowed to stand, it will result in the underutilization of PET cameras, which could be used to detect cardiovascular disease. An example is "hibernating" heart muscle, which results in equivocal results if a SPECT scan is utilized. The potential impact would be a disservice to Americans and increased treatment costs of invasive therapy (i.e. coronary artery bypass graft), paid for by CMS.

10. Unlike MRI, Cardiac PET is not a high volume procedure and is not widely used by Medicare patients.

11. Therefore, proposed new and the assignment of a single APC 0307 and HCPCS Code 78492, and a single reimbursement rate and the methodology utilized is simply flawed. The result will be that the proposed rate will be inadequate to ensure appropriate access for Medicare beneficiaries.

12. The decrease proposed simply does reflect the actual costs that are associated with providing patient care and the impact of this would be catastrophic for cardiac patients and their families,

nuclear cardiologists and technicians, hospitals, the small businesses that provide mobile cardiac PET and pharmaceutical and medical device companies. The potential result upon the CMS and the taxpayer would be a greatly increased financial burden and the substitution of more costlier and invasive medical procedures such as cardiac catheterizations.

13. Myocardial PET is an unusual case, specifically a low volume procedure. It is requested that special consideration be given in accordance with CMS reimbursement policy.

14. Fluctuation may have resulted in CMS utilizing erroneous or skewed cost data.

15. The median cost of this drug was not taken into account by CMS.

16. CMS does not base the payment rate on accurate claims data as required by statute. In accordance with the Regulatory Flexibility Act (RFA) as relates to underpayment the verifiable information presented herein reflects the actual, widely available, market-based pricing of mobile cardiac PET or the short-term rental or lease of a Rubidium-82 generator and infusion cart.

17. There has been massive underreporting of consumption and data corruption in the CMS-1506-P, CMS-4125-P HOPPS CY 2007 Payment Rates Proposed Rule.

18. The RFA requires Federal agencies to consider alternatives to their rules to ease the burden on small businesses.

19. Protections granted under the Administrative Procedures Act are being violated.

20. Bio-Nucleonics seeks redress in accordance with the Federal Advisory Committee Act.

21. Bio-Nucleonics respectfully requests that the CMS abide by own proposal on Pages 144 and 145 and to exempt Myocardial PET, also granting an exception to the 2 times rule limit on the variation of costs as Myocardial PET is an unusual case consisting of a low-volume item in terms of the number of procedures performed consisting of 2,979 claims as shown in the CMS-1506 P Document, Page 195, and the number of doses of the radionuclide (A9555) consisting of 3,837 units utilized in 2005 X$239.83, as shown in the CMS-1506 P Document, Page 283.

22. Decreasing reimbursement does not follow the spirit of CMS's own policy, or the recommendation of the APC Panel. The CMS specifically stated the following in the Federal Register, "In cases where costs show significant fluctuation, we believe it is appropriate to mitigate the potential for underpayment". It is requested that this objective be implemented for multiple study myocardial PET reimbursement.

23. The Regulatory Flexibility Act requires agencies to consider alternatives to their rules to ease the burden on small businesses. Our sales price is determined in great part by what the U.S. Department of Energy and the Federal laboratories charge for radioisotope feedstocks. The cost of a radionuclide and processing are much higher than conventional drugs and the profit margin is much less. If we discontinue production of any radiopharmaceutical (the likely result of decreased reimbursement) oncological and cardiac care costs will be driven up even higher, the quality of healthcare will be decreased and there is no assurance that we will be able to economically produce other radiopharmaceuticals; products that could save CMS many millions of dollars each year. This will further exacerbate a difficult state of affairs for us as an already disadvantaged small business and manufacturer of proven cost–effective radiopharmaceuticals.

24. In accordance with the RFA as relates to underpayment the verifiable information presented herein reflects the actual, widely available, market-based pricing for the rental of a Rubidium-82

Generator and Infusion Cart, for the time needed to perform a PET Scan, for nuclear medicine technician time, for disposables (catheters and the disposable tubing and valves that need to be replaced daily) and for interpretation of the scan by a nuclear cardiologist. CMS's payment rate simply does not reflect the inherent costs and at which a broadly based, national sample are routinely able to procure this radiopharmaceutical. Respectfully, we ask the CMS to comply with its stated objective of "We believe it is appropriate to mitigate the potential for underpayment" as stated in the August 12, 2003 Federal Register.

The Economics of Cardiac PET

1. Using PET scanning rather than other types of imaging as the first tool to diagnose heart-vessel blockages is more accurate, less invasive and saves dollars, a study by University at Buffalo researchers has shown.

2. The broad-based Moran Study using 2006 Medicare claims data contradicts the view that imaging payments under HOPPS accurately reflects actual costs of performing a procedure. In fact, what would be paid is below the cost of performing a multiple study cardiac PET procedure.

3. The cost-savings that PET offers in being able to divert normal patients from receiving coronary angiography studies are considerable. The average cost of a PET study is about $1,480 (including Medicare patient and co-pay rates and technical and professional fees), compared to $3,270 for a cardiac catheterization.

4. By extrapolating these costs of one study's 233-person population, sending these patients for cardiac catheterization would have cost a total of $762,000. But by using PET instead after nondiagnostic SPECT, the cost would only be $528,000, even if 25% of the abnormal patients also went on to receive coronary angiography.

5. 890 sites reported they utilize a mobile service to provide PET or PET/CT imaging capability, resulting in a total of 1,400 sites offering PET imaging services. The 890 sites using mobile PET report using the mobile service for an average of 1.2 days per week per site. Assuming that the mobile vans are scheduled with no downtime between sites, an estimated 210 mobile vans serve these 890 sites. In 2001, the estimated average annual volume of clinical PET procedures per site was 385. Fixed PET sites conducted an average of 860 procedures per site in 2001, while mobile PET sites logged an average of 190 per site, and sites with gamma cameras that have coincidence-detection upgrades (NM-CD) performed 195 procedures per site. Currently, providers can offer PET procedures using a fixed PET scanner, a PET scanner in a mobile van. An estimated only 4 to 5% of PET scans were cardiac exams.

6. CMS pays separately for drugs on the basis of "the average acquisition cost of the drug". In fact, the average acquisition cost of the radionuclide is considerably more than what is reimbursed, (A9555, $239.83 a unit) because unlike most other radiopharmaceuticals, it is generator derived. Generators must be replaced at a cost of $28,500 a month, so if the patient load decreases, the cost per procedure increases dramatically. Many hospitals where myocardial PET is practiced utilize a mobile PET generator for a half a day or a day at a fixed cost. Therefore a multiple study takes more PET scanner time, more nuclear medicine technician time, longer scan and set-up time, more rental time, more supplies, more time to interpret the scan, and certainly costs more than a single study.

7. The radionuclide generator used to deliver a short-lived dose of the radionuclide used for myocardial PET costs about $500 an hour to rent, usually from a small business, and there is usually a minimum rental time, which is 4 hours or a full day. In some locations a mobile PET camera is utilized which can cost around $70,000 a month to rent. Typically, at most facilities only one to four cardiac PET scans are performed. The proposed CY 2007 payment rate of $721.26 for a

multiple procedure is woefully inadequate to cover even a portion of these costs. At the 2007 proposed reimbursement rate, it is estimated that a hospital would have to perform more than eight myocardial PET scans a week to break even, not including compensation for the nuclear medicine technologist, nuclear cardiologist, nurse or physician's assistant and an administrator.

8. Another potential consequence of the proposed CMS' rule will be increasing numbers of hospitals may substitute expensive but more highly reimbursable cardiac catheterization procedures, costing American taxpayers and the CMS hundreds of millions of dollars more for the treatment of cardiovascular disease than is already being spent. It is not known how the reimbursement figure was arrived at, what the relevant weight was or how the reduction was derived, but it certainly does not reflect the real acquisition cost of this drug. Clearly, this situation is untenable and needs to be expeditiously readjusted. The decreased usage of cardiac PET stress tests to detect cardiovascular disease will likely result in CMS paying at least $200 million more each year for cardiac catheterizations, balloon angioplasties and stenting, coronary artery bypass surgery and hear transplantations than it did in 2005, (10,000 patients at a $20,000 savings per patient), resulting from additional costs for procedures, supplies, hospital visits, CT Scans and tertiary care.

