Submitter : **Mr. Stanford Miller** **Date: 10/10/2006**

Organization : **Neuronetics, Inc**

Category : **Device Industry**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1321-P-718-Attach-1.DOC

#718

NEURONETICS

October 9, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P
P.O. Box 8015
Baltimore, MD 21244-8015

VIA ELECTRONIC DELIVERY

RE: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for CY 2007 and Other Changes to Payment Under Part B; Proposed Rule; CMS-1321-P

To Whom It May Concern:

Neuronetics, Inc. (Neuronetics) is pleased to respond to the proposed rule and request for comments published by CMS in the August 22, 2006 Federal Register.

Neuronetics is the manufacturer of a transcranial magnetic stimulation (TMS) system that is currently under review by the FDA for the treatment of major depression. In response to Neuronetics' application and with the support of the American Psychiatric Association and the American Neurological Association, the AMA released (January 2006) and implemented (July 2006) two new category III CPT codes for TMS:

- 0160T Therapeutic repetitive transcranial magnetic stimulation treatment planning
- 0161T Therapeutic repetitive transcranial magnetic stimulation treatment delivery and management, per session

In addition, the AMA deleted a category III CPT code which is now obsolete (0018T).

	CPT/HCPCS	Status	Description
ADDED CODES	0160T	C	Transcranial mag stim planning
	0161T	C	Transcranial mag stim delivery
DELETED CODE	0018T	C	Transcranial magnetic stimulation

Neuronetics agrees with CMS that the status indicator of "C" (carriers price the code) is appropriate at this time.

One Great Valley Parkway, Suite 2 / Malvern, PA 19355 / t 610-640-4202 / f 610-640-4206 / www.neuronetics.com

In addition, Neuronetics looks forward to the deletion of 0018T, which will ensure appropriate coding for this important procedure.

Additional Background Information

Neuronetics has developed the NeuroStar TMS Therapy™ system for the treatment of major depression. The NeuroStar is not FDA cleared and is not being used in clinical practice outside of research protocols. Importantly, there are no TMS devices that are FDA cleared at this time for any therapeutic indication. Therapeutic use is the intended use described by 0160T and 0161T. Neuronetics expects the NeuroStar to be cleared for use by the FDA in January 2007 and Neuronetics plans to launch the NeuroStar in the first quarter of 2007.

TMS is a non-invasive technique for stimulating cortical neurons resulting in reduction of depressive symptoms in a difficult-to-treat population. The NeuroStar TMS Therapy system consists of both capital equipment and single use devices (one device needed per treatment). TMS therapy will typically be outpatient and consist of daily treatments over a number of weeks. TMS may be used as maintenance therapy as well. Psychiatrists will administer TMS Therapy, and a typical treatment session lasts roughly 45 minutes. TMS represents a unique technology with unique applications, requiring specific equipment and a specialized operator skill set.

A more detailed overview of the NeuroStar is included as Appendix A. An overview of a TMS Therapy procedure described by these new codes is included as Appendix B.

* * * *

Thank you for the opportunity to comment on the CY 2007 proposed rule. We are happy to provide additional information upon request. If you have any questions regarding these comments, please do not hesitate to contact me at 610-640-4202, ext 1002 or 770-420-8225. My email is smiller@neuronetics.com.

Sincerely,
Neuronetics, Inc.

Stanford W. Miller
Vice President, Health Policy and Access

Attachments:

Appendix A	NeuroStar TMS Therapy™ System Product Profile
Appendix B	Clinical Vignettes for Transcranial Magnetic Stimulation (TMS) for the Treatment of Major Depression (CPT 0160T and 0161T)

Appendix A

NeuroStar TMS Therapy™ System Product Profile

The NeuroStar TMS Therapy system consists of a treatment chair with a coil alignment system and a mobile stimulator console. The components of the mobile stimulator console can be seen in Figure 1 below. The stimulator is operated by the physician via the touch panel display were patient data is entered, information determined in the procedure described by 0160T are stored for future recall and use, and the treatment sessions described in 0161T are programmed and subsequently controlled.

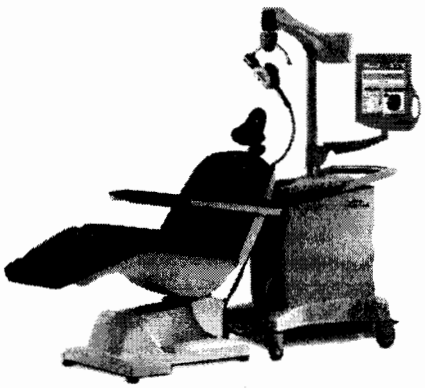

Figure 1: NeuroStar TMS Therapy System

Figure 2: Physician Installing SenStar Treatment Link

TMS Therapy is performed on major depression patients in the position shown in Figure 1 above. Note the coil is placed over the left prefrontal cortex while the patient remains awake and alert for the treatment. The system is capable of producing very significant magnetic field strength in very brief 200 microsecond pulses. These pulses are of the intensity sufficient to excite the surface of the cortex inducing neuronal firing and subsequent neurotransmitter release. System operation requires the use of a single use device called the SenStar treatment link for each treatment session. It fits between the treatment coil and the patient providing an integral link. It performs several important functions to facilitate safe and effective treatments. The functions include:

- Contact sensing to ensure good patient contact throughout the treatment course, maximizing potential efficacy
- Magnetic field strength output monitoring to facilitate safe and effective treatments
- Partial surface E-field cancellation to facilitate high patient adherence to protocol
- Serves as a hygiene barrier from patient to patient

The SenStar™ treatment link fits on the outer surface of the coil for easy replacement. (Figure 2 above)

Appendix B

Clinical Vignettes for Transcranial Magnetic Stimulation (TMS) for the Treatment of Major Depression (CPT 0160T and 0161T)

TYPICAL PATIENT

The patient is a 34-year-old female who presents with a clinical diagnosis consistent with DSM-IV defined Major Depressive Disorder. Her symptoms include severely depressed mood on a daily basis, diminished interest and enjoyment of usual activities, decreased sexual interest, initial insomnia and disrupted sleep patterns, guilt feelings, somatic distress including gastrointestinal complaints and diffuse musculoskeletal pain, intermittent suicidal ideation, anxiety, and diminished ability to concentrate leading to impairment in work and routine household responsibilities. She has failed to receive benefit from an adequate trial of antidepressant pharmacotherapy, and her treating physician has now included the possible use of electroconvulsive therapy as an appropriate treatment option. She has no unstable medical conditions, and has no contraindications to TMS Therapy. A patient similar to the one described here, but in whom medication therapy is either contraindicated, or where the patient is intolerant of such medications, is also a good candidate for TMS Therapy.

- **0160T Therapeutic repetitive transcranial magnetic stimulation treatment planning**

Dose determination and targeting are performed at the initial assessment and at clinically appropriate points periodically during a course of TMS Therapy. With each dose determination and targeting session a comprehensive medical appraisal is made to determine any relevant medical history that may be expected to influence the patient's risk profile with regard to the use of TMS, or to have led to an alteration in the patient's previously determined dose level.

The patient is seated comfortably in the treatment chair and the physician applies a headset to the patient which will assist in locating both the site over the primary motor cortex where the motor threshold (MT) will be determined and the location over the prefrontal cortex where the magnetic stimulation will be delivered. Next, the patient is provided with ear plugs and their head is placed in the headrest and the headset is adjusted for patient head size and comfort. Prior to placement of the electromagnetic coil on the patient's head, a component is attached to the face of the coil which assists the physician in measuring coil proximity to the scalp, improves the comfort during the procedure and provides system confirmation of the appropriate output magnetic field strength. Patient specific information that has been entered in the TMS Therapy system in advance of the treatment session is verified with the patient and the electromagnetic coil is then placed on the patient's head over the motor strip area above the ear on the same hemisphere as where the treatment stimulation will be delivered. For determination of the motor threshold (MT), the TMS system is set to a pulse rate of less than 1 Hz. Operationally, the MT value is defined as the lowest level of system output power which produces a visible movement in the contra-lateral thumb or next most proximate digit, as observed by the evaluating physician. The physician moves the coil across the surface of the scalp overlaying the area of motor cortex in a systematic grid pattern, to identify the optimal MT location, adjusting the stimulator output in a gradual fashion until the optimal location on the motor strip that controls the movement of the thumb or finger is found. This location is marked on the headset for future use since the same headset is ordinarily used throughout a course of therapy. The stimulator output power is now titrated to determine the exact output power that is sufficient to induce a motor response, but in no excess. This process is repeated in a standardized manner four

times with the final value computed by the system by finding the 50% probability power level of the known probability distribution that best fits the physician's observations of the thumb movement. The output power level determined by this process is called the MT value. This value is saved in the TMS Therapy system and rechecked periodically throughout a course of therapy on subsequent treatment days as needed based on the medical determination of the treating physician. The physician then measures 5cm anterior on an oblique saggital arc ending up over the prefrontal cortex which will be the site of therapeutic stimulation. This position is also marked on the headset to future use. The coil is positioned on the patient's head by combining this location information with proximity sensor feedback to determine the coil resting position. The coil is then fixed to remain in good contact with the patient's head for the duration of treatment. This process typically takes up to one hour for the first MT determination, and may take 30 to 45 minutes on repeat determinations. After MT is determined, the treatment is now ready to begin.

- **0161T** **Therapeutic repetitive transcranial magnetic stimulation treatment delivery and management, per session**

Once the headset is in place on the patients head, the MT value is determined and the coil is in the treatment position, then the treatment can begin. The prescribed treatment parameters are selected by the physician and stored in the system. A typical treatment will consist of 10 Hz stimulation at an intensity of 120% of the MT value. At this frequency and intensity, the stimulation is typically delivered in 4 second bursts beginning 30 seconds apart. A total of 75, 4 second bursts are delivered to the patient to total 3000 stimulations per treatment session. A typical treatment session takes about 45 minutes. During the treatment session, the patient must be closely monitored at all times to ensure good coil to head contact. If this is lost due to patient motion or other factors, the system provides an alarm to the physician, and the coil must be repositioned before continuing treatment to facilitate the most robust outcomes possible. The user must monitor the system continually and respond to these and any other alarm conditions indicated by the system. In addition, the physician must monitor the patient's clinical status for comfort and tolerability and, if necessary adjust coil position and potentially, customize the stimulation parameters to mitigate discomfort. Finally, although the risk is extremely low (<1%), patients must also be monitored for any signs or symptoms that may indicate the emergence of an ictal event, and the physician must be ready to respond if necessary.

This procedure is repeated daily, Monday through Friday for an average duration of 4 to 6 weeks, followed by a taper phase of 3 days/week for one week, then 2 days/week for one week and finally 1 day for the last week. This schedule constitutes a typical complete course of therapy which may vary up to 30 days depending on patient response.

Periodic review of a patient's clinical status should be performed during a course of TMS Therapy, to determine whether adjustment of the treatment parameters is required. This assessment should include an evaluation of the tolerability of the procedure itself and the clinical management of the more common adverse events, such as headache or pain, or more complex medical phenomena, such as pre-ictal signs and symptoms. Clinical evaluation to determine the medical significance of these observations should include a detailed discussion of the types of events experienced by the patient, and the temporal course of these events, and whether they abate between treatment sessions. The patient's clinical history should also be periodically reviewed to assess the presence of other events or routine health habits, including but not limited to changes in medications, caffeine or nicotine intake, or sleep; that may be expected to alter the patient's motor threshold (MT), requiring that a new motor threshold (MT) value be determined. This

management session typically takes approximately 15 minutes to 30 minutes for a typical patient and is performed periodically throughout a course of treatment.

PROCEDURE NOTE

The two codes which make up the components of a course of TMS Therapy are mutually exclusive. Treatment planning (0160T) must always be completed prior to the initial treatment delivery session (0161T). Treatment planning with new MT determination will be performed periodically throughout a course of treatment, dependent on a patient's clinical response, tolerability of the procedures, and general medical judgment of the treating physician. Treatment delivery will be performed as prescribed by the treating physician over a number of days, typically organized into sequential and continuous five day blocks of treatment. The treatment management portion of 0161T may be performed less frequently (for the typical patient) than the treatment delivery portion of 0161T. Both portions of 0161T may be performed on the same day. When 0160T and 0161T are performed on the same day, they are mutually exclusive procedures with no overlap in resource use or provider time requirements.

Submitter : **Dr. Jeffery Ward** **Date: 10/10/2006**

Organization : **Puget Sound Cancer Centers**

Category : **Physician**

Issue Areas/Comments

Provisions of the Proposed Rule

Provisions of the Proposed Rule

I would like to comment on the proposed changes to ASP calculations for Part B medications. In particular I would like to comment on the comments regards bundled contracts of Part B drugs. To my understanding this proposed rule is a response to Ortho Biotech objections to the decision of Amgen to bundle its products Aranesp, Neulasta, and Neupogen in contracts that provide discounts and rebates based on portfolio utilization. If I assess correctly the assertion is that the bundling results in a inappropriate financial incentives to provide Amgen products exclusively, and that furthermore this constrains beneficiary access to high quality care and appropriate care by incentivizing the use of Amgen's Aranesp product over Ortho Biotech's Procrit.

I disagree with this assertion. I have practiced Oncology long enough to remember when the only drug available was Procrit. The advent of Aranesp has been a great boon to my patients. First it has supplied an aspect of competition that allows them to pay lower copays. Ortho Biotech had a monopoly for a long time. There were no drug discounts or rebates. If not for Aranesp, the ASP on Procrit would be much higher than it is now. Second, Aranesp is, simply put, a better drug. It is every bit as effective in stimulating erythopoiesis, yet provides a versatility of administration regimens and ease of administration that is not available with Procrit. The convenience of dosing it less frequently and adapting it to the patients chemotherapy regimen is a quality of life issue for patients that cannot be overestimated. I do not need a bundled contract to use Aranesp for the bulk of my patients.

That being said, it should be understood that I am under no compulsion to use Aranesp by either my contract or my clinic. I can and do use Procrit when circumstances favor it. I believe that the two drugs, in fact, are somewhat analagous to the use of neulasta and neupogen. Though in most circumstances, Neulasta, the longer acting drug, is preferable to the clinical circumstances and maximizes quality of life, there are times when a shorter acting drug, such as Neupogen, is invaluable. Conversely, no one contractually or otherwise restricts my ability to provide Neupogen or Neulasta to my patients if I fail to use Aranesp.

In fact, closed formularies that restrict the use of medications for Medicare patients, are almost exclusively a byproduct of DRG's and inpatient drug use. That is where potential for abuse of bundled contracts is greatest given that contracts include a much larger spectrum of medications, both oral and parenteral. It would seem that to target bundling only in Medicare Part B covered drugs, and not similarly target bundling in part A, where I presume Ortho Biotech is a much bigger player than Amgen, is to selectively punish Amgen for developing a portfolio of medications specific to oncology supportive care, a sphere that Ortho Biotech has largely neglected, bringing no new products to it since Procrits advent.

Finally let me comment on the proposal to dictate a formula for assigning discounts in a bundled contract such that discounts may be assigned to a drug in excess of the amount of it actually being used. This would seem to subvert the intent of ASP to reflect the actual cost of the drug and holds the potential to set an ASP + 6% that is actually below the cost that the drug can be acquired without bundling, having the exact opposite effect intended.

Thank you for the opportunity to comment on this issue.

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

Organization :

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

"see attachment" David Fern MD

CMS-1321-P-720-Attach-1.DOC

#720

DeKalb Surgical Associates, P.C.

