

Submitter : Dr. Pacita Colanta
Organization : Colanta Hematology & Oncology Center
Category : Physician

Date: 10/10/2006

Issue Areas/Comments

GENERAL

GENERAL

Dear Sirs, I am writing to express my concern regarding changes to the ASP calculation system. Any reduction in ASP further erodes the likelihood of future survivability of private oncology practices. Current media representation of gouging physicians and drug companies does not reflect the tough environment in medical oncology today. I am part of a three physician group that serves Hudson County, New Jersey. Over 75% of our practice serves Medicare patients in the Bayonne & Jersey City area. As cancer becomes more of a chronic treatable condition, the ability of private oncology practices to survive is important to the community we serve. Recent Medicare reforms have forced us to reassess our business models and our corporate structure allows us the economies of scale and efficiencies that CMS desires. In this environment, it is important for our practice to know that ASP reimbursement reflects prices actually found in the marketplace. It is important that ASP calculations reflect the regional differences in not just price but in the cost of staying open everyday. Please do not impose theoretical factors or calculations in computing ASP prices. The Amgen Portfolio Contract does not unduly bind our practice, but it has been a useful tool in gaining discounts not normally available to us. Our growing oncology practice and infusion center has both easily and readily adapted Aranesp in the use with the new chemotherapy regimens. We remain Procrit users and we find appropriate uses for both agents. Amgen does not restrict our ability to buy other drugs. We have in the past used a Procrit/Neulasta combination, forsaking any rebates from Amgen in favor of Procrit rebates. We are free to explore this avenue again if our physicians see it as medically needed. I am concerned with any action on your part that will further diminish drug reimbursements related to chemotherapy. We should be wary of following the road that has led to the same consequences of the OB/GYN field. I do not see the Amgen contract as an impediment to our practice and urge you to maintain or increase ASP values.

Submitter : Mr. Michael Parini
Organization : Pfizer Inc
Category : Drug Industry

Date: 10/10/2006

Issue Areas/Comments

Background

Background
See attachment

GENERAL

GENERAL
See attachment

Impact

Impact
See attachment

Provisions of the Proposed Rule

Provisions of the Proposed Rule
See attachment

CMS-1321-P-941-Attach-1.PDF

Pfizer Inc
235 East 42nd Street
New York, NY 10017-5755



October 10, 2006

BY ELECTRONIC DELIVERY

Honorable Mark B. McClellan
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 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 Policy Under Part B

Dear Administrator McClellan:

I am writing on behalf of Pfizer Inc, a research-based, global pharmaceutical company dedicated to the discovery and development of innovative medicines and treatments that improve the quality of life of people around the world. We appreciate the opportunity to comment on the Physician Fee Schedule Proposed Rule,¹ and look forward to working with the Centers for Medicare & Medicaid Services (CMS) to ensure that the final rule protects patient access to needed medicines, promotes high quality healthcare, and improves health outcomes.

¹ 71 Fed. Reg. 48,981 (Aug. 22, 2006).

I. General Comments

As described below, Pfizer is very concerned about the proposed reductions in Medicare payments to physicians in the Proposed Rule and the potential for these reductions to impede access to quality health care. We urge CMS to consult carefully with the Congress to ensure that the impact of these proposed changes on beneficiary access is appropriately recognized by lawmakers. We also appreciate CMS' efforts through the Proposed Rule to solicit additional comments on the calculation and submission of average sales price (ASP) data, now that the industry has had experience with the ASP reporting requirements for almost two years. Because the ASP methodology determines payment for most drugs and biologicals reimbursed under Medicare Part B, even minor changes in the methodology can have a significant impact on patient access, and, thus should be considered very carefully. We comment specifically below on the issues of bona fide service fees, the estimation methodology for lagged exempted sales, and widely available market price (WAMP) determinations.

II. Reductions in Physician Payments

As set out in the Proposed Rule, payment rates for physicians are projected to decrease by 5.1 percent in 2007 by application of the statutory sustainable growth rate (SGR) formula.² As CMS is aware, the SGR is a complex formula, introduced in 1997, that sets a target amount of

² *Id.* at 49,077.

spending for physician services provided under Part B.³ Under the SGR formula, CMS sets expenditure targets by applying a growth rate to spending during a base period, and makes an annual adjustment to payment rates designed to bring actual spending in line with the targets.⁴ The growth rate is comprised of four components: inflation in the prices of goods and services used by physicians' practices and the prices that Medicare pays for "incident-to" services (such as physician-administered drugs), as measured by the Medicare Economic Index; changes in Medicare enrollment; changes in the real gross domestic product (GDP); and the impact on spending of changes in relevant law or regulations (such as coverage for new services).⁵

The third prong of this mechanism -- changes in the GDP -- has been widely criticized because it is designed to measure increases in the volume and intensity of Medicare physician services and uses as a proxy for these increases the growth rate for the national economy. Because the growth in physician services has outstripped the national rate of growth in recent years, this formula virtually ensures a negative adjustment to payment rates to bring spending in line with the targets. Specifically, every year since 2002, application of the SGR formula has resulted in a proposed reduction in payment rates. Beginning in 2003, Congress has stepped in every year to prevent these reductions from taking effect.

³ 42 U.S.C. 1935w-4(f).

⁴ *Id.*

⁵ 42 U.S.C. 1935w-4(f)(2).

While we recognize that CMS does not have the authority to change the SGR formula, we urge the agency to communicate to Congress, as it considers revisions to the SGR adjustment later this year, the potential impact of the proposed reduction on beneficiary access to health care. Pfizer is concerned that this adjustment, together with the changes to the physician work and practice expense relative value units (RVUs) that CMS proposed earlier this year,⁶ could impede Medicare beneficiaries' access to quality care by making it economically unfeasible for some physicians to continue serving Medicare patients or providing the current level of services to such patients. In a recent analysis, the Congressional Budget Office forecasted that some physicians will likely respond to continuing reductions in payment rates by "declining to participate in the Medicare program."⁷ This could also result in an overall increase in Medicare costs if physicians are forced to send their Medicare patients to the hospital for treatment.

With respect to proposed revisions to physician payment rates this year that are within CMS's authority to change -- i.e., the proposed changes to the physician work and practice expense RVUs -- we urge the agency to carefully evaluate the combined effects of these adjustments and the contemplated SGR adjustment before implementing the former proposals. It may be that certain physician specialties will be particularly disadvantaged by these various

⁶ 71 Fed. Reg. 37,169 (June 29, 2006).

⁷ Congressional Budget Office, "The Sustainable Growth Rate Formula for Setting Medicare's Physician Payment Rates," Economic and Budget Issue Brief (Sept. 6, 2006) at 3.

changes. If so, we urge CMS to make appropriate revisions in the RVU proposals, or, at a minimum, delay the issuance of the final rule until Congress has addressed the SGR adjustment.

III. ASP Issues

A. Fees Not Considered Price Concessions

We support CMS' decision to define "bona fide services fees" that should not be considered price concessions, and fully concur with the first two criteria that, to be excludable, the fee must: (i) be for bona fide services; and (ii) not exceed fair market value. However, the third proposed criteria, that "the fee must not be passed on, in whole or part, to downstream customers," would be impossible for manufacturers to incorporate in their ASP calculation and reporting.

As a practical matter, manufacturers have no control over, or knowledge of, GPOs' arrangements with their members. As a result, manufacturers are not in a position to determine whether a GPO passes any portion of its fees on to its members (i.e., downstream customers). Under these circumstances, we urge CMS to clarify that, so long as the fees paid by a manufacturer to the GPO are fair market value for bona fide services, they should not be considered price concessions for ASP purposes. Ultimately, the price comparisons with WAMP and average manufacturer price (AMP) mandated by the statute will likely identify instances

where other forms of price concessions are not being captured in the ASP calculations and trigger the appropriate remedy.

B. Estimation Methodology for Lagged Exempted Sales

Manufacturers are required to exclude from the ASP calculation sales that are exempt from Medicaid Best Price.⁸ However, it is currently unclear what methodology should be used for recognizing exempted sales that become known on a delayed basis (i.e., because of chargebacks and rebates). CMS has now proposed using a 12-month rolling average methodology for estimating exempted sales that become known on a lagged basis.⁹ We share CMS' concern that, under current practice, there is potential for quarter-to-quarter variations in ASP resulting from lack of application of a consistent methodology. Therefore, although we do not necessarily endorse the particular method proposed by CMS, we support a uniform approach that will provide for consistency across the board. For this reason, we request that CMS finalize a methodology for recognizing delayed sales that will apply uniformly to all ASP calculations.

C. Widely Available Market Prices and the AMP Threshold

Under current law, if the HHS Office of Inspector General finds that the ASP for a drug or biological exceeds the WAMP or the AMP by a predetermined threshold, he is authorized to

⁸ 42 U.S.C. § 1395w-3a(c)(2).

⁹ 71 Fed. Reg. at 49,002.

substitute a lower payment rate for 106% of ASP.¹⁰ This threshold was set at 5% in 2005 and 2006. For 2007, CMS is proposing to continue using 5% as the threshold, and has requested comments on, among other things, the appropriate timing and frequency of the ASP and WAMP comparisons.¹¹

Pfizer supports CMS' proposal to continue the 5% threshold for exercising the Secretary's authority to compare ASP with WAMP. We also commend CMS for requesting comment on important operational issues relating to these price comparisons, and believe it would be premature for CMS to exercise this authority until these operational issues have been resolved. One critical operational issue is that CMS should have reliable and valid data indicating that the ASP for a drug exceeds its WAMP or AMP by more than the threshold percentage on an ongoing basis before considering whether it may be appropriate to disregard the ASP and substitute a payment rate below 106% of the ASP. In this regard, we believe it is essential that the OIG survey incorporate more than one quarter of data before making a rate substitution. Obviously, there are a myriad of factors that can contribute to a one-quarter ASP aberration. Thus, the Secretary should exercise his discretion to lower the payment rate only upon a finding that ASP is systematically exceeding WAMP or AMP by more than the threshold for a sustained period.

¹⁰ 42. U.S.C. § 1395w-3a(d)(3).

¹¹ 71 Fed. Reg. at 49,004.

We also believe that CMS should encourage the OIG to develop a study methodology for conducting these price comparisons through the notice and comment process, as Congress envisioned in directing the OIG to carry out these studies.¹² To appropriately identify and address operational issues such as the one discussed above, the OIG should publish its general methodologies for carrying out these studies and solicit stakeholder comments about potential refinements that could help to improve the reliability of the study results.

IV. Conclusion

We appreciate the opportunity to comment on the important issues raised by the Proposed Rule and urge you to address these concerns in a manner that fully protects patient access to necessary medications and promotes high quality healthcare. Please let us know if we can provide you with any additional information or other assistance.

¹² See H.R. Conf. Rep. 108-391 (2003).

Submitter : Ms. Dawn Hopkins
Organization : Society of Interventional Radiology
Category : Health Care Professional or Association

Date: 10/10/2006

Issue Areas/Comments

GENERAL

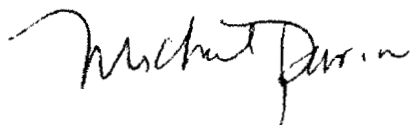
GENERAL

See Attachment

CMS-1321-P-942-Attach-1.PDF

Honorable Mark B. McClellan
October 10, 2006
Page 9

Sincerely,

A handwritten signature in black ink, appearing to read "Michael J. Parini". The signature is written in a cursive style with a large initial "M" and a long, sweeping underline.

Michael J. Parini
Sr. Corporate Counsel



11-942

Society of Interventional Radiology
3975 Fair Ridge Drive
Suite 400 North
Fairfax, VA 220330
(703) 691-1805, www.SIRweb.org

October 10, 2006

Mark McClellan, MD, PhD
Administrator
Leslie Norwalk
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1512-PN
75000 Security Boulevard
Baltimore, MD 21244-1850

Submitted electronically via CMS Web site with endorsed copy mailed this day

RE: "Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B [CMS-1321-P]; proposed rule - including comment on the *DRA PROPOSALS-Defining Imaging Subject to the DRA Reimbursement Cap* "

Dear Administrator McClellan/Norwalk:

The Society of Interventional Radiology (SIR) is a physician association with over 4,000 members that represents the majority of practicing vascular and interventional radiologists in the United States. SIR offers the following general and specific comments:

SIR commends CMS for providing coverage for ultrasound screening for Abdominal Aortic Aneurysm (AAA). Additionally, SIR appreciates the prompt update to the price of the vertebroplasty kit; reflective of diligence work of CMS staff responsible for ensuring the expansion and maintenance of accurate direct practice expense inputs.

SIR remains very concerned regarding the impending cuts to reimbursement for freestanding interventional radiology procedures provided in the overall efficient and cost-savings non-facility setting resulting from both the Deficit Reduction Act (DRA) reimbursement cap on imaging services and the severe reductions in reimbursement for many interventional radiology services and procedures resulting from an absence of non-facility practice expense input data. The comments contained here in, provide guidance to more accurately define "imaging" subject to the DRA imaging reimbursement cap and we propose that for those codes lacking direct inputs for the non-facility setting, we implore CMS to designate the non-facility practice expense (PE) reimbursement rate as "carrier price" with instruction provided to carriers that the facility PE RVU is the minimum reimbursement rate allowed and that every reasonable consideration should be made to requests to establish an accurate and fair non-facility PE RVU at the local level.

Ultrasound Screening for Abdominal Aortic Aneurysm (AAA)

SIR commends CMS for supporting coverage and reimbursement for ultrasound screening for Abdominal Aortic Aneurysm. We look forward to working with CMS in the development of a National Coverage Determination providing clear guidance regarding these new Medicare beneficiary benefit. We suggest that CMS mandate that sites providing this new benefit have

certification from either the ICAVL (Intersocietal Commission for the Accreditation of Vascular Laboratories) and/or ACR (American College of Radiology). We additionally recommend that CMS includes hard copy archival of images and separate report of the screening study as required for all imaging examinations as a required attributes of this examination. Ultrasound screening for AAA should be no less stringently specified than screening for breast cancer by mammography.

Definition of Imaging Subject to DRA Reimbursement Cap- *“Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B [CMS-1321-P]; proposed rule; DRA PROPOSALS-Defining Imaging Subject to the DRA Reimbursement Cap”*

For purposes of defining imaging services subject to the technical component payment cap of the lesser of the HOPPS APC rate or technical component Physician Fee Schedule reimbursement rate by the DRA, SIR finds that *imaging should be defined as the use of noninvasive techniques to image all parts of the body and thereby diagnose an array of medical conditions*. These techniques include the use of ionizing radiation (x-rays and CT scans), Magnetic Resonance Imaging, ultrasound and scans obtained after the injection of radio nucleotides (bone scans, PET imaging etc).

Another type of distinctly different "imaging" is the use of real-time, imaging guidance to guide interventions such as percutaneous angioplasty or hepatic embolization. In these types of procedures, imaging is essential in that it is used to guide the placement of catheters, balloons, stents, and other medical devices. Such imaging would never be provided in the absence of an intervention and without this type of imaging only open surgical procedures would be possible. Imaging provided in support of the performance of an intervention, replacing open surgical procedures, innately provides cost savings to the healthcare system and SIR does not believe that this type of real-time, imaging guidance was the intended focus of the DRA imaging reimbursement cap. These imaging guidance services are differentiated within CPT by the inclusion of the nomenclature "radiological supervision and interpretation" or "imaging supervision and interpretation" within the code descriptors and SIR asserts that these services are not subject to the DRA reimbursement cap.

Concerns with Undeveloped Non-Facility Practice Expense Inputs for Many Interventional Radiology Services and Procedures

SIR reiterates concerns raised in our earlier comments to CMS regarding the "PRACTICE EXPENSE – Medicare Program; Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology [CMS-1512-PN]" regarding the substantial decreases to non-facility reimbursement for many interventional radiology services and procedures resulting from undeveloped non-facility direct practice expense inputs including supplies, equipment and non-physician clinical staff time.

Request to have direct PE inputs developed and reviewed for a handful of these codes (stent placement, renal Bx, and fallopian tube occlusion) was made to the RBRVS Update Committee (RUC). The time frame afforded and sheer magnitude of interventional radiology codes, which span the entire gamete of CPT, requiring the development of direct PE inputs did not allow for initial identification of all codes lacking inputs and due to the amount of work associated with the development of practice expense input recommendations. We were not able to bring all of these codes forward for review by the RUC-PERC in the current cycle. Additionally, for the handful of codes that were recently brought forward, the RUC elected not to act; requesting that these PE inputs be considered at the next RUC meeting in February of 2007. We respectfully request that

Society of Interventional Radiology

CMS support the ongoing development of direct non-facility PE inputs for codes missing this data throughout the coming year with issuance of revised non-facility PE RVU amounts presented throughout the year in subsequent updates to the 2007 Physician Fee Schedule.

We commend CMS for providing instruction that services for which there is a "NA" in the non-facility setting are reimbursable. However, instructing carriers to pay these services using the facility PE RVU rate does not support adequate reimbursement for the direct PEs provided in the non-facility setting, particularly for device intensive interventional radiology services. For those codes lacking direct inputs for the non-facility setting, we implore CMS to designate the non-facility PE reimbursement rate as "carrier price" with instruction provided to carriers that the facility PE RVU is the minimum reimbursement rate allowed and that every reasonable consideration should be made to requests to establish an accurate and fair non-facility PE RVU at the local level. We assure CMS that the utilization of these services in non-facility setting will be negligible, with few practices able or willing to provide these services without an establishment reimbursement rate accurately reflecting for non-facility direct PE. A listing of these services is included as Attachment A.

If SIR can be of any assistance as CMS continues to consider and review this issue, please do not hesitate to contact Dawn Hopkins, director of reimbursement and health policy at (800) 488-7284, ext. 588, Hopkins@SIRweb.org,

Sincerely,

[Endorsed copy mailed this day]

[Endorsed copy mailed this day]

Gary P. Siskin, MD
Co-chair, Economics Committee

Sean M. Tutton, MD
Co-chair, Economics Committee

CC: Ken Simon, MD, CMS
Edith Hambrick, MD, CMS
Carolyn Mullen, CMS
Pamela West, CMS
Katharine L. Krol, MD, SIR
Michael E. Edwards, MD, SIR
Richard A. Baum, MD, SIR
Harvey Neiman, MD, ACR
Maurine Spillman-Dennis, ACR
Angela Choe, ACR
Sherry Smith, AMA
Todd Klemp, AMA
Jennifer Gajewski, SIR
Dawn R. Hopkins, SIR

Attachment A -

Designate Carrier Priced for Non-facility or -TC/Global for 7XXXX codes

32405	biopsy lung
35490	atherectomy
35491	atherectomy
35492	atherectomy
35493	atherectomy
35494	atherectomy
35495	atherectomy
36500	venous catheterization for selective organ blood sampling
37183	revision TIPS
37200	transcatheter biopsy
37201	transcatheter infusion
37202	transcatheter infusion
37204	embo
37205	stent
37206	stent
37209	exchange catheter during infusion Tx
37250	IVUS
37251	IVUS
38200	inject for splenoportography
38790	inject for lymphangiography
38792	senitel node
47500	inject for cholngiography
47505	inject for cholngiography
49180	biopsy abdominal/retroperitoneal mass
49420	insertion cath for drainage
49427	injection evaluate peritoneal-venous shunt
50200	renal biopsy
50390	aspiration/inject renal/pelvis cyst
50392	catheter renal pelvis for drainage
50393	intro ureteral catheter or stent
50395	intro guide renal/pelvis with dilation nephrostomy tract
50396	manometric studies
50688	change ureterostomy tube
51605	inject urethocystography
54500	biopsy testis
54800	biopsy epididymis
58615	fallopian tube occlusion
59001	amniocentesis
74190	peritoneogram
74235	removal foreign body esophageal with balloom catheter
74300	cholangiography and/or pancreatography intraoperative
74301	cholangiography and/or pancreatography intraoperative
74305	cholangiography and/or pancreatography intraoperative
74340	introduction long gastrostomy tube
74355	percutaneous plcement gastrostomy tube
74360	intraluminal dilation strictures/obstruction esphagus

Society of Interventional Radiology

74363	percutaneous transhepatic dilation of strictures/obstructions
74420	urography, retrograde
74425	urography antegrade
74440	vasography, vesiculography, epididymography
74445	corpora cavernosography
74450	urthrocystography
74470	renal cyst study
74742	transcervical catheterization of fallopian tube
74775	perineogram
75801	lymphangiography
75803	lymphangiography
75805	lymphangiography
75807	lymphangiography
75810	splenoportography
75894	embo
75896	infusion
75898	angio through existing catheter
75900	exchange catheter during infusion Tx
75940	IVC filter placement
75946	IVUS
75960	stent
75970	transcatheter biopsy
75980	biliary drainage
75982	placement drainage cath
75992	atherectomy
75993	atherectomy
75994	atherectomy
75995	atherectomy
75996	atherectomy
76001	fluoro > one hour
76012	vertebroplasty
76013	vertebroplasty
76362	CT guidance tissue ablation
76394	MR guidance tissue ablation
76940	US guidance tissue ablation
76986	US guidance intraoperative

CMS-1321-P-943

Submitter : Mr. Steve Kowske
Organization : Aurora Health Care
Category : Hospital

Date: 10/10/2006

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-943-Attach-1.DOC



Aurora Health Care

#943

Govt & Community
Relations
Forest Home Center
3305 West Forest Home
Avenue
P. O. Box 343910
Milwaukee, WI 53234-3910

T (414) 647-3072
F (414) 671-8751
www.AuroraHealthCare.org

October 10, 2006

Mark McClellan MD PhD
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1506-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: New Technology APCs – Section C Pages 19553 and 49554

Aurora Health Care appreciates the opportunity to comment on the Medicare Hospital Outpatient Prospective Payment System CY 2007 proposed payment rates published in the August 23, 2006 Federal Register. Aurora Health Care owns and operates the following Hospitals in eastern Wisconsin.

Aurora St. Luke's Medical Center	Provider # 52-0138
Aurora Sinai /Medical Center	Provider # 52-0064
Aurora Medical Center – Washington County	Provider # 52-0038
Aurora Medical Center – Oshkosh	Provider # 52-0198
Aurora Medical Center - Manitowoc County	Provider # 52-0034
Aurora BayCare Medical Center	Provider # 52-0193
Aurora Medical Center – Kenosha	Provider # 52-0189
Aurora Medical Center – Sheboygan County	Provider # 52-0035
Aurora Lakeland Medical Center	Provider # 52-0102
Memorial Hospital of Burlington	Provider # 52-0059
West Allis Memorial Hospital	Provider # 52-0139

New Technology APC's

The proposed rule includes changes to the Ambulatory Payment Classifications (APC's) for G0339 and G0340. These APC's involve payment for image guided robotic stereotactic radiosurgery first treatment and subsequent treatments. Moving these codes would result in a reduction in payment for code G339 of (\$1,190.39) and (\$833.32) for code G0340. Based upon the average number of treatments required a reduction of (\$2,837.03) would occur. Use of new cutting edge technology such as the Gamma Knife, requires extensive capital resources, and substantial training time for staff and physicians. Very often the costs of operating such equipment is not accurately reflected by the overall hospital cost to charge ratio used to set the reimbursement for the APC. In order to avoid sticker shock for commercial payors, and in order to get the commercial payors to endorse the new technology rather than traditional treatments, the charge markup for these types of services is a lot lower than the overall charge markup for the hospital. This is commonly known as charge compression. The payment reduction which is proposed, will inhibit the patient's ability to be treated with this life saving technology due to hospitals not wanting to invest in this technology because of lack of payment

Hospital Quality Data

Aurora Health Care would like to take issue with the following aspects regarding mandatory implementation of the HCAHPS Patient Satisfaction Survey in order to receive the full inflationary payment increase for Medicare patients.

1. Having to send out a second survey is prohibitively expensive should the patient not send back the first survey.
2. The length of the survey is too long, lessening our ability to add in our own questions, and taking away from our historical measures that we have tracking for the last six years. If the survey is too long the patient will not fill it out, and require us to send out another one. Please see first comment regarding the second survey.
3. The required sample size of 300 per year is too many for the smaller hospitals to get enough responses. As a result, we will be unable to utilize our existing survey because there is not a sample of patients left after complying with the HCAHPS Protocol. In effect, to be compliant with HCAHP Protocol in order to receive the proposed market basket update, assuming the rule is passed, our hospitals, especially our smaller ones, have little choice but to abandon our present methodology, in lieu of the more expensive HCAHPS methodology.
4. For the facilities, participating in the national rollout, it takes too long for the benchmark data to be returned (one year). The data is not very meaningful when it takes that long to obtain the results.
5. Participating in HCAHPS is going to require expensive remodeling of our current custom web-based reporting system.
6. Hospitals that participated in the 2006 dry-run should be allowed to join the national implementation in 2007 without having to go through the dry-run again

Device Dependant APC's

When ICD's and pacemakers are replaced due to warranty related recalls, very often there upgrades required for the device. Even though the manufacturer will not charge us for the device itself, the hospital still gets charged for the upgrade. Reduction of payment of the APC to take into account that the replacement is free of charge from the manufacturer, does not adequately take into account the cost of the upgrade. Therefore, the hospital is incurring a loss on the replacement of the device so critical to the patient. The reduction to the payment needs to be adjusted when an upgrade is warranted.

Aurora HealthCare would like to thank CMS for the opportunity to submit our comments on this very important proposed regulation. Should you have any questions, please feel free to call me at 414-647-3429.

Sincerely,

Steve Kowske
Regulatory and Reimbursement Manager
Aurora Health Care

Submitter : Daniel Dowdy

Date: 10/10/2006

Organization : Amarillo Urology Associates, L.L.P.

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment. Thanks, Dan Dowdy

CMS-1321-P-944-Attach-1.DOC

CMS-1321-P-945

Submitter :

Date: 10/10/2006

Organization :

Category : Attorney/Law Firm

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

H 946

American Chiropractic Association

October 10, 2006

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
CHIROPRACTIC SERVICES DEMONSTRATION, PROVISIONS: RESOURCE-BASED
PRACTICE EXPENSE RELATIVE VALUE UNIT PROPOSALS

The American Chiropractic Association (ACA) would like to express our deep concerns about adopting certain provisions of this rule as written, specifically those related to the chiropractic services demonstration project and the budget neutrality adjustments under CMS' "Five-Year Review" rule.

CHIROPRACTIC SERVICES DEMONSTRATION

ACA continues to object to the manner in which CMS is calculating budget neutrality related to the chiropractic services demonstration project. Per the August 22, 2006 Federal Register proposed rule (71 Fed Reg 49066): "As we stated in FY 2006 PFS, we would make adjustments in the national chiropractor fee schedule to recover the costs of the demonstration in excess of the amount estimated to yield budget neutrality... Any needed reduction would be made in the 2010 and 2011 physician fee schedules as it will take approximately 2 years to complete the claims analysis." As ACA stated in a November 15, 2004 letter to the Office of Research, Development and Information:

"The ACA is troubled by CMS' proposal to offset the costs of the demonstration projects with reductions to chiropractors alone, and not reductions to all items and services included under Part B. ACA believes the Congressional intent in this area is clear: In funding the demonstration, the law directs the Secretary to "provide for the transfer from the Federal Supplementary Insurance (Part B) Trust Fund ... of such funds as are necessary for the costs of carrying out the demonstration projects under this section" (See §651(f)(A)). And while CMS relies on the language in subsection (B) that directs the Secretary to "ensure" budget neutrality, the language itself doesn't tell the Secretary how to do it - that directive resides in subsection (A) immediately above. The ACA is not opposed to budget neutrality; it only objects to the means by which CMS plans to ensure it. CMS' plan to offset the demonstration's costs with payment reductions to existing chiropractic services only, and not with reductions to the totality of services payable under the Part B Trust Fund as directed, is flawed. The ACA believes strongly that the totality of funds under Part B, not a discrete minority of services within it, should finance the demonstration programs."