About Cardiac PET

Cardiac PET (positron emission tomography) is the newest and most powerful modality for detection and treatment of cardiovascular disease. PET is the newest, most powerful and accurate noninvasive test available to reveal or rule out the presence of coronary disease facilitating the most effective course of treatment. It not only provides an accurate assessment of blood flow to the heart, it indicates whether the appropriate treatment lies in transplant or bypass surgery. The advantage of the technology is that unlike SPECT, Cardiac PET enables evaluation of both myocardial perfusion and viability, delivering rapid patient throughput and superb image quality. The combination of PET and a diagnostic radiopharmaceutical enables delivery of the benefits of advanced cardiac PET stress testing to patients. This provides cardiologists with a new tool more sensitive and specific to cardiac disease than other imaging modalities, reducing equivocal results, saving the CMS and private insurers costs associated with invasive cardiac catheterization procedures, costly bypass surgery and non-beneficial drugs, shortened examination times, patient comfort, enables diagnosis of obese patients, delivers less than one tenth the radiation exposure of any other modality, and does not require additional technical training for physicians.

PET can more accurately define a host of disease processes that conventional, anatomic-based imaging alone (CT, X-Ray or MRI), oftentimes before symptoms appear. It traces molecular and functional processes in the body. PET can compliment any oncology, neurology or cardiology service, providing a non-invasive analytical tool for coronary artery disease, cancer and neurological conditions. Only PET delivers diagnostic performance in a fraction of the time that it takes for a conventional stress test. A myocardial perfusion study can be performed in only 40 minutes or less, compared to 2 to 3 hours for SPECT. This translates into added patient comfort, convenience and high throughputs.

The broader availability of PET imaging enhances diagnostic capabilities of patients that have or are suspected of having cardiovascular disorders or at-risk situations, early enough to make a difference. The clinical value of cardiac PET to deliver superb image quality is proven and well accepted. Regional myocardial perfusion can be evaluated to determine the presence and severity of coronary artery disease and impaired blood flow, response to treatment can be monitored and significant prognostic value has been demonstrated for predicting cardiac events including death and myocardial infarction.

Cardiac PET metabolic imaging PET can differentiate viable from nonviable myocardium in patients with ischemia is helpful in patient selection of those benefiting from revascularization, and can also identify "hibernating" tissue that may recover function after a procedure. Mismatch between blood flow and radionuclide uptake can predict post revascularization improvement, symptomatic relief and survivals. The information obtained can help avoid unnecessary and costly invasive procedures.

PET can be used to pinpoint the appropriate form of intervention, reducing the potential for equivocal results that may lead to high-risk procedures such as cardiac catheterization, transplantation and bypass surgery.

Unlike any other imaging modality, PET perfusion stress testing is more specific than SPECT, giving rise to few false negatives, and is more sensitive, resulting in fewer false positives. Unlike PET, SPECT studies are oftentimes compromised due to poor image quality or attenuation artifacts. PET can be used with improved diagnostic confidence in patients after an inconclusive SPECT scan. With PET there is considerably lower radiation exposure to patients and medical staff than SPECT.

Myocardial perfusion PET is both useful and prognostically predictive in a heterogeneous patient population with challenging SPECT scans. Cardiac PET following nondiagnostic SPECT resolved all of the patients except five, and these findings influence the coronary arteriogram rates. The majority of the patients in the study had a normal PET and were associated with a low likelihood of short-term events, obviating unnecessary coronary angiography.

If the proposed procedural "bundling" allowed to pass, this will further exacerbate a difficult state of affairs for us and others as already disadvantaged small businesses and manufacturers of cost–effective radiopharmaceuticals as well as the small businesses that provide mobile PET services. Please keep in mind that the RFA requires Federal agencies to consider alternatives to their rules to ease the burden on small businesses.

A reimbursement reduction by CMS in 2007, for multiple study myocardial PET could be an unfortunate one for the many thousands of Medicare recipients with cardiovascular symptoms or disease. The fact is that the drastic decrease in the payment rate proposed by CMS will result in the underutilization of a cost effective, proven diagnostic that needs to be expeditiously adjusted in order to accurately reflect the actual cost of a multiple scanning procedure.

CMS would be "shooting itself in the foot" and being "penny-wise and pound foolish" by setting the reimbursement rate for a dose of Strontium-89 so low that many hospitals, which are bottom line driven, will gravitate to procedures or to products where they can make a substantial profit.

As a potential result of this flawed CMS reimbursement proposed policy for myocardial PET for 2007, more and more Americans with heart disease or those suspected may be misdiagnosed needlessly, and their care and well being will be affected. With the CMS setting the standard, insurance companies are likely to follow suit, thus inflating the number of patients not receiving treatment. This flawed policy will result in increased costlier cardiac catheterization procedures, a decrease in quality-of-life and a dramatic rise in the cost of health care.

Also, what could be attributable to reduced CMS reimbursement for myocardial PET is that the uninsured will probably not be receiving this form of treatment at public hospitals, and the policy could also carry over to Medicaid patients. Since the number of uninsured is increasing nationwide, Medicaid costs are expected to increase even more dramatically and will be even further impacted unfavorably by the underutilization of this important diagnostic.

Through the use of myocardial PET, the CMS could achieve a substantial savings in health care treatment costs, at the same time through high specificity and accuracy only available with PET, decreasing the need for more invasive interventional procedures and improve the quality-of-life of patients suffering from cardiovascular disease. Pharmacoeconomic data supports this assumption.

Cardiac PET stress tests are used to check the health of the coronary arteries for functionally significant obstructions (narrowing), which can reduce blood flow to heart muscle and lead to the heart muscle becoming "starved" of oxygen. This condition is called coronary artery disease. Symptoms can include chest pain and shortness of breath. With coronary artery disease there is an increase in the possibility of a myocardial infarction (heart attack). PET cardiac scans are more accurate than other cardiac stress tests such as Thallium-201 SPECT (Single Photon Emission Computed Tomography) in the detection of heart disease and provide enhanced quantification. Because of this increase in accuracy, invasive catheterizations

can often be avoided in those patients who do not need it. Knowing about these obstructions can help the physician decide the best course of further diagnostic tests and treatment, such as catheterization, when necessary.

Because the radionuclides used in cardiac PET are so short lived, the patient must undergo pharmacological stress, and the radioisotope must be injected at peak stress through an infusion system. Clinical data show that cardiac PET's almost instantaneous ability to image a patient provides very high accuracy in identification of ischemia. In addition, it reduces a stress and rest test to 45 minutes, compared with routine SPECT myocardial stress imaging, which takes place over three to four hours.

Cardiac PET has also proven beneficial for difficult-to-image patients. Because of the limitations of SPECT, obese patients generally cannot be imaged. Those patients who need to undergo pharmacological stress are those who are usually the sickest; those are the patients for whom cardiac PET provides a significant advantages.

In one study, PET was able to resolve 98% of the nondiagnostic SPECT studies, reclassifying patients as either normal or abnormal. PET scans were normal in 170 patients (73%), and only 58 patients (25%) were reclassified as abnormal. Only three patients in the normal group went on to have coronary angiography within 60 days of PET (none of whom turned out to have significant coronary disease). Of the 58 abnormal patients, 29 were referred to coronary angiography within 60 days of PET and 18 had revascularization. Of the 29 patients who received angiography, 20 had significant coronary disease.

Conaway calculated the cost-savings that PET offers in being able to divert normal patients from receiving coronary angiography studies. The average cost of a PET study is about $1,480 (including Medicare patient and co-pay rates and technical and professional fees), compared to $3,270 for a cardiac catheterization. By extrapolating these costs to the study's 233-person population, Conaway said that sending all the patients to cardiac cath would have cost a total of $762,000. But by using PET instead after nondiagnostic SPECT, the cost would only be $528,000, even if 25% of the abnormal patients also went on to receive coronary angiography.

Rubidium-82 myocardial perfusion PET is both useful and prognostically predictive in a heterogeneous patient population with challenging SPECT scans. PET following nondiagnostic SPECT is resolute and these findings influence the coronary arteriogram rates. The majority of these patients had a normal PET and were associated with a low likelihood of short-term events, obviating unnecessary coronary angiography.

Cardiac PET specificity is 95% or greater versus 45% for SPECT and sensitivity for PET is 95% versus 88% for SPECT meaning a much lower incidence of false negatives and false positives, that can result in unnecessary but costly invasive procedures being performed. With cardiac PET, there is the potential to reduce cardiac care costs by 20% to 50%.

