Submitter : **Ms. Karen Ryan** **Date: 10/10/2006**

Organization : **Geisinger Health System**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

Please see attached comments on the Medicare OPPS proposed rule from Geisinger Health System, Danville PA

CMS-1506-P-483-Attach-1.DOC

FF 1183

Geisinger
Health System

Heal. Teach. Discover. Serve.

October 9, 2006

Leslie Norwalk
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1506-P
P.O. Box 8011
Baltimore, MD 21244-1850

REF: CMS 1506-P
Comments on Proposed Medicare Outpatient Prospective Payment Changes for Calendar Year 2007
(Federal Register – August 23, 2006)

Dear Ms. Norwalk:

The purpose of this letter is to provide comments on the Centers for Medicare and Medicaid Services ("CMS") "Proposed changes to the hospital outpatient prospective payment system for CY 2007". These proposed regulations were published in the Federal Register on August 23, 2006.

Geisinger Health System ("GHS") is an integrated healthcare system with corporate offices located in Danville, PA. The Geisinger Health System includes Geisinger Medical Center (provider #39-0006), a 388 bed rural tertiary care center located in Danville, PA, Geisinger Wyoming Valley Medical Center (provider #39-0270), a 148 bed acute care facility located in Wilkes-Barre, PA and Geisinger South Wilkes-Barre (provider #39-0169), a 168 bed acute care facility also located in Wilkes-Barre, PA.

We have reviewed the proposed rule, and are providing comments on several issues, as follows:

I. Hospital Quality Data

CMS is proposing to link the annual OPPS market basket update to the submission of the twenty one (21) inpatient quality indicators under the RHQDAPU (Reporting Hospital Quality Data for Annual Payment Update) program.

As with the inpatient market basket update, providers that do not submit quality data are subject to a 2.0% reduction in the annual update factor.

Although we applaud CMS's efforts to promote quality of care and improved outcomes in the most cost efficient manner, the linking of the annual outpatient market basket increase to the inpatient measures is not appropriate due to the diverse nature of outpatient services in comparison to inpatient services. The majority of inpatient quality measures are related to specific inpatient care that cannot be correlated to the outpatient environment.

We do not dispute CMS's intention to link the annual outpatient increase to a system of quality measures similar to the IPPS. CMS, however, should develop a separate list of measures that will be more appropriate for outpatient care, and should not adopt the market basket reduction until this new separate list of measures be developed with a similar process of reporting such indicators.

II. APC Relative Weights – Revision of Overall Cost to Charge Ratio

CMS states that currently there are two different calculations of cost to charge ratios (CCR) that are used by both CMS and the Fiscal Intermediaries (FI) for purposes of payment modeling, and payment of outlier cases.

GHS agrees with CMS that only our overall CCR should be used for all purposes related to the OPPS. Both CMS and FI should adopt a single CCR calculation. This would allow for more consistent application and calculation of the CCR.

However, if CMS also determines that by revising the calculation, there is a negative impact to providers by lowering the outlier payments, then this change should be made on a budget neutral basis.

III. Drug Administration

CMS requests comments from providers on the significant changes to drug administration coding that occurred for FY 2006. There was significant confusion in the crosswalk of HCPC's and CPT codes, specifically with regard to subsequent/sequential infusions. This area could use additional clarification.

We are in agreement of the proposal to pay facilities separately for the first hour and each additional hours of infusion as the related payment prior to this proposal was associated with a per visit and was not reflective of the total costs associated with the total number of hours a patient would receive an infusion. We feel that his would relieve some of the burden hospitals face in regard to the extent of services being provided and reimbursed.

We would also like to comment on the payment for C8952 in that separate payment is only made to a facility upon injection of a different drug during one encounter. We would like to request that this be reviewed to provide payment to a facility for each injection regardless of the substance injected. It is not being suggested that payment be made for each attempt but for each actual injection to better reflect the cost associated with the services being provided. There are few drugs that have separate reimbursement in comparison to all potential drugs and by reimbursing for only the injection when a

different substance is administered does not accurately reflect the number of injections being provided to a patient during an encounter and its' associated costs.

IV. Proposed Payment Changes for Blood and Blood Products

GHS does not agree with the OPPS methodology for determining payments for Blood and Blood Products. Our Blood Bank has experienced many years of payments lower than actual costs of blood and blood products from our blood suppliers.

GHS Blood Bank has looked at the research on this topic and finds that many studies in recent years have shown that hospital information on costs for blood are not accurate from lack of proper billing practices and complexities in reporting.

Our Blood Bank acknowledges that the APC payments have begun to increase but they still fall short of the actual costs of the product costs. For instance, The proposed APC payment for Leukoreduced Red Cells while increasing about 8% in the 2007 OPPS Proposal still falls short of the American Red Cross charge of $184.61 for this product. In our Blood Bank this is the highest volume service that is billed.

We would like to see CMS begin to set payment rates with consideration to actual industry cost data supplied by the American Red Cross and other blood supplier organizations.

V. Proposed Payment Changes for G0332 IVIG Preadministration-Related Services

GHS does not agree with the OPPS proposal to eliminate the additional and separate payment for IVIG Preadministration-Related Services currently being reimbursed through the billing of code G0332.

GHS Pharmacy is still receiving their IVIG shipments by allotment only. This is an indication of the fact that there is still a shortage of IVIG. This allotment delivery system is also an indication that the manufacturers of IVIG continue to have trouble meeting demand for the product. They are using this allotment system because they are concerned of depleting their IVIG supply, and having a continuous demand that they cannot meet.

Code G0332 was created in 2006 to allow hospitals to bill for Preadministration-Related Services and to offset their related expenses through a separate $75 payment. It was intended to provide payment for the additional resources expended with locating and acquiring adequate IVIG, preparing for the infusion, rescheduling patients if the product is not available, etc.

Since IVIG deliveries continue to come in allotments, and some level of shortage still exists, providers are still going to incur the additional expenses for securing and preparing IVIG, now without the offset G0332 gave them last year.

Please continue to keep code G0332 as a separately billable and payable service.

VI. OPPS: Non Pass Through Drugs, Biologicals and Radiopharmaceuticals

CMS proposes to reduce the payment for "specified covered outpatient drugs" from the CY2006 level of Average Sales Price (ASP) + 6% to ASP + 5% in FY2007.

ASP + 6% is the reimbursement that physicians receive if they administer a drug in the physician's office setting.

CMS states that based on a review of FY2005 claims data, the median cost of "specific covered outpatient drugs" approximates ASP + 5%. This level of payment would include all overhead costs of drugs and pharmaceuticals.

The payment for drugs and pharmaceuticals in a physician's office should not exceed the payment for those same drugs in a hospital. Hospitals must absorb a significant amount of overhead expense that is not incurred in a physician office setting including the salary expense of pharmacists that mix, calculate dosages and dispense complicated pharmaceuticals.

It is inconceivable that CMS would reimburse a drug administered in a physician's office at a higher rate than the same drug administered in a hospital outpatient setting.

We disagree with the CMS proposal, and request that the payment for drugs and pharmaceuticals remain at ASP + 6%.

VII. Visits – ED and Clinic Evaluation and Management Codes

CMS is proposing several different changes to Emergency Department (ED) and Clinic Evaluation and Management codes. These include:

1. Establishment of seventeen (17) HCPC's Level II codes for the use of assigning Emergency Department visits, (12 codes – differentiation between ED that provides 24 hour care) and Physician office visits (5 codes)
2. Creation of eleven (11) new APC's for payment of ED and Physician office visits.

CMS is also proposing national guidelines for the coding of ED and Physician office visits. These coding guidelines have been developed by AHA and AHIMA and are currently being reviewed by CMS. CMS states that national coding guidelines will be in place by CY 2008, and that providers will be given six-twelve months notice before implementation.

We agree with CMS's differentiation in coding and payment rates of Type A and Type B Emergency departments. Type A Emergency Room provides emergency care and must be staffed 24/7, so higher payment is warranted for these ED departments.

GHS currently utilizes ACEP (American College of Emergency Physicians) guidelines to determine Level 1 – Level 5 Coding of Emergency Room visits. CMS has stated that until national coding guidelines are implemented, providers should continue to utilize their internally developed guidelines.

We have reviewed the financial impact of transitioning from our current ACEP guidelines to the proposed AHA/AHIMA. The major difference in the coding guidelines is that ACEP utilizes types of interactions to determine Level 1 – 5 code assignment, where the AHA/AHIMA guidelines utilizes both types and number of interactions to determine code assignment.

We are concerned with the potential for significant redistribution of payments utilizing the proposed guidelines, and urge CMS to more thoroughly review the guidelines and make recommended changes to alleviate potential significant payment reductions to providers for ED services.

Based on a review of a sample of cases at Geisinger Medical Center, the change in code levels (and subsequent payments) from the currently used ACEP guidelines to the proposed guidelines reflect a significant payment reduction (32%) in ED visit reimbursement. The primary driver of this reduction in reimbursement is a change in the codes from current Level 4 to a Level 2 under the proposed guidelines.

We encourage CMS to thoroughly evaluate the proposed coding guidelines, and address the potential redistribution of payment, so that providers are not significantly impacted by a change in coding guidelines.

Thank you for the opportunity to comment on these proposed regulations.

Sincerely,

Karen Ryan

Karen Ryan
Director, Hospital Reimbursement
Geisinger Health System
Danville, PA

KR/vj

H:/pub/proposed medicare opps changes comments FY2007.dot

Submitter : Ms. Ellen Cooke **Date:** 10/10/2006

Organization : MeritCare Health System

Category : Hospital

Issue Areas/Comments

Myocardial PET Scans

Myocardial PET Scans

Comments: Myocardial PET Scans

We are writing in response to a proposed reimbursement decrease for myocardial PET perfusion imaging (HCPC 78492). It is our understanding that the decrease is based on the median cost reported by hospitals in 2005 ($721.00). MeritCare s cost to provide the myocardial PET is in excess of $2,000 excluding the full allocation of the rubidium generator. The proposed 70% reimbursement reduction will result in such a financial loss that we may be forced to discontinue this service. MeritCare is the only organization in North Dakota and the surrounding region that offers this exam.

MeritCare is among a small number of healthcare providers in the United States that is equipped to provide this exam. In 2005, we were the 25th organization to contract for rubidium generators (rubidium is the radioisotope used for PET perfusion imaging). Today, there are still less than 100 organizations contracted with the supplier of the rubidium generators. That being said, we are concerned that the median cost ($721.00) is distorted by the small number of organizations included in the calculation. Specifically, the rubidium has a high monthly fixed cost that would result in variability across providers based on the number of scans performed.

Dr. David Clardy, a MeritCare cardiologist, wrote the comments below. Dr. Clardy s comments highlight the importance and efficacy of myocardial PET in treating the patients in this region.