PROVISIONS: RESOURCE-BASED PRACTICE EXPENSE RELATIVE VALUE UNIT PROPOSALS

Budget Neutrality Adjustments Under CMS' "Five-Year Review" Rule

The ACA submitted comments on August 21, 2006, in response to the June 29, 2006 Federal Register (71 Fed. Reg. 37170) request for public comments on the five-year review of work relative value units (RVUs) and proposed changes to the practice expense methodology. We would like to reiterate our concerns:

The rule proposes increased payment to some physicians to reward management of care and "face time" with providers through increased valuation of higher-level evaluation and management (E/M) services. The ACA agrees that management of care and "face time" is important and that E/M services have been historically undervalued, but we would like any changes to be considered within the context of the larger healthcare community. The projected four billion dollar increase in reimbursement for E/M services triggers a budget neutrality provision. On page 37241, under "Budget Neutrality," CMS discusses their options related to this issue, outlining either the application of ten percent reduction in work RVUs or a five percent across the board reduction in the conversion factor. In the rationale, CMS states "we believe it is more equitable to apply the adjustment across services that have work RVUs" as this "would impact only those services that have physician work RVUs" and the conversion factor method would "negatively impact all PFS services." ACA wishes to state that we do not view this as an either/or proposition, in that CMS does have an opportunity make the negative impact of the proposal much less dramatic by phasing in the new valuation of E/M services. Additionally, while ACA understands that neither of the choices outlined by CMS will make all parties happy, we respectfully disagree with CMS' assessment that their proposed mechanism is equitable.

Specifically, the proposal disproportionately affects those providers who cannot bill or do not frequently use the E/M codes and will derive no benefit from the increased E/M payment, including doctors of chiropractic. The 10% reduction in work RVUs is balanced out for providers who utilize these higher-level E/M codes, but for doctors of chiropractic who spend a considerable amount of face time with patients but are prevented by law from billing these services, the proposal in the five-year review notice fails to recognize the value of our time.

Under the proposed rule, doctors of chiropractic in 2007 in will face a negative eight percent impact due to the combined work RVU reduction and practice expense (PE) revision (seven percent work, one percent PE). Within four years (by 2010), the combined impact of the work RVU and proposed PE changes will total -11%. These would be in addition to the reduction in the fee schedule conversion factor due to the "sustainable growth rate" (SGR) required under current law, which is expected to result in at least a 5.1% cut in 2007. All things being equal, doctors of chiropractic will be subjected to a 13.1% decrease in reimbursement next year alone. The ACA will continue to voice our objections to the overall payment system but would specifically ask CMS to reconsider the budget neutrality provision of this proposed rule, as it further aggravates a difficult situation.

The proposed cuts undermine Congress' goal of having a Medicare payment system that preserves patient access and achieves greater quality of care. ACA believes that the proposed system of reimbursement is unfair and potentially jeopardizes access to care for millions of the elderly and disabled. CMS can and should explore ways to value face time without disproportionately reducing patient access to care by some providers. At this time when there is an increased focused by CMS on preventative and well-oriented care, we find it inexplicable that a rule would put an undue burden on providers who provide such services routinely.

Thank you for your consideration. Should you have any questions, please contact Jaime Mulligan at jmulligan@acatoday.org or 703-812-0246.

Sincerely,



Kevin Corcoran
Executive Vice President



1701 Clarendon Boulevard, Arlington, VA 22209
(703) 276-8800 Fax: (703) 243-2593 www.acatoday.com Email: memberinfo@amerchiro.org

CMS-1321-P-947

Submitter : Dr. John Lyman
Organization : Emergency Department Practice Management Assoc.
Category : Health Care Provider/Association

Date: 10/10/2006

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

CMS-1321-P-947-Attach-1.DOC

#947



8405 Greensboro Drive, Suite 800
McLean, VA 22102
Phone: (703) 506-3292
Fax: (703) 506-3266

October 10, 2006

By Electronic Submission

Mark McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
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; 71 Fed. Reg. 48, 982 (August 22, 2006).

Dear Administrator McClellan:

On behalf of the Emergency Department Practice Management Association (EDPMA), I write today to submit formal comments to the Centers for Medicare and Medicaid Services' (CMS) proposed rule regarding 2007 physician payment under Medicare as published in the Federal Register on August 22, 2006 (Proposed Rule).

EDPMA is the organization that advocates for emergency physician groups and their partners to enhance quality patient care through operational excellence and financial stability. EDPMA members include emergency department medical groups, emergency department billing companies, and business partners who support emergency department medical groups. EDPMA members represent approximately one-third of all of the emergency department visits in the U.S. through direct patient care or support services to physicians and providers.

We greatly appreciate the opportunity to provide CMS with our comments on the Proposed Rule and its potential impact on Emergency Departments.

Emergency Departments: Our Safety Net Stretched to the Limits

Americans trust that when they need urgent medical attention the Emergency Departments will be there to help. EDPMA members are working day and night to ensure that quality health care is available to Americans whenever they need it. But the ever-increasing demands on the Emergency Department mean that our safety net is stretched to, and in some cases, beyond its limits.

Visits to the Emergency Department are on the rise while the number of facilities is declining. According to the Institute of Medicine (IOM), the number of emergency department visits increased by 27 percent from 1993 to 2003, although the population increased by only 12 percent. During the same period, 425

Emergency Departments closed, and the number of hospital beds decreased by 200,000. Proof of the stress on our nation's Emergency Departments is the IOM finding that an ambulance is diverted to a different hospital every minute due to overcrowding.

Cuts Threaten Emergency Departments, Physicians, and Medicare Patients

The 5.1 percent cut to the Medicare Physician Fee Schedule for 2007 comes on the heels of a freeze in payments during 2006. Medicare physician payments over the past five years have not kept pace with CMS' own annual inflation costs measured by the Medical Economic Index (MEI) and the current Sustainable Growth Rate (SGR) formula is anticipated to deliver more cuts in future years. It is time for CMS to intervene on behalf of good medicine and work with the physician community to develop an alternative to the SGR that will provide adequate payments to physicians for services rendered to Medicare patients.

In response to the cuts in the Medicare physician fee schedule, some community providers may limit the number of Medicare beneficiaries seen in their offices. In contrast, Emergency Departments cannot under federal law turn away those in need of emergency services regardless of payment. As the number of available primary care physicians shrinks, increasing numbers will turn to the Emergency Department for the treatment of acute and chronic conditions.

This increased influx of Medicare patients into the Emergency Department is in addition to the already large numbers of uninsured and underinsured patients (including those with Medicaid and limited private insurance) cared for in the Emergency Department every day. The Census Bureau recently reported that 46.6 million people were without health insurance coverage in 2005 representing 15.9 percent of Americans. These figures represent 1.3 million Americans added to the ranks of the uninsured between 2004 and 2005. The Emergency Department is where millions of uninsured Americans receive urgent healthcare services regardless of their ability to pay, and cuts to the Medicare physician fee schedule place in jeopardy this important safety net.

RVU, Budget Neutrality, and Practice Expense

As stated in our comments submitted on August 21, 2006 in response to CMS-1512-PN: Medicare Program; Five-Year Review of Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology, 71 Fed. Reg. 37, 170 (June 29, 2006), EDPMA is supportive of both the RUC recommendations and CMS' proposed regulations with regard to work relative value units (RVUs) for Evaluation and Management (E/M) services.

However, EDPMA strongly asserts that CMS should continue its long-standing policy of applying the budget neutrality adjustments to the conversion factor and not to the RVUs. If the RVUs are reduced to accommodate budget neutrality, the improvements to valuation of E/M services will be reduced as well and the full benefit of these improvements will not be achieved. Similarly, CMS proposes to use physician work RVUs negatively adjusted for budget neutrality as the basis for allocation of direct costs. The actual and full RVUs should be used to allocate indirect costs regardless of the final outcome on budget neutrality.

In addition, CMS should not utilize supplemental survey data from specialty societies until a new multi-specialty survey has been completed in order to eliminate inequities among the specialties. To this end, EDPMA calls upon CMS to move forward with a new multi-specialty survey that is well designed to ensure the reporting of common data elements in a timely and equitable manner. This survey must

properly accommodate emergency physician groups, allow for data collection at the practice level, and include the expenses associated with the provision of uncompensated care.

EDPMA Urges Delay of MEI-Related Changes Until Publication and Comment

In April 2006, CMS estimated that the 2007 Medicare physician fee schedule would be reduced by 4.6 percent. With the announcement of the Proposed Rule, CMS stated its intention to reduce the fee schedule by an additional 0.5 percent to reach a negative 5.1 percent update. This further reduction is due to a downward revision of the Medicare Economic Index (MEI) measuring annual increases in the cost of operating medical practices.

As CMS' actions with regards to the MEI were not included in the text of the Proposed Rule, it is difficult for the public to ascertain the rationale and details of the MEI change. What is available to the public is a Fact Sheet on the MEI released August 8, 2006 explaining the nature of the MEI and attributing the 0.5 percent additional reduction in the physician fee schedule update to a downward revision of the MEI. The Fact Sheet further indicates that the MEI revision was based on a new measure of productivity provided by the Bureau of Labor Statistics and lower projections of inflation.

EDPMA is greatly concerned that CMS has exacerbated the cuts facing Medicare physicians by instituting this policy change relating to the MEI. EDPMA is also concerned that CMS has made a substantial policy change without formal notice in the *Federal Register* and adequate opportunity for public comment. EDPMA urges CMS to withhold any changes relative to the MEI until such a time as formal notice has been given and public comment solicited and reviewed in accordance with the Administrative Procedures Act.

Supplier Access to Claims Billed on Reassignment (Section II, Subsection J)

In Section II, Subsection J of the Proposed Rule, CMS proposes to amend the reassignment regulations by requiring that both independent contractors and employees have "unrestricted access" to claims submitted by an entity. Specifically, CMS proposes to modify 42 C.F.R. § 424.80(d)(2) to read:

The supplier who furnishes the service has unrestricted access to claims submitted by an entity for services provided by that supplier. This paragraph applies irrespective of whether the supplier is an employee or whether the service is provided under a contractual arrangement. If an entity refuses to provide, upon request, the billing information to the supplier performing the service, the entity's right to receive reassigned benefits may be revoked under § 424.82(c)(3).

CMS would also revise the title of this subsection to correspond to this modification.

In the preamble to the Proposed Rule, CMS states that this proposal was prompted by one inquiry from an employed emergency physician who alleges he was denied access to billing records for services furnished. 70 Fed. Reg. 49,058. CMS also points to the Conference Report for the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) which "states that the Conference Committee supports appropriate program integrity efforts for any entities billing the Medicare program, including entities with independent contractors as well as employees." Id.

EDPMA supports strong Medicare program integrity safeguards. Moreover, EDPMA believes, and has commented accordingly in the past, that appropriate program integrity safeguards should be applied to entities with employed physicians as well as to entities who work with independent contractors.

Therefore, EDPMA supports CMS following the intent behind MMA's change to the reassignment statute to apply program integrity standards evenly to entities enrolled with the Medicare program.

With regard to this particular standard of "unrestricted access to claims submitted," EDPMA has noted in earlier comments provided to CMS that it is not clear how physician access to claims submitted data will correspond to improved program integrity, i.e., correspond to correct claims being submitted to the Medicare program. We believe there may be more practical approaches for physicians to ensure that all Medicare program requirements are being met by the entity submitting bills to the Medicare program. For example, EDPMA supports physician involvement in compliance programs which are structured to address risk areas particular to their operations.

CMS states that since January 1, 2005, one physician alleges he has been denied such a request. It is unclear how Medicare, or its contractors, investigated this particular allegation or how the Medicare program would investigate such allegations in the future. We assume that the billing entity's right to receive reassigned benefits would not be revoked based on such an allegation without full due process.

EDPMA is also concerned that providing "unrestricted access to claims submitted" is not a clear requirement for the billing entity to meet. Under the HIPAA-mandated American National Standards Institute (ANSI) formatted 837-P electronic Medicare claims, the "claims submitted" are fields of electronic data that require the detailed implementation guide from the appropriate Medicare contractor to decipher the data fields. Provider and contractor systems are large main frame computers that do not interface easily with the personal computers likely to be used by the individual physician supplier. Finally, these implementation guides may run several pages and may also vary significantly from contractor to contractor.

As noted above, EDPMA does not believe that regulating unrestricted access to all submitted claims is the best method CMS can employ to ensure Medicare's program integrity. However, if CMS chooses to continue its emphasis in this area, we support applying these requirements to all entities submitting claims to the Medicare program.

We appreciate the opportunity to provide formal comments to CMS' proposed Medicare regulations. Please feel free to contact me or EDPMA's Managing Director, Cherilyn Cepriano, at (703) 506-3292 regarding these comments or any other issues facing emergency medicine.

Sincerely,



John Lyman, MD, FACEP
Chair, Board of Directors

Submitter : Ms. Lourdes Hernandez
Organization : Michael S. Buchholtz, MD, PC
Category : Physician

Date: 10/10/2006

Issue Areas/Comments

GENERAL

GENERAL

In our practice we base our decisions to treat a patient on clinical effectiveness. We also accommodate patients as to reduce the number of office visits. For this reason in many situations we utilize Aranesp as it is more convenient for the patients since it is not a weekly injection and it can eventually become necessary at two, three, or even four week intervals. Therefore, The Amgen portfolio provides our practice with more choices. However, in instances where patients are able to come into the office on a weekly basis we utilize Procrit. Also, please be aware that we prefer again to use therapies that would reduce the number of patient visits and it is for this reason that we utilize Neulasta instead of Neupogen as it is a long lasting agent (i.e Neupogen 7-10 visits; Neulasta 1 visit). Therefore, our choices of therapies, contrary to what has been published in the media, are based on the patients needs.

Somehow, there is a perception that the oncologists are choosing therapies based on contract terms and this is absolutely untrue for our practice. However, if CMS continues to determine and ASP reimbursement that is lower than the actual cost of the drug, we are forced to utilize the drug that CMS is forcing oncologists to use. Since the ASP reimbursement continues to be based on a theoretical price that is not readily available we are forced to take advantage of all available discounts as the ASP continues to be lower than the actual cost of the drug. Oncologists need to continue to have a choice of therapy for their patients and depriving the patients to all available treatment options is totally unacceptable.

Also, please be advised that the more choice that we have the more reduction in drug pricing we see. Having only one therapy option available not only does not give the oncologists many options for therapies but it also affects the financial viability of the medical practice because we are obligated to purchase what could be and usually is a very expensive drug.

Please make a policy that would allow oncologists to continue to have all treatment options for cancer patients.

Submitter :

Date: 10/10/2006

Organization :

Category : Nurse Practitioner

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-949-Attach-1.DOC

CMS-1321-P-949-Attach-2.DOC

#949-1

October 9, 2006

Centers for Medicare and 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: File code CMS-1321-P Criteria for National Certifying Bodies- Advanced Practice Nurses

To Whom It May Concern:

The undersigned represent national advanced practice nursing organizations whose missions support the educational preparation and certification of nurse practitioners (NPs). Through the collective activities of our organizations, we share a common goal of promoting high quality, safe and cost-efficient health care services delivered by NPs. It is in the interest of this goal that we are responding to the proposed rule "Medicare Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B" (42CFR Parts 405, 410, et al) as announced in the Federal Register on August 22, 2006.

In the discussion of proposed changes to CFR 410.76 as noted on page 49066, CMS noted its intent to establish standards to guide recognition of certification organizations eligible for participation in CMS programs. We wish to inform CMS that standards for recognition have already been established by the profession that should be used by CMS to make such determinations. To inform your work, we would like to summarize several key points that reflect our collective declarations about certification for NP specialties:

* NP education and certification of specialty practice remains the standard for credentialing and regulation of NP practice. Board certification of the NP specialties of Adult NP, Adult Acute Care NP, Family NP, Gerontology NP, Neonatal NP, Pediatric NP, Pediatric Acute Care NP, Women's Health NP and Psych/Mental Health NP has been already recognized for licensure and credentialing.

*Sub-specialty NP certification provides added value to NP specialty board certification. Sub-specialty NP practice builds on the NP specialty preparation and promotes an increased depth of knowledge to provide focused high quality care for specific diseases, systems and settings. Examples would include an Adult NP who sub-specializes in Diabetes management or Forensics.

National accreditation of educational and certification programs assures that appropriate quality standards are addressed. Eligibility to sit for board certification is determined by graduation from educational programs preparing NPs that are nationally accredited by a nursing accrediting organization recognized by the Department of Education. Both specialty and sub-specialty

certification examinations should be nationally accredited through the National Commission on Certifying Agencies or the American Board of Nursing Specialties Accreditation Council. We request that the already established standards such as those printed in the National Council of State Boards of Nursing (NCSBN) Criteria for Advanced Practice Regulation be used by CMS. We hope that this information is helpful as you consider developing standards for recognizing NP certification organizations.

Sincerely:

American Academy of Nurse Practitioners Certification Program
Jan Towers 202-966-6414

American Association of Critical Care Nurses Certification Corporation
Carol Hartigan 949-268-7507

National Certification Corporation
Betty Burns 312-951-0207

National Organization of Nurse Practitioner Faculties
Kitty Werner 202-289-8044

Pediatric Nursing Certification Board
Janet Wyatt 301-330-2921

#949-2

October 9, 2006

Centers for Medicare and 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: File code CMS-1321-P Criteria for National Certifying Bodies- Advanced Practice Nurses

To Whom It May Concern:

The undersigned represent national advanced practice nursing organizations whose missions support the educational preparation and certification of nurse practitioners (NPs). Through the collective activities of our organizations, we share a common goal of promoting high quality, safe and cost-efficient health care services delivered by NPs. It is in the interest of this goal that we are responding to the proposed rule "Medicare Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B"(42CFR Parts 405, 410, et al) as announced in the Federal Register on August 22, 2006.

In the discussion of proposed changes to CFR 410.76 as noted on page 49066, CMS noted its intent to establish standards to guide recognition of certification organizations eligible for participation in CMS programs. We wish to inform CMS that standards for recognition have already been established by the profession that should be used by CMS to make such determinations. To inform your work, we would like to summarize several key points that reflect our collective declarations about certification for NP specialties:

* NP education and certification of specialty practice remains the standard for credentialing and regulation of NP practice. Board certification of the NP specialties of Adult NP, Adult Acute Care NP, Family NP, Gerontology NP, Neonatal NP, Pediatric NP, Pediatric Acute Care NP, Women's Health NP and Psych/Mental Health NP has been already recognized for licensure and credentialing.

*Sub-specialty NP certification provides added value to NP specialty board certification. Sub-specialty NP practice builds on the NP specialty preparation and promotes an increased depth of knowledge to provide focused high quality care for specific diseases, systems and settings. Examples would include an Adult NP who sub-specializes in Diabetes management or Forensics.

National accreditation of educational and certification programs assures that appropriate quality standards are addressed. Eligibility to sit for board certification is determined by graduation from educational programs preparing NPs that are nationally accredited by a nursing accrediting organization recognized by the Department of Education. Both specialty and sub-specialty

certification examinations should be nationally accredited through the National Commission on Certifying Agencies or the American Board of Nursing Specialties Accreditation Council. We request that the already established standards such as those printed in the National Council of State Boards of Nursing (NCSBN) Criteria for Advanced Practice Regulation be used by CMS. We hope that this information is helpful as you consider developing standards for recognizing NP certification organizations.

Sincerely:

American Academy of Nurse Practitioners Certification Program
Jan Towers 202-966-6414

American Association of Critical Care Nurses Certification Corporation
Carol Hartigan 949-268-7507

National Certification Corporation
Betty Burns 312-951-0207

National Organization of Nurse Practitioner Faculties
Kitty Werner 202-289-8044

Pediatric Nursing Certification Board
Janet Wyatt 301-330-2921

- Because she is focusing only on urological issues, we believe that our pathologist is not only more competent in interpreting our specimens than a typical reference lab pathologist, but that her urology-specific interpretive skills will continue to improve over time.
- We have moved some services that were formally "out-sourced" to an "in-house" status. Our Texas-licensed and board-certified pathologist supervises the personnel who prepare our slides for interpretation and she enhances quality control. She also influences and improves our human tissue and specimen collection and shipping procedures.
- Finally, we have been told that CMS' rules will address program abuse caused by the owners of so called "pod labs" like ours. We believe the lab owners have been indiscriminately accused of over-utilizing services, generating unnecessary medical services, taking kickbacks, splitting fees illegally or incorrectly and committing other fraudulent acts. Our data confirms that, in our practice, no over-utilization or other types of abuse is occurring. For instance, when the academic scholars of urology concluded that the standard of care should be to obtain 12 prostate biopsy cores (up from 6), we changed to 12. However, we have not changed our biopsy or other pathology procedures since we opened our lab, although it would be financially beneficial to do so.

In conclusion, the physicians of Amarillo Urology Associates, L.L.P. believe that our lab provides medically necessary and efficient services for our patients. Our lab produces results that are quick, accurate and cost efficient. We do not over utilize pathology services. CMS and other insurance carriers often require that providers substantiate the services rendered. Comparable results might be obtained from an outside reference lab, but we are now confident in the results we attain in our "in-house" lab setting. We further believe that CMS is premature in its conclusion that small physician owned and controlled uro-pathology labs like ours should be eliminated. We appreciate your careful consideration of our request.

Thank you very much. Sincerely, s/ Daniel A. Dowdy

Submitter :

Date: 10/10/2006

Organization :

Category : Attorney/Law Firm

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-950-Attach-1.PDF

The treatment and reimbursement policy established in the Proposed Rule does not comport with sound medical practices and, moreover, would not improve the health of diabetic Medicare beneficiaries that reside in SNFs. We believe that CMS has a key opportunity to improve diabetes care in this vulnerable population and firmly establish practice guidelines that can be adopted by physicians and institutional providers participating in the Medicare program. As discussed above, a series of clinical studies have demonstrated that tight control of glucose levels leads to significant decreases in the incidence of complications seen in many diabetic patients. Furthermore, the patient population in today's long-term care setting is substantially older and more medically complex than ever before, and current practices for treating diabetes in these patients must be adopted. We, therefore, urge CMS to take the logical next step by affirmatively establishing clinically-proven policies and protocols for combating diabetes in non-ambulatory residents of nursing facilities and other institutions.

To that end, we support the two proposed protocols for "finger stick" blood glucose determinations that were designed, respectively, by the AHCA and Highmark Medicare Services ("Highmark").⁵ The AHCA and Highmark protocols facilitate the identification of blood glucose trends, feedback of test results to facility professionals and physicians, and more timely decisions regarding the delivery of treatments that require glucose values (e.g., the precise amount of additional insulin to be administered pursuant to the physician's blood glucose monitoring protocol). Importantly, both the AHCA and Highmark protocols would further ensure that blood glucose testing services submitted for payment under Medicare Part B are reasonable and medically necessary: first, they establish an immediate physician notification requirement for any substantial deviation of blood glucose levels, and; second, both protocols provide an appropriate timeframe for reporting patterns of beneficiary glucose results to the physician who prescribed the individual's blood glucose monitoring plan. In other words, once a physician determines that a series of blood glucose tests is reasonable and necessary for diagnosing or treating diabetes in the beneficiary, the physician will review the series of tests on a trended basis in order to determine whether another order for glucose monitoring is necessary.

Moreover, the AHCA and Highmark protocols both address CMS's apparent concerns about unending "standing orders" because they create a series of opportunities for the physician to periodically review the trended test results, the appropriateness of the treatment regime, and the frequency of monitoring for each individual patient. Each proposed protocol also creates a clear structure to distinguish between blood glucose determinations to assist in the management of unstable or at-risk patients and blood glucose determinations as part of routine monitoring of stable diabetic patients. Accordingly, adoption of either protocol would mitigate the risk of unnecessary blood glucose testing, a clear objective of the Proposed Rule, without the additional administrative burdens that a requirement

⁵ The Highmark protocol is in draft form, as it has not yet been adopted by Highmark.

national significance that cannot, and should not, be relegated to a general "one-size-fits-all" regulatory requirement, we urge CMS to withdraw the Proposed Rule.

VII. CMS Failed to Adequately Perform the Regulatory Impact Analysis

CMS's Regulatory Impact Analysis (the "RIA") of the Proposed Rule is also problematic, in part because it is devoid of rationale or evidence that could justify the Proposed Rule. Pursuant to a number of executive orders and acts of Congress, CMS is obligated to perform a RIA in order to examine the Proposed Rule's anticipated monetary effect on the Medicare program and, more importantly, estimate the impact on access and the quality of care provided to Medicare beneficiaries. The RIA must also adequately describe the alternatives considered in developing the rule. In the case of the Proposed Rule, CMS not only failed to adequately complete these mandatory assessments, but does not mention the proposed blood glucose testing requirements at all in its RIA. See 71 Fed. Reg. 49,068-49,078. Consequently, the Proposed Rule must be withdrawn.

VIII. The Proposed Rule Does Not Comport with the Paperwork Reduction Act of 1995

CMS has also failed to consider the extensive information collection and paperwork burden that the Proposed Rule's physician certification requirements would place upon Medicare providers and contractors. Congress enacted the Paperwork Reduction Act of 1995 (the "Paperwork Reduction Act") in order to minimize the paperwork burden for individuals, small businesses, and federal contractors, among others, that result from the collection of information by or for the federal government. 44 U.S.C. § 3501. Accordingly, the Paperwork Reduction Act requires CMS to publish a notice in the Federal Register to seek public comments on the proposed collection of information with a 60-day comment period, and otherwise consult with members of the public and affected agencies concerning each proposed collection of information. Id. § 3506(c)(2)(A). While the agency has attempted to include such public notice in the preamble to the Proposed Rule, CMS asserts that only its proposed recordkeeping requirements for independent diagnostic testing facilities ("IDTFs") will impose an information collection requirement on the public. See 71 Fed. Reg. 49,068. CMS completely ignores the paperwork burden associated with the proposed blood glucose testing regulation and, thus, the public notice provided in the Proposed Rule is insufficient to meet the requirements of the Paperwork Reduction Act.

By requiring physicians to certify the medical necessity of each individual blood glucose test, the Proposed Rule would effectively impose a significant information collection requirement on physicians, SNFs, and the fiscal intermediaries that process Part B claims for blood glucose testing services. First, treating physicians would be required to render prescription orders for each glucose test administered to their patients (which could be three or four additional orders per day, per patient). Second, SNF personnel would be obligated to document each additional physician order in each patient's medical

record, resulting in additional paperwork and written communications between the SNF and each prescribing physician. Lastly, the fiscal intermediaries processing the resulting Part B claims would be faced with vast amounts of additional paperwork, particularly when conducting desk audits or reviews to determine the medical necessity of each individual blood glucose test administered to a Medicare beneficiary residing in a SNF.

CMS is attempting to implement a Proposed Rule that not only deviates from current best medical practices and the requirements of the Medicare statute, but would encumber providers and fiscal intermediaries with additional information collection requirements without the public notice proscribed by the Paperwork Reduction Act. We strongly urge the agency to withdraw the Proposed Rule until CMS can adequately evaluate the additional burdens that will be placed on participating SNFs, physicians, and the agency's administrative contractors, and engage in a collaborative discussion with Medicare providers, beneficiaries, physicians and other caregivers on a policy that reflects medical best practices and the realities of caring for this segment of the Medicare population.

