YALE-NEW HAVEN HOSPITAL

October 10, 2006

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

Re: Comments on Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates Proposed Hospital Coding and Payments for Visits

Dear Dr. McClellan:

The Yale New Haven Hospital ("YNHH" or the "Hospital") is pleased to provide these comments on proposed changes to the "Hospital Outpatient Prospective Payment System (OPPS) and Calendar Year 2007 Payment Rates" published on August 23, 2006 at 71 *Fed. Reg.* 49506 *et seq.* YNHH is a 944-bed tertiary care hospital located in New Haven, Connecticut which serves as a teaching hospital for the Yale School of Medicine. The Hospital is a major provider of health care services within the State of Connecticut. YNHH also provides comprehensive tertiary care services to patients referred to it from throughout the New England region as well as from foreign countries. The Hospital provides over 250,000 days of inpatient care and almost half a million outpatient visits per year. YNHH's outpatient activities include services to over 100,000 patients who seek care on an emergency basis from YNHH's emergency department facilities.

Last year YNHH provided comments on the proposed calendar year (CY) 2006 OPPS rule which raised questions concerning CMS' policies governing payment for emergency department services provided to Medicare beneficiaries in provider-based components of hospital emergency departments. While the preamble to the final CY 2006 OPPS rule did not address payment issues related to hospitals which have established provider-based components to their main emergency departments for less than 24 hours a day, the proposed CY 2007 OPPS rule does address this issue. The YNHH very much appreciates CMS' willingness to examine this issue as part of its CY 2007 OPPS rulemaking.

"Proposed Hospital Coding and Payment for Visits"

I. Background and Summary of Comments

In July of 2004 YNHH established a second site to provide emergency room services in Guilford, Connecticut at a location known as YNHH's Shoreline campus (hereinafter "Shoreline facility"). The Shoreline facility is located approximately 15

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miles from YNHH's main campus in New Haven, Connecticut. YNHH received a Certificate of Need from the Connecticut Office of Health Care Access to establish a satellite facility at the Guilford location. Among other things,[1] the Certificate of Need provides that YNHH is to provide emergency department trauma level services at the Guilford location. Consistent with the Certificate of Need, commencing in July of 2004, YNHH has provided emergency department services at the YNHH Shoreline campus as a provider-based component of its main emergency department which is located at its main campus in New Haven, Connecticut. Also, in conformity with the Certificate of Need, YNHH provides emergency department services at the Shoreline facility less than 24 hours a day. The Shoreline facility is scheduled to operate 16 hours per day[2]. A patient who presents at the Shoreline facility with an emergency medical condition is treated the same way as a patient who presents at the emergency department at YNHH's main campus. The patient is assessed, stabilized, and referred to the proper component within the YNHH system or to another hospital or provider as appropriate. The time to complete this process is equivalent for patients who access emergency department services at the YNHH New Haven and Guilford locations. CMS has recognized that YNHH has met all provider-based requirements under 42 C.F.R. §413.65 in establishing the Shoreline facility. Thus, it is clear that the YNHH provides emergency department services at the Shoreline facility as an integral part of the emergency department services it provides at its main hospital in New Haven, Connecticut which is open 24 hours per day.

The preamble to the proposed rule states that "facilities" which operate less than 24 hours a day should not use emergency department codes in billing the Medicare program even though they provide emergency room services to Medicare program beneficiaries. CMS bases this conclusion on a portion of the *Current Procedural Terminology* ("CPT") code definition of the term "emergency department" which has been adopted by the American Medical Association and refers to an emergency department being available 24 hours per day. In the proposed rule CMS proposes to establish "Type A" hospital and "Type B" hospital emergency department rates. The sole distinction in the proposed definition of these emergency department rates is whether a department or facility is open 24 hours per day, 7 days per week. Emergency department Type A rates are proposed to be paid for services provided in facilities open 24 hours a day, 7 days per week. Type B payments are proposed to be paid for emergency services provided in departments or facilities which are not scheduled to operate either 7 days per week or 24 hours per day. Both Type A and B payments are proposed to be paid based on 5 new G codes. The difference in proposed reimbursement under the new G codes between Type A and Type B payments are as follows:

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[1] YNHH also provides radiology and laboratory services at the Shoreline facility. Emergency services, however, constitute 100 % of the professional patient care services provided at the YNHH Shoreline facility.

[2] YNHH provides emergency department services beyond the 16 hour per day scheduled time on an as needed basis.

	Type A	Type B
Level 1	$51.41	$49.93
Level 2	$84.79	$62.12
Level 3	$133.98	$83.67
Level 4	$214.88	$105.50
Level 5	$332.14	$130.98

See 71 *Fed. Reg.* 49614.

The substantial difference between Type A and Type B rates is due to CMS proposing to establish Type B payments at clinic rate levels. Clinic rates do not reflect the scope and intensity of medical resources used and required by patients in need of hospital emergency services. This is clear since the base amount for clinic rates are derived from clinic cost centers and not from emergency department cost centers. Type B rates do not reflect the skilled labor, ancillary intensity, capital and other resources which are required to provide medically necessary care to patients who require emergency department services. The preamble to the proposed rule states that CMS has not collected data on the cost of services provided in hospital facilities for which it is proposing to pay Type B rates and that, at some non-specified time in the future, after engaging in data collection, CMS may revise its policy. 71 *Fed. Reg.* 49681. For the reasons stated in these comments YNHH is of the view that the proposed Type B rates should not be applied to hospital provider-based facilities which, under CMS' provider-based rules, function as an integral component of a hospital's 24 hour, 7 day per week emergency department. We strongly believe that CMS has an obligation to set rates under OPPS which reflect and pay for the medical resources used by Medicare beneficiaries. Clinic rates do not do so and CMS has not suggested to the contrary in the preamble to the proposed rule.

Since 2004 the YNHH has, in fact, collected cost data on services provided at the Shoreline component of its emergency department. This data is presented with these comments and demonstrates that the Type B clinic rates contained in the proposed rule are wholly inadequate and would consistently underpay the cost of emergency services provided to Medicare beneficiaries. We wish to underscore that the hospital emergency department system existing in the State of Connecticut includes YNHH as one of three hospitals which provides the general public with hospital emergency services at provider-based components of their emergency departments. These services and facilities are resources which are needed and used by the general public, including Medicare beneficiaries. The establishment of these emergency department services is consistent with the goal of the Medicare EMTALA policies to foster the creation of dedicated emergency departments ("DED") as essential community resources.

We have taken special note of the statement in the preamble to the proposed rule that: "It is important to note that G-codes may be recognized [used] by other payors". 71 *Fed. Reg.* 49607. It is, therefore, important to underscore that implementation by the Medicare program of Type B emergency department rates which have not been demonstrated to be related to hospital cost will consistently underfund hospital

emergency room cost and could lead to a destabilization of financing of hospital emergency services in the State of Connecticut.

YNHH believes there are very few hospital provider-based emergency department facilities in the nation. In light of the data presented with these comments which we believe demonstrates that the proposed Type B rates are inadequate to pay for hospital emergency department resource use, we strongly recommend that CMS provide reimbursement for these services at hospital emergency department rates when they are provided in a provider-based component of a 7 day, 24 hour hospital emergency department which existed on or before October 1, 2004. This policy would allow CMS to collect the data it desires to determine whether to reimburse these services at established emergency department rates or on some other basis. This recommendation also takes into consideration the concern articulated at page 49615 of the preamble to the proposed rule to the effect that CMS does not wish to provide incentives for hospitals to reduce their hours of emergency department coverage. Under our recommendation only hospitals which maintain full-time 7 day, 24 hour emergency departments which provide **additional** provider-based emergency department services on or before October 1, 2004 would be reimbursed at emergency department rates. YNHH is not proposing that CMS adopt any policy that provides a financial incentive for hospitals to reduce the times or hours of operation of any emergency department services. To the contrary our recommendations are limited to enhanced emergency department services that it appears only a few hospitals provide **on a provider-based basis**. We believe this recommendation is consistent with the objective of CMS which is that emergency department services be available to the general public. In this manner CMS would be acting to preserve the status quo in terms of access to emergency department services while it engages in the data collection to determine the comparability of costs and services provided by hospital based emergency departments with clinics and hospital emergency departments.

We do suggest that CMS provide for a site of service identifier for the billing of services provided by hospital provider-based emergency department facilities as well as the collection of costs in a separate cost center which will enable CMS to separately study provider-based hospital emergency departments' cost and resource use. YNHH has undertaken this type of data inquiry and has compared the cost and service levels of the YNHH Shoreline emergency department activities with those at the YNHH's main campus and with emergency departments and clinics nationally. The outcome of this data analysis is presented with these comments. On a cost basis we found that the cost of services provided at the Shoreline component of YNHH's emergency department is approximately 190% higher than the national median cost for emergency departments and 425% higher than the national median costs of clinics. A comparison of levels of patient services similarly shows that services provided by YNHH at the Shoreline facility are more intensive than services provided by hospital emergency departments and clinics on a national basis.