Cardiac PET is an exciting and very important addition to our armamentarium of noninvasive cardiac imaging at MeritCare. Its superior imaging qualities and accuracy is extensively documented in cardiology and radiology literature. Cardiac PET has been available at our institution since 2005 and its favorable impact on patient care has already become apparent. The proposed reduction in reimbursement for cardiac PET would therefore significantly impair our ability to deliver the best quality of care to our cardiac patients.

The best use of PET imaging appears to be in the obese patient and in the patient with a certain type of body habitus which are all likely to increase the likelihood of false-positive SPECT scans. It also is appropriate in the patients with previous inconclusive SPECT scans. Most of these patients would have to go on to coronary angiography if PET imaging were not available. This is strongly supported by the literature and our own experience. Over a 3-month period, from October through December 2006, 49 SPECT scans, interpreted as inconclusive, equivocal or probably abnormal went on to have PET scans, of which 36 were normal. In all probability, without the PET option, these patients would have ended up in the cardiac catheterization laboratory.

In light of the information provided above, we request that CMS do a more thorough evaluation of costs and charges for HCPC 78492. As this technology becomes more widely adopted, there will be a broader base of organizations from which to obtain data. Our own cost/charge data supports the need for reimbursement as it stands today ($2,484.88) and we believe that with closer scrutiny, other institutions costs and charges will be equal or higher than ours. Thank you for your reconsideration.

Submitter : **Mrs. Kimberly Cantor** **Date: 10/10/2006**

Organization : **Association of Women's Health, Obstetric and Neona**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-485-Attach-1.PDF

#485

AWHONN
Association of Women's Health, Obstetric and Neonatal Nurses

Promoting the health of women and newborns.

October 10, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8015
Baltimore, MD 21244-8015

Dear Center for Medicare and Medicaid Services:

The Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN) appreciates the opportunity to provide comment on the Center for Medicare and Medicaid Services (CMS) proposed rule regarding the Medicare Program; 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 71 FR 48982, August 22, 2006.

AWHONN is a national membership organization of 22,000 nurses, and it is our mission to promote the health and well-being of women and newborns. AWHONN members are staff nurses, nurse practitioners, certified nurse-midwives, and clinical nurse specialists who work in hospitals, physicians' offices, universities, and community clinics throughout the United States. Through AWHONN, our members receive the most up-to-date information and cutting-edge, high quality resources that help enhance safety and provide superior patient care.

AWHONN is commenting on one specifics section of this proposed rulemaking:
O. Proposal to Establish Criteria for National Certifying Bodies That Certify Advanced Practice Nurses.

AWHONN acknowledges that currently CMS regulations do not provide a full list of recognized or approved national certifying bodies for nursing practitioners (NPs) and clinical nurse specialists (CNSs). We are concerned that creating a list of "approved" certifying bodies could become a complex and tedious process for CMS and require updating as the dynamics of the profession evolve. AWHONN supports an approach that would require CMS to accept certifying bodies based on their adherence to either the National Commission for Certifying Agencies (NCCA) or the American Board of Nursing Specialties (ABNS). These organizations have developed their own recognition policies and procedures. National entities that certify NPs and/or CNSs must obtain certification from either NCCA or ABNS.

We appreciate the CMS' efforts to bring this issue before the health care community for comment. As an association of nursing professionals, we support the full use of NPs and CNSs in clinical practice. Providing opportunities for all certified national certifying bodies to be recognized by CMS is a critical step in facilitating current and future health care delivery needs.

Thank you for the opportunity to comment. If you have any questions or concerns, do not hesitate to contact me at 202-261-2430.

Sincerely,

Karen Peddicord

Karen Peddicord, RN, PhD
Interim Executive Director

2000 L Street, NW, Suite 740 ~ Washington, DC 20036
(202) 261-2400 ~ Fax: (202) 728-0575 ~ www.awhonn.org

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

Organization : The Alliance of Dedicated Cancer Centers

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachments

CMS-1506-P-486-Attach-1.PDF

CMS-1506-P-486-Attach-2.PDF

CMS-1506-P-486-Attach-3.PDF

#1186

Oncology Watch

From the Roundtable: Multidisciplinary coordination expedites care, builds volumes

09/25/2003

As supported by a recent *Cancer* study (Buchholz et al., 9/15/03), multidisciplinary care models can foster collaborative treatment planning and a more responsive, individualized approach to cancer care. According to *Multidisciplinary Care Coordinators,* a 2003 Oncology Roundtable Practice Brief, hospitals can organize service offerings by using care coordinators who schedule specialty consultations, refer patients to appropriate support services, and provide patient education, among other roles. Acting as the "glue" that holds multidisciplinary programs together, coordinators can ultimately help build volumes and increase patient satisfaction.

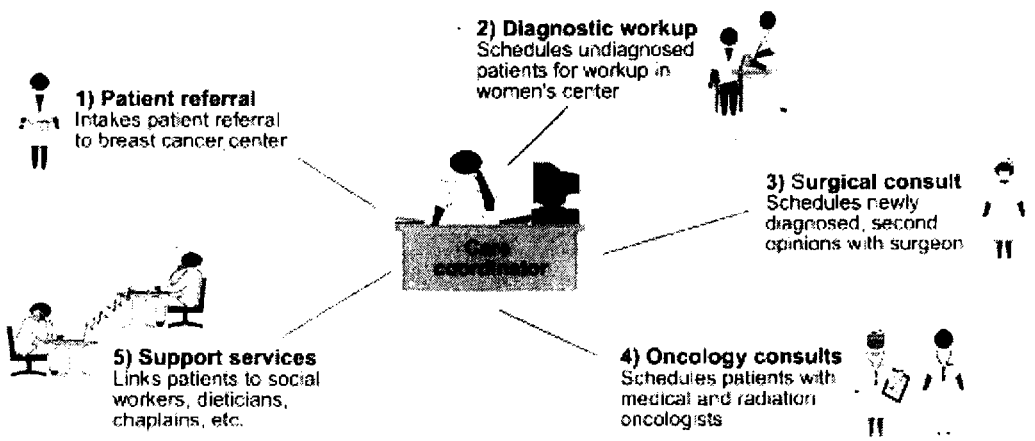
Multidisciplinary clinic central to care model

At the heart of the coordinated care model is the multidisciplinary clinic, which brings clinicians—including medical, surgical, and radiation oncologists—together to discuss individual patient cases and develop comprehensive treatment plans. Multidisciplinary clinics are either physical clinics—in which specialists from several disciplines meet one to two times per week in a single location for patient visits—or virtual clinics—in which patients receive separate, but closely spaced specialty consults that are typically scheduled by a care coordinator. Although a physical clinic provides a forum for specialists to develop a consensus regarding treatment recommendations, a virtual clinic may just as effectively provide seamless patient care when the creation of a physical clinic is not feasible due to space, time, or other constraints.

Care coordinator guides patients, physicians through clinic process

Though multidisciplinary programs vary as to the level of specialist collaboration, timing of consults, and degree of patient support provided, an almost universal feature is the presence of a care coordinator—typically a registered nurse (RN)—who oversees cancer patients' progress through the diagnosis and treatment process. As the title suggests, a significant component of the multidisciplinary care coordinator's role involves care coordination—from organizing treatment planning conferences to scheduling patient consults with specialists and support services.

Care coordinator orchestrates patient's visit to multidisciplinary clinic



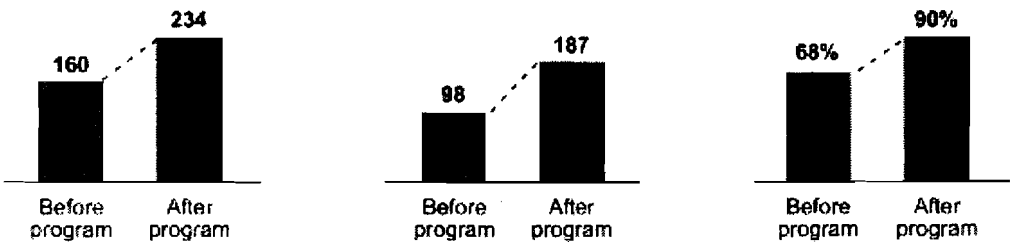
Source: Oncology Roundtable, *Multidisciplinary Care Coordinators*, 2003.

In addition to their organizational and educational roles, multidisciplinary care coordinators often assume secondary roles in improving program functioning and encouraging more patient-focused care. For example, coordinators often sit on quality improvement committees, contribute to cancer center marketing and planning efforts, or facilitate patient focus groups to gauge satisfaction and areas for improvement.

Integrated efforts improve patient satisfaction, volumes

Roundtable research suggests that the additional costs of employing a care coordinator are offset by the clinical and service benefits of a multidisciplinary program. Several coordinator-based multidisciplinary cancer clinics have reported significant increases in patient satisfaction and, consequently, program volumes, which are bolstered through word-of-mouth advertising.

Multidisciplinary care generates significant ROI at Maple Hospital[1]



[1] Pseudonymed institution

Source: Oncology Roundtable, *Multidisciplinary Care Coordinators*, 2003

For more information

Members interested in additional information on developing and implementing multidisciplinary care models are encouraged to access the Oncology Roundtable's Practice Brief, *Multidisciplinary Care Coordinators: Implementation Guide for Advancing Patient-Focused Care*, online at Advisory.com.

#1506 - 2

The Alliance of Dedicated Cancer Centers:
Arthur G. James Cancer Hospital and Richard J. Solove Research Institute
City of Hope National Medical Center
Dana-Farber Cancer Institute
Fox Chase Cancer Center
H. Lee Moffitt Cancer Center and Research Institute
M.D. Anderson Cancer Center
Memorial Sloan-Kettering Cancer Center
Roswell Park Cancer Institute
Seattle Cancer Care Alliance
Sylvester Comprehensive Cancer Center

October 10, 2006

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

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

Dear CMS Administrator:

On behalf of the Alliance of Dedicated Cancer Centers (the "Centers"), an alliance of ten nationally recognized institutions focusing exclusively on the care of cancer patients, I am writing to comment on the Proposed Rule that would revise the Medicare prospective payment system for hospital outpatient services, as published in the Federal Register on August 23, 2006 (71 Fed. Reg. 49,506) (the "Proposed Rule"). The Cancer Centers, individually listed above, appreciate the opportunity to comment on this Rule. Please note that our comments on two issues -- drugs and drug administration services -- were submitted separately earlier in the comment period, but we are resubmitting them, along with our comments on other issues, in this comprehensive comment letter.

DISCUSSION

In the following comments, the Centers identify a number of concerns about payment for cancer services under the Proposed Rule.

