Submitter : Dr. Harvey Neiman

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Organization : American College of Radiology

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

Medicare Program: Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007; Proposed Rule

CMS-1321-P-535-Attach-1.PDF

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October 6, 2006 www.cms.hhs.gov/eRulemaking

Mark McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Service
Department of Health and Human Services
Attention: CMS-1321-P
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007; Proposed Rule

Dear Dr. McClellan:

The American College of Radiology (ACR), representing over 32,000 diagnostic radiologists, interventional radiologists, radiation oncologists, nuclear medicine physicians and medical physicists, is pleased to submit comments on the proposed notice "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007" published in the Federal Register on August 22, 2006. We will address the Deficit Reduction Act proposals; miscellaneous radiology supply and equipment issues; the global period for brachytherapy; independent diagnostic testing facility requirements; the reassignment rule; and the impact of the geographic practice cost index on physician practices in Puerto Rico.

Deficit Reduction Act Proposals

A. Multiple Procedure Reduction

The ACR appreciates the Centers for Medicaid and Medicare Services' (CMS) decision to not implement a 50 percent payment reduction for the technical component of multiple procedures performed on contiguous body areas in the same session for 2007. The ACR agrees that there are some efficiencies in clinical labor activity when certain combinations of multiple imaging procedures are performed in the same session. However, we do not agree that these efficiencies are uniform across all families and we do not believe the data support a 50 percent reduction. CMS proposes to exercise its discretion in the case of imaging services potentially affected by both the multiple imaging procedure reduction and the Outpatient Prospective Payment System (OPPS) cap by applying the multiple imaging procedure reduction **first** and then the OPPS cap. We compliment CMS for taking this step to minimize the negative consequences of these interrelated policies, and we support this approach, since it will somewhat abate what could have been an unintended compounding of payment reduction. However, in light of the DRA, the ACR believes that **any** technical component reduction for contiguous imaging is inappropriate and should be eliminated, since the Ambulatory Payment Classification (APC) payment rate already accounts for any cost-efficiencies incurred when contiguous body parts are examined.

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B. Reduction in TC for Imaging Services Under the Physician Fee Schedule (PFS) to Outpatient Department (OPD) Payment Amount

As required by the DRA, CMS proposes to cap Medicare payment amounts for certain imaging services at the amount paid to hospitals under the OPPS. ACR views this policy as ill-advised and inappropriate, and believes it will lead to inequitable payment amounts and compromise Medicare beneficiaries access to high quality imaging services. However, we recognize that CMS is simply attempting to implement a statutory requirement. Nevertheless, we believe that CMS should use its discretionary authority to the greatest extent possible to limit the potential disruption to patient access. This could be done by tightly circumscribing the list of affected services as noted below.

Definition of Diagnostic Imaging

In the Deficit Reduction Act of 2005, section 5102 (B) describes imaging as follows:

> "(B) Imaging Services Described. For purposes of subparagraph (A), imaging services described in this subparagraph are imaging and computer-assisted imaging services, including X-ray, ultrasound (including echocardiography), nuclear medicine (including positron emission tomography), magnetic resonance imaging, computed tomography, and fluoroscopy, but excluding diagnostic and screening mammography."

In the proposed rule, CMS defines imaging as services that provide visual information regarding areas of the body that are not normally visible, thereby assisting in the diagnosis or treatment of illness or injury. CMS considered the CPT® 7XXXX series codes for radiology services and added other CPT codes and alpha-numeric HCPCS codes that describe imaging services. The ACR believes that the list of procedures affected by the DRA should not include imaging guidance for interventional procedures. While supervision and interpretation codes for diagnostic angiography may meet the definition of an imaging procedure, the ACR believes that supervision and interpretation for endovascular procedures such as angioplasty, stent placement, and imaging guidance for biopsy, injections or drainage do not.

Recently, imaging guidance has been incorporated into new CPT codes for surgical procedures to include cryoablation of the prostate, endovascular stent placement in the carotid artery and bone ablation. These codes are not affected by the DRA and for consistency, when imaging guidance is used to facilitate a surgical procedure, those codes should not be defined as diagnostic imaging nor included on the list of codes subject to the DRA provisions.

