Submitter : Dr. Boyd Helm **Date:** 10/10/2006

Organization : Dr. Boyd Helm

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1321-P-793-Attach-1.DOC

#793

BATON ROUGE CARDIOLOGY CENTER

Boyd E. Helm, M.D., F.A.C.C., F.S.C.A.I.
Joseph M. Cefalu, M.D., F.A.C.C.
Kevin L. Kilpatrick, M.D., F.A.C.C.
Terry L. Zellmer, M.D., F.A.C.C.
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Venkat R. Surakanti, M.D., F.A.C.C.
Evens Rodney, M.D., F.A.C.C.
Darrin M. Breaux, M.D., F.A.C.C.
Boyd M. Helm, M.D.
James R. Calvin, M.D., F.A.C.C., Emeritus

5231 Brittany Drive, Baton Rouge, Louisiana 70808, Phone: 225/769-0933, Fax: 225/769-6255

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Coronary Atherectomy & Stents
Cardiac Rehabilitation
Pacemaker Implantation Follow-up
Lipid Management
Endoscope Evaluation
Electrophysiologic Studies
Radiofrequency Catheter Ablation
Fibrillation Implantation Follow-up

October 9, 2006

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

Dear Dr. McClellan:

On behalf of Baton Rouge Cardiology Center and our 11 individual practicing cardiologists, we appreciate the opportunity to submit these comments to the Centers for Medicare & Medicaid Services ("CMS") regarding the above proposed Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B; Proposed Rule ("Proposed Rule"). We are concerned about several provisions that will impact Medicare beneficiaries' access to services in outpatient cardiac centers, particularly those related to cardiac catheterizations. Specifically, we are concerned about the payment method proposed for cardiac catheterization related procedures. The Cardiovascular Outpatient Center Alliance ("COCA"), of which we are a member, will address the CMS proposal to require standards for Independent Diagnostic Testing Facilities ("IDTFs"). Our concerns related to the payment method are outlined below.

Payment Method

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

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

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

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

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

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

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

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

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

Sincerely,

Boyd E. Helm

Boyd E. Helm, M.D., F.A.C.C., F.S.C.A.I.

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

Organization : SMS

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-794-Attach-1.DOC

#794

Reference File Code CMS-1321-P
Section (N) Public Consultation for Medicare Payment for
New Outpatient Clinical Diagnostic Laboratory Tests
Subsection (3) Other Laboratory Tests
Provision (b) Blood Glucose Monitoring in SNFs

BACKGROUND

As identified by the House, Ways and Means Committee Report and finalized by the Conference Committee Report (copies attached) Section 4554 of the Balanced Budget Act of 1997 (BBA-1997) the Negotiated Rulemaking Committee on Clinical Diagnostic Laboratory Tests (Committee) was formed to develop National Policies for the Medicare Part B Clinical Laboratory Tests Benefit.

Congress' statutorily mandated establishment of the Negotiated Rulemaking Committee, in essence, preempted the field of payment and coverage for the Medicare Part B laboratory benefits. The Committee's National Coverage Determinations and Administrative Policies became binding on the Secretary (HHS) in accordance with Section 4554(b) of the BBA-1997 no later than January 1, 1999.

As published in the Federal Register on November 23, 2001 pursuant to Section 4554(b) of the BBA-1997 and subject to a Final Agreement of the Committee dated August 31, 1999 (copy attached), 23 national policies were developed by the Negotiating Committee. These national policies were designed to promote uniformity and integrity through universal simplified administrative requirements to be followed for all laboratory covered services without any differentiation/distinction as to where the services were provided. (See attached synopsis of Committee's key applicable Final Administrative Policies for Clinical Diagnostic Laboratory Tests)

One of the Negotiated Rulemaking Committee's 23 National Policies (commonly referred to as a National Coverage Determination or NCD) addressed Blood Glucose Testing. This often utilized laboratory service is universally accepted as needed to be performed (up to several times a day) for a Medicare Part B beneficiary who is afflicted with **diabetes** or similar illness/medical condition. (Copy of the final NCD for Blood Glucose Testing is attached)

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)
AUGUST 22, 2006 PUBLICATION OF PROPOSED RULE
BLOOD GLUCOSE MONITORING IN SNFs

CMS states that the purpose of its publication contained in the Federal Register dated August 22, 2006 is to take an opportunity to restate its long standing policy on coverage of blood glucose monitoring services and proposes to codify physician certification requirements for blood glucose monitoring in SNFs.

Prior to the issuance of Program Memorandums AB-00-099 (August 24, 2000) and AB-00-108 (December 1, 2000) CMS published that it had no national policy for blood glucose testing (monitoring). The issuance of these two instructions were the initial publications issued by CMS to its Medicare contractors.