Respectfully submitted,

Thomas C. Fox
Jason M. Healy
REED SMITH LLP

#950

ReedSmith

Reed Smith LLP
1301 K Street, N.W.
Suite 1100 - East Tower
Washington, D.C. 20005-3373
202.414.9200
Fax 202.414.9299

October 10, 2006

BY ELECTRONIC MAIL

Anita Greenberg
U.S. Department of Health and Human Services
Centers for Medicare & Medicaid Services
Attn: CMS-1321-P
7500 Security Boulevard
Mail Stop C4-26-05
Baltimore, Maryland 21244

Re: CMS-1321-P: Medicare Program; Proposed Blood Glucose Testing Rule (42 C.F.R. § 424.24(f)), Included in the Proposed Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B

Dear Ms. Greenberg:

Reed Smith LLP ("Reed Smith") appreciates the opportunity to address several key issues raised by the proposed blood glucose monitoring requirements for Medicare Part B beneficiaries that reside in skilled nursing facilities ("SNFs"). These requirements are included in the proposed rule, *CMS-1321-P: Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B*, issued by the Centers for Medicare & Medicaid Services ("CMS") on August 22, 2006. See 71 Fed. Reg. 48,981.

Reed Smith represents a number of nursing home operators in the United States and, in some cases, individual Medicare beneficiaries. In the past few years, CMS and its contractors have increasingly used informal guidance documents, loose interpretations of existing statutes and regulations, and unsupported local coverage determinations ("LCDs") to restrict the coverage and availability of regular blood glucose testing services for Medicare Part B beneficiaries who reside in SNFs. Recently, we represented a Medicare Part B beneficiary with advanced diabetes before the Departmental Appeals Board ("DAB") in a direct challenge to the blood glucose testing LCD published by Mutual of Omaha in its capacity as a Medicare fiscal intermediary. After reviewing the LCD record for this coverage policy, we determined that it was almost entirely bereft of legitimate supporting evidence in the form of medical literature and data, clinical best practices, and an honest consideration of written comments. However, before the administrative law judge ("ALJ") could render a decision on the merits of the LCD, Mutual of Omaha voluntarily withdrew the policy and took the unusual (and we believe indefensible) stance of arguing that it will continue to deny beneficiary claims for blood glucose

testing using the policies in the now-retired LCD. Our experience with this appeal, and the mounting concerns of our nursing home clients about CMS's policies on blood glucose testing, have prompted us to submit these written comments to the proposed changes to physician certification requirements for blood glucose testing services (the "Proposed Rule").¹

As set forth below, the importance of effectively treating and managing diabetes in institutionalized Medicare beneficiaries cannot be understated. Current clinical evidence and medical literature clearly support the medical necessity and reasonableness of a physician-prescribed protocol of repeat blood glucose monitoring in diabetic patients. Accordingly, requiring physicians to individually order and certify the medical necessity of each "finger stick" blood glucose test administered to a Part B-eligible nursing home resident is inconsistent with the Medicare statute and regulations, as well as longstanding CMS policy. More importantly, CMS provides no clearly articulated rationale in support of the Proposed Rule, which deviates significantly from the current best practices in diabetes management and seeks to impose unnecessary burdens on Medicare providers and fiscal intermediaries.

We respectfully urge CMS to withdraw the Proposed Rule to ensure that our clients' ongoing efforts to provide the highest quality of SNF care are not unnecessarily hindered. CMS has a key opportunity to establish effective treatment and reimbursement policies for treating and preventing diabetes, and we trust that CMS will pay serious attention to our comments as required by law. To that end, we encourage CMS to seriously consider the proposed protocol for blood glucose monitoring advanced by the American Health Care Association ("AHCA") and the Alliance for Quality Nursing Home Care (the "Alliance"). We believe the adoption of such a protocol, based upon the current medical evidence and clinical best practices, will result in a coverage policy that best serves the critical needs of institutionalized Part B beneficiaries with diabetes.

Below are the facts concerning the LCD appeal and its unusual outcome, followed by the overwhelming evidence in support of withdrawing the Proposed Rule and adoption of a coverage policy based upon current medical evidence and a legitimate desire to address the dire health care needs of this portion of the Medicare population.

I. The Medicare Beneficiary LCD Appeal Exposed the Invalidity of CMS's Restrictive Coverage Policies Related to Blood Glucose Testing Services

A. Procedural History

¹ Because we are only commenting on the blood glucose testing provisions of the Proposed Rule, references to the Proposed Rule in these comments refer solely to the preamble discussion and proposed regulation relating to blood glucose testing.

On March 28, 2006, we filed a Complaint with supporting exhibits on behalf of a Medicare Part B beneficiary residing in a SNF (the Aggrieved Party or Beneficiary), challenging the validity of Mutual of Omaha's ("Mutual's") LCD on blood glucose testing as legal authority for denying Medicare coverage of her blood glucose tests. The Aggrieved Party is a 72 year old individual with advanced diabetes and blindness as a result of that illness. Her condition requires blood glucose testing four times a day to maintain control over her blood glucose levels. This frequency of blood glucose testing is supported by the orders of her physician.

Although the ALJ ordered Mutual, as the contractor, or CMS to file the LCD record with the ALJ and the Aggrieved Party no more than 30 days from April 19, 2006, both Mutual and CMS failed to submit the LCD record within this time period. Twenty seven (27) days late, on June 14, 2006, Mutual filed the LCD record with the Aggrieved Party and it contained virtually no documented support for the LCD.²

On July 18, 2006, the Aggrieved Party timely filed the Aggrieved Party's Statement pursuant to 42 C.F.R. § 426.425(a) in support of the Aggrieved Party's request that the LCD at issue be invalidated. The Statement summarizes the Aggrieved Party's analysis of the LCD record. It shows in great detail that the LCD record is incomplete and wholly inadequate to support the policies enunciated in the LCD when evaluated under the reasonableness standard at 42 C.F.R. § 426.425(a). There is virtually no documented support for the LCD in the LCD record. Significantly, the LCD record includes *no medical evidence* to support the policies in the LCD. Accordingly, the Aggrieved Party requested that the ALJ invalidate the LCD as a matter of law, upon summary judgment.

On August 11, 2006, six days before Mutual's response to the Aggrieved Party's Statement and Motion for Summary Judgment were due, Mutual mailed a Response to Beneficiary's Complaint, a Response to Aggrieved Party's Motion for Summary Judgment, and a letter to the ALJ. The first item was filed in lieu of a response to the Aggrieved Party's Statement, as required by 42 C.F.R. § 426.425(b). With amazing coincidence, Mutual stated that, as of the same date (August 11, 2006), it has "retired" its LCD on blood glucose testing. Mutual then proceeded to argue that the LCD – which was then on its fifth publication, publicly available on its web site, and widely distributed to interested parties as its official statement of coverage policy for blood glucose testing – is not being used to deny claims for blood glucose testing submitted by the Aggrieved Party. Rather, Mutual stated that claims for blood glucose testing are denied if they are not medically necessary. With this slight of hand maneuver,

² Because the regulation at 42 C.F.R. § 426.425(a) gives the Aggrieved Party 30 days (or more for good cause) after receipt of the LCD record to file a Statement, on June 15, 2006 we moved for an extension of 30 days to file the Aggrieved Party's Statement. The ALJ issued an Order dated June 28, 2006 extending the schedule for filing the Aggrieved Party's Statement by amending the date of the April 19, 2006 Order to May 19, 2006.

Mutual is improperly relying upon the same restrictive coverage policies in the LCD after it has been retired. The Aggrieved Party accepted Mutual's decision to retire the LCD. However, as discussed more fully below, the Aggrieved Party strongly objected to the trickery Mutual now seeks to engage in to continue to deny needed blood glucose testing services to Medicare Part B residents of SNFs now that the LCD has been exposed to be without any medical support, and the policies described therein invalid as a matter of law. Among the unsupported coverage policies now retired is a requirement that a physician order be obtained prior to each blood glucose test, as CMS has now proposed in the Proposed Rule. From our review of similar LCDs published by other CMS contractors, we know that this is a common basis for contractors to deny reimbursement for blood glucose testing.

B. A Retired LCD Is Invalid and Its Policies Can No Longer Be Enforced

We believe that Mutual has acted contrary to the clear language and intent of the LCD appeal regulations in this appeal. Its insistence that it will continue to deny blood glucose testing claims in the same manner as before is tantamount to a fraud upon the DAB, the Aggrieved Party, and thousands of other Medicare beneficiaries whose claims for blood glucose testing have been or will be denied even after the LCD has been invalidated as part of these proceedings. Mutual has taken the position that it can continue to enforce the restrictive coverage policies enunciated in its LCD on blood glucose testing even *after* it has voluntarily retired that policy. When confronted with overwhelming evidence that the LCD is unsubstantiated, Mutual believes that it can simply withdraw the LCD – its official coverage policy on blood glucose testing – to discontinue the DAB proceedings *and* continue to enforce the very same coverage policy to deny claims.

Mutual insists that it can do this because the LCD is not referenced by name on claims denials that it sends to beneficiaries, although in five different versions it represented Mutual's official policy on blood glucose testing. The Aggrieved Party argued that this is nothing more than a "slight of hand" or mirage and asked the ALJ not to condone this conduct for two primary reasons: (1) the restrictive coverage policies discussed in the LCD are now invalid by operation of law; and (2) Mutual's deliberate choice not to reference the LCD by name on claims denials is a mere technicality that does not protect the LCD policies from challenge by affected parties, including this Beneficiary. The ALJ stated in his decision that Mutual's withdrawal of its LCD deprived him of jurisdiction under the regulations to further adjudicate these issues. We believe CMS would be making the same mistakes as Mutual and other contractors by finalizing the Proposed Rule because it sets forth one of the same primary coverage criteria as Mutual's LCD – individual physician orders prior to each blood glucose test – which we have shown to be unsupported by the medical evidence.

C. The LCD's Restrictive Coverage Policies Are Now Invalid by Operation of Law

Mutual's withdrawal of its blood glucose testing LCD has the same legal effect as an ALJ decision to invalidate that LCD under the reasonableness standard, pursuant to 42 C.F.R. § 426.460(b). As such, Mutual is required to reopen denied claims of the Beneficiary and adjudicate those claims, and any new claims submitted by the Beneficiary, for blood glucose testing services without using the invalid policies reflected in the LCD, now that it is withdrawn. Any and all claims submitted to Mutual for blood glucose testing services with dates of service on or after August 11, 2006 must be adjudicated without using the invalid policies in the LCD.

CMS stated very clearly in the preamble to the rules governing these LCD appeal procedures that it is the policy or policies discussed in the LCD that are invalid when the LCD is retired, not just the document itself:

Retiring an LCD or withdrawing an NCD would result in the retired/withdrawn *policy* no longer applying in the claims adjudication process for services rendered on or after the date that the *policy* is retired/withdrawn. Moreover, the aggrieved party would be granted individual claim review. Since a claimant would receive the same relief that would have been available had the adjudicator found that the relevant LCD or NCD was not valid, there would be no reason to continue the appeal.

Medicare Program: Review of National Coverage Determinations and Local Coverage Determinations; Final Rule, 68 Fed. Reg. 63,692, 63,698 (November 7, 2003) (emphasis added). CMS added that:

When we retire/withdraw an LCD/NCD *we will not apply those policies for services furnished after the retirement/withdrawal date* and we will reprocess the aggrieved party's affected claims *without applying the retired/withdrawn policy*.

Id. (emphasis added).

Therefore, the Aggrieved Party requested that the ALJ take official notice, pursuant to his authority granted under 42 C.F.R. § 426.405(c), of the fact that Mutual cannot deny claims for blood glucose testing services on or after August 11, 2006 (i) using any of the restrictive coverage policies discussed in the now-retired and invalid LCD on blood glucose testing, or (ii) based on its policy interpretations discussed in the LCD of other authorities (including Transmittal AB-00-108, Medicare Claims Processing Manual § 90.1, and 42 C.F.R. § 410.32).

D. Mutual's Deliberate Choice Not to Reference the LCD by Name on Claims Denials Is a Mere Technicality that Does Not Protect the LCD Policies From Challenge by Affected Parties, Including This Beneficiary

The Medicare statute defines an LCD as “a determination by a fiscal intermediary or carrier under part A or part B, as applicable, respecting whether or not a particular item or service is covered on an intermediary—or carrier—wide basis under such parts, in accordance with section 1862(a)(1)(A).” 42 U.S.C. § 1395ff(f)(2)(B). Simply stated, the LCD is an official statement of the contractor’s policies on the coverage of specific items or services for Medicare reimbursement. It applies to claims for the listed items or services whether the contractor proclaims it on every claim determination, or chooses not to mention it on any. It is binding on claimants until retired or otherwise invalidated. And once it is no longer valid – as was the case here – the coverage policies enunciated in that LCD can no longer be enforced by the contractor.

Mutual’s LCD on blood glucose testing is now retired and invalid, and so are all of its policies discussed in that LCD interpreting Medicare authorities (including Transmittal AB-00-108, Medicare Claims Processing Manual § 90.1, and 42 C.F.R. § 410.32) to establish when Mutual will and will not reimburse claims for blood glucose testing services. This proposition is indisputable. The LCD record shows how Mutual created the LCD. In December 2000, CMS issued Transmittal AB-00-108. Mutual’s LCD on blood glucose testing, now in its fifth version, had an original effective date of September 4, 2001. However, the LCD record includes documentation that indicates Mutual was aware of the soon-to-be-published national coverage determination (“NCD”) on blood glucose testing, and that the NCD would not contain the limiting policies that Mutual borrowed from Transmittal AB-00-108 and further elaborated upon in its LCD. In fact, after the NCD was published, Mutual was given a clear written warning by the CMS Region VII office that the challenged LCD language does not appear in the NCD and should *not* be included in the LCD because it conflicts with the NCD, as health care providers had argued. Others who reviewed the draft LCD internally expressed similar concerns about the legitimacy of language in the LCD that does not appear in the NCD and the negative impact the LCD would likely have on patient care by discouraging testing. Mutual chose to ignore these warnings and publish the LCD anyway, with the same objectionable language, knowing full well that its LCD is not supported by the NCD and that patient care could suffer.

Effective November 23, 2001, CMS promulgated the NCD to address Medicare coverage of blood glucose testing. The NCD specifically encourages frequent testing of blood glucose levels for diabetic patients and acknowledges that it may be reasonable and necessary to measure quantitative blood glucose in stable, non-hospitalized patients who are unable or unwilling to do so. The NCD does not provide any specific limitations to testing. In plain language, the NCD acknowledges that specific diagnosis codes, such as diabetes, support repeat testing, especially where there is a confirmed continuing risk of glucose metabolism abnormality.

The restrictive coverage policies in Mutual’s now-retired and invalid LCD on blood glucose testing can no longer be applied to providers and beneficiaries that Mutual services. The LCD was

Mutual's attempt to reflect, in one document, its coverage limitations on blood glucose testing services. Mutual started with the broadly permissive coverage policy of the NCD on blood glucose testing. Mutual then added the restrictive coverage policy language from Transmittal AB-00-108 (*e.g.*, "prompt" notification of test results to the ordering physician). Mutual finished with its own unsupported policy interpretations of Transmittal AB-00-108 (that "prompt" means before the next test); the Medicare Claims Processing Manual § 90.1 (which Mutual interprets to prohibit coverage of blood glucose testing for SNF residents, as opposed to coverage for beneficiaries in their own homes); and 42 C.F.R. § 410.32 (which Mutual interprets to prohibit standing physician orders for blood glucose testing). Now that the LCD is retired and invalid, all of the coverage limitations on blood glucose testing services reflected in the LCD are unenforceable by law. Any other conclusion or result would be a total perversion of justice and fraud upon the Aggrieved Party and the thousands of other Medicare beneficiaries whose claims have been or will be denied.

We have provided this information so that CMS understand how its contractors are improperly dealing with Medicare Part B beneficiary claims for blood glucose testing services under the LCDs that have been published. CMS should avoid the same mistakes by withdrawing the Proposed Rule and developing a new rule that is based upon medical evidence and clinical best practices, not short-sighted restrictions on coverage for these necessary services.

II. The Proposed Rule Is Inconsistent with Applicable Legal Authorities

A. The Medicare Statute and Regulations Support Coverage of Blood Glucose Monitoring

A physician-ordered protocol of blood glucose monitoring, which may include a prescribed series of blood glucose tests over a designated period of time, clearly meets the requirements of the Social Security Act (the "Act") and the Medicare regulations. The Act is the foremost authority for Medicare Part B coverage for blood glucose testing. The applicable section of the Act is the general requirement that the service be "reasonable and necessary for the diagnosis or treatment of illness or injury." 42 U.S.C. § 1395y(a)(1)(A). Under this requirement, blood glucose monitoring is reasonable and necessary for the diagnosis or treatment of the blood glucose metabolism abnormalities that are the hallmark of diabetes. Necessarily then, a physician-prescribed protocol for blood glucose testing is also reasonable and necessary for detecting and treating diabetes, particularly considering that the frequency of testing is determined based upon the needs of the individual beneficiary.

In recognition of the fact that Congress provided for Medicare Part B coverage of blood glucose testing services, the Medicare regulations further describe the circumstances under which blood glucose testing is reasonable and necessary. The regulations define blood glucose testing with a device approved for home use as a "diagnostic laboratory test." 42 C.F.R. § 493.15. For Medicare beneficiaries residing in a SNF, coverage exists for diagnostic laboratory tests if they are "ordered by the physician who is

treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem." *Id.* § 410.32(a). Thus, the only requirement in the Medicare regulations for blood glucose monitoring to be reasonable and necessary is an order by the treating physician for such testing. Nothing in the Medicare regulations imposes any additional requirements, and it would be inappropriate and inconsistent for CMS to implement a new rule – as proposed to be codified at 42 C.F.R. § 424.24(f) – that would require physician orders for each individual blood glucose test that is part of a reasonable and necessary protocol of blood glucose monitoring.

B. The National Coverage Determination Supports Coverage of Reasonable and Necessary Blood Glucose Monitoring

Effective November 23, 2001, CMS promulgated the National Coverage Determination ("NCD") to address Medicare coverage of blood glucose testing. The NCD specifically encourages frequent testing of blood glucose levels for diabetic patients and acknowledges that it is reasonable and necessary to measure quantitative blood glucose in stable, non-hospitalized patients who are unable or unwilling to do so. The NCD does not provide any specific limitations to testing. In plain language, the NCD acknowledges that specific diagnosis codes, such as diabetes, support repeat testing, especially where there is a confirmed continuing risk of glucose metabolism abnormality. Significantly, the NCD has been revised and expanded since its effective date of November 23, 2001, but the fundamental policy of covering and supporting blood glucose testing with a home-use device has not changed.

The NCD notes that using a device approved for home testing has become a standard of care for control of blood glucose, even in the inpatient setting. Importantly, the NCD neither requires nor suggests that frequent testing is unreasonable or lacks medical necessity for beneficiaries diagnosed with diabetes. Moreover, the NCD does not suggest that treating physicians must order individual blood glucose tests in lieu of a carefully designed protocol of repeat blood glucose monitoring. Rather, the NCD merely limits coverage for beneficiaries with "nonspecific signs, symptoms, or diseases not normally associated with disturbances in glucose metabolism" (*i.e.*, patients without a diagnosis of diabetes) to a single test unless the results are abnormal or there is a change in clinical condition. According to the NCD, specific diagnosis codes such as diabetes support repeat testing, especially where there is a "confirmed continuing risk of glucose metabolism abnormality." Diabetes is a disease that is not only "associated with" disturbances in glucose metabolism, but is defined as "a syndrome characterized by hyperglycemia [abnormally high blood glucose] resulting from absolute or relative impairment in insulin secretion and/or insulin action." *See Merck Manual of Diagnosis and Therapy* § 2, Ch. 13, pg. 1. Beneficiaries with a diagnosis of diabetes who reside in SNFs and other institutional settings almost always have such a continuing risk. Therefore, longstanding CMS policy, as reflected in the NCD, clearly supports coverage of claims for regular blood glucose testing of beneficiaries with a diagnosis of diabetes.

Specifically, the NCD states that “[f]requent home blood glucose testing by diabetic patients should be encouraged,” and that “[t]he convenience of the meter or stick color method . . . has become a standard of care for control of blood glucose, even in the inpatient setting.” 66 Fed. Reg. 58,846 (Nov. 23, 2001). The NCD also states that “[d]epending upon the age of the patient, type of diabetes, degree of control, complications of diabetes, and other co-morbid conditions, more frequent testing than four times annually may be reasonable and necessary. . . . [R]epeat testing may be indicated where results are normal in patients with conditions where there is a confirmed continuing risk of glucose metabolism abnormality.” *Id.* Taking into account the health factors of institutionalized diabetics, nowhere in the NCD are there specific limitations on the frequency of testing, and nowhere is there mention of requiring an order for each blood glucose test administered to patient with a “confirmed continuing risk of glucose metabolism abnormality.” The NCD simply lists the number of maladies that may require blood glucose testing and reiterates that reasonable and necessary tests will be reimbursed. *See id.* at 58,846, 58,848.

Put simply, CMS should not break from its medically-sound and longstanding policy by requiring a physician to individually certify each blood glucose test administered to a beneficiary that, in the medical opinion of the physician, requires repeat blood glucose testing in order to diagnose and treat diabetes. A physician-prescribed protocol of repeat blood glucose testing services meets the NCD criteria when performed on a diabetic beneficiary who has a continued risk of glucose metabolism abnormality. The NCD clearly states that such testing should be encouraged. Such blood glucose testing services also meet the reasonable and necessary criteria. They are ordered by the treating physician, furnished by qualified personnel, in an appropriate setting, and furnished in accordance with accepted standards of medical practice for the treatment of diabetes. Moreover, all such tests are performed at a frequency determined by the particular beneficiary’s treating physician to meet his or her specific medical needs.

III. CMS Must Withdraw the Proposed Rule under the Administrative Procedures Act Because CMS Has Failed to Articulate Any Rationale or Basis for the Proposed Rule

In the preamble to the Proposed Rule, CMS asserts that the proposed blood glucose testing regulation is a codification of “long-standing policy” on the coverage of blood glucose monitoring services. *See* 71 Fed. Reg. at 49,065. Nonetheless, the only “authority” cited by CMS is Program Memorandum AB-00-108 (Dec. 1, 2000), and a CMS manual provision, Chapter 7 of the Medicare Claims Processing Manual (CMS Pub. 100-04), entitled “Skilled Nursing Facility Part B Billing.” Neither of these documents provides any clinical or legal support for the Proposed Rule, and both are contrary to the legal authorities cited above.³ Moreover, the preamble discussion references no

³ Nonetheless, aspects of the Program Memorandum actually support coverage of physician-ordered protocols for repeated blood glucose testing. Specifically, the Program Memorandum

the agency's failure to utilize sufficient research data in the Proposed Rule hindered the opportunity for meaningful public comment. The court held that it "is not consonant with the purpose of a rule-making proceeding to promulgate rules on the basis of inadequate data." Instead, the issuing agency "must disclose in detail the thinking that has animated the form of a Proposed Rule" and provide a reasoned analysis of the data. Id.

Like Portland Cement, CMS's failure to provide any evidence or data regarding blood glucose monitoring and the resulting absence of reasoned scrutiny provides no opportunity for the public to offer meaningful support or criticism of the Proposed Rule. It is also questionable whether CMS adequately revisited Program Memorandum AB-00-108 and Chapter 7 of the Medicare Claims Processing Manual – both of which clearly contradict the "reasonable and necessary" requirement of the Act and the NCD – before codifying their policies in the Proposed Rule. Consequently, CMS has disclosed neither a purposeful rationale nor any evidence that would lend credence to the restrictions set forth in the Proposed Rule. Accordingly, we respectfully request that CMS withdraw the proposed blood glucose testing rule until such time that the agency obtains and considers sound clinical evidence, current best practices of medicine, and claims data such that the public may meaningfully contribute to the rulemaking process.

IV. The Proposed Rule Does Not Comport with Current Best Medical Practices in Detecting and Treating Diabetes

As noted above, the preamble discussion accompanying the Proposed Rule does not discuss any clinical studies or medical articles about blood glucose testing or the health care needs of diabetic patients. Accordingly, it would appear that the proposed blood glucose regulation was developed without consideration of current medical literature and clinical authorities, which advocate regular blood glucose testing for institutionalized diabetics. We respectfully submit that a careful review of these authorities would lend no support for the position taken by CMS in the Proposed Rule.

A. Blood Glucose Testing is a Cornerstone of Diabetes Care

Blood glucose testing to monitor glucose levels in the blood, as performed by patients and health care providers, is considered a cornerstone of diabetes care. See Position Statement: Tests of Glycemia in Diabetes, American Diabetes Association, *Diabetes Care* 25:S97-S99, Supp. 1 (Jan. 2002), pg. S97. The results of these tests are used to assess the efficacy of therapy and to guide adjustments in medical nutrition therapy, exercise, and medications to achieve the best possible blood glucose control. See id.

Clinical authorities support the use of sliding scale insulin administration supported by glucose testing for nursing home residents, although prolonged use of sliding scale insulin is not recommended. See Managing Diabetes in the Long-Term Care Setting: Clinical Practice Guideline, American Medical

Directors Association (AMDA) (2002), pg. 26. This approach uses a base dose of intermediate or long acting insulin, and regular insulin, supplemented by regular insulin administered by the nurse based on the patient's blood sugar and the treating physician's orders. The established best practice is for the physician to set the frequency of the testing and a range for the blood glucose values of the specific patient. Blood glucose testing (or monitoring), a measurement of glucose in the blood that can be done at any time on a portable machine, has long been used to assess blood glucose levels for diabetics. Blood glucose testing is typically performed by placing a drop of blood on a reagent strip, which uses a chemical substance to react to the amount of glucose in the blood. The portable machine then reads the strip and displays the results as a number on a digital display. Physicians are notified when glucose values go above or below the specified parameters. Adjustments are made to the base (and supplemental) dose when necessary. This treatment protocol is essentially the same whether the patient is being treated at home, as a hospital inpatient, or in a SNF, and is consistent with existing Medicare requirements and the policy established in the NCD.

This type of glucose testing is particularly important in elderly patients where their age has compromised the body's homeostatic ability to maintain a normal body state having stability and uniformity on its own. To help elderly diabetics maintain a homeostatic state, the clinical practice model of the AMDA recommends a blood glucose test on admission, bedside glucose testing several times a day (more frequently if the patient's glucose level is poorly controlled), daily blood glucose review, and physician alert when values fall below or above the recommended range or a range indicated in the physician-ordered protocol of blood glucose monitoring. See id. pgs. 11, 27-28, 39-42. The American Diabetes Association also recommends blood glucose testing of type 1 diabetics three or more times daily. See Standards of Medical Care in Diabetes, American Diabetes Association, Diabetes Care 2004, Vol. 27, pg. S20; Position Statement: Tests of Glycemia in Diabetes, American Diabetes Association, Diabetes Care 25:S97-S99, Supp. 1 (Jan. 2002), pg. S97. Such glucose testing should not be confused with screening tests, routine or standing orders. Regular testing, when prescribed as part of a treatment protocol specifically designed to meet the needs of the individual beneficiary, is medically necessary to avoid certain short and long-term complications of diabetes, and to assess the efficacy of ongoing treatment.