Based on the definition above, the ACR believes that the DRA list needs to be further refined to exclude interventional radiology codes as we believe that the DRA was not intended to include imaging guidance that is integral to the performance of interventional treatment or diagnostic procedures.

Exclusion of Carrier-Priced Services

The ACR believes that a case can be made for excluding carrier-priced services, such as PET, from the list of services subject to the payment limitations required under section 5102 of the DRA. While the proposed rule argues that such carrier-priced services are "within the statutory definition of imaging services and are also within the statutory definition of PFS services," we believe there are other factors

that need to be taken into account in determining whether carrier-priced services should be subjected to the DRA-mandated payment limitations. To begin with, section 5102 of the DRA speaks of the technical component established under the physician fee schedule, and by definition, carrier-priced services do not have a technical component calculated in the usual manner or published in the *Federal Register*. Further, the DRA provision in question speaks specifically about the technical component prior to the application of the relevant geographic adjustment factor. Once again, it may not be possible to tease apart the various components of a carrier-priced payment amount for a service or to assure oneself that the portion of the fee in question has not been adjusted for geographic considerations by the carrier. By making these points, we do not wish in any way to imply that we believe that some imaging services somehow "deserve" to experience a payment limitation while others do not. We are simply urging CMS to exercise its discretion to limit the application of what the ACR considers to be an inappropriate payment policy, particularly when it involves procedures that do not have a specific technical component value published in the Federal Register.

Effects of Professional Liability Insurance (PLI) Payments as a Result of DRA

Since 1999, the ACR has been expressing concern to CMS that the malpractice relative values (MPRVUS) are inappropriately assigned between the professional component (PC) and technical component (TC). The ACR advocates that physicians incur the highest costs for malpractice insurance and are ultimately responsible when a study is in question in a malpractice case. Therefore, the ACR has taken the longstanding position that the MPRVUS assigned to the TC should more appropriately be placed in the PC and vice versa. Although CMS' methodology did not allow for this change in the past, it was felt that medical practices who bill globally would still benefit from the global malpractice values. Now that the Deficit Reduction Act will cause severe cuts in the technical component of many imaging codes, this will also significantly cut the total malpractice value paid and malpractice funding available in the Medicare Trust Fund.

The ACR requests that CMS consider implementing ACR's previous requests to simply reverse the malpractice rate paid in the TC and PC to more accurately reflect where the liability risks and costs exist.

Provisions

A. Practice Expense Review Committee

CMS proposes to accept Practice Expense Review Committee (PERC) recommendations for all new codes that went through the Relative Value Update Committee from September 2005 through April 2006. ACR welcomes this decision.

However, the ACR believes that the new CMS practice expense methodology has caused inappropriate reductions in payment for certain procedures. The ACR believes that as we review the causes for these reductions that further refinement of direct inputs may be appropriate and requests that CMS support a society's ability to take these codes back to the PERC for review if necessary to insure accurate inputs and equipment costs.

B. Low and High Osmolar Contrast Media

The ACR agrees with CMS's proposal to delete low osmolar and high osmolar contrast media from the practice expense database because they are separately reimbursed under the fee schedule.

C. Medical Supplies, Equipment, Imaging Rooms

The ACR appreciates CMS's proposal to accept and implement updates to the various imaging rooms, the pricing for certain radiology equipment as submitted, and the updated cost information for the vertebroplasty kit.

D. Supply for code 50384

The ACR agrees with CMS's proposal to delete a ureteral stent from the practice expenses for code 50384 (Removal (via snare/capture) of internally dwelling ureteral stent via percutaneous approach, including radiological supervision and interpretation). The ACR agrees that this supply item was submitted in error.

E. Table 2: Equipment Items Needing Specialty Input for Pricing and Proposed Deletions

The ACR supports CMS's efforts to keep pricing information updated in the practice expense database. The ACR appreciates CMS's decision to accept the cost information submitted on the film alternator.