The above instructions were issued despite CMS' (HHS) confirmed concurrence with the proposed rule provision published by the Committee (Negotiated Rulemaking Committee on Clinical Diagnostic Laboratory Tests) in the Federal Register dated March 10, 2000. The Committee's unanimous agreement precluded any participant from taking any action to inhibit the proposed regulation as final and published by the Department of Health and Human Services (HHS) through the Health Care Financing Administration (currently known as CMS).

In PM AB-00-108, CMS, addressing laboratory services, restates Section 1862(a)(1)(A) of the Social Security Act requirement that the service needs to be reasonable for the diagnosis and treatment of an illness in order to be covered by Medicare. CMS cites 42 CFR 410.32 and 411.15 for the proposition that the physician must order the test/service and use the result in the management of the beneficiary's specific medical problem. However, CMS went further to include the following additional requirement: **"Implicitly, the laboratory result must be reported to the physician promptly in order for the physician to use the result and instruct continuation or modification of patient care; this includes the physician order for another laboratory service."** Clearly by their own terms, CMS confesses that the statute or regulations do not require such criteria in order for a SNF to perform a treating physician ordered subsequent laboratory test.

We are submitting the comment below as part of our objection to the proposed rule by CMS which is based on previous publications that are in conflict with or unsupported under the Congressionally binding Negotiated Rulemaking Committee on Clinical Diagnostic Laboratory Tests' NCD and Administrative Policies.

COMMENT

In the proposed rule section which is identified and entitled *Blood Glucose Monitoring in SNFs*, CMS proposes that a standing order is not sufficient for a treating physician to order a series of blood glucose tests is contrary to current medical practice and is clearly motivated by CMS' confirmed irresponsible desire not to pay for this laboratory testing service. The resultant effect is that Medicare beneficiaries will be required to duplicatively pay both through the Medicare Part B premiums and individually for these specific testing services if it is not covered by CMS (for the time being under Medicare law and regulations). Additionally, Medicare beneficiaries who are unable to pay privately will cause such charges to be submitted to alternative secondary payors including the Medicaid program or other federally funding program sources. This condition will result in the Medicare Part B beneficiaries receiving advanced beneficiary notices and the beneficiaries and/or other payor sources (which may be partially funded by CMS) bearing the unfair financial burden of these tests, supplies and other related services.

Submitted by:
James J. Giger

October 10, 2006

Submitter : Mr. Jason Chandler **Date:** 10/10/2006

Organization : BrainLAB, Inc.

Category : Private Industry

Issue Areas/Comments

GENERAL

GENERAL

Please see the attached comment letter. Thank you for your consideration.

CMS-1321-P-795-Attach-1.DOC

#795

BrainLAB

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brainlab.com

October 9, 2006

Via Hand Delivery and Electronic Submission

Mark B. McClellan, M.D., Ph.D.
Administrator, Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attn: CMS-1321-P
7500 Security Boulevard
Baltimore, Maryland 21244

Re: CMS-1321-P -- Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 -- **Request to Remove CPT 77421 Stereoscopic X-Ray Guidance from List Subject to DRA / Hospital Outpatient Cap**

Dear Dr. McClellan:

BrainLAB appreciates this opportunity to submit comments on the proposed rule setting payment policies under the Physician Fee Schedule ("PFS") for Calendar Year 2007 and Other Changes to Payment Under Part B, 71 Fed. Reg. 48981 (August 22, 2006). BrainLAB develops, manufactures, and markets software-driven medical equipment to provide advanced radiotherapy, radiosurgery, and neurosurgery services, among other things. Accordingly, the company is keenly interested in the impact CMS's proposed changes to PFS payments for 2007 would have on patient access to physician services performed using its technologies.

Specifically, our recommendations are as follows:

- BrainLAB wishes to encourage CMS to refine the list of radiology imaging procedures subject to the cap imposed by the Deficient Reduction Act of 2005 ("DRA"); and

- We respectfully request that CMS remove CPT Code 77421 stereoscopic x-ray guidance for localization of target volume for the delivery of radiation therapy from the list of "imaging" procedures subject to the DRA / hospital outpatient payment cap.

As you know, in the DRA, Congress mandated that the PFS payment for certain imaging services not exceed the payment rate under the Hospital Outpatient Prospective Payment System ("HOPPS"). We believe that the DRA was not intended to include imaging guidance that is integral to and inseparable from the performance of an interventional radiology treatment during the same outpatient encounter. The DRA, section 5102 (B) describes imaging as follows:

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

In the proposed rule, CMS defines imaging as services that provide visual information regarding areas of the body that are not normally visible, thereby assisting in the diagnosis or treatment of

illness or injury. CMS considered the "7XXXX series" of CPT codes for radiology services plus some additional CPT / HCPCS codes that describe imaging services.