II. CMS's Statutory Responsibilities as well as Existing Data Warrant Payment at Full Emergency Department Rates

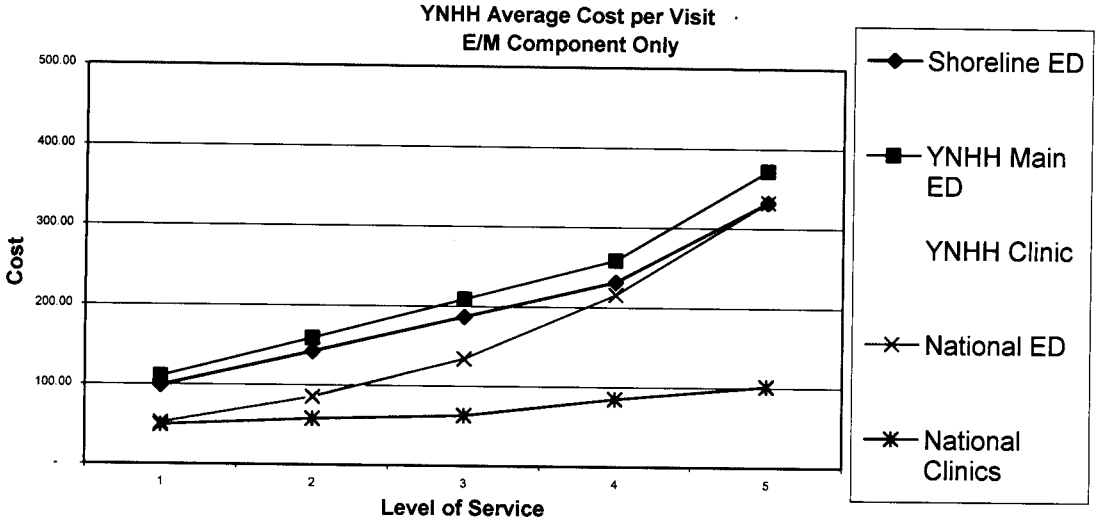
In Section 1833(t)(2)(A) of the Social Security Act, Congress requires that the OPPS classification system be composed of groups of services, so that services within each group are comparable both clinically and with respect to the medical resources used to provide patient care. At no place in the preamble to the proposed rule does CMS suggest that the clinic level rates it is proposing meet the clinical comparability requirement of law or that they account for medical resources used to provide Medicare beneficiaries with medical emergency department care. CMS does acknowledge in the preamble to the rule that "these emergency departments may provide a broader range and intensity of hospital services and require significant resources . . . in comparison with typical outpatient clinics . . .", but does not provide any type of analysis to quantify whether any differences exist in patient resource use to group these services with clinic and not emergency department services for payment purposes. 71 *Fed. Reg.* 49608.

YNHH has engaged in its own study of cost and resource use by patients who receive emergency department services at the Shoreline facility. In particular we have examined the actual cost of providing emergency department services and have demonstrated that if viewed as a discreet entity, Shoreline's cost per visit is 190% higher than emergency department visits nationally and 425% higher than clinic visits nationally. We have also measured ancillary services and patient severity levels using CMS' authorized patient visit service intensity levels and found that patient services intensity at the Shoreline facility is consistent with service levels at YNHH's New Haven campus and exceeds ancillary use intensity on a national basis. In addition, we have reviewed the clinical characteristics of patients receiving care at Shoreline and have determined they are a different population than those who are cared for in clinics. We have made an assessment of medical technology and equipment required and used at the Shoreline facility which are not usually available in clinics. We have also reviewed professional skilled staffing including standby staff which are required to render emergency department services and are not provided or paid for by the Medicare program in reimbursable clinic services.

Shoreline's Cost Per Visit is Higher than to Emergency Departments and Clinics Nationally

YNHH has been able to compare costs, level of visit and ancillary usage (intensity) for the Shoreline facility with the YNHH main emergency department, YNHH clinics, and data for all clinics and emergency departments on a national basis. [3]
The comparison of hospital costs between these settings is graphically demonstrated as follows:

[3] National cost and patient visit level data was derived from CY 2005 "true median cost" from CMS 1506P Median Costs for Hospital Outpatient Services Reported by HCPCS. Cost is based on single frequency claims. Cost information is inclusive of Evaluation and Management cost and services and exclusive of associated ancillaries. YNHH individual data is based on hospital internal records which are available and are subject to audit as part of the Medicare cost reporting process.



The above data is for the Evaluation and Management component only of hospital cost which is reimbursed through emergency department or clinic rates (APCs) by CMS. When YNHH compares the average cost per visit for each type of care above, we have determined that services provided at the Shoreline component of our emergency department are on average, approximately 425% more costly and intensive, than the average provided in clinics nationally and 190% more costly than the average provided in emergency rooms nationally.

Shoreline's Ancillary Costs and Usage are Substantially Higher than those of Clinics

We acknowledge that Medicare reimburses providers separately for ancillary services under OPPS. However, we do believe that the use of ancillaries associated with either an emergency room visit or a clinic visit serves as a proxy for the intensity of illness of the patients we treat. In this regard, we have determined that the average usage of ancillary tests[4] (of any type, including radiology, laboratory, pharmacy and other services) associated with an emergency room or clinic visit is as follows:

Service Location	Average Number of Ancillary Tests per Visit
Main Campus Emergency Room	10.62
Shoreline Emergency Room	7.67
Clinics	3.02

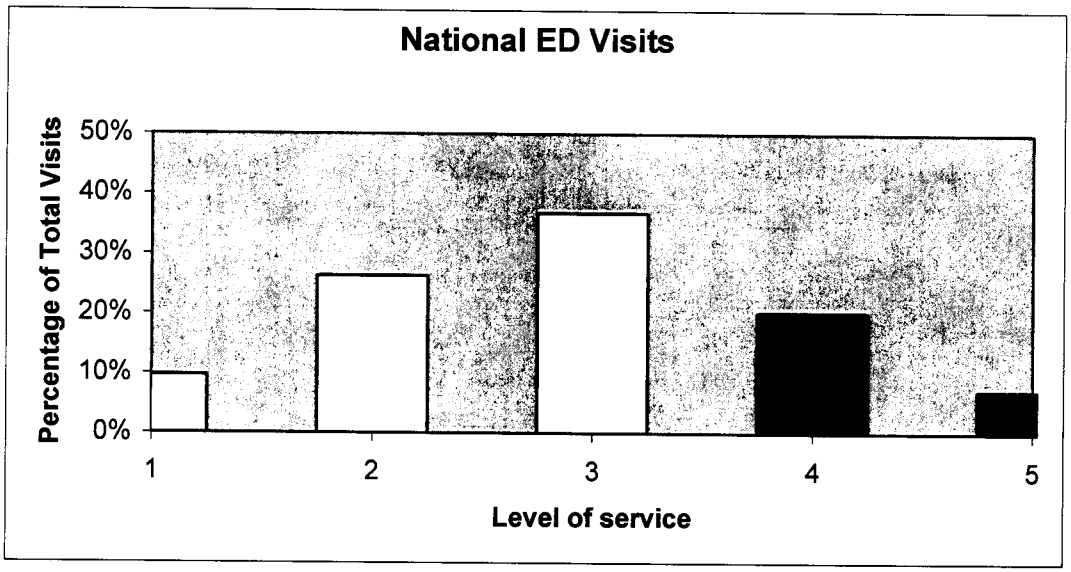
In the preamble to the CY 2003 OPPS rule, CMS provided findings that over 50% of emergency department visits included multiple procedure claims for, i.e., ancillaries. 67 *Fed. Reg.* 52092 at page 52134 (August 9, 2002). Also, in that same rulemaking CMS stated a related finding that over 50% of clinic visits represent single and not multiple

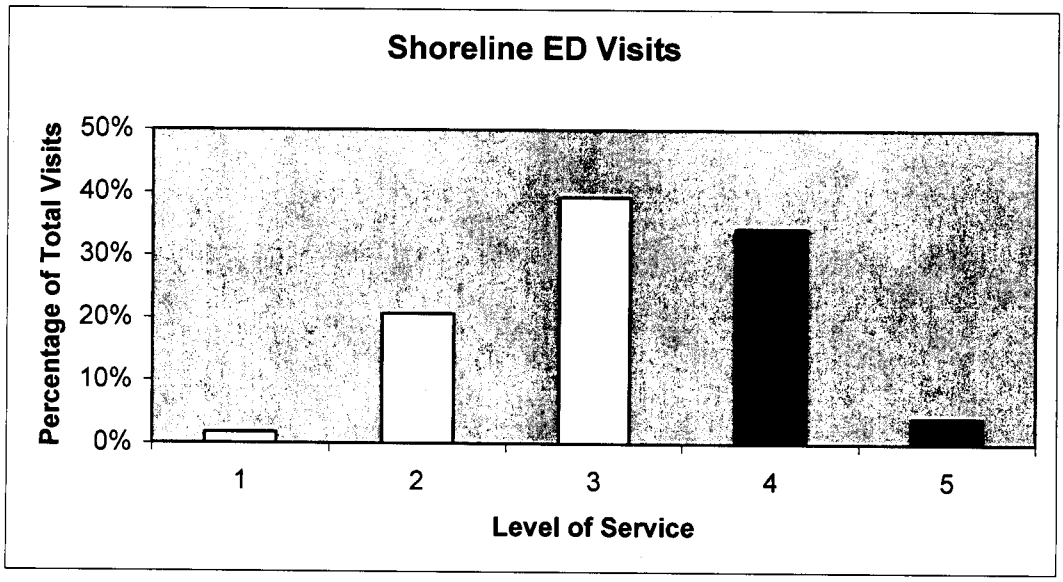
[4] Ancillaries are derived from YNHH's Medicare billed data for fiscal year 2005 and are subject to Medicare audit.