Miscellaneous Coding Issues

A. Global Period for Remote Afterloading High Intensity Brachytherapy Global Procedures

High intensity brachytherapy codes 77781, 77782, 77783 and 77784 are currently assigned a 90 day global period. In the proposed rule, CMS proposes to assign a global period of XXX for these codes to permit separate payment each time the services are provided and allow payment to be based on the actual service provided. CMS states that it is difficult to assign a relative value for a "typical" patient based on a global period of 90 days due to increasing variability in treatment regimens. The ACR supports this proposal and recommends that CMS change the global period for codes 77781, 77782, 77783 and 77784 from a 90 day to XXX global period.

Independent Diagnostic Testing Facility (IDTF) Issues

The Office of Inspector General (OIG) found a potential $71 million in improper payments made to IDTFs and as a result, CMS proposes that each IDTF be required to meet 14 standards, which resemble those that currently apply to suppliers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS), in order to obtain or retain enrollment in the Medicare program. In addition to the following comments on the specific elements of this proposal, the ACR recommends that CMS consider a requirement for all non-facility diagnostic testing to comply with IDTF rules.

1. Operate in compliance with all applicable licensure and regulatory requirements;

   The ACR believes that this proposed standard is too broad. Specifically, which licensure and regulatory requirements would CMS require? Would they be state requirements or new federal requirements? Since there is no uniformity among current state requirements, the ACR recommends that CMS draft minimum federal requirements that all IDTFs must adhere to.

2. Provide complete and accurate information on its enrollment application;

   The ACR believes that this standard is very basic and should already be in place under the current IDTF and enrollment rules.

3. Maintain a physical facility (not a post office box or commercial mailbox);

   The ACR supports this standard as it will be useful, especially with regard to conducting inspections as suggested in proposed standard 14.

4. Have all applicable testing equipment available at the physical site, excluding portable equipment;

   The ACR has no comments as this standard seems to be a logical follow-up to the proposed standard 3.

5. Maintain a primary business phone under the name of the business;

   The ACR believes that this standard should already be in place under the current IDTF rule.

6. Have a comprehensive liability insurance policy of at least $300,000 or 20 percent of its average annual Medicare billings, whichever is greater, that covers both the place of business and all customers and employees;

   The ACR recommends that CMS explain how insurance for IDTFs advances the stated purpose of protecting beneficiaries and the Trust Fund. The ACR also recommends that CMS more precisely define the type of insurance an IDTF should carry, and boost the minimum threshold of comprehensive liability coverage to $1 million individual or $3 million in aggregate liability limit.

7. Agree not to directly solicit patients;

   The ACR agrees strongly with this proposed standard, although CMS must be very specific on what is the definition of "solicit". For instance, if an orthopedic surgeon has a long-time patient that may need an MRI on a particular visit and the surgeon offers an MRI at his facility, is that soliciting? Also, would this standard mean that an imaging-only facility could not advertise to the general public or work with physicians who do not have a financial interest in the facility to arrange a referral relationship?

8. Answer beneficiaries' questions and respond to their complaints;

This standard, as written, is fairly basic and subject to wide variation in compliance. The ACR would prefer a standard that requires an IDTF to have a written standard operating procedure for response to patient questions and complaints and a requirement to keep such questions and complaints on file.

9. Openly post these standards for review by patients and the public;

   The ACR supports this standard.

10. Disclose to the government any person having ownership, financial or control interest, or any other legal interest in the supplier;

    The ACR supports this standard.

11. Have its testing equipment calibrated per equipment instructions and in compliance with applicable national standards;

    The ACR supports this standard, but recommends that it be modified to state that equipment must be evaluated by a qualified medical physicist or other appropriate expert (depending upon the type of equipment being used by a given IDTF).

12. Have a technical staff on duty with the appropriate credentials to perform tests;

    The ACR supports this standard.

13. Have proper medical record storage and retrieval capabilities;

    The ACR supports this standard, but, considering the rapid evolution but sporadic prevalence of digital image storage capacity, would like to have significant input into what would constitute "proper medical record storage and retrieval capabilities."

14. Permit CMS or its agent/contractor to conduct unannounced on-site inspections.

    The ACR supports this standard.

Supervision

The ACR supports the proposal to limit the number of IDTF's a physician can supervise to no more than three sites.