In a patient with symptoms suggestive of coronary artery disease, a central clinical issue is to determine whether a coronary angiogram is necessary for further work-up. A variety of non-invasive imaging tests, including PET and SPECT scans, have been investigated as a means of identifying reversible perfusion defects, which may reflect coronary artery disease, and thus identify patients who may benefit from further work-up with an angiogram.

The ACC/AHA guidelines note that PET imaging "appears to have better overall accuracy for predicting recovery of regional function after revascularization in patients with left ventricular (LV) dysfunction than single photon techniques (i.e., SPECT scans)."

PET has been most thoroughly researched as a technique to assess myocardial viability to determine candidacy for a coronary revascularization procedure. For example, a patient with a severe stenosis

identified by coronary angiography may not benefit from revascularization if the surrounding myocardium is non-viable. A fixed perfusion defect, as imaged on SPECT scanning or stress thallium echocardiography, may suggest nonviable myocardium. However a PET scan may reveal metabolically active myocardium, suggesting areas of "hibernating" myocardium that would indeed benefit from revascularization. The most common PET technique for this application consists of a perfusion tracer and a metabolic marker of glucose utilization. A pattern of uptake in areas of hypoperfusion (referred to as blood flow mismatch) suggests viable, but hibernating myocardium. The ultimate clinical validation of this diagnostic test is the percentage of patients who experience improvement in left ventricular dysfunction after revascularization of hibernating myocardium, as identified by PET scanning.

I share in the CMS objective of reducing the cost of healthcare, and am aware that under CMS reimbursement, hospitals sometimes get less than the actual cost for some products, irrespective of the impact of cost of living adjustments. However, the profit margin to hospitals, radiopharmacies and especially to us for a Myocardial PET Procedure, (78492), not a high volume procedure, saves money for CMS and the taxpayer.

Respectfully, we also ask the CMS to comply with its objective as stated in Section 1833(t) (9) (A) of the Act requiring the Secretary to revise the relative payment weights taking into account new cost data and other relative information and factors, in the Federal Register, wherein the CMS states that "we believe it is appropriate to mitigate the potential for underpayment", and in an 8/15/03 press release, quoting former Former Administrator Scully, "We want to make certain that Medicare pays for the drugs and services it covers..."

To reiterate, as of August, 2006, reimbursement is $2484, so that if the proposed 2007 Medicare reimbursement reduction is enacted, patient, hospitals and clinics would lose money on procedure. If the HOPPS reimbursement rate stands, hospitals will receive much less than the actual cost of providing the service including all discounts and rebates, even after patient co-pay. Medicare reimbursement will further exacerbate a difficult state of affairs for us as a small business manufacturer of radiopharmaceuticals. Bio-Nucleonics' suggests a proposed solution for reimbursement readjustment; an equitable and fair reimbursement rate of $2,484, reestablishing the 2006 rate for this procedure.

The CMS needs to reevaluate the potential impact on patients and take patient access into account when developing regulations to implement the proposed reduction. CMS should conduct a detailed analysis of offsetting savings and efficiencies brought about by the substitution of imaging for more invasive and costly procedures that do not reduce cost or improve quality. Early diagnosis saves money and lives. This is especially where cardiac PETcomes into play.

This is to thank the CMS staff in advance for taking the time to investigate this matter, for the opportunity of presenting a suggested solution for this problem to CMS and hopefully, to resolve this situation. Should you have any questions, please contact me at your convenience at 305 576-0996 or by e-mail at ssatz@bionucleonics.com.

Sincerely,

Stanley Satz
President

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

Organization : **Radiosurgery Medical Group**

Category : **Other Health Care Professional**

Issue Areas/Comments

OPPS

OPPS

See attached

CMS-1506-P-374-Attach-1.PDF

A 574

RSMG | RADIOSURGERY MEDICAL GROUP, INC.

October 9, 2006

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

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

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

New Technology APCs

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

P.O. Box 33865 San Diego, CA 92163-3865
Phone: 858.505.4100 I Fax: 858.751.0601

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

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

CY 2002

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

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

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

In the November 30, 2001 Federal Register CMS also indicated that it was planning to adopt a new HCPCS code for fractionated (i.e. staged) radiosurgery procedures, which

1 Federal Register, November 30, 2001, page 59865.
2 Federal Register, November 30, 2001, page 59866.

P.O. Box 33865 San Diego, CA 92163-3865
Phone: 858.505.4100 | Fax: 858.751.0601

was introduced in a March 28, 2002 Program Memorandum3. 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 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

---

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

4 Federal Register November 30, 2001, page 59868

P.O. Box 33865 San Diego, CA 92163-3865
Phone: 858.505.4100 I Fax: 858.751.0601

New Technology APCs
[CMS-1506-P; CMS-4125-P] RIN 0938-AO15
Section c, Pages 49553 and 49554

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).

Proposed CY 2007 APC Changes

We believe that the changes proposed by CMS for CY 2007 are based on flawed methodology. The Hospital Outpatient Prospective Payment System (OPPS) was intended by Congress to be resource-based, as reflected in hospital cost and charge data. The question is ***whether the APC rates adopted by CMS for a covered service for which***

P.O. Box 33865 San Diego, CA 92163-3865
Phone: 858.505.4100 I Fax: 858.751.0601

there is inadequate and inconsistent claims history appropriately reflect the relative clinical utility and whether the rate established by CMS reflects a reasonable estimate of the resources involved.

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

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

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

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

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

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

   The basis for determining the proposed APC rate for CY 2007 for image-guided robotic stereotactic radiosurgery was a review of claims data for G0339 and G0340. Of the 486 claims analyzed for 2004, 15% of the claims came from centers using the G0339 code which did not have an image-guided robotic

P.O. Box 33865 San Diego, CA 92163-3865
Phone: 858.505.4100 I Fax: 858.751.0601

stereotactic radiosurgery system. As a result, inclusion of their data in the calculation of the appropriate APC results in a lower median cost. The average cost, as indicated in the Identifiable Data Set Hospital OPPS file for CY 2004 for true image-guided robotic stereotactic centers (CyberKnife) is reported at $6,203.27 per unit. For non-CyberKnife centers, the average cost is $3,479.65. The range in costs and charges is not surprising since the code has been used by centers that do not provide image-guided robotic stereotactic radiosurgery services.

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

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

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

Historical Precedent – Gamma Knife New Technology Codes

We also note that CMS is proposing to assign the Gamma Knife to a higher APC, while

P.O. Box 33865 San Diego, CA 92163-3865
Phone: 858.505.4100 | Fax: 858.751.0601

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

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

G0339 and G0340 Code Descriptors

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

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

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

P.O. Box 33865 San Diego, CA 92163-3865
Phone: 858.505.4100 I Fax: 858.751.0601

New Technology APCs
[CMS-1506-P; CMS-4125-P] RIN 0938-AO15
Section c, Pages 49553 and 49554

CY 2004 and CY 2005 Data Variability Summary

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

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

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

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

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

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

P.O. Box 33865 San Diego, CA 92163-3865
Phone: 858.505.4100 | Fax: 858.751.0601

Conclusion

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

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

Recommendations

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

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

► CMS continue to work with CyberKnife centers to establish accurate and adequate

P.O. Box 33865 San Diego, CA 92163-3865
Phone: 858.505.4100 I Fax: 858.751.0601

New Technology APCs
[CMS-1506-P; CMS-4125-P] RIN 0938-AO15
Section c, Pages 49553 and 49554

reimbursement for image-guided robotic stereotactic radiosurgery (r-SRS).

Sincerely,

Douglas G. Myking, M.B.A.
Chief Financial Officer
Radiosurgery Medical Group, Inc.
5395 Ruffin Road, Suite 103
San Diego, CA 92123
Phone: (619) 220-4100
Email: dmyking@rmgmed.com

P.O. Box 33865 San Diego, CA 92163-3865
Phone: 858.505.4100 | Fax: 858.751.0601

Submitter : **Mrs. Denise Merlino** **Date: 10/09/2006**

Organization : **Society of Nuclear Medicine**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-375-Attach-1.PDF

#215

snm
advancing molecular imaging & therapy

1850 Samuel Morse Drive
Reston, VA 20190-5316
Tel: 703.708.9000
Fax: 703.708.9015
www.snm.org

October 9, 2006

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

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

ATTN: FILE CODE CMS-1506-P

Re: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates; Proposed Rule

Dear Administrator Norwalk:

We are sending this supplemental letter to the Centers for Medicare and Medicaid Services (CMS) to reaffirm our position and requests stated in our September 19, 2006 comments to the Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates; Proposed Rule, and our meeting with CMS on October 2, 2006.