A. Drugs, Biologicals and Radiopharmaceuticals

1. Average Sales Price + 5% and Pharmacy Handling/Overhead Costs

CMS proposes to pay for specified covered outpatient drugs in 2007 on the basis of average sales price (ASP), with ASP + 5% reflecting payment for average acquisition costs and pharmacy overhead/handling costs.[1] The Centers recognize that CMS was required by the Medicare Modernization Act (MMA) to change how it pays for drugs starting in 2006 and that, in the absence of average acquisition cost data, CMS is authorized to use ASP unless Competitive Acquisition Program data is available. We commented on this issue last year when CMS proposed, and made final for 2006, that separately payable drugs would be reimbursed at ASP + 6%. The Centers believe that payment rates at this level are grossly inappropriate, because they do not begin to cover our acquisition or overhead/handling costs -- particularly since several new mandates (e.g., USP797,[2] NIOSH[3]) require the Centers to expend even more resources in our pharmacies. We provided detailed information on both of these mandates and the costs associated with them for a number of our Centers in last year's comments; thus, while we can provide these comments upon request, we will not repeat that information here.

The Centers continue to believe that CMS is incorrect in its assumption that using a percentage increase over the ASP to set payment rates for most separately payable and pass-

---

[1] 71 Fed. Reg. 49,506, 49,585 (Aug. 23, 2006).

[2] See U.S. Pharmacopoeia, Proposed Revisions to USP Chapter 797, available at: http://www.usp.org/healthcareInfo/pharmInfo (January 2004 revisions - without opportunity for public comment – to recommendations on the preparation of sterile intravenous medications in response to isolated but highly publicized cases of patient harm resulting from contaminated medications produced outside of hospital pharmacies).

[3] See National Institute for Occupational Safety and Health Alert, September 2004, available at: http://www.cdc.gov/niosh/docs/2004-165/ (introducing new recommendations for pharmacy and nursing handling of hazardous drugs).

through drugs is sufficient to cover both our drug acquisition and pharmacy overhead/handling costs. We, like many others, urged CMS to find an administratively simple solution to capture pharmacy handling data in our comments last year. At a minimum, CMS must carefully consider the impact of unfunded mandates on pharmacy overhead/handling costs and identify a mechanism to factor them into the overall drug payment policy.

It is difficult to understand why CMS is suggesting decreasing the current drug APC payment rates from ASP + 6% to ASP + 5% for 2007. Given that the current rates are already inadequate, this 1% decrease in how we are currently paid is inappropriate. Therefore, we strongly oppose CMS' proposal to further reduce drug APC reimbursement rates. The Centers' oncology clinics already face increased patient loads as physicians have been forced to turn certain types of patients away from their private office practices in the face of falling drug reimbursement. At the Centers, we do not have the same ability to direct patients to another setting, and yet we face even higher pharmacy overhead/handling costs and receive lower reimbursement in the aggregate because we do not receive separate payment for packaged drugs. As such, we fail to understand how CMS can reimburse physicians in the private office setting at a higher rate for separately payable drugs, nor do we understand why CMS would reintroduce the site of service differential between the physician and hospital settings that it eliminated for 2006 by reimbursing all separately payable drugs at the same rate – ASP + 6%.

Moreover, the Centers were very disappointed that CMS did not comment in the 2006 final OPPS rule on the merits of our suggestion to review hospital cost report data as an alternative to CMS' proposal to require category C-codes to capture pharmacy overhead/handling cost data. In that comment letter, we suggested that CMS study hospital cost report data and determine if handling costs could be extracted from this existing data source.

This method could potentially be used as an alternative, or just a stopgap until methodological issues can be resolved with CMS' proposal.

Alternatively, CMS could require each Fiscal Intermediary (FI) to provide a "pharmacy overhead/handling cost collection" survey to the hospitals it services, collect the completed surveys from the hospitals, and transmit the data back to CMS. This approach has been used for a number of purposes in the past, including to collect data for the payment-to-cost ratio[4] used in the transitional outpatient payment calculations; the wage index and occupational mix information for both OPPS and IPPS; and, most recently, for the outpatient cost-to-charge-ratio.[5] In all of these cases, hospitals submitted the requested calculations and data to their respective FIs using a very prescriptive method and the FIs, in turn, used these data for payment purposes.

The Centers believe that CMS can utilize a similar approach to obtain data on provider drug handling charges and costs. Collecting these data from all hospitals (and using the same formula, cost report line numbers, and consistent methodology) will allow CMS to establish a more realistic pharmacy/drug handling fee by creating either a flat add-on percentage or separate APC payment rates. Although the 2004 cost reports will not contain cost data related to the impact of the two unfunded mandates mentioned above, it will provide CMS a much better starting point for estimating pharmacy overhead/handling costs. As more current cost report data becomes available, CMS should continue updating its estimates of pharmacy overhead/handling costs (if this approach is selected as a method to set drug handling APC payments).

In sum, the Centers urge CMS to continue paying for all separately payable drugs according to the ASP + 6% methodology. We further urge CMS to exercise its authority and provide an add-on payment that would cover pharmacy overhead/handling costs, which would

[4] See CMS, Program Memorandum A-01-51 (April 13, 2001).
[5] See CMS, Program Memorandum A-03-004 (Jan. 17, 2003).

help offset our increased costs associated with the unfunded mandates discussed above. In addition, we recommend that CMS convene a special meeting of the APC Advisory Panel dedicated to the issues of pharmacy overhead/handling data capture and charge compression. To date, these issues have not been addressed by CMS and the result is continued underpayments and/or inappropriate payments for drug and device APCs. Clearly, there are no simple solutions to this problem. We are, however, optimistic that bringing stakeholders together would be an important starting point to discuss these issues from both a technical and hospital operations perspective.

2. Drug packaging threshold

CMS has proposed to retain the drug packaging threshold resulting in no separate APC payment for drugs with a per administration cost below the threshold. The proposed threshold for CY 2007 is increased by $5 to $55, with a provision for an annual inflationary update thereafter.[6] The Centers do not agree with the continued use of a drug packaging threshold for several reasons, which we outline below.

First, eliminating the drug packaging threshold will allow CMS to align its drug payment policy across the physician office setting and hospital outpatient departments since all drugs are reimbursed separately in the physician office setting regardless of cost, while drugs with a per administration cost of less than $55 are proposed to be "packaged" in the hospital setting. The transition away from using average wholesale price as the basis for drug reimbursement in both settings to the use of ASP is one example of how CMS has aligned payment policy across the two settings in the past. CMS eliminated the separately payable drug site of service differential for 2006 by paying for drugs in both settings using ASP + 6%. CMS also worked to create consistency across the two settings by moving towards requiring similar codes and rules for

[6] 71 Fed. Reg. at 49,582.

reporting drug administration services. Conversely, the 2007 proposal to pay hospitals using ASP + 5%, while continuing to pay physicians in the office setting using ASP + 6%, is a problematic divergence from that alignment.

Second, CMS often states that the charges for packaged drugs and other packaged items (e.g., supplies and other services) are included in the development of other APC payment rates. The Centers understand that the concept of packaging is consistent with prospective payment systems; however, this concept only works if the charges associated with packaged services, including drugs, are actually being included in the APC rate-setting process. The Centers believe the majority of packaged drug charges are on multiple procedure claims, and are never factored into the payment rate of other APCs. The Centers analyzed data from the first six months of our own 2005 drug administration claims data, which showed that packaged drugs with HCPCS codes represented 5.83% of total drug charges, and only 17.91% (of the 5.83% of HCPCS coded packaged drug charges) appeared on single procedure claims. This demonstrates that the vast majority (82.09%) of packaged drug charges with HCPCS codes appear on multiple procedure claims, and thus would not be factored into the APC rate-setting process. The Centers presented the above information at the March 2006 APC Advisory Panel meeting, and we are disappointed that CMS did not respond to the Panel's recommendation that CMS should prepare an analysis that discloses the actual percentage of packaged drug charges appearing on single procedure claims used in the APC rate-setting process.

Since CMS already goes through the process of identifying single and multiple procedure claims, the Centers believe it would be relatively easy for CMS to isolate the percentage of packaged charges appearing on single procedure claims and again request that CMS disclose this information. Specifically, the Centers request that CMS release the total charges associated with

all packaged HCPCS and revenue codes billed by providers. Once this number has been isolated, CMS should calculate the percentage of packaged dollars associated with single and pseudo-single procedure claims as this will inform the public of the actual percentage of packaged dollars in aggregate included in the rate-setting process. Finally, the Centers ask CMS to isolate the universe of drug administration claims and disclose the total charges associated with packaged drug HCPCS and revenue codes along with the percentage that appear on single and pseudo-single procedure drug administration claims. This will serve to inform the public of the percentage of packaged drug charges appearing on drug administration claims that are being factored into drug administration APC payment rates.

Third, and related to the discussion above regarding packaged drug charges, the Centers are concerned that a disproportionate percentage of packaged charges, often with higher mark-ups, are being discarded and therefore not factored into the APC rate-setting process. Packaged drugs are typically older and lower in cost. Providers using a tiered mark-up structure may end up applying higher mark-ups to these drugs and lower mark-ups to their higher cost, separately payable drugs. Therefore, if a large percentage of packaged drug charges - charges that CMS and MedPAC claim reflect our pharmacy handling/overhead charges - are not being used in the rate-setting process, then CMS cannot reasonably assert that ASP + 5% is sufficient to cover both acquisition and pharmacy handling/overhead. If packaged drug charges are NOT being factored into the APC rate-setting process, then CMS' estimate of ASP + 5% for 2007 is incorrect and should be analyzed more extensively. Since CMS has not yet disclosed the percentage of total packaged drug charges that appear on single or pseudo-single procedure claims, we do not know whether (or where) the majority of packaged drug charges and hence our pharmacy overhead is being factored into the payment rates of separately payable APCs.

This is another reason for CMS to conduct the analyses mentioned above and disclose the information to the public. If our hypothesis is correct and CMS is not factoring in the majority of packaged drug charges, then this is further justification for the provision of separate payment for all HCPCS coded drugs, regardless of their median cost, as this will help to offset some of our pharmacy overhead/handling expense.

Finally, in 2006, CMS eliminated separate APC payment for multiple injections of the same drug/substance. Therefore, it must be recognized that hospitals lose money on both the second and subsequent drug administration (i.e., injections) service of the same drug and also on the drug itself when the drug administered is packaged. This results in a compounded loss in payment for hospitals. Alternatively, physicians in their office setting only have to absorb the loss of the second and subsequent administrations, as they are paid for each billed drug regardless of the median cost of the drug.

If CMS does not implement the recommendation to eliminate the drug packaging threshold, it will continue to perpetuate a site of service differential between the physician office setting and the hospital setting with respect to drug reimbursement. This disparity is unacceptable, particularly if packaged charges are not being factored into the APC rate-setting process. If CMS rejects our recommendation to pay for all HCPCS coded drugs separately, then it must find a way to truly use packaged drug charges in the APC rate-setting process, or else hospital payments will continue to be compromised. The Centers have provided CMS with packaging logic in the past to generate additional single procedure claims for drug administration and are willing to work with CMS to develop logic to isolate packaged drug charges so they can be appropriately allocated to drug administration APCs for the rate-setting process.