Place of Service

CMS proposes to define the "point of the actual delivery of service" as the correct "Place of Service" for the claim form in the case of diagnostic testing performed outside the IDTF's physical location.

For reasons of patient safety, quality of examination, and potential environmental hazard, the ACR believes that there should be limited medically necessary reasons to perform radiological or other medical imaging procedures at a beneficiary's residence.

Reassignment Rule and Physician Self-Referral

The ACR shares the CMS concern "that allowing physician group practices or other suppliers to purchase or otherwise contract for the provision of diagnostic tests and then to realize a profit when billing Medicare may lead to patient and program abuse." We strongly support the intent of CMS to address this issue in the proposals it has made in this rule. Specifically, the ACR agrees completely with the language proposed by CMS to amend § 424.80 of its regulations. **The ACR also believes that "diagnostic tests in the Designated Health Services (DHS) category of radiology and certain other imaging services" should not be excepted from CMS's proposed reassignment changes.** Published evidence has shown that diagnostic test volume has increased dramatically in recent years, causing higher costs for federal and private payers.

The Medicare Payment Advisory Commission and the Blue Cross and Blue Shield Association reported in 2003 that diagnostic imaging was the fastest growing type of medical expenditure in the United States, with an annual growth rate of nine percent that more than doubles general medical procedures.[1] Blue Cross data in 2005 confirms that diagnostic imaging continues to accelerate in the United States.[2] More importantly, this development has resulted in medically unnecessary diagnostic tests being performed on patients.[3]

The ACR has advocated that Congress and CMS adopt quality standards to reverse this disturbing trend, ensure program integrity and safeguard against patient abuse. Consequently, we believe that the proposed reassignment changes could advance those critical objectives by influencing many physicians, medical groups and other entities to separately bill the technical and professional components of diagnostic studies. Although CMS focuses on suspect "pod lab" pathology arrangements that apparently involved potential fee-splitting and anti-kickback violations, the ACR maintains that those fraud and abuse concerns also apply in certain diagnostic test arrangements within the Designated Health Services (DHS)category of "radiology and certain other imaging services." For example, the ACR has learned of arrangements where the technical component (TC) for MRI procedures performed under a lease arrangement is billed to Medicare at a significant markup to the supplier's actual charge to the billing entity.

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[1] Hackbarth GM, Reischauer RD, Miller ME. Assessing payment adequacy and updating payments for physician services. *Medicare Payment Advisory Commission Report to Congress*, March 2003. BlueCross BlueShield Association, *Medical Technology as a Driver of Healthcare Costs: Diagnostic Imaging* (2003).

[2] Blue Cross and Blue Shield Association, *Medical Cost Reference Guide, Section 4, Projected Growth in Imaging Procedures, U.S. Market 1998-2008* (2006).

[3] Moskowitz H, Sunshine J, Grossman D, Adams L, Gelinas L. The effect of imaging guidelines on the number and quality of outpatient radiographic examinations. *AJR* 2000; 175:9-15. See also Litt AW, Ryan DR, Batista BA, et al., Relative Procedure Intensity with Self-Referral and Radiologist Referral: Extremity Radiography. *Radiology* 2005;235:142-147.

The ACR also strongly supports adoption of further amendments to § 424.80(d) that CMS is considering in regard to when a physician or medical group can bill for a reassigned professional component (PC) of a diagnostic test, and recommends that diagnostic tests in the DHS category of radiology and certain other imaging procedures not be excepted from those amendments. The amendments under consideration, if included in the final rule, would serve as a logical and supportive corollary to the proposed amendments regarding the TC.

The ACR is aware of arrangements in which the billing entity reportedly does not pay an independent contractor physician the full professional component fee, yet bills Medicare for the entire PC while retaining an amount that cannot be attributable to legitimate billing or other administrative expenses. **Therefore, the ACR firmly believes that an anti-markup provision should apply to the reassignment of the PC of diagnostic tests performed under a contractual arrangement.** In response to the request for comments on "how to determine the correct amount that should be billed to the Medicare program", the ACR suggests that CMS use the same language it has proposed for the TC anti-markup provision, i.e. "the amount billed to Medicare by the billing entity, less the applicable deductibles and coinsurance may not exceed the lowest of the following amounts:

- The physician or other supplier's net charge to the billing physician or medical group
- The billing physician's or medical group's actual charge
- The fee schedule amount for the service that would be allowed if the physician or other supplier billed directly."