The medical literature clearly indicates that day-to-day control of insulin levels reduces the severity of existing consequences of diabetes, and can prevent the onset of new symptoms and complications. Diabetes is common in the nursing home setting, with over 18 percent of nursing home residents having this disease. See Managing Diabetes in the Long-Term Care Setting: Clinical Practice Guideline, American Medical Directors Association (AMDA) (2002), pg. 2. The literature demonstrates that nursing home patients have a high prevalence of cognitive and physical impairment and need help in daily activities and maintaining recommended dietary and exercise regimens. The prevalence of these impairments is higher among diabetic nursing home patients than in the nursing home population as a

whole, which increases the complexity of diabetes management, and makes it unlikely that these patients can manage their diabetes on their own. See id., pg. 3. Diabetic nursing home residents are susceptible to hyperglycemia (a condition that impairs cognition, decreases pain thresholds, impairs vision, increases the risk of infections and may increase the risk for falls) and hypoglycemia (which, untreated, can cause falls or permanent neurological impairment). See id. Nursing home residents are frequently unable to perceive or communicate hypoglycemic symptoms. See id. “Frequent monitoring of blood glucose levels is critical to avoid hypoglycemia and its consequences.” Subacute Care for Seniors: Management of Elderly Diabetic Patients In the Subacute Care Setting, A. Lee, MD, Clinics In Geriatric Medicine, 16:4 (Nov. 2000), reprinted at <http://home.mdconsult.com>, pg. 8.

Treatment guidelines for diabetes published by numerous medical societies establish that glucose monitoring is reasonable and necessary for the treatment of diabetes patients, and leave the frequency of the testing to the medical judgment of the treating physician, based on the patient’s individual circumstances. See Managing Diabetes in the Long-Term Care Setting: Clinical Practice Guideline, American Medical Directors Association (AMDA) (2002), see especially pgs. 39-41. Regular blood glucose testing is part of an overall, individualized treatment care plan for diabetes management, along with a meal plan, activity and physical therapy, treatment with oral antidiabetic agents and/or insulin, foot/wound care, and pain management. See id. pg. 16. Regular monitoring of blood glucose levels helps achieve target ranges for blood glucose control; reduce the risk of lower-extremity infections, ulcers, and limb loss; control pain and neuropathic symptoms; and reduce the progression of other diabetic complications. See id., pgs. 16-17.

The insulin needs of patients with diabetes can vary from one patient to another, from day to day, even from hour to hour. Most nursing home patients have type 2 diabetes but a sizable proportion have combined therapy with insulin orders for treatment. Regular testing is particularly important because blood glucose levels frequently vary depending on the time of day, as demonstrated in a study conducted by the National Institute of Diabetes and Digestive and Kidney Diseases and Social, and Scientific Systems, Inc., published in the December 27, 2000, Journal of the American Medical Association. See Diurnal Variation in Fasting Plasma Glucose, JAMA (Dec. 27, 2000), pg. 5; see also Merck Manual of Diagnosis and Therapy § 2, Ch. 13, pgs. 9-10 (discussing the “dawn phenomenon”).

During the past decade, clinical trials have demonstrated the importance of glycemic control, as measured through regular blood glucose testing, to prevent and reduce the complications of diabetes. See The Importance of Tight Glycemic Control, J.E. Gerich, MD, The American Journal of Medicine, 118:9A (September 2005), reprinted at <http://home.mdconsult.com>, pg. 4. Several new therapeutic agents have become available to improve and monitor glycemic control in patients with type 2 diabetes, including less painful and continuous monitoring devices. See id. Although continuous monitoring is not at issue with respect to the Proposed Rule, the optimization of glycemic control by any means has

Submitter : Ms. Margaret Boiano
Organization : VNUS Medical Technologies, Inc.
Category : Private Industry

Date: 10/10/2006

Issue Areas/Comments

GENERAL

GENERAL

Please see attached comments. Thank you.

CMS-1321-P-951-Attach-1.DOC



#951

October 9, 2006

Via Electronic

Mark McClellan, MD, PhD, Administrator
 Centers for Medicare and Medicaid Services
 Department of Health and Human Services
 Attention: **CMS-1321-P**
 Mail Stop C4-26-05
 7500 Security Boulevard
 Baltimore, MD 21244-1850
<http://www.cms.hhs.gov/eRulemaking>

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 Changes to the Practice Expense Methodology

Dear Dr. McClellan:

On behalf of VNUS Medical Technologies, Inc. (VNUS), we are pleased to submit comments to the Centers for Medicare and Medicaid Services (CMS) on the proposed changes. VNUS is a leading manufacturer of the technology used in endovenous ablation therapy of incompetent veins (e.g., varicose ulcers and venous insufficiency). For elderly Medicare patients; this is a crucial therapy to reduce painful swelling in the legs, restore mobility and function, and enable patients to regain and enjoy a high quality of life.

As stated in the proposed rule, CMS is proposing changes to computing Practice Expenses to ensure that CMS's payment systems are updated to reflect changes in medical practice and the relative value of services. MedPac also reported in their March 2006 Report to Congress that the commission recommended improvements that will help reduce the number of physician fee schedule services that are misvalued, thereby making payment more accurate.

We agree with the philosophy of both CMS and MedPac and the need for improvements in the system for calculating of the payment of the services rendered. However, we are concerned about the accuracy and proposed change to the PE relative units for CPT Codes 36475 and 36476 for the Endovenous Radiofrequency Ablation Procedures. These cuts do not truly reflect the cost associated in doing these procedures..

1. **36475-** *endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency, first vein treated*
2. **36476-** *endovenous ablation therapy ..., inclusive of all imaging guidance ..., second and subsequent veins treated in a single extremity through separate access sites.*

Code	2006 Non-Facility PE RVUs	CMS Proposed 2007 Non-Facility PE RVUs	CMS Proposed 2010 Non-Facility PE RVUs	2006 vs. 2010 total % variance	2006 Facility PE RVUs	CMS Proposed 2007 Facility PE RVUs	CMS Proposed 2010 Facility PE RVUs	2006 vs.2010 total % variance
36475	51.54	47.77	36.90	(28%)	2.54	2.39	1.97	(22%)
36476	7.9	7.42	6.04	(24%)	1.14	1.08	.89	(22%)

➤ **Impact of Practice Expense Changes for CPT codes 36475 and 36476**

The proposed PE reduction will have a significant impact on utilization of these procedures in the non-facility setting for Vascular Surgery, General Surgery and Interventional Radiology. It will also be especially difficult for them given the combined impact with the proposed rule of reducing the conversion factor by 5.1% in 2007. For example, this combined impact of PE changes along with the conversion factor reduction reduces reimbursement for CPT 36475 by 11.2% from 2006 to 2007.

We are concerned about the accuracy and decrease in PE RVU calculations for the RF ablation procedures (CPT 36475 and 36476) for the following reasons:

- These recently established CPT codes were reviewed and evaluated by RUC with the appropriate cost data related to this technology late in 2004 and entered into the CPEP database for establishment of 2005 payment rates beginning January 1, 2005. It is unclear what new data CMS used to revalue the PE expenses for CPT 36475 and 37646 that we determine from survey and cost data using a bottoms up cost analysis performed so recently by RUC.
- CMS has indicated it is using utilization data for determining new PE RVUs. However, the methodology for this is unclear. For CPT codes 36475 and 36476, a significant portion of the non-facility practice expense is related to office staff labor and disposable supplies used for each procedure with only modest cost associated with the amortization of fixed assets. As a result use of utilization rates for modifying the NFPE for these codes is inappropriate since the labor and supply costs per procedure are the critical cost elements. In addition, the elimination of the C-Code for endovenous RF ablation at the end of 2004, further resulted in missing cost data for the period January through March 2005 in which CMS gathered data (utilization and cost data?) for the PE reduction calculation.

These cuts in reimbursement will make it financially less practical for physicians to perform these safe and effective procedures in the office setting and ultimately result in more patients treated in the hospital setting which will be more costly to Medicare due to the sum of cost to pay APC- related reimbursement fees plus professional fees to physicians. These cuts may also result in a loss of access to care for Medicare beneficiaries.

In sum, our recommendations for PE RVU Methodology for CPT codes 36475 and 36476 are as follows:

- We strongly encourage CMS to continue to use the RUC calculated PE RVUs for CPT codes 36475 and 36476 and thus eliminate the proposed reductions for 2007 and beyond in PE RVUs for endovenous procedures described by those CPT codes
- Since the goal is to improve the accuracy of Medicare's payments and achieve better value for Medicare spending. We urge **CMS to avoid changes that could drive more patients to receive hospital care when they can be more cost-effectively be treated safely and efficaciously in the office setting.**
- The 2006 PE RVUs as shown in the below table should remain the same for 2007.

CPT	Description	2006 Non- Facility PE RVUs	2006 Facility PE RVUs
36475	Endovenous RFA, 1 st vein treated	51.54	2.54
36476	Endovenous RFA, vein add-on	7.9	1.14

Should you have any questions, please contact me at 408-360-7560 or Gail Daubert at 202.414.9241. Thank you for your consideration.

Sincerely,



Margaret Boiano
Director of Reimbursement
VNUS Medical Technologies, Inc.

Submitter : Kirk Deininger
Organization : Reliant Healthcare Solutions Inc.
Category : Other Health Care Provider

Date: 10/10/2006

Issue Areas/Comments

GENERAL

GENERAL

See attached.

CMS-1321-P-952-Attach-1.PDF

#952



October 10, 2006

Hon. Mark B. McClellan, M.D.,PhD.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

COMMENT TO: "IDTF Issues – Alternative Tests in Residential Settings"

File Code CMS-1321-P: Comments Related to Proposed Rulemaking re: 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:

Reliant Healthcare Solutions, Inc. is pleased to provide this comment letter to the "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"). Reliant Healthcare Solutions is a medical support service organization focused providing medical products and related services to patients in residential settings. We wish to comment specifically to CMS' request for public comment regarding other types of tests that can be safely and appropriately used in a residential setting.

CMS has long recognized the benefits of enabling beneficiaries with diabetes to maintain glycemic control in order to avoid long-term complications. By covering blood glucose testing supplies for beneficiaries with Type 1 or Type 2 diabetes, it is now possible for almost anyone to acquire self-testing supplies. Unfortunately, despite increasing expenditures for blood glucose monitoring supplies over the past 10 years, long-term glucose control (as measured by Glycated Hemoglobin – A1c) have actually worsened.¹

We believe that part of the problem relates to the expenditures for testing of stable Type 2 patients. At the August 2006 Medicare Coverage Advisory Committee (MCAC) meeting on Glycemic Control, Dr. Art Lurvey stated that there is too much testing for

¹ Diabetes Care 2004;27:17-20.

CONFIDENTIAL

Reliant...

HEALTHCARE SOLUTIONS

stable Type 2 patients because testing rarely leads to changes in therapy. Furthermore, he indicated that testing by Type 2 patients rarely leads to therapy changes.

We believe that another part of the problem is that costly Durable Medical Equipment (DME) can be provided to beneficiaries by product distributors with no assurance that the actual test results are integrated into the patient's glycemic control regimen. Over the years the OIG has identified concern with aggressive marketing tactics directed at beneficiaries with diabetes.² Such practices lead to improper utilization of an important medical tool. We believe that this is evidence that the DME model is fundamentally flawed and is not an efficient use of this nation's healthcare dollars. While Competitive Bidding for blood glucose products should help reduce the cost that Medicare pays for these blood glucose testing supplies, it does not address the larger and more costly issue of waste and abuse. Although blood glucose device manufacturers have been highly critical of CMS' efforts to implement Competitive Bidding, there is little evidence to suggest that they have done anything to help prevent waste and abuse in their distribution channels.

Recent advancements in medical technology have created new options for monitoring patients with diabetes in remote locations and at alternative time periods. We would like to recommend several alternative strategies that would enable CMS to provide access to these technologies using an alternative distribution model that imposes accountability on the part of the provider. The objective would be to ensure that patient-generated tests are actually used and integrated into the patients overall glycemic control regimen.

Specifically, we recommend that CMS evaluate the addition of three types of diabetes-related diagnostic services that can be safely and appropriately used in a residential setting as an alternative to office testing when deemed appropriate by the beneficiary's treating physician. These services can be provided using technology that has been cleared for home-use by the FDA. In all of the following scenarios payment to the IDTF would be based on the IDTF's collection and reporting of test results back to the treating physician.

	Problem	Recommendation
1	A1c testing is underutilized as a tool to control glycemic control. ³	Allow patients to self-test using an A1c testing device that has been cleared by the FDA for home-use (CPT 83037). The A1c testing supplies would be provided by a physician or an approved IDTF who would need to ensure that the test results were promptly communicated to the patient's treating physician.

² OEI-03-00-00091

³ New England Journal of Medicine 2003; 348:26:2635-2645.

Reliant...

HEALTHCARE SOLUTIONS

2.	Blood glucose testing for non-insulin beneficiaries with Type 2 diabetes is believe to have limited value. ⁴	Allow patients to self-test using a Glycated Protein device that has been cleared by the FDA for home-use (CPT 82985QW). Glycated Protein is an intermediate term measure of glycemic control. Glycated Protein has already been deemed to be medically necessary and may be a more relevant and more cost-effective tool in the care of stable non-insulin using Type 2 patients. Testing supplies and test reporting would provided by a physician or an approved IDTF that would ensure that the patient-generated test results were promptly communicate to the patient's treating physician.
3.	Medicare coverage for continuous glucose monitoring does not yet exist.	Pending additional clinical data which demonstrates the medical necessity of continuous glucose monitoring, enable patients to self-test using systems that have been cleared by the FDA for home-use. Assuming that future clinical supports the medical necessity of continuous monitoring for selected patients, CMS could offer these systems as an alternative to daily blood glucose monitoring. Testing supplies and test reporting would provided by a physician or an approved IDTF that would ensure that the continuous values were communicated to the patient's treating physician on a real time basis.

Although the clinical benefits of regular glucose monitoring are well-documented, so too are the associated problems of fraud and abuse. It is my belief that by allowing beneficiaries to self-test using alternative, short- and intermediate-term glycemic control tools, CMS can impose increased accountability on providers. Unlike blood glucose monitoring under the DME model, CMS can be assured that tests are actually being used by the patient's treating physician.

I would be pleased to discuss these recommendations with you further.

Sincerely,

Kirk Deininger
 Chief Executive Officer
kdeininger@inrcare.com
 Phone: 925.456.5010

⁴ Public comments by Dr. Art Lurvey at the August, 2006 Medicare Coverage Advisory Committee (MCAC) meeting on Glycemic Control.

Submitter : Dr. Stanton Champion

Date: 10/10/2006

Organization : Urology Tyler, PA

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : Mrs. Tamara Schwartz
Organization : BioTech Laboratory, Inc.
Category : Other Health Care Professional

Date: 10/10/2006

Issue Areas/Comments

Background

Background

Diabetic patients health jeopardized.

RE: Revisions to 42 CFR 424.24(f) BLOOD GLUCOSE MONITORING IN A SNF

BioTech Laboratory services over two hundred skilled nursing facilities, all of which have diabetic patients that receive a combination of accu-checks (fingersticks), blood glucose levels (venipuncture) and Hemoglobin A1C (venipuncture), to monitor the ongoing treatment of their chronic condition.

When reading the proposed rules, I cannot decipher whether this is intended to address the daily fingersticks or the less frequently ordered blood glucose levels and Hemoglobin A1C s. In any case, diabetes is a disease that must be micromanaged by the medical team of professionals who care for the patient. The system of using daily fingersticks along with occasional blood glucose testing and hemoglobin A1C testing provides a variety of checks and balances to the patient s treatment.

The proposed rule implies that blood glucose testing that is ordered on a routine basis (IE. daily, monthly, quarterly) is not covered; however, these orders are orders in the patient s chart are medically necessary as documented, and ordered at the frequency the physician believes to be indicated for the management of the patient s long term medical condition. The physician reviews and signs these orders monthly. Results of testing are communicated to the physician routinely, and the physician modifies the patient s medication as necessary based on test results.

The proposed rule seems as though it interferes with the physician s ability to manage the treatment of the patient. Without monitoring on a routine basis, the patient s health can be jeopardized in a very short time period. Your consideration of the above points is appreciated. Sincerely,

Tamara Schwartz
BioTech Laboratory, Inc.
10114 Woodfield Lane
St Louis, MO 63132
314.432.5030 x 340
Tamara.Schwartz@BioTechXray.com

Submitter : Ms. Maya Bermingham

Date: 10/10/2006

Organization : Pharmaceutical Research and Manufacturers Associat

Category : Drug Association

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1321-P-955-Attach-1.PDF

Conan P. Grames
Senior Vice President
General Counsel



October 10, 2006

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

Dear Dr. McClellan:

Enclosed please find the comments of the Pharmaceutical Research and Manufacturers of America (PhRMA) regarding Solicitation of Comments on Medicare proposed physician fee schedule rule published by the Centers for Medicare and Medicaid Services (CMS).

If you have any questions, please do not hesitate to call Maya Bermingham directly at (202) 835-3478.

Sincerely,

Conan P. Grames

Enclosure



October 10, 2006

VIA HAND DELIVERY AND E-MAIL

<http://www.cms.hhs.gov/eRulemaking>

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

**Re: CMS-1321-P; Comments Regarding the Proposed
Physician Fee Schedule Rule for Calendar Year 2007**

Dear Dr. McClellan:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to submit comments on the Medicare proposed physician fee schedule rule published by the Centers for Medicare and Medicaid Services (CMS).¹ PhRMA is a voluntary nonprofit organization representing the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier, and more productive lives. PhRMA companies are leading the way in the search for cures.

PhRMA has a long-standing interest in ensuring that Medicare beneficiaries have access to the most appropriate therapies, both in physicians' offices and other outpatient and inpatient settings. Given the importance of Medicare's payment system in supporting beneficiaries' access to appropriate care, we appreciate and support CMS' ongoing efforts to identify opportunities for improving the accuracy of Average Sales Price (ASP) calculations and the resulting ASP-based payment rates. In the proposed physician fee schedule rule for 2007, CMS has requested additional comments on its April 6, 2004 interim final rule on ASP reporting (because stakeholders had little experience with ASP at the time they commented on that rule), and also has developed a number of thoughtful proposals for addressing various questions regarding ASP calculations, many of which involve difficult and highly complex issues concerning manufacturers' calculation procedures. Our comments on the proposed rule therefore focus on its provisions regarding ASP calculations.

¹ 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, 71 Fed. Reg. 48982 (Aug. 22, 2006).

Pharmaceutical Research and Manufacturers of America

PhRMA's detailed comments are set out below. They principally concern the section of the proposed rule on "ASP issues." We have also addressed one issue in the section of the proposed rule on "DRA Proposals"; payment for administration fees for Part D vaccines; and an echocardiography imaging drug administration issue.

* * *

A. ASP Issues

1. Fees Not Considered Concessions

CMS notes in the proposed rule that it has received requests for clarification on the treatment of administrative fees, service fees, and fees to pharmacy benefit managers (PBMs) in ASP calculations. In connection with fees to PBMs and group purchasing organizations (GPOs), CMS proposes to clarify that "bona fide service fees that are paid by a manufacturer to an entity, whether or not the entity takes title to the drug, are not considered price concessions." CMS proposes to define bona fide service fees as fees "paid by a manufacturer to an entity that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on, in whole or in part, to a client or customer of an entity, whether or not the entity takes title to the drug." Fees to GPOs or PBMs would not be considered price concessions "insofar as, and to the extent that," they satisfy the bona fide service fee definition.

CMS is considering providing guidance on: (1) "the types of services that may qualify as bona fide services" (which could vary by drug category); (2) "the approach or methodology manufacturers must use to determine the fair market value of bona fide services" (and seeks comments specifically on whether "fees tied to performance of a service, fixed fee, revenue generated by product sales, or other basis may represent fair market prices"); and (3) "appropriate methods for determining whether a fee is passed on in whole or in part."

The proper treatment of fees paid to purchasers (or PBMs or GPOs) in ASP calculations is an important issue, and we appreciate CMS' effort to provide further guidance in this area. Appropriate guidelines for distinguishing service fees from price concessions on the manufacturer's products are important both to help ensure that ASP calculations are not understated (which creates a risk of inadequate ASP-based payment rates to providers that can lead to access problems for Medicare beneficiaries) and to permit manufacturers to acquire needed services in the most efficient manner. A key concern in this area, which informs many of the specific recommendations detailed below, is crafting criteria for determining whether a certain fee is a bona fide service fee excluded from ASP that will: (1) accommodate evolution in the marketplace in arrangements between manufacturers and their customers; and (2) provide the flexibility necessary to address existing arrangements appropriately.

a. **General Principles for Determining Whether Services Qualify as “Bona Fide Services” for ASP Calculation Purposes**

A threshold issue raised by the proposed rule is determining the types of services that qualify as “bona fide services” for purposes of calculating ASP. CMS should recognize that “bona fide services” include any services performed on a manufacturer’s behalf that serve a manufacturer’s commercially reasonable business purposes and thus have utility to the manufacturer. Ultimately, only an individual manufacturer is in the best position to determine the particular services that are necessary and useful in meeting its business needs, which is the proper standard for identifying “bona fide” services, the fees for which should be distinguished from product price concessions. To reflect this standard, we would also recommend that CMS clarify its proposal describing bona fide services as services “that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement.” Clarifying this language is important because there are certain services that, by their nature, a manufacturer could obtain only from a purchaser of its products. If purchasers did not offer these services, then a manufacturer could not perform the services itself or contract for their performance with another party, but this does not mean that the services do not serve the manufacturer’s business needs. To address this point, CMS should revise its proposed guidance to state explicitly that “bona fide” services are not limited to those that the manufacturer could perform itself or find an alternative contractor to perform; instead, the standard to apply is whether the manufacturer obtains the services to meet its business needs.

These general principles require careful, fact-specific application; thus, they will not always lend themselves to blanket generalizations about whether a certain category of service constitutes a “bona fide service”; instead, in many instances individual manufacturers will need to evaluate the relevant facts and circumstances and make case-by-case determinations about whether particular services satisfy the bona fide service standard. Some of the services to which manufacturers might apply this standard include, for example, inventory management, prompt processing of orders, reduction in number of orders, provision of sales and inventory data, and refill reminders and similar services. To help ensure that these services (and others) are classified appropriately for ASP purposes, it is important that CMS instruct individual manufacturers to evaluate whether the services in question are necessary and useful in meeting that manufacturer’s commercially reasonable business needs, rather than attempting to make across-the-board determinations about fact-specific questions requiring an understanding of companies’ individualized business needs and service arrangements.

b. **“Pass-through” of Service Fees and the Definition of Bona Fide Services**

It is critical that CMS develop criteria for defining bona fide services that will be feasible for manufacturers to apply. With respect to this concern, for example, manufacturers are unlikely

to have access to certain data that CMS assumes will be available for purposes of applying the "bona fide service fee" criteria.

In particular, the criterion that bona fide service fees "are not passed on, in whole or in part, to a client or customer of any entity [receiving the fee]" appears to be based on the assumption that manufacturers know whether a fee was passed on by its recipient to the recipient's own clients or customers. This is generally not the case. Moreover, including a criterion that would affirmatively require manufacturers to obtain information concerning transactions between downstream entities would create serious problems. Manufacturers have no authority to demand that payment recipients disclose to the manufacturer whether they have shared the payment in question with their own customers or clients, and there is no guarantee that payment recipients would agree voluntarily to such disclosures. The payment recipient might reject such disclosure provisions due to, for example, concerns about its ability to preserve the confidentiality of this competitively sensitive information once it was routinely disclosed to manufacturers; concerns about the administrative burdens associated with such reporting obligations; or concerns about the potential liability risks associated with furnishing manufacturers with information that would be used in the manufacturer's ASP calculations, and that could thus result in incorrect reimbursement rates if the information turned out to be inaccurate in some respect. Consequently, manufacturers simply might be unsuccessful in negotiating contractual provisions requiring disclosure of pass-through information, or they could experience prolonged delays in negotiating contracts to acquire needed services.

Given these problems, we urge CMS to eliminate downstream payment arrangements as one of the criteria for determining whether a particular fee qualifies as a "bona fide service fee" for ASP purposes. We believe this criterion could often be infeasible to apply, and that the other criteria of the bona fide service fee definition proposed by CMS (as refined and clarified to address the issues discussed above) should be adequate without consideration of the pass-through issue, which is not relevant to whether a service fee is bona fide. The key inquiry is whether the manufacturer acquires the service to meet its business needs, not how the recipient of the fee uses it.

c. Treatment of Service Fees for Financial Accounting Purposes vs. ASP Calculation Purposes

We note that CMS has asked for comments on how Medicare's guidance on the treatment of service fees for ASP calculation purposes may differ with the treatment of service fees for financial accounting purposes, and any implications that this may have for manufacturers. PhRMA believes that the treatment of service fees for ASP calculation purposes should not necessarily be determined by their treatment for accounting purposes, as there are a number of reasons why it may be appropriate to have different rules for accounting purposes than for purposes of calculating pricing metrics such as ASP.

Under guidance issues by the Financial Accounting Standards Board (FASB), manufacturers must treat fees paid to a distributor as a price concession if the identified benefit to the manufacturer is not sufficiently separable from the distributor's product purchases so that the manufacturer could have received the benefit by contracting with another party.² As discussed above, certain services that manufacturers acquire from purchasers could only be performed by purchasers; such services would not meet the FASB's "sufficiently separable" standard even though they may meet the manufacturer's business needs and could thus qualify as "bona fide" services for ASP calculation purposes. Given the different purposes served by financial accounting standards and ASP calculations (showing the financial position of a business vs. calculating an average product price that is used to establish providers' reimbursement rates), CMS should not incorporate financial reporting standards into its ASP guidance on bona fide services; instead, CMS should confirm explicitly that manufacturers need not treat service fees as price concessions in their ASP calculations merely because the fees would be treated in this manner for financial accounting purposes.

d. Determining Fair Market Value

PhRMA recommends that CMS clarify that bona fide service fees can be determined in any manner that reasonably measures the fair market value of the specific itemized services included in the contract, including fees that are determined on a percentage of sales basis. CMS also should clarify that a separate itemized payment for each individual service that is covered by a contract is not necessary. Manufacturers should be permitted to pay a service fee that covers an array of services provided and still be compliant with the bona fide service fee definition.

e. GPO Administrative Fees

Administrative fees paid by a manufacturer to a GPO are a unique type of arrangement that Congress and the HHS Office of Inspector General (OIG) have previously addressed in the context of the anti-kickback statute. GPOs use the combined purchasing power of their members (hospitals or other types of healthcare providers) in order to negotiate discounted prices with manufacturers on behalf of GPO members, which then make purchases at the discounted prices negotiated by the GPO. To help ensure that GPOs could continue to perform these price negotiation functions, Congress enacted a statutory safe harbor (and the OIG adopted a similar regulatory safe harbor) protecting administrative fees paid by a manufacturer to a GPO from anti-kickback liability.³ Both the statutory and regulatory safe harbors broadly protect GPO administrative fees from anti-kickback liability as long as the GPO makes certain disclosures regarding the administrative fees.

² FASB Guidance, EITF 01-09, Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products).

³ SSA § 1128B(b)(3)(C); 42 CFR § 1001.952(j).

CMS' proposed position that administrative fees paid by a manufacturer to a GPO must meet certain bona fide service fee requirements in order to be excluded from ASP calculations and not treated as discounts is not consistent with the anti-kickback safe harbor on GPO administrative fees, which was designed to reduce barriers that otherwise could discourage manufacturers from paying fees to GPOs; consistent with this goal, the safe harbor provides broad protection to GPO administrative fees, without requiring any determination that the administrative fees paid by manufacturers constitute "bona fide service fees." By contrast, the CMS proposal could discourage administrative fees to GPOs (by requiring that these fees be included in ASP calculations, unless they meet the general criteria for qualifying as a "bona fide service fee") and thereby thwart the purpose of the GPO safe harbor. To ensure that the ASP calculation rules do not work at cross purposes with the GPO safe harbor, CMS should therefore revise its proposal and provide explicitly that GPO administrative fees meeting the safe harbor criteria are not "price concessions" for purposes of ASP calculations.