However, listing all the 7XXXX codes by virtue of their position in CPT is a very broad approach that may not be consistent with the intent of Congress. On this BrainLAB agrees with the American College of Radiology ("ACR") and other specialty societies that the list of procedures affected by the DRA should not include the 7XXXX codes that describe imaging guidance for interventional procedures. While supervision and interpretation codes for diagnostic angiography may meet the definition of an imaging procedure, we agree with ACR that imaging guidance for biopsy and certain radiation treatments (such as CPT 77421 stereoscopic x-ray guidance for localization of target volume for radiation therapy) do not.

As you may know, imaging guidance has been incorporated into several new CPT codes for surgical / therapeutic procedures such as cryoablation of the prostate, endovascular stent placement, and bone ablation, and these CPT codes are not affected by the DRA cap. Unfortunately, a few interventional and therapeutic radiology codes, those in the 7XXXX series, remain subject to the DRA provision, including CPT 77421. These codes are similar to those excluded from the DRA cap in that they are integral to a therapeutic treatment. Thus, in the interest of consistency, BrainLAB believes that, when imaging guidance is used to facilitate a surgical procedure or radiation treatment, those codes should not be defined as diagnostic imaging nor included on the list of codes subject to the DRA provisions.

Moreover, recent cost data for the technical component was recently reviewed by CMS and used to establish the non-facility relative value units for CPT 77421 stereoscopic x-ray guidance, effective January 1, 2006.

The ACR and other specialty societies have recommended that CMS further refine the DRA list to exclude "interventional and therapeutic" radiology codes such as 77421. If action is not taken, doctors will not be adequately reimbursed for the significant expenses associated with providing these services in the physician office setting. As a result, they may not be able to afford to provide these valuable services to patients. BrainLAB supports the ACR's recommendations and respectfully requests that CMS act now to preserve patient access to interventional/ therapeutic radiology procedures by excluding CPT 77421 stereoscopic x-ray guidance from the DRA list.

We appreciate your attention to this important matter. Please contact me at 440.213.3951 or Gail Daubert at 202.414.9241 for any further information you may need.

Sincerely,

Jason Chandler

Jason Chandler
Director of Business Development, BrainLAB

cc: Carolyn Mullen, CMS, Deputy Director, Practitioner Services (via email)
Pam Kassing, Senior Director, Economics and Health Policy, American College of Radiology
Trish Crishock, ASTRO

Submitter : Dr. Joseph Cefalu **Date:** 10/10/2006

Organization : Dr. Joseph Cefalu

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1321-P-796-Attach-1.DOC

BATON ROUGE CARDIOLOGY CENTER

Boyd E. Helm, M.D., F.A.C.C., F.S.C.A.I.
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231 Brittany Drive, Baton Rouge, Louisiana 70808, Phone: 225/769-0933, Fax: 225/769-6255

October 9, 2006

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

Sincerely,

Joseph Cefalu, M.D., F.A.C.C.

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

Organization : Systematic Management Systems

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
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. Kevin Kilpatrick **Date:** 10/10/2006

Organization : Dr. Kevin Kilpatrick

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1321-P-798-Attach-1.DOC

#198

BATON ROUGE CARDIOLOGY CENTER

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

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

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

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

Sincerely,

Kevin Kilpatrick, M.D., F.A.C.C.

Submitter : Ms. Alice Smith **Date:** 10/10/2006

Organization : EPOCH Senior Living

Category : Long-term Care

Issue Areas/Comments

GENERAL

GENERAL

I am uncertain if the document attachment was complete. This MAY be a duplicate to Temporary comment number 93206. See attached.

CMS-1321-P-799-Attach-1.DOC

#709

EPOCH Senior Living
51 Sawyer Road, Suite 500
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October 6, 2006

Anita Greenberg
U.S. Department of Health and Human Services
Centers for Medicare & Medicaid Services
7500 Security Boulevard
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:

EPOCH Senior Living, a Skilled Nursing Facility Provider, is pleased to have the opportunity to comment on 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 related to blood glucose monitoring in skilled nursing facilities.

We are in full support of the comments and position submitted by The American Health Care Association ("AHCA") and the Alliance for Quality Nursing Home Care (the "Alliance") and respectfully urge CMS to withdraw the proposed rule and to adopt the recommendations of AHCA and the Alliance.