These supplemental remarks reinforce especially the concern of the Society of Nuclear Medicine for the future introduction of new radiopharmaceuticals, if the proposed method for setting reimbursement for 2007 remains unchanged. We believe that greater than 50% of all radiopharmaceuticals used in this country are underpriced by a reimbursement system that relies on hospital or department CCR reduced data; and that with that system, nearly all radiopharmaceuticals that cost hospitals more than $200 are moderately to severely undervalued, some up to ten times in this proposed 2007 Rule. This pertains especially to therapeutic radiopharmaceuticals and diagnostic imaging radiolabeled monoclonal antibody products. The proposed 2007 pricing structure, we believe, will discourage any manufacturer from launching a lengthy and costly program to develop a new commercial radiopharmaceutical even if research has shown that it has unique clinical value.

We have appended a Table "Radiopharmaceutical Cost Comparisons" (Addendum A) that supports our conclusion about the disparity of hospital cost data, especially for higher cost items. (note: this Table is updated from our meeting with CMS on October 2.)

The SNM will be working with the nuclear medicine community to assess other feasible means by which CMS could acquire more accurate radiopharmaceutical hospital acquisition cost data.

snm
advancing molecular imaging & therapy

1850 Samuel Morse Drive
Reston, VA 20190-5316
Tel: 703.708.9000
Fax: 703.708.9015
www.snm.org

Cardiac CTA Codes

The SNM 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, should not be included in any Nuclear Medicine APC. **We recommend that CMS remove all Cardiac CTA codes from Nuclear Medicine APCs and place them in appropriate non-Nuclear Medicine New technology APCs**. We will defer to comments being submitted by other medical specialties regarding the exact placements of those procedures. We strongly oppose CMS placing NON-nuclear medicine technology procedure codes in any nuclear medicine APC, as that destroys the clinical and resource homogeneity of the APC, something that we have worked with CMS to develop since the inception of the HOPPS.

Radiopharmaceutical Reimbursement

HCPCS Applications for 2008 Cycle

During the October 2nd meeting, the SNM noted that we continue to work with the HCPCS workgroup regarding radiopharmaceutical HCPCS codes and descriptions. **We believe there is a need for more refinement of the current codes including new codes to accurately reflect all the forms** and varying costs of radiopharmaceuticals used by nuclear medicine providers today. We believe the hospital costs are not accurately reflected in some of the current CMS data given the absence of these codes from the system. The SNM and ACR jointly submitted 5 HCPCS applications and one application was submitted by a manufacturer for the 2008 cycle:

- Indium In-111 Labeled White Blood Cells, diagnostic, per study dose
  - Providers may be using HCPCS code A9547 *Indium In-111 oxyquinoline, diagnostic, per 0.5 millicurie* or A4641 RP, diagnostic, NOC for this code in 2006 and 2007
- Indium In-111 Labeled Platelets, diagnostic, per study dose
  - Providers may be using HCPCS code A9547 *Indium In-111 oxyquinoline, diagnostic, per 0.5 millicurie* or A4641 RP, diagnostic, NOC for this code in 2006 and 2007
- Technetium Tc-99m HMPAO Labeled White Blood Cells, diagnostic, per study dose
  - Providers may be using HCPCS code A9521 *Technetium Tc-99m exametazime, diagnostic, per study dose, up to 25 millicuries* or A4641 RP, diagnostic, NOC for this code in 2006 and 2007.
- Iodine I-123 Sodium Iodide, diagnostic, per millicurie, (for I-123 administrations greater than 600 uCi and to accommodate for typical doses of 2-4 mCi for diagnostic whole body imaging)
  - Providers may be using HCPCS code A9516 *Iodine I-123 sodium iodide capsule(s), diagnostic, per 100 microcuries* or A4641 RP, diagnostic, NOC for this code in 2006 and 2007.
- Technetium Tc-99m Filtered Sulfur Colloid, per study dose
  - Providers may be using HCPCS code A9541 *Technetium Tc-99m sulfur colloid, diagnostic, per study dose, up to 20 millicuries* or A4641 RP, diagnostic, NOC for this code in 2006 and 2007.
- Iodine I-123 iodobenguate, diagnostic, per study dose

snm
advancing molecular imaging & therapy

1850 Samuel Morse Drive
Reston, VA 20190-5316
Tel: 703.708.9000
Fax: 703.708.9015
www.snm.org

- Providers may be using HCPCS code A9508 *Iodine I-131 iobenguane sulfate, diagnostic, per 0.5 millicuries* or A4641 RP, diagnostic, NOC for this code in 2006 and 2007.

HCPCS codes are needed for these radiopharmaceuticals as they have very different chemical forms and greatly varying costs from the available codes. The current CMS claims data likely averages the costs of the two or three different forms of radiopharmaceuticals. Due to providers' choices for HCPCS codes to report these radiopharmaceuticals, CMS is effectively underpaying for one form and overpaying for the other form, which we strongly object to this practice. This is apparent in looking at the CMS claims data for HCPCS code A9539 *Technetium Tc-99m pentetate, diagnostic, per study dose, up to 25 millicuries* and new HCPCS code A9567 *Technetium Tc-99m pentetate, diagnostic, aerosol, per study dose, up to 75 millicuries.*

HCPCS Code A9554

The SNM has also identified , **A9554 Iodine I-125 Sodium Iothalamate,** which is likely to be an issue due to its current description. In 2004 and 2005 at the open CMS HCPCS meetings, the SNM requested a description of per 10 uCi for this radiopharmaceutical. In 2006, CMS published a per study dose description up to 10 uCi. A typical dose of this radiopharmaceutical, however, is 20 to 100 uCi, and the cost of a 100-uCi vial is approximately $2,247, including shipping. CMS claims data and radiopharmaceutical cost are likely to be incorrect in future claims until we are able to work with the HCPCS committee to identify the issue and resolve the confusion.

HCPCS Code A9529

During our October 2, 2006 meeting with CMS, we requested that CMS re-review its claims data for HCPCS code A9529. The SNM has evaluated the claims data for HCPCS codes A9529 and C9404 (the generic version of the I-131 solution) and, based on our analysis, respectfully request that CMS consider that in circumstances where only one cent ($0.01) separates a product from a class of other products that are paid separately, **CMS consider and pay separately and not package the product into a procedure.** CMS staff responded to our request to verify our calculations, and confirmed that the claims data places radiopharmaceutical A9529 just one cent away from the $55.01 separately payable figure . We respectfully ask that CMS review the four other I-131 radiopharmaceuticals – A9516, A9517, A9528, A9530 –which are to be separately paid in CY 2007. These radiopharmaceuticals represent different I-131 versions of capsules versus solutions and diagnostic versus therapeutic and should all be paid separately as well as A9529 for 2007.

CMS Radiopharmaceutical Claims Data

As stated in our September 19, 2006 comments and during our recent meeting, the SNM believes that CMS' radiopharmaceutical claims data is flawed , **and we again request that CMS continue with the current cost-to-charge (hospital CCR) payment methodology for CY 2007** while we investigate other payment methods for 2008 and beyond.

snm
advancing molecular imaging & therapy

1850 Samuel Morse Drive
Reston, VA 20190-5316
Tel: 703.708.9000
Fax: 703.708.9015
www.snm.org

One of the SNM's main concerns with CMS' proposed methodology is that, for some products, the claims data is not representative of the true cost. This is especially egregious for radiopharmaceuticals that cost greater than $200 (See Addendum A.) This is also true for certain products that have gone on and off the market over the years, leaving large gaps in the claims data for these radiopharmaceuticals.

The SNM hopes to work with CMS in determining the best payment methodology for all radiopharmaceuticals. At the 2006 winter/spring APC Panel Meeting, CMS made available its 2005 claims data. This data and the analyses that CMS ran and shared were extremely useful. The SNM **encourages CMS to run the 2006 claims data and make it available to the public as soon as it's available.** Such data and analyses are critical in determining a proper payment methodology for the upcoming year.