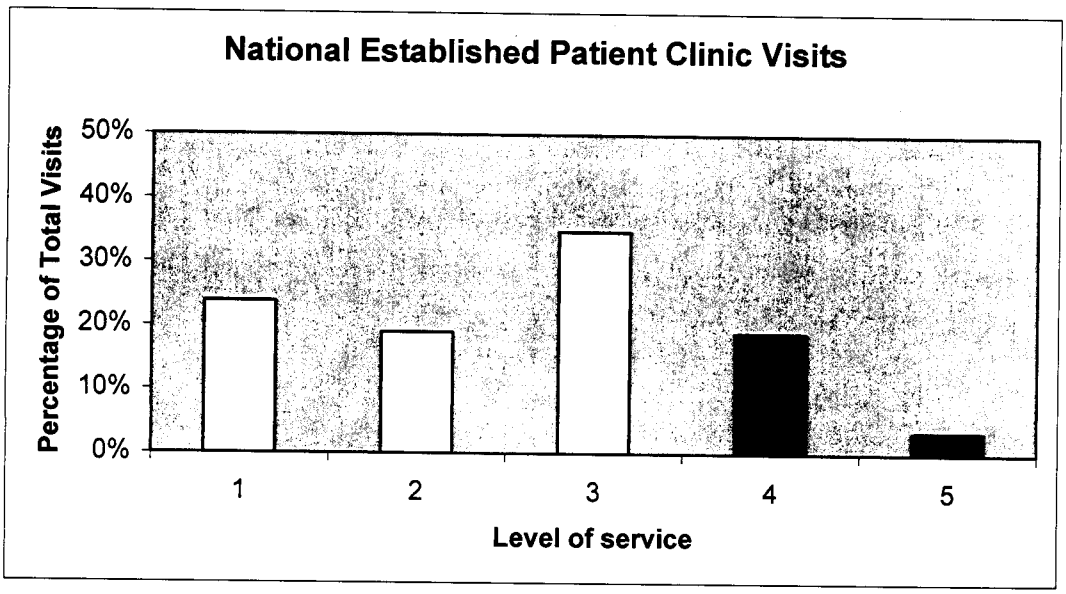
claims, i.e., zero ancillaries. Id. The foregoing data demonstrates that patients at Shoreline use over 250% more ancillaries than clinic patients. The Shoreline patients represent patients who generate multiple procedure claims and who, based on CMS' own study of billing data have the same characteristics of ancillary usage as other emergency department patients. CMS should pay for these patients at full emergency department rates in order to conform to its statutory mandate under Section 1883(t)(2)(A) of the Social Security Act.

Shoreline's Level of Services Compared to Emergency Departments and Clinics Nationally

We believe that the level of complexity of emergency visits to the Shoreline facility as compared to the level of visits to emergency departments and clinics nationally are especially compelling. The comparisons are as follows:







Typical Emergency Medical Conditions Treated at Shoreline

In addition to the above financial and patient ancillary use statistics the type of emergency medical conditions that YNHH treats at its Shoreline campus are not comparable to clinic patients. Examples of typical emergency cases which are seen at Shoreline are described below. These cases could not be treated in a clinic because the intensity of the services and resources provided and needed would not be available in a clinic.

AMA CPT 99285 Clinical Example = Emergency department visit for a patient with an acute onset of chest pain compatible with symptoms of cardiac ischemia and/or pulmonary embolus.

→ Shoreline Case = Patient arrives by ambulance having suffered a cardiac arrest. Emergency department physician attempts resuscitation. Patient expires and is transported to hospital morgue.
→ Shoreline Case = Patient arrives by ambulance with chest pain. After evaluation, patient is transported by ambulance to the hospital cardiac catheterization lab for primary angioplasty and stenting, bypassing the main campus emergency department.

AMA CPT 99285 Clinical Example = Emergency department visit for acute febrile illness in an adult, associated with shortness of breath and an altered level of alertness.

→ Shoreline Case = Patient with known seizure disorder arrives by ambulance in status epilepticus. Shoreline emergency department attending administers seizure medications and febrile convulsions arrest. Patient is discharged.

AMA CPT 99285 Clinical Example = Emergency department visit for a patient with a new onset of a cerebral vascular accident.

→ Shoreline Case = Patient arrives by ambulance having suffered syncope/ collapse. Patient is diagnosed with an aneurysm and transported by ambulance to the hospital for direct admit.

Medical Resources Used at Shoreline Facility

The Shoreline facility maintains the following emergency department medical resources (equipment and supplies) for use in serving its patients. These resources, in the aggregate, are typical of emergency department and not non-emergency clinic resources.

- Telemetry – three (3) hard wire monitors including pressure line system, ST segment analysis, five (5) to seven (7) telemetry packs
- Ventilator and supplies
- Ultrasound
- MRI
- CT scanner
- General radiology
- Uncrossmatched blood – 10 units
- PYXIS units
- Biphasic defibrillator
- Adult and pediatric code carts
- Slit lamp
- Bair Huggers
- Warming lights – adult and pediatric
- LMA intubation catheters
- Rapid sequence induction drugs
- Peritoneal dialysis supplies – adult and pediatric
- Tenchoff catheter supplies – adult and pediatric
- Thoracotomy trays
- Tracheostomy trays
- Trauma resuscitation trays
- OB Delivery Kits

Shoreline Staffing

Additionally, YNHH provides staffing at the Shoreline campus for emergency room services which has a higher skill mix and higher related cost than is typical for clinics. Staffing at the Shoreline campus includes one physician, one physician's assistant, as well as three to four registered nurses -- four registered nurses are on staff during the weekends. All physicians are board certified or board eligible in Emergency Medicine and serve on the faculty at the Yale School of Medicine. All physicians practice at the Shoreline facility and at the YNHH main campus emergency department. Physicians, physician assistants, and registered nurses on staff at the Shoreline facility are all certified in Advanced Life Support.

Cost[5] and Resource Use at Shoreline Compared to CMS Proposed Payment Rates

YNHH Medicare Cost & Expected Payment Profile
E/M Services Only

Level Of Service	# Visits	% of Visits	FY2005 Visit Cost	YNHH Wage Adjusted Type "B" CY07 Proposed Payment	YNHH Wage Adjusted Type "A" CY07 Proposed Payment
Shoreline ED					
Level 1	26	2%	98.67	58.47	60.20
Level 2	312	21%	142.12	72.75	99.29
Level 3	593	39%	186.56	97.98	156.90
Level 4	518	34%	230.99	123.55	251.64
Level 5	62	4%	332.12	153.39	388.96

We request that CMS consider the foregoing demonstration that the cost and resource use expended by YNHH to provide emergency services at its Shoreline campus exceed the costs and resources used to provide services by a significant segment of hospital based emergency departments that operate on a 24 hour basis nationally. This information directly responds to the question presented in the preamble to the proposed rule[6] whether a 24 hour duration requirement for emergency department services is a predictor of hospital cost or resource use. We believe that YNHH has demonstrated that the cost and resource use at its Shoreline satellite facility are greater than a significant segment of emergency departments which operate on a 24 hour 7 day basis throughout the nation. In order that CMS meet its statutory mandate to adequately pay for resources used by Medicare beneficiaries it should provide for payment to the YNHH and similarly situated hospitals at the full emergency department rate for services provided in provider-based emergency department facilities.

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[5] The costs are based on fiscal year 2005 as recorded on YNHH's as filed cost report. They are not updated to fiscal year 2007 and are therefore, conservatively stated.
[6] See 71 *Fed. Reg.* 49608

III. The 24 Hour Requirement

a) CMS has Authorized Hospitals to Deviate from CPT Definitions

In the original OPPS rule CMS instructed hospitals to develop their own levels of codes that relate to hospital resource use and in so doing, specifically instructed hospitals that CMS would not expect their assignment of different levels of codes to correlate with the codes reported by physicians.

> "We will hold each facility accountable for following its own system for assigning the different levels of HCPCS codes. As long as the services furnished are documented and medically necessary and the facility is following its own system which reasonably relates the intensity of hospital resources to the different levels of HCPCS codes, we will assume that it is in compliance with these reporting requirements as they relate to the clinic emergency department visit code reported on the bill. Therefore, we would not expect to see a high degree of correlation between the code reported by the physician and that reported by the facility."

68 *Fed. Reg.* 18434 at page 18451 (April 7, 2000).

The HCPCS codes referred to are inclusive of CPT codes. The above acknowledgement that hospitals may deviate from CPT code definitions is consistent with CMS' determination that CPT codes do not account for hospital resource use and provides an ample legal and policy basis for CMS not to apply the 24 hour component of the CPT code definition of an emergency department when a hospital operates its emergency department at multiple locations.

b) Shorelines Meets the CPT Definition of Emergency Department

Even if the 24 hours a day CPT definition is applicable, the Shoreline facility meets the definition. In the preamble to the proposed rule, CMS states that:

> "CPT defines an emergency department as 'an organized hospital-based facility for the provision of unscheduled episodic services to patients who present for immediate medical attention. The facility must be available 24 hours a day.' 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 a day should not use the emergency department codes."

70 *Fed. Reg.* 49607.

The Shoreline facility meets each of the three components of this definition. First, it is an organized hospital provider-based facility which CMS has concluded meets all of the provider-based requirements at 42 C.F.R. §413.65. Second, it provides unscheduled episodic services to patients who present for immediate medical attention. Third, as a provider-based facility Shoreline facility is an integral part of YNHH's main campus emergency department authorized by a Certificate of Need issued by the State of Connecticut. YNHH is authorized to provide emergency services at Shoreline as an extension of YNHH's main campus emergency department which is open 24 hours a day. **Shoreline is therefore part of a 24 hour hospital emergency department**. CMS should accordingly find that it meets the 24 hour requirement as it is considered a functional part of the YNHH main campus emergency department.

c) CPT Codes Established by the American Medical Association

CMS' sole reason for proposing to pay for emergency department services provided at a provider-based campus such as the Shoreline facility at clinic rates is that the CPT codes established by the American Medical Association (AMA) for emergency department services reference that "[t]he facility must be available 24 hours a day." However, the CPT codes which were adopted by the AMA for physicians do not measure facility input and resources.

The Secretary, in the context of rulemaking, repeatedly has acknowledged that CPT codes are inadequate to define hospital resource use including hospital emergency department resource use. In its Medicare claims processing manual, CMS notes that the CPT codes it uses are "more descriptive of practitioner than of facility services." Medicare Claims Processing Manual (Pub. 100-4), Chapter 5.