John S. Kennedy, M.D., F.A.C.S., Alexander D. Park, M.D., F.A.C.S., Michael J. Cornwell, M.D., F.A.C.S., David R. Fern, M.D., F.A.C.S., Michael S. Champney, M.D.

October 4, 2006

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

Attention: 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

Dear Administrator:

We appreciate the opportunity to provide comment on the CMS proposed Physician Rule #CMS-1321-P. CMS has proposed drastic cuts in the RVUs assigned to the global fee schedule for breast brachytherapy. We would like to highlight the negative impact these proposed rates will have on breast conservation therapy since we currently recommend a 5-day radiation therapy treatment option (balloon brachytherapy) for clinically specific Medicare beneficiaries.

The RVUs are scheduled to reduce each year in the transition period and the total reduction for this treatment is -31% as illustrated in the table below. This is unacceptable. We find the patients are more compliant with 5-day breast brachytherapy versus the standard course of radiation treatments which can run from 6-8 weeks.

CPT Code	Description	2006 RVUs	2010 RVUs	Variance
19296	Placement of a radiotherapy afterloading balloon catheter into the breast for interstitial radioelement application	129.74	89.31	-31%

This procedure takes place in the procedure room in our office. A patient must meet strict selection criteria before we surgically implant the balloon catheter that delivers the radiation; and because of the time involved in planning, catheter implantation and device cost, the proposed RVU reduction will result in this procedure no longer being available for Medicare women. The cost of the procedure will exceed the proposed reimbursement and every patient will be forced to have the procedure in the hospital – which is a significant waste of healthcare dollars. The office is the preferred site of service, and office placement should be the site of service used to reduce unnecessary Operating Room costs.

There are several RVUs that are decreasing by more than 5%. I recommend that CMS implement a floor equal to a 5% reduction and that this floor remain in effect during the time required for CMS and the RUC to re-evaluate the data applicable to these RVUs, specifically, breast brachytherapy. I am willing to provide data to my specialty society so that they may in turn provide the necessary data to CMS and the RUC. This will help CMS prepare a more informed proposal in the readjustment of RVUs that pertain to breast brachytherapy.

Respectfully,

David McTeer MD

cc: Senator Mike Enzi, Chair, Senate Health, Education, Labor and Pensions Committee
Senator Dianne Feinstein, Co-Chair, Senate Cancer Committee
Senator Sam Brownback, Co-Chair, Senate Cancer Committee
Senator Thad Cochran, Chairman, Senate Appropriations Committee
Representative Michael Bilirakis, Energy and Commerce Health Subcommittee
Representative Ginny Brown-Waite, Co-Chair, Congressional Caucus for Women's Issues
Representative Katherine Harris, Member House Cancer Caucus
Representative Ileana Ros-Lehtinen, Vice Chair, Congressional Caucus for Women's Issues
Carolyn Mullen, Deputy Director, Division of Practitioner Service
Helen Pass, MD, FACS, President, American Society of Breast Surgeons
Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

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

Organization :

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

"SEE ATTACHMENT" MICHAEL CHAMPNEY MD

CMS-1321-P-721-Attach-1.DOC

#721

DEKALB SURGICAL ASSOCIATES, P.C.

John S. Kennedy, M.D., F.A.C.S., Alexander D. Park, M.D., F.A.C.S., Michael J. Cornwell, M.D., F.A.C.S., David R. Fern, M.D., F.A.C.S., Michael S. Champney, M.D.

October 4, 2006

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

Attention: CMS-1506-P for Hospital Outpatient Prospective Payment System (OPPS) Rule Breast Brachytherapy

Dear CMS Administrator,

Thank you for the opportunity to provide comments on file #CMS-1506-P for the CY 2007 / 2008 CMS proposed Hospital Outpatient Prospective Payment System (OPPS). I have concerns regarding your proposed changes.

I recommend Partial Breast Irradiation Therapy for carefully selected Breast Cancer patients. With Partial Breast Irradiation Therapy, a woman can complete her Radiation treatments in five days. The women are more compliant - which ultimately reduces her risk of breast cancer recurrence.

The reassignment of CPT codes 19296 & 19297 to APC #0030 is not sufficient payment for the catheter which is priced at $2,750. Our recommendation is for CPT codes 19296 & 19297 to remain under APC #1524 for at least one more year so additional data can be collected on this service.

Thank you for implementing this recommendation. We would like to continue servicing your Medicare patients with breast brachytherapy services when clinically indicated.

Respectfully,

cc: Senator Mike Enzi, Chair, Senate Health, Education, Labor and Pensions Committee
Senator Dianne Feinstein, Co-Chair, Senate Cancer Committee
Senator Sam Brownback, Co-Chair, Senate Cancer Committee
Senator Thad Cochran, Chairman, Senate Appropriations Committee
Representative Michael Bilirakis, Energy and Commerce Health Subcommittee
Representative Ginny Brown-Waite, Co-Chair, Congressional Caucus for Women's Issues
Representative Katherine Harris, Member House Cancer Caucus
Representative Ileana Ros-Lehtinen, Vice Chair, Congressional Caucus for Women's Issues
Carol Bazell, MD, Director, Division of Outpatient Care
Helen Pass, MD, FACS, President, American Society of Breast Surgeons
Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

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

Organization :

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

"SEE ATTACHMENT" MICHAEL CHAMPNEY MD

CMS-1321-P-722-Attach-1.DOC

#722

DeKalb Surgical Associates, P.C.

John S. Kennedy, M.D., F.A.C.S., Alexander D. Park, M.D., F.A.C.S., Michael J. Cornwell, M.D., F.A.C.S., David R. Fern, M.D., F.A.C.S., Michael S. Champney, M.D.

October 4, 2006

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

Attention: 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

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The RVUs are scheduled to reduce each year in the transition period and the total reduction for this treatment is -31% as illustrated in the table below. This is unacceptable. We find the patients are more compliant with 5-day breast brachytherapy versus the standard course of radiation treatments which can run from 6-8 weeks.

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There are several RVUs that are decreasing by more than 5%. I recommend that CMS implement a floor equal to a 5% reduction and that this floor remain in effect during the time required for CMS and the RUC to re-evaluate the data applicable to these RVUs, specifically, breast brachytherapy. I am willing to provide data to my specialty society so that they may in turn provide the necessary data to CMS and the RUC. This will help CMS prepare a more informed proposal in the readjustment of RVUs that pertain to breast brachytherapy.

Respectfully,

cc: Senator Mike Enzi, Chair, Senate Health, Education, Labor and Pensions Committee
Senator Dianne Feinstein, Co-Chair, Senate Cancer Committee
Senator Sam Brownback, Co-Chair, Senate Cancer Committee
Senator Thad Cochran, Chairman, Senate Appropriations Committee
Representative Michael Bilirakis, Energy and Commerce Health Subcommittee
Representative Ginny Brown-Waite, Co-Chair, Congressional Caucus for Women's Issues
Representative Katherine Harris, Member House Cancer Caucus
Representative Ileana Ros-Lehtinen, Vice Chair, Congressional Caucus for Women's Issues
Carolyn Mullen, Deputy Director, Division of Practitioner Service
Helen Pass, MD, FACS, President, American Society of Breast Surgeons
Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

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

Organization :

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

"SEE ATTACHED" MICHAEL CORNWELL MD

CMS-1321-P-723-Attach-1.DOC

restrictive. Given advances in digital technology and networking, a physician may expertly supervise a larger number of rural or free-standing EEG labs, for example. The AAN requests data from CMS to support the change before it is made.

Promoting the Effective use of Health Information Technology (HIT)
In the proposed rule, the administration made the statement that adopting HIT is a "normal cost of doing business" (*Federal Register*, p. 49067). Clearly, the up-front expense of adopting a HIT is out of reach for lower income practices. We ask that CMS take a more aggressive approach in pressuring Congress for financial relief for these smaller practices. In addition, the AAN notes that CMS has slowed in disseminating standards for the technology, and this discourages practices from making large HIT purchases on equipment that may very quickly become obsolete. The AAN fully supports the adoption of HIT, but asks that CMS offer more financial relief and sooner adoption of HIT standards.

The AAN appreciates the opportunity to comment on this proposed rule and continues to be grateful for your consideration of our remarks. If you have any questions regarding the above comments, please contact Katie Kuechenmeister at the AAN offices at kkuechenmeister@aan.com or by phone at 651-695-2783.

Sincerely,

Laura B. Powers, MD
Chair, Medical Economics and Management Committee

Submitter : **Dr. Robert Provenzano** **Date: 10/10/2006**

Organization : **Renal Physicians Association**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-732-Attach-1.WPD

#732

RPA

Renal Physicians Association

October 6, 2006

Mark McClellan, MD, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1321-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: Medicare Program: Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Part B (CMS-1321-P) Proposed Rule

Dear Dr. McClellan:

The Renal Physicians Association (RPA) is the professional organization of nephrologists whose goals are to ensure optimal care under the highest standards of medical practice for patients with renal disease and related disorders. RPA acts as the national representative for physicians engaged in the study and management of patients with renal disease. We are writing to provide comments on selected portions of the 2007 Medicare Fee Schedule Proposed Rule.

RPA's comments will focus on the following issues:

- **Work Relative Value Units (WRVUs) for Inpatient Dialysis Services**
- **Payment changes for multiple imaging services affecting vascular access care commonly provided to kidney patients;**
- **The composite rate payment formula for dialysis facilities; and**
- **Continued use of the Sustainable Growth Rate (SGR) formula in the physician fee schedule.**

BACKGROUND

Work RVUs/Most Recent Changes to the Fee Schedule

In the Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology, CMS' promulgated its decision to adopt the recommendations from the American Medical Association's Relative Value Update Committee (RUC) regarding the work RVUs for E&M services. In our comments on this

regulation, we concurred with the RUC that there was compelling evidence to review the E&M services due to the use of incorrect assumptions in the previous valuation of these services, and noted that RPA believes that values proposed in the Five-Year Review notice will more closely reflect the physician work involved in providing these services. RPA's comments on that regulation addressed the applicability of the E&M work RVU increases to outpatient and inpatient dialysis services. This comment is intended to provide greater specificity regarding the inpatient dialysis services.

In our comments on the previous rule, we noted that CMS indicates in the notice that the agency agreed with the RUC's recommendation to incorporate the full increase for the E&M codes into the surgical global periods for each CPT code with a global period of 010 and 090. RPA proceeded to state our belief that the outpatient and inpatient dialysis services that use E&M codes as "building blocks" or components of their valuation should have the full increases for the E&M codes incorporated into their values as well. This passage of the comment concluded by noting that the inpatient service codes (CPT Codes 90935-90947) are reported to describe both hemodialysis and dialysis procedures other than hemodialysis with the common daily E&M services related to the patient's renal disease on the day of the procedure.

In the Medicare Physician Fee Schedule Proposed Rule for CY 1995 published on December 8, 1994, and Transmittal 1776, Change Request 2321 of the Medicare Claims Manual, HCFA/CMS states in both documents that "we will bundle payment for subsequent hospital visits (CPT code 99231 through 99233) and follow-up inpatient consultations (CPT codes 99261 through 99263) into the fee schedule amounts for inpatient dialysis (CPT codes 90935 through 90457)." While follow-up inpatient consultations (CPT codes 99261 through 99263) have been deleted from the fee schedule for payment purposes, the subsequent hospital visit codes are of course still part of the fee schedule, and RPA urges CMS to add the increase for the mid-level subsequent hospital visit, CPT code 99232, to the work RVUs for the four inpatient dialysis codes. The increase in work RVUs for CPT code 99232 was 0.33 RVUs. Following is a chart providing the impact of the increases on the inpatient dialysis codes, and the impact of the increase on CPT code 99232, in order to allow for comparison on a relativity basis:

CPT Code	2005 Work RVU	Our Proposed 2006 Work RVU	% Increase
99232	1.06	1.39	31%
90935	1.22	1.55	27%
90937	2.11	2.44	15%
90945	1.28	1.61	25%
90947	2.16	2.49	15%

As the chart indicates, all of the increases for the inpatient dialysis codes would be proportionately less than the increase for the mid-level subsequent hospital visit code. Further, these changes would help maintain relativity between the subsequent hospital visit code family and the inpatient dialysis code family (although it would not maintain this relativity at current levels). As RPA noted in its comments on the Five-Year Review pertaining to relativity, "as an example it is illustrative that in 2004 the reimbursement for CPT code 90935 was roughly equivalent to a level three subsequent hospital visit (CPT code 99233), and if left unchanged the proposed 2007 values will result in a reimbursement level that would be roughly equivalent to a

level two subsequent hospital visit (CPT code 99232). Such a change in relativity does not have face-value validity."

For these reasons, RPA strongly urges CMS to upwardly adjust the work RVUs for each inpatient dialysis code by 0.33 to maintain both equity and relativity with the E&M code family as noted above. These recommended changes are separate from, and intended to complement, similar recommendations for change affecting outpatient dialysis services that were addressed in our comments on the Five-Year Review.

DRA PROPOSALS

As noted in RPA's comments to the Agency on the Five-Year Review and the Revised Practice Expense Methodology, we recognize the policymaking constraints placed upon CMS by legislative mandates such as the Deficit Reduction Act (DRA), and we support efforts to exercise more comprehensive oversight of the provision of imaging services due to the tremendous growth in utilization of those services. However, RPA continues to feel obligated to point out the disconnect between implementation of changes for multiple imaging services affecting vascular access care and broader policy goals in this area.

It is our understanding that the reduced technical component payment for multiple imaging procedures, when combined with other planned fee schedule reductions, will have the immediate effect of reducing payments for outpatient office-based (i.e. "access center") vascular access services by approximately 6-7% starting in January, 2007. These reductions run counter to several salient points regarding vascular access services, including:

(1) The existence of CMS' own Fistula First program, which is intended to "ensure that kidney patients receive the most optimal form of vascular access and to seek to avoid vascular access complications through appropriate monitoring and intervention" as noted on the Fistula First website;

(2) The increased expense to the Medicare program of providing these services associated with the likely shift back to the hospital-based setting for this care in some areas; and

(3) The fact that Medicare beneficiary satisfaction and convenience is optimized when vascular access services of this nature are provided in the outpatient setting.

For these reasons, we continue to urge the Agency to develop a more nuanced methodology of implementing the DRA changes that does target the areas of inappropriate growth in utilization of imaging services, but does not have the unintended consequence of negatively impacting the appropriate provision of vascular access services to kidney patients.

ESRD PROVISIONS

In general, RPA supports CMS' proposals with regard to the composite rate payment methodology for dialysis facilities. While RPA concurs with the Agency's proposals in the areas of the drug add-on adjustment and the reimbursement for separately billable drugs, we would urge CMS provide greater clarity in both areas.

Regarding the drug add-on adjustment, RPA recommends that CMS, rather than use the producer price index (PPI) and develop a utilization estimate of its own as described in the proposed rule,

should instead use a more established and comprehensive index like the National Health Expenditure to determine the drug add-on adjustment. Such a change will promote consistency and predictability for this component of the composite rate payment. For separately billable drugs, we urge the Agency to specifically state that the rate will be the average sales price (ASP) +6 percent, and that this rate will be locked in for at least calendar year 2007. It is our opinion that making both of these changes will provide greater stability in reimbursement for 2007 and provide CMS with the opportunity over the next year to make any necessary changes.