Among other services, EPOCH Senior Living currently provides skilled nursing and rehabilitation in eight facilities in the northeast. We have relationships with three separate fiscal intermediaries all of whom have varying interpretations of CMS Program Memorandum AB-00-108 (Dec. 1, 2000), and CMS manual provision, Chapter 7 of the Medicare Claims Processing Manual (CMS Pub. 100-04), entitled "Skilled Nursing Facility Part B Billing". Blood glucose testing has been denied on various grounds, including but not limited to "the "documentation did not support the blood glucose monitoring services billed as evidenced by the following: no signs/symptoms of a clinically unstable medical condition; no prompt notification of the physician regarding the abnormal blood glucose values; no physician's medical management of the patient regarding the abnormal blood glucose values". We believe, as do some Administrative Law Judges when such cases are brought upon appeal, that there is no basis for such interpretations.

Frequent blood glucose testing can be essential in the proper management and treatment of patients suffering from diabetes, including nursing home residents who may be unable to self-test. Physicians treating nursing home residents who suffer from diabetes – particularly those who require insulin therapy – regularly order nursing staff to monitor blood glucose frequently in order to administer proper insulin doses, and to provide dietary supplements, so that blood glucose levels are well controlled and the adverse health effects caused by diabetes are minimized. Results of each test are recorded in the patient's chart, and are reviewed by the treating physician during regular visits and used to determine whether and how to adjust the patient's insulin, oral medication, testing, and dietary regimen. During such visits, the physician will typically sign a new order, thus certifying the medical necessity for the further treatment and testing and documenting that the previous test results have in fact been reported to the physician promptly and used by the physician in treating the patient. In EPOCH's view, this process leads to proper documentation of medical necessity and meets the conditions for reimbursement under applicable regulations.

EPOCH has nevertheless been subjected to routine claim denials by Medicare intermediaries, who erroneously assert that blood glucose tests are only reimbursable if there is direct physician intervention between each test. In other words, even if a diabetic resident requires blood glucose tests four times daily to ensure proper insulin dosing and diet control by the nursing staff, and even further physician adjustments to the treatment regimen must be made based on an accumulation of multiple test results over time – the tests will not be reimbursed unless the result of each single test is reported to the physician, reviewed, and used as the basis for the physician to order the next single test. We, like many other facilities and as set forth by AHCA and the Alliance, believe this is arbitrary and violates the overriding principle of the statute that medically necessary diagnosis and treatment of specific medical conditions is covered. Accordingly, EPOCH has appealed these denials, has obtained reversal with one intermediary (AHS), and has an appeal currently pending with the Medicare Appeals Council on a denial by Mutual of Omaha.

In connection with the pending administrative appeal, we have obtained testimony from Dr. Kenneth Snow, Acting Director of Adult Diabetes at the Joslin Center, a leading institution devoted to research and treatment of diabetes. We thought it would be helpful to share with you portions of his written testimony, which were directed to a particular case (patient identifying information is being withheld) that we view as not at all atypical of the situations where intermediaries are routinely denying reimbursement:

> "The use of standing orders to the nursing staff for blood glucose monitoring, dietary adjustments, and sliding scale insulin dosing was entirely consistent with accepted standards of care. *No medical purpose is served by having a physician*

review the result of each blood glucose test multiple times per day, and the results of any given test or series of tests over a short period of time are not relevant to the need for further tests to be performed on diabetic patients. That type of physician intervention is practiced neither for diabetics who self-administer insulin nor for diabetic patients who are incapacitated and require nursing assistance for diabetes control. Ms. -------, as a brittle diabetic, was in constant need of insulin treatment in doses that would vary within a specified range depending on her level of blood sugar at the time the dose was to be administered, and needed to adjust diet between injections as needed to prevent hypoglycemia. As Ms. --------- was incapacitated, frequent blood glucose tests were essential to controlling her diabetes, a standing order providing for such frequent testing was the only effective way to provide the nursing staff with information needed to dose insulin within the prescribed parameters, and to know when it was appropriate to provide Ms. ------- with a glass of juice or a cookie to prevent hypoglycemia. And, Ms. ------- was going to require multiple daily blood glucose tests irrespective of the results of any single blood glucose test or series of tests."

(Emphasis added.)