In the proposed FY 2006 outpatient rule the Secretary stated that:

> "In the November 15, 2004 final rule with comment period (69 FR 65838), we noted our primary concerns and direction for developing the proposed coding guidelines for emergency department and clinic visits."

70 *Fed. Reg.* 42740 (July 25, 2005).

In the preamble to the FY 2004 outpatient rule, the Secretary stated that CPT codes do not reflect or properly describe emergency medical services.

> "Because these codes were defined to reflect only the activities of physicians, they are inadequate to describe the range and mix of services provided to patients in the clinic and emergency department settings (for example, ongoing nursing care, preparation for diagnostic tests and patient education. . . .

> We agree with those commenters who believe that CPT codes for E/M services describe different levels of physician effort, and therefore, fail to accurately describe facility resources used to provide E/M services." (emphasis added)

68 *Fed. Reg.* 63461 & 63463 (November 7, 2003).

See also 67 *Fed. Reg.* 66790 (November 1, 2002) ("It is generally agreed, however, that [these codes] do not describe well the range and mix of services provided by facilities to clinic and emergency patients..."); 67 *Fed. Reg.* 52133 (August 9, 2002) ("the level of service for emergency and clinic visits should be determined by resource consumption that is not otherwise separately payable"); 65 *Fed. Reg.* 18451 (April 7, 2000) ("HCPCS codes appropriately represent different levels of physician effort, they do not adequately describe non-physician resources"); and 63 *Fed. Reg.* 47566 (September 8, 1998) ("CPT codes are more descriptive of physician effort than of facility use...").

The Secretary again acknowledges that CPT codes are inadequate to measure facility input and resources in the proposed rule. See 71 *Fed. Reg.* 49609 ("As we have previously noted, the CPT codes were defined to reflect the activities of physicians and do not always describe well the range and mix of services provided by hospitals during visits of emergency department patients.") and 71 *Fed. Reg.* 49680 ("However, since the beginning of the OPPS, we have acknowledged that the CPT E/M codes do not adequately describe the facility resources required to perform the services.")

YNHH views the above statements by CMS as an acknowledgement that CPT codes do not form the type of classification system which is demanded by Section 1833(t)(2)(A) of the Act to provide for payment of, among other things, emergency department services. The assignment of services to Ambulatory Payment Classifications ("APCs") is based on an analysis of charges assigned to various cost reporting cost centers. The costs and charges related to less than full-time, provider-based satellite facilities are collected, we believe, within the emergency department cost center on Medicare cost reports and are not reflected in any way in the outpatient clinic cost centers used to establish rates of payment for hospital clinic visits under OPPS. The relegation of services provided by emergency departments that operate less than 24 hours a day to "clinic" status for payment purposes decreases the accuracy of payment since the charge data upon which the clinic rates are based excludes emergency services. Assigning clinic rates to emergency departments that operate less than 24 hours a day is inconsistent with the objective of Section 1833(t)(2)(A) that services be reflected in medically coherent (i.e. like) groups for payment purposes. As a matter of law and public policy, CMS should not substitute clinic payment rates, which reflect non-emergency clinic resources, for services that patients customarily receive in an emergency department offering emergency department resources. YNHH believes this point is underscored by the fact that, in the absence of the Shoreline facility, patients would still seek emergency department services and receive those services, not clinic services, albeit on a less timely basis.

d) The 24 Hours a Day Standard Has Never Been Adopted in Rulemaking

The 24 hours a day, 7 days a week standard, is a standard of the American Medical Association (AMA). It was not previously adopted in rulemaking. Similarly, the CPT code definitions were never identified in a rulemaking process as changing the definition of facilities – recognized as emergency departments under the OPPS. These CPT codes, and specifically, the AMA requirement that emergency services must be available 24 hours a day, are not contained in any regulation. As a matter of law, CMS should not substitute clinic payment rates, which reflect non-emergency clinic resources, for services that patients customarily receive in an emergency department with emergency department resources.

The Administrative Procedure Act, 5 U.S.C. §551 et seq., requires that an agency such as CMS provide notice in the Federal Register prior to implementing a substantive standard and that interested persons be afforded the opportunity to participate by means of written comment or oral presentation. 5 U.S.C. §552(a)(1)(D), (E) and §553(b), (c). The AMA requirement that emergency services must be available 24 hours a day, which forms the basis for CMS' proposal to pay Type B emergency departments at the clinic rate instead of the emergency department rate while it collects and analyzes data, has not been the subject of notice and final rulemaking in accordance with the Administrative Procedure Act. Thus, CMS should pay Type B emergency departments at the emergency department rate until it concludes its rulemaking and analysis of this issue which CMS anticipates would be in the CY 2009 OPPS.

e) Past Practice of CMS

We do not agree with a statement in the preamble to the proposed rule concerning CMS' past practice with respect to emergency departments that are open for less than 24 hours a day[7]. As noted above, in the past, the Secretary has not engaged in a process of public notice and comment to change the policy which clearly existed prior to the OPPS to reimburse services provided by hospital-based, less than full-time emergency department facilities like the Shoreline facility on the same basis as all emergency department facilities are reimbursed by the Medicare program. CPT code definitions were never identified, in any rulemaking process, as changing Medicare pre-OPPS policy which recognizes facilities like the Shoreline facility as part of a hospital's emergency department **for payment purposes**. Indeed, to the contrary, and as discussed in Part III. c, of these comments, the Secretary explicitly has recognized that CPT codes are not an appropriate basis to classify patients with respect to hospital facility use, including emergency department resource use for payment purposes. Medicare-Medicaid Conditions of Participation (CoPs) and regulations promulgated under EMTALA recognize hospital provider-based emergency department facilities which operate less than 24 hours per day, like the Shoreline facility, as part of the emergency department of

[7] 71 *Fed. Reg.* 49607

a hospital and hold them accountable to provide emergency services and not clinic services.

Given the absence of formal rulemaking on this issue, and particularly, the acknowledgement that CPT codes are inadequate to define hospital resource use, CMS' direction to YNHH not to bill at emergency department rates is a departure from past policy which raises significant questions of law and policy. See Mercy Medical Skilled Nursing Facility v. Thompson et al., Civil Action Nos. 99-2765, 01-2014, 02-2252, and 02-2253, (D.C. Cir. May 14, 2004), p.2, CCH Medicare-Medicaid Guide, ¶301,455 (Program Memorandum which departed from the Secretary's prior ten year policy of reimbursing in full all atypical service costs above the routine cost limit violated the Administrative Procedure Act because "it constitutes a change in the Secretary's definitive interpretation made without following the required notice-and-comment procedures.") The United States District Court for the District of Columbia noted it did not matter whether the policy was written. "Any significant alteration of that established practice requires notice and an opportunity for those affected to comment. To hold otherwise would grant agencies the power to reinterpret regulations at will so long as their prior interpretations, no matter how established, had not been written down." Id. at p.3. See Tenet Healthsystem Hospitals, Inc. d/b/a St. Charles General Hospital and Tenet Healthsystem Hospitals, Inc. d/b/a Century City Hospital v. Shalala, Civil Action No. 97-3499, (E.D. La. Nov. 4, 1998), CCH Medicare-Medicaid Guide, ¶300,116 and cases cited (Broad deference is not appropriate where an agency's new interpretation of its regulations conflicts with a prior interpretation on which plaintiffs reasonably relied). See also Vencor, Inc. v. Shalala, 988 F. Supp. 1467 (N.D. Ga. Dec. 23, 1997), CCH Medicare-Medicaid Guide, ¶300,053 (Memorandum which set forth a geographic proximity requirement for hospitals and skilled nursing facilities operation under a written transfer agreement was unreasonable, arbitrary and capricious, where a geographic proximity requirement was not set forth in the statute or regulation and the new policy departed from prior longstanding policy and was adopted without notice and comment); Hospital Therapy Services of Georgia, Inc. v. Shalala, Civil Action No. 1:95-CV-2951-JOF, slip op. (N.D. Ga. Aug. 14, 1997), CCH Medicare-Medicaid Guide, ¶45,744 (the same Memorandum at issue in Vencor, supra, which imposed a geographic proximity requirement where the Medicare program's prior policy allowed reimbursement claims irrespective of the distance between the hospitals and skilled nursing facilities, was found to be unlawful because it was not in accordance with law, constituted unlawful rulemaking under the Administrative Procedure Act, and was vague, arbitrary and capricious). These cases stand for the well-established rule of administrative law that an agency such as CMS may not change its policy *sub silentio*. Roadway Express, Inc. v. NLRB, 647 F.2d. 415, 419 (C. A. 4 1981).

Proposed "Descriptor" of Hospital Emergency Department

The description (referred to in the proposed rule as "long descriptor[8]") defines a hospital emergency department, in part, as a visit provided in an emergency department "licensed by the State." Some states, including the State of Connecticut do not discreetly

[8] See 71 *Fed. Reg.* 49608 and 49610, Tables 33 and 34.

license hospital emergency departments. Instead, these states license hospitals and either authorize or permit a hospital to operate an emergency department. For example, the State of Connecticut has authorized the Shoreline facility through the Certificate of Need process. Accordingly, we recommend the description of an emergency department be revised to delete the words "licensed by the State" and instead to provide "authorized or permitted by the State."

Based on the foregoing YNHH requests that CMS provide that existing hospital provider-based emergency department services be paid at full emergency department rates. We believe this is consistent with the statutory goals Congress has established for OPPS and necessary to provide adequate financing for essential emergency services. We look forward to participating in CMS' study of this issue.

Should CMS have any questions concerning these comments please contact YNHH's legal counsel in this matter, Edward D. Kalman, at (617) 227-7660 or via e-mail at ekalman@beharkalman.com.