OTHER ISSUES

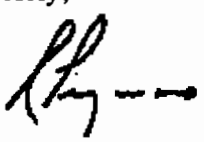
Use of the SGR Formula in the Medicare Physician Fee Schedule

RPA recognizes that similar to other issues affecting Medicare physician payment, the use of the Sustainable Growth Rate (SGR) formula has its basis in authorizing legislation, and thus addressing potential changes outside of Congressional action is complex. Nonetheless, it is the opinion of the RPA and the balance of organized medicine that there are administrative steps that the Agency could take to correct the flaws in the SGR. Further, we strongly believe that Congress would welcome such an effort. RPA therefore calls on CMS to openly and creatively seek revisions to the existing SGR formula.

As noted in RPA's comments in previous years, the structural flaws in the SGR formula are well documented. These shortcomings include: (1) the inappropriate link between the performance of the overall economy and the actual cost of providing physician services; (2) the continued inclusion of the cost of physician-administered drugs in its formula calculation (despite the fact that physicians have no control over the price of drugs); and (3) the fact that the full cost of new Medicare benefits and coverage decisions are not accounted for in the SGR target. In the NPRM CMS includes a section entitled *Promoting Effective Use of Health Information Technology (HIT)* that discusses the Administration's recognition of the potential of HIT to facilitate improvements in the quality and efficiency of health care services. Accordingly, many physician practices are evaluating investment in the HIT necessary to achieve these improvements. However, the continued use of an outmoded reimbursement methodology that results in projected negative updates in the Medicare physician fee schedule for the next five years or more will limit such improvements, and is simply unacceptable. RPA believes that the SGR must be replaced with a reimbursement mechanism linked to increases in the actual costs of medical practice to not only facilitate investment in HIT and other improvements, but also to allow the practice of medicine to remain viable.

As always, we welcome the opportunity to work collaboratively with CMS in its efforts to improve the quality of care provided to the nation's ESRD patients, and we stand ready as a resource to CMS in its future endeavors. Any questions or comments regarding this correspondence should be directed to RPA's Director of Public Policy, Rob Blaser, at 301-468-3515, or by email at rblaser@renalmd.org.

Sincerely,



Robert Provenzano, M.D.
President

Submitter : Dr. JUDITH HONDO **Date:** 10/10/2006

Organization : The Vein & Aesthetic Center of Boston

Category : Radiologist

Issue Areas/Comments

Background

Background

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.

GENERAL

GENERAL

CMS 1321-P
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,
Judith Hondo, MD
The Vein & Aesthetic Center of Boston
333 Elm Street, Ste 205
Dedham MA 02026
jhondo@veinfix.com

Impact

Impact

see comments below

Provisions of the Proposed Rule

Provisions of the Proposed Rule

see comments below

Submitter : Dr. ELIZABETH FOLEY **Date:** 10/10/2006

Organization : THE VEIN & AESTHETIC CENTER OF BOSTON

Category : Radiologist

Issue Areas/Comments

Background

Background

MAKING THESE REVISIONS AS PROPOSED WILL IMPACT NEGATIVELY ONT HE MEDICARE POPULATIONS' ACCESS TO QUALITY HEALTH CARE. THE REDUCTION IN REIMBURSEMENT RATES WILL ULTIMATELY LIMIT ACCESS TO PHYSICIANS WHO PERFORM THESE TREATMENTS.

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

Respectfully submitted,
ELIZABETH FOLEY, MD
THE VEIN & AESTHETIC CENTER OF BOSTON
333 ELM STREET
DEDHAM MA 02026
EFOLEY@VEINFIX.COM

Impact

Impact

SEE GENERAL COMMENTS

Provisions of the Proposed Rule

Provisions of the Proposed Rule

SEE GENERAL COMMENTS

Submitter : **Dr. Jaime Furman** **Date: 10/10/2006**

Organization : **Jaime Furman M.D P.A**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1321-P-735-Attach-1.TXT

CMS-1321-P-735-Attach-2.DOC

#7351

CMS 1321 P

"REASSIGNMENT AND PHYSICIANS SELF –REFERRAL"

Dear Sir/ Madam:

I want to thank you for allowing me to submit my comments. My name is Jaime Furman, I am a physician and a pathologist with fellowships in surgical and urologic pathology. Currently, I am working in a "condo" or "pod" laboratory in San Antonio, Texas.

I am not a lawyer, nor an expert in the Medicare regulations, therefore I am only going to give here some comments about my experience in this type of laboratories.
I am a physician with a specialty in anatomic pathology. During the last 16 years I have worked very hard in order to provide patients and students the best professional and ethical service I could. Before my current job, I worked in the University Hospital and was an Associate Professor of Pathology in the local medical school. I did my training at Washington University in St Louis and the University of Florida at Gainesville. My responsibilities included interpretation and diagnosis of histology samples, teaching urologic pathology to the second year medical students, urology and pathology residents. My professional life in the academic center was successful and promising.

In the year 2004 I learned that a pathology laboratory focusing on urologic pathology was opening in San Antonio. A few months later I joined the urology "condo' lab.
My experience in the new laboratories has been positive. The model of the condo lab allows the pathologist to focus on a specific area of pathology and provide a high of expertise and efficiency that cannot be reached in other type of practices. This high level of expertise allows the pathologist to give the patients a very accurate diagnosis and the clinician the necessary information to initiate the appropriate treatment.

Many students and residents rotate in our laboratories and I have signed a contract with the University of Texas that allows residents to come to our laboratories and benefit from our experience in the diagnosis of urologic cancer. Furthermore, currently I am working on the creation of a guide for urologists to study urologic pathology. This setting also allows me to become involved in academic activities. Periodically I give lectures about urologic pathology. Last September I was invited to Colombia, in South America to give several conferences in urologic pathology

One of the benefits of the "condo" laboratory is that the interaction with the urologist is very close and allows clinician and pathologist to work as a team to the benefit of the patient. The urologists are confident that the same pathologist interprets all the biopsies and provides a level of uniformity and consistency absent in other settings. Urologists have related to me the difficulties they had in the past from "traditional" referral laboratories to obtain an accurate diagnosis. Another positive feature of the model is the

rapid turnaround time to sign the pathology cases. Most of our cases are signed between 24- 48 hours after received, minimizing delays and problems to patients.

Some national pathologist organizations of which I am currently an active member (CAP) have invoked that the level of medical attention we provide is suboptimal. Nothing is further from reality. Hundreds of second opinions requested by clinicians and patients agree with our interpretations and confirm that the quality of diagnosis is excellent. The clinicians in other institutions and patients confirm these findings and no complaints have been received in more than two years. On several occasions we had encounter cases that were erroneously interpreted in other centers and were correctly interpreted by us.

Hundreds of patients went for surgical removal of the prostate gland after our diagnosis of cancer. The pathologists agree with the initial diagnosis we provided and confirmed the diagnosis of cancer in the surgical resection.

Recently, I submitted an abstract for the USCAP (United States and Academic of pathology) meeting for the year 2007 titled:

"EXPERIENCE WITH PROSTATE NEEDLE BIOPSIES IN A SPECIALIZED UROLOGIC PATHOLOGY LABORATORY (CONDO LABORATORY)"

The number of prostate carcinomas (cancer) detected in my laboratory (37.2%) was higher than in most publications from other centers (19 -20%). In other words, I detected many more cases of cancer in a similar number of biopsies. This finding negates the argument presented in the proposed changes that mention "fraud" and "generation of unnecessary biopsies."

In addition, the cases of inconclusive diagnosis (atypia) were very small compared to other centers. The findings contradict completely the arguments of abuse of self referral by clinicians. The high number of cancer diagnosis made, clearly validates that the urologists were correct in requesting the biopsies in most of these patients.

I also want to comment that our quality control in my experience is one of the most complete that I have encountered in my practice as a pathologist. The entire process is under the control of the urologist and pathologist and can be corrected immediately if necessary.

An allegation made by pathology organizations is that "others" benefit from our job and that we do not receive the entire professional component and a third party benefit from our work. This is a deceitful argument because in my previous academic jobs the institution I worked for did not give me either the complete professional component for my professional services and I received a salary for far less compensation than now for equal amount of hours. Most institutions do not paid pathologist for the full professional component.

Our work conditions are very favorable and we have the adequate equipment and resources to perform the job. I resent the implication that we perform the job under poor conditions with "minimal equipment." The resources are satisfactory for performing the job and the channels of communication are open to repair or change some of the equipment if necessary. The histology technologists that work in the laboratories are great professionals and some of the more experienced in San Antonio and South Texas. The quality generated in the laboratories of the histology material is very good and allows us to perform our job and provide a good diagnosis.

Many critics of the "condo" laboratories originated from pathology organizations that I respect and I am currently a member. The allegations range from suboptimal medical quality, over-utilization, abusive arrangement and fraud. I want to be clear and definitive that all of these charges are unsubstantiated and false. No one from these pathologist organizations have ever contacted us. Most of the negatives comments are only speculations. The origin of these charges are special interest groups with a financial agenda in ending this new type of laboratories.

New types of practices and models arise in other medical specialties. Pathology is not different. Initial criticisms are expected and should help to improve a new idea. Regulations are also necessary and welcome in order to avoid abuses. At the same time a good functional model should be embraced as a new approach and not destroy under false accusations for pure financial concerns. The objective of medicine is to serve patients well and with dedication. This is a novel approach to serve patients, urologists and pathologists. Today in the United States the health system is facing critical problems that traditional models have not solved. New concepts and models should be studied and regulated but also encouraged. I work hard with great dedication and I am proud of what I am doing.

In summary we :

- provide excellent diagnostic services
-serve patients with dedication
-are efficient
-work hard
-have a great work team
-help urologist to treat patients
-reject fraud and abuse
-welcome well intentioned critics
-serve the community
-want to be treated fairly by all regulatory agencies

I have confidence that the truth and decency are going to prevail over obscure interests and political motivated organizations. I have faith that at the end we will prevail and will continue serving our patients, serving the urologist, and serving the pathology

community. I encourage everybody to look at this model with an open mind and not to falsely implant prejudices. I told the truth on the best of my knowledge in these comments.

I hope I am contacted by any member of your organization or any legislative body that wants to hear the truth and is interested in improving medical services in our country.
My phone is 210- 764 0045
E-mail karja@sbcglobal.net

Thank you

Sincerely,

Jaime Furman, M.D.
Urologic Pathologist

Associate Professor of Pathology
University of Texas Health Science Center San Antonio

#735-2

CMS 1321 P

"REASSIGNMENT AND PHYSICIANS SELF –REFERRAL"

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E-mail karja@sbcglobal.net

Thank you

Sincerely,

Jaime Furman, M.D.
Urologic Pathologist

Associate Professor of Pathology
University of Texas Health Science Center San Antonio

Submitter : **Mrs. Anne Marie Bicha** **Date: 10/10/2006**

Organization : **American Gastroenterological Association**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-736-Attach-1.DOC

October 10, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1321-P
P.O. Box 8015
7500 Security Boulevard
Baltimore, MD 21244-8015

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

Dear Dr. McClellan:

The American Gastroenterological Association (AGA), the American Society for Gastrointestinal Endoscopy (ASGE) and the American College of Gastroenterology (ACG) welcome the opportunity to comment on the proposed changes to the physician fee schedule for 2007. Our three societies represent virtually all practicing gastroenterologists in the United States.

Negative Update for 2007

We are extremely concerned about the proposed 5.1% payment cut for 2007. While we recognize that the Sustainable Growth Rate (SGR) is largely outside of the control of CMS, as we mentioned in our comments last year, we are very disappointed that CMS has not done what it can to moderate the adverse impact of this obviously flawed procedure. CMS has not taken the advice of organized medicine and many members of Congress to remove expenditures for drugs from the SGR formula on a retrospective basis.

As CMS recognizes, if the SGR formula is not fixed, physicians will receive negative updates of approximately 5 percent each year through at least 2013. This is unsustainable for physicians. If not resolved, the flawed SGR could destroy access to necessary health care for beneficiaries, which is the reason the Medicare program was created. We are hopeful that Congress will provide relief from the SGR and enact a modest update for 2007 while continuing to work toward a permanent solution and equitable payment system for physicians.

Thank you for the opportunity to submit these comments. If we may provide additional information, you may contact Anne Marie Bicha, AGA Director of Regulatory Affairs, at 240-482-3223, Bernard Patashnik, Consultant to ASGE at 202-833-0007, or JoAnn Willis, ACG, at 301-263-9000.

Sincerely,

Jack A. DiPalma, MD, FACG
President, American College of Gastroenterology

Gary W. Falk, MD, FASGE
President, American Society for Gastrointestinal Endoscopy

David A. Peura, MD
Chair, American Gastroenterological Association

Submitter : Jill Rathbun **Date:** 10/10/2006

Organization : Society of Gynecologic Oncologists

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

The Society of Gynecologic Oncologists appreciates the opportunity to comment on the standardized packages for supplies and equipment and the practice expense methodology. Please "See Attachment."

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

Organization : **Society of Gynecologic Oncologists**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Please See Attachment

CMS-1321-P-738-Attach-1.DOC

The SGO appreciates the opportunity to provide comments on this proposed rule. If the Society can provide CMS with additional information regarding this matter, please do not hesitate to contact Jill Rathbun, SGO Director of Government Relations at 703-486-4200.

Sincerely,

Gary S. Leiserowitz, MD
Gary S. Leiserowitz, MD
Chair, Coding and Reimbursement Ctme.

Carol L. Brown, MD
Carol L. Brown, MD
Chair, Government Relations Ctme.

Submitter : Mrs. SUSAN ZELL **Date:** 10/10/2006

Organization : COVENANT MEDICAL GROUP

Category : Nurse

Issue Areas/Comments

Background

Background

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GENERAL

GENERAL

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.

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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 require high salaries 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
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.

Being a nurse for a general surgeon, I have seen many older patients who have extremely painful and swollen legs due to severe varicose veins who could benefit from these procedures. Decreasing RVU would hamper physicians from providing these necessary procedures for patients.

Sincerely,

Susan W. Zell RN
Lubbock, Texas 79410
szell@covhs.org

Impact

Impact

SEE GENERAL COMMENT BELOW.

Provisions of the Proposed Rule

Provisions of the Proposed Rule
SEE GENERAL COMMENT BELOW.

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

Organization : **American Society of Nephrology**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

CMS-1321-P-743-Attach-1.DOC

#74

ASN
THE AMERICAN SOCIETY OF NEPHROLOGY

1725 I Street NW • Suite 510 • Washington, DC 20006
Tel 202-659-0599 • Fax 202-659-0709 • www.asn-online.org

October 10, 2006

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

Re: **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'*

Dear Dr. McClellan:

The American Society of Nephrology (ASN) is a professional association with approximately 10,000 members. Of this membership, about 95% are physicians, with the remaining members being basic scientists with a primary interest in renal disease. Virtually every licensed nephrologist in the United States is a member of the ASN, with an additional 3,000 nephrologists from 82 other countries comprising the remainder of our membership. The Society promotes excellence in the care of patients with kidney disease through promulgating innovative research related to renal disease, providing continuing medical education to physicians and scientists dedicated to the improved understanding and treatment of renal disease, and supporting advocacy for policy that improves the quality of care delivered to our patients.

The ASN welcomes the opportunity to respond to the recent proposed revisions by Centers for Medicare and Medicaid Services (CMS) regarding reimbursement for physicians. The ASN commends CMS for its willingness to work with the renal community on the important issues and challenges facing End-Stage Renal Disease (ESRD) patients, physicians and dialysis providers.

The ASN, in conjunction with other renal organizations, urges CMS to:

- Establish price and utilization estimates that are tied to an existing index or based on accurate data to use to calculate the update to the drug add-on adjustment;
- Explicitly state that for Calendar Year 2007, CMS will reimburse separately billable drugs at Average Sales Price (ASP) +6 percent; and
- Explain the methodology used by CMS to calculate the budget neutrality factor for the geographic wage index.