3. **Intravenous Immune Globulin (IVIG)**

IVIG (Intravenous Immune Globulin) is a blood product that is used extensively in bone marrow transplants. For 2006, CMS created a temporary HCPCS G-code, G0332 (for *pre-administration related services for IV infusion of immunoglobulin [IVIG], per infusion encounter*) in recognition of the extra resources that hospitals must expend due to the IVIG shortage and to help offset those costs. In the Proposed Rule, CMS states that its review of the IVIG marketplace indicates that a separate IVIG pre-administration payment is no longer necessary in 2007.[7]

As CMS is aware, there continues to be an ongoing nationwide supply shortage of IVIG. Because of the Iraq war, *all* blood products continue to be in short supply. Therefore, the Centers do not understand why CMS proposes to eliminate the pre-administration IVIG G-code and associated APC payment rate.

As a result of the ongoing shortage, the Centers and other providers must purchase IVIG "off contract" (i.e., at whatever price the secondary market suppliers believe the market can bear). In this type of environment, unforeseen clinical necessity sometimes mandates that we purchase IVIG at acquisition prices that are much higher than the APC reimbursement for the product. Additionally, the IVIG shortage necessitates that the Centers' pharmacies purchase whichever formulation is available, so that this important drug therapy can be provided to our patients when they need it.

The Centers recognize that CMS has proposed paying for additional hours of infusion therapy separately beginning in 2007.[8] According to the Proposed Rule, this reimbursement is intended to cover the additional nursing resources that are incurred during additional hours of

[7] 71 Fed. Reg. at 49,604.
[8] Id. at 49,600.

infusion therapy. CMS should not expect this payment to cover the extra facility resources expended related to the shortage of IVIG. The resources expended as a result of the IVIG shortage are completely separate from the payment for additional hours of infusion therapy, which is correlated to the nursing time and resources expended to provide this therapy.

The Centers therefore urge CMS to continue providing separate APC reimbursement for HCPCS G-code, G0332. We are very concerned about our ability to maintain beneficiary access to this important drug therapy for our bone marrow transplant, neurology, hematology, and HIV/AIDS patients.

4. **Radiopharmaceuticals**

The Centers believe that it is important for CMS to continue paying for brachytherapy and radiopharmaceuticals at cost. The frequent code and descriptor changes have likely resulted in poor and incomplete claims data. CMS does not have the advantage of using 2006 claims data yet, where payment is based on charges reduced to cost and the revised codes. We believe this data will generate more accurate and appropriate payment rates for use in 2008. Therefore, relying on median cost data from 2005 as the basis for setting 2007 APC payment rates is premature and could impact beneficiary access to care, since the calculated payment rates are understated due to data-related issues.

The Centers recognize that OPPS is a budget neutral system and that providing separate payment for all HCPCS coded drugs, maintaining ASP + 6% for all separately payable drugs, and continuing to pay cost for brachytherapy and radiopharmaceuticals will take money away from other APCs. However, OPPS is still evolving and, over the years, much consideration has been given to developing appropriate payment rates for high-cost devices and device-related APCs, including the use of external data and dampening mechanisms even when claims data

were available. The Centers ask CMS to examine the category of drugs, biologicals, and radiopharmaceuticals in the same manner. Payment policy decisions over the past few years have resulted in the continued ratcheting down of payment for cancer-related services. If CMS does not provide adequate reimbursement for drugs, biologicals, and radiopharmaceuticals, then providers who administer them in the outpatient setting will incur disproportionate losses and access to care for Medicare beneficiaries may be compromised.

B. Drug Administration

For the past four years, the Centers have strongly supported improving drug administration coding and payment policy under OPPS. We are pleased that CMS has proposed a number of changes for drug administration services for 2007, including proposals to expand the number of drug administration APC groups; moving away from per-visit payment to per-service payment; and providing for separate payment for additional hours of infusion therapy. The Centers anticipate continued refinements for drug administration coding, billing, and reimbursement under OPPS. The Centers' comments on drug administration for 2007 fall into three main areas: coding, payment, and other issues for 2007. We address each of these separately below.

1. Coding Policy

The Centers are concerned with CMS' proposal to continue requiring providers to report a combination of HCPCS C-codes and CPT codes to report drug administration services in 2007. This is how all providers report drug administration services to Medicare. However, our other payers require the full set of 2006 drug administration CPT codes to be reported. This has resulted in a situation where hospitals must report one way to Medicare (HCPCS C-codes and CPT codes) and a different way to non-Medicare payers (CPT codes), resulting in an enormous administrative and operational burden.

Because more drug administration CPT codes exist than HCPCS C-codes, and because providers are required to charge all payers the same, providers were forced to learn how to code and bill all of the CPT drug administration codes this year. We trained our charging staff, updated internal systems and processes, and revised our encounter forms to reflect the full range of 2006 drug administration CPT codes. This was necessary because, even though all of the CPT codes were not required for Medicare, they were required by our other payers. The result is that the Centers and most other providers are currently using the full set of CPT codes to charge non-Medicare payers for drug administration services at the point of care, and converting the CPT codes into C-codes for Medicare billing on the back-end, through edits in the billing system or by conducting manual reviews. It is worth noting that several of the Centers created bill edits in their bill scrubbers but found them to be unreliable and ultimately decided to have specialized and dedicated coding staff review each record manually before submitting claims to Medicare. Having dedicated FTEs reviewing records and monitoring the coding and billing process is extremely resource intensive and operationally burdensome. Nevertheless, we have been forced to "make it work" through significant training and education efforts, internal edits, and manual review.

As CMS is aware, the Centers were never in favor of implementing the new 2006 drug administration CPT codes, since those fundamentally differ from the 2005 drug administration CPT codes (which the Centers strongly supported). We maintain our earlier position: that the 2006 drug administration CPT codes are not applicable in the hospital setting and should not be the final system of codes used to report drug administration services under OPPS in the future. Our position is based on the fact that the CPT codes were created by physicians, for physician

use; in fact, the CPT Editorial Panel now seems to recognize that the codes are not optimal for the hospital setting and has indicated a willingness to revise them.

Since the Centers, like many other providers are already required to report the full range of CPT codes to non-Medicare payers, and a partial set to CMS, a move to the full use of drug administration CPT codes will streamline the administrative process. This will enable providers to charge all payers in the same manner. We are prepared to use the full set of drug administration CPT codes in 2007. However, we urge CMS to view this as an interim solution only. It is essential that CMS address the fact that the drug administration CPT codes need further revision for hospital use. The Centers urge CMS to work with the AHA and the CPT Editorial Panel to make the necessary revisions so that, by 2008, the CPT codes for drug administration will be appropriately applicable and easy to use in the hospital setting.

The Centers are concerned about both the long-term applicability of the new CPT codes and descriptions, as well as the narrative guidance included in the CPT book. As noted, the codes were created for, and by, physicians for use in the private office setting without regard to the educational, operational, and financial impact of hospital setting implementation. The CPT Editorial Panel did not have hospital use in mind when it made significant changes to the drug administration codes and descriptions, since hospitals were still reporting Q-codes at that time and Medicare had not yet decided to require CPT codes. A combination of bad timing, lack of communication, and poor coordination between CMS and the CPT Editorial Panel has resulted in the burdensome requirement that hospitals must report new codes for drug administration services in part to CMS, and in full to many other payers. Nonetheless, the Centers continue to support the use of CPT codes from 2005 and previous years instead of the old Q-codes, as CPT coding allows for greater differentiation among infusion and injection services.

For this reason – despite opposing the current CPT codes and drug administration descriptions – the Centers believe that CMS' movement to the full use of CPT codes would reduce much of our current operational burden related to charging different payers with different code sets. It may also create the necessary impetus for CMS to work with the AHA and the CPT Editorial Panel to revise the current CPT codes and descriptors to ensure their applicability in the hospital setting. The Centers therefore urge CMS to move to full implementation of CPT codes for reporting drug administration services under OPPS for 2007. We also urge CMS to immediately begin working with the AHA and the CPT Editorial Panel to revise the codes and descriptions for drug administration services to ensure that they are equally applicable in both the physician and hospital settings. The Centers would be pleased to provide CMS with recommendations on how to revise existing CPT code descriptions to make them appropriate and usable in the hospital setting.

2. APC Payment Groupings and Payment Policy

The Centers applaud CMS for using 2005 provider claims data to create six new drug administration APCs, and for proposing to allow separate payment for each additional hour of infusion therapy. The Centers also support CMS' proposal to pay for drug administration services on a per-service basis similar to other APC services (instead of the per-visit payment which has been the case for drug administration services since OPPS' inception). We encourage CMS to make this proposal final for 2007. As a result of this proposed change, we expect that the OCE/PRICER logic will be revised so that claims are processed appropriately regardless of whether the CPT and C-code coding methodology is retained or if full use of CPT drug administration codes is implemented. At a minimum, this means allowing the OCE/PRICER to

generate multiple APC payments when multiple units of the same code are reported, or when multiple APCs are generated as a result of the full use of CPT codes.

The Centers have carefully reviewed CMS' Preamble Table 30.2 and agree with the new APC payment structure. However, we are concerned about the placement of several codes into APC groups. First, the Centers agree with CMS' proposed assignment of C8952 into the Level III Drug Administration APC and expect that, if CMS moves to the full use of CPT drug administration codes for 2007, the analogous CPT code, 90774 (therapeutic, prophylactic or diagnostic injection, IV push, single or initial substance/drug), would be assigned to this same level. We question where CMS will place CPT 90775 (therapeutic, prophylactic or diagnostic injection, each additional sequential intravenous push of a new substance/drug), since it does not have an analogous HCPCS C-code. The Centers believe this code should also be placed in the Level III Drug Administration APC since the same facility resources are required whether a single injection or multiple injections of the same or a different drug are given. If the resources required are the same, the reimbursement should be the same as well.

Second, the Centers are concerned about the APC assignment and associated payment rates for the following three chemotherapy administration codes:

- 96440 (Chemotherapy administration, pleural cavity requiring and including thoracentesis);
- 96445 (Chemotherapy administration, peritoneal cavity requiring and including peritoneocentesis);
- 96450 (Chemotherapy administration into CNS requiring and including spinal puncture).

These chemotherapy administration services are far more invasive (e.g., they require catheters inserted into body cavities) and require more facility resources than the other drug administration services assigned to the same APCs. CMS proposes to place CPT codes 96440 and 96445 in a

Level IV Drug Administration APC (APC 439), with a proposed payment rate of $97.50; and CPT code 96450 in a Level VI Drug Administration APC (APC 441), with a proposed payment rate of $154.31. The payment rates for these services are exceptionally low. For CPT codes 96440 and 96445 (drug administration plus the associated procedure as described in the code descriptors above), the payment rate is even lower than the APC payment rate for the procedure alone. For CPT code 96450, the payment rate is only slightly higher than the code for the procedure itself. Table 1 below clearly shows the APCs and associated payment rates for the three stand-alone surgical procedures and the three chemotherapy administration services, which include the surgical procedure as part of the service.