Sincerely,

Kathleen Farren
Corporate Director of Reimbursement
Yale-New Haven Health System

NATIONAL PATIENT ADVOCATE FOUNDATION

A National Network for Healthcare Reform

October 10, 2006

HAND DELIVERED

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

Re: **CMS-1506-P**

Dear Dr. McClellan:

The National Patient Advocate Foundation (NPAF) is a non-profit organization dedicated to improving access to healthcare services through policy reform. The advocacy activities of NPAF are informed and influenced by the experience of patients who receive counseling and case management and co-payment relief services from our companion organization, the Patient Advocate Foundation (PAF), which specializes in mediation for access to care, job retention, and relief from debt crisis resulting from diagnosis with a chronic, debilitating or life-threatening disease. In fiscal year July 1, 2005 – June 30, 2006, PAF was contacted by 6 million patients requesting information and/or direct professional intervention in the resolution of access disputes. Of that number, 27% were Medicare beneficiaries and 85.1% were individuals dealing with a diagnosis of cancer.

NPAF would like to thank you for the opportunity to comment on the "Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates Proposed Rule" (the "Proposed Rule") published in the *Federal Register* on August 23, 2006[1] As requested, we have keyed our comments to the issue identifiers in the Proposed Rule. We hope CMS finds our recommendations helpful as it finalizes the rule for 2007.

OPPS: NONPASS-THROUGH DRUGS, BIOLOGICALS, AND RADIOPHARMACEUTICALS

I. NPAF urges CMS to accept the APC Panel's recommendation to maintain payment for non-pass-through drugs at ASP plus 6% in 2007

CMS proposes to reduce payment for drugs without pass-through status to average sale price (ASP) plus 5%. NPAF urges CMS to rescind this proposal and accept instead the Ambulatory Payment Classifications (APC) Panel's recommendation to maintain reimbursement for all separately payable drugs under the hospital outpatient prospective payment system (HOPPS) – pass-through and non-pass-through alike – at the reimbursement rate set under the Physician Fee Schedule, which is ASP plus 6%.

[1] 71 *Fed. Reg.* 49504 (Aug. 23, 2006).

Further, we encourage CMS to adopt our recommendations to clarify certain aspects of the proposed definition of *bona fide* service fees that are to be excluded from the ASP calculation and to treat prompt pay discounts extended to wholesalers as fees that also should be excluded. These ASP recommendations are discussed in more detail in the comments NPAF filed on CMS-1321-P, "Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment under Part B," published in the *Federal Register* on August 22, 2006.[2] Consistent with the intent of the MMA, the revisions to ASP we espouse will make that reimbursement metric more representative of prices available to providers in the marketplace.

NPAF has long been committed to maintaining beneficiary access to new, innovative cancer therapies in hospital outpatient departments. Our recommendation to reimburse all separately payable HOPPS drugs at ASP plus 6% using an ASP value determined in a way that more accurately reflects market pricing in 2007 is a product of this commitment. Because many of the cancer drugs currently viewed as the standard of care are not available to hospitals or any other retail class of trade at discounted prices and because wholesaler prompt pay discounts are not routinely passed on to their customers, without the changes we are advocating, we fear beneficiary access will be severely compromised.

Medicare's current payment rate for separately payable drugs does not adequately reimburse hospitals for their drug acquisition costs, much less their pharmacy services costs. The APC Panel heard testimony at its August 26, 2006 meeting that the current Medicare payment rate of ASP plus 6% fails to cover the cost of over 50 percent of the separately payable drugs on many hospital formularies. A recent survey conducted by the Association of Community Cancer Centers (ACCC) confirms the APC Panel testimony. The ACCC survey indicates the proposed Medicare payments of ASP plus 5% will not be sufficient to cover the cost of five of the eight common oncology therapies considered in the survey.[3] The majority of survey respondents indicated that the proposed CY 2007 reimbursement will be insufficient to cover the acquisition and pharmacy-related overhead costs for the following drugs: Neulasta (pegfilgrastim); Taxotere (docetaxel); Velcade (bortezomib); Eloxatin (oxaliplatin); and Aranesp (darbepoetin). Also, approximately 37 to 42 percent of survey respondents indicated that the proposed CY 2007 reimbursement will be insufficient to cover the acquisition and pharmacy-related overhead costs for the following drugs: Herceptin (trastuzumab); Rituxan (rituximab); and Avastin (bevacizumab). Finally, the majority of survey respondents predicted their costs would be greater than the proposed 2007 Medicare payment rate by more than $100 per cancer therapy.

The proposed reduction to ASP plus 5% will make what is already a difficult financial situation for many hospitals even worse. We are concerned some hospitals, particularly those in rural areas where costs typically run higher or those that serve as safety net providers, simply will not be able to continue offering outpatient chemotherapy services under the 2007 Proposed Rule. Others may have to limit the availability of certain more innovative and costly cancer treatments on their formularies. Still others may be forced to offer certain therapies only on an inpatient basis. Although a baseline study of 2004

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[2] 71 *Fed. Reg.* 48982 (Aug. 22, 2006).

[3] ACCC's Survey on Hospital Outpatient Department Drug Reimbursement Levels is available at http://www.accc-cancer.org/media/media_hopdsurvey06.asp.

Medicare claims data by Duke University Institute of Research entitled, *"The Medicare Modernization Act and Changes in Reimbursement for Outpatient Chemotherapy: Do Patients Perceive Changes in Access to Care?"*, coupled with a Web-based convenience survey of Medicare beneficiaries in early 2005 found no statistically significant differences in time to treatment or site of treatment for Medicare beneficiaries with cancer before the MMA and in the first year (2004) of the MMA's implementation, it did note some apparent dislocations in access in rural areas and among Medicare beneficiaries without supplemental insurance, including an increase in inpatient treatment. The report recommended interpreting these findings with caution, however, because these beneficiary subgroups were too small to permit the covariate adjustments needed to determine whether the findings reflected baseline differences between the pre-MMA and post-MMA cohorts.[4] This particular "solution" to cost pressures that could develop as a result of the drug reimbursement rates proposed for 2007 will not only deprive patients of care in the most clinically appropriate, patient-friendly setting but also increase costs to the healthcare system as a whole.

In many areas throughout the U.S., hospitals are the sole site of service for Medicare beneficiaries. In testimony to the House Ways and Means Subcommittee on Health on July 13, 2006, Mark Miller, Executive Director of the MedPAC, stated that many oncology practices have stopped treating Medicare beneficiaries.[5] As a result, the number of Medicare beneficiaries transferred to hospital outpatient departments increased in 2005.[6] These patients and their families could be left with no or limited service option in their communities if the proposed drug reimbursement cuts force hospitals to trim standard-of-care therapies from their formularies or shut their outpatient infusion centers.

II. NPAF urges CMS to continue to work with the oncology community over the next year to develop a reimbursement methodology for pharmacy service and handling costs

Under the Proposed Rule, there would be no separate reimbursement for hospital pharmacy services and handling costs. Rather, those costs would be subsumed in the proposed ASP plus 5% payment rate for non-pass-through drugs. NPAF strongly disagrees with CMS' conclusion that ASP plus 5% is an appropriate proxy for both acquisition and overhead costs associated with separately payable drugs provided in hospital outpatient departments. NPAF urges CMS to continue to work with MedPAC and the oncology community to develop an appropriate reimbursement methodology for pharmacy services and handling costs because we are convinced adequate reimbursement is key to preserving the availability of high-quality, high-value outpatient care options for Medicare beneficiaries and their families battling cancer.

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[4] *The Medicare Modernization Act and Changes in Reimbursement for Outpatient Chemotherapy: Do Patients Perceive Changes in Access to Care?*, Kevin A Schulman *et al.*, Duke Center for Clinical and Genetic Economics, Duke Clinical Research Institute (Sept. 15, 2006), funded by The Global Access Project. For complete study, visit www.npaf.org

[5] Medicare Part B Drugs and Oncology: *Testimony before the Subcommittee on Health Committee on Ways and Means U.S. House of Representatives* (July 13, 2006) (Statement of Mark E. Miller, PhD, Executive Director, Medicare Payment Advisory Commission).

[6] *Id.*

We understand that prior to the MMA, Medicare payments under OPPS covered both drug acquisition costs and the pharmacy services and handling costs associated with drug inventories. However, the MMA required CMS to reduce payment rates to hospital outpatient departments for separately payable drugs to the costs hospitals incur to acquire them. Because Congress recognized the potential significance of this change in policy, it also directed MedPAC to study pharmacy services and handling costs.[7] In its June 2005 report to Congress, MedPAC cited studies that found pharmacy service overhead costs (such as salaries and benefits for pharmacists and technicians and supplies) make up 26% to 28% of pharmacy departments' direct costs.[8] The MedPAC report concluded these costs were substantial and recommended an adjustment be made to the HOPPS reimbursement methodology to appropriately compensate hospitals for both their drug acquisition costs and their pharmacy service and handling costs associated with those drugs.[9]

A 2005 study conducted by the University of Utah Pharmacotherapy Outcomes Research Center for The Global Access Project entitled, *"Documentation of Pharmacy Cost in the Preparation of Chemotherapy Infusions in Academic and Community-Based Oncology Practices"*, also assessed the costs associated with handling infusion drugs. The Utah Study collected cost data from two hospital outpatient infusion centers in Utah and Wisconsin and from two physician office-based cancer centers in Virginia and Alabama. The University of Utah study concluded significant handling costs were associated with the infusion of chemotherapy drugs in both types of community settings. Those costs derive from drug storage, inventory management, waste management, equipment required to handle and administer the drugs, supplies, shipping, drug preparation and insurance management. In summary, the University of Utah study calculated that each dose of an infused drug includes a preparation cost of approximately $36.03, which is neither captured nor reimbursed. This is in addition to the acquisition cost of the drug.[10]

The Proposed Rule indicates CMS based its decision to reduce payment to ASP plus 5% on its analysis of mean unit costs from hospitals' claims data and the MedPAC survey discussed above that found hospitals generally set charges high enough to reflect handling costs and acquisition costs. We believe CMS' reliance on hospital charges is misplaced because hospital charges do not accurately reflect pharmacy and handling costs. The MedPAC report indicated hospitals do not have precise information about their pharmacy expenses. Further, it concluded hospitals charges may not appropriately reflect that drugs administered in outpatient departments generally require more preparation time than drugs administered to inpatients.