Additionally, the ASN supports the Agency's decision to reimburse for blood flow monitoring, medical nutritional therapy, and diabetes self-management training. These are important preventive treatment options that can have a positive impact on the ability of physicians, facilities, and patients to slow the progression of and better manage kidney disease.

The ASN submits the following comments on various aspects of the CMS *'Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006.'*

I. ESRD Provisions: Drug Add-On Adjustment

The ASN applauds CMS' proposal to update the drug add-on adjustment using an index rather than recalculating the update. However, we have some concerns regarding the methodology used to calculate the update. It is not clear how CMS obtained a PPI equaling 4.9 or how CMS determined the pricing movement between 2004 and 2005.

Also, the use of *retrospective* PPI data and *current* utilization data to calculate the update to the drug add-on adjustment is inconsistent. CMS should use current data for both categories.

As an alternative, ASN encourages CMS to use the National Health Expenditure instead. It provides both a price and a utilization update, and using it would resolve concerns about calculating a utilization update.

II. Average Sales Price (ASP) Issues

The ASN appreciates the Agency noting that separately billable drugs will be reimbursed "based on section 1847A of the Act." (71 *Federal Register* at 79004). However, we encourage the Agency to be more direct in the Final Rule and to state expressly that for Calendar Year 2007 the Secretary will reimburse separately billed drugs at ASP+6 percent. This statement would be consistent with the statutory mandate and provide needed clarity for the renal community.

III. ESRD Provisions: Geographic Wage Index

As CMS continues to implement the geographic wage index, ASN encourages CMS to examine the effect of the changes on facilities. Also, we have concerns regarding a lack of transparency in the calculation of budget neutrality factor in the Proposed Rule, and we request that CMS provide the data and methodology used in this calculation. This would allow the renal community to assess the impact of the proposed changes, as small changes to the geographic wage index have an enormous impact on small providers.

IV. Patient Services: Blood Flow Monitoring, Medical Nutritional Therapy, and Self-Management for Diabetics

ASN is pleased that CMS recognizes three important services that can help improve care for patients and allow them to learn to better manage their disease. We encourage CMS in its efforts to provide coverage for these and other services that can help slow the progression of kidney disease and give patients who have kidney failure have a higher quality of life.

As is indicated in the Kidney Care Quality and Improvement Act, which the ASN enthusiastically supports, the ASN strongly supports further support for blood flow monitoring services. Once patients are diagnosed with kidney failure, they must obtain an access for dialysis. Blood flow monitoring services allow dialysis professionals to assess a patient's access and determine whether additional maintenance services are required before a problem occurs. These services enhance the accuracy of the dialysis service being provided and therefore the quality of care that the patient receives. Blood flow monitoring services also eliminates indirect costs by reducing patient morbidity and the number of required hospital tests for a dialysis patient. This preventative care is critically important in maintaining the patient's well-being. The ASN encourages CMS to ensure that these services are covered in all appropriate settings, not just physicians' offices.

ASN also supports increased coverage for medical nutritional therapy. The limited access to nutritional therapists is problematic for many patients with Stage 3 and 4 kidney disease. Medical nutritional therapy and counseling are important tools to assist patients in improving their nutritional status and to control the levels of several critical electrolytes in their bodies, such as potassium (which can lead to fatal arrhythmias) and phosphorus (which has a long term effect on bones and cardiovascular disease). The availability of nutritional therapy will help patients to learn how to better manage their disease and will improve their quality of life.

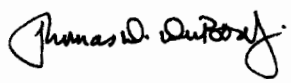
Finally, the ASN supports the proposal regarding diabetes self-management services. As diabetes is a precursor to chronic kidney disease, patients who manage their diabetes effectively will slow the progression or even the onset of kidney disease. The more opportunities patients have to learn how to manage their disease, the less likely it is that they will need dialysis services. The ASN encourages CMS to continue to explore additional services that help slow the progression of chronic kidney disease.

The ASN encourages CMS to continue to provide incentives for educational and preventive services. These programs not only help to prevent the onset of chronic kidney disease, but also help dialysis professionals to manage their patients better.

V. Closing

On behalf of the ASN, I would like to thank you for your willingness to consider our comments about the Proposed Rule. We believe that our proposed recommendations and future dialogue between the ASN and CMS will prove helpful in the exchange of ideas and viewpoints when formulating workable solutions now and in the future. We welcome your response to our recommendations and the opportunity to contribute to the final guidelines.

Sincerely,



Thomas DuBose, Jr., MD
ASN President

Submitter : Mr. Gary Walker **Date:** 10/10/2006

Organization : Allen Dell, PA

Category : Attorney/Law Firm

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Impact

Impact

REASSIGNMENT AND PHYSICIAN SELF-REFERRAL

CMS-1321-P-744-Attach-1.PDF

#7

MICHAEL N. BROWN
KELLIE A. CAGGIANO
DAVID D. FERRENTINO
DAVID FORZIANO
MATTHEW J. FOSTER
MELISSA A. HAAS
RICHARD A. HARRISON•
TABATHA A. LIEBERT
MARIAN P. McCULLOCH ⊥
DEBRA M. METZLER
ROBERT A. MORA
BENJAMIN G. MORRIS
ELIANE I. PROBASCO
AMY D. SINGER
DONALD W. STANLEY, JR. ⊥⊥
GARY WALKER

⊥ BOARD CERTIFIED, MARITAL & FAMILY LAW
• BOARD CERTIFIED, CITY, COUNTY & LOCAL GOVERNMENT LAW
⊥⊥ CERTIFIED STATE & FEDERAL MEDIATOR

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A PROFESSIONAL ASSOCIATION

Of Counsel
JOSEPH G. HEYCK, JR
NATHAN B. SIMPSON

WRITER'S EMAIL:
gwalker@allendell.com

October 10, 2006

VIA EMAIL

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

Re: **CMS-1321-P**

Dear Madam or Sir:

I am submitting these comments in response to the proposed rules published in the Federal Register, Volume 71, Number 163, on August 22, 2006. My comments relate to file code **CMS-1321-P**. My comments focus solely on:

REASSIGNMENT AND PHYSICIAN SELF-REFERRAL

On page 49056, you state that CMS is considering further amendments to Sec. 424.80 to "impose certain conditions on when a physician or medical group can bill for a reassigned PC of a diagnostic test." You then list certain requirements for such billing, which currently are in the Claims Processing Manual, Chapter 1, Section 30.2.9.1 (the "Purchased Interpretation Rule").

Although it is not explicitly stated on page 49056, it appears from earlier discussion in the Federal Register that the amendment you are considering will be limited to reassignment from an independent contractor physician, and not reassignment from an employed physician.

The proposed application of the Purchased Interpretation Rule to a reassignment from an independent contractor physician to a physician or a group practice is not appropriate because it would disrupt legitimate, cost-effective arrangements in which physicians provide services as independent contractors.

In today's medical practice environment, independent contractor arrangements with physicians are wide spread and such arrangements do not necessarily result in over-utilization or increased costs to Medicare.

For example, I represent a 45 physician, multi-specialty group practice that provides a wide range of primary care and specialty services to its patients, including diagnostic imaging services. The practice owns all of its imaging equipment and employs the technologists who operate that equipment. However, the group does not have a sufficient volume of imaging services to necessitate employing its own radiologist.

Rather, the group engages the services of board-certified radiologists from a radiology group through an independent contractor arrangement between my client and the radiology group. That arrangement is structured in a manner that fully complies with all applicable laws and regulations, including the provisions related to program integrity and program safeguards. There is absolutely nothing in the arrangement that provides incentives for, or results in, over-utilization.

Each radiologist who provides interpretations to the group practice has filed an 855R just as have the group's employed physicians. The radiologists provide medical direction for the diagnostic imaging services and test interpretations, and the group's employed physicians provide the direct supervision of the performance of the technical component. The group is responsible to Medicare for both the technical component and the interpretation, just as the group is for the other services of its employed physicians.

While I am confident that the group's utilization of diagnostic imaging services is consistent with similar multi-specialty groups, if the group's utilization for some reason were higher than similar groups, the Medicare carrier would detect that utilization level just as it can detect higher utilization of services provided entirely by the group's employed physicians.

The Purchased Interpretation Rule was never intended to apply to interpretations of tests performed for a medical group's own patients when those interpretations are provided to the group by an independent contractor physician who reassigns his payment to the group. On the contrary, by its very terms, it is intended to apply situations in which entities other than physician groups perform tests referred to such entities by physicians, on those entities purchase the test interpretation from a physician or medical group.

If you amend the rules as you describe, that amendment will allow test interpretations to be performed SOLELY by employed physicians of a group and not by physicians who are independent contractors of such group. That change will not solve the perceived problem; however, in many situations, it likely will disrupt patient care.

As you know, there is a shortage of radiologists and, for a variety of business and financial reasons, radiology groups are reluctant to allow their employed radiologists to be part-time employees of other physician groups. However, those radiology groups do enter into independent contractor arrangements through which the radiology groups provide interpretations for other physician groups.

The amendment presents a significant risk that physician groups will not be able to employ radiologists on a part-time basis to provide interpretations of tests performed the physician groups. The tests WILL be performed, but the amendment simply would shift the performance of those tests from the physician groups to hospitals or free-standing imaging centers. That shift will not solve the

perceived problem and clearly would unnecessarily inconvenience patients and potentially delay the delivery of care.

It is over-reaching and unjustified to try to force fit the Purchased Interpretation Rule by applying it to situations in which a medical group contracts with a radiology group to provide interpretations of tests performed for the billing group's own patients.

It appears from the discussion in the Federal Register that the primary motivation in proposing the changes to Section 424.80 and in considering the other changes is based on concerns related to possible abuse and over-utilization related to pod labs. However, the proposed changes you are considering are far too broad, and unnecessarily harm legitimate business arrangements that have no abuse or over-utilization. I am not aware of any data to support a contention that there is over-utilization or abuse resulting solely from a medical group's engaging independent contractor physicians to interpret tests performed by the medical group.

Whatever the problems are with respect to pod labs, and even to possible concerns regarding other situations involving over-utilization, those problems are not solved by imposing unnecessary restrictions on patient care provided by physician groups.

Increases in Medicare spending for diagnostic imaging are not caused by multi-specialty group's providing diagnostic imaging services. On the contrary, increased costs do result from new, improved technology and from defensive medicine which is practiced to avoid malpractice liability. If you merely deny a physician group the ability to provide diagnostic imaging services to its own patients, you will not decrease the utilization of new technology or the level of defensive medicine. Rather, you simply will shift its location from medical group to a hospital or free-standing center.

Clearly, there are medical practices which over-utilize diagnostic and ancillary services; however, there are far more practices composed of physicians who are honest, reputable doctors who do not over-utilize diagnostic and ancillary services, but who have invested substantial sums of money in long-term debt related to providing diagnostic and ancillary services to their patients, and those investments have been made in complete conformity with, and reliance upon, existing rules applicable to such care.

Although I strongly encourage you not to adopt the proposed changes, if you do so, it is important to provide a reasonable time period in which medical groups may unwind their existing arrangements; given the above-described long-term financial investments, a reasonable period would be five years.

Thank you for your attention to these comments.

Sincerely,

Gary Walker

Gary Walker

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

Organization : **American Academy of Audiology**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

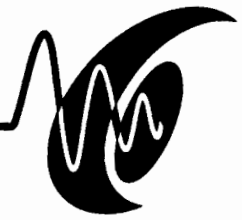
See the following attachments: 1) Comment letter, 2) Attachment

CMS-1321-P-745-Attach-1.DOC

CMS-1321-P-745-Attach-2.DOC

#745

AMERICAN ACADEMY OF AUDIOLOGY



October 10, 2006

VIA ELECTRONIC MAIL

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

Re: CMS-1321-P -- Comments on the Medicare Physician Fee Schedule Proposed Rule for Calendar Year 2007

COMMENT TOPICS: PROVISIONS, IDTF ISSUES

The American Academy of Audiology (the Academy) appreciates the opportunity to comment on the Medicare Physician Fee Schedule Proposed Rule (Proposed Rule).[1] The Academy is the world's largest professional organization of audiologists, and has over 10,000 active members who practice in medical centers, hospitals, private practice, schools, government or military health facilities, agencies, and colleges or universities. Our members provide state-of-the-art hearing and balance diagnostic services and treatment to Medicare beneficiaries exhibiting hearing impairment and balance disorders.

The Academy comments specifically on CMS-1321-P, the proposed rule that would implement the Medicare Physician Fee Schedule (MPFS) for calendar year 2007.

The Academy commented previously on CMS-1512-PN, the proposed notice that introduced fundamental changes to the MPFS practice expense (PE) methodology. In

those comments, we recommended that prior to implementing significant adjustments to payments, the new methodology should be independently validated, which could be done during the four-year transition period for the new PE methodology.

We have also urged CMS to establish work values for the audiology codes that currently have no assigned work RVUs. We are renewing this request and continue to believe that the assignment of work to these codes is the fairest and most consistent solution to the problem of insufficient payment and one that would make it unnecessary to create a special methodology to accommodate codes without work RVU's.

CMS has wisely chosen to remedy the payment problem associated with certain non-physician work pool (NPWP) codes by assigning work RVUs. CMS has proposed assigning work values to the Medical Nutrition Therapy codes, a demonstration that assigning work is a viable solution for former NPWP codes. In the interest of fairness, consistency, and accurate payment, the audiology codes should also be assigned work because there is professional work performed when the services corresponding to these codes are delivered. The professional work in these codes should be valued and paid relative to physician work. This approach should be taken with all current "zero" work codes. It is unnecessary to apply this change to technical components of codes which might be billed separately but do have associated professional work in the professional component.

The work component of each service in the MPFS is used to describe the relative value of the work involved in furnishing that service as compared to other physician services.

Congress decided that certain services typically performed by non-physicians should be considered "physicians' services" for reimbursement purposes and should be paid according to the physician fee schedule.[2] Congress did not direct that these services be reimbursed according to a separate formula that excludes work.

Rather, Congress directed CMS to value these services according to the amount of physician work relative to all of the other services in the physician fee schedule. Because Congress has directed that payment be valued based on the physician work value, it is most coherent and equitable to assign a physician work value to these codes. The fact that payment is based on a value that has been determined to represent an equivalent relative value for physician service fulfills the objective of the relative value fee schedule.

In other words, the professional work of audiologists should be valued relative to equivalent physician work. We are not suggesting necessarily that the work of audiologists be considered physician work. Rather, the audiologist's professional work should be paid based on the relative value of equivalent physician work RVUs. . The Academy respectfully suggests that in order for the work of audiologists to be properly recognized and paid for, CMS should determine a fair and reasonable work value for the audio logy codes, which is indexed to physician work units so that the total RVUs for each code can be treated consistently relative to other codes in the MPFS.

In summary, the Academy notes the progress CMS has demonstrated in dealing with the complex task of changing to the new Practice Expense methodology, especially the

elimination of the "zero work pool" and integration of those codes into the general methodology. We are disappointed that CMS has yet to complete this integration by assigning work RVUs to the audiology codes. We are hopeful that through CMS's recognition of the need for work RVUs to value similarly situated dietician codes, fair and consistent treatment of the audiology codes will soon follow.