2. Estimation Methodology for Lagged Exempted Sales

Manufacturers must exclude sales that are exempt from Best Price from ASP (e.g., "sales" to State Pharmacy Assistance Programs or Medicare Part D plans). CMS proposes a uniform approach to the method manufacturers use to exclude exempted sales that only become known to the manufacturer on a lagged basis, i.e., "exempted sales identified through chargeback or rebate processes."⁴ Manufacturers would be required to "use a 12-month (or less, if applicable) rolling average ratio methodology to estimate exempted sales known on a lagged basis (through chargebacks or rebates." The methodology would be similar to the 12-month rolling average methodology for estimating lagged price concessions. CMS stated that this approach was recommended by manufacturers, but also seeks suggestions for less-complicated alternatives.

While PhRMA believes there may be advantages and disadvantages associated with the estimation methodology laid out in the proposed rule, we believe there are significant benefits associated with adopting a consistent approach to lagged exempted sales for ASP calculations. Consequently, we encourage CMS to adopt a consistent approach to this issue (whether a refined version of the approach specified in the proposed rule, or an alternative) that avoids the risk of producing distortion in manufacturers' pricing calculations.

As CMS develops a uniform approach, PhRMA recommends that CMS carefully consider certain issues that could produce distortion in the calculated ASP. Problems may be created by exempting sales to ineligible purchasers (entities that take title to the product) and also exempting sales to ineligible entities that act as payers and only reimburse providers for the purchase of the product (e.g. Part D plans, SPAPs). For example, a sale to a PHS entity should be excluded from the ASP calculation. However, if the unit were subsequently reimbursed by a

⁴ Id.

Part D plan, the sale and unit would be exempted again, thus, understating ASP units resulting in a distorted ASP. Any methodology for estimating lagged exempted sales could have a significant impact on ASP calculations and deserves close study.

CMS also should give manufacturers the option to use alternative methodologies based on reasonable assumptions. In the event that CMS does not allow manufacturers to rely on alternative methodologies, CMS should give manufacturers two quarters lead time to implement any methodology it ultimately adopts.

3. Nominal Sales

The Deficit Reduction Act of 2005 (DRA) narrowed the Best Price exemption for "nominal" sales so that beginning in 2007 it would only apply to nominal sales (sales below 10% of AMP for that period) that are made to certain entities (i.e., 340B covered entities, intermediate care facilities for the mentally retarded, State-owned or operated nursing facilities, and other safety-net providers identified by CMS).⁵ CMS proposes to carry over this narrower definition of nominal sales to the ASP nominal sales exemption, but also requests comments on whether it should adopt an ASP-specific definition of nominal sales differing from the definition used for Best Price purposes.

PhRMA supports CMS' proposal to continue using the Best Price definition of nominal sales in ASP calculations. PhRMA believes that it would provide no real benefit and would create unnecessary confusion to maintain different definitions for different government programs.

PhRMA urges CMS to allow manufacturers to use 10% of the previous quarter's AMP as the price threshold for determining nominal price so that ASP calculations do not have to wait until the completion of current quarter AMP calculations to identify nominal sales excludable from ASP.

PhRMA also recommends that CMS maintain a list of the entities that are eligible to receive sales at nominal prices, similar to the database of 340B covered entities maintained by the Health Resources and Services Administration.

4. Bundled Price Concessions

In the proposed rule, CMS is considering issuing guidance on how bundled pricing arrangements should be treated in ASP calculations, with the goal of ensuring that ASP "is an accurate reflection of market prices for Part B drugs and that the treatment of bundled price concessions in the ASP calculation does not create inappropriate financial incentives."⁶ CMS

⁵ Social Security Act (SSA) § 1927(c)(1)(D).

⁶ 71 Fed. Reg. at 49004.

solicits comments on various aspects of bundling arrangements (e.g., different bundling structures that may exist, the extent to which Part B drugs are bundled with non-Part B drugs or with non-drug products); on what effect bundling arrangements may have “on the ASP calculation, on beneficiary access to high-quality appropriate care (including access to drugs that may not have clinical alternatives), and on costs to the Medicare program and beneficiaries”; and on potential methodologies for apportioning bundled discounts.⁷

PhRMA believes that clear guidelines are critical to ensuring that manufacturers can carry out their reporting obligations in compliance with all applicable laws and regulations. Predictability is essential for compliance reasons. Yet at the same time, PhRMA is concerned that any methodology adopted may be inelastic and fail to foster beneficial arrangements. To help ensure that any additional guidance that CMS ultimately issues on the treatment of bundled price concessions in ASP calculations provides the clarity, elasticity, and the predictability needed and results in improved accuracy, therefore, CMS should publish a specific proposal in draft form and give stakeholders a meaningful opportunity to comment.

5. Price Concessions for NDCs With Less Than 12 Months of Sales and for Redesignated NDCs

In response to manufacturers’ questions regarding calculating the “12 month rolling average” for NDCs with less than 12 months of sales, CMS proposes that the period used to estimate lagged price concessions be the “number of months the NDC has been sold.”⁸ CMS also notes in the proposed rule that manufacturers could include or exclude current-period data in calculating the rolling average, as long as they were consistent across NDCs, which is a helpful clarification recognizing that either of these two approaches are appropriate and consistent with the existing regulations on the rolling average calculation.

When a NDC is changed and “lagged price concessions offered for the prior NDC remain in effect,” CMS proposes that the manufacturer use 12 months (or the total number of months of sales of the prior and re-designated NDCs, if less than 12 months) of sales and price concession data from the prior and redesignated NDCs to estimate lagged price concessions for the redesignated NDC.⁹ This principle would not apply when a product is repackaged or relabeled by a different manufacturer or relabeler or is privately labeled.

⁷ Id. CMS also notes that its discussion of bundling should not be construed as an authorization of any pricing practices that contravene any laws, legal decisions, or regulations; manufacturers must comply with all applicable laws, including the Stark law, other relevant anti-kickback laws, antitrust laws, and laws governing fair trade practices. See id. at 49003-04.

⁸ Id. at 49003.

⁹ Id.

PhRMA supports CMS' proposal regarding estimating lagged price concessions for NDCs with less than 12 months of sales. PhRMA also generally supports CMS' proposal regarding estimating lagged price concessions for redesignated NDCs. However, PhRMA requests that CMS provide additional information about the circumstances under which this proposal would and would not apply. In the preamble, CMS refers to events such as a change to labeler code, package design modification, and other "non-drug feature" changes as situations when the proposal would apply. PhRMA would like clarification on situations when the proposal would not apply, such as when a product receives a new NDC-9. Also, we ask CMS to explain how this proposal would address situations in which the original and redesignated NDCs were sold concurrently. For example, CMS should clarify how manufacturers should combine price concession data for both products to estimate lagged price concessions for both products. In addition, we note that the issue of redesignated NDCs may need to be revisited at a future point, since FDA will be issuing regulations on registration as drug listings that are expected to result in FDA assigning NDCs; while we do not anticipate FDA's final regulations having any implications for the treatment of redesignated NDCs in ASP calculations, this should be determined once FDA's regulations are finalized.

6. Widely Available Market Prices and AMP Threshold

CMS has statutory authority to disregard the ASP for a drug if the HHS Office of Inspector General (OIG) finds that the drug's ASP exceeds its widely available market price (WAMP) or AMP by the "applicable threshold percentage" (currently 5%).¹⁰ CMS proposes to continue the 5% threshold (for both WAMP and AMP) for 2007.

CMS also notes that there are "operational issues associated with Medicare's authority to substitute a lower payment rate for a drug if the OIG finds and informs the Secretary, at such times as the Secretary may specify, that the ASP exceeds the WAMP or AMP by more than the established threshold."¹¹ CMS seeks comment on "operational issues such as the timing and frequency of the ASP, AMP, and WAMP comparisons and effective date and duration of the rate substitution."¹²

PhRMA agrees with CMS regarding the importance of the operational issues associated with Medicare's authority to substitute a lower payment rate for a drug if the OIG finds that the ASP exceeds the WAMP or AMP by more than the established threshold, and believes it would be premature for CMS to exercise this authority until key operational issues have been resolved. With respect to the timing and frequency of price comparisons, we believe CMS should have data indicating that the ASP for a drug exceeds its WAMP or AMP by more than the threshold

¹⁰ See SSA § 1847A(d)(3).

¹¹ 71 Fed. Reg. at 49004.

¹² Id.

percentage on an ongoing basis before considering whether it may be appropriate to disregard the ASP and substitute a payment rate below 106% of ASP. If CMS only has a "snapshot" showing that a drug's ASP exceeds its WAMP or ASP by more than the threshold percentage for one quarter, it lacks sufficient information to evaluate whether such a finding is an aberration reflecting unusual factors unique to that quarter, or a transient phenomenon that could shortly reverse itself, as opposed to a sustained pattern; as a result, a one-quarter snapshot would not provide an adequate evidentiary foundation for considering extraordinary steps such as substituting a lower payment rate for the usual 106% of ASP payment formula. Accordingly, it would be helpful for the OIG to design its price comparison studies so that a finding that ASP exceeds the AMP or WAMP by more than the threshold would be based on a sustained multi-quarter pattern (rather than a one-quarter snapshot), and we hope CMS will encourage the OIG to adopt such an approach.

More generally, the utility of these studies comparing ASP with WAMP or AMP could be enhanced if the OIG developed its study methodology through the notice-and-comment process, as Congress envisioned in directing the OIG to carry out these studies.¹³ Stakeholders have expressed concerns about a number of methodological issues associated with the price comparison studies conducted to date,¹⁴ and, particularly now that several of these studies have been conducted and methodological issues have been identified, it may be an opportune time for the OIG to publish its general methodology for carrying out these studies and solicit stakeholder comments about potential refinements that could help to improve the reliability and robustness of the study results. CMS should not implement any payment changes until these methodological issues are resolved.

7. Payment for Separately Billable Drugs Furnished in Connection with Renal Dialysis Services

In its final physician fee schedule rule for 2006, CMS stated that payment for a separately billable dialysis-related drug furnished during 2006 would be based on Social Security Act §

¹³ See H.R. Conf. Rep. 108-391 (2003), 2004 U.S.C.C.A.N. 1808, 1958-59 ("The Conferees intend that the Secretary, in making determinations to use the widely available market price, rather than the ASP, would provide a number of procedural and substantive safeguards to ensure the reliability and validity of the data used to make such determinations. These safeguards would include notice and comment rulemaking, identification of the specific sources of information used to make such determinations, and explanations of the methodology and criteria for selecting such sources.").

¹⁴ As one example, our understanding is that one of the OIG's studies found that the ASP for a drug exceeded its AMP by more than 5% based on the initially reported AMP, although the AMP was later restated and (as restated) did not exceed the ASP by the 5% threshold; given that AMP restatements are a common practice, it would be useful for the OIG to consider how restatements that occur before the completion of an ASP-AMP comparison study should be taken into account in its findings. Another example of methodological concerns that has been raised involves the units used in calculating weighted AMPs for 11-digit NDC codes, which apparently reflect ASP-relevant sales units rather than AMP-relevant units.

1847A. CMS now clarifies in the 2007 proposed rule that it intended this payment methodology to apply to 2006 and subsequent years (unless it specifies otherwise). PhRMA supports this approach. To avoid any possibility of confusion, CMS should state explicitly in the final rule for 2007 that payment based on SSA § 1847A refers to the 106% of ASP payment formula.

8. Medicare Part B Coverage

In connection with its discussion of ASP issues, CMS reiterates that The Medicare Part D program does not change Medicare Part B coverage for drugs.¹⁵ CMS has previously issued extensive guidance on the relationship between Part B and Part D drug coverage. PhRMA supports CMS' clarification regarding Part B and Part D coverage of drugs and biologicals and encourages CMS to continue its efforts to provide guidance as appropriate.

B. DRA Proposals

The proposed rule would amend 42 C.F.R. § 410.160 to implement the DRA provision concerning payment for colorectal cancer screening tests. That provision exempts such tests from the Part B deductible, effective 2007.¹⁶ PhRMA supports this provision and the corresponding proposed change in the regulation, which will increase the availability of these tests to Medicare beneficiaries and thank CMS for revising the regulations to make the policy clear.

C. Payment for Administration Fees for Part D Vaccines

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) expressly defines Part D drugs to include vaccines. Vaccines have enormous potential and can help patients avoid disease and save the government significant money in unnecessary health care costs. Thus, assuring appropriate access to vaccines is critical. There are currently over 200 vaccines in development in the United States, many of which could be indicated for the Medicare population.¹⁷ As Administrator McClellan said in his recent speech to the Institute of Health Technology Studies, CMS needs to promote coverage policies that encourage innovation. Part D plans include vaccines on their formularies; however, if there is not an effective CMS-endorsed approach to ensuring access to Part D vaccines, innovation and patient access could be impacted. As vaccines are largely administered in a physician office, which is different from most drugs dispensed under Part D by pharmacies, there are unique Part B issues to ensure appropriate

¹⁵ Id. at 49000.

¹⁶ See 71 Fed. Reg. at 48999.

¹⁷ Adis R&D Insight Database, 23 June 2006. For example, the development of a vaccine to prevent staphylococcal infection will be particularly important for the Medicare population and could reduce a significant public health risk.

reimbursement of physicians for their vaccine administration in order to assure patient access. Currently there is not a clear policy for payment of physician administration of vaccines.

Subject to certain exclusions, vaccines are listed expressly as covered Part D drugs under MMA.¹⁸ There are a number of exclusions under Part D, including that drugs may not be covered under Part D if they are covered under Part B.¹⁹ In addition, MMA allows a plan to exclude coverage of any drug for which payment would not be made if Section 1862(a) of the Social Security Act (SSA) applied. Section 1862(a)(1)(A) excludes coverage for items and services that are not reasonable and necessary for the diagnosis and treatment of illness and injury. However, there is a vaccine exception to the exclusion. Under Section 1862(a)(1)(B), vaccines expressly covered under Part B are expressly exempted from the exclusion. CMS in the final Part D rule, determined that as MMA referenced Section 1862(a) generally (which includes the vaccine exemption) and not just Section 1862(a)(1)(A), that the only way to read these sections consistently along with the express intent of Congress to cover vaccines under Part D was to find that these sections were not intended to exclude vaccines from Part D coverage if the vaccines are reasonable and necessary for preventing illness. Furthermore, to give effect to the vaccine coverage, CMS determined that Part B would pay for the administrative costs of the vaccine since CMS chose to define the Part D dispensing fee to exclude vaccine administration.

Thus, in the Part D final rule, CMS clearly and repeatedly stated that physicians' administration fees for Part D vaccines were payable under Part B. For example, the final rule stated that "costs of vaccine administration may be included in physician fees under Part B since Part B pays for the medically necessary administration of non-covered drugs and biologicals."²⁰ CMS reiterated this point in its Coordination of Benefits guidance for 2006 (issued on July 1, 2005), stating that "[c]osts directly related to vaccine administration may be included in physician fees under Part B, since Part B pays for the medically necessary administration of non-Part B covered drugs and biologicals."

Recently, however, CMS suddenly renounced this regulatory policy in a recent guidance document and asserted that Part B could not pay administration fees for Part D vaccines.²¹

¹⁸ SSA, § 1860D-2(e).

¹⁹ SSA, § 1860D-2(e)(2)(B). Part B only covers influenza, pneumococcal, and hepatitis B vaccine for high risk patients.

²⁰ 70 Fed. Reg. 4194, 4231 (Jan. 28, 2005). See also *id.* (in the future, CMS may develop crossover procedures where physicians would submit a claim for the Part D vaccine and administration fee directly to the Part B carrier, which would forward the Part D vaccine charge to the Part D plan); *id.* at 4328 ("Costs directly related to vaccine administration may be included in the physician fees under Part B, since Part B pays for the medically necessary administration of non-Part B covered drugs and biologicals").

²¹ See May 8, 2006 CMS memorandum to Part D sponsors from Abby L. Block, Director of CMS' Center for Beneficiary Choices, concerning "Increasing Part D Vaccine Access" (the "May 8th Guidance"); CMS FAQ ID no. 7685 (July 14, 2006) (addressing the question: "Are Part D vaccine administration costs covered under Part B?").

Although not articulated in the recent guidance, we understand that CMS may be concerned that it is creating a "slippery slope" if it allows coverage for reasonable and necessary services in connection with the prevention of illness rather than only those services that are reasonable and necessary for the diagnosis and treatment of injury or illness. That should not be the concern. CMS' harmonization of a number of provisions in Section 1862(a) and in MMA that are unique to vaccines was solely to provide beneficiaries with access to vaccines and give effect to Congress' express coverage of vaccines under Part D. Thus, CMS' interpretation is unique to vaccines.

Moreover, CMS' original analysis and decision to allow Part B coverage for vaccine administration fees in the final rule was inextricably linked to its other decision to narrowly define dispensing fees and preclude Part D coverage of administration fees.²² Therefore, we urge CMS to retain its original interpretation and to provide a code to physicians to bill for the administration of Part D vaccines. In the absence of a clear and appropriate means to bill for the time involved in education, counseling and administration in connection with Part D vaccines, administration of vaccines may be disincentivized, thereby undermining the express intent of Congress in covering these vaccines.

We note that a clear policy of covering administration of Part D vaccines under Part B is also necessary to avoid the confusion physicians may face in attempting to interpret and follow CMS' recent statements on Part B payments associated with Part D vaccines. In its July 14, 2006 FAQ on this issue, CMS suggested that while Part D vaccine administration fees (along with office visits that are "primarily for the purpose of administering a noncovered injection") are not covered by Part B, other services associated with Part D vaccines might be billable to Part B in some cases.²³ Specifically, "conceptually additional time and resources related to discussions concerning Part D vaccines could be billed as part of another qualifying Part B office visit"; e.g., "if a beneficiary presents with a condition that qualifies for a Part B office visit, the physician could include the counseling of a Part D vaccine (including a discussion of possible treatment interactions) into this Part B visit, and the office visit could be covered by the carrier as necessary for the treatment of an illness (as determined by the carrier)."

We are concerned that physicians would have difficulty interpreting and applying this guidance, particularly as the rationale for allowing Part B payment for vaccine-related counseling services but not administration services is unclear. In addition, physicians seeking to comply strictly with this guidance might feel that patients cannot be promptly vaccinated during an

²² 70 Fed. Reg. at 4231.

²³ The July 14th FAQ largely is based on an interpretation of the Medicare Benefits Policy Manual that if the vaccine is not covered because it is not reasonable and necessary for the treatment of illness or injury, then the office visit is not covered. However, CMS already has determined that vaccine are covered for the reasonable and necessary prevention of illness so it would not make sense to not cover the administration of those vaccines as not being reasonable and necessary.

“illness-related” office visit due to a risk that the entire office visit would be disallowed on the theory that its “primary” purpose was vaccine administration; this would be an unfortunate outcome that results in lost opportunities for vaccination and goes against public health principles. As the American Medical Association and twelve other medical societies emphasized in a June 29, 2006 letter to CMS “The recognized standard of public health practice is that patients be immunized whenever the physician has the opportunity and the patient needs the vaccine, otherwise patients may be lost to follow-up and not get vaccinated at all.” (Emphasis added.)

Thus, CMS should provide for an administration fee under Part B for Part D drugs in the same way it treats administration of Part B vaccines. CMS should assign a HCPCS code for Part D vaccine administration so that physicians could submit the claim to the Part B carrier in the same manner that they do for administration of Part B vaccines. This approach is less confusing to physicians, will ensure vaccine administration at the time of an office visit, and is less susceptible to program integrity concerns.

D. Echocardiography Imaging Drug Administration Issue

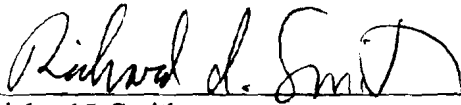
Echocardiography procedures are used to evaluate patients with various cardiac disorders. In approximately 20% of cases, echocardiographic images are suboptimal and repeat studies or additional testing may be required. In many of these cases, echocardiographic imaging drugs are used to enhance images, and clinical studies have shown that echocardiographic imaging drugs can salvage up to 58-91% of unevaluable images. Echocardiographic imaging drugs are administered intravenously. Although Medicare pays separately for echocardiographic imaging drugs, no separate payment is made for the intravenous administration of these drugs. Current coding edits do not allow providers to report the intravenous administration of these drugs separate from the imaging procedure. Unlike other imaging procedures involving contrast (e.g., computed tomography and magnetic resonance imaging), there are no codes that describe echocardiographic procedures performed with contrast imaging drugs. Echocardiography procedure codes were developed before echocardiographic imaging drugs were approved by the FDA; none of these procedure codes mention use of contrast imaging drugs. The costs for intravenous administration of echocardiographic imaging drugs are not insubstantial, and none of these costs are reflected in the resources supporting the payment rates for echocardiography procedures. We urge CMS to remove any edits from the Correct Coding Initiative (CCI) that combine intravenous injection code(s) into codes for the associated echocardiography procedures. Deleting the CCI edits should remove financial disincentives limiting appropriate use of echocardiography imaging drugs and should encourage appropriate use of contrast enhancement, to help salvage images when the echocardiographic image is suboptimal.

* * *

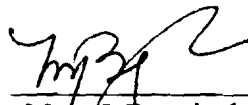
Dr. Mark B. McClellan
October 10, 2006
Page 15

PhRMA hopes that these comments will be useful to CMS in developing the final physician fee schedule rule for 2007. We look forward to further dialogue on opportunities to enhance beneficiaries' access to care through improvements in the ASP-based payment system, and trust that CMS will not hesitate to contact us with any questions, comments, or requests for additional information.

Sincerely,



Richard I. Smith
Senior Vice President for
Policy, Research, and Strategic Planning



Maya J. Bermingham
Assistant General Counsel

Submitter : Dr. Kent Webb
Organization : Trinity Vascular Institute
Category : Physician

Date: 10/10/2006

Issue Areas/Comments

Background

Background

These revisions will have a negative impact on Medicare patients and their access to health care, as reductions in reimbursement will severely limit access to qualified physicians who are the providers of these procedures.

GENERAL

GENERAL

CMS-1321-P

Thank you for the opportunity to respond to the CMS proposal of August 8, 2006 regarding proposed changes in the physician fee schedule for CPT 36478 and 36489, Endovenous Laser Ablation.

Areas of concern:

1. Our practice employs full time Registered Vascular Technologists (RVT) to provide high quality ultrasound imaging services. There is a nationwide shortage of RVT's as they are highly skilled and require yearly recertification and credentialing. Our practice spends upwards of \$150,000 plus benefits per year for our 2 superb RVT's. It will be impossible to comply with CMS guidelines to have an RVT present for these procedures if the RVU's and reimbursements continue to decrease. Additionally there are proposed cuts for reimbursement for vascular ultrasound, as well as a 5.1% across the board proposed cut for Medicare services. All of these cuts will cripple the ability of physicians to perform this extremely important procedure and result in loss of access of care for Medicare beneficiaries.

2. RVUs have been steadily reduced from 2005 levels for Endovenous Laser Ablation from 46.91 in 2006 to 43.53 in 2007, and 40.84 in 2008. The Laser generator has a high initial acquisition cost of around \$38,000, as well as the disposable laser catheter kits, drapes gowns anesthetic solution, tubing, etc that costs several hundred dollars per patient.

3. The values for radiofrequency vein ablation (36475 & 36476) have been consistently higher than endovenous laser ablation despite the higher acquisition cost for the Laser Generator, which raises the cost of laser ablation (36478) to equal or higher than radiofrequency ablation (36475).

I am requesting 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.

4. I should add that if the RVU levels continue to drop, it may not be economically feasible to continue these minimally invasive procedures in our office. The alternative would include going back to old-fashioned surgical saphenous vein stripping in the hospital, with the attendant costs of hospital, operating room, anesthesia, recovery room, etc, etc.

Several of my patients have had a vein stripping operation on one leg years ago, and then have endovenous laser ablation of the other leg. Without question they always tell me that the laser ablation was much easier on them, with decreased pain, morbidity, and faster return to work and activities of daily living when compared to the vein stripping.

I would consider it an honor to discuss this further with the members of your committee.

Sincerely,

Kent P. Webb, MD
Trinity Mother Frances Vascular Institute
1327 Troup Highway
Tyler, TX 75701
webbk@tmfhs.org

Impact

Impact

See General Comment Statement below

Provisions of the Proposed Rule

Provisions of the Proposed Rule

See General Comment Statement below

Submitter : Mr. Santiago Mu?oz
Organization : University of California Health System
Category : Hospital

Date: 10/10/2006

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-957-Attach-1.PDF



OFFICE OF THE PRESIDENT --
CLINICAL SERVICES DEVELOPMENT

OFFICE OF THE PRESIDENT
1111 Franklin Street
Oakland, CA 94607-5200
Phone: (510) 987-9071
Fax: (510) 763-4253
<http://www.ucop.edu>

October 10, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building, Room 443-G
200 Independence Ave, SW
Washington, DC 20201

SUBJECT: **CMS-1321-P** Medicare Physician Fee Schedule 2007

Dear Administrator McClellan:

Thank you for the opportunity to comment on the proposed revisions to the Medicare physician fee schedule for calendar year 2007. These comments are provided on behalf of the University of California (UC) Health System and its nearly five thousand faculty physicians. While the proposed rule includes various items designed to protect and improve health care access for Medicare beneficiaries, we are extremely concerned with the conversion factor (CF) payment update of -5.1% scheduled to occur under the Sustainable Growth Rate (SGR). We urge the Centers for Medicaid and Medicare Services (CMS) to amend the rule and help mitigate the deleterious impact of this physician payment cut.

Since the Medicare program's inception, UC's faculty physicians have been committed to caring for a large share of the Medicare population. Currently, nearly a quarter of all clinical activity by UC physicians is dedicated to Medicare beneficiaries. The commitment of our physicians, nurses, and staff to medically vulnerable patients – including Medicare beneficiaries – is the foundation of the UC Health System. UC physicians ensure that Medicare beneficiaries have access to a range of high quality healthcare services; this includes primary and preventive care as well as highly advanced care in quaternary settings, such as burn and cancer centers. UC faculty also educates and trains medical students, residents, and other health professionals who will become the next generation of caregivers for the Medicare population. Finally, UC faculty physicians conduct clinical research that informs the country's healthcare providers on effective and efficient healthcare strategies for all Americans.

For all of these reasons, the UC Health System wholeheartedly endorses CMS's efforts to improve access for Medicare beneficiaries, including expanding Medicare's preventive services. Unfortunately, the negative physician payment update is not consistent with the

Submitter : Mr. Matthew Eyles
Organization : Wyeth Pharmaceuticals
Category : Drug Industry

Date: 10/10/2006

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1321-P-958-Attach-1.PDF

#958

Wyeth Pharmaceuticals
500 Arcola Road
Collegeville, PA 19426

Matthew D. Eyles
Assistant Vice President
Public Policy
484 865 5132 tel
484 865 6420 fax

Wyeth

BY ELECTRONIC DELIVERY

October 10, 2006

Mark McClellan, M.D., Ph.D.
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Ave., 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)

Dear Dr. McClellan:

Wyeth Pharmaceuticals appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services proposed rule for the Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 (MPFS Proposed Rule). Wyeth Pharmaceuticals, a division of Wyeth, is one of the world's largest research driven pharmaceutical and healthcare products companies with leading products in the areas of women's health care, cardiovascular disease, central nervous system, inflammation, transplantation, hemophilia, oncology, vaccines and nutritional products.