Radiopharmaceutical Payment Methodologies

As stated in our previous comments and during the recent meeting, the SNM is concerned that true radiopharmaceutical handling costs are not reflected in the current charge data being acquired by CMS. We do not believe that there is any fixed or sliding dollar amount or percentage that would accurately account for the handling costs of each and every radiopharmaceutical, but we do believe that hospitals could accurately determine radiopharmaceutical handling costs on average for each individual procedure. This would be consistent with policies under the RBRVS. **Therefore, the SNM strongly recommends that CMS direct hospitals to include the handling costs of radiopharmaceuticals in their charges for nuclear medicine procedures.**

During our October 2, 2006 meeting, the SNM reviewed several potential sources for long-term rate setting for radiopharmaceutical payment data. These sources included: manufacturers, hospitals claims data, physician office data, surveys, and central radiopharmacies. The SNM believes that the most reliable source for collecting useful and quality data is central radiopharmacies, which provide over 90% of radiopharmaceuticals used by hospitals. Given this, the SNM plans to work with the NM APC Task Force and other interested parties in conducting a brainstorming session of how best to go about collecting and analyzing data from central radiopharmacies. The SNM hopes to work collaboratively with CMS in this endeavor and looks forward to meeting with CMS following the release of the final rule to discuss this further.

Again, the SNM appreciates the opportunity to comment on this HOPPS 2007 Proposed Rule to the CMS. Should you find it appropriate to do so, the SNM is ready to discuss any of its comments on the above issues. Please contact the Society of Nuclear Medicine coding and reimbursement advisor, Denise A. Merlino at dmerlino@snm.org, or at 781-435-1124.

Respectfully Submitted,

Gary Dillehay, M.D., FACR, FACNP
Chairman, Coding & Reimbursement Committee

Kenneth McKusick, M.D., FACR, FACNP
SNM Member, CPT Advisory Committee

snm
advancing molecular imaging & therapy

1850 Samuel Morse Drive
Reston, VA 20190-5316
Tel: 703.708.9000
Fax: 703.708.9015
www.snm.org

cc: Herb Kuhn, CMS
Kenneth Simon, MD, CMS
Edith Hambrick, MD, CMS
James Hart, CMS
Carol Bazell, MD, CMS
Joan Sanow, CMS
SNM Coding & Reimbursement Committee
Nuclear Medicine APC Task Force

Addendum A

snm advancing molecular imaging & therapy

1850 Samuel Morse Drive
Reston, VA 20190-5316
Tel: 703.708.9000
Fax: 703.708.9015
www.snm.org

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O
1	HCPCS 2006 & other years for comparison	Description	Comments	Final 2006	Prop 2007	CY 2005 Final Rate	CMS Proposed 2007 Rate	SNM Survey 2002 Mean Cost	GAO Acq Cost Survey 2004 Average Purchase Price	Mini 2006 SNM Survey AVG	CMS Mean Unit Cost 2005 Data	CMS 2005 Days	CMS 2005 Units	CMS Days / CMS Units	Days/unit X Mean Cost
2	A4641	Radiopharm dx agent noc RADIOPHARMACEUTICAL, DIAGNOSTIC, NOT OTHERWISE CLASSIFIED	Providers should ONLY use this code in the absence of a specific diagnostic RP HCPCS code. (eg F-18 sodium flouride, I-123 MIBG, In-111 WBC, Tc99m labeled WBC)	N	N	Packaged	Packaged	N/A	n/a	n/a	$62.37	77747	92076	1.18	$73.86
3	A4642 and C1066	In111 satumomab INDIUM IN-111 SATUMOMAB PENDETIDE, DIAGNOSTIC, PER STUDY DOSE, UP TO 6 MILLICURIES	In 2004 and 2005 description is per dose.	H	K	$1,390.25	$192.12	$1,470.45 $1,494.41	n/a	$1,915.05	$192.12	557	613	1.10	$211.44
4	A9500	Tc99m sestamibi TECHNETIUM TC-99M SESTAMIBI, DIAGNOSTIC, PER STUDY DOSE, UP TO 40 MILLICURIES	None	H	K	$106.32	$82.58	$100.69 $97.69	$75.15	$88.59	$82.58	380256	608483	1.60	$132.14
5	A9502	Tc99m tetrofosmin TECHNETIUM TC-99M TETROFOSMIN, DIAGNOSTIC, PER STUDY DOSE, UP TO 40 MILLICURIES	None	H	K	$104.58	$73.81	$74.82	$70.70	$80.37	$73.81	222588	353488	1.59	$117.22
6	A9503	Tc99m medronate TECHNETIUM TC-99M MEDRONATE, DIAGNOSTIC, PER STUDY DOSE, UP TO 30 MILLICURIES	None	N	N	Packaged	Packaged into APC rate	$19.44	n/a	$13.13	**$24.67**	297031	299306	1.01	$24.86

snm
advancing molecular imaging & therapy

1850 Samuel Morse Drive
Reston, VA 20190-5316
Tel: 703.708.9000
Fax: 703.708.9015
www.snm.org

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O
1	**HCPCS 2006 & other years for comparison**	**Description**	**Comments**	**Final 2006**	**Prop 2007**	**CY 2005 Final Rate**	**CMS Proposed 2007 Rate**	**SNM Survey 2002 Mean Cost**	**GAO Acq Cost Survey 2004 Average Purchase Price**	**Mini 2006 SNM Survey AVG**	**CMS Mean Unit Cost 2005 Data**	**CMS 2005 Days**	**CMS 2005 Units**	**CMS Days / CMS Units**	**Days/unit X Mean Cost**
7	A9504	Tc99m apcitide TECHNETIUM TC-99M APCITIDE, DIAGNOSTIC, PER STUDY DOSE, UP TO 20 MILLICURIES	Acutect; this product has gone on and off the market in 2004 and 2005 due to manufacturing issues which were resolved. We are again checking if this product is on the market in 2006.	H	N	$415.00	Packaged into APC rate	$350.46	n/a	$437.12	$51.16	994	994	1.00	$51.16
8	A9505 CMS combined generic code yes	TL201 thallium THALLIUM TL-201 THALLOUS CHLORIDE, DIAGNOSTIC, PER MILLICURIE	C9400 Thallium generic per mCi, CMS used 2005 claims data for rate setting and did not list separately units or costs in public file.	H	K	$18.29	**$27.18**	$32.87 $35.27	$17.18	$18.49	**$27.18**	132448	407956	3.08	$83.72
9	A9507	In111 capromab INDIUM IN-111 CAPROMAB PENDETIDE, DIAGNOSTIC, PER STUDY DOSE, UP TO 10 MILLICURIES	None	H	K	$1,915.23	$928.19	$1,774.30	$1,801.12	$1,914.18	$928.19	2109	2109	1.00	$928.19
10	A9508	I131 iodobenguate, dx IODINE I-131 IOBENGUANE SULFATE, DIAGNOSTIC, PER 0.5 MILLICURIE	MIBG, caution, there are therapeutic uses of this product along with diagnostic uses, providers should use A9699 for therapeutic use of this RP.	H	K	$996.00	$429.55	N/A	n/a	$1,986.00	$429.55	423	593	1.40	$602.18