The Academy would also like to reiterate the comments it made last year regarding direct practice expense inputs. At that time, we noted that the clinical labor rate for audiologists does not adequately cover all payroll expenses for audiologists. In particular, the clinical labor rate of $.52 per minute does not account for any fringe benefits, which represent approximately 28 percent of a worker's compensation. We request that the clinical labor rate be increased by at least $.15 per minute to cover fringe benefit costs associated with audiologist salaries. We also commented that the direct practice expense inputs for certain audiology equipment are based on old data and do not reflect the full complement of equipment needed, current pricing, or technological advancements. The codes that have inaccurate direct expense inputs for equipment are identified in the attachment to these comments.

Lastly, the Academy would like to express its support for CMS' proposal to establish quality standards for independent diagnostic testing facilities (IDTFs). The proposed standards are intended to prevent "fly by night" operations that may engage in fraud and abuse. The Academy is aware that IDTFs have been used as a vehicle for fraudulent practices. For example, we are aware of at least one instance in which a mobile IDTF

without licensed audiologists or appropriate equipment traveled around to retirement communities furnishing audiology diagnostic services to Medicare beneficiaries. As a result, Medicare may have been billed for audiology services that were sub-standard, unnecessary, or both. The proposed regulation would prevent such fraud by requiring, for example, that IDTFs maintain a physical facility at an appropriate site, house necessary equipment at that site except for portable equipment, and operate in accordance with all applicable federal and state licensure requirements. The Academy endorses this proposal.

The Academy appreciates the opportunity to offer these comments and looks forward to working with CMS on these issues. If you would like to discuss these comments, please contact Lisa Miller, Director of Reimbursement at (703) 226-1063 or via email at LMiller@audiology.org.

Sincerely,

Paul M. Pessis, Au.D.
President

Attachment

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[1] See Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and other changes to payment under Part B, 71 Fed. Reg. 48982 (Aug. 22, 2006).

[2] Hearing and balance tests are covered as "other diagnostic tests," which are included in the definition of "physicians' services" paid under the fee schedule. 42 U.S.C. §§ 1395w-4(a)(1), (j)(3) and 1395x(s)(3). While other services not paid under the fee schedule may also involve professionals, Congress did not provide that those services be reimbursed as "physicians' services."

We have identified several codes that do not reflect the current equipment expenses incurred by audiologists. For your convenience, we have listed these items in the following table:

CPT Code	Direct Practice Expense Input Corrections	Reason for the Correction
92567, 92568, and 92569	Equipment costs for these codes should be increased by approximately $7,847.47. • The equipment costs do not reflect the price of a diagnostic tympanometer, which is approximately $7,995. CMS lists $2,648.53. The price that CMS lists appears to be based on the price for a screening tympanometer, which is being replaced with a diagnostic tympanometer. • A computer desktop with monitor, which should have a price of $2,501, should be added to the equipment list.	Technological Advancement and Missing Equipment
92551, 92552, 92553, 92555, 92556, 92557, 92562, 92563, 92564, 92565, 92571, 92572, 92573, 92575, 92576, 92577, 92579, 92582, 92583, 92596, 92620, 92621 and 92625.	Equipment costs for these codes should be increased by approximately $3,999. The equipment costs do not reflect the current price for audiometers and do not list the additional equipment associated with PC-based audiometers, which is the current technology used by audiologists. • The price for the audiometer should be at least $6,450. CMS lists $6,250. • PC-based audiometers require (a) additional equipment, including insert phones and a sound field, all of which have an additional cost of approximately $1,298, and (b) a computer desktop with monitor, which should have a price of $2,501. CMS does not list any of this equipment.	Price Increase, Missing Equipment and Technological Advancement

CPT Code	Direct Practice Expense Input Corrections	Reason for the Correction
92587 and 92588	Equipment costs for these codes should be increased by approximately $3,721. • The price for the OAE-otoacoustic emission system does not reflect the current price for the equipment, which is approximately $9,000. CMS lists $7,780. • A computer desktop with monitor, which should have a price of $2,501, should be added to the equipment list.	Price Increase and Missing Equipment
92601, 92502, 92603, and 92604	Equipment costs for these codes should be increased by approximately $1,498. The equipment costs do not reflect the current price for audiometers and do not list the additional equipment associated with PC-based audiometers, which is the current technology used by audiologists. • The price for the audiometer should be at least $6,450. CMS lists $6,250. • PC-based audiometers require additional equipment, including insert phones and a sound field, all of which have an additional cost of approximately $1,298. • The cost of the computer desktop with monitor is already listed for these codes.	Price Increase and Technological Advancement
92585	Equipment costs should be increased by approximately $1,275. • The equipment costs listed do not reflect the costs for an ABR with an ASSR capability that audiologists are currently using. This equipment approximately costs $28,275. CMS lists $27,000.	Technology Advancement

Gordon N. Stowe and Associates, Inc.

3420 Cavalier Trail, Unit C1 Cuyahoga Falls, OH 44224-4967
Ph: (330) 926-0594 Fx: (330) 926-0765

QUOTATION

QUOTE#: 34561
PAGE: 1 OF 3
DATE: 9/8/2005

TO:

Debbie Abel, M.A., Ccc-A
Alliance Audiology
Suite E
1207 W. State Street
Alliance, OH 44601

330/821-2012

Please Respond to Office Indicated Above.

VALID THRU: **10/8/2005**

Terms Net 30 Days
Proposed Shipping Date 30 Days AFTER Receiving Order.

ACCT#: ALL601

Sales/Service Centers: Chicago, Cleveland, Dayton, Detroit, Indianapolis, Kansas City, Memphis, Milwaukee, St. Louis
Corporate Headquarters: 1-800-323-4371

QTY	DESCRIPTION	EACH	TOTAL
1	GSI 61 CLINICAL AUDIOMETER W/RS232 PORT Two channel diagnostic audiometer, 125-12000 Hz, -10 to 120dB range, Storage and transmission of audiogram. Separate calibration of transducers. One year warranty. Built-in Free Field Amplifier.	6,450.00	6,450.00
1	Paired eartone 3A inserts	535.00	535.00
1	Grason Stadler GSI-61 basic binaural soundfield speakers (90 dB HL in a 6' by 6' room).	525.00	525.00
1	Installation of audiometer and soundfield, and soundfield equalization	238.00	238.00
1	MADSEN OTOFLEX 100- DIAGNOSTIC INCLUDES: TYMPANOMETRY- 226 Hz AND 1000 Hz REFLEXES REFLEX DECAY ETF-P COMPUTER NOT INCLUDED Computer requirements: Windows XP Pro	7,995.00	7,995.00
1	Biologic Audx Plus- Includes Audx box , Probe, Power supply, Box will hold up to three protocols when used as a hand held unit. One OAE Modality. System can be used connected to computer for complete DP gram analysis or used as a handheld unit for portablility and then information can be downloaded into the computer database.(Computer not included)	9,000.00	9,000.00

Gordon N. Stowe and Associates, Inc.

3420 Cavalier Trail, Unit C1 Cuyahoga Falls, OH 44224-4967
Ph: (330) 926-0594 Fx: (330) 926-0765

QUOTATION

QUOTE#: 34561
PAGE: 2 OF 3
DATE: 9/8/2005

TO:

Debbie Abel, M.A., Ccc-A
Alliance Audiology
Suite E
1207 W. State Street
Alliance, OH 44601

330/821-2012

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Sales/Service Centers: Chicago, Cleveland, Dayton, Detroit, Indianapolis, Kansas City, Memphis, Milwaukee, St. Louis
Corporate Headquarters: 1-800-323-4371

QUOTE#: 34561
PAGE: 2 OF 3
DATE: 9/8/2005

1	Biologic Navigator Pro EP System with ASSR, Bone Conductor, Graph Master, Stimulus Envelopes, Two Channels, Digital Filters, Computer included.	28,275.00	28,275.00

Gordon N. Stowe and Associates, Inc.

3420 Cavalier Trail, Unit C1 Cuyahoga Falls, OH 44224-4967
Ph: (330) 926-0594 Fx: (330) 926-0765

QUOTATION

QUOTE#: 34561
PAGE: 3 OF 3
DATE: 9/8/2005

TO:

Debbie Abel, M.A., Ccc-A
Alliance Audiology
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Alliance, OH 44601

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QUOTE#: 34561
PAGE: 3 OF 3
DATE: 9/8/2005

Y2K COMPLIANCE

As a distributor/representative, Gordon N. Stowe and Associates can not certify nor accept responsibility for instrumentation manufactured by other firms as meeting Y2K compliance. However, if requested, we are able to supply a letter from the manufacturer certifying instrument Y2K compliance.

PURCHASE AGREEMENT

Customer (identified below) agrees to buy and Gordon N. Stowe & Associates, Inc. ('Vendor') agrees to sell the equipment and supplies (the 'Equipment') listed above. The purchase of the Equipment is subject to the terms and conditions described herein.
The following 'Terms and Conditions' page dated 9/1/98 is an integral part of this Agreement and the sale of all Equipment, whether sold by Vendor as a distributor or as a manufacturer representative. Acceptance of this quote/agreement may preclude, at the option of the invoicing party, use of a credit card as a form of payment.

GORDON N. STOWE & ASSOCIATES, INC:

BY: Kristin L. Wysmierski

NAME: Kristin Wysmierski

DATE: 9/8/2005

ACCEPTED BY CUSTOMER:

BY: _____
Authorized Signature

NAME: _____
Type or Print

DATE: _____

kw

Submitter : W. Robert Lee, MD **Date:** 10/10/2006

Organization : American Brachytherapy Society (ABS)

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-746-Attach-1.PDF

#

ABS American Brachytherapy Society

12100 Sunset Hills Road, Suite 130, Reston, VA 20190 703-234-4078 fax 703-435-4390

October 10, 2006

The Honorable Mark McClellan, M.D., Ph.D.
Administrator, Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P
PO Box 8010
7500 Security Boulevard
Baltimore, MD 21244-8010

Delivered via internet: http://www.cms.hhs.gov/eRulemaking/01_Overview.asp

RE: CMS-1321-P: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule for CY 2007 and Other Changes to Payment under Part B

Dear Dr. McClellan:

On behalf of the American Brachytherapy Society (ABS), we are pleased to submit comments in response to Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule for CY 2007 and other Changes to Payment under Part B.

Founded in 1978, the American Brachytherapy Society (ABS) is a nonprofit organization that seeks to provide insight and research into the use of brachytherapy in malignant and benign conditions. The organization consists of physicists, physicians, and other health care providers interested in brachytherapy.

ABS is concerned about the Relative Value Units (RVUs) assigned to brachytherapy procedures. We are encouraged by CMS' actions regarding some of the elements of the proposed practice expense methodology; however, there is still more that can be done to ensure future access for Medicare beneficiaries to brachytherapy.

ABS recommends that CMS more closely examine the impact of all 2007 Medicare Part B payment policies that impact brachytherapy procedures. Reductions in the proposed practice expense relative value units (RVUs) combined with the forecasted reductions in the annual update factor, and the Deficit Reduction Act imaging provisions could have a significant impact on the provision of radiation oncology procedures to Medicare beneficiaries in a freestanding radiation oncology center.

Deficit Reduction Act (DRA)

ABS is appreciative that the majority of radiation oncology procedures were exempted from the DRA cap on technical component payments under the Physician Fee Schedule. Brachytherapy procedures should never be considered imaging procedures.

Sustainable Growth Rate (SGR)

The proposed rule indicates that payment rates for physicians' services will be reduced by 5.1% in 2007. This reduction is due to a requirement in the statutory formula attributed to the substantial growth in overall Medicare spending in 2005. In addition, CMS anticipates further negative updates in future years.

ABS understands that CMS is required to update to the conversion factor annually based upon the SGR formula, however, we do not support reductions under the SGR system forecasted for 2007 and subsequent years. The SGR formula is directly related to the gross domestic product and does not appropriately reflect increases in health care costs. We believe that the SGR formula should not include the costs of Medicare-covered outpatient drugs and should account for the cost savings associated with new technologies.

ABS recommends that CMS replace the SGR formula with a method that allows payment updates to keep pace with increased physician practice health care costs.

Global Period for Remote Afterloading High Intensity Brachytherapy Procedures

Remote Afterloading High Intensity Brachytherapy procedures (CPT 77781-77784) are used to treat many clinical conditions. Patients usually receive multiple fractions over a one to thirty day period. Currently, the remote afterloading high intensity brachytherapy procedures have a 90-day global period. CMS proposes to assign a global period of "XXX" to all Remote Afterloading High Intensity Brachytherapy procedures.

Many patients receive multiple fractions per day making accurate reporting of remote afterloading high intensity brachytherapy procedures difficult. Each patient treatment varies based upon the type and stage of cancer being treated, making the current 90-day global period quite burdensome for almost all cases treated.

ABS agrees with CMS that the global period for CPT 77781-77784 be updated to "XXX".

HDR Brachytherapy

We would like to call special attention to the impact that reductions in two High Dose Rate (HDR) brachytherapy relative value units (RVUs) will have on the provision of brachytherapy services to Medicare beneficiaries treated in freestanding radiation oncology centers. Under the proposed practice expense methodology, two of the HDR Brachytherapy codes (77781 and 77782) are slated to be significantly reduced over the four-year transition period.

These specific HDR CPT codes (77781 and 77782) are the primary procedures reported for ovarian, breast and cervical cancer treatments. The proposed reductions may force providers and patients to resort to other cancer treatments that may not be the best treatment option for the patient, due to decreased reimbursement. Patients should have continued access to all cancer treatment options in the physician office or freestanding center.

These proposed changes in the RUVs may limit access to care for women with breast cancer. Many female beneficiaries, including the elderly and those who live a significant distance from a radiation therapy facility, cannot meet the demands of a daily treatment for 6-7 weeks. Breast brachytherapy offers a shorter treatment option for patients by reducing treatment to 5 days. By decreasing the length of a course of radiation therapy and improving quality of life for these women, healthcare providers can dramatically increase the number of women opting for brachytherapy as an alterative treatment. In order for this to happen, reimbursement for HDR brachytherapy procedures must receive adequate and appropriate payment.

ABS requests that CMS establish a threshold for reductions at a maximum of 10%. During this period of time, CMS and the RUC should re-evaluate the data that leads to these reductions.

Summary and Recommendations

Appropriate payment for radiation oncology procedures is necessary to ensure that Medicare beneficiaries will continue to have full access to high quality cancer treatment in freestanding radiation oncology centers. The effect of multiple CMS proposals on the technical component and global payment for some of the HDR brachytherapy procedures could be devastating to freestanding radiation oncology centers providing cancer care to Medicare beneficiaries.

In summary, The American Brachytherapy Society recommends that CMS:

- **Exempt brachytherapy procedures from DRA cap;**
- **Replace the SGR formula with a method that permits updates to keep pace with physician practice health care costs;**
- **Finalize the global period for CPT 77781-77784 to "XXX"; and**
- **Establish a threshold for brachytherapy reductions at a maximum of 10% per year.**

We hope that CMS will take these issues under consideration during the development of the 2007 Physician Fee Schedule Final Rule. Should CMS staff have additional questions, please contact us.

Thank you for your consideration of these important issues.

Sincerely,

W. Robert Lee, M.D., M.S.
w.robert.lee@duke.edu
President
(919) 668-7342

D. Jeffrey Demanes, M.D.
jdemanes@cetmc.com
Chairman, ABS Socioeconomics Committee
(877) 238-1437

Submitter : **Dr. Martin Schwarze** **Date: 10/10/2006**

Organization : **Cardiology Diagnostics, Ltd.**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-747-Attach-1.PDF

CMS-1321-P-747-Attach-2.PDF

October 10, 2006

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

Re: Proposed Rule; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B (Federal Register, August 22, 2006)

Dear Dr. McClellan:

On behalf of Cardiology Diagnostics, Ltd., we appreciate the opportunity to submit these comments to the Centers for Medicare & Medicaid Services ("CMS") regarding the above proposed Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B; Proposed Rule ("Proposed Rule"). We are concerned about several provisions that will impact Medicare beneficiaries' access to services in outpatient cardiac centers, particularly those related to cardiac catheterizations. Specifically, we are concerned about the payment method proposed for cardiac catheterization related procedures. The Cardiovascular Outpatient Center Alliance ("COCA"), of which we are a member, will address the CMS proposal to require standards for Independent Diagnostic Testing Facilities ("IDTFs"). Our concerns related to the payment method are outlined below.