Administrative Law Judges and even an AHS hearing officer have adopted the same approach in rejecting coverage denials as arbitrary and capricious. In In re: Extendicare Health Services, SSA No. 999-29-2319, ALJ Stephen Ahlgren observed:

> "If as the evidence shows, the standard of care in many cases requires the monitoring of blood sugar two or three times daily in order to maintain tight control, the nursing home would be obligated to contact the physician two or three times daily, even when no change in treatment was warranted. As a practical matter, physicians dealing with the medical problems of patients in immediate need will undoubtedly resent being contacted unless there appears to be a need for a new order. Nursing home personnel, already hard pressed, will find it impossible to contact physicians' two or three times daily only to report no recommendations for change in treatment. *The LMRP will in fact discourage the frequent monitoring of blood glucose, contrary to both the national coverage policy and to the standards of medical practice"* (emphasis added).

To the same effect, *see In re: Extendicare Health Services,* SSA No. 999-30-0088, Office of Hearings and Appeals, Falls Church, VA at 2 (Stewart, ALJ, August 12, 2004) ("Expecting a physician to check every day on the results and make changes based on each report in isolation is neither cost-effective nor warranted for good health."). In EPOCH's successful in-person appeal of a denial at AHS, the hearing officer noted that "...providers should not be expected to report each individual [blood glucose] test result to a physician before a follow-up test can be performed. Requiring providers to do so would be unreasonable and could seriously jeopardize patient care."

We urge CMS to give full consideration and support to the AHCA and Alliance position and continue to allow for full reimbursement for medically necessary blood glucose testing provided to Medicare beneficiaries residing in skilled nursing facilities, when ordered by the resident's treating physician for the treatment of diabetes (and other diagnoses as indicated in the NCD). We oppose any regulation that would require as a condition for reimbursement physician intervention between each blood glucose test in circumstances where it simply is not warranted by good medical practice.

Respectfully submitted,

Alice Smith
Medicare Specialist
EPOCH Senior Living
BST99 1518904-1.054454.0015
DRAFT 10/11/06

Submitter : **Ms. Andree Gardner** **Date: 10/10/2006**

Organization : **National Renal Administrators Association**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-800-Attach-1.PDF

National Renal Administrators Association

October 10, 2006

The Honorable Mark McClellan
Administrator
Centers for Medicare and Medicaid Services
U. S. Department of Health and Human Services
Hubert H. Humphrey Building
Room 445-G
200 Independence Ave., S. W.
Washington, D. C. 20201

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

Dear Administrator McClellan:

The National Renal Administrators Association (NRAA) welcomes the opportunity to comment on the "Proposed Rule for Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B." We will focus our comments on the "End Stage Renal Disease Related Provisions" of the proposed regulation.

The NRAA is a voluntary organization representing professional managers of dialysis facilities and centers throughout the United States. Our Association represents free-standing and hospital-based facilities, which are for-profit and non-profit providers located in urban, rural, and suburban areas and serving dialysis patients in all settings. The NRAA is the only organization that represents the full spectrum of dialysis providers.

Before addressing the specific provisions in the proposed regulation, we want to again emphasize that, unlike most providers participating in the Medicare program, those who care for dialysis patients do not have a statutory mechanism to update their reimbursement on an annual basis. As you know, we must seek Congressional action in order to gain an increase in the composite rate. Currently, Medicare payments do not cover the patient's dialysis treatment costs. MedPAC has recommended that the composite rate be increased by 2.65 percent in 2007.

NRAA members are committed to providing their patients with the best possible care. But the current reimbursement system makes it difficult to fulfill this commitment. To ensure the quality of care that Medicare beneficiaries deserve and to guarantee reasonable access to dialysis services, it is essential that Congress provide an annual update mechanism. We ask the Administration to join with us in urging the Congress to move expeditiously on enacting appropriate legislation that will place our members on an equal footing with other providers under the Medicare program.

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Turning to the proposed regulation, we would urge the Centers for Medicare and Medicaid Services (CMS) to **consider adopting a proxy to estimate the update to the drug add-on adjustment for Calendar Year 2007 and allow for forecast error adjustments to ensure that the estimates are correct.**

NRAA supports the use of an index to establish the update to the drug add-on adjustment. However, we are concerned that the proposed Rule's methodology does not provide an accurate estimate of either 2007 prices or utilization of End Stage Renal Disease (ESRD) separately billable drugs. We endorse the recommendations outlined in The Moran Company's report "The Proposed ESRD Prospective Payment System Update for CY 2007: Evaluating Technical Options for Improved Payment Accuracy," conducted on behalf of, and submitted to you by, the Kidney Care Council. The Report recommends that CMS (1) use a proxy for CY 2007 to calculate the update and (2) establish a mechanism that would allow for forecast error adjustments if the estimates are incorrect.

Given The Moran Company's valid concerns about the data and methodology regarding the price and utilization estimates used to calculate the update to the drug add-on adjustment in the proposed Rule, we encourage CMS to clarify how it developed its estimates. NRAA further encourages CMS to re-examine its estimates of price and utilization for purposes of calculating the update to the drug add-on adjustment.