The ACR also supports CMS's efforts to change the definition of "centralized building" in the regulations to address certain space ownership or leasing arrangements that seek to meet the "physician services" or "in-office ancillary services" exceptions. However, we are concerned that inclusion of a minimum 350 square feet in the definition of "centralized building" would not effectively curtail potential program or patient abuse that could occur through provision of diagnostic tests in the DHS category of radiology and certain other imaging services. **The ACR therefore suggests that CMS consider a larger and more appropriate minimum square footage in the definition of "centralized building" for those specific DHS.**

Alternatively, the ACR would more strongly recommend that CMS require that all "non-facility" provision of diagnostic tests in the DHS category of radiology and certain other imaging services be subject to the rules for Independent Diagnostic Testing Facilities (IDTF). The ACR agrees with the proposal that the "centralized building" permanently contain the necessary equipment. We also believe that the potential for "pod" type abuse for radiology and imaging services would be minimized by requiring the group practice using the "centralized building" under the physician services exception or the in-office ancillary services exception to employ, in that space, a nonphysician employee or independent contractor who will perform services exclusively for the group for at least 35 hours per week. CMS is considering such a policy (at least in the case of pod labs) and we believe that it is reasonable and should be applied more broadly.

Finally, the ACR also supports amending the regulation to allow the reassigning supplier to have unrestricted access to claims information submitted to Medicare by the billing entity, irrespective of whether the supplier is an employee or an independent contractor of the billing entity.

Geographic Practice Cost Indices (GPCI)

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Effective January 1, 2007, CMS is mandated to drop the current floor of 1.00 for the work GPCI. CMS seeks suggestions on alternative ways that CMS could administratively reconfigure payment localities that could be developed and proposed in future rulemaking. In this regard, the ACR remains concerned that the current GPCI for Puerto Rico is making it difficult for physician practices to retain professional and technical staff, who are being recruited away by physician offices from locales with much higher GPCIs, particularly in the State of Florida. We, therefore, urge CMS to examine more carefully the reasonableness of the data for Puerto Rico that are used in constructing the applicable GPCI and to consider alternative data sources or ways to configure payment localities that would address these concerns.

Conclusion

Thank you for the opportunity to comment on this proposed notice. The ACR encourages CMS to continue to work with physicians and their professional societies. The ACR looks forward to a continuing dialogue with CMS officials about these and other issues affecting radiology. If you have any questions or comments on this letter or any other issues with respect to radiology, please contact Angela Choe at 800-227-5463 ext. 4556 or via email at achoe@acr.org.

Respectfully Submitted,

Harvey L. Neiman, MD

Harvey L. Neiman, MD, FACR
Executive Director

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Submitter : Dr. Eric Zickgraf

Date: 10/06/2006

Organization : St. Catherine Hospital

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1321-P-536-Attach-1.PDF

Community Healthcare System

Community Foundation Of Northwest Indiana, Inc.

Community Hospital
St. Catherine Hospital
St. Mary Medical Center

October 6, 2006

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

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

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

New Technology APCs

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

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

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

CY 2002

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

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

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

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

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[1] Federal Register, November 30, 2001, page 59865.
[2] Federal Register, November 30, 2001, page 59866.
[3] CMS Program Memorandum A-02-026, 2002 Update of the Hospital Outpatient Prospective Payment System (OPPS), March 28, 2002.

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

CMS designated G0251 for treatment completed in stages, and priced the treatment using the payment for a single stage treatment (G0173), dividing the payment by 5, and allowing up to five payments. Under the payment methodology, each staged treatment was set at the national rate of $1,125, which did not reflect the consistent use and cost of resources for each treatment.[4] As a result of this initial payment rate calculation methodology, CyberKnife centers continued to be underpaid for treatments 2-5.