snm
advancing molecular imaging & therapy

1850 Samuel Morse Drive
Reston, VA 20190-5316
Tel: 703.708.9000
Fax: 703.708.9015
www.snm.org

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O
1	**HCPCS 2006 & other years for comparison**	**Description**	**Comments**	**Final 2006**	**Prop 2007**	**CY 2005 Final Rate**	**CMS Proposed 2007 Rate**	**SNM Survey 2002 Mean Cost**	**GAO Acq Cost Survey 2004 Average Purchase Price**	**Mini 2006 SNM Survey AVG**	**CMS Mean Unit Cost 2005 Data**	**CMS 2005 Days**	**CMS 2005 Units**	**CMS Days / CMS Units**	**Days/unit X Mean Cost**
11	A9510	Tc99m disofenin TECHNETIUM TC-99M DISOFENIN, DIAGNOSTIC, PER STUDY DOSE, UP TO 15 MILLICURIES	None	H	N	Packaged	Packaged into APC rate	$35.29	n/a	$46.75	$48.13	8820	8873	1.01	$48.42
12	A9512	Tc99m pertechnetate TECHNETIUM TC-99M PERTECHNETATE, DIAGNOSTIC, PER MILLICURIE	None	N	N	Packaged	Packaged into APC rate	N/A	n/a	$1.43	$5.21	16883	140057	8.30	$43.22
13	A9516 & C1087	I123 iodide cap, dx IODINE I-123 SODIUM IODIDE CAPSULE(S), DIAGNOSTIC, PER 100 MICROCURIES	**PENDING CMS decision:** SNM & ACR jointly submitted HCPCS 2008 application for a change to this description and creation of a new code to describe larger 1-4 mCi per study doses of this RP.	H	K	Packaged	$27.44	$30.30	n/a	$29.12	$27.44	32098	73760	2.30	$63.06
14	A9517 combined generic code yes	I131 iodide cap, rx IODINE I-131 SODIUM IODIDE CAPSULE(S), THERAPEUTIC, PER MILLICURIE	C9402 I131 generic iodide cap, rx CMS used 2005 claims data for rate setting.	H	K	$6.57	$14.54	$6.57	n/a	$13.40	$14.54	9836	231507	23.54	$342.22
15	A9521 & C1096	Tc99m exametazime TECHNETIUM TC-99M EXAMETAZIME, DIAGNOSTIC, PER STUDY DOSE, UP TO 25 MILLICURIES	**PENDING CMS decision:** SNM & ACR jointly submitted HCPCS 2008 application for a change to this description (used for brain imaging) and creation of a new code to describe use for infection imaging with WBCs, cost vary among these RPs.	H	K	$778.13	$317.07	$435.23	$455.59	$559.85	$317.07	4258	4355	1.02	$324.29

snm
advancing molecular imaging & therapy

1850 Samuel Morse Drive
Reston, VA 20190-5316
Tel: 703.708.9000
Fax: 703.708.9015
www.snm.org

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O
1	**HCPCS 2006 & other years for comparison**	**Description**	**Comments**	**Final 2006**	**Prop 2007**	**CY 2005 Final Rate**	**CMS Proposed 2007 Rate**	**SNM Survey 2002 Mean Cost**	**GAO Acq Cost Survey 2004 Average Purchase Price**	**Mini 2006 SNM Survey AVG**	**CMS Mean Unit Cost 2005 Data**	**CMS 2005 Days**	**CMS 2005 Units**	**CMS Days / CMS Units**	**Days/unit X Mean Cost**
16	A9524 blood volume studies (volumex)	I131 serum albumin, dx IODINE I-131 IODINATED SERUM ALBUMIN, DIAGNOSTIC, PER 5 MICROCURIES	In 2004 and 2005 the SNM recommended to the CMS HCPCS workgroup changing the description to per 25 uCi, this **was not adopted.** *(CMS should consider data trimming out any units of less than 5)*	H	K	Packaged	$36.78	N/A	n/a	$272.00	$36.78	356	1543	4.33	$159.41
17	A9526	Nitrogen N-13 ammonia NITROGEN N-13 AMMONIA, DIAGNOSTIC, PER STUDY DOSE, UP TO 40 MILLICURIES	None	H	K	$109.86	$230.77	N/A	n/a	No Survey Information Available	$230.77	63	80	1.27	$293.04
18	A9528 combined generic code yes	Iodine I-131 iodide cap, dx IODINE I-131 SODIUM IODIDE CAPSULE(S), DIAGNOSTIC, PER MILLICURIE	C9403 Iodine I-131 iodide cap, generic, dx CMS used 2005 claims data for rate setting.	H	K	$6.57	$24.86	product on survey but not comparable descriptions	n/a	$20.81	$24.86	4246	20556	4.84	$120.35
19	A9529 combined generic code yes	I131 iodide sol, dx IODINE I-131 SODIUM IODIDE SOLUTION, DIAGNOSTIC, PER MILLICURIE	C9404 I131 iodide sol, generic, dx CMS used 2005 claims data for rate setting. *NOT listed separately in CMS file on web site, assume CMS already combined this data in what was reported.*	H	**N**	$9.73	Packaged into APC rate	product on survey but not comparable descriptions	n/a	$35.00	$16.11	799	2728	3.41	**$55.0039**
20	A9530 combined generic code yes	I131 iodide sol, rx IODINE I-131 SODIUM IODIDE SOLUTION, THERAPEUTIC, PER MILLICURIE	C9405 I131 iodide sol, generic, rx CMS used 2005 claims data for rate setting.	H	K	$9.73	$12.60	product on survey but not comparable descriptions	n/a	$9.11	$12.60	1931	66609	34.49	$434.63
21	A9531	I131 max 100uCi IODINE I-131 SODIUM IODIDE, DIAGNOSTIC, PER MICROCURIE (UP TO 100 MICROCURIES)	None	H	N	Packaged	Packaged into APC rate	product on survey but not comparable descriptions	n/a	$32.50	$2.83	1928	26941	13.97	$39.55

snm
advancing molecular imaging & therapy

1850 Samuel Morse Drive
Reston, VA 20190-5316
Tel: 703.708.9000
Fax: 703.708.9015
www.snm.org

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O
1	HCPCS 2006 & other years for comparison	Description	Comments	Final 2006	Prop 2007	CY 2005 Final Rate	CMS Proposed 2007 Rate	SNM Survey 2002 Mean Cost	GAO Acq Cost Survey 2004 Average Purchase Price	Mini 2006 SNM Survey AVG	CMS Mean Unit Cost 2005 Data	CMS 2005 Days	CMS 2005 Units	CMS Days / CMS Units	Days/unit X Mean Cost
22	A9532	I125 serum albumin, dx IODINE I-125 SERUM ALBUMIN, DIAGNOSTIC, PER 5 MICROCURIES	None	H	N	Packaged	Packaged into APC rate	N/A	n/a	No Survey Information Available	$37.18	47	57	1.21	$45.09
23	A9535	Injection, methylene blue INJECTION, METHYLENE BLUE, 1 ML	Not a Radiopharmaceutical.	K	N	**New**	Packaged into APC rate	**NEW**	n/a	No Survey Information Available	NEW	New	New		
24	A9536 was A9511 per mCi & C1095 per dose	Tc99m depreotide TECHNETIUM TC-99M DEPREOTIDE, DIAGNOSTIC, PER STUDY DOSE, UP TO 35 MILLICURIES	Neotec, we are checking but believe this product is temporarily off the market in 2006.	H	K	$37.79 per mCi	$67.91	$148.06 per mCi & $678.93 per dose	n/a	No Survey Information Available Product may not be on market in 2006	$50.87	582	777	1.34	$67.91
25	A9537 was A9513 per mCi & C1097 per dose	Tc99m mebrofenin TECHNETIUM TC-99M MEBROFENIN, DIAGNOSTIC, PER STUDY DOSE, UP TO 15 MILLICURIES	None	N	N	Packaged per mCi	Packaged into APC rate	$32.94 per dose	n/a	$37.44	$15.46	39174	116308	2.97	$45.90
26	A9538 was A9514 per mCi	Tc99m pyrophosphate TECHNETIUM TC-99M PYROPHOSPHATE, DIAGNOSTIC, PER STUDY DOSE, UP TO 25 MILLICURIES	None	N	N	Packaged per mCi	Packaged into APC rate	N/A	n/a	$24.27	$8.07	5483	28528	5.20	$41.99

snm advancing molecular imaging & therapy

1850 Samuel Morse Drive
Reston, VA 20190-5316
Tel: 703.708.9000
Fax: 703.708.9015
www.snm.org

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O
1	HCPCS 2006 & other years for comparison	Description	Comments	Final 2006	Prop 2007	CY 2005 Final Rate	CMS Proposed 2007 Rate	SNM Survey 2002 Mean Cost	GAO Acq Cost Survey 2004 Average Purchase Price	Mini 2006 SNM Survey AVG	CMS Mean Unit Cost 2005 Data	CMS 2005 Days	CMS 2005 Units	CMS Days / CMS Units	Days/unit X Mean Cost
27	A9539 was A9515 per mCi & C1098	Tc99m pentetate TECHNETIUM TC-99M PENTETATE, DIAGNOSTIC, PER STUDY DOSE, UP TO 25 MILLICURIES	None	N	K	Packaged per mCi	**$56.77**	$24.74 per dose	n/a	$24.19	**$4.97**	18523	211597	11.42	$56.77
28	A9540 was A9519 per mCi & C1094	Tc99m MAA TECHNETIUM TC-99M MACROAGGREGATED ALBUMIN, DIAGNOSTIC, PER STUDY DOSE, UP TO 10 MILLICURIES	None	N	N	Packaged per mCi	Packaged into APC rate	$12.22 per mCi	n/a	$16.71	$12.20	43389	129742	2.99	$36.48
29	A9541 was A9520 per mCi &C1202 per dose	Tc99m sulfur colloid TECHNETIUM TC-99M SULFUR COLLOID, DIAGNOSTIC, PER STUDY DOSE, UP TO 20 MILLICURIES	**PENDING CMS decision:** SNM & ACR jointly submitted HCPCS 2008 application for a change to this description (used for liver/spleen imaging) and creation of a new code to describe use for lymph node imaging with filtered SC, cost vary among these RPs.	N	N	Packaged per mCi	Packaged into APC rate	$26.09	n/a	$30.00	$22.86	37417	54505	1.46	$33.30
30	A9542 C1082	In111 ibritumomab, dx INDIUM IN-111 IBRITUMOMAB TIUXETAN, DIAGNOSTIC, PER STUDY DOSE, UP TO 5 MILLICURIES	SNM has great concern regarding CMS proposed payment rates for these RPs.	H	K	C1082 $2,419.78	$1,344.34	N/A	n/a	$2,316.00	$1,344.34	384	384	1.00	$1,344.34