Because the payment to cost ratio for dialysis payment, including separately billable drugs, remains negative (MedPAC "Report to the Congress, 2006"), it is important that the method used to calculate the update results in an accurate assessment of the price and utilization changes to ensure economic stability for kidney care providers.

Regarding the price estimate, NRAA appreciates the value of using the Producer Price Index (PPI). However, we are concerned that the forecast outlined in the proposed Rule is significantly lower than it should be. The proposed Rule states that CMS estimates the PPI to be 4.9 percent. The current reported PPI for 2006 is 6.3 percent. Looking at the 2004/2005 PPI would result in 5.1 percent. If CMS determines it is appropriate to continue to use the PPI to estimate price changes, we request that you review the 2006 PPI and other data to ensure that in the final Rule the PPI estimate reflects the most current data available.

NRAA is also concerned about the data and methodology CMS uses in the proposed Rule to estimate utilization changes. We agree that CMS's current volume data are not stable and, as such, cannot be used to estimate accurately changes in volume. Without accurate data, CMS proposes a methodology that relies on less than complete data and results in a conclusion that utilization is flat. NRAA is concerned that this analysis does not accurately reflect the true trends in drug utilization.

Although it is unlikely that there has been double-digit growth in utilization for separately billable drugs, the analysis conducted by The Moran Company suggests that utilization is slightly higher and not flat. The data upon which CMS bases its estimate are not the most recent data available about separately billable drugs. Additionally, we are concerned that CMS has assumed, without having data to confirm its conclusion, that the new EPO Monitoring Policy will result in a significant decrease in the utilization of EPO. Respectfully, CMS should not incorporate unsubstantiated assumptions into a calculation as complex as estimating utilization. Because of these problems and based upon its review of the proposed Rule and CMS data, The Moran Company concludes that the use of the proposed methodology is flawed. These flaws make it difficult to ensure that any utilization estimate accurately reflects reality.

NRAA agrees with The Moran Company's suggestion that CMS **use the National Health Expenditure (NHE) index for purposes of determining the update to the drug add-on adjustment**. The benefit of the NHE index is that, unlike the PPI, it includes both price and utilization changes. We appreciate the concerns about Part D data distorting the NHE. However, as The Moran Company discusses, CMS can easily separate the Part D and Part B data so that the update would be determined looking only at trends in Part B drugs. Therefore, NRAA urges CMS to use the NHE as a proxy for price and utilization changes until CMS has credible data that will allow it to estimate price and utilization more accurately.

In addition to using the correct proxy in the short-term, CMS should also **establish a mechanism that will allow it to check and, if necessary, correct its estimates on a prospective basis until it has stable data** with which to estimate price and utilization changes. We agree with the suggestion outlined in The Moran Company report that CMS should temporarily adopt a mechanism that would allow it to forecast error adjustments of prior price and utilization estimates before calculating the next year's update to ensure that any estimating errors do not accumulate. This approach is consistent with CMS policies in other parts of the Medicare program, most notably in the MedicareAdvantage program payments to health plans. For example, if the estimates were incorrect for 2007, CMS could use the correct numbers to adjust the 2007 update before calculating the 2008 update. This mechanism would be necessary only until CMS has accurate volume data for ESRD drugs. NRAA encourages CMS to adopt such a mechanism for a limited time in addition to using an adjusted NHE as a proxy to ensure that updating the drug add-on adjustment is done in as accurate a manner as possible.

We would urge that the final Rule expressly state that **CMS will reimburse separately billable drugs at ASP+6 percent in 2007.** Given the importance of separately billable drugs to the reimbursement for dialysis services, it is vital that the rates be stable and predictable. We appreciate CMS noting that separately billable drugs will be reimbursed "based on section 1847A of the Act." However, we would encourage CMS to be more direct in the final Rule and to state expressly that for CY 2007, the Secretary will reimburse separately billable drugs at ASP+6 percent. This statement would be consistent with the statutory mandate and provide needed clarity. We urge that the preamble and the text of the Rule make it clear that the reimbursement rate is ASP+6 percent.

As CMS continues to implement the geographic wage index, **the budget neutrality calculation should be clarified and the methodology clearly explained.** We are concerned that the proposed regulation does not have the necessary transparency. The modifications to the geographic wage index have an enormous impact on small providers. Erroneous calculations that reduce the composite rate can force these providers to close their doors or forego improvements that can lead to better quality of care for their patients. To have faith in the new wage index, they need to understand that the budget neutrality factor is being calculated correctly. NRAA urges CMS to provide the data and methodology it used to calculate the budget neutrality factor in the final Rule to allow our membership to assess the impact of the proposed changes and confirm their accuracy.