TABLE 1[9]

CPT/ HCPCS	Short CPT Description	APC	APC Payment
32000	Drainage of chest	0070	224.20
49080	Puncture, peritoneal cavity	0070	224.20
62270	Spinal fluid tap, diagnostic	0204	138.43
96440	Chemotherapy, intracavitary	0439	97.50
96445	Chemotherapy, intracavitary	0439	97.50
96450	Chemotherapy, into CNS	0441	154.31

The proposed APC payment rate for CPT codes 32000 for drainage of the chest (thoracentesis) and for 49080 for puncture, peritoneal cavity (peritoneocentesis) is significantly higher than the APC payment rate for the two chemotherapy administration codes which include these procedures as part of the overall service. It is only logical that the surgical procedure

[9] Id.

provided along with chemotherapy administration should result in a higher APC payment than either service rendered alone -- yet this is not the case. Although CPT code 96450 -- which includes both chemotherapy administration and the lumbar puncture procedure (CPT 62270) -- has a slightly higher APC payment rate than CPT code 62270 when provided on its own, this increase is not sufficient to cover the extra costs associated with providing two services instead of one.

Therefore, the Centers urge CMS to move procedure codes 96440, 96445, and 96450 out of the proposed APC groups to which they are currently assigned. CMS should either create a new APC group with a significantly higher payment rate, or simply instruct providers to report both the surgical procedure code and the drug administration procedure code as separate line items. CMS will need to turn off the hospital Correct Coding Initiative edits related to these code pairs so the OCE/PRICER can generate a separate APC payment for each separately billed service.

Finally, as stated above, we believe it will be easier for hospitals to report the full set of CPT codes to all payers, including Medicare, in 2007. As such, we have provided the following cross-walk from CPT codes to APC groupings for CMS to use in 2007. It should be noted that our mapping is quite similar to the information that CMS provided to the APC Advisory Panel at its March 2006 meeting.

TABLE 2

2007 APC	Drug Administration APC Level	SI	Proposed CY 2007 APC Median	CPT/HCPCS Code	Description	Notes
				90472	Immunization admin, each add	
				90473	Immune admin oral/nasal	
				90474	Immune admin oral/nasal addl	
				90779	Ther/prop/diag inj/inf proc	
				95115	Immunotherapy, one injection	
0436	LEVEL I	S	$10.71	96549	Chemotherapy, unspecified	
				90772	Ther/proph/diag inj, sc/im	
				90471	Immunization admin	
				95117	Immunotherapy injections	
				95144	Antigen therapy services	
				95145	Antigen therapy services	
				95146	Antigen therapy services	
0437	Level II	S	$25.49	95147	Antigen therapy services	
				95148	Antigen therapy services	
				95149	Antigen therapy services	
				95165	Antigen therapy services	
				95170	Antigen therapy services	
				G0008	Admin influenza virus vac	
				G0009	Admin pneumococcal vaccine	
				90773	Ther/proph/diag inj, ia	
				90774	Ther/proph/diag inj, iv push, single or intial substance/drug	
				90775	Ther/proph/diag inj, iv push, each additional sequential intravenous push of a new substance/drug	
				90761	Intravenous infusion for therapy/diagnosis; each additional hour	
0438	Level III	S	$48.99	90766	Intravenous infusion for therapy/diagnosis/prophylaxis; each additional hour, up to 8 hours	
				96401	Chemo, anti-neopl, sq/im	
				96402	Chemo hormon antineopl sq/im	
				96405	Chemo intralesional, up to 7	
				96406	Chemo intralesional over 7	
				96542	Chemotherapy injection	
				96411	Chemotherapy administration; intravenous push technique, each additional substance/drug	
				96409	Chemotherapy administration; intravenous push technique, single or initial substance/drug	
				96420	Chemo, ia, push technique	
				96415	Chemotherapy administration, intravenous; infusion technique; each additional hour up to 8 hours	
0439	Level IV	S	$97.84	96423	Chemotherapy administration, intra-arterial; infusion technique; each additional hour up to 8 hours	
				90767	Intravenous infusion, for therapy/diagnosis/prophylaxis; additional sequential infusion, up to 1 hour	
				96440	Chemotherapy, intracavitary	Move to new APC or allow payment for this code + the procedure code
				96445	Chemotherapy, intracavitary	Move to new APC or allow payment for this code + the procedure code
				90760	Intravenous infusion, hydration; initial up to 1 hour	
				90765	Intravenous infusion, for therapy/diagnosis/prophylaxis; initial, up to 1 hour	
0440	Level V	S	$112.94	96417	Chemotherapy administration, intravenous; infusion technique; each additional sequential infusion, up to 1 hour	
				96521	Refill/maint, portable pump	
				96522	Refill/maint pump/resvr syst	
				96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug	
				96416	Chemo prolong infuse w/pump	
				96422	Chemo ia infusion up to 1 hr	
0441	Level VI	S	$154.86	96425	Chemotherapy, infusion method	
				96450	Chemotherapy, into CNS	Move to new APC or allow payment for this code + the procedure code
				C8957	Intravenous infusion for therapy/diagnosis; initiation of prolonged infusion (more than 8 hours), requiring use of portable or implantable pump	Keep as C-code
Packaged		N/A	N/A	90768	Intravenous infusion, for therapy/diagnosis/prophylaxis; concurrent infusion (report only once per encounter)	

3. **Additional Drug Administration Issues**

CPT codes are not intuitive for hospital use, as noted above. For this reason, the Centers and other providers have asked the CPT Editorial Panel and the AHA for information, examples, and clear guidance on applying concepts such as initial, sequential, and concurrent services. Guidance has not been forthcoming to date, however. Therefore, we urge CMS to release detailed guidance on these and other drug administration issues that have been the subject of much debate this year.

A second issue stems from the fact that, for 2006, CMS recognized that it was unnecessary to include time (hours) in the code descriptors for the add-on infusion codes (C8951 and C8955), which allowed providers to report one line item for the first hour of infusion and a second line item for the additional hours with no maximum unit of service limit. However, the analogous drug administration CPT codes do have an upper limit of "up to eight additional hours," which means that additional line items of the add-on codes would have to be reported for infusions greater than nine hours and 31 minutes. If CMS moves to the full use of CPT codes for drug administration in 2007, it should allow hospitals to "ignore" the limit of 8 additional hours in the description of the add-on infusion codes. This will enable hospitals to report these services as they report them today, and in a manner that does not create additional administrative burdens for hospital billing systems.

A third issue CMS will need to address if it moves to the full use of CPT codes for drug administration in 2007 is how providers should report the "initiation of prolonged infusion (more than 8 hours) for therapy or diagnosis requiring the use of a portable or implantable pump." For 2006, CMS released a new HCPCS Level II code (C8957) to report this service, but no equivalent CPT code currently exists. The Centers agree with CMS' decision to create this code,

as it allows providers to report prolonged non-chemotherapy infusions. If CMS moves forward with the full use of CPT codes for drug administration in 2007, we suggest that it continue to allow providers to report C8957. We do not believe this will be problematic in reporting to other payers, since there is no existing CPT code for this service.

Finally, if CMS does not move forward with the full use of CPT codes (choosing to retain a combination of HCPCS C-codes and CPT codes for reporting drug administration services), it must provide clear guidance on how hospitals should report hydration and a therapeutic infusion when provided during the same visit (but not concurrently). There is currently only one code (C8950) to report both services. An example of this situation is as follows: a patient presents to the hospital and receives an hour of medically necessary hydration, followed by an hour of an antibiotic infusion. Both infusions are separate and distinct and both are given for an hour, yet Medicare has only one code to report both services. Because CMS has always employed per-visit payment for drug administration services, this has not been an issue, as Medicare has to date only ever paid for the first hour of an infusion service. With per-service payment proposed for drug administration services in 2007, the Centers expect to receive payment for the actual services they provide. In the example above, the Centers would expect to receive two APC payments: one for the first hour of hydration, and one for the first hour of the antibiotic infusion.

CMS must clarify how it expects providers to report the above scenario. For example, CMS might allow two units of the first hour code (C8950) to be reported without any modifier and have the OCE generate two APC payments. Alternatively, CMS might require two separate line items of C8950, one with modifier –59. It should be noted that, in the physician office setting, this scenario currently results in two separate payments through the use of different codes for hydration and for therapeutic infusion. CMS should allow the same payment result in

the hospital setting even if it chooses to stay with a combination of CPT and HCPCS C-code reporting in 2007.

The Centers also urge CMS to review its policy of not allowing separate payment for multiple IV push injections of the same drug. Prior to 2006, providers reported IV push injections using CPT code 90784, which did not include any descriptor language limiting reporting based on whether the same drug or a new drug was pushed. Hospitals billed and received payment for each separately identifiable IV push reported, regardless of the drug. This is significant, as hospitals often push the same drug multiple times during a single patient visit and the facility resources, including nursing time, are no different whether the same drug or a different drug is provided to the patient. When hospitals administer an IV push injection of a packaged drug, providers lose reimbursement for both the IV push injection service and the drug, which we believe is grossly inappropriate. The Centers recommend that CMS revisit its policy on this issue and allow separate payment of multiple IV pushes regardless of whether the same or different drug is pushed.

C. Hospital Coding and Payment for Visits (E/M Services)

CMS is proposing to introduce 17 new HCPCS G-codes to report evaluation and management (E/M) clinic, emergency department, and dedicated emergency department (DED) visits.[10] Without accompanying national E/M coding guidelines, the Centers do not support the implementation of these new codes.

Although the proposed new G-codes map easily to existing CPT E/M codes, we believe it will cause administrative issues to implement new codes and new guidelines separately. The Centers and other providers already encounter situations in which non-Medicare payers refuse to accept G-codes. CMS should be aware that providers currently face numerous situations in

[10] 71 Fed Reg. at 49,611.

which reporting services with different code sets to different payers results in claim denials, especially by non-Medicare payers, and in some cases by Medicaid. For example, some payers question the reporting of CPT E/M codes because they believe we are double billing, despite the fact that CMS has explicitly stated that hospital reporting of E/M CPT codes covers facility overhead and/or resource consumption. We are concerned that implementing the new G-codes will result in other payers denying claims. Further, some of the Centers have experienced situations in which some payers do not recognize clinic visit revenue codes, such as 510, while other payers still do not recognize HCPCS G-codes, even though this is an approved HIPAA code set. Alternatively, some payers allow the G-codes into their system but often will not pay based on them. The problem is further exacerbated because payers are inconsistent about which G-codes they will accept -- a given payer may accept some G-codes, but not others. This makes it very difficult to manage the codes in the charge description master (CDM) and often requires manual changes/edits in our claims scrubber software, all leading to extra time and resources spent on simply getting a bill out the door.