Not only is CMS' proposal to pay for drugs and pharmacy handling at a reduced rate of ASP plus 5% inconsistent with the findings of MedPAC and the University of Utah study, it is at odds with the recommendations of the APC Panel as well. At its August 2006 meeting, the APC Panel urged CMS to work with the oncology community to evaluate pharmacy

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[7] MMA, Pub. L. No. 108-173, § 621(a)(1), 117 Stat. 2066, 2307 (2003), amending Social Security Act § 1833(t)(14)(A)(iii), 42 U.S.C. § 1395l(t)(14)(A)(iii).

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

[9] *Id.*

[10] GAP Study, "Documentation of Pharmacy Cost in the Preparation of Chemotherapy Infusions in Academic and Community-Based Oncology Practices," D. Brixner, *et al.*, University of Utah Pharmacotherapy Outcomes Research Center. For complete study, visit www.npaf.org

services and handling costs and develop a new payment methodology that will appropriately pay hospitals for costs of safely handling and delivering cancer therapies. We endorse that recommendation and strongly urge CMS to follow the Panel's advice both to ensure continued beneficiary access to quality cancer care in the outpatient setting and to protect the health and well-being of hospital staff that are required to handle and admix the cytotoxic agents used to treat cancer.

III. NPAF urges CMS to continue its policy of not applying equitable adjustment to drugs

NPAF commends CMS for continuing its policy not to use equitable adjustments to set payment rates for separately payable drugs. NPAF continues to support the elimination of equitable adjustment and any comparable standards, such as functional equivalence, that restrict patient access to therapeutic alternatives and discourage innovation in biologic research and the development of life-saving therapies. On November 14, 2002, and on October 8, 2004, NPAF provided comments to CMS on the potential use of a functional equivalence standard to set reimbursement levels for drugs, biologicals and radiopharmaceuticals, expressing concern that such a reimbursement methodology would be detrimental to patient access. As stated in our comments of October 8, 2004, the "elimination of equitable adjustment assures patients that CMS understands the need to support a process of discovery that encourages innovators to continue their quest to eliminate and control the advance of disease through biologic research."

OPPS: DRUG ADMINISTRATION

IV. NPAF urges CMS to finalize its proposed drug administration APCs to ensure hospitals are paid appropriately for drug administration services

NPAF commends CMS for creating six new APCs for drug administration services and providing separate payment for the additional hours of infusion. Currently, hospitals only receive payment for the initial hour of infusion. Accordingly, they are not adequately compensated for lengthy drug administration services. We urge CMS to finalize the proposed new APCs to allow payment for second and subsequent hours of infusion in the final rule. We believe that this is an important step to ensuring that Medicare beneficiaries continue to have access to complex chemotherapy treatments in the hospital outpatient setting. It also is consistent with a basic promise of the MMA – a promise that Medicare reimbursement rates will accurately reflect the costs associated with each service component furnished by a provider of care.

V. NPAF urges CMS to ensure that hospitals are appropriately reimbursed for all the drug administration services that they provide to cancer patients

To make hospital outpatient payments for drug administration more consistent with payments in the physician office setting and with the realities of cancer care, NPAF would like to encourage CMS to go even further and take steps to ensure outpatient departments will be paid appropriately for all drug administrations via intravenous push. Hospitals currently do not receive any reimbursement for the second push administration of the same drug during a chemotherapy session. Nor do HOPPS payments for push administration

services recognize the additional work and costs associated with push administrations where two drugs are packaged.

In addition, NPAF seeks a change in the payment policies applicable when a patient receives a hydration infusion during an encounter in which a therapeutic infusion is administered. Currently, a hospital that administers both a one-hour hydration infusion and a one-hour therapeutic infusion would be paid for one hour of infusion under APC 440 and a reduced rate for the subsequent hour for the other infusion under APC 437. However, under the physician fee schedule, a physician office is reimbursed for the full rate for the first hour of each infusion. We recommend CMS adopt a similar policy for hospitals and allow hospitals to be reimbursed using an initial infusion code for both infusions.

NEW TECHNOLOGY APC

VI. NPAF urges CMS to assign PET/CT to APC 1514 for 2007 and 2008

CMS proposed to move PET/CT from a new technology APC (APC 1514) to a clinical APC (APC 308) for 2007. Because proper staging of cancers plays a critical role in the effective implementation of clinical guidelines and the provision of high-quality, high-value cancer care and because PET/CT scans are now the technology of choice for staging, NPAF is particularly concerned about the Proposed Rule's drastic 31% cut in reimbursement for PET/CT. We are concerned that at the proposed reimbursement rate Medicare beneficiaries will not have access to PET/CT scans which largely have replaced PET as the standard of care. Accordingly, NPAF urges CMS to accept the APC Panel's recommendation to keep PET/CT in APC 1514 for 2007.

We are concerned that the claims data being used to set payment rates under the Proposed Rule may be flawed because we understand many hospitals have not yet updated their chargemasters to separate charges for PET and PET/CT and more accurately reflect the cost of the newer technology. We recommend that PET/CT remain in a new technology APC for a minimum of two years to allow hospitals time to establish PET/CT-specific charges that more accurately reflect the costs associated with the service.

NPAF would again like to thank CMS for the opportunity to submit formal comments on the 2007 Hospital Outpatient Prospective Payment System Proposed Rule. We strive to make dialogue with the agency about payment policies give voice to the concerns of Medicare beneficiaries dealing daily with the burdens of a chronic, debilitating or life-threatening disease. We would be happy to discuss our comments with you if you have any questions about our recommendations for improving Medicare beneficiaries' access to cancer care.

Respectfully submitted,

Nancy Davenport-Ennis
Chief Executive Officer

Gail P. McGrath
President

October 6, 2006

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

ATTN: FILE CODE CMS-1506-P

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

Dear Administrator McClellan:

e^+ healthcare (e^+) welcomes the opportunity to comment on the proposed rule, CMS-1506-P, Hospital Outpatient Payment System and Calendar Year (CY) 2007 Payment Rates, published in the Federal Register on August 23, 2006. In doing so, e^+ is commenting on the portions of the rule that concern payment rates for positron emission tomography coupled with computed tomography (PET/CT).

e^+ develops and operates imaging centers that offer PET/CT scanning services. The combination of PET and CT into a single imaging modality offers the most comprehensive, non-invasive information today regarding cancer location and metabolism. PET/CT scans are a life-saving technology that can localize and identify tumors, including those obscured from scarring due to surgery, radiation, or drug therapy, and determine whether a tumor is malignant or benign. PET/CT scans have proved to be a critical component of cancer therapy by offering patients earlier diagnosis, more accurate staging and treatment planning, better monitoring of cancer therapies, and a reduction in invasive procedures.

e^+ is concerned that the proposal to reassign PET/CT from a new technology Ambulatory Payment Classification (APC) to APC 308 - with a reduction in payment from $1,250 to $865 – may have an adverse impact on Medicare beneficiaries receiving care at hospital outpatient departments as

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well as freestanding imaging centers, whose payment is linked to hospital outpatient rates under the DRA. Further, e^+ believes the proposed 30% payment reduction in the proposed rule is based on insufficient claims data; fixes reimbursement below the cost of providing PET/CT; fails to recognize the higher costs of PET/CT over conventional PET; and also fails to take into account the demonstrated specific clinical benefits of PET/CT for Medicare patients and for the Medicare program.

For these reasons, discussed more fully below, e^+ respectfully requests that the Centers for Medicare and Medicaid Services (CMS) adopt the August 23, 2006 recommendation of the APC Advisory Panel and maintain PET/CT in its current new technology APC at the rate of $1,250.

1. Insufficient Medicare Claims Data

PET/CT did not have a Current Procedural Terminology (CPT) code when CMS set payment rates for CY 2005 as part of its rulemaking process. The American Medical Association created three new CPT codes (78814, 78815 and 78816) for PET with concurrent CT when it was used for attenuation correction and anatomical localization and not for diagnostic purposes. In March 2005, CMS assigned the three new CPT codes to New Technology APC 1514 at a payment rate of $1,250 in its Hospital Outpatient Quarterly Update Transmittal 514. PET/CT remained in the APC at a payment rate of $1,250 for CY 2006 as well.

In arguing for its proposal to reassign PET/CT from the new technology APC to a separate and existing APC, CMS contends it has sufficient data on which to base the decision. However, the proposal is based on an Agency analysis of Medicare claims data from only nine months of CY 2005. e^+ points out that CMS' decision to move conventional PET from a new technology classification, on the other hand, is based on a review of five years worth of claims data. This is consistent with CMS' policy of keeping a service within a new technology APC until there is "sufficient data to assign it to a clinically appropriate APC group," as the Agency states in the proposed rule. e^+ believes that sufficient data do not exist to support a similar decision with respect to PET/CT because PET/CT CPT codes were not implemented until April 2005.