As a core principle, Wyeth believes it is important to ensure Medicare beneficiary access to clinically appropriate drugs and biologicals by adequately reimbursing healthcare providers for the costs of acquiring and administering these important therapies. In addition, we believe it is critical for rulemaking to occur through open and transparent processes. Many stakeholders—but especially CMS—recognize the growing importance of transparency in the healthcare system. The MPFS Proposed Rule addresses a number of significant new issues, and we believe the outcomes for Medicare beneficiaries and providers would be improved

Page 2
Dr. Mark McClellan, Administrator
October 10, 2006
CMS-1321-P

if CMS relied more upon Notice of Proposed Rulemaking (NPRM) procedures in promulgating rules. Our specific comments address the following issues:

- Colorectal cancer screening deductible
- Average sales price (ASP) and related issues
- Clotting factor furnishing fee
- Payments for end-stage renal disease (ESRD) drugs and biologicals
- Adequate reimbursement for drug administration services, especially for vaccines

Colorectal Screening Deductible

Wyeth supports CMS' proposal to exempt colorectal cancer screening from the Part B deductible.

The MPFS Proposed Rule would amend 42 C.F.R. § 410.160 to implement the Deficit Reduction Act (DRA) provision¹ concerning payment for colorectal cancer screening tests and exempts such tests from the Medicare Part B deductible, effective January 1, 2007. Timely screening is key to discovering growths in the colon and removing them before they become cancerous. Wyeth supports this proposal, which will increase beneficiary access to these tests and help to contain this deadly disease in its early stages.

ASP-Related Issues

CMS intends to issue a final rule to implement MMA provisions related to the calculation and submission of manufacturers' average sales price (ASP) data. This section of our comment letter addresses several ASP-related issues.

Bona Fide Service Fees

Wyeth supports CMS' proposed definition of "bona fide service fees" and requests further clarification of the definition through the NPRM procedure.

CMS proposes to define "bona fide service fees" as "fees paid by a manufacturer to an entity that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise not perform (or contract for) and that are not passed on, in whole or in

¹ See 71 Federal Register at 48999.

Page 3
Dr. Mark McClellan, Administrator
October 10, 2006
CMS-1321-P

part, to a client or customer of an entity, whether or not the entity takes title to the drug.”

Wyeth supports CMS’ proposed definition of “bona fide service fees” and believes that this definition addresses a key area of potential risk identified in the 2003 OIG Compliance Program Guidance for Pharmaceutical Manufacturers relating to manufacturers’ relationships with purchasers and their agents. Price concessions and other remuneration to purchasers related to a sale, directly or indirectly, implicate the Anti-kickback statute.

However, we request that CMS provide manufacturers with a clearer understanding as to how to determine when a fee qualifies as a “bona fide service fee.” Again, when CMS provides guidance, Wyeth requests that such guidance be provided in a formal rulemaking so that we have an opportunity to comment.

ASP Payment Calculations

Wyeth supports CMS’ proposal to clarify that bona fide service fees paid to entities that are not direct purchasers should not be treated as price concessions for purposes of ASP calculations.

In the Proposed Rule, CMS proposes that “bona fide service fees” not be considered price concessions. Wyeth agrees with CMS that fees meeting the bona fide service fee criteria should not be considered price concessions for the calculation of ASP.

CMS also proposes to clarify that fees, including service fees, administrative fees and other fees, paid to group purchasing organizations or pharmacy benefit managers are not considered price concessions as long as they satisfy the definition of “bona fide service fee.” Wyeth agrees that bona fide services fees paid to entities that are not direct purchasers, should not be included in the ASP calculation. GPOs, for example, negotiate contracts on behalf of their members (e.g., hospital groups, nursing home groups, and other healthcare entities) but do not purchase for them. In return for the services provided by GPOs, manufacturers may provide bona fide administrative fees to GPOs. However, customarily, it is the responsibility of each individual entity to purchase drugs or biologicals on their own behalf based on the GPO-negotiated contract.

We urge CMS to eliminate any reference to PBMs, GPOs, and any other organization that is not a direct purchaser of drugs or biologicals.

Fair Market Value

Wyeth agrees with CMS' definition of bona fide service fees and the need for further guidance around the methodology for determining "fair market value" for such services. Wyeth also recommends that CMS' guidance on the methodology go through the NPRM procedures.

In the MPFS Proposed Rule, CMS defines bona fide service fees as "fees paid by a manufacturer to an entity that represent *fair market value* for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform, or contract for, in the absence of the service arrangement, and that are not passed on, in whole or in part, to a client or customer of an entity, whether or not the entity takes title to the drugs."² CMS also states that it is "considering providing further guidance on or revising the approach or methodology manufacturers must use to determine the fair market value of bona fide services performed on their behalf."³ Wyeth concurs with CMS about the need to provide manufacturers with a clear, understandable and proper fair market value standard. In addition, we ask that any CMS guidance addressing a methodology for determining fair market value be supported by market research and go through NPRM procedures.

Estimation Methodology for Lagged Exempt Sales

Wyeth believes that CMS should adopt a consistent approach to lagged exempt sales across the ASP and Average Manufacturers Price (AMP) calculations.

CMS proposes a uniform approach to the method manufacturers use to exclude exempted sales that only become known to the manufacturer on a lagged basis, for example, exempted sales identified through a chargeback or rebate process.⁴ Manufacturers identify many ASP-ineligible sales through chargebacks and rebates that may not be available at the time ASP is calculated. We encourage CMS to adopt an approach and an estimation methodology for lagged exempt

² 71 Federal Register at 49,001

³ 71 Federal Register at 49,001

⁴ Id

sales that is consistent for both ASP and AMP and avoids the risk of producing distortions in the manufacturers' pricing calculations.

Nominal Sales

Wyeth recommends that CMS maintain the DRA definition of "nominal sales" as sales below 10% of AMP in the same quarter.

CMS requests comments on whether it should adopt an ASP-specific definition of nominal sales differing from the definition used for DRA Best Price (BP) purposes. Under recent changes resulting from the DRA, nominal sales for BP are defined as sales below 10% of AMP in the same quarter for which AMP is computed and that are made to certain qualified entities--for example, 340B and other safety-net providers. Wyeth requests that CMS continue to use the existing Best Price definition of nominal sales in ASP calculations. There is no clear rationale for creating an ASP-specific definition on nominal sales. Furthermore, it would be administratively burdensome for manufacturers to maintain different definitions for different government programs.

Wyeth would support CMS' decision to allow manufacturers to use 10% of the previously reported AMP as the price threshold for determining nominal price. This ensures that manufacturers do not have to wait until the current quarter AMP calculation is completed to identify nominal sales excluded from AMP. Wyeth also requests that CMS maintain a list of entities that are eligible to receive sales at nominal prices, similar to the database of 340B covered entities maintained by the Health Resources and Services Administration.

Bundled Price Concessions

Wyeth agrees that clear and predictable guidelines around bundled price concessions are important to ensure accurate reporting in ASP data and recommends that CMS develop such guidelines through NPRM procedures.

CMS states that it is considering issuing guidance on how bundled pricing arrangements should be treated in ASP calculations to ensure that ASP "is an accurate reflection of market prices for Part B drugs and that the treatment of bundled price concessions in the ASP calculation does not create inappropriate financial incentives." We agree that clear, predictable guidelines are critical to ensuring that manufacturers can report their ASP data in compliance with CMS'

regulations. Therefore, we request that CMS publish an NPRM in draft form and provide industry with a meaningful opportunity to comment on any methodology issued to guide manufacturers in their treatment of bundled price concessions.

Other Price Concessions - Redesignated NDCs

Wyeth requests that CMS provide additional guidance regarding which specific changes to an NDC meet the criteria to establish a redesignated NDC.

When an NDC is changed and “lagged price concessions for the prior NDC remain in effect,” CMS proposes that manufacturers use 12 months of sales and price concession data from the prior and redesignated NDC to estimate lagged price concessions for the redesignated NDC.⁵ Manufacturers are required to use the total number of months of sales of the prior and redesignated NDC if less than 12 months of sales data is available.⁶ CMS has clearly identified an exception to this new calculation for products where the NDC is changed because the product is relabeled or repackaged by a different manufacturer or privately labeled. However, we request additional guidance regarding what specific changes to an NDC meet the criteria to establish a redesignated NDC, and the circumstances under which the redesignation criteria and new calculation would apply.

Clotting Factor Furnishing Fee

Wyeth applauds CMS’ proposal to increase the clotting factor furnishing fee and encourages the agency to implement the increase in the final rule once consumer price index (CPI) data for medical care is available.

CMS proposes to increase the furnishing fee by the percentage increase in the CPI for medical care for the twelve-month period ending June 2006.⁷ Without an increase in the clotting factor furnishing fee, providers of clotting factor—especially hemophilia home care companies—could eventually be forced to withdraw from the Medicare market. If that occurs, hemophilia patients could be denied clinically appropriate access and may not receive prompt treatment for bleeds associated with their disease. In addition to the significant physical and emotional harm to hemophilia patients, it could result in a shifting of care to other

⁵ 71 Federal Register at 49003

⁶ 71 Federal Register at 49003

⁷ 71 Federal Register at 49004

more costly sites of service, such as emergency rooms or hospital outpatient departments. Wyeth applauds CMS' proposal and believes it is important for CMS to publish the updated furnishing fee in the final rule once the CPI data is available.

ESRD Provisions

Wyeth supports reimbursement of all ESRD drugs and biologicals at no less than ASP+6% when separately billed by freestanding or hospital-based ESRD facilities.

Before 2006, CMS based reimbursement for ESRD drugs and biologicals on the prior year's acquisition cost data. In 2006, CMS changed the reimbursement methodology to ASP+6%. ASP-based reimbursement is the best option available under the statute because it is consistent with the formula used to pay for other Part B drugs. Therefore, Wyeth supports the proposal to maintain ESRD drug reimbursement at no less than ASP+6%.

Drug Administration Services

CMS should ensure adequate reimbursement for drug administration services and address the contradictions in its Part B and Part D policies regarding payment of administration fees for vaccines.

Appropriate access to vaccines is of critical importance to all Medicare beneficiaries. Wyeth believes the CMS policy is unclear regarding the reimbursement of the physician-related drug administration services, especially for vaccines. Furthermore, Wyeth is very concerned that beneficiaries will lose access to or encounter significant restrictions in receiving important vaccines if the cost of administering the vaccine is not covered.

In the *Part D Coordination of Benefits Guidance for 2006*, CMS stated, "costs directly related to vaccine administration may be included in physicians fees under Part B, since Part B pays for the medically necessary administration of non-Part B covered drugs and biologicals." However, recent guidance to Part D plans suggested that payment of administration fees available under Part B only applies to vaccines covered under Part B. The policies in these two documents appear to be contradictory.

Page 8
Dr. Mark McClellan, Administrator
October 10, 2006
CMS-1321-P

Wyeth requests that CMS provide for a separate administration fee to be paid under Part D in the same way it does for the administration of Part B vaccines. To promote consistency and transparency across Medicare programs, CMS should assign a Health Care Common Procedure Coding System (HCPCS) code for Part D vaccine administration so that physicians could submit the claim to the Part B carrier in the same manner that they do for administration of Part B vaccines. This approach would be less confusing to physicians, ensure vaccine administration at the time of an office visit, and be less susceptible to program integrity concerns.

Conclusion

Wyeth appreciates the opportunity to comment on the issues outlined in the 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. We look forward to our continued work with CMS to ensure that Medicare beneficiaries receive appropriate access to vital drug and biological therapies covered under the Medicare program. If you have any questions about Wyeth's comments, please do not hesitate to contact me.

Sincerely,

A handwritten signature in cursive script that reads "Matthew D. Eyles".

Matthew D. Eyles

Submitter : Dr. Stanton Champion

Date: 10/10/2006

Organization : Urology Tyler, PA

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : Dr. Craig Schwartz
Organization : Vein Centers for Excellence of KC
Category : Physician

Date: 10/10/2006

Issue Areas/Comments

Background

Background

Impact

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

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:

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 employ 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 than 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,

<Your Name>
<Your City, State>
<email address>

Impact

Impact

Provisions of the Proposed Rule
See General Comment below.

Provisions of the Proposed Rule

Provisions of the Proposed Rule

Background
See General Comment Below

Submitter : Dr. Stanton Champion

Date: 10/10/2006

Organization : Urology Tyler, PA

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-961-Attach-1.DOC

#961

Department of Health and Human Services
Centers for Medicare and Medicaid Services, HHS

Re: Urology Tyler, PA Comments to CMS regarding CMS-1321-P
Proposed changes to Reassignment and Physician Self-Referral Rules Relating to
Diagnostic Tests

Dear Sir or Madam:

This letter is submitted in response to the request of the Centers for Medicare and Medicaid Services ("CMS") for comments regarding proposed revisions to the Medicare payment policies under the physician fee schedule for calendar year 2007 ("Proposed Revisions"). Specifically, the comments of this commentator address those proposed revisions as they relate to the existing Medicare **Reassignment Rules ("Reassignment Revisions")** and the existing **physician Self-Referral Regulations ("Self-Referral Revisions")**.

Most importantly, this commentary also addresses CMS's stated purpose in the Proposed Revisions: the elimination of small centralized pathology laboratories. Because this stated purpose raises significant concerns separate and apart from the language of the proposed revision, that issue is addressed first in this commentary. With that introduction, specific commentary is set forth below:

I. Unsupported Rationale for the Elimination of Centralized Pathology Laboratories

In explaining its rationale, for the Proposed Revisions, CMS makes the conclusory statement that remotely located centralized pathology laboratories ("Path Labs") pose significant fraud and abuse risks. Nothing within the Proposed Revisions provides any hint of why CMS has reached this conclusion, nor is there any indication that CMS has undertaken any sort of balanced analysis, looking carefully at the potential benefits – both in terms of improved quality of care and financial economy to the program – of these arrangements. This commentator urges CMS to carefully analyze these arrangements from a risk-benefit analysis prior to undertaking broad-sweeping revisions purportedly specifically designed to eliminate their existence. **We would also like to note the OIG has conducted an audit into our physician-owned pathology lab, but the results are not yet known. That audit is not yet finalized, however, CMS has taken comments from pathology organizations and published a proposed rule before receiving the report of its own investigative agency.**

The need for a balanced analysis is also apparent in light of the stated concern, apparently voiced by commentators in response to Phase II Interim Final Regulations ("IFC") that Path Labs would encourage over-utilization. CMS expressly took note of commentary and stated that, with regard to its centralized building requirement; it was "persuaded by commentators who responded to the Phase II IFC that our present definition may encourage the unnecessary ordering of ancillary services." (August 22, 2006 Federal Register, page 49056)

Just as it is the case with all types of treatment modalities, there may be bad Path Labs that encourage over-utilization and provide no corresponding program and patient benefits, and there are good Path Labs that protect against over-utilization and significantly improve the quality of patient care. The CBLPath path lab model addressed in Advisory Opinion 04-17 was obviously submitted by the commercial lab industry with a vested economic interest in portraying all physician-owned labs as violating the tenants prescribed by the April 2003 Advisory Opinion on Passive Physician Joint Ventures. As addressed later herein, physician-owned Path Labs can be integrated into a physician's active medical practice and structured to protect against over-utilization concerns. The commercial lab industry cannot provide the benefits outlined herein that are unique to physician-owned Path Labs, and commercial labs stand to lose profits if physician-owned Path Labs such as our model continue to operate.

CMS should also take note that the radiologist lobby used similar over-utilization arguments with Congress over the last two years to push through statutory restrictions on the reassignment rules. Those attempts failed - and for good reason. It was promoted by those whose economic interests would be furthered by such restrictions. The promotion of specific economic interests, disguised in a rationale of alleged over-utilization, ignores what should be the fundamental purpose of the regulations: improved quality outcomes in an economically efficient manner. **If the number of patients treated and specimens processed do not materially vary due to where the specimens are processed, it simply boils down to who gets the reimbursement. Regardless of the venue of where the specimens are processed, the treating physician must always document the medical necessity for the testing. Elevated PSA counts, age, DRE (digital rectal exam) results, and prior medical history are not subjective criteria that can be manipulated by physicians motivated by financial gain.**

Therefore, it is the commentator's opinion that CMS is considering rule changes to eliminate physician-owned Path Labs, but instead should be ensuring that patients receive economical quality care. Elimination of physician-owned Path Labs does not accomplish that goal but instead eliminates competition and interrupts continuity of care.

The remainder of this commentary focuses on specific benefits of physician-owned Path Labs as well as appropriate ways in which over-utilization risks could be addressed, without sacrificing those benefits.

II. Benefits of Path Lab Arrangements

It is virtually impossible to overstate the importance of early detection and accurate professional interpretation to successful treatment of prostate cancer. Physician-owned path labs provide significant, unique benefits in the promotion of early detection. The specific benefits of these types of arrangements include the following:

(1) Quality Assurance and Outcomes Tracking: A properly structured physician owned Path Lab allows the treating physician to maintain control of the entire process beginning with physical exam, blood work results, tissue collection and processing, interpretation of prostate tissue, and ending with appropriate follow-up and treatment of the patient. This ability

to supervise and direct the entire process makes information and outcomes tracking much simpler, efficient, and reliable.

In addition, as a direct result of the Path Lab existing under the supervision and control of the treating physicians, it has been our experience that the flow of relevant information regarding the patient's condition between the pathologist and the treating physician has increased dramatically. Questions regarding the specimen collection process and clarification of pathology findings are easily accomplished. The same Board Certified pathologist is interpreting each tissue sample collected from the patients at our urology office. The pathologist is accustomed to the technique the urologist uses to collect the tissue, therefore the pathologist is in a position to detect an outlier in expected quality. In the past, when there was a unique situation with a patient's tissue, the pathologist has recognized the exception, and phoned the urologist. Prior to the physician-owned Path Lab arrangement, this type of vital exchange was difficult at best and often impossible.

Certainly, one might argue that the ideal situation might be one in which the physician-owned Path Lab was located in the same building as the office of the treating physician. However, the primary effect of a "same building" restriction would be to limit physician controlled Path Labs to large practices in metropolitan areas that could afford to equip and fully utilize a full-time Path Lab. Additionally, it would be very difficult for a medium size or small practice to employ a full-time pathologist in the "same building". The end result of such a restriction would invariably result in increasing disparate treatment among Medicare patients, with the potential to disproportionately adversely affect care provided to patients in rural or small communities.

(2) Expertise. The use of physician-owned Path Labs allows specialization by pathologists that previously has only been seen in the largest medical centers or reference laboratories. Prior to the establishment of its Path Lab, Urology Tyler had no choice but to use a commercial lab or general pathologists for interpretations. While these pathologists are certainly competent, the level of expertise of pathologists who limit their practice to urology, such as in our Path Lab, allows the pathologist to obtain the highest level of expertise by virtue of this specialized experience. In fact, this model follows the government's own methodology, employed at the Armed Forces Institute of Pathology, where the technical staff and pathologists are specialized in a specific area of interest, with urology being one of those areas.

(3) Availability of Communication and Consultation. In addition to the foregoing, the physician-owned Path Lab offers a fairly unique opportunity for pathologists who work together in Path Lab arrangements and who specialize in uropathology, to consult with each other in-house on a regular basis. This allows for on-site, immediate consultation in addition to the availability of the treating physician to clarify and consult with the pathologists.

III. Controlling the Risk of Over-utilization

It is our position that regulations could be adopted that place specific requirements on physician-owned Path Labs that will address over-utilization concerns, while preserving the obvious benefits of these types of arrangements. Such regulations could also ensure that the physician-owned Path Labs are actively integrated into the urologist's professional practices, as

opposed to being suspect passive joint ventures. Ultimately, broadly defined wholesale prohibitions do not serve the interests of patient care or the government's interest in economically efficient care. The overbroad nature of the proposed regulations will likely create roadblocks to improved patient care and outcomes, resulting in delayed treatment and ultimately increased treatment costs. **Moreover, new regulations have the potential to do nothing other than to promote the economic interests of one health care group (the commercial lab industry) over another (physician practices).**

It is this commentators position that the best way to ensure that physician-owned Path Labs are maximizing their potential for improving care and outcomes, while discouraging over-utilization is by ensuring that these arrangements are not passive investments of the treating physicians. Our physicians are actively involved in the direction and supervision of our Path Lab. We are responsible for the services provided by our Path Lab. With our model in mind, this commentator believes the following recommendations, specific to this type of arrangement, would balance those two important interests:

(1) Treating physician groups who own Path Labs should be required to appoint a member of their group as an active physician liaison for the lab, with audit and utilization oversight responsibilities. The physician liaison's duties should include periodic on-site visitation to the Path Lab. (Urology Tyler has a Lab Director, and we do periodic on-site visits.)

(2) Ownership in the Path Lab should include an investment and ownership in all the necessary equipment to operate the Path Lab, the equipment should be permanently located in space reserved exclusively for the ownership group, and reserved exclusively for use by the group. (All equipment was purchased and paid for by Urology Tyler. It is used exclusively for the group's pathology.)

(3) Space requirements should be sufficient to provide exclusively reserved space that is adequate to prepare and perform the interpretations. This commentator is not opposed to specific space requirements, as long as they are rationally related to the amount of space required to safely and competently perform the service. The current 350 square feet space requirement in the proposed regulations is arbitrary and has no rational relationship to the square footage necessary to safely and competently perform the lab service. For purposes of State integrated regulatory oversight and the convenience of practice groups to oversee operations, it may be logical that the physician-owned Path Labs should be located in the same State as the practice group.

(4) Periodic consultation and quality assurance should be required, including periodic meetings between the practice group physician liaison (Lab Director) and the pathologist to review results and take appropriate action for improvement of defined deficiencies.

(5) Protocols should be established to ensure refinement of the specific criteria for pathology testing and methods for tracking and addressing outliers.

(6) To ensure active practice integration, an independent contractor "physician in the group practice" (the Pathologist) should only be able to provide professional or technical services on behalf of the group practice, and for which the group practice bills or collects, if the services

are provided on the premises of the group practice as historically defined in the Stark Statute. This would discourage the contractual reassignment of services by Pathologists whose only relationship with the billing practice group exists on paper. Further, in 2004 CMS clarified that diagnostic tests provided by leased employees, such as lab technicians, are not "purchased tests" for purposes of the rule. That argument is strengthened when the leased lab technician is supervised by a Pathologist who has a direct independent contractor relationship with the practice.

(7) We agree that if a group practice intends to bill for the technical component of a path lab services, it ought to also perform the professional component of that same service. The Stark Statute clearly allows that professional component to be performed by the group practice through a Pathologist who is a physician in the group practice.

(8) Consistent with current CLIA regulations that were promulgated to ensure quality lab standards, a single pathologist is currently limited to being the medical director of five or fewer Path Labs.

(9) Regulatory oversight is required in the form of refined credentialing criteria which incorporate the above recommendations. In fact, the auditing recommendations set forth above should be applied to all pathology laboratories, regardless of ownership or location.

It is this commentators belief that more stringent credentialing regulations under the general criteria set forth above would not only serve to promote quality of care and economic efficiency in Path Labs, but would more than adequately address passive investment and over-utilization concerns.

Urology Tyler's Path Lab provides superior pathology service to our urologists and their patients without additional cost to Medicare. Our pathologist is a fully credentialed and Board Certified physician who has additional knowledge and expertise in urology. This qualifies pathologist to deliver a level of service to our patients that an unknown commercial lab cannot give. Our lab was formed under the letter of the law and has been providing outstanding care to our patients for two and a half years. We promote any concept that protects the Medicare patient and the program from fraud and abuse, however, the new rule, as proposed by CMS, will not achieve that goal or improve care to our patients.

Respectfully submitted,

Stanton P. Champion, MD, President
Urology Tyler, PA

Submitter : Dr. Lee Adler

Date: 10/10/2006

Organization : AIAI

Category : Physician

Issue Areas/Comments

Impact

Impact

DRA PROPOSALS

Section 5102b1 specifically refers to procedures included in the "Physician Fee Schedule to OPD Payment Amount for Imaging Services." PET and PET/CT technical components are carrier based and not included in the Physician Fee Schedule. Therefore the inclusion of the CPT codes for PET and PET/CT services "(4) Special rule for imaging services" is not specifically mandated by the DRA and is at the discretion of CMS. Yet the CPT codes for PET and PET/CT have been included in CMS' interpretation of Imaging services for which the rule will be applied.

Implementation of the "Special rule for imaging services" on PET/CT would cause the majority of outpatient PET/CT centers in particular to operate at a loss even if the HOPPS rate is maintained at the 2005 rate of \$1250 per whole body PET/CT scan. If, as planned the the HOPPS rate drops to \$850 per whole body PET/CT scan in 2007, the procedure will be performed at a more significant loss for an even larger majority of out patient imaging centers. For a powerful technology that unlike its predecessors has had to prove its worth in the era of evidenced based medicine, it would be unfortunate to have the majority of outpatient providers close their doors.

Given the extraordinary degree of disruption that applying 5102b1 to PET and PET/CT services would have on the availability of PET and PET/CT services in both rural and inner city locations, I urge that CMS continue to allow local carriers to set the technical reimbursement for these procedures based upon local issues.

Submitter : Dr. Robert Kuske
Organization : Arizona Oncology
Category : Physician

Date: 10/10/2006

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1321-P-963-Attach-1.DOC

Submitter : Ms. Mary Ann Shacklett
Organization : Community Foundation of Northwest Indiana, Inc
Category : Hospital

Date: 10/10/2006

Issue Areas/Comments

Background

Background
See attachment

GENERAL

GENERAL
See Attachment

Impact

Impact
See Attachment

Provisions of the Proposed Rule

Provisions of the Proposed Rule
See Attachment

CMS-1321-P-966-Attach-1.DOC

#963

September 8, 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:

I appreciate the opportunity to provide remarks on the Centers for Medicare and Medicaid Services' proposed rule, published in the Federal Register on August 22, 2006. This letter is written to share my concern regarding the proposed reduction in professional fees for radiation/oncology brachytherapy services.

As a free standing center it is important to offer the full scope of radiation services to Medicare beneficiaries. However, with the proposed reductions in RVUs along with the conversion factor reduction it makes it difficult to extend brachytherapy options to Medicare patients. Brachytherapy is a vital therapy that must be available to Medicare beneficiaries when clinically appropriate. Brachytherapy not only encompasses Breast cancer, but prostate cancer as well. CMS is urged to consider the value of the free standing center and the cost effective efficiencies it can extend to the system especially when compared to the Outpatient Hospital setting. With that said, the preparation and effort to properly create a treatment plan is quite time consuming. The proposed reduction to all brachytherapy codes, especially CPT 77781, will not adequately cover the time and involvement required to prepare a patient for brachytherapy. If the reduction does take place, CMS will be limiting access to brachytherapy for Medicare patients.

I have attached a table for your review which shows the drastic reductions for many of the services that we offer at our clinics. As you can see many of them far exceed a 5% reduction. This could severely affect my ability to offer brachytherapy services to Medicare patients.

CPT Code	Description	Units	2006 RVU	2006 Average Rate	2010 RVU	Variance 2010 to 2006	Variance 2010 to 2006
99245	office consult, comprehensive	1	5.91	\$224	6.25	\$1	0%
77263	physician treatment planning, complex	1	4.41	\$167	4.16	(\$18)	-10%
77470	special treatment procedure	1	14.64	\$555	4.55	(\$391)	-71%
76370	CT for planning	1	4.29	\$163	5.48	\$35	21%
77370	special medical physics consult	1	3.68	\$139	2.51	(\$49)	-35%
77290	simulation, complex (contour volumes)	1	9.02	\$342	15.22	\$206	60%
77326	Brachytherapy isodose plan	1	3.78	\$143	3.89	(\$3)	-2%
77300	dose calc	10	2.26	\$856	1.80	(\$209)	-24%
77336	weekly medical	1	3.15	\$119	1.08	(\$81)	-67%

	physics consult						
77280	simulation, simple	5	4.62	\$875	5.27	\$72	8%
77781	Afterloading HDR brachy (1-4 source positions)	10	23.69	\$8,978	6.58	(\$6,611)	-74%
						(\$7,049)	-56%

NOTE: 2006 CF is \$37.8975 with assumption for 2010 using proposed CF of \$35.9647; applicable to Physician Fees

My recommendation as a Radiation Oncologist at a free standing center is to freeze the current RVUs and, if needed, only reduce the conversion factor or at the very least make it no more than a 5% reduction on any CPT code. I feel this will be in the best interest of the Medicare patient and allow the free standing center to continue to offer brachytherapy as an option.