In addition, we fear the creation of another situation in which providers are forced to report one set of codes to Medicare and another to non-Medicare payers, thus requiring the creation of back-end fixes to map G-codes to CPT codes in order to report the same services to other payers. Currently we face this situation with requirements to report drug administration services one way to Medicare and a different way to other payers. This dual coding and reporting situation necessitates enormous amounts of staff education, system updates and creation of edits, manual work, and complex back-end fixes. We would prefer to avoid another complicated, time-consuming, and resource-intensive situation like this when the benefits to CMS or hospitals for simply reporting new G-codes for E/M services without standard national

E/M coding guidelines are unclear.

The Centers, like other providers, have spent considerable amounts of time developing their own facility-specific guidelines and training staff on their use. We have updated our encounter forms and charge tickets to reflect codes and definitions currently in use. Implementing new codes without guidelines will force providers to invest additional time and effort to update staff, forms, and systems. In particular, for those providers currently using three levels of E/M codes with "new" and established" distinctions, the administrative burden to realign their current facility E/M criteria to five levels without the "new" and "established" patient distinction will be burdensome to say the least. It is not clear what the benefit of moving to new codes will be without the benefit of having a set of consistent national facility visit guidelines, because the coded data that CMS will receive will continue to be driven by each individual facility's specific guidelines based on their definition of levels and resource consumption. This means CMS will have new codes in its data set, but the data still will not allow CMS to make meaningful comparisons of resource consumption across hospitals.

Taken together with other payer issues, these changes will cause problems for the Centers and other providers. CMS should take these issues into consideration when it releases new codes, guidelines, and/or Medicare specific coding/billing instructions. The Centers urge CMS to delay implementing new E/M codes until national guidelines are available. Releasing new codes with accompanying national E/M coding/billing guidelines for hospital reporting will relieve the administrative burden of making updates twice. It will also simplify discussions with our other payers as we expect that they will accept new codes if they are accompanied by new guidelines for hospital reporting.

The Centers understand that, as a result of EMTALA, CMS may need to implement the

five new DED visit G-codes immediately to allow hospitals providing urgent care services in a non-ER setting to report their services accurately.[11] To accomplish this, CMS should consider giving hospitals a choice of reporting either the CPT E/M codes or the new G-codes. CMS can simply assign all of the codes to the appropriate APCs so that the OCE generates appropriate payment. This will allow CMS to begin collecting data (especially for the DED G-codes) without creating an administrative burden for providers. If this solution is adopted, providers with no payer issues and providers that operate DEDs may elect to implement some or all of the G-codes, while others, like the Centers, would continue to use the CPT E/M codes until national guidelines are released.

1. National Guidelines Development Process

The Centers are pleased to offer comments on several of the eight issue areas for which CMS requested input regarding development of national hospital visit coding guidelines.

a. Three Versus Five Levels of Codes

The Centers agree with CMS' proposal to have five levels of APC payment for clinic visits and emergency department visits.[12] If national guidelines are to be based on an updated version of the original American Hospital Association (AHA)/American Health Information Management Association (AHIMA) model,[13] then that model will need to be updated to reflect five levels of clinic and emergency department visits respectively, and CMS will also need to carefully consider how to value the facility resources expended in specialty clinics.

[11] 71 Fed. Reg. at 49,609.
[12] 71 Fed. Reg. at 49,611.
[13] The AHA and the AHIMA have formed an independent expert panel, the Hospital Evaluation and Management Coding Panel.

b. Lack of Clarity for Some Interventions

The Centers believe that, once national hospital visit coding guidelines are in place, hospital staff charged with assigning visit levels will understand how to interpret and apply the guidelines. Naturally, this will lead to improved documentation and result in appropriate visit level assignment. Additionally, if CMS can provide more specific examples on its concerns around documentation and visit level selection, the Centers may be able to better assist CMS in understanding some of the documentation issues that resulted from testing the AHA/AHIMA model.

c. Treatment of Separately Payable Services

The Centers agree with CMS that using separately payable interventions as a proxy for increased resource utilization may be useful to help providers select the most appropriate visit level, and should be incorporated into national visit guidelines.[14] Notably, the inclusion of separately payable services in the guidelines should not preclude providers from separately billing the actual procedures rendered. To that end, CMS must make clear to providers that reporting the visit code along with the procedures performed does not constitute "double reporting."

d. Concerns of Specialty Clinics

In our 2004 proposed OPPS rule comments, we generally supported the AHA/AHIMA model. Our biggest concern was – and still remains – how specialty versus non-specialty clinics will be able to differentiate the resources they expend, given that both may assign the same visit level and receive the same reimbursement for rendering very different types of care. We understand CMS' concern about whether a single set of national guidelines can be applicable across all clinic settings, and more specifically whether a single set of guidelines can be used to

[14] 71 Fed. Reg. at 49,616.

meet the needs of specialty clinics.[15] We have given this considerable thought over the years, and while it would certainly be easier to have a single set of national facility coding guidelines, we share CMS' concern as to whether guidelines can be created that have such broad applicability. To that end, we set out our concerns in more detail below.

Ultimately, if CMS elects to create a single set of national facility coding guidelines, it must factor in patient complexity resulting from the culmination of the interventions provided. Additionally, the staff time expended on patient care needs to be included – specifically, time spent on patient education and the counseling and coordination of care, as these two elements are crucial in understanding the resources expended by specialty clinics, including oncology compared to patients treated in non-specialty clinics.

The Centers continue to encourage CMS to review a patient-complexity model that is diagnosis-driven and therefore factors in both interventions and time. If factoring in diagnosis is not a viable option, then CMS must find a way to account for both the type of interventions performed and the interplay of staff resources and time – as neither component alone is adequate to accurately capture the facility resources expended and hence the appropriate selection of a facility visit level.

The Centers urge CMS to create guidelines and documentation requirements that allow services that add material costs, beyond room set-up and basic nursing, to be counted towards the selection of the visit level. For example, oncology clinics provide intensive support services including dietary planning and evaluation, psychological and spiritual counseling, pain management, discharge planning, and patient and family education on self-care. These services greatly enhance the efficacy of treatment and the patient's quality of life, and are essential to patients with severe illnesses. These services also increase the cost of an individual outpatient

[15] 71 Fed. Reg. at 49,617.

visit, and as such they should be reimbursed by CMS either through separate new HCPCS/CPT codes or through incorporation of these services into CMS' national guidelines.

The original AHA/AHIMA guidelines included services like "arrangements and/or social services intervention," "scheduling/coordination of ancillary services," and "patient acuity warranting simultaneous care by hospital staff (more than one-on-one)" as contributory factors. Such services increase facility resources expended, and should count towards the selection of a higher facility visit level. The Centers support the inclusion of these services and request that CMS clearly define them in the final guidelines.

The national guidelines should also reference all resources provided by "qualified hospital staff," rather than being limited to nursing staff. In specialty clinics, it is very common for multiple professional disciplines to be involved in planning and providing the best care for the beneficiary. Oncology clinics in particular expend significant resources to employ nurses specially trained and certified in oncology. These nurses are more difficult to recruit, and their salary requirements are typically higher than regular staff nurses. Oncology clinics also generally provide a higher level of ancillary support services, including dietary, palliative care, psychosocial therapy, etc. These services, which are necessary for cancer patients, typically result in longer patient visits and the use of more staff resources than for patients seen in a non-specialty clinic. Finally, much of the training provided to our nurses goes above and beyond what staff nurses receive due to the fact that oncology nurses see more complex patients. For example, our nurses are trained to provide what may be simple procedures when provided to normal patients, but become complex when administered to oncology patients. As an example, a blood draw is a simple procedure when performed on a non-cancer patient, yet it becomes more complex when provided to a cancer patient who may have bad veins due to his or her

chemotherapy/radiation therapy treatment. As a result, more time and care is required to complete this seemingly simple procedure for the oncology patient. Our nurses are trained and equipped to handle this and other similar situations, and are expected to maintain their proficiency. Nurses in oncology clinics are also required to successfully complete additional education that allows them to administer chemotherapy drugs. This education ensures that the staff administering chemotherapy drugs is knowledgeable about the drugs, their side effects, the correct administration techniques, and specific monitoring requirements. In addition to being certified in oncology, our nurses also obtain certification in wound care, GI procedures, and conscious sedation services as they relate to oncology patients.

The Centers' oncology clinics also have Ph.D level pharmacists on each infusion floor, providing some, if not all, of the following services: reviewing medication interactions/adverse reactions; monitoring the multiple medications our patients are typically prescribed; working with physicians on initiating orders, providing discharge counseling, reviewing labs and providing input to physicians on the results, and guiding the overall medication therapy required for the patient. These services, rendered by highly specialized staff, result in an increase in time and facility resources expended by oncology clinics as compared to non-specialty clinics.

In addition to having highly specialized staff, oncology clinics and perhaps other specialty clinics typically provide multi-disciplinary assessment, treatment, and care to their patients. The draft AHA/AHIMA guidelines seem to overlook this concept, yet we believe it is critical to include it in the national facility level guidelines CMS is developing.

A 2003 article published in Oncology Watch describes the importance of multidisciplinary care and specifically states:

...multidisciplinary care models can foster collaborative treatment planning and a more

> responsive, individualized approach to cancer care. According to Multidisciplinary Care Coordinators, a 2003 Oncology Roundtable Practice Brief, hospitals can organize service offerings by using care coordinators who schedule specialty consultations, refer patients to appropriate support services, and provide patient education, among other roles. Acting as the "glue" that holds multidisciplinary programs together, coordinators can ultimately help build volumes and increase patient satisfaction. ... At the heart of the coordinated care model is the multidisciplinary clinic, which brings clinicians—including medical, surgical, and radiation oncologists—together to discuss individual patient cases and develop comprehensive treatment plans. Multidisciplinary clinics are either physical clinics—in which specialists from several disciplines meet one to two times per week in a single location for patient visits—or virtual clinics—in which patients receive separate, but closely spaced specialty consults that are typically scheduled by a care coordinator. Although a physical clinic provides a forum for specialists to develop a consensus regarding treatment recommendations, a virtual clinic may just as effectively provide seamless patient care when the creation of a physical clinic is not feasible due to space, time, or other constraints.[16]

The Centers agree with the approach described by the Oncology Watch article, and we strive to provide multidisciplinary care to our oncology patients. A copy of the article is attached as Appendix 1. Below, the Centers offer additional background information on the type of care provided and resources expended in oncology clinics. We urge CMS to consider this information carefully, as it applies not only to cancer patients, but also to patients with other complex, chronic conditions who require specialized treatment. Following this discussion, we offer recommendations on how CMS can begin to address the needs of specialty clinics as they relate to the development of national facility visit level guidelines.