Payment Method

Under the proposed rule CMS states that the payment for cardiac catheterization related procedures (e.g. CPT code 93510 TC, 93553 TC and 93555 TC) will be established by the Medicare carriers. The change in the payment method appears only in Addendum B, and CMS provides no explanation or justification in the body of the proposed rule for this change. We object to this approach because it is inconsistent with the overall policy of basing Medicare payment rates for physician services on a national fee schedule methodology. We are also concerned that if carrier pricing were to be implemented, the carriers would look to the values in the June 29, 2006 Notice that addressed the changes to the methodology for the development of practice expense (PE) relative value units (RVUs). Therefore, we request that CMS give serious consideration to addressing the flaws in the proposed changes to the bottom up "PE" methodology for procedures where the technical component (TC) can be billed separately. We know that developing an adequate solution will take time and, therefore, request that CMS set the 2007 relative value units for the three codes listed based on the 2006 values.

We urge CMS to use the current relative value units as the basis for determining reimbursement for these procedures rather than relying on the Medicare carriers to price these services. By doing so, CMS will be able to set a reimbursement rate that fairly reflects the costs of performing these procedures. This recommendation is supported by actual data from outpatient centers. COCA sponsored a study to estimate the costs of performing a cardiac catheterization (CPT Code 93510 TC) in an outpatient center. The study results demonstrated that the 2006 Part B physician fee schedule payment approximates the average cost of providing these services. As a result, we do not believe that a new pricing methodology is necessary.

The current relative value units result in a payment rate that is in relative parity with the payment amount hospitals receive under the hospital outpatient prospective payment system. In fact, the 2006 physician fee schedule payments for the three CPT codes included in the Ambulatory Procedure Classification ("APC") for cardiac catheterizations are 93 percent of the relevant APC rate.

Cardiac catheterizations that are billed through the Medicare physician fee schedule are performed primarily in cardiology groups and freestanding centers which are grouped into a diverse group of diagnostic testing facilities known as IDTFs.

We believe that the development of unique standards for each type of diagnostic testing facilities will facilitate the development of a consistent Medicare policy for outpatient cardiac catheterization services. The standards will provide a solution to the issue that cardiac catheterization labs faced when the national coverage determination for outpatient catheterizations was rescinded because of the change of scope in the CMS contracts with the Peer Review Organizations in January 2006.

The need to develop unique standards for each type of diagnostic testing facility provider is consistent with the observation that CMS made in the Proposed Rule regarding the practice expense for different types of remote cardiac monitoring and anticoagulation monitoring. Similar to CMS's observation that these types of IDTFs are different, we believe that cardiac catheterization centers are unique and that their cost structure and quality standards are similar regardless of whether they are performed in a cardiology practice or an independent outpatient center. The COCA cost study shows that the cost profile of outpatient cardiac centers is quite different from the average profile of all IDTFs. We believe the COCA cost analysis will be helpful to CMS as it begins to develop standards, specifically for cardiac outpatient centers because the data can be used to estimate the impact that each standard has on practice expenses. The cost study will also be helpful as CMS works to develop a practice expense RVU for cardiac catheterization procedures that reflect the resources needed to perform the service.

In summary, we have grave concerns about the use of carrier-based pricing for procedures that are offered nationwide and historically have been paid according to the physician fee schedule methodology. The carrier based pricing approach is more often used for new services where there is insufficient data on which to determine a national rate. We have previously described our concerns with the proposed 2007 PE RVUs for

the cardiac catheterization-related procedures, and, therefore, request that the 2006 rates be frozen so that payments reflect the costs of performing the procedure in the outpatient setting and are on par with the APC rate for a comparable family of cardiac catheterization-related procedures. In addition, we also note that carrier-based pricing has the potential to create disparities in beneficiary co-payment liability.

We thank you for the opportunity to describe our concerns about the proposed rule, specifically as it relates to payment for cardiac catheterization-related procedures and the development of standards for centers that perform these procedures on an outpatient basis.

Sincerely,

Cardiology Diagnostics, Ltd.
2325 Dougherty Ferry Rd, Suite 205
St. Louis, MO 63122

Martin W. Schwarze, D.O.
Gary Vlahovich, D.O.
K. Bryan Trimmer, D.O.
Marc K. Lewen, D.O.
Martin B. Ast, M.D.
George A. Williams, M.D.
Diana L. Westerfield, D.O.
Andrea K. Moyer, M.D.
Michael A. Missler, D.O.

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

Organization : **Concerned Pathologists**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See attached Microsoft Word document, which contains comments on the provisions of the proposed rule pertaining to reassignment and physician self-referral.

CMS-1321-P-748-Attach-1.DOC

CMS-1321-P
REASSIGNMENT AND PHYSICIAN SELF-REFERRAL

Concerned pathologists submit these comments in response to the amendments proposed by the Centers for Medicare & Medicaid Services ("CMS") to the reassignment and physician self-referral rules relating to diagnostic tests.[1] We commend CMS for addressing the problems associated with so-called pod laboratories ("pod labs"). Pod labs are but one example of a variety of arrangements which circumvent the Stark Act and Stark Regulations prohibitions on financial arrangements between referring physicians and persons or entities that provide pathology services. The variety of arrangements that circumvent Stark are much broader than those addressed by the proposed regulations.

We strongly urge CMS to broaden its final rules to address not just pod labs and some independent contractor arrangements, but also other arrangements which are the functional equivalent of those arrangements. CMS properly should prohibit all arrangements which provide financial incentives to referring physicians and thus violate at least the spirit of the Stark Act's prohibitions against physician self-referral. Below, we provide our comments on CMS's proposed rules and propose changes that we believe CMS should adopt to address the physician self-referral problem.

Comments on CMS's Proposal

Pathology pod labs are but one manifestation of contractual agreements between referring physicians and pathologists antithetical to the policies embodied in the Stark self-referral regulations. The Stark regulations prohibit physician referrals to entities in which the physician has a financial relationship.[2] The policies underlying these regulations ensure that physicians base their medical decisions upon quality of care considerations, not upon considerations of personal financial gain. The Stark regulations help protect the Medicare program from over utilization of services.

Relying upon exceptions to the Medicare payment reassignment[3] and Stark[4] regulations, many pathologists and physician group practices have entered into contractual relationships that run afoul of the Stark Act and regulations' underlying policies, if not their plain language. Under such contractual arrangements, pathologists reassign their Medicare payments for their professional services to referring physicians in exchange for lesser compensation. This permits the referring physicians to bill for, and profit from, the pathology tests that the physicians refer to the pathologist. Consequently, referring physicians have a financial incentive to over utilize the pathologists' services, as each referral yields the referring physician a profit.

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[1] 71 Fed. Reg. 48981 (Aug. 22, 2006).
[2] 42 C.F.R. § 411.353.
[3] 42 C.F.R. § 424.80.
[4] 42 C.F.R. § 411.355(b).

We commend CMS for recognizing "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 in the form of over utilization of services and result in higher costs to the Medicare program."[5] Yet, CMS's proposed rules do not go far enough towards prohibiting referring physicians from profiting from their ordering of pathology services. Furthermore, the proposed rules are too narrowly tailored to the phenomenon of pod labs, leaving unaddressed the larger, more fundamental problem of other structures and arrangements that result in the over utilization of Medicare services.

We agree that pod lab arrangements are particularly subject to fraud, waste and abuse. By providing referring physicians with profits from pathology, pod labs provide referring physicians with strong incentives to over utilize the pathologists' services. Thus, because pod labs exacerbate the potential for Medicare fraud and abuse inherent in contractual agreements in which referring physicians profit off of pathologists' services, we fully support CMS's initiatives to restrict pod labs' operations.

Yet, the proposed amendments' singular focus upon pod labs does not address many functionally equivalent arrangements between referring physicians and pathologists which are driven by the referring physicians' desire to profit from the work of pathologists. For example, proposed new paragraph 42 C.F.R. § 424.80(d)(3), adding new conditions for reassignment of the technical component payment of diagnostic tests services, by its terms applies only to contractual arrangements and not to employer-employee relationships.[6] This loophole allows referring physicians to hire someone as an employee and evade the new conditions in § 424.80(d)(3). Similarly, the proposed amendments to 42 C.F.R. § 411.351 continue to allow referring physicians to profit from pathologists' services as long as the facility in which the services are performed meet the more restrictive definition of "centralized building."[7]

Herein lies the weakness of CMS's proposed regulations: by singularly focusing upon the superficial characteristics of pod labs, the proposed regulations fail to address the underlying financial incentive structure exploited and exacerbated by the pod lab arrangement. CMS's proposed amendments address pod labs, as currently incarnated. The amendments do not, however, prohibit referring physicians from establishing restructured relationships with pathologists which achieve the same objectives. Specifically, a number of structures provide economic incentives to the referring physicians and are economically indistinguishable from the prohibited pod labs. The core problem which new regulatory amendments should address is not that of the pod lab, *per se*, but rather the ability of referring physicians to profit from the services performed by pathologists.

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[5] 71 Fed. Reg. at 49054.
[6] *Id.* at 49084.
[7] *Id.* at 49081.

contractual arrangement with the physician or other supplier who performed the professional component, each of the following conditions must be met:

(A) The test must be ordered by a physician that is both financially independent of the person or entity performing the test, and also financially independent of the physician or medical group performing the interpretation.

(B) The physician or medical group performing the interpretation does not see the patient.

(C) The physician or medical group billing for the interpretation must have performed the technical component of the test.

(ii) For purposes of paragraph (d)(4)(i)(A) of this section, a physician ordering the test is financially independent of the person or entity performing the test, or of the physician or medical group performing the interpretation, if the ordering physician, or a member of the ordering physician's immediate family as defined in § 411.351, receives no direct or indirect compensation based on the volume or value of referrals for the performance or interpretation of the test, as provided in § 411.352 (g) and § 411.352(j).

Amendments to 42 C.F.R.. § 411.352

In addition to the reassignment regulations, the Stark regulations should also be tightened up to preclude the "pro-forma" group practices that are thinly veiled disguises to financial relationships providing a financial benefit to referring physicians. In order to do so, we propose a new prong to the definition of "group practice", § 411.352(j), which ensures that referring physicians within a group practice cannot profit from reassigned Medicare payments for pathology services performed by members of, or physicians in, the group practice.

(j) *Special rule for allocating profits derived from pathology services.* Notwithstanding § 411.352(i), in a group practice composed of (1) Gastroenterologists, Urologists and/or Dermatologists who comprise at least seventy-five percent of the physicians in the group and (2) one or more Pathologists in the group who provide pathology services for the other members of the group practice, all of the revenues derived from pathology services shall be used exclusively to pay for the direct costs of the pathology services and compensation of the physicians performing or supervising pathology services, except that pathology may be asked to make a contribution to the overhead of the practice that does not exceed, as a percentage of net revenues, the percentage contribution to overhead made from revenues of the other specialties.

The intent of the foregoing is to establish, as part of the regulatory requirements for a qualifying group practice, a prohibition on the referring specialties from profiting from the services of pathology to which those physicians refer. Stated differently, the foregoing language, or other regulatory language with the same effect, needs to be adopted to prohibit the referring physicians from profiting from their referrals for pathology services. Referring physicians should not be able to avoid a prohibition on profiting from referrals through the creation of a "pro forma" group practice that is the functional equivalent of the pod lab. Note, we are proposing limiting the application of the rule to those specialties which have been most prominently identified as involved in pod labs and other similar financial arrangements providing them with a financial incentive for their referrals of pathology specimens.

Conclusion

We appreciate this opportunity to comment on CMS's proposed rules. While we commend CMS for taking a strong first step towards the elimination of pod labs, we respectfully request that CMS expand the scope of its rulemaking and address the more fundamental problem of contractual arrangements that allow referring physicians to profit from the Medicare services performed by pathologists.

Submitter :

Date: 10/10/2006

Organization :

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See attached

CMS-1321-P-749-Attach-1.DOC

#749

October 10, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
CMS-1512-PN
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

RE: Proposed Rule: Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B (Federal Register August 22, 2006)

Dear Mr. McClellan:

On behalf of The Heart Health Center, a medical practice consisting of seven board certified cardiologists, we appreciate the opportunity to submit these comments to the Centers for Medicare & Medicaid Service ("CMS") regarding the above proposed Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B; Proposed Rule ("Proposed Rule"). We are concerned about several provisions that will impact Medicare beneficiaries' access to services in outpatient cardiac centers, particularly those related to cardiac catheterizations. Specifically, we are concerned about the payment method proposed for cardiac catheterization related procedures. The Cardiovascular Outpatient Center Alliance ("COCA"), of which we are a member, will address the CMS proposal to require standards for Independent Diagnostic Testing Facilities ("IDTFs"). Our concerns related to the payment method are outlined below.

Payment Method

Under the proposed rule CMS states that the payment for cardiac catheterization related procedures (e.g. CPT code 93510 TC, 93553 TC and 93555 TC) will be established by the Medicare carriers. The change in the payment method appears only in Addendum B, and CMS provides no explanation or justification in the body of the proposed rule for this change. We object to this approach because it is inconsistent with the overall policy of basing Medicare payment rates for physician services on a national fee schedule methodology. We are also concerned that if carrier pricing were to be implemented, the carriers would look to the values in the June 29, 2006 Notice that addressed the changes to the methodology for the development of practice expense (PE) relative value units (RVUs). Therefore, we request that CMS give serious consideration to addressing the flaws in the proposed changes to the bottom up "PE" methodology for procedures where the technical component (TC) can be billed separately. We know that developing an adequate solution will take time and, therefore, request that CMS set the 2007 relative value units for the three codes listed based on the 2006 values.

We urge CMS to use the current relative value units as the basis for determining reimbursement for these procedures rather than relying on the Medicare carriers to price these services. By doing so, CMS will be able to set a reimbursement rate that fairly reflects the costs of performing these procedures. This recommendation is supported by actual data from outpatient centers. COCA sponsored a study to estimate the costs of performing a cardiac catheterization (CPT Code 93510 TC) in an outpatient center. The study results demonstrated that the 2006 Part B physician fee schedule payment approximates the average cost of providing these services. As a result, we do not believe that a new pricing methodology is necessary.

The current relative value units result in a payment rate that is in relative parity with the payment amount hospitals receive under the hospital outpatient prospective payment system. In fact, the 2006 physician fee schedule payments for the three CPT codes included in the Ambulatory Procedure Classification ("APC") for cardiac catheterizations are 93 percent of the relevant APC rate.

In our response to CMS' Proposed Changes to the Practice Expense Methodology (Federal Register, June 29, 2006) we outlined our concerns with the proposed changes to the PE Methodology, i.e., use of a bottom-up methodology and the elimination of the non-physician work pool. The proposed payment rates resulting from the use of the practice expense RVUs for the left heart catheterization procedure alone (CPT code 93510 TC) reduce payment levels in 2007 by 16 percent, and by 2010 make overall reductions of 53 percent. The flaws in the methodology, particularly as they relate to the cardiac catheterization procedure codes were described in general in our comment letter of August 18, 2006, and more specifically in the August 22, 2006 comment letter submitted by COCA.