CY 2003

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

CY 2004

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

CY 2005

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

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

CY 2006

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

Proposed CY 2007 APC Changes

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

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

It is our understanding from the CyberKnife Coalition that CMS is required to have a minimum of two years of claims data before moving a HCPCS code from a new technology to a clinical APC. Like the Coalition, we also believe that CMS does not have meaningful two-year data upon which to base the proposed changes to the APC placement of G0339 and G0340. We support the CyberKnife Coalition's assertions that:

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

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

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

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

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

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

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

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

Historical Precedent – Gamma Knife New Technology Codes

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

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

CY 2004 and CY 2005 Data Variability Summary

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

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

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

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

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

It was our hope to have received the Coalition's analysis of the CY 2005 Identifiable Data Set Hospital OPPS file, which was to be released at the beginning of September. It was, however, recalled by CMS. We regret that the comment period was not adjusted to allow interested parties to review this important data in the preparation of their comments. As we have indicated,

however, we expect the same problems will be evident in the CY 2005 Identifiable Data Set Hospital OPPS file and we urge CMS to review the 2005 data with our comments in mind.

Conclusion

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

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

Recommendations

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

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

Sincerely,

Eric Zickgraf, PhD, FACR
Director, Medical Physics
Community Healthcare System
901 MacArthur Blvd., Munster, IN
219.836.6390 / ezickgraf@comhs.org

Submitter : Dr. edward setser **Date:** 10/06/2006

Organization : Dr. edward setser

Category : Physician

Issue Areas/Comments

Background

Background

revisions as proposed will negatively impact provision/access to health care. reduction in reimbursement rates ultimately limit the number of qualified, well trained physicians willing to offer the service and subsequently access to the service.

GENERAL

GENERAL

with regard proposed changes in physician fee schedule for CPT 36478 and CPT 36479.

RVUs have consistently been reduced from 2005 levels. practice expense, initial acquisition costs, disposable costs continue to rise. the service rendered is unchanged. how do you justify your proposal? I would very much like to discuss this with a member of your committee; preferably one who has consistently absorbed a yearly reduction in income, in the face of rising personal/practice
costs, and increasing workload. Though you remain largely anonymous, your committee is largely responsible for the rationing of health care in the US, and the degradation of qualified applicants in many surgical subspecialities - please refer to results of recent residency match program in cardiac surgery. If your aim is to force physicians offering these services to not participate in Medicare programs, and limit procedures therefore to those with private insurance/adequate resources, then you are on the right track. when do you stop, and when will you apply your formulas to the drug/device companies.

Impact

Impact

see below

Provisions of the Proposed Rule

Provisions of the Proposed Rule

see below

Submitter : Mrs. Rose M. Garcia

Date: 10/06/2006

Organization : Community Healthcare System

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-538-Attach-1.PDF

Submitter : Wendy Wifler **Date:** 10/06/2006

Organization : CyberKnife Coalition

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See attached document

We appreciate the opportunity to submit comments on 42 CFR Parts 405, 410, 411, 414, 415, and 424 [CMS-1321-P] RIN 0938-AO24 Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B.

CMS-1321-P-539-Attach-1.PDF

CYBERKNIFE
CKC
COALITION

October 4, 2006

Reference file code: CMS-1321-P

Submitted electronically via Word document attachment
http://www.cms.hhs.gov./eRulemaking

We appreciate the opportunity to submit comments on 42 CFR Parts 405, 410, 411, 414, 415, and 424 [CMS-1321-P] RIN 0938-AO24 Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B.

Image-guided robotic stereotactic radiosurgery (r-SRS) is both an alternative to surgery and an adjunct to radiotherapy involving a defined set of clinical resources to deliver effective treatment. Image-guided robotic stereotactic radiosurgery is not radiotherapy, as it is intended to ablate identifiable lesions, while preserving normal tissue adjacent to the target volume, rather than treat microscopic disease. The CyberKnife® is a complex image-guided robotic stereotactic radiosurgery system (r-SRS), delivering radiosurgical precision throughout the body, for as many treatments (fractions) as the clinician deems necessary for a given situation. CMS currently allows for up to five fractionated image-guided robotic stereotactic radiosurgery treatments and our data indicate that treatments average 3 fractions per course of treatment. Clinicians and patients have recognized the benefits of radiosurgery, which include no incisions, no anesthesia, lower risk of complications, and, therefore, improved patient quality of life.