At the Centers, a team of specialists creates a multidisciplinary plan of care for the treatment of each patient's disease continuum. The team monitors and modifies this plan over time. This model is only possible because of the number and proximity of expert cancer clinicians at the Centers. In our institutions, the medical oncologist, pathologist, hematologist, radiologist, radiation oncologist, and surgical oncologist all work together intensely to develop

[16] See Oncology Watch, "From the Roundtable: Multidisciplinary Coordination Expedites Care, Builds Volumes" (Sept. 25, 2003).

treatment plans and provide care in a coordinated manner. This model, while costly on the front end, is more cost effective over the course of the disease than the typical community-based model. While the unique care provided by the Centers leads to increased facility costs for each individual outpatient visit, significant efficiencies can be achieved over the long term. In this regard, a recent review of long-term cost outcomes at a multidisciplinary melanoma clinic affiliated with a major cancer center found that third-party payers saved approximately $1,600 per patient in this setting, relative to care provided in the community. Savings were attributed to reduced numbers of laboratory tests and diagnostic radiology procedures, and fewer overall visits for patients treated in the multi-disciplinary clinic.[17] Involving multiple types of clinicians and devoting more time up front to accurate diagnosis and treatment planning helped to prevent wasteful and ineffective treatments.

This treatment methodology has several other advantages. First, the care received by the patient is collaborative. Each clinician provides his or her expertise in a given treatment modality to design a diagnosis and treatment plan that offers the best chance for survival. Multidisciplinary care is especially important to the patient when there is no clear consensus on the superior treatment. Moreover, because the Centers are so specialized, they often draw patients from a wide geographic area. Multidisciplinary care provided to a patient in one location on the same day is more effective and convenient for the patient than multiple trips to different locations (clinics). The use of different locations impedes collaboration between physicians, is inconvenient, and can delay the delivery of care. For these reasons, patient satisfaction is enhanced when care is multi-disciplinary.[18]

---

[17] See Donald J. Fader et al., "The multidisciplinary melanoma clinic: A cost outcomes analysis of specialty care," 38 J. Am. Acad. Dermatology 742-751 (1998).

[18] See Molly Gabel et al., "Multi-disciplinary Breast Cancer Clinics: Do They Work?", 79 Cancer 2380-2384 (1997).

Patients seeking second opinions are common among those receiving E/M clinic visits at the Centers. Many patients who are referred to the Centers have already had prior cancer treatment elsewhere. These patients often bring outside films and extensive medical records for review by our experts. They often have multiple medical and/or surgical problems relating to their advanced metastatic disease, or to the toxicities resulting from prior therapies. For previously treated patients, evaluations are extremely lengthy and complex, and result in higher costs compared to the average hospital.

In addition, providing quality care to elderly Medicare patients requires intense review of many factors that impact the choice of treatment plans. These factors include: co-morbidities that may make the patient more vulnerable to complications from chemotherapy; socio-economic circumstances that impact the risk of complications or noncompliance; the patient's level of functional dependence in daily living activities; recognition of frailty (a condition which dictates palliation of symptoms rather than attempted cure); an assessment of emotional and cognitive conditions; and an estimate of life expectancy.[19] For example, at one Cancer Center's Senior Adult Oncology Program, an extensive evaluation of new elderly patients (comprehensive geriatric assessment) is performed by clinic staff. In this assessment, a dietician reviews the patient's nutritional status; a social worker evaluates the patient's mental status and the availability of caregivers; and a nurse practitioner assesses the patient's performance of instrumental activities of daily living. In addition, a primary nurse discusses the patient's concerns and a pharmacist reviews the patient's current medications and checks for polypharmacy (concurrent use of several medications). This initial evaluation lasts approximately 2.5 hours and occurs prior to the medical E/M performed by the physicians.

[19] See Lodovico Balducci & Martine Extermann, "Management of Cancer in the Older Person: A Practical Approach," 5 Oncologist 224, 229-31 (2000).

Although these evaluations are costly to perform, they result in significant improvements in treatment. Among the first 200 patients evaluated, the clinic staff found that between 36-94% had significant co-morbidity (depending on the scale used), 19% had malnutrition, 22% had memory disorders, 41% had polypharmacy, 18% were dependent in at least one Activity of Daily Living, and 72% were dependent in at least one Instrumental Activity of Daily Living.[20] All of these conditions affect either prognosis or the choice of treatment plans and must be addressed.

As mentioned above in the Oncology Watch article, multidisciplinary care can occur in one physical location in terms of the different clinicians working together, or it can occur in multiple locations through virtual means. The end result is that the patient receives coordinated care. However, a critical issue is how and where the patient receives this care.

At the Centers, it is very common for our patients to be in a single clinic setting for the entire day, particularly if they are seeing multiple physicians. For example, our breast cancer patients typically occupy one exam/treatment room for six to eight hours where they are seen by: the surgeon for an initial consult; the medial oncologist to discuss a post-procedure plan of care; a plastic surgeon to discuss possible reconstruction issues and options; a physical therapist to address lymphedema issues and add their treatment to the plan of care; and other staff providing nutrition counseling, palliative care, and psychosocial counseling. In fact, it is not uncommon for cancer patients to suffer from depression: in one Center, more than 50% of cancer patients were found to suffer from depression. These patients benefit from the counseling services provided by the oncology clinic, yet this type of care is not appropriately factored into the OPPS payment system.

For the above scenario, we are currently only able to report a single E/M visit code since the patient is only seen in one clinic setting. This is the case even though the patient has had

[20] See id. at 233.

consults with multiple physicians. While each physician is able to bill for his/her time on the professional side, the facility is limited to one visit level despite the fact that enormous amounts of facility resources are expended to coordinate and provide high quality care to the patient. Interestingly enough, if the patient were to have his or her consults in three separate clinic settings across a hospital, then the hospital would be allowed to report separate visit levels with the appropriate modifier(s) and condition code(s) according to CMS' instructions. However, treating patients across multiple departments or on multiple floors is not convenient, safe, or comfortable for the patient. Therefore, at the Centers, we work diligently to coordinate the care our patients receive and do our best to send our clinicians to the patients, even though this does not benefit us from an APC reimbursement perspective. While we bring our clinicians to the patients, it is nearly impossible operationally to have them all present to discuss the patient's care at the same time, thus precluding us from reporting HCPCS G-code G0175, (scheduled interdisciplinary team conference (minimum of three exclusive of patient care nursing staff) with patient present) to try and address the nuances of more complex patients. In the April 2000 final rule, CMS stated the following:

> ...we note that the comment did prompt us to develop a code for billing those visits during which numerous physicians see a patient concurrently, for example, a surgeon, medical oncologist, and radiation oncologist for a cancer patient, to discuss treatment options and to ensure that the patient is fully informed. In this instance, each physician is addressing the patient's care from a unique perspective. If several physicians see a patient concurrently in the same clinic for the same reason, the hospital would bill for one clinic visit using an appropriate visit code even though each physician would bill individually for his or her professional services. We have established a code for hospitals to use in reporting a scheduled medical conference with the patient involving a combination of at least three health care professionals, at least one of whom is a physician. That code is G0175, Scheduled interdisciplinary team conference (minimum of three, exclusive of patient care nursing staff) with patient present.[21]

[21] 65 Fed. Reg. 18,434, 18,452 (April 7, 2000).

The Centers believe CMS tried to address the concept of multidisciplinary care provided by specialty clinics when it created HCPCS G0175, but the code's definition is restrictive and does not recognize the way care is regularly coordinated or provided to patients. Operationally, hospitals are simply unable to coordinate medical staff such that they are present at the same time to discuss the patient's plan of care, but rather that care is provided by multiple clinicians on the same day to the patient at separate times. The current definition of HCPCS G0175 essentially precludes it from ever being billed even though patients in specialty clinics, including oncology, typically see multiple clinical staff on the same date of service. CMS' own claims data from 2005 essentially reflects this, as there are only 1699 units of G0175 from 42 providers present in the claims database.

The Centers urge CMS to recognize that the location in which care is provided in the hospital is not as relevant to resource consumption as the time spent with the patient by the clinical staff and the interventions/services provided. As such, it should be irrelevant whether a patient sees three physicians in three separate clinics, or three physicians in a single clinic. However, the existing multidisciplinary team conference G-code cannot be billed in the latter situation. Notably, even if we were to schedule our patients differently in order to bill this code, the current reimbursement level is grossly inadequate to cover the facility resources expended when multidisciplinary care is provided to our oncology patients.

For these reasons, the Centers recommend that CMS revise the definition for HCPCS G0175 so that it truly reflects multidisciplinary care and assign it to a higher paying APC. The revised definition should include language related to the coordination and counseling of patient care by multiple physicians and ancillary staff. In addition to redefining the G-code, CMS should assign this revised code to a separate APC – essentially a sixth level of clinic visits

analogous to critical care, which is a sixth level of care in the emergency department. Critical care patients in the emergency department typically see multiple caregivers and have life-threatening conditions, thus increasing the facility resources required beyond even the highest emergency department level. Similarly, patients requiring multidisciplinary care in a specialty clinic - whether for cancer or other complex illnesses such as diabetes, AIDS or heart disease - also require more resources than even the highest clinic visit level currently captures. These patients may occupy an exam room for six to eight hours and see clinical staff throughout the day but, for their comfort and convenience, they are not moved from one clinic to another. While there may be minimal nurse involvement during some of these visits, the patient will see multiple physicians over the course of the single visit. At a minimum, the clinic or treatment room remains occupied and unavailable for other patients during that time, resulting in increased facility resources being consumed.

The Centers also request that CMS create two new HCPCS G-codes analogous to the following CPT codes available for physician use for prolonged care:

- CPT code 99354 - Prolonged physician service in the office or other outpatient setting requiring direct (face-to-face) patient contact beyond the usual service (e.g., prolonged care and treatment of an acute asthmatic patient in an outpatient setting); first hour (list separately in addition to code for office or other outpatient Evaluation and Management service).
- CPT code 99355 - Prolonged physician service in the office or other outpatient setting requiring direct (face-to-face) patient contact beyond the usual service (e.g., prolonged care and treatment of an acute asthmatic patient in an outpatient setting); each additional 30 minutes (list separately in addition to CPT code 99354).

Both of these are add-on codes and are used when the physician's face-to-face time with a patient goes 30 minutes or more beyond the typical care provided during the E/M visit. The Centers recommend the creation of two new G-codes analogous to the above physician CPT codes for use in hospital outpatient departments to report prolonged care provided by qualified hospital

personnel, as described above. This is one way that CMS can recognize the time and resources expended by specialty clinics. The table below shows how the CPT codes are currently billed in the physician office setting, and our proposal of how new G-codes could be reported by hospital outpatient departments.