Medicare Claims Data Do Not Reflect True OPPS Cost of Providing PET/CT

By focusing on claims data from 2005, CMS analyzed claims submitted by hospitals that may not have updated their chargemasters to account for the costs of PET/CT as distinct from PET. Hospitals typically do not update chargemasters more than once per year and, in some instances, are barred from more frequent updates by contracts with

managed-care insurers. Claims from a hospital at the end of CY 2005 would not have included cost data specific to PET/CT CPTs until after the period captured by the CMS claims analysis. The "close relationship" CMS describes between median costs for PET and PET/CT in its analysis of hospital claims data is, therefore, not based on the similarity in costs for PET and PET/CT but on an analysis of claims from providers who did not update their chargemasters to accommodate new CPT codes that were implemented during the calendar year. Vanguard Health Systems testified at the August 23, 2006 APC Advisory Panel meeting that hospitals often do not update chargemasters for new technologies for two or three years. This supports our conclusion that the CMS analyses do not reflect the true costs of providing PET/CT in a hospital setting.

2. Fixed Hospital Costs are Higher for PET/CT Than for Conventional PET

The current cost of a new PET/CT scanner is $1.8 million, almost twice as much as the $1 million price for a PET scanner. Associated maintenance costs also are twice as expensive for a PET/CT scanner and the average salary for a technologist who operates a PET/CT scanner is $70,000, compared with a $45,000 salary for the operator of a conventional PET scanner.

CMS conceded in its CY 2006 final HOPPS rule that PET/CT scanners may be more expensive to buy and maintain than PET scanners but said that "a PET/CT scanner is versatile and may also be used to perform individual CT scans" if demand for PET/CT scans is limited. In the proposed CY 2007 rule, CMS again implies that the higher costs associated with PET/CT can be offset by their use for CT-only scans. CMS states that "many newer PET scanners also have the capability of rapidly acquiring CT images for attenuation correction and anatomical localization."

However, a survey of the Academy of Molecular Imaging members who provide PET/CT showed that most do not use their PET/CT scanners to provide CT-only scans. This is the case for e^+ as well. CMS has offered no data to support its contention that the cost of PET/CT scanners may be offset by use for CT-only scans.

3. APC Advisory Panel Recommends Maintaining PET/CT in New Technology APC

After hearing presentations by CMS and AMI on August 23, 2006, the Panel voted in favor of keeping PET/CT in a New Technology APC for 2007 at a payment of $1,250. Panel members weighed whether it was typical for CMS to remove a technology from such an APC based on three quarters of data, whether it was unusual to assign two technologies with

significantly differing cost structures in the same APC and at what point hospitals that generate claims data typically update chargemasters on which data is based. The American College of Cardiology, the Society of Nuclear Medicine and the Association of Dedicated Cancer Centers supported the recommendation that PET/CT remain in the New Technology APC.

However, CMS proposes removing PET/CT from its New Technology APC and assigning both conventional PET and PET/CT to the same APC. e^+ contends that this is not in keeping with Medicare regulations. The proposed rule clearly states that all items and services within a given APC group must be "comparable clinically and with respect to resource use." Further, with respect to new technologies, CMS has said: "After we gain information about actual hospital costs incurred to furnish a new technology service, we will move it to a clinically-related APC group with comparable resource costs. If we cannot move the new technology to an existing APC because it is dissimilar clinically and with respect to resource costs from all other APCs, we will create a separate APC for such service." (65 FR18476, 18478 (April 7, 2000)).

Further, CMS errs in equating PET and PET/CT on a clinical basis, stating in the proposed rule that "the scans have obvious clinical similarity as well." Identifying the exact areas of increased fluorodeoxyglucose avidity, which is enabled by use of PET/CT as opposed to PET alone, leads to significant changes in patient management and allows more precise guidance of interventions such as surgery and radiation therapy. PET/CT reduces the number of equivocal interpretations by 50% compared to PET alone because the anatomic localization provided by the CT portion of the PET/CT helps to differentiate active disease from normal physiologic uptake. PET/CT scans also provide information regarding metabolic activity as well as size of individual lesions so that those measurements may be compared in subsequent examinations and enable a more accurate assessment of a patient's response to a given therapy.

In summary, PET/CT has revolutionized cancer care by integrating PET and CT scans into a single device that can identify and stage tumors more accurately, providing better clinical results that PET alone and minimizing errors and unnecessary surgeries – both of which benefit Medicare patients and the Medicare program, which correctly is concerned with quality outcomes and prudent use of resources. The benefits of PET/CT include earlier diagnosis, more precise treatment planning and better monitoring of treatment therapy. $e+$ also notes that the Food and Drug Administration has concluded that PET/CT is a distinct medical device from PET in its pre-market approvals and regulations.

e^+ believes there is substantial support for PET/CT to be maintained in a New Technology APC for 2007 and paid at a rate of $1,250 per scan.

This support includes analyses of the cost of providing PET/CT in a hospital setting, the significantly higher cost of PET/CT technology over that of conventional PET scans and by the clinical benefits of the combination of PET and CT in the new technology of PET/CT. Further, the APC Advisory Panel, which is charged by CMS with providing counsel to the Agency on such issues, has also recommended the same.

We thank you for considering our comments on the proposed rule and offer e^+'s assistance in developing payment policies and other regulations with respect to PET/CT in the future.

Sincerely,

Timothy M. Petrikin
President and CEO

APMA
American Podiatric Medical Association

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October 2, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
Room 445-G
Hubert H. Humphrey Building
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Washington, DC 20201

RE: CMS-1506-P
Comments on Medicare Program; The Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; CY 2007 Update to the Ambulatory Surgical Center Covered Procedures List; the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates; Medicare Administrative Contractors; and Reporting Hospital Quality Data for FY 2008 Inpatient Prospective System Annual Payment Update Program – HCAHPS® Survey, SCIP, and Mortality; Proposed Rule (71 Fed. Reg. 49506, August 23, 2006)

Dear Dr. McClellan:

The American Podiatric Medical Association (APMA), the national association representing more than 11,500 of America's foot and ankle physicians and surgeons, is pleased to present comments on the proposed rule, *Medicare Program; The Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; CY 2007 Update to the Ambulatory Surgical Center Covered Procedures List; the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates; Medicare Administrative Contractors; and Reporting Hospital Quality Data for FY 2008 Inpatient Prospective System Annual Payment Update Program – HCAHPS® Survey, SCIP, and Mortality.*

While the APMA recognizes that the proposed rule covers a wide range of issues, we wish to focus our comments on the following three areas:

Procedures Proposed for Addition to the Ambulatory Surgical Center (ASC) List

We agree with the addition of codes 13122 *(Repair, complex, scalp, arms, and/or legs; each additional 5 cm or less)* and 13133 *(Repair, complex, forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands and/or feet; each additional 5 cm or less)* to the list of procedures proposed for addition to the ASC list effective January 1, 2007. We believe that since these codes will be reported as add-on codes to either 13120 *(Repair, complex, scalp, arms, and/or legs; 1.1 cm to 2.5 cm)* or 13131 *(Repair, complex, forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands and/or feet; 1.1 cm to 2.5 cm)*, which are assigned to ASC Payment Group 2 or to codes *13121*

(Repair, complex, scalp, arms, and/or legs; 2.6 cm to 7.5 cm) or 13132 *(Repair, complex, forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands and/or feet; 2.6 cm to 7.5 cm)*, which are assigned to ASC Payment Group 3, the assignment of ASC Payment Group 1 to the newly added codes is appropriate.

Section 5103

The APMA has reviewed the list of procedures subject to Section 5103 of the Deficit Reduction Act (DRA), which requires CMS to substitute the OPPS payment amount for the ASC standard overhead amount for surgical procedures performed at an ASC on or after January 1, 2007, but prior to the revised payment system when the ASC standard overhead amount exceeds the OPPS payment for the procedure. While we understand that CMS is implementing this provision as directed by the DRA, we are concerned that the impact on ASCs may be greater than expected. Several procedures commonly performed by podiatric physicians and surgeons are among those subject to the DRA cap and some procedures will experience significant changes in payments as a result of the cap. We believe that ASCs must be fairly and appropriately reimbursed for the costs associated with the delivery of procedures in that setting.

While we acknowledge that we are not the experts on the costs associated with the delivery of care in an ASC vs. in the out-patient setting, we recognize that costs may vary in different settings. We encourage CMS to carefully consider feedback received from ASC providers as the agency implements these payment changes. If ASC providers are able to offer convincing evidence that the DRA cap adversely impacts their ability to provide quality care to Medicare beneficiaries, we would encourage CMS to investigate those claims in detail.

Proposed APC-Specific Policies

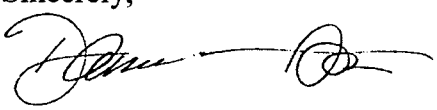
Skin Replacement Surgery and Skin Substitutes

The APMA supports the 2007 proposed assignment of CPT codes 15170-15176, 15300-15321, 15340-15366, and 15420-15431 to Ambulatory Payment Classification (APC) 25.
In particular, we are pleased that CPT codes 15340 (*Tissue cultured allogeneic skin substitute; first 25 sq cm or less*) and 15341 (*Tissue cultured allogeneic skin substitute; each additional 25 sq cm*) have been assigned to APC 25 because we believe it more accurately accounts for all of the work, including debridement, associated with the application of tissue cultured allogeneic skin substitutes. We urge CMS to maintain, at a minimum, APC 25 for codes 15340 and 15341. We appreciate CMS's dedication to ensuring that CPT codes are assigned to the proper APC.

American Podiatric
Medical Association, Inc.

We appreciate the opportunity to offer these comments. In the near future, we will provide separate comments in response to the ASC 2008 Payment System and CY 2008 Payment Rates. If you have questions concerning our comments, please contact Dr. Nancy L. Parsley, Director of Health Policy and Practice, at (301) 581-9233.