Image-guided robotic stereotactic radiosurgery is substantially more resource-intensive than other forms of linac-based systems. It was for this reason that CMS created separate HCPCS codes to distinguish these technologies. Further, it is clear that the resources required for image-guided robotic stereotactic radiosurgery treatment are the same regardless of whether the treatment is performed in the first or a subsequent session.

Image-guided robotic stereotactic radiosurgery is a capital intensive technology, and, due to the relatively small number of patients for whom it is clinically appropriate (as compared with, for example, conventional external beam technology), it is not necessarily cost-efficient for a single hospital to provide these services by itself. Robotic stereotactic radiosurgery facilities that are associated with a particular hospital are typically available for use only by physicians on staff at that hospital, thus restricting their ability to serve the larger community and limiting access. Allowing carriers to pay for the technology when provided in freestanding centers would facilitate cost sharing

among a number of hospitals (and others) to provide these services, improving device access to a more diverse population of patients in a given geographic region.

Comment:

A number of temporary codes have been established to enable hospitals to report the technical component costs of image-guided robotic stereotactic radiosurgery (r-SRS) treatment (HCPCS Codes G0339 and G0340). The proposed Rule regarding the Physician Fee Schedule for 2007 designates codes G0339 and G0340 as "C – Carriers price the code."

This is consistent with the technical component radiation oncology services of all kinds that are reimbursed under the Physician Fee Schedule, and have been since the inception of the Physician Fee Schedule methodology.

Recommendation:

The CyberKnife Coalition respectfully recommends and encourages CMS to:

- *Adopt the proposed change to include HCPCS Level II codes G0339 and G0340 on the CY 2007 PFS, classifying the codes with the modifier "C" to indicate that they may be carrier priced.*

We support this modification that would clearly establish carrier authority to cover image-guided robotic stereotactic radiosurgery in freestanding settings, subject to their establishment of appropriate quality assurance measures to ensure patient safety and regulatory compliance, to the satisfaction of the carrier.

We appreciate your consideration of our comment.

Sincerely,

Linda F. Winger, MSc, FACHE
Vice President
Georgetown University Hospital
3800 Reservoir Rd., NW
Washington, DC 20007
Linda.F.Winger@MedStar.net
202-444-8054

Submitter : **Dr. Saundra Spruiell** **Date: 10/06/2006**

Organization : **Oklahoma Vein Specialists**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-540-Attach-1.TXT

Impact

Making these revisions as proposed will impact negatively on the Medicare populations' access to quality health care. The reduction in reimbursement rates will ultimately limit access to physicians who perform these treatments.

Provisions of the Proposed Rule

See General Comment below.

Background

See General Comment Below

General Comment

CMS-1321-P
Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and other Changes to Payment Under Part B
Proposal dated August 8, 2006

I am responding to the CMS proposal of 8/8/06 regarding the proposed changes in the physician fee schedule for CPT 36478 and CPT 36479 Endovenous Laser Ablation.

I have reviewed the proposed 2007 fully implemented, non-facility practice expense (PE) RVUs for CPT codes 36478 and 36479 and find several issues of great concern:

1. RVUs have consistently been reduced from 2005 levels:
    a. 2006: 46.91
    b. 2007: 43.53
    c. 2008: 40.84

    While practice expenses consistently rise, (salaries, utilities, etc.) it has become increasingly difficult to provide these necessary services. In order to comply with CMS guidelines, the ultrasound component of the procedure requires that the physician employee a Registered Vascular Technologist (RVT) to provide imaging services. These highly skilled technologists are in drastic shortage and therefore are in high demand and as such command extremely high salaries in excess of $70,000 per year plus benefits. Given the limited number of these procedures that the average physician performs per year it is impossible to comply with CMS guidelines if the RVUs and subsequent reimbursements continue to drop!

    As you know, the 2007 Medicare Physician Fee Schedule is already scheduled for a 5.1% across the board cut in reimbursement. Additionally, there are proposed cuts for non-invasive vascular imaging (vascular ultrasound). All these cuts will cripple the ability of physicians to perform this extremely important procedure and ultimately result in a loss of access to care for Medicare beneficiaries.