We firmly believe that **CMS should encourage patient services such as self-management for diabetes, blood flow monitoring and nutritional therapy through appropriate reimbursement.** We are pleased that CMS recognizes that these services can improve care for patients and encourage them to learn to better manage their disease. NRAA encourages CMS to continue its efforts to provide coverage for these and other services that can assist in slowing the progression of kidney disease and help patients who have kidney failure achieve a better quality of life.

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One precursor to chronic kidney disease is diabetes. Patients who manage their diabetes effectively will slow the progression or prevent the onset of chronic kidney disease. The more opportunities patients have to learn how to manage their disease, the less likely they will need dialysis services. We enthusiastically support the proposal regarding diabetes self-management services. Patient education and training is critical and we applaud CMS for recognizing its importance in the proposed Rule.

It is generally recognized that for most hemodialysis patients, an AV fistula is the best type of access. Monitoring a patient's access, whether fistula, graph, or catheter, is crucial to assuring that the patient can receive the appropriate treatments. **NRAA strongly supports additional resources for blood flow monitoring services.** These services allow dialysis professionals to assess a patient's blood flow rate and vascular access and determine whether additional maintenance services are required before a problem occurs. By enhancing the accuracy of the services, blood flow monitors improve the quality of care that patients receive and eliminate indirect costs by reducing patient morbidity and the number of required hospital tests. CMS should recognize the importance of providing patients with flow monitoring services and ensure coverage with appropriate payment for these services.

We fully support expanding coverage for medical nutritional therapy to non-diabetic patients. Limited access to nutritional therapists denies patients with Stage 3 and 4 kidney disease important information and education in better managing their disease. Medical nutritional therapy and counseling are important services to assist patients in improving their nutritional status and to control several critical electrolytes, such as potassium and phosphorous. The availability of nutritional therapy will help non-diabetic patients learn how to better manage their disease.

NRAA is extremely pleased that CMS recognizes in the proposed Rule these important preventive services. These types of programs not only help to prevent the onset of chronic kidney disease, but also help dialysis professionals better manage their patients. We encourage CMS to continue to provide incentives for improved educational and preventive services.

The NRAA greatly appreciates the opportunity to comment on the proposed Rule. We would be pleased to respond to any questions you may have and to work with you to assure appropriate implementation of the final Rule. We look forward to continuing to work with CMS on all issues affecting the dialysis community.

Sincerely,

Andree Gardner
President
National Renal Administrators Association

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

Organization : **Cytyc Corporation**

Category : **Device Industry**

Issue Areas/Comments

GENERAL

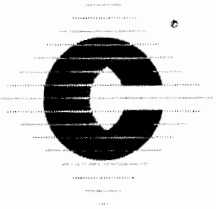
GENERAL

please see attachment

CMS-1321-P-801-Attach-1.DOC

#801

CYTYC



Via Electronic Submission

October 10, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator, Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attn: CMS-1506-P
7500 Security Boulevard
Baltimore, Maryland 21244

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:

Cytyc welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services' ("CMS") Medicare Physician Fee Schedule proposed rule for calendar year 2007. In particular, we wish to express our concerns regarding CMS's proposal in the areas of breast cancer. Specifically, we will address the proposed changes in RVUs and the significant impact they will have for breast conservation therapy and we will respectfully request that CMS consider a maximum decrease of no more than a 10% reduction and this maximum remain in effect during the required time for CMS and the RUC to re-evaluate the data applicable to RVUs associated with breast conservation therapy.

Cytyc Corporation, a medical device company, provides therapeutic and screening technologies for multiple areas of women's health. In the area of therapeutics, Cytyc manufactures the MammoSite® Radiation Therapy System (RTS) the most widely used method of breast brachytherapy to treat breast cancer and the NovaSure® System, the most widely used method of second generation endometrial ablation to treat abnormal uterine bleeding.

Abnormal Uterine Bleeding

Abnormal uterine bleeding is also known as menorrhagia, a common disorder defined as excessive blood loss during menstruation. Menorrhagia is a clinical condition, defined as a total blood loss exceeding eighty milliliters per cycle. Women suffering from menorrhagia commonly use more than twenty sanitary napkins or tampons in a single day and often times miss work and cannot participate in normal life activities such as caring for loved ones. The NovaSure® System is approved to reduce or eliminate excessive menstrual bleeding due to benign causes in women who have completed childbearing. The NovaSure® System uses precisely controlled amounts of impedance controlled radio frequency energy to remove the endometrial lining of the uterus. For women who have long suffered from menorrhagia, this next-generation option provides the possibility that their extreme symptoms will be relieved and their lifestyle improved, without a dramatic or extreme effect on their body. Second generation endometrial ablation technology provides alternatives to women who would typically undergo drug therapy, dilation & curettage (D&C), rollerball ablation, or hysterectomy. These second generation technologies provide a safe and less invasive alternative to treat this de-habilitating condition.