snm advancing molecular imaging & therapy

1850 Samuel Morse Drive
Reston, VA 20190-5316
Tel: 703.708.9000
Fax: 703.708.9015
www.snm.org

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O
1	**HCPCS 2006 & other years for comparison**	**Description**	**Comments**	**Final 2006**	**Prop 2007**	**CY 2005 Final Rate**	**CMS Proposed 2007 Rate**	**SNM Survey 2002 Mean Cost**	**GAO Acq Cost Survey 2004 Average Purchase Price**	**Mini 2006 SNM Survey AVG**	**CMS Mean Unit Cost 2005 Data**	**CMS 2005 Days**	**CMS 2005 Units**	**CMS Days / CMS Units**	**Days/unit X Mean Cost**
31	A9543 was C1083	Y90 ibritumomab, rx YTTRIUM Y-90 IBRITUMOMAB TIUXETAN, THERAPEUTIC, PER TREATMENT DOSE, UP TO 40 MILLICURIES	SNM has great concern regarding CMS proposed payment rates for these RPs.	H	K	C1083 $20,948.20	$12,130.20	N/A	$19,614.96	$19,903.00	$12,130.20	362	362	1.00	$12,130.20
32	A9544 was C1080	I131 tositumomab, dx IODINE I-131 TOSITUMOMAB, DIAGNOSTIC, PER STUDY DOSE	SNM has great concern regarding CMS proposed payment rates for these RPs.	H	K	C1080 $2,241.00	$1,368.17	N/A	n/a	$3,320.00	$1,368.17	249	249	1.00	$1,368.17
33	A9545 was C1081	I131 tositumomab, rx IODINE I-131 TOSITUMOMAB, THERAPEUTIC, PER TREATMENT DOSE	SNM has great concern regarding CMS proposed payment rates for these RPs.	H	K	C1081 $19,422.00	$11,868.78	N/A	n/a	$22,460.00	$11,868.78	191	191	1.00	$11,868.78
34	A9546 was C1079	Co57/58 COBALT CO-57/58, CYANOCOBALAMIN, DIAGNOSTIC, PER STUDY DOSE, UP TO 1 MICROCURIE	Product is off the market in 2005 and 2006, see A9559 for Shillings tests performed in 2006.	N	K	$221.78 per 0.5 mCi	$149.44	N/A	n/a	No Survey Information Available	$7.78	125	2401	19.21	$149.44
35	A9547 was C1091	In111 oxyquinoline INDIUM IN-111 OXYQUINOLINE, DIAGNOSTIC, PER 0.5 MILLICURIE	**PENDING CMS decision:** SNM & ACR jointly submitted HCPCS 2008 application to delete this code and creation of two new codes to describe use for WBC and Platelet Imaging, cost vary among these RPs.	H	K	$373.50	$306.51	N/A	n/a	$589.63	$306.51	4296	4591	1.07	$327.56

snm advancing molecular imaging & therapy

1850 Samuel Morse Drive
Reston, VA 20190-5316
Tel: 703.708.9000
Fax: 703.708.9015
www.snm.org

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O
1	HCPCS 2006 & other years for comparison	Description	Comments	Final 2006	Prop 2007	CY 2005 Final Rate	CMS Proposed 2007 Rate	SNM Survey 2002 Mean Cost	GAO Acq Cost Survey 2004 Average Purchase Price	Mini 2006 SNM Survey AVG	CMS Mean Unit Cost 2005 Data	CMS 2005 Days	CMS 2005 Units	CMS Days / CMS Units	Days/unit X Mean Cost
36	A9548 & C1092	In111 pentetate INDIUM IN-111 PENTETATE, DIAGNOSTIC, PER 0.5 MILLICURIE	None	H	K	$224.10	$262.81	$590.28	n/a	$603.32	$262.81	5065	6381	1.26	$331.09
37	A9549 was C1122 per vial	Tc99m arcitumomab TECHNETIUM TC-99M ARCITUMOMAB, DIAGNOSTIC, PER STUDY DOSE, UP TO 25 MILLICURIES	CEA-Scan; We are checking if this RP is still on the market in 2006	H	K	C1122 $1079.00 per vial	$255.95	$1,494.53	n/a	$1,661.35	$255.95	145	145	1.00	$255.95
38	A9550 was C1200 per vial & Q3006 per 5 mCi	Tc99m gluceptate TECHNETIUM TC-99M SODIUM GLUCEPTATE, DIAGNOSTIC, PER STUDY DOSE, UP TO 25 MILLICURIES	None	H	K	packaged	**$236.53**	$38.16	n/a	$56.67	**$25.55 & $190.54**	48 & 58	48 & 72	1.0 & 1.5	
39	A9551 was C1201 per vial	Tc99m succimer TECHNETIUM TC-99M SUCCIMER, DIAGNOSTIC, PER STUDY DOSE, UP TO 10 MILLICURIES	None	H	K	$118.52 per vial	$84.79	$203.00	n/a	$160.89	$84.79	447	447	1.00	$84.79
40	A9552 was C1775	F18 fdg FLUORODEOXYGLUCOSE F-18 FDG, DIAGNOSTIC, PER STUDY DOSE, UP TO 45 MILLICURIES	C9408 Generic F18 fdg CMS used 2005 claims data for rate setting.	H	K	$221.11	$235.56	$35.66 mean $378.00 median SNM checking	$287.90	$250.00	$235.56	136012	136012	1.00	$235.56

snm advancing molecular imaging & therapy

1850 Samuel Morse Drive
Reston, VA 20190-5316
Tel: 703.708.9000
Fax: 703.708.9015
www.snm.org

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O
1	HCPCS 2006 & other years for comparison	Description	Comments	Final 2006	Prop 2007	CY 2005 Final Rate	CMS Proposed 2007 Rate	SNM Survey 2002 Mean Cost	GAO Acq Cost Survey 2004 Average Purchase Price	Mini 2006 SNM Survey AVG	CMS Mean Unit Cost 2005 Data	CMS 2005 Days	CMS 2005 Units	CMS Days / CMS Units	Days/unit X Mean Cost
41	A9553 was C9000 per 0.25 mCi &C9102 per 50 uCi	Cr51 chromate CHROMIUM CR-51 SODIUM CHROMATE, DIAGNOSTIC, PER STUDY DOSE, UP TO 250 MICROCURIES	None	H	K	packaged	$167.62	N/A	n/a	$282.50	$150.45 & $135.65	438 & 279	488 & 326	1 & 1.16	
42	A9554 was C9103 per 10 uCi	I125 iothalamate, dx IODINE I-125 SODIUM IOTHALAMATE, DIAGNOSTIC, PER STUDY DOSE, UP TO 10 MICROCURIES	Glofil; In 2004 and 2005 the SNM at the open CMS HCPCS meeting requested a description of per 10 uCi for this RP, in 2006 CMS published a per study dose description up to 10 uCi. A typical dose of this RP is 20 to 100 uCi and the cost of a 100 uCi vial is approx $2,247. including shipping.	H	N	packaged	Packaged into APC rate	N/A	n/a	$116.33	$15.99	476	1382	2.90	$46.42
43	A9555 was Q3000	Rb82 rubidium RUBIDIUM RB-82, DIAGNOSTIC, PER STUDY DOSE, UP TO 60 MILLICURIES	None	H	K	$153.39	$239.83	n/a	n/a	No Survey Information Available	$239.83	2059	3837	1.86	$446.93
44	A9556 Q3002 & C9434	Ga67 gallium GALLIUM GA-67 CITRATE, DIAGNOSTIC, PER MILLICURIE	C9434 Ga67 gallium generic per mCi CMS used 2005 claims data for rate setting.	H	K	$27.10	$22.73	$24.30	n/a	$19.70	$22.73	3597	15880	4.41	$100.35
45	A9557 was Q3003	Tc99m bicisate TECHNETIUM TC-99M BICISATE, DIAGNOSTIC, PER STUDY DOSE, UP TO 25 MILLICURIES	None	H	K	$370.60	$254.46	$344.78	n/a	$401.85	$254.46	1622	1652	1.02	$259.17