Cardiac catheterizations that are billed through the Medicare physician fee schedule are performed primarily in cardiology groups and freestanding centers which are grouped into a diverse group of diagnostic testing facilities known as IDTFs.

We believe that the development of unique standards for each type of diagnostic testing facilities will facilitate the development of a consistent Medicare policy for outpatient cardiac catheterization services. The standards will provide a solution to the issue that cardiac catheterization labs faced when the national coverage determination for outpatient catheterizations was rescinded because of the change of scope in the CMS contracts with the Peer Review Organizations in January 2006.

The need to develop unique standards for each type of diagnostic testing facility provider is consistent with the observation that CMS made in the Proposed Rule regarding the practice expense for different types of remote cardiac monitoring and anticoagulation monitoring. Similar to CMS's observation that these types of IDTFs are different, we believe that cardiac catheterization centers are unique and that their cost structure and quality standards are similar regardless of whether they are performed in a cardiology practice or an independent outpatient center. The COCA cost study shows that the cost profile of outpatient cardiac centers is quite different from the average profile of all IDTFs. We believe the COCA cost analysis will be helpful to CMS as it begins to develop standards, specifically for cardiac outpatient centers because the data can be used to estimate the impact that each standard has on practice expenses. The cost study will also be helpful as CMS works to develop a practice expense RVU for cardiac catheterization procedures that reflect the resources needed to perform the service.

In summary, we have grave concerns about the use of carrier-based pricing for procedures that are offered nationwide and historically have been paid according to the physician fee schedule methodology. The carrier based pricing approach is more often used for new services where there is insufficient data on which to determine a national rate. We have previously described our concerns with the proposed 2007 PE RVUs for the cardiac catheterization-related procedures, and, therefore request that the 2006 rates be frozen so that the payments reflect the costs of performing the procedure in the outpatient setting and are on par with the APC rate for a comparable family of cardiac catheterization-related procedures. In addition, we also note that carrier-based pricing has the potential to create disparities in beneficiary co-payment liability.

We thank you for the opportunity to describe our concerns about the proposed rule, specifically as it relates to payment for cardiac catheterization-related procedures and the development of standards for centers that perform these procedures on an outpatient basis.

Sincerely,

Allen D. Soffer, M.D., F.A.C.C.

Robert G. Kopitsky, M.D., F.A.C.C.

Patricia L. Cole, M.D., F.A.C.C.

Stephen J. Pieper, M.D., F.A.C.C.

Paul A. Robiolio, M.D., F.A.C.C.

Clark R. McKenzie, M.D., F.A.C.C.

Jackie L. Grosklos, M.D., F.A.C.C.

CMS-1321-P-750

Submitter : Dr. Nancy Chornick **Date:** 10/10/2006

Organization : National Council of State Boards of Nursing

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachments

CMS-1321-P-750-Attach-1.PDF

NCSBN
National Council of State Boards of Nursing

111 E. Wacker Drive, Suite 2900
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312.525.3600
www.ncsbn.org

October 10, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P
P.O. Box 8015,
Baltimore, MD 21244-8015

Re: O. Proposal to establish criteria for National Certifying Bodies that Certify Advanced Practice Nurses

In reference to the above, I would like to bring to your attention that the National Council of State Boards of Nursing has already established criteria for national certifying bodies. There criteria have been used since 2002 for the purpose of assuring boards of nursing that APRN certification examinations can be used for regulatory purposes.

The National Council of State Boards of Nursing (NCSBN) is a not-for-profit organization whose membership comprises of the boards of nursing in the 50 states, the District of Columbia, and four United States territories, American Samoa, Guam, Northern Mariana Islands and the Virgin Islands. The purpose of the NCSBN is to provide an organization through which boards of nursing act and counsel together on matters of common interest and concern affecting the public health, safety and welfare, including the development of licensing examinations in nursing.

Most boards of nursing require certification by a national certifying body as one prerequisite for state authorization to practice as an advanced practice nurse. In this way, states may fulfill their obligation for public protection if certification programs are able to demonstrate their sufficiency for regulation purposes. Since the mid 1990s, the NCSBN has been working with national certifying bodies to assure that boards of nursing have psychometrically sound and legally defensible certification examinations that are suitable for regulatory purposes. In 2002, the NCSBN approved the *Criteria for Certification Programs*.

The criteria are based on the assumption that certification examinations that are legally defensible for regulatory purposes measure only job-related knowledge, skills, and abilities, are entry-level, require minimal level competence, are psychometrically sound, and the education of the candidate is consistent with the APRN certification examination taken. Other testing practices reflected in accepted testing standards such as no discriminatory practices, security of examination content and appropriate accommodation for disabilities were also considered during the development of the criteria.

The *Criteria for Certification Programs* are based on the above principles and reflect a complete picture of the criteria needed. The NCSBN criteria are attached.

NCSBN has compared our criteria with available APRN certification programs and determined that the following organizations meet the criteria: American Academy of Nurse Practitioners, American Nurses Credentialing Center, National Certification Corporation for Obstetric, Gynecologic and Neonatal Nursing Specialties and Critical Care Certification Corporation. It is our belief that The National Board on Certification of Hospice and Palliative Care Nurses

(NBCHPN) and the Oncology Nurses Certification Corporation do not meet the NCSBN criteria due in part to a lack of focus-specific educational programs and a narrow scope of practice not appropriate for regulation.

We believe these criteria will meet your needs and eliminate the need to develop additional criteria. I would be happy to answer any questions you may have regarding the NCSBN Criteria for Certification Programs. My direct number is 312 525-3646; email; nchornick@ncsbn.org.

Sincerely,

Nancy Chornick

Nancy Chornick, PhD, RN, CAE
Director of Practice and Credentialing

NCSBN
National Council of State Boards of Nursing

111 E. Wacker Drive, Suite 2900
Chicago, IL 60601-4277
312.525.3600
www.ncsbn.org

CRITERIA FOR EVALUATING CERTIFICATION PROGRAMS

Criteria	Elaboration
I. The program is national in the scope of its credentialing.	A. The advanced nursing practice category and standards of practice have been identified by national organizations. B. Credentialing services are available to nurses throughout the United States and its territories. C. There is a provision for public representation on the certification board. D. A nursing specialty organization that establishes standards for the nursing specialty exists. E. A tested body of knowledge related to the advanced practice nursing specialty exists. F. The certification board is an entity with organizational autonomy.
II. Conditions for taking the examination are consistent with acceptable standards of the testing community.	A. Applicants do not have to belong to an affiliated professional organization in order to apply for certification offered by the certification program. B. Eligibility criteria rationally related to competence to practice safely. C. Published criteria are enforced. D. In compliance with the American Disabilities Act. E. Sample application(s) are available. 1) Certification requirements included 2) Application procedures include: • procedures for assuring match between education and clinical experience, and APRN specialty being certified, • procedures for validating information provided by candidate, • procedures for handling omissions and discrepancies 3) Professional staff responsible for credential review and admission decisions. 4) Examination should be administered frequently enough to be accessible but not so frequently as to over-expose items. F. Periodic review of eligibility criteria and application procedures to ensure that they are fair and equitable.
III. Educational requirements are consistent with the requirements of the advanced practice specialty.	A. Current U.S. registered nurse licensure is required. B. Graduation from a graduate advanced practice education program meets the following requirements: 1) Education program offered by an accredited college or university offers a graduate degree with a concentration in the advanced nursing practice specialty the individual is seeking 2) If post-masters certificate programs are offered, they must be offered through institutions meeting criteria B.1. 3) Both direct and indirect clinical supervision must be congruent

	with current national specialty organizations and nursing accreditation guidelines 4) The curriculum includes, but is not limited to: • biological, behavioral, medical and nursing sciences relevant to practice as an APRN in the specified category; • legal, ethical and professional responsibilities of the APRN; and • supervised clinical practice relevant to the specialty of APRN 5) The curriculum meets the following criteria: • Curriculum is consistent with competencies of the specific areas of practice • Instructional track/major has a minimum of 500 supervised clinical hours overall • The supervised clinical experience is directly related to the knowledge and role of the specialty and category C. All individuals, without exception, seeking a national certification must complete a formal didactic and clinical advanced practice program meeting the above criteria.
IV. The standard methodologies used are acceptable to the testing community such as incumbent job analysis study, logical job analysis studies.	A. Exam content based on a job/task analysis. B. Job analysis studies are conducted at least every five years. C. The results of the job analysis study are published and available to the public. D. There is evidence of the content validity of the job analysis study.
V. The examination represents entry-level practice in the advanced nursing practice category.	A. Entry-level practice in the advanced practice specialty is described including the following: 1) Process 2) Frequency 3) Qualifications of the group making the determination 4) Geographic representation 5) Professional or regulatory organizations involved in the reviews
VI. The examination represents the knowledge, skills and abilities essential for the delivery of safe and effective advanced nursing care to the clients.	A. The job analysis includes activities representing knowledge, skills and abilities necessary for competent performance. B. The examination reflects the results of the job analysis study. C. Knowledge, skills and abilities, which are critical to public safety, are identified. D. The examination content is oriented to educational curriculum practice requirements and accepted standards of care.
VII. Examination items are reviewed for content validity, cultural bias and correct scoring using an established mechanism, both before use and periodically.	A. Each item is associated with a single cell of the test plan. B. Items are reviewed for currency before each use at least every three years. C. Items are reviewed by members of under-represented gender and ethnicities who are active in the field being certified. Reviewers have been trained to distinguish irrelevant cultural dependencies from knowledge necessary to safe and effective practice. Process for identifying and processing flagged items is identified. D. A statistical bias analysis is performed on all items.

	E. All items are subjected to an "unscored" use for data collection purposes before their first use as a "scored" item. F. A process to detect and eliminate bias from the test is in place. G. Reuse guidelines for items on an exam form are identified. H. Item writing and review is done by qualified individuals who represent specialties, population subgroups, etc.
VIII. Examinations are evaluated for psychometric performance.	A. Reference groups used for comparative analysis are defined.
IX. The passing standard is established using acceptable psychometric methods, and is re-evaluated periodically.	A. Passing standard is criterion-referenced.
X. Examination security is maintained through established procedures.	A. Protocols are established to maintain security related to: 1) Item development (e.g., item writers and confidentiality, how often items are re-used) 2) Maintenance of question pool 3) Printing and production process 4) Storage and transportation of examination is secure 5) Administration of examination (e.g., who administers, who checks administrators) 6) Ancillary materials (e.g., test keys, scrap materials) 7) Scoring of examination 8) Occurrence of a crisis (e.g., exam is compromised, etc)
XI. Certification is issued based upon passing the examination and meeting all other certification requirements.	A. Certification process is described, including the following: 1) Criteria for certification decisions are identified 2) The verification that passing exam results and all other requirements are met 3) Procedures are in place for appealing decisions B. There is due process for situations such as nurses denied access to the examination or nurses who have had their certification revoked. C. A mechanism is in place for communicating with candidate. D. Confidentiality of nonpublic candidate data is maintained.
XII. A retake policy is in place.	A. Failing candidates permitted to be reexamined at a future date. B. Failing candidates informed of procedures for retakes. C. Test for repeating examinees should be equivalent to the test for first time candidates. D. Repeating examinees should be expected to meet the same test performance standards as first time examinees. E. Failing candidates are given information on content areas of deficiency. F. Repeating examinees are not exposed to the same items when taking the exam previously.
XIII. Certification maintenance program, which includes review of qualifications and continued competence, is in place.	A. Certification maintenance requirements are specified (e.g., continuing education, practice, examination, etc.). B. Certification maintenance procedures include: 1) Procedures for assuring match between continued competency

	measures and APRN specialty 2) Procedures for validating information provided by candidates 3) Procedures for issuing re-certification C. Professional staff oversee credential review. D. Certification maintenance is required a minimum of every 5 years.
XIV. Mechanisms are in place for communication to boards of nursing for timely verification of an individual's certification status, changes in certification status, and changes in the certification program, including qualifications, test plan and scope of practice.	A. Communication mechanisms address: 1) Permission obtained from candidates to share information regarding the certification process 2) Procedures to provide verification of certification to Boards of Nursing 3) Procedures for notifying Boards of Nursing regarding changes of certification status 4) Procedures for notification of changes in certification programs (qualifications, test plan or scope of practice) to Boards of Nursing
XV. An evaluation process is in place to provide quality assurance in its certification program.	A. Internal review panels are used to establish quality assurance procedures. 1) Composition of these groups (by title or area of expertise) is described 2) Procedures are reviewed 3) Frequency of review B. Procedures are in place to insure adherence to established QA policy and procedures.

Submitter : Leticia DeWilde **Date:** 10/10/2006

Organization : American Cancer Society

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-751-Attach-1.DOC

#75

October 10, 2006

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

RE: CMS-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; Proposed Rule

Dear Dr. McClellan:

On behalf of the American Cancer Society ("the Society") and its millions of volunteers and supporters, we respectfully submit the following comments for your consideration regarding the Centers for Medicare & Medicaid Services' (CMS') revisions to payment policies under the Physician Fee Schedule (PFS) for Calendar Year (CY) 2007, CMS-1321-P, as published in the Federal Register on August 22, 2006.

As you may know, cancer is a disease that disproportionately affects the elderly—according to the Society's 2006 Facts & Figures, more than 60 percent of all new cancer diagnoses occur in the elderly population. As the nationwide voluntary health organization committed to eliminating cancer as a major health problem, the American Cancer Society has a particular interest in ensuring that our nation's seniors have access to high quality cancer prevention, early detection, and treatment tools through the Medicare program. Given the importance of outpatient services to cancer patients, the Society appreciates the opportunity to provide you with comments on the PFS and looks forward to working with CMS to strengthen the Medicare program.

Summary

The American Cancer Society applauds several of the changes proposed in the PFS. We are very pleased that the proposed rule includes an exception from the Part B annual deductible for colorectal cancer screenings. Among our legislative efforts, we have worked to eliminate cost-sharing for mammography and colonoscopy, as well as extend the six-month timeframe allowed for a "Welcome to Medicare" Visit. We are also pleased that CMS will be taking further steps to increase health information transparency. We would be very interested in working with CMS on its transparency project and we stand ready to work with you in spreading the word about the important policy change in excepting colorectal cancer screenings from the annual deductible. However, the Society is very concerned about the potential detrimental effect on the speed of use and access to services that will be caused by the many reductions in payment proposed in this regulation.

Proposed Physician Fee Schedule Changes

National Government Relations Office
901 E Street, NW, Suite 500, Washington, DC 20004 t) 202.661.5700 f) 202.661.5750

Provisions

The American Cancer Society is committed to ensuring that Medicare beneficiaries have access to necessary cancer screenings and quality care. The Society is concerned that the 5.1 percent reduction in payments to physicians, combined with the five-year review of work relative value units and the new practice expense methodology (described in a separate proposed notice published on June 29, 2006), and the proposed adjustments for payments to imaging services under the Deficit Reduction Act of 2005 (DRA), could diminish Medicare beneficiaries' access to quality care. Specifically, we are concerned that the proposed payment reductions may limit or delay access to preventive services and diagnostic procedures critical to their receiving optimal care. We ask that CMS carefully monitor and evaluate the effects on access of any final changes.