Thank you again for the opportunity to express my opinion on this rule.

Sincerely,

Robert Kuske, MD

Robert Kuske, MD
Radiation Oncologist
Arizona Oncology
8994 E. Desert Cove Ave
Scottsdale, AZ 85260

cc: Senator John Kyl, AZ, (R)

cc: Carolyn Mullen, Deputy Director,
Division of Practitioner Services

cc: American Society of Therapeutic Radiation and Oncology
Prabhakar Tripuraneni, MD, Chair, American Society of Therapeutic Radiation and Oncology

Submitter : Dr. David Huang

Date: 10/10/2006

Organization : Dr. David Huang

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

"See Attachments"

CMS-1321-P-964-Attach-1.DOC

#964

September 8, 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:

Thank you for this opportunity to provide remarks on the Centers for Medicare and Medicaid Services' proposed rule, published in the Federal Register on August 23, 2006. This letter is written to share my concern regarding the proposed reduction in professional fees for radiation/oncology brachytherapy services.

The proposed reductions for the RVUs namely the Work RVUs will not allow me to offer the most appropriate treatment options for my Medicare patients. Brachytherapy is an important therapy offered for breast cancer patients because it allows the radiation to be given in 5-7 days, which allows the process to move very quickly so that other treatments (chemotherapy) can be started as well. The Work component of the RVUs that you are proposing to reduce by at least 23% comprises the Physician's time to perform a service, technical skills and physical and mental effort involved in treating the patients. The preparation and effort to properly create a treatment plan is very time consuming. The proposed reduction to all brachytherapy codes, especially CPT 77781, will not adequately cover the time and involvement required to prepare a patient for brachytherapy. If the reduction does take place, CMS will be limiting access to brachytherapy for Medicare patients. Choice, quality and availability is key for the beneficiary.

I would like to recommend that CMS review the proposed Work RVU reduction for brachytherapy. Please sustain the current brachytherapy codes, and if needed, make a reduction to the conversion factor. Thank you for your time and consideration in the review of this issue and I strongly advise CMS to reconsider the significant impact the proposal outlines. Thank you for the opportunity to express my opinion

Sincerely,

David Huang, MD

David Huang, M.D.
Radiation Oncologist
Northridge Hospital
18300 Roscoe Blvd
Northridge, CA 91328

cc: Senator Barbara Boxer, CA (D)
Senator Diane Feinstein, CA (D)

Congresswoman Lois Capps, CA, (D)

cc: Carolyn Mullen, Deputy Director,
Division of Practitioner Services

cc: American Society of Therapeutic Radiation and Oncology
Prabhakar Tripuraneni, MD, Chair, American Society of Therapeutic Radiation and Oncology

Submitter : Dr. J Leonard DeCarlo

Date: 10/10/2006

Organization : Urology Tyler, PA

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-965-Attach-1.DOC

#965

Department of Health and Human Services
Centers for Medicare and Medicaid Services, HHS

Re: Urology Tyler, PA Comments to CMS regarding CMS-1321-P
Proposed changes to Reassignment and Physician Self-Referral Rules Relating to
Diagnostic Tests

Dear Sir or Madam:

This letter is submitted in response to the request of the Centers for Medicare and Medicaid Services ("CMS") for comments regarding proposed revisions to the Medicare payment policies under the physician fee schedule for calendar year 2007 ("Proposed Revisions"). Specifically, the comments of this commentator address those proposed revisions as they relate to the existing Medicare **Reassignment Rules ("Reassignment Revisions")** and the existing physician **Self-Referral Regulations ("Self-Referral Revisions")**.

Most importantly, this commentary also addresses CMS's stated purpose in the Proposed Revisions: the elimination of small centralized pathology laboratories. Because this stated purpose raises significant concerns separate and apart from the language of the proposed revision, that issue is addressed first in this commentary. With that introduction, specific commentary is set forth below:

I. Unsupported Rationale for the Elimination of Centralized Pathology Laboratories

In explaining its rationale, for the Proposed Revisions, CMS makes the conclusory statement that remotely located centralized pathology laboratories ("Path Labs") pose significant fraud and abuse risks. Nothing within the Proposed Revisions provides any hint of why CMS has reached this conclusion, nor is there any indication that CMS has undertaken any sort of balanced analysis, looking carefully at the potential benefits – both in terms of improved quality of care and financial economy to the program - of these arrangements. This commentator urges CMS to carefully analyze these arrangements from a risk-benefit analysis prior to undertaking broad-sweeping revisions purportedly specifically designed to eliminate their existence. **We would also like to note the OIG has conducted an audit into our physician-owned pathology lab, but the results are not yet known. That audit is not yet finalized, however, CMS has taken comments from pathology organizations and published a proposed rule before receiving the report of its own investigative agency.**

The need for a balanced analysis is also apparent in light of the stated concern, apparently voiced by commentators in response to Phase II Interim Final Regulations ("IFC") that Path Labs would encourage over-utilization. CMS expressly took note of commentary and stated that, with regard to its centralized building requirement; it was "persuaded by commentators who responded to the Phase II IFC that our present definition may encourage the unnecessary ordering of ancillary services." (August 22, 2006 Federal Register, page 49056)

Just as it is the case with all types of treatment modalities, there may be bad Path Labs that encourage over-utilization and provide no corresponding program and patient benefits, and there are good Path Labs that protect against over-utilization and significantly improve the quality of patient care. The CBLPath path lab model addressed in Advisory Opinion 04-17 was obviously submitted by the commercial lab industry with a vested economic interest in portraying all physician-owned labs as violating the tenants prescribed by the April 2003 Advisory Opinion on Passive Physician Joint Ventures. As addressed later herein, physician-owned Path Labs can be integrated into a physician's active medical practice and structured to protect against over-utilization concerns. The commercial lab industry cannot provide the benefits outlined herein that are unique to physician-owned Path Labs, and commercial labs stand to lose profits if physician-owned Path Labs such as our model continue to operate.

CMS should also take note that the radiologist lobby used similar over-utilization arguments with Congress over the last two years to push through statutory restrictions on the reassignment rules. Those attempts failed – and for good reason. It was promoted by those whose economic interests would be furthered by such restrictions. The promotion of specific economic interests, disguised in a rationale of alleged over-utilization, ignores what should be the fundamental purpose of the regulations: improved quality outcomes in an economically efficient manner. **If the number of patients treated and specimens processed do not materially vary due to where the specimens are processed, it simply boils down to who gets the reimbursement. Regardless of the venue of where the specimens are processed, the treating physician must always document the medical necessity for the testing. Elevated PSA counts, age, DRE (digital rectal exam) results, and prior medical history are not subjective criteria that can be manipulated by physicians motivated by financial gain.**

Therefore, it is the commentator's opinion that CMS is considering rule changes to eliminate physician-owned Path Labs, but instead should be ensuring that patients receive economical quality care. Elimination of physician-owned Path Labs does not accomplish that goal but instead eliminates competition and interrupts continuity of care.

The remainder of this commentary focuses on specific benefits of physician-owned Path Labs as well as appropriate ways in which over-utilization risks could be addressed, without sacrificing those benefits.

II. Benefits of Path Lab Arrangements

It is virtually impossible to overstate the importance of early detection and accurate professional interpretation to successful treatment of prostate cancer. Physician-owned path labs provide significant, unique benefits in the promotion of early detection. The specific benefits of these types of arrangements include the following:

(1) Quality Assurance and Outcomes Tracking: A properly structured physician owned Path Lab allows the treating physician to maintain control of the entire process beginning with physical exam, blood work results, tissue collection and processing, interpretation of prostate tissue, and ending with appropriate follow-up and treatment of the patient. This ability

to supervise and direct the entire process makes information and outcomes tracking much simpler, efficient, and reliable.

In addition, as a direct result of the Path Lab existing under the supervision and control of the treating physicians, it has been our experience that the flow of relevant information regarding the patient's condition between the pathologist and the treating physician has increased dramatically. Questions regarding the specimen collection process and clarification of pathology findings are easily accomplished. The same Board Certified pathologist is interpreting each tissue sample collected from the patients at our urology office. The pathologist is accustomed to the technique the urologist uses to collect the tissue, therefore the pathologist is in a position to detect an outlier in expected quality. In the past, when there was a unique situation with a patient's tissue, the pathologist has recognized the exception, and phoned the urologist. Prior to the physician-owned Path Lab arrangement, this type of vital exchange was difficult at best and often impossible.

Certainly, one might argue that the ideal situation might be one in which the physician-owned Path Lab was located in the same building as the office of the treating physician. However, the primary effect of a "same building" restriction would be to limit physician controlled Path Labs to large practices in metropolitan areas that could afford to equip and fully utilize a full-time Path Lab. Additionally, it would be very difficult for a medium size or small practice to employ a full-time pathologist in the "same building". The end result of such a restriction would invariably result in increasing disparate treatment among Medicare patients, with the potential to disproportionately adversely affect care provided to patients in rural or small communities.

(2) Expertise. The use of physician-owned Path Labs allows specialization by pathologists that previously has only been seen in the largest medical centers or reference laboratories. Prior to the establishment of its Path Lab, Urology Tyler had no choice but to use a commercial lab or general pathologists for interpretations. While these pathologists are certainly competent, the level of expertise of pathologists who limit their practice to urology, such as in our Path Lab, allows the pathologist to obtain the highest level of expertise by virtue of this specialized experience. In fact, this model follows the government's own methodology, employed at the Armed Forces Institute of Pathology, where the technical staff and pathologists are specialized in a specific area of interest, with urology being one of those areas.

(3) Availability of Communication and Consultation. In addition to the foregoing, the physician-owned Path Lab offers a fairly unique opportunity for pathologists who work together in Path Lab arrangements and who specialize in uropathology, to consult with each other in-house on a regular basis. This allows for on-site, immediate consultation in addition to the availability of the treating physician to clarify and consult with the pathologists.

III. Controlling the Risk of Over-utilization

It is our position that regulations could be adopted that place specific requirements on physician-owned Path Labs that will address over-utilization concerns, while preserving the obvious benefits of these types of arrangements. Such regulations could also ensure that the physician-owned Path Labs are actively integrated into the urologist's professional practices, as

opposed to being suspect passive joint ventures. Ultimately, broadly defined wholesale prohibitions do not serve the interests of patient care or the government's interest in economically efficient care. The overbroad nature of the proposed regulations will likely create roadblocks to improved patient care and outcomes, resulting in delayed treatment and ultimately increased treatment costs. **Moreover, new regulations have the potential to do nothing other than to promote the economic interests of one health care group (the commercial lab industry) over another (physician practices).**

It is this commentators position that the best way to ensure that physician-owned Path Labs are maximizing their potential for improving care and outcomes, while discouraging over-utilization is by ensuring that these arrangements are not passive investments of the treating physicians. Our physicians are actively involved in the direction and supervision of our Path Lab. We are responsible for the services provided by our Path Lab. With our model in mind, this commentator believes the following recommendations, specific to this type of arrangement, would balance those two important interests:

(1) Treating physician groups who own Path Labs should be required to appoint a member of their group as an active physician liaison for the lab, with audit and utilization oversight responsibilities. The physician liaison's duties should include periodic on-site visitation to the Path Lab. (Urology Tyler has a Lab Director, and we do periodic on-site visits.)

(2) Ownership in the Path Lab should include an investment and ownership in all the necessary equipment to operate the Path Lab, the equipment should be permanently located in space reserved exclusively for the ownership group, and reserved exclusively for use by the group. (All equipment was purchased and paid for by Urology Tyler. It is used exclusively for the group's pathology.)

(3) Space requirements should be sufficient to provide exclusively reserved space that is adequate to prepare and perform the interpretations. This commentator is not opposed to specific space requirements, as long as they are rationally related to the amount of space required to safely and competently perform the service. The current 350 square feet space requirement in the proposed regulations is arbitrary and has no rational relationship to the square footage necessary to safely and competently perform the lab service. For purposes of State integrated regulatory oversight and the convenience of practice groups to oversee operations, it may be logical that the physician-owned Path Labs should be located in the same State as the practice group.

(4) Periodic consultation and quality assurance should be required, including periodic meetings between the practice group physician liaison (Lab Director) and the pathologist to review results and take appropriate action for improvement of defined deficiencies.

(5) Protocols should be established to ensure refinement of the specific criteria for pathology testing and methods for tracking and addressing outliers.

(6) To ensure active practice integration, an independent contractor "physician in the group practice" (the Pathologist) should only be able to provide professional or technical services on behalf of the group practice, and for which the group practice bills or collects, if the services

are provided on the premises of the group practice as historically defined in the Stark Statute. This would discourage the contractual reassignment of services by Pathologists whose only relationship with the billing practice group exists on paper. Further, in 2004 CMS clarified that diagnostic tests provided by leased employees, such as lab technicians, are not "purchased tests" for purposes of the rule. That argument is strengthened when the leased lab technician is supervised by a Pathologist who has a direct independent contractor relationship with the practice.

(7) We agree that if a group practice intends to bill for the technical component of a path lab services, it ought to also perform the professional component of that same service. The Stark Statute clearly allows that professional component to be performed by the group practice through a Pathologist who is a physician in the group practice.

(8) Consistent with current CLIA regulations that were promulgated to ensure quality lab standards, a single pathologist is currently limited to being the medical director of five or fewer Path Labs.

(9) Regulatory oversight is required in the form of refined credentialing criteria which incorporate the above recommendations. In fact, the auditing recommendations set forth above should be applied to all pathology laboratories, regardless of ownership or location.

It is this commentators belief that more stringent credentialing regulations under the general criteria set forth above would not only serve to promote quality of care and economic efficiency in Path Labs, but would more than adequately address passive investment and over-utilization concerns.

Urology Tyler's Path Lab provides superior pathology service to our urologists and their patients without additional cost to Medicare. Our pathologist is a fully credentialed and Board Certified physician who has additional knowledge and expertise in urology. This qualifies pathologist to deliver a level of service to our patients that an unknown commercial lab cannot give. Our lab was formed under the letter of the law and has been providing outstanding care to our patients for two and a half years. We promote any concept that protects the Medicare patient and the program from fraud and abuse, however, the new rule, as proposed by CMS, will not achieve that goal or improve care to our patients.

Respectfully submitted,

Stanton P. Champion, MD, President
Urology Tyler, PA

#966



Community Healthcare System

Community Foundation Of Northwest Indiana, Inc.

Community Hospital
St. Catherine Hospital
St. Mary Medical Center

October 6, 2006

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

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

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

New Technology APCs

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

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

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

CY 2002

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

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

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

In the November 30, 2001 Federal Register CMS also indicated that it was planning to adopt a new HCPCS code for fractionated (i.e. staged) radiosurgery procedures, which was introduced in a March 28, 2002 Program Memorandum³. While CMS eventually adopted the new HCPCS code - G0251 - this code did not specify that it be used only for image-guided treatment with robotics. (The descriptor for this code was "linear accelerator-based stereotactic radiosurgery,

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

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

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

fractionated treatment, per session, maximum 5 sessions per course of treatment.”). This code only became effective July 1, 2002.

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

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

CY 2003

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

CY 2004

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

⁴ Federal Register November 30, 2001, page 59868

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

CY 2006

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

Proposed CY 2007 APC Changes

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.

2. 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. Our institution did begin CyberKnife operation until May 2005.

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

3. Further, the CyberKnife Coalition's analysis of the CY 2004 Identifiable Data Set Hospital OPSS 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 OPSS 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.

4. In addition, the 2004 Identifiable Data Set Hospital OPSS 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 OPSS file is 1,311. The total CY 2004 Medicare claims for Georgetown University Hospital (an institution not included in the Identifiable Data Set Hospital OPSS 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 OPSS 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 OPSS file for G0339 and G340 together.*

The CY 2004 Identifiable Data Set Hospital OPSS file clearly does not provide a sound basis for modifying the APC classification in light of the relatively low number of appropriate claims, the

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

Historical Precedent – Gamma Knife New Technology Codes

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

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

CY 2004 and CY 2005 Data Variability Summary

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

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

Of the 25 centers reported in the 2004 Identifiable Data Set Hospital OPPS file using G0339 / G0340 – only 16 centers or 64% of those listed have dedicated image-guided robotic SRS equipment. The CY 2004 data is a mixture of data from all kinds of stereotactic radiosurgery procedures using various treatment modalities with vastly differing resource requirements. A

clearer distinction among SRS codes through continued code descriptor refinement will help facilitate the collection of data for all types of SRS services and the eventual establishment of appropriate permanent rates for each, respectively.

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

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

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

Conclusion

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

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

Recommendations

- ▶ No changes should be made in the APCs or payment rates for G0339 (APC 1528) and G0340 (APC 1525) for CY 2007.
- ▶ CMS continue to work with CyberKnife centers to establish accurate and adequate reimbursement for image-guided robotic stereotactic radiosurgery (r-SRS).

Sincerely,

Mary Ann Shacklett, Senior Vice President Finance & CFO
Community Foundation of Northwest Indiana, Inc.
901 Mac Arthur Boulevard, Munster, Indiana 46321
219-836-4540, mshacklett@comhs.org

Submitter : A B
Organization : A B
Category : Individual

Date: 10/10/2006

Issue Areas/Comments

Background

Background

TEST

Submitter : Mr. Mitchel Williams
Organization : Palmetto GBA
Category : Health Care Industry

Date: 10/10/2006

Issue Areas/Comments

GENERAL

GENERAL

In regards to standards for IDTF providers (ref pages 227-236)

We recommend that IDTF providers be required to maintain liability insurance in the amount of \$300,000 and to allow for retroactive revocation of the IDTF billing numbers back to the to the date or any lapse in insurance coverage. This is similar in nature to DMEPOS Supplier Standard # 10 as set forth in 42 CFR 424.57(c)

In addition, we recommend that one contractor issue guidance and enroll all IDTFs nationally as DMEPOS suppliers are enrolled by the National Supplier Clearinghouse.

Submitter : Dr. Juan Agostini
Organization : Vein& Laser specialists PC
Category : Physician

Date: 10/10/2006

Issue Areas/Comments

Background

Background

Further reduction in reimbursement for CPT codes # 34478 and 34479 will have a negative impact in the ability of the Medicare population to access specialized quality care.

GENERAL

GENERAL

These procedures are minimally invasive and can be performed in the physicians office therefore resulting in significant savings to the system. However they require expensive equipment and trained personnel. Practice expenses continue to rise making it increasingly difficult to provide this important and necessary treatment if further reductions in reimbursement are instituted.

Impact

Impact

Reduction of RVU for CPT codes 34478 and 34479 .

Provisions of the Proposed Rule

Provisions of the Proposed Rule

See general comment

Submitter : Dr. Astrid Morrison
Organization : St. Anthony Hospital Cyberknife Center
Category : Physician

Date: 10/10/2006

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-970-Attach-1.DOC

#970

October 4, 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 OPSS 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 Memorandum³. While CMS eventually adopted the new HCPCS code - G0251 - this code did not specify that it be used only for image-guided treatment with robotics. (The descriptor for this code was "linear accelerator-based stereotactic radiosurgery, fractionated treatment, per session, maximum 5 sessions per course of treatment."). This code only became effective July 1, 2002.

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

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

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

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

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

CY 2003

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

CY 2004

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

CY 2005

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

⁴ Federal Register November 30, 2001, page 59868

CY 2006

At the August, 2005 APC Panel meeting, stereotactic radiosurgery codes including G0339 and G0340 were discussed. The Data Subcommittee reported its analysis of the CY 2004 Identifiable Data Set Hospital OPDS 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 OPSS 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 OPSS 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 OPSS 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 OPSS file is 1,311. The total CY 2004 Medicare claims for Georgetown University Hospital (an institution not included in the Identifiable Data Set Hospital OPSS 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 OPSS 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 OPSS file for G0339 and G340 together.*

The CY 2004 Identifiable Data Set Hospital OPSS 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 OPSS 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 OPSS 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 OPSS 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 OPSS 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,

Astrid E. Morrison, MD
Cyberknife Center at St. Anthony Hospital
1011 N. Dewey
Oklahoma City, OK 73104

Submitter : Dr. Janet Durham
Organization : Wisconsin Society of Pathologists, Inc.
Category : Physician

Date: 10/10/2006

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-971-Attach-1.DOC

**Comments of the
Wisconsin Society of Pathologists, Inc
on the Revisions to Payment Policies Under the
Physician Fee Schedule for Calendar Year 2007
[CMS-1321-P]**

The Wisconsin Society of Pathologists, Inc. is pleased to have the opportunity to comment on the proposed revisions to payment policies under the physician fee schedule for calendar year 2007 (the "Proposed Rule"). 71 Fed. Reg. 48982 (Aug. 22, 2006). Wisconsin Society of Pathologists, Inc. (WSP) is a professional society of pathologists practicing in the state of Wisconsin. Our WSP members perform a variety of services that are reimbursed under the physician fee schedule. Thus, WSP members will be significantly affected by the changes in the Proposed Rule. WSP's comments on the Proposed Rule focus on the revisions to the reassignment and physician self-referral rules, and changes to the rules governing how anatomic pathology services are billed.

PROVISIONS

REASSIGNMENT AND PHYSICIAN SELF-REFERRAL

The Wisconsin Society of Pathologists, Inc. is very pleased that CMS is taking action designed to curb the growth of so-called "pod" or condo laboratories. *Id.* at 49054. These arrangements give referring physicians the opportunity to earn revenues based on their own referrals for services performed by other physicians. The Medicare program has always expressed concern about such arrangements and has numerous provisions in place to curb such abuses. CMS is taking an important step in its revision to the reassignment rules and the Stark self-referral laws as a way of curbing these abusive arrangements. However, WSP believes that in order to be effective in addressing the pod issue, CMS must implement not only the independent contractor reassignment revisions that pertain to the technical and professional components of anatomic pathology, but also measures that would limit the use of part-time employee pathologists in such arrangements.

As CMS recognizes, there are two different, but related, means of curbing these practices: first, clarify the provisions of the prohibition on reassignment, which is designed specifically to prevent Medicare from paying physicians for work performed by others, except in limited situations and second, modify the Stark self-referral law, which is designed to prevent physicians from profiting by referring business to entities with which they have a financial relationship. As CMS notes, many pod arrangements are established either in contravention of these requirements or by taking advantage of ambiguities that exist. Generally, WSP is supportive of the changes that CMS is making, but we are aware of additional helpful proposals to clarify or more closely define the requirements set out by CMS, as well as to address the issue of part-time employees

Changes to the Reassignment Rule

In the area of the changes to the prohibition on reassignment, CMS makes the following proposals:

- Clarify that physicians acting pursuant to the contractual arrangement exception must still meet the requirements applicable to the purchase of diagnostic testing, with regard to the professional component.

WSP position: supports applying current purchased-service limitations in situations of reassignment where the ordering physician that sees the patient is purchasing the professional interpretation from a pathologist, even if the service is reassigned under the contractual arrangement exception. Ordering physicians that bill for purchased diagnostic tests should not be able to circumvent the requirements by calling the purchased service a service performed under a contractual arrangement. However, WSP does not support making the requirements across the board for all reassigned services under the contractual arrangement exception because of the potential unintended consequences for longstanding and legitimate practice arrangements among pathologists and pathology groups. Pathology groups that choose to engage another pathologist as an independent contractor and reassign payment rely on the contractual arrangement exception without risk of program abuse.

- CMS requests comments on what additional limitations should be put on the purchase of the professional component.

WSP position: no additional limitations are necessary on PC purchase, beyond the need to apply the purchased-service rules that already exist and clarifying that they apply in the contracted reassignment setting. But WSP does not oppose an anti-markup provision for the PC, similar to the requirements for the purchase of the TC, to protect against other abuses by ordering physicians billing for diagnostic testing.

- CMS asks whether all diagnostic testing in the designated health services (“DHS”) category should be covered or whether it should apply specifically to pathology; and whether any of the provisions should apply to services performed on the premises of the billing entity, and if so, how to define the premises appropriately.

WSP position: no comment

Stark Self Referral Provisions

As CMS recognizes, in order to limit these types of practices in all areas, it is also necessary to further clarify certain specific provisions or exceptions in the Stark self-referral law. WSP agrees that this is imperative. We are especially concerned that in response to changes in the reassignment rules, discussed above, many pod

arrangements will simply restructure and hire pathologists as part-time employees, which could circumvent the purpose of many of these changes. WSP believes that the Stark law may provide the most direct way of curbing these new abuses. Therefore, before discussing the other changes proposed by CMS to the Stark provisions, we wish to make one additional proposal designed to limit part-time pathologists.

Part-Time Employment of Pathologists

WSP is concerned that in response to the provisions in the Proposed Rule, existing and new arrangements may be restructured so that pathologists will be retained as part-time employees rather than independent contractors. For example, a pathologist could become a part-time employee of several different groups under arrangements that potentially satisfy both the reassignment rules and the physician service or in-office ancillary services exceptions to the Stark self-referral provisions. From the standpoint of the group practice and the retained pathologist, the arrangement need not differ significantly from an independent contractor relationship. Thus, WSP considers it to be essential that CMS address both structures in its rulemaking.

The Wisconsin Society of Pathologists, Inc. recognizes that some groups may decide to hire their own pathologist, but they should be required to make the same investment in salaries and capital that any other business would have to make in that endeavor and undertake the same type of business risk. They should not be able to avoid that requirement by re-characterizing an "independent contractor" pathologist as a "part-time employee" pathologist, without incurring the additional costs and risk attendant to hiring that person. Without some limitation on this practice, groups will simply restructure without any risk and continue to profit from their own referrals. The Wisconsin Society of Pathologists, Inc. believes that the part-time employee concern could be addressed through modifications in the "group practice" requirements under the Stark self-referral rules or, potentially, through changes in the employee reassignment provision.

We are aware of, and **support** suggested alternative regulatory proposals that would address this issue through the "substantially all" requirements for group practices under Stark. In essence, they would require that, in addition to the group practice as a whole having to perform at least 75% of its patient care services through the group, each individual member would need to perform at least one-half of its patient care services through the group. Such a provision could be limited to pathology services. Alternatively, CMS could, in the same provision of Stark establish a maximum number of group practices to which any one pathologist could belong. The Wisconsin Society of Pathologists, Inc. would strongly support this approach. These are more fully described in the comments of the American Clinical Laboratory Association, so they need not be repeated in detail here.

Basically, if a pathologist arrangement did not meet this requirement, then the group practice would not be able to bill for pathology services that it refers to the pathologist. We believe that such a provision would limit restructuring that might be anticipated in response to the proposed changes in the contractor reassignment rules.



October 10, 2006

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

Executive Director

Ann L. Elderkin, P.A.

Officers

Steven R. Goldring, M.D.

President

Barbara Kream, Ph.D.

President-Elect

Elizabeth Shane, M.D.

Past-President

Keith A. Hruska, M.D.

Secretary-Treasurer

Councilors

Maria Luisa Brandi, M.D., Ph.D.

Roberto Civitelli, M.D.