snm
advancing molecular imaging & therapy

1850 Samuel Morse Drive
Reston, VA 20190-5316
Tel: 703.708.9000
Fax: 703.708.9015
www.snm.org

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O
1	**HCPCS 2006 & other years for comparison**	**Description**	**Comments**	**Final 2006**	**Prop 2007**	**CY 2005 Final Rate**	**CMS Proposed 2007 Rate**	**SNM Survey 2002 Mean Cost**	**GAO Acq Cost Survey 2004 Average Purchase Price**	**Mini 2006 SNM Survey AVG**	**CMS Mean Unit Cost 2005 Data**	**CMS 2005 Days**	**CMS 2005 Units**	**CMS Days / CMS Units**	**Days/unit X Mean Cost**
46	A9558 was Q3004	Xe133 xenon 10mci XENON XE-133 GAS, DIAGNOSTIC, PER 10 MILLICURIES	None	N	N	packaged	Packaged into APC rate	$22.87	n/a	$21.80	$21.98	23617	32145	1.36	$29.92
47	A9559 was Q3012 per 0.5 uCi CMS C9013 no description	Co57 cyano COBALT CO-57 CYANOCOBALAMIN, ORAL, DIAGNOSTIC, PER STUDY DOSE, UP TO 1 MICROCURIE	This product has been on and off the market in 2005, it is currently on the market in 2006. See low volume number in 2005 due to product being off market.	N	K	$85.49	$63.74	N/A	n/a	$153.48	$101.39	3	3	1.00	$101.39
48	A9560 was Q3010 per mCi	Tc99m labeled rbc TECHNETIUM TC-99M LABELED RED BLOOD CELLS, DIAGNOSTIC, PER STUDY DOSE, UP TO 30 MILLICURIES	None	H	K	Packaged per mCi	**$132.95**	$62.62 & $65.62	n/a	$63.08	**$10.00**	20662	274695	13.29	$132.95
49	A9561 was Q3009 per mCi & C1058 per vial	Tc99m oxidronate TECHNETIUM TC-99M OXIDRONATE, DIAGNOSTIC, PER STUDY DOSE, UP TO 30 MILLICURIES		N	N	Packaged per mCi	Packaged into APC rate	$22.87 & $19.68	n/a	$24.75	**$3.24**	94804	1351017	14.25	$46.17
50	A9562 was Q3005 per mCi	Tc99m mertiatide TECHNETIUM TC-99M MERTIATIDE, DIAGNOSTIC, PER STUDY DOSE, UP TO 15 MILLICURIES	None	H	K	$31.13 per mCi	$180.08	$133.41	$27.40 per mCi NOT per Dose	$171.23	$34.86	23306	120392	5.17	$180.08

snm advancing molecular imaging & therapy

1850 Samuel Morse Drive
Reston, VA 20190-5316
Tel: 703.708.9000
Fax: 703.708.9015
www.snm.org

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O
1	HCPCS 2006 & other years for comparison	Description	Comments	Final 2006	Prop 2007	CY 2005 Final Rate	CMS Proposed 2007 Rate	SNM Survey 2002 Mean Cost	GAO Acq Cost Survey 2004 Average Purchase Price	Mini 2006 SNM Survey AVG	CMS Mean Unit Cost 2005 Data	CMS 2005 Days	CMS 2005 Units	CMS Days / CMS Units	Days/unit X Mean Cost
51	A9563 was Q3007 per mCi	P32 Na phosphate SODIUM PHOSPHATE P-32, THERAPEUTIC, PER MILLICURIE	None	H	K	$94.98	$117.11	$281.40	n/a	$142.50	$117.11	307	623	2.03	$237.65
52	A9564 was Q3011 per mCi	P32 chromic phosphate CHROMIC PHOSPHATE P-32 SUSPENSION, THERAPEUTIC, PER MILLICURIE	None	H	K	$147.25	$222.35	n/a	n/a	$230.00	CMS did not List	not listed	not listed		
53	A9565 was Q3008	In111 pentetreotide ***NOTE: Description change from per 3 mCi to per mCi effective 2006*** INDIUM IN-111 PENTETREOTIDE, DIAGNOSTIC, **PER MILLICURIE**	Providers may misread this description due to the changes, even when we surveyed our committee members on this code we often received costs per dose not per mCi or per 3 mCi, the SNM may consider submitting a HCPCS application or do more intense education with current description.	H	K	$1079 per 3 mCi	$185.60	$1,102.86 per dose 5 mCi average dose therefore $221.00 per mCi	$1,279.55 per 3 mCi	$279.18	$185.60	2856	4546	1.59	$295.42
54	A9566	Tc99m fanolesomab TECHNETIUM TC-99M FANOLESOMAB, DIAGNOSTIC, PER STUDY DOSE, UP TO 25 MILLICURIES	RP was on market in 2005 but off market in 2006, RP may be back on market in 2007 or 2008 but unsure at this point.	H	K	$1,045.80	$527.31	NEW RP	n/a	No Survey Information Available	$527.31	New	New		$0.00
55	A9567	Technetium TC-99m pentetate aerosol TECHNETIUM TC-99M PENTETATE, DIAGNOSTIC, AEROSOL, PER STUDY DOSE, UP TO 75 MILLICURIES	Typically a more expensive version of A9539 which CMS plans to pay separately, we suggest in the absence of data CMS at a minimum pay the same as they would for A9539.	H	N	New	Packaged into APC rate	New RP	n/a	$62.50	$0.00	New	New	New	New

snm
advancing molecular imaging & therapy

1850 Samuel Morse Drive
Reston, VA 20190-5316
Tel: 703.708.9000
Fax: 703.708.9015
www.snm.org

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O
1	HCPCS 2006 & other years for comparison	Description	Comments	Final 2006	Prop 2007	CY 2005 Final Rate	CMS Proposed 2007 Rate	SNM Survey 2002 Mean Cost	GAO Acq Cost Survey 2004 Average Purchase Price	Mini 2006 SNM Survey AVG	CMS Mean Unit Cost 2005 Data	CMS 2005 Days	CMS 2005 Units	CMS Days / CMS Units	Days/unit X Mean Cost
56	A9600	Sr89 strontium STRONTIUM SR-89 CHLORIDE, THERAPEUTIC, PER MILLICURIE	Typical dose for this procedure is 3 to 4 mCi a dose of less than 2 would not be appropriate therefore CMS should consider data trimming any units less than 2 to see if this appropriately pays this RP	H	K	$406.16	$533.58	$1,416.60	n/a	$787.00	$533.58	519	1311	2.53	$1,347.83
57	A9605	Sm 153 lexidronm SAMARIUM SM-153 LEXIDRONAMM, THERAPEUTIC, PER 50 MILLICURIES	None	H	K	$907.33	**$1,316.41**	Faulty Data'	n/a	$1,107.92	**$1,316.41**	959	1631	1.70	$2,238.86
58	A9698	Non-rad contrast material noc NON-RADIOACTIVE CONTRAST IMAGING MATERIAL, NOT OTHERWISE CLASSIFIED, PER STUDY	Not a Radiopharmaceutical.	N	N	new	Packaged into APC rate	new	n/a	No Survey Information Available		New	New		$0.00
59	A9699	Radiopharm rx agent noc RADIOPHARMACEUTICAL, THERAPEUTIC, NOT OTHERWISE CLASSIFIED	Providers should ONLY use this code in the absence of a specific Therapeutic HCPCS code. (eg I-123 MIBG therapy and I-131 MIBG therapy)	N	N	N/A	Packaged into APC rate	N/A	n/a		$87.47	New	New		$0.00