Example of Reporting Prolonged S	CPT Codes	New G-codes
less than 30 minutes (less than 1/2 hour)	Not reported separately	Not reported separately
30-74 minutes (1/2 hr. - 1 hr. 14 minutes)	99354 X 1	Gaaaa X 1
75 - 104 minutes (1 hr. 15 minutes - 1 hr. 44 minutes)	99354 X 1 and 99355 X 1	Gaaaa X 1 and Gbbbb X 1
105 - 134 minutes (1 hr. 45 minutes - 2 hr. 14 minutes)	99354 X 1 and 99355 X 2	Gaaaa X 1 and Gbbbb X 2
135 - 164 minutes (2 hr. 15 minutes - 2 hr. 44 min)	99354 X 1 and 99355 X 3	Gaaaa X 1 and Gbbbb X 3
165 - 194 minutes (2 hr. 45 min - 3 hr. 14 min)	99354 X 1 and 99355 X 4	Gaaaa X 1 and Gbbbb X 4

The Centers are concerned that many of our complex, multidisciplinary visits which require both the time and involvement of multiple physician and non-physician staff will inappropriately be classified as low-level visits under the current AHA/AHIMA model unless CMS includes specific language either in the selection of the visit level or as contributory factors that count towards assigning a higher visit level. If it makes up greater than 50% of the visit duration, the counseling and coordination of patient care should result in the assignment of a higher visit level. This concept exists today for the physician office setting, but because national guidelines do not yet exist, it has not been applicable in the hospital setting. The 2006 CPT Manual states:

> When counseling and/or coordination of care dominates (more than 50%) the physician/patient and/or family encounter (face-to-face time in the office or other outpatient setting or floor/unit time in the hospital or nursing facility), then **time** may be considered the key or controlling factor to qualify for a particular level of E/M services. This includes time spent with parties who have assumed responsibility for the care of the patient or decision making whether or not they are family members (e.g., foster parents, person acting in locum parentis, legal guardian). The extent of counseling and/or coordination of care must be documented in the medical record.[22]

In addition to the above, discussion of polypharmacy issues, dietary planning and evaluation, psychological and spiritual counseling, pain management, discharge planning, palliative care, patient family education on self-care, and the provision of other ancillary-related services should also count towards the selection of an appropriate visit level because facility resources are expended when these important services are provided. It is critical that CMS release new facility level visit codes and guidelines that take into consideration the more resource-intensive services provided by highly specialized staff in specialty clinics treating complex patients. These patients require many hours of care, and utilize more resources than the average patient in a non-specialty clinic. It is very important that CMS' new national facility coding guidelines should recognize this, because it will enable the agency to pay appropriately for this important care and facilitate collection of accurate data.

e. Differentiation between New and Established Patients, and Between Standard Visits and Consultations

The Centers recognize that coding will be simplified if we are not required to differentiate between new and established patients. However we believe that the resources required to care for these types of patients is different. The fact that CMS did not find a difference between these patient types in its median cost data may be due to the fact that each hospital was required to create its own E/M guidelines. Therefore, real differences in cost

[22] American Medical Association, CPT 2006 Current Procedural Technology, at 7.

among these types of patients may simply be masked at present. CMS should bear this in mind as it reviews historical E/M data for the distribution of visits, charges, and costs. For the near future, the Centers believe it is important to maintain a distinction between new and established patients, and to build this distinction into the national E/M coding guidelines. Maintaining separate codes will allow CMS to collect data according to standardized national facility visit guidelines, which it can then review to see if true resource differences exist between new and established patients. If CMS elects to eliminate the distinction between new and established patients, at a minimum, it should allow a new patient visit to count as a contributory factor under the AHA/AHIMA facility level guidelines because this allows for a recognition of the higher resources involved with new patients.

D. Radiology Procedures

The Centers applaud CMS' position to not apply a payment reduction for multiple imaging procedures.[23] We agree that the economies of scale associated with imaging during the same session are already reflected in the cost reports and that further discounting is not warranted.

E. Packaged Services

The Centers appreciate that CMS is proposing to designate specific CPT codes as "special packaged codes," and to allow separate payment for them when billed on a date of service without any other OPPS payable service.[24] We understand that CMS is clarifying for future claim submission that, if a packaged service (status indicator "N") is the sole service performed at a visit, and there are no other separately identifiable services to justify a hospital visit code, the hospital should not bill a visit code in lieu of the packaged service, even though it

[23] 71 Fed. Reg. at 49,568.
[24] Id. at 49,535.

is the sole service rendered on a given date of service.

The Centers would like to point out that the commentary in the Proposed Rule is different from formal instructions released by CMS in the past where providers were specifically instructed, in the case of wound care for example, to report a low-level visit code when non-selective wound debriedment was the only service rendered. The Centers are concerned with CMS' discussion of this issue in the Proposed Rule, because packaged OPPS services are only packaged to other OPPS services, and not to fee schedule services such as lab or rehabilitation. Therefore, the Centers have a data concern with respect to this issue. We agree that it will be rare for a packaged service to be the sole service rendered to a patient, and hence billed on a claim. However, while providers should be able to report the claim to CMS when this does occur, the current Outpatient Code Editor (OCE) logic will not allow this, as such claims are returned to the provider. If CMS never receives these claims, it will be unable to make future determinations about changing the status of a packaged service to a "special packaged" code. The Centers believe it is important for hospitals to be able to submit all of their claims to CMS, even if they result in no separate OPPS payment, for two reasons. First, it is consistent with CMS' policy of documenting the actual services rendered to a Medicare beneficiary. Second, it will enable CMS to make special packaged code determinations in the future. Therefore, the Centers ask CMS to clarify whether claims with only packaged services billed on them (claims that are returned to the provider via the OCE) will be accessible in the claims database used for rate-setting. If not, the Centers request that CMS consider allowing providers to report a modifier in the instances when a packaged service is the sole service rendered to a patient in order to bypass OCE edit 27 so that the claim is available to CMS for future use.

F. New Technology APCs

For CY 2007, CMS is proposing to move PET imaging (CPT codes 78608, 78811, 78812 and 78813) out of New Technology APC 1513 to a clinically unique APC (308) based on having five years of claims data and median cost information for this technology.[25] Additionally, CMS is proposing to move PET/CT imaging (CPT codes 78814, 78815 and 78816) out of New Technology APC 1514 into the same new APC 308 on the basis that median cost information from 2005 claims suggests that PET/CT imaging is no more costly than PET imaging alone.[26] The Centers are concerned that CMS may not have examined the consistency of the data and may not have adequate cost information upon which to base the APC payment for PET/CT, resulting in a low payment rate that could impede beneficiary access to this developing technology. We support our concerns with the following observations:

First, there appears to be less than one full year of claims data on which to base the median cost information for PET/CT since the new PET/CT CPT codes were not introduced until January 2005. As CMS is well aware from its experience with OPPS to date, providers take some time after new codes are released to fully integrate the changes into their Charge Description Master, train staff, and make the necessary charge/price changes internally.

CMS indicated in the Proposed Rule that it based its claims analysis and median cost information on a subset of 362 providers who billed at least one PET and PET/CT code during calendar year 2005. Since the PET/CT codes were not implemented until 2005, the Centers are concerned that 2005 claims information is not an appropriate source from which to draw cost and payment information. It is likely that providers who were utilizing PET/CT did not change to the new PET/CT codes until early in 2005 and their claims may erroneously appear to have both

[25] 71 Fed. Reg. at 49,552.
[26] 71 Fed. Reg. at 49,553.

PET and PET/CT services, when in fact they only had PET/CT services. Additionally, less than one full year is entirely too short a period to evaluate new technologies, such as PET/CT, that are still developing.

Significantly, the new generation PET/CT scanners that are now coming to market are considerably different from the first generation machines. The first generation scanners combined PET technology with CT technology and enabled images to be fused together in a single session to enhance the information available to the radiologist. The newer generation machines involve a more fully integrated PET/CT technology that is much different than simply combining the PET and CT technologies. The capital component of this new technology, and the related maintenance agreements, are far more expensive than the first generation PET/CT technology. This new cost information is not present in the 2005 claims information.

Even if CMS does not accept the premise that PET/CT technology is still developing, there is a significant cost difference between a PET and PET/CT scan due to the initial capital investment and the higher cost maintenance agreement. The Centers' own cost comparisons show that the average initial investment for a PET/CT machine is nearly $600,000 higher than for a PET only machine. Additionally, information from one of the Centers indicates that the cost differential on a service agreement between the two machines amounts to $105,000 annually. It is difficult to understand how the claims information that CMS has collected does not support a higher PET/CT cost, unless there are flaws with the data collection and analysis process.

One possible explanation for the flaws in the median cost information is that, while new codes were implemented in 2005 to differentiate the billing for PET/CT vs. PET, there remain inconsistencies and anomalies in the way cost information is compiled via the Medicare cost

reports and, importantly, in the underlying ratio of cost-to-charge calculations. The Centers' own analysis shows that three Centers break out PET (and PET/CT) imaging on a separate cost report line, while the other Centers report PET (and PET/CT) as part of their diagnostic radiology departments. The effect of this is that the high-cost services (PET) are blended down to the average cost of a pool of both high-cost and low-cost imaging services. The lack of a standardized methodology for differentiating PET from other diagnostic imaging services is likely a contributing factor in inappropriately valuing the cost of this new technology. It is also likely that this same inability to differentiate costs on the cost report is leading to a blending of cost between PET and PET/CT services, resulting in the higher costs of PET/CT being undervalued.

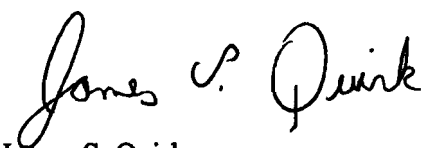
The Centers recognize that CMS assigns payment to a New Technology APC only when they do not have adequate claims data upon which to determine the median cost of performing a procedure and when they expect the services' clinical resources to differ from all other procedures already assigned to a clinical APC. The Centers are willing to accept the premise that CMS has collected five years of claims information for PET services and has a basis to assign payment to such services. However, the Centers strongly disagree with CMS' decision to move PET/CT codes out of its New Technology APC and into a separate clinical APC.

The Centers respectfully request that CMS maintain CPT codes 78814, 78815, and 78816 in New Technology APC 1514 until such time that the technology moves from a "developing" state to a stable technology and CMS is able to release clear guidelines about some of the cost-to-charge ratio issues raised in this comment. Alternatively, at a minimum, the Centers urge CMS to recognize the added capital and maintenance costs of PET/CT vs. PET alone so that beneficiaries are more likely to have access to this important clinical technology.

* * * * *

Thank you for your willingness to consider our views. We hope that CMS will address the concerns described above, and make the necessary adjustments to OPPS to ensure equitable reimbursement for state-of-the-art cancer care. If you have any questions or require additional information, please contact the Cancer Centers' technical consultant on OPPS matters, Ms. Jugna Shah, at (215) 888-6037.

Sincerely,



James S. Quirk
Executive Director
Alliance of Dedicated Cancer Centers