2. The proposed conversion factor (CF) for 2007 has been reduced from 2006, thus further decreasing reimbursement for endovenous laser treatment.

3. Values for codes 36475 and 36476, radiofrequency vein ablation have been consistently higher that those for laser ablation:
    a. 2006: 51.5
    b. 2007: 47.77

c. 2008: 44.52

Each of these technologies are comparable especially when we look at both the initial capital acquisition cost ($37,900 for laser and $25,000 for RF) and the, per patient supply costs ($360 for laser and $750 for radiofrequency for the procedure kits PLUS disposable sterile supplies such as drapes, gowns, Anesthetic solution, IV bags and tubing to name just a few). While the per patient supply cost may be slightly higher for 36475 (radiofrequency ablation), the significantly higher acquisition cost for 36478 (laser ablation) raises the overall physician's cost of delivering the service to the same level (possibly even higher).

I would request that the fully implemented, non-facility practice expense RVU remain at the 2006 rate for 36475 of 51.5 and that the RVU for 36478 be increased to this same level.

I would be happy to discuss this further with members of your committee.

Respectfully submitted,

Saundra S. Spruiell, D. O.
Oklahoma City, OK
sspruiell@ocaheart.com

Submitter : **Dr. Jim Melton** **Date: 10/06/2006**

Organization : **Oklahoma Cardiovascular Associates**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-541-Attach-1.RTF

Impact

Making these revisions as proposed will impact negatively on the Medicare populations' access to quality health care. The reduction in reimbursement rates will ultimately limit access to physicians who perform these treatments.

Provisions of the Proposed Rule

See General Comment below.

Background

See General Comment Below

General Comment

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Respectfully submitted,

Jim G. Melton, D. O.
Oklahoma City, OK
jmelton@ocaheart.com

Submitter : Tammy Chambers **Date:** 10/06/2006

Organization : The Center for Cancer and Blood Disorders

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

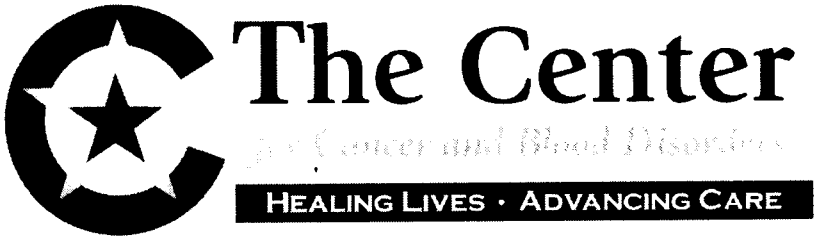
GENERAL

"See Attachment"

CMS-1321-P-542-Attach-1.DOC

CMS-1321-P-542-Attach-2.DOC

542 #1



October 6, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Reference File Code: CMS-1321-P

Submitted electronically via Word document attachment
http://www.cms.hhs.gov./eRulemaking

We appreciate the opportunity to submit comments on 42 CFR Parts 405, 410, 411, 414, 415, and 424 [CMS-1321-P] RIN 0938-AO24 Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B.

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Recommendation:

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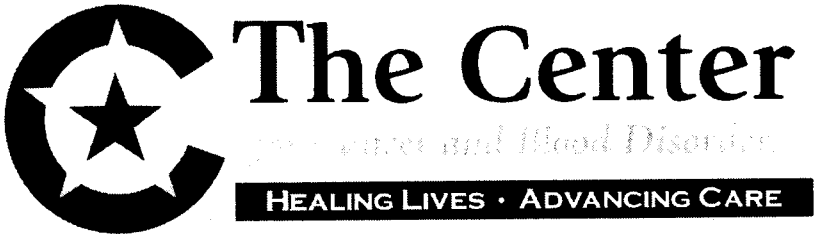
We appreciate your consideration of our comment.

Sincerely,

Tammy Chambers
Director of Contracting
The Center for Cancer and Blood Disorders

542 #2



October 6, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
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Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Reference File Code: CMS-1321-P

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Sincerely,

Tammy Chambers
Director of Contracting
The Center for Cancer and Blood Disorders