Michael J. Econs, M.D.

Theresa A. Guise, M.D.

Mark C. Horowitz, Ph.D.

René Rizzoli, M.D.

Janet Rubin, M.D.

Thomas C. Spelsberg, Ph.D.

René St. Arnaud, Ph.D.

2006 Program Co-Chairs

Juliet Compston, M.D., FRCP

Harald Jueppner, M.D.

ASBMR 29th Annual Meeting

September 16-19, 2007

Hawaii Convention Center

Honolulu, Hawaii, USA

RE: CMS-1321-P Revision 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 Society for Bone and Mineral Research (ASBMR) is the premier professional, scientific and medical society for the promotion of bone and mineral research and the translation of that research into clinical practice. The ASBMR has a membership of nearly 4,000 physicians, basic research scientists and clinical investigators.

ASBMR is concerned that if the currently proposed Medicare Physician Fee Schedule for axial dual energy X-ray absorptiometry (DXA) and/or Section 5102 (b) of the Deficit Reduction Act takes effect on January 1, 2007, axial DXA testing will significantly decrease from the non-facility/private practice setting as physicians' operating costs will be greater than reimbursement for the tests. These regulatory and legislative actions will severely restrict patient access to bone density testing thereby undermining the effort by CMS to effectively screen Medicare beneficiaries for osteoporosis.

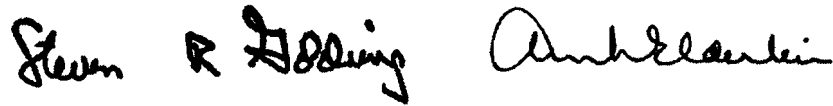
While ASBMR appreciates the effort of the CMS to establish equitable reimbursement policies for such diagnostic procedures as DXA and vertebral fracture assessment (VFA), we would like to express support for the letter submitted to you by the International Society for Clinical Densitometry (ISCD) detailing the flaws in the data used by CMS to reach its conclusions.

The ASBMR urges you to reconsider and withdraw these substantial cuts in the proposed rule that reduces Medicare reimbursement for these important technologies used to screen and identify individuals at risk for osteoporotic fracture. The aging of the U.S. population provides a clear demographic imperative that this preventable disease be detected and treated, thereby preventing unnecessary pain and disability, preserving quality of life and minimizing the significant societal costs associated with bone fractures. Please do all you can to support bone health and quality patient care by requesting that these proposed cuts be reversed.

ASBMR Letter to Centers for Medicare & Medicaid Services (CMS)

Page 2

Respectfully,

Handwritten signatures of Steven R. Goldring and Ann L. Elderkin.

Steven R. Goldring, M.D.
ASBMR President

Ann L. Elderkin, P.A.
ASBMR Executive Director

cc: Neil Binkley, M.D., CCD, *ISCD President*

Submitter : Mr. Thomas Bartrum
Organization : Waller Lansden Dortch & Davis
Category : Attorney/Law Firm

Date: 10/10/2006

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-973-Attach-1.PDF

Thomas E. Bartrum
(615) 850-8705
thomas.bartrum@wallerlaw.com

October 10, 2006

VIA ELECTRONIC SUBMISSION

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

Re: CMS-3121-P, Section II, Subsections I and L.

Dear Dr. McClellan:

I am pleased to submit these comments on the above-listed subsections of the Centers for Medicare & Medicaid Services' ("CMS") proposed rule entitled *Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B*, as published in the Federal Register, Vol. 71, No. 162, pages 48982-49252 (August 22, 2006). My comments are limited to the above-indicated sections.

As a preliminary matter, it should be understood that these comments are being submitted as my personal comments and do not reflect the position of either my law firm, Waller Lansden Dortch & Davis, LLP, or any client of mine or my law firm.

I applaud CMS ongoing efforts to improve awareness and understanding of the intersections between Medicare's payment rules and Medicare's fraud and abuse and self-referral prohibitions. This is especially important as providers and suppliers consider new health care delivery arrangements that may technically comply under one regulatory scheme but pose considerable uncertainty under other regulatory schemes. This is especially relevant in the rapidly growing imaging industry where new delivery sites raise concerns about the quality and medical necessity of imaging services.

I do, however, have certain concerns regarding the appropriateness, need and practicality of some of CMS' proposed regulatory amendments as well as a regulatory amendment that CMS is still considering. Each of my concerns is addressed below under the appropriate heading.

Section II, I. Incorporation of Purchased Diagnostics Rule in the Reassignment Exception for Independent Contractor Arrangements (42 C.F.R. § 424.80(d)(3)).

My primary concern with respect to this proposed amendment is that it is unnecessary. As you are aware, the Purchased Diagnostics Rule (42 U.S.C. § 1395u(n)(1); 42 C.F.R. § 414.50) is not an exception to Medicare's reassignment prohibition. Instead, it is both a separate authorization for CMS to pay someone other than the supplier of the technical component for the provision of that service and a payment limit on physician billing.

Historically, CMS has taken the position that situations implicating the Purchased Diagnostics Rule (i.e., situations where the physician performed the interpretation and is billing globally for both the purchased technical component and the interpretation), do not result in a reassignment. Instead, the purchasing physician is considered to be the supplier the technical component for purposes of the reassignment prohibition. Accordingly, in the Medicare Claims Processing Manual (Pub. 100-04), CMS unequivocally takes the position that in Purchased Diagnostic Rule situations, "[n]o formal reassignment is necessary." Pub. 100-04, Chapter 1, Section 30.2.9 (Rev. 464).

Further, regardless of whether the proposed amendment is included in the final rule, the Purchased Diagnostics Rule would apply whenever a physician or medical group bills globally for a diagnostic test for which they furnished the professional interpretation but purchased the technical component of the test. That is, the Purchased Diagnostics Rule is a payment rule and as such, regardless of the reassignment prohibition, it is an independent billing obligation on physicians and medical groups.

Not only is the independence of the Purchased Diagnostics Rule widely known in the provider community, but CMS clearly removed any doubt about its independent application in the reassignment context when it amended 42 C.F.R. § 424.80(a) as part of the Fiscal Year 2005 physician payment update. Specifically, the regulation currently reads that, "Nothing in this section alters a party's obligations under . . . the rules regarding physician billing for purchased diagnostic tests."

Another concern is simply that the proposed amendment would result in all independent contractual arrangements involving the technical component of diagnostic services being treated as purchased services. Conceptually, there would appear to be a valid distinction between: (i) the situation where a physician truly purchases the technical component of a diagnostic test (e.g., an X-ray), interprets the X-ray, and then attempts to bill globally for the X-ray service ("Situation 1") and (ii) the situation where the physician enters into an independent contractor agreement with a portable X-ray supplier whereby the X-ray supplier furnishes the equipment to the physician's office and provides certain know-how for the service (e.g., staff training, post-billing audit and protocols), and the physician's staff performs the X-ray (under the physician's supervision and malpractice coverage), and the physician bills globally for the service ("Situation 2"). I would take the position that Situation 1 would implicate the Purchased Diagnostics Rule and Situation 2 would result in neither a reassignment nor a Purchased Diagnostics Rule situation. That is, there is a valid distinction between a physician merely purchasing the service and a physician contracting for certain of the necessary components for furnishing the service.

In the past, Situation 2 could be structured so that if a Medicare contractor ever took the position that the facts resulted in a reassignment, the physician could rely upon the organized health care delivery system exception so long as the service were furnished on the physician's premises. In fact, in such situations, the physician may have filed an 855R simply to be safe. However, upon implementation of the independent contractor exception, CMS did away with both the Payment to Facility and Payment to Organized Health Care Delivery System (Medicare Carriers Manual, Part III, § 3060.2 & 3060.3 (Feb. 1993) (Rev. 1445)). The independent contractor exception is the only valid means by which a physician in Situation 2 could protect himself or herself from an allegation that the arrangement constituted a prohibited reassignment. By imposing the Purchased Diagnostics Rule on all independent contractor arrangement, physicians are forced into treating all such arrangements as purchases of the technical component under the Purchased Diagnostics Rule or defending themselves against allegations that they are violating reassignment prohibition (and potentially being subject to civil monetary penalties and exclusion)

Similarly, the proposed amendment to the definition of the “physician in the group” at 42. C.F.R. § 411.351 would appear to impose the Purchased Diagnostic Rule on all situations where an independent contractor physician in a group practice is furnishing or supervising the technical component of a diagnostic test. It is unclear how a contractual relationship with a physician to furnish or supervise the furnishing of a technical component would always constitute a purchase of the service. In such situations, the physician is simply furnishing certain of the inputs necessary to furnish the technical component of the service. The group practice contracting with the physician would typically have liability on the space, have liability on the equipment, and the services of the independent contractor physician could be subject to the group practice’s malpractice insurance. In such situations, the group practice is clearly not purchasing the technical component from the physician in the group.

As counsel for the requestor in Advisory Opinion 04-17 regarding pod laboratory arrangements, I understand CMS’ frustration with such arrangements; however, the imposition of the Purchased Diagnostics Rule on every contractual arrangement involving the technical component of a diagnostic test will needlessly complicate many existing and perfectly legitimate arrangements. Instead, I recommend that CMS more clearly articulate those situations that would implicate the Purchased Diagnostics Rule from those situations that would not. Further, I suggest that CMS more clearly articulate the relationship between the reassignment rule and the Purchased Diagnostics Rule while continuing its education efforts as to the independent obligation to comply with the Purchased Diagnostics Rule.

Section II. I. Incorporation of Purchased Diagnostics Rule in the Definition of “Physician in the Group” (42 C.F.R. § 411.351)

As mentioned above, the proposed amendment to the definition of the “physician in the group” at 42. C.F.R. § 411.351 would appear to impose the Purchased Diagnostic Rule on all situations where an independent contractor physician in a group practice is furnishing or supervising the technical component of a diagnostic test. It is unclear how a contractual relationship with a physician to furnish or supervise the furnishing of a technical component would always constitute a purchase of the service. In such situations, the physician is simply furnishing certain of the inputs necessary to furnish the technical component of the service. The group practice contracting with the physician would typically have liability on the space, have liability on the equipment, and the services of the independent contractor physician could be subject to the group practice’s malpractice insurance. In such situations, the group practice is clearly not purchasing the technical component from the physician in the group.

Section II, I: Incorporation of the Purchased Interpretation Rule in the Reassignment Exception for Independent Contractor Arrangements.

In the proposed rule, CMS indicated that it is considering further amending the reassignment exception to specifically incorporate the requirements of the purchased interpretation rule in the independent contractor exception to the reassignment prohibition. In my opinion, such action would be very disruptive to existing relationships, provide limited protection from program abuse, and would appear to undermine the flexibility that Congress intended when it enacted the independent contractor exception.

There is no independent statutory or regulatory basis for the purchased interpretation rule. The rule is solely a creature of Medicare manual process and, as such, has very limited precedential value in an appeals situation. Further, unlike the Purchased Diagnostics Rule, the purchased interpretation rule has no independent applicability. It does not limit payment and, therefore, only provides a means by which Medicare can pay a purchaser when the arrangement cannot otherwise be structured to comply with the reassignment prohibition.

For this reason, upon passage of the independent contractor exception to the reassignment prohibition, most suppliers structured their arrangements with interpreting physicians to comply with independent contractor exception instead of the purchased interpretation rule. Not only did this flexibility allow freestanding imaging centers to contract with non-radiologists to furnish certain interpretations (e.g., cardiologists to read 64-slice CTA), but it allowed hospital-based radiology groups to contract with independent contractor teleradiology providers.

Many arrangements that would be affected by the changes that CMS are considering are legitimate arrangements that pose minimal risk of abuse while furnishing quality health care services to Medicare beneficiaries. For instance, a freestanding imaging center may have an independent contractor relationship with a cardiologist to furnish interpretations for CTA. The cardiologists may provide reads only for his or her patients or may provide reads on patients sent to the imaging center by other physicians. The imaging center may desire to bill globally and pay the cardiologist a fair market value fee per each read. This desire may stem from the fact that many commercial insurers will only accept a single global bill for payment or from the fact that the imaging center wants to control billing to ensure the accuracy of all claims submitted and so as to prevent double billing.

If CMS decides to move forward with incorporating the purchased interpretation rule into the independent contractor exception, it is unclear whether such a cardiologist could continue to be able to furnish interpretations for his or her patients for service which the imaging center bills globally. Technically, it would appear that an IDTF would not be covered by the proposed rule since it appears to

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.

CY 2006

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

Proposed CY 2007 APC Changes

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

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

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

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

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

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

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

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

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

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

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

Historical Precedent - Gamma Knife New Technology Codes

We also note that CMS is proposing to assign the Gamma Knife to a higher APC, while reclassifying image-guided robotic radiosurgery to a lower APC. CMS noted that *it is a "mature technology [with] stable median costs"* (CMS-1506-P, p 157). This would be an accurate

reflection of the Gamma Knife, a technology in existence for 30 years with significant and mature data with which to establish an appropriate median cost.

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

CY 2004 and CY 2005 Data Variability Summary

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

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

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

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

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

Submitter : Dr. dennis olson

Date: 10/10/2006

Organization : solo practice

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

These are important procedures and breakthroughs. It is unrealistic to continue to lower payment rates and continue to allow malpractice rates to increase.

Provisions of the Proposed Rule

Provisions of the Proposed Rule

cpt 36478 cpt36479

Submitter : Dr. Wayne Gradman

Date: 10/10/2006

Organization : Beverly Hills Vein Center

Category : Physician

Issue Areas/Comments

Background

Background

Re reductions to codes 36475 and 36478. These revisions will deter physicians from treating Medicare patients with venous disease. This problem affects tens of thousands of elderly individuals who finally have access to effective, minimally invasive techniques done in an office (vs hospital) setting. The cost of treating neglected disease runs into the hundreds of millions of dollars annually. Minimally invasive office techniques provide needed services to the elderly.

GENERAL

GENERAL

I am responding to proposed changes to codes 36475 and 36478. Please observe that the RVUs for these codes are now to be consistently reduced from 2005 levels, when the codes were introduced. @006:46.91, 2007: 43.53, 2008: 40.84. The cost of providing these services has actually increased, particularly when one realizes that an ultrasound technician and two nurses are typically necessary to complete the procedure. These are increasing, not decreasing fixed costs. When added to the proposed 5.1% overall cut in reimbursement and the proposed reduction for all imaging procedures, the final reimbursement will not pay for the substantial fixed costs of these procedures. If physicians cannot cover their office costs, they will be obliged to treat their patients in the hospital, where the costs to CMS are substantially higher, and where the elderly are understandably reluctant to go. If the disease process is ignored, the eventual cost of treatment rises exponentially, at even greater cost to CMS. I urge you to keep the fully implemented, non-facility practice expense RVU to remain at the 2006 rate for 36475 and increase the RVU to 36478 to this level as well.

Impact

Impact

See Background and General

Provisions of the Proposed Rule

Provisions of the Proposed Rule

Codes 36475 and 36478 were recently added to the CPT list. They bundled several previous codes into one, and now include the procedure, the equipment, provision for ancillary personnel and ultrasound services.

Submitter : Dr. Lawrence Fanelly
Organization : The Ohio Society of pathologists
Category : Physician

Date: 10/10/2006

Issue Areas/Comments

GENERAL

GENERAL

The Ohio Society of Pathologists wishes to append this statement to our comments sent by e-mail: We are aware of additional ideas which we believe are valuable, which came to our attention after our original comments were submitted, and which are in the comments by the College of American Pathologists, the Texas Society of Pathologists, and others. We therefore ask that CMS acknowledge that additional communication between interested parties may be needed in order to determine the optimal language for the final rule, in order to avoid penalizing any legitimate non-abusive arrangements while preventing the abusive ones.

Lawrence Fanelly, D.O.
President, The Ohio Society of Pathologists

Submitter :

Date: 10/10/2006

Organization :

Category : Nurse Practitioner

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1321-P-979-Attach-1.DOC

#979

October 9, 2006

Centers for Medicare and 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: File code CMS-1321-P Criteria for National Certifying Bodies- Advanced Practice Nurses

To Whom It May Concern:

The undersigned represent national advanced practice nursing organizations whose missions support the educational preparation and certification of nurse practitioners (NPs). Through the collective activities of our organizations, we share a common goal of promoting high quality, safe and cost-efficient health care services delivered by NPs. It is in the interest of this goal that we are responding to the proposed rule "Medicare Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B"(42CFR Parts 405, 410, et al) as announced in the Federal Register on August 22, 2006.

In the discussion of proposed changes to CFR 410.76 as noted on page 49066, CMS noted its intent to establish standards to guide recognition of certification organizations eligible for participation in CMS programs. We wish to inform CMS that standards for recognition have already been established by the profession that should be used by CMS to make such determinations. To inform your work, we would like to summarize several key points that reflect our collective declarations about certification for NP specialties:

* NP education and certification of specialty practice remains the standard for credentialing and regulation of NP practice. Board certification of the NP specialties of Adult NP, Adult Acute Care NP, Family NP, Gerontology NP , Neonatal NP, Pediatric NP, Pediatric Acute Care NP, Women's Health NP and Psych/Mental Health NP has been already recognized for licensure and credentialing.

*Sub-specialty NP certification provides added value to NP specialty board certification. Sub-specialty NP practice builds on the NP specialty preparation and promotes an increased depth of knowledge to provide focused high quality care for specific diseases, systems and settings. Examples would include an Adult NP who sub-specializes in Diabetes management or Forensics.

National accreditation of educational and certification programs assures that appropriate quality standards are addressed. Eligibility to sit for board certification is determined by graduation from educational programs preparing NPs that are nationally accredited by a nursing accrediting organization recognized by the Department of Education. Both specialty and sub-specialty

certification examinations should be nationally accredited through the National Commission on Certifying Agencies or the American Board of Nursing Specialties Accreditation Council. We request that the already established standards such as those printed in the National Council of State Boards of Nursing (NCSBN) Criteria for Advanced Practice Regulation be used by CMS. We hope that this information is helpful as you consider developing standards for recognizing NP certification organizations.

Sincerely:

American Academy of Nurse Practitioners Certification Program
Jan Towers 202-966-6414

American Association of Critical Care Nurses Certification Corporation
Carol Hartigan 949-268-7507

National Certification Corporation
Betty Burns 312-951-0207

National Organization of Nurse Practitioner Faculties
Kitty Werner 202-289-8044

Pediatric Nursing Certification Board
Janet Wyatt 301-330-2921

Submitter : Dr. Bruce Hoyle
Organization : Dr. Bruce Hoyle
Category : Physician

Date: 10/10/2006

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

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

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

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

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

While practice expenses consistently rise, (salaries, utilities, etc.) it has become increasingly difficult to provide these necessary services. In order to comply with CMS guidelines, the ultrasound component of the procedure requires that the physician employ 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 than 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.

The facts as stated above I have respectfully plagiarized from a fellow member of the American college of phlebology. I would now like to elaborate on these proposed changes as it affects my neighborhood in California. Wages of all ancillary personnel, our cost of supplies, rent have all gone up while reimbursements have gone down. More and more of my colleagues are opting out of Medicare. These proposed changes affect one of the most important advances in the treatment of venous disease in decades. Venous insufficiency is a progressive and disabling condition traditionally treated in hospital with the somewhat primitive technique of stripping. We now have a more modern technology that can be done in an outpatient or even office setting and surely this offers some health-care savings. The government now wants to progressively decrease reimbursement to the point we will no longer do the procedure. Is this truly the direction we want the health care for our seniors to take?

Impact

Impact

See General Comment below.

Provisions of the Proposed Rule

Provisions of the Proposed Rule

See General Comment below.

Submitter : Dr. Wayne Gradman
Organization : Beverly Hills Vein Center
Category : Physician

Date: 10/10/2006

Issue Areas/Comments

Background

Background

Re: Reductions to codes 36475 and 36478. These revisions will sharply deter physicians from treating Medicare patients with chronic venous disease. This problem affects tens of thousands of elderly individuals who finally have access to effective, minimally invasive techniques done in an office (vs hospital) setting. The cost of treating neglected disease runs into the hundreds of millions of dollars annually. Minimally invasive office techniques provides needed services to the elderly, who might otherwise avoid treatment (conventional surgery) until their problem becomes intractable. Reduced payments will result in reduced access.

GENERAL

GENERAL

I am responding to proposed changes to codes 36475 and 36478. Please note that the RVUs for these codes are to be consistently reduced from 2005 levels, when the codes were introduced.

2006: 46.91

2007: 43.53

2008: 40.84

The cost of providing these services have actually increased, particularly when one realizes that an ultrasound technician and two nurses are typically necessary to complete the procedure. These costs are increasing, not decreasing. When added to the proposed 5.1% overall cut in reimbursement and the proposed reuction for all imaging procedures, the final reimbursement will not cover the substantial fixed costs of the procedures. If physicians cannot cover their office costs, they will be obliged to treat their patients in the hospital, where the costs to CMS are substantially higher, and where the elderly are understandably reluctant to go. If the disease process is ignored, the eventual cost of treatment rises exponentially, at even greater cost to CMS (tens of thousands are hospitalized each year to treat the consequences of late stage venous disease.) I urge CMS to keep the fully implements, non-facility practice expense RVU to remain at the 2006 level for code 36475 and to increase the RVU for 36478 to his level as well.

Impact

Impact

Codes 36475 and 36478 were recently added to the CPT list. They bundled several previous codes into one, and now include the procedure itself, the extensive needed equipment, the ancillary personel (including 1-2 nurses) and ultrasound services (equipment and technician).

Provisions of the Proposed Rule

Provisions of the Proposed Rule

See Provisions and Impact

Submitter : Dr. michael arata

Date: 10/10/2006

Organization : Dr. michael arata

Category : Physician

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

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. For example to comply with CMS guidelines, the ultrasound component of the procedure requires that the physician employ a Registered Vascular Technologist (RVT) to provide imaging services. These 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 fall!

2. Values for codes 36475 and 36476, radiofrequency vein ablation have been consistently higher than those for laser ablation. 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.

Submitter : Mr. Simon Abrahms
Organization : Saint Louis University Hospital
Category : Hospital

Date: 10/10/2006

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-983-Attach-1.DOC

#983

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 Memorandum³. While CMS eventually adopted the new HCPCS code - G0251 - this code did not specify that it be used only for image-guided treatment with robotics. (The descriptor for this code was "linear accelerator-based stereotactic radiosurgery, fractionated treatment, per session, maximum 5 sessions per course of treatment."). This code only became effective July 1, 2002.

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

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

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

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

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

CY 2003

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

CY 2004

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

CY 2005

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

⁴ Federal Register November 30, 2001, page 59868

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 1 st	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.

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.

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,

Ryan Nestrick
Saint Louis University Hospital
Administrative Fellow
3635 Vista Ave.
Saint Louis, MO 63110

Submitter :

Date: 10/11/2006

Organization :

Category : Physician

Issue Areas/Comments

Background

Background

This proposal is detrimental to MediCare patients and oncology clinics. We use the therapy we believe to be the best for the patient. We purchase these medications and receive rebates and reimbursement. This represents the true market price of the products whether they are in the same contract or not. The intent of ASP + 6% was to reflect the actual market price of products. This change should not be made. It will lead to significantly unpredictable price fluctuations that will not reflect our market costs.

Competition has helped reduce costs for our patients and the healthcare system. By taking one company and punishing it because it has done well is not the intent of ASP+6 pricing. Why should a nephrology clinic have their MediCare reimbursement decrease on Aranesp below a price that is available in the market since they do not use Neulasta?

Impact

Impact

It is not the intent of CMS to adjust the ASP to a price that is not available in the market place. Shifting rebates from one product to another (for companies that offers multiple products) would be punitive to one company. The oncology offices that wish to have the choice of medications would be unfairly penalized, as well as choosing the therapy we physicians feel would be the best choice.

Provisions of the Proposed Rule

Provisions of the Proposed Rule

I have seen the reimbursement for my MediCare patients get lower and lower over the last 3 years. One area that is good is my patients co-pays have also gone down. I have been able to make this work for my clinic. I am able to plan on my reimbursement and rebates since the payments and rebates have stabilized. This proposal to make one product have the ASP linked to the rebates of another product defeats the initial intent of the ASP model of payments. Following this proposal will lead to less choice for me as a physician, fewer options for my patients, and, increased cost to the entire system.

Submitter : Mr. Ryan Nestrick
Organization : Saint Louis University Hospital
Category : Hospital

Date: 10/10/2006

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-984-Attach-1.DOC

#984

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 OPSS 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 Memorandum³. While CMS eventually adopted the new HCPCS code - G0251 - this code did not specify that it be used only for image-guided treatment with robotics. (The descriptor for this code was "linear accelerator-based stereotactic radiosurgery, fractionated treatment, per session, maximum 5 sessions per course of treatment."). This code only became effective July 1, 2002.

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

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

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

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

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

CY 2003

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

CY 2004

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

CY 2005

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

⁴ Federal Register November 30, 2001, page 59868

CY 2006

At the August, 2005 APC Panel meeting, stereotactic radiosurgery codes including G0339 and G0340 were discussed. The Data Subcommittee reported its analysis of the CY 2004 Identifiable Data Set Hospital OPSS 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 (OPSS) 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 OPSS 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 OPSS 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 OPSS 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 OPSS file is 1,311. The total CY 2004 Medicare claims for Georgetown University Hospital (an institution not included in the Identifiable Data Set Hospital OPSS 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 OPSS 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 OPSS file for G0339 and G340 together.*

The CY 2004 Identifiable Data Set Hospital OPSS 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 OPSS 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 OPSS 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 OPSS 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 OPSS 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,

Ryan Nestruck
Saint Louis University Hospital
Administrative Fellow
3635 Vista Ave.
Saint Louis, MO 63110

Submitter : Dr. bipin solanki
Organization : Dr. bipin solanki
Category : Physician

Date: 10/10/2006

Issue Areas/Comments

Background

Background

this proposal will result negatively on medicare patients'access to quality health care .the reduction 8inreimbursment rate will ultimately limt access to physicians who perform these treatments.

GENERAL

GENERAL

CMS-1321-P

I am responding to cms proposal of 08/08/06 for lowering reimbursement for cpt code 36478 and 36479. RVUs have consistently been reduced from 2005 level while practice expenses are rising each year. Above procedures have higher acuisition costs of equipments i.e. Laser unit, 37 to 40K, ultra sound machines 35 to 50K, the services of RVT technicians and RN nurse, salaries between 60 to 70K and not to mention disposal supplies, kits ranging from \$350 to \$500 for each procedure. All these add up to 60 to 70% expense ratio to deliver these services in an office setting. If the same services are performed in the hospital settings the cost will rise significantly.

As you know medicare physicians' fees are already scheduled to be reduced by 5% across the board in 2007. Additionally there are proposals to reduce vascular imaging services. all these cuts will cripple the ability of a physician to perform this extremely important procedure and ultimately will result in a loss of quality care to Medicare beneficiaries.

I would request that fully implemented non facility expense RVUs remain at the 2006 rate for 36475 of 51.5 amd RVUs for 36478 be increased to the same level. I will be more than happy to discuss this in detail if you like.

Thank you.

B.Solanki, M.D.

Impact

Impact

see general comments below

Provisions of the Proposed Rule

Provisions of the Proposed Rule

see general comments below

Submitter : Dr. Michael Aruta
Organization : Renewal Medical Specialists
Category : Physician

Date: 10/10/2006

Issue Areas/Comments

Background

Background

Impact

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

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:

- 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 employ 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 than 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.

Respectfully submitted,
Michael J. Aruta, MD

Impact

Impact

Provisions of the Proposed Rule
See General Comment below.

Provisions of the Proposed Rule

Provisions of the Proposed Rule

Background
See General Comment Below.