Sincerely,



David M. Schofield, DPM
President

137

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October 6, 2006

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

Re: Proposed Rule: Medicare Program; The Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; Proposed Rule (CMS-1506-P; CMS-4125-P)

Dear Dr. McClellan:

The American College of Radiation Oncology ("ACRO") appreciates the interest of the Centers for Medicare and Medicaid Services (CMS) in receiving comments on the Proposed Rule that addresses the Hospital Outpatient Prospective Payment System (OPPS) and CY 2007 Payment Rates (CMS-1506-P; CMS-4125-P). With a current membership of approximately 1000, ACRO is a dedicated organization that represents radiation oncologists in the socioeconomic and political arenas. ACRO's mission is to promote the education and science of radiation oncology, to improve oncologic service to patients, to study the socioeconomic aspects of the practice of radiation oncology, and to encourage education in radiation oncology. Our members practice in both freestanding centers and hospital outpatient departments.

ACRO would like to extend its appreciation for the opportunity to comment on the proposed regulations.[1] This letter will comment on the following sections:

- Definition of a brachytherapy source;
- Facility payment cuts for three stereotactic radiosurgery codes;
- Proposed reductions in breast brachytherapy facility payments;
- Stereoscopic x-ray guidance (CPT code 77421);
- Complex interstitial radiation source application (APC 0651); and
- Proposed separately payable brachytherapy sources for CY 2007.

[1] "The Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; Proposed Rule" *Federal Register*, Volume 71, No. 163, August 23, 2006, p. 49505.

A. Definition of a Brachytherapy Source

ACRO supports CMS's definition of a brachytherapy source as outlined below.

> *"We (CMS) have considered the definition of the term "brachytherapy source" in the context of current medical practice and in light of the language in section 1833(t)(2)(H) of the Act. We are proposing to define a device of brachytherapy eligible for separate payment under the OPPS as a "seed or seeds (or radioactive source)" as indicated in section 18333(t)(2)(H) of the Act, which refers to sources that are themselves radioactive, meaning that the sources contain radioactive isotope."* [2]

B. Facility Payment Cuts for Stereotactic Radiosurgery Codes

CMS has proposed changing the APC assignment for several stereotactic radiosurgery treatment delivery codes. CMS's rationale is that it now has two years of claims data and adequate information on the appropriate compensation for these services.[3] As noted in the proposed OPPS regulations, the coding for stereotactic services has been changing significantly over time. The most recent code change was set forth in the CY 2006 OPPS final rule when CMS discontinued HCPCS codes G0242 and G0338.

ACRO believes that G0173 (non-image guided, non robotic accelerator based stereotactic radiosurgery) and G0339 (image guided robotic linear accelerator based stereotactic radiosurgery) are comparable clinical interventions. We support the placement of these two codes in the same APC. We would like to work with CMS on exploring issues of parity on G251 (linear accelerator based fractions 2-5) and G240 (robotic stereotactic radiosurgery fractions 2-5) as well. We are also willing to assist CMS to carefully crosswalk the new CPT codes to the APCs.

ACRO continues to be concerned about CMS's assumptions on the speed in which technology is disseminated as well as the ability for providers to fully account for costs (and thus accurately charge) for technology that is moving out of academic institutions and becoming an integral part of community based practice. It is our belief that technology disseminates more slowly than assumed by CMS. It appears to be a reasonable assumption that, as technology is more widely available in more centers, a "market" price can be calculated. It is ACRO's belief that three years of data would provide additional information from more centers, allowing for the price established to reflect the experience of a larger number of providers. In addition, three years of data would allow for less weight to be placed on the charges from the first year – a year when providers are learning how to accurately account for the costs of the service. While we appreciate that the codes have been available for longer than two years, they have neither been stable nor have the services generally been available outside of large, teaching institutions. Therefore, ACRO requests that CMS gather one more year of claims data prior to determining an OPPS price for stereotactic radiosurgery.

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[2] CMS-1506- P, *Federal Register*, August 23, 2006, p. 49599.
[3] Ibid, p. 49553-4.

C. Proposed Reductions in Breast Brachytherapy Facility Payments

Three breast brachytherapy codes are moving from new technology codes where they have been for one year to clinical APCs. Of the three codes, the following two are faced with dramatic reductions.

HCPCS Code	Descriptor	APC Proposed for 2007	Proposed Rate for 2007	Change in Payment from 2006 to 2007	Percent Change from 2006 to 2007
19296	Place po breast cath for rad	0030	$2534	($716)	-22%
19297	Place breast cath for rad	0029	$1822	($928)	-34%

ACRO is concerned that there are too few claims to accurately move these two codes from the New Technology APCs, where they have been for one year, to clinical APCs. As additional evidence for the inadequacy of the claims data, ACRO notes that the balloon catheters used in both procedures (19296 & 19297) cost approximately $2750 per procedure. The payments as proposed above would not cover the cost of the catheter, let alone the other services being offered to the patient. Consistent with our stance on stereotactic radiosurgery, ACRO believes that three years is the appropriate timeframe for gathering complete data and developing an accurate APC assignment. This ensures that the technology is more widely diffused within the provider community, allowing a more stable, "standard" price to be determined.

D. Stereoscopic X-ray Guidance (CPT code 77421)

Stereoscopic x-ray guidance for localization of target volume for the delivery of radiation therapy is a new CPT code for 2006. We note that CMS has proposed two different prices for this code – Table 10 indicates a price of $88.39 [4] and Addendum B lists the price at $60.14.[5] Regardless of which is the correct rate, ACRO believes that both CMS and the provider community have insufficient experience with this code to appropriately assign it to an APC. Therefore, ACRO supports continuation of 77421 as a new technology code with the payment of $75.00.

E. Complex Interstitial Radiation Source Application (APC 0651)

CMS and ACRO agree that the payment for complex interstitial radiation source application (APC 0651) has been unstable.[6] ACRO observes two primary sources for the instability: (1) providers have not reliably billed for these sources; and (2) the code has been used to bill for a heterogeneous mix of patients including:

[4] Ibid, p. 49556.
[5] Ibid, p. 49817.
[6] Ibid, p. 49563.

- low dose rate brachytherapy manual loading of iridium for treatment of such conditions as sarcomas or breast cancer;
- permanent low dose rate brachytherapy using radioactive iodine for prostate cancer; and
- insertion of applicators for brachytherapy for gynecological or other tumors.

Therefore, the charge data has been erratic over time. ACRO supports the development of codes that will create a more homogeneous set of claims data. It is our hope that such an effort may lead to a more stable payment for complex interstitial radiation source application.

F. Proposed Separately Payable Brachytherapy Sources for CY 2007

Table 29 sets forth the APC assignments for various brachytherapy sources.[7] When combined with Addendum A[8], the following payment rates are established by CMS.

Source	Price
Gold 198, per source	$27.65
Iodine-125, per source	$35.42
Palladium-103, per source	$48.90
Brachytherapy solution, Iodine-125, per MCi	$19.32
High activity iodine-125, greater than 1.01 MCi, per source	$25.68
Linear source, Palladium-103, per 1 mm	$39.15

Source	Price
High dose rate iridium-192, per source	$134.93
Non-high dose rate Iridium-192, per source	$31.44
Yttrium-90, per source	$16,789
Cesium-131, per source	$90.00
High activity Palladium-103, greater than 2.2mCi, per source	$54.29
Ytterbium-169, per source	$25.68

ACRO is unclear as to the source of information used to calculate these source prices. How can high activity iodine-125 greater than 1.01 MCi per source ($25.68) be priced less than Iodine-125, per source ($35.42)? The Government Accountability Office (GAO) study[9] indicated that it was not feasible at this time to calculate a price of Iridium. The Iridium price suggested here seems far to low based on the experience of our members. Iridium is a reusable source with a three month use life. The correct compensation for Iridium must be dependent on the number of uses per source.

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[7] Ibid, p. 49597.
[8] Ibid. p. 49715.
[9] "Rates for Certain Radioactive Sources Used in Brachytherapy Could be Set Prospectively" July 2006, United States Government Accountability Office, Report to Congressional Committees, July 2006, GAO-06-635.

As a result of these issues, ACRO feels strongly that CMS needs to continue payment on a cost to charge ratio until CMS can clarify data issues. In the interim, the GAO study has provided sufficient information to justify establishing a price for Iodine-125 ($35.42 per source) and Palladium-103 ($48.90 per source) as specified above. ACRO would support established prices for these two sources only.

Conclusion

In this letter, ACRO has commented on more than one occasion that additional claims data is highly desirable. Three years of claims information not only increases the number of data points, but also ensures that new technology has spread more widely through the provider community, allowing a more stable "standard" price to be determined. This increases the accuracy by which CMS establishes its price. This is not an argument for a higher price, but one supporting CMS's own goal of making "...payments that are appropriate for the services that are necessary for treatment of Medicare beneficiaries."[10]

ACRO's comments on the OPPS regulations seek to ensure ongoing access to radiation oncology services. In many communities, hospital outpatient units are the key providers of radiation services. Maintaining patient access is crucial since our patients often require services 5 days a week for many weeks of life saving therapy. Patient accessibility and continuity are key components of service quality.

ACRO appreciates the opportunity to comment on the regulations. We hope that our comments highlight our sincere interest in making radiation oncology services cost effective, properly reimbursed and readily accessible to cancer patients.

Sincerely,

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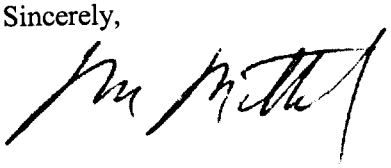
Bethesda, Maryland 20816

Sincerely,



Michael Kuettel, M.D., Ph.D.
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cc: Terrence Kay, Centers for Medicare and Medicaid Services
Herb B. Kuhn, Centers for Medicare and Medicaid Services
Leslie V. Norwalk, Centers for Medicare and Medicaid Services

[10] CMS-1506-P, *Federal Register*, August 23, 2006, p. 49551.