We are particularly troubled by the cuts to imaging services under Medicare. For example, while the payments for all imaging services are being reduced, screening mammograms (CPT/HCPCS 76092) and digital screening mammograms (CPT/HCPCS G0202) are being cut by nearly seven dollars. Similarly, the combined impact of these proposed reductions on some relevant physician specialties indicates that Radiology will see a 16 percent reduction in reimbursement and Radiation Oncology will see a seven percent reduction. The Society is concerned that reimbursement for mammography services may be insufficient to cover the costs for many providers and that further disincentives through reductions in payments will increase delays or reduce access to breast cancer screening for women by encouraging sites to do fewer procedures and train fewer skilled mammographers.

In addition, the Society is concerned with the effects that these reductions will have on such important services as the "Welcome to Medicare" Visit (initial preventive exam, CPT/HCPCS G0344), which currently has a low utilization rate of about two percent. We are afraid that further cuts in payments for preventive services and cancer screenings (e.g., the rule proposes a more than 10 dollar cut for screening colonoscopies for high risk individuals, G0105) will have serious consequences on beneficiary health.

The Society has expressed concerns in the past that the payment for the "Welcome to Medicare Visit" may be insufficient to compensate physicians for the services provided. We are very concerned that the proposed payment may not adequately compensate physicians for their time, and result in visits that fail to include all of the appropriate education, counseling, and referrals. The Society urges you to reconsider the proposed reductions in payment for this benefit and other life-saving cancer screenings, and raise them to levels that will not act as disincentives for providers and make them unavailable to patients.

DRA Proposals

Payment for Multiple Imaging Procedures for 2007

The American Cancer Society is pleased that CMS has proposed to maintain the multiple imaging payment reduction at its current 25 percent level. However, we continue to be concerned with the impact of the multiple imaging procedure reductions on imaging procedures. In the Final PFS for CY 2006, CMS stated that it would phase-in the proposed 50 percent multiple procedure reduction for the technical component (TC) of selected imaging services belonging to one of 11 imaging families over two years, proposing a 25 percent reduction in 2006 and reducing the payments by 50 percent thereafter beginning in 2007. CMS currently makes full payment for the highest priced procedure and reduced payments for each additional procedure by 25 percent, when more than one procedure from the same imaging family is performed during the same session on the same day.

We are concerned that such reductions, coupled with the other proposed PFS payment reductions, could create a barrier to access for many patients needing imaging procedures.
Cancer patients frequently use imaging procedures both in terms of staging their disease and in monitoring the efficacy of cancer treatment, and the procedure is increasingly used by some women at high risk for breast cancer in conjunction with a mammogram. Cutting reimbursement for imaging procedures performed in the same session may well create a barrier to access for many patients if reimbursement rates are too low. Patients may be asked to revisit their providers for sequential procedures, not only delaying their definitive diagnosis and subsequent treatment, but at potentially great personal emotional and financial inconvenience. Therefore, the Society plans to closely monitor the impact of these reductions on patients' access to care.

Section 5113—Proposed Non-Application of the Part B Deductible for Colorectal Cancer Screening Tests

We are very pleased that the proposed rule includes an exception from the Part B annual deductible for colorectal cancer screenings. The Society has always been concerned that such financial requirements placed on patients, including payments made towards a deductible, prevent them from accessing valuable benefits. Since studies show that cost-sharing has the effect of reducing the probability of patients using preventive services, we will continue to advocate for the elimination of cost-sharing for all cancer screenings.

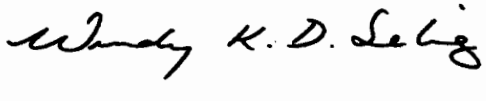
Health Care Information Transparency Initiative

The Society is pleased that CMS will be taking further steps to increase health information transparency. We agree that consumers can benefit from access to useful information on the price and quality of health care items and services. We would be very interested in working with CMS on its transparency project and receiving the health care data gathered to measure cost and quality of care information at the physician and hospital levels.

Conclusion

This proposed physician fee schedule has the potential to affect millions of Medicare beneficiaries diagnosed and living with cancer. We appreciate the hard work that you and your agency have put into implementing the many provisions of this proposed rule. We want to take this opportunity to thank you for all your hard work and dedication in the implementation of many other regulations, demonstration programs, projects, and policies that had a tremendous impact on patients diagnosed and living with cancer. It was a pleasure working with you and stand ready to work with the incoming Acting Administrator to improve the health outcomes and reduce the cancer burden among Medicare beneficiaries.

Respectfully,



Daniel E. Smith
National Vice President
Federal and State Government Relations

Wendy K. D. Selig
Vice President
Legislative Affairs

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.

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.

Submitter : Mrs. Deborah McNeilance **Date:** 10/10/2006

Organization : Clinical Oncology Associates

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Before the Amgen Portfolio contract was set into place, we were struggling with only having one choice of medication to treat our patients. The cost of Procrit combined with Neulasta caused us to be constantly underwater. Introducing the Amgen portfolio has created a choice for our practice. Because Aranesp is only given 2 times a week (along with Neulasta) versus Procrit once a week we have been able to see more patients without adding additional staff. The patients also appreciate the fact they do not have to come to the office every day (with Neupogen) or every week (with Procrit). This has also reduced the expense through Medicare as the EM charges are reduced to every two weeks versus once a week or every day. In the event our practice chooses to purchase a greater quantity of Aranesp or Neulasta we have the opportunity to earn extra rebates which help offset some of the loss we take on other drugs which are currently in the negative with regard to reimbursement. Our clinic is almost 50% medicare population. In light of this, it has been a constant battle to try to stay afloat and survive the constant reimbursement reductions. There are so many supplies and services we cannot bill for and thus take a loss on. With the Amgen portfolio we can have an opportunity to try to make up some of the loss.

There have been times when a patient reacts better to Procrit versus Aranesp, therefore, we give the patient Procrit. It is a good thing to have a choice.

Because the drug of choice can change with any given patient, it is a concern to me that CMS would take for granted most practices are receiving a discount or rebate and factor this into the ASP system. This is not always the case and the reimbursement is so slim already I fear this change would cause some practices to lose their choice of drug and in some cases could drive physicians out of business. We cannot keep enduring constant cut backs and still provide optimal patient care. Most practices can hardly afford to keep adequate staff and are basically buying drug from day to day to keep their operations afloat. CMS needs to recognize there has to be fair compensation for services. Especially in Michigan, we are all struggling to keep our practices viable. CMS needs to allow proper reimbursement and recognize programs such as the Amgen portfolio not only helps the practice with choice of treatment and some discount to help in other areas but it also helps CMS. You are ultimately paying less for services rendered.

It is interesting that for a long time Ortho Biotech marketed the only growth factor drug and did not offer many discounts on their drug. Now that Aranesp is a choice I have seen huge reductions and rebates on Procrit. Again, they recognize the drug of choice is different for every patient. They also recognize the practices are suffering because of constant reimbursement cut backs. It it time CMS realized physicians cannot practice medicine when they are making zero profit and sometimes falling to the red. We have to be able to pay our bills and care for our patients. Please allow programs such as the Amgen portfolio help the practices survive these very difficult times - for the patient's sake.

Submitter : **Ms. Christine Filipovich** **Date: 10/10/2006**

Organization : **National Asocition of Clinical Nurse Specialists**

Category : **Nurse Practitioner**

Issue Areas/Comments

Background

Background

See attachment; Comments related to clinical nurse specialists

GENERAL

GENERAL

See attachment

Impact

Impact

October 10, 2006

ATTN: CMS-1321-P
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8015
Baltimore, MD 21244-8015

RE: Federal Register 71 FR 48982, August 22, 2006. 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. Comments on page 49065: O. Proposal to Establish Criteria for National Certifying Bodies That Certify Advanced Practice Nurses.

Dear Sir/Madam:

The National Association of Clinical Nurse Specialists (NACNS) was founded in 1995 to enhance and promote the unique, high value contribution that the clinical nurse specialist brings to the health care system. NACNS policies and services are designed to meet the needs of the over 65,000 clinical nurse specialists in the United States. NACNS is pleased to provide comments on Federal Register 71 FR 48982, August 22, 2006 proposed rulemaking, specifically O. Proposal to Establish Criteria for National Certifying Bodies That Certify Advanced Practice Nurses, found on page 49065.

Clinical Nurse Specialists (CNSs) have existed for over 50 years and serve in critical health care roles. Advanced practice registered nurses (APRNs) play a vital role in the provision of primary and tertiary care to large segments of the U.S. population. Of the different advanced practice nursing roles, the CNS roles continue to evolve with separate skills, education, training, licensure and credentialing. Increasingly, with the growth of health care needs in society, and the looming health professional shortages, it is anticipated that the role of the CNS will expand and grow to meet societal health care delivery demands.

NACNS appreciates the fact that the Centers for Medicare & Medicaid Services (CMS) does not intend to overly restrict program requirements so that CNSs who specialize in areas of practice other than those certified by the American Nurses Credentialing Center (ANCC) are restricted from participating under the CNS benefit and from rendering care to patients in need of specialized services. (December 31, 2002 final rule) NACNS also understands the need for CMS to set criteria to recognize national certifying bodies that certify advanced practice nurses.

NACNS appreciates the need for CMS to ensure that Medicare and Medicaid recipients receive care from qualified, credentialed providers; and therefore, we recommend that:
CMS consider adopting a model that recognizes national certifying bodies that certify advanced practice nurses. Entities that certify advanced practice nurses would be recognized by CMS if they are credentialed by the National Commission for Certifying Agencies (NCCA) or the American Board of Nursing Specialties (ABNS). These organizations have developed consistent, national policies and procedures for recognizing certifying examinations that adhere to their nationally establish standards.

Thank you in advance for the opportunity to provide comments about this proposed rulemaking. If you have any questions or concerns, do not hesitate to contact our Executive Director, Christine Filipovich at (717) 234-6799.

Sincerely,

Kelly A. Goudreau, DSN, RN, CNS
President

Submitter : Mrs. Janice Ryba **Date:** 10/10/2006

Organization : Community Hospital

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Contact Person:
Janice L. Ryba
Divison Director, Regulatory & Rehabilitative Services
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Munster, IN 46321
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jryba@comhs.org

CMS-1321-P-755-Attach-1.DOC

#75

Saint Louis University Hospital

October 9, 2006

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

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

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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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.

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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.

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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).

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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.

<u>Historical Precedent – Gamma Knife New Technology Codes</u>

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,

Damon R. Harbison
Saint Louis University Hospital
Radiation Medicine and CyberKnife Program
3635 Vista Ave.
Saint Louis, MO 63110

Submitter : Mr. Rick Davis **Date:** 10/10/2006

Organization : Palm Coast Imaging

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

The federal government would serve itself more efficiently by closing the loophole in Stark II pertaining to the exception for in-office ancillary services. More specifically, medical imaging and outlawing time lease arrangements. Case in point: A physician who has two office locations in Ft. Myers, FL., one next to our imaging center (IDTF) and one elsewhere has not referred two CAT scan (CT) patients to us in any given week within the past two years. However, he recently installed CT in his other office location and now boasts of doing 40 to 50 CT s per week. Another despicable act witnessed was when a physician put her own pocket book ahead of the concerns of her patient. A highly claustrophobic patient came to us as we utilize an advance open MRI scanner. The patient begged the physician to have her scan at our facility, but the physician refused and insisted the patient be scanned in a closed MRI unit that her group leases time on. The patient was extremely upset and we suggested that she report this to her insurance company. These lease time deals were constructed purely to circumvent the Stark law whereby the imaging equipment is not located in the physician s office yet they pump their patients through these centers and bill for the services as if it were performed in their offices. Another case in point: A local Neurologist would not send his patients to this older, open MRI scanner in town because of its poor image quality. That was, until he purchased the MRI center, then it became fine for all of his patients to be scanned in. Reducing the reimbursements will not prevent physicians from increasing their utilizations when the money goes directly into their pockets. Many install old antiquated equipment to minimize overhead and to achieve cash flow sooner. Physician offices with medical imaging equipment are not regulated, can operate without a radiologist on site and they don t have to employ certified technologists. The same Technologist who is not certified to perform exams in our IDTF can and does in the medical practice next door and the government pays for these tests. Why the double standard, it is a sad state of affairs when the federal government automatically assumes that by not being a physician you are more likely to be involved with fraud when in fact the direct opposite is most definitely occurring. IDTF s do not have their own patient base to refer to it s self. To survive as an IDTF one must provide a better service for patients and their physicians so that the reputable physicians will refer to our imaging center. As an IDTF we must conform to a host of stringent laws and regulations set forth by federal and state government. At a minimum, all imaging entities should be regulated. The regulations alone would deter most medical doctors from implementing in-office medical imaging for the sole purpose of lining their pockets. When I have tried to educate physicians to the laws and regulations, I have been met with statements such as the government is too involved with homeland security to worry about me padding my Medicare charges . We run a tight ship, comply with all regulations and never involve ourselves in lease deals or other gray areas no matter how many times we are approached by physicians. If the federal government were truly interested in medical imaging cost containment they would readdress and close the loophole in Stark II. causing medical imaging to be performed by qualified, regulated and accredited facilities that do not and cannot self refer by virtue of not having their own patient base. The patients deserve the highest level of quality and care.

Guillermo Ferrer, MD. FACS
Northeast Surgical Group, LLP
8 Brentwood Drive Suite A
Ithaca, NY 14850

Impact

Impact

See General Comment below

Provisions of the Proposed Rule

Provisions of the Proposed Rule

See General Comment below

Submitter : Mr. Damon Harbison **Date:** 10/10/2006

Organization : Saint Louis University Hospital

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-757-Attach-1.DOC

CMS-1321-P-757-Attach-2.DOC

Saint Louis University Hospital

October 9, 2006

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

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

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.

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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,

Damon R. Harbison
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Submitter : Dr. Guillermo Ferrer **Date:** 10/10/2006

Organization : Dr. Guillermo Ferrer

Category : Physician

Issue Areas/Comments

Background

Background

The revisions as proposed will have a negative impact on the Medicare population who suffer from venous disease. The reduction of the reimbursement rates will ultimately limit access to physicians who perform these treatments which address venous disease. This is a quality of health and quality of life issue. People who suffer from venous disease have pain and difficulty standing, walking. Many patients can and do develope ulcers which cost thousands of dollars to treat. Current technology for treating venous disease includes laser or radio frequency laser ablation. Without treatment the ulcers will not heal and patients will continue to require far more expensive treatment at wound care facilities or primary care offices only to have the ulcer reopen. Ongoing treatment of the symptoms will not cure the underlying problem and the ultimate costs will be greater than the actual procedure costs to correct this condition.

GENERAL

GENERAL

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:

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

Thc costs of running a medical practice including salaries, utilities, malpractice insurance, and medical supplies consistently rise as the reimbursement rates continue to fall. How can we as physicians continue to work in an environment where it has become increasingly difficult to provide these neccssary services to patients?

Not only have malpractice insurance rates for physicians risen 30% per but the malpractice rates for Physician Assistants have doubled in the last year. Of course you are painfully aware of the rise in utility bills as the cost of oil rises. The cost of gasoline, which has hovers around $3.00 per gallon, has a dire effect, especially on our practice. In order to address the elderly population in the rural areas of upstate New York, our practicc including doctors, nurses and support staff travels to outlaying offices in Syracuse, Vestal and Horseheads, New York every week. How can we continue to help our elderly if we can not pay even our basis expenses?

As you know, the 2007 Medicare Physician Fee Schedule is already scheduled for a 5.1% across the board cut in reimbursement. Additionally, therc arc proposcd 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 incrcased to this same level.

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

Respectfully submitted,

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Impact

Impact

See General Comment below

Provisions of the Proposed Rule

Provisions of the Proposed Rule

See General Comment below