CPT 58563 – Endometrial Ablation

CMS has proposed reductions in the RVUs for 58563, the CPT codes assigned for hysteroscopy, surgical; with endometrial ablation. These reductions are scheduled to reduce by 30% as illustrated in the table below:

CPT Code	Description	2006 RVUs	2010 RVUs	Variance
58563	hysteroscopy, surgical; with endometrial ablation	63.25	44.6	-30%

Once it is determined a woman is suffering from menorrhagia and is eligible for second generation endometrial ablation, the surgeon and the patient currently have the choice to perform the surgery in the operating room or in the surgeon's office in the appropriate sterile setting. The proposed RVU reduction will result in this procedure no longer being available as an option for women who choose to have the surgery in the physician's office, since the cost of the procedure and the necessary equipment will exceed the proposed reimbursement impacted by the change in RVUs. The office is a preferred site of service for some women and this option should be available for them.

Breast Brachytherapy

Breast brachytherapy is targeted radiation therapy where the radiation source is placed inside the tumor cavity via a special balloon catheter, a.k.a. the MammoSite® RTS, and only delivers radiation to the area where cancer is most likely to recur. This technique limits radiation to healthy tissue, lungs and heart, thus reducing the likelihood of the possible side effects experienced during whole beam radiation. Unlike whole beam radiation where the woman requires 5-6 weeks of radiation *every day*, breast brachytherapy is *completed in 5 days*.

Cytyc Corporation manufactures the unique balloon catheter, a.k.a. the MammoSite® RTS, which is the delivery mechanism for the radiation source used in breast brachytherapy a type of breast conservation treatment. The catheter may be surgically placed in the tumor cavity following the lumpectomy by a breast surgeon. This surgical procedure may take place in the operating room or in the surgeon's office in the appropriate sterile setting. Once the catheter is in place, the patient is in the care of the radiation oncologist. The radiation oncologist provides treatment planning, numerous consults and the actual treatment for the patient. During treatment, a high dose radiation source (Iridium 192) is delivered from a machine to the catheter twice a day for five days.

Approximately 80% of women diagnosed with breast cancer are detected in the early stages of the disease, when there is a 97% rate of five-year survival. The National Cancer Institute (NCI) has stated that breast-conservation therapy (lumpectomy followed by radiation therapy) is preferable to mastectomy for most early-stage cancer patients, with comparable long-term recurrence and survival rates. It is the standard of care to remove the malignant tumor and to follow up with radiation therapy.

However, according to the SEER data, up to 19% of women who undergo breast conservation surgery do not proceed to radiation therapy as is the standard of care. These women who forgo radiation have a threefold increase in risk of recurrence of the tumor according to a study published in the J. of National Cancer Institute, 2004. We know that a majority of local recurrences after breast conserving therapy occur at or near the tumor bed.

RVUs for 19296 – Catheter Implant for Breast Brachytherapy

CMS has proposed reductions in the RVUs for 19296, the CPT codes assigned for placing the unique catheter required for breast conservation therapy. These reductions are scheduled to reduce by 31% as illustrated in the table below:

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

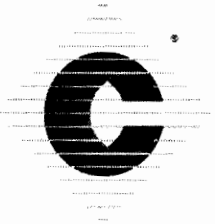
Once it is determined a woman is eligible for breast brachytherapy based on the strict patient selection criteria, the catheter that delivers this radiation must be surgically implanted. This procedure may take place in the operating room or, in some cases, in the physician's office as previously mentioned. Because of the time involved in planning and implanting the catheter, as well as the cost of the device, the proposed RVU reduction will result in this procedure no longer being available as an option for Medicare eligible women who choose to have the surgery in the physician's office, since the cost of the procedure will exceed the proposed reimbursement. The office is a preferred site of service for some Medicare eligible women and this option should be available for them.

RVUs for 99245, 77263, 77470, 76370, 77370, 77290, 77326, 77300, 77336, 77280, 77781 – Breast Brachytherapy Treatment Planning and Delivery

In order to provide breast conservation surgery and treatment, surgeons must partner with a radiation oncologist who has the necessary equipment and training to deliver breast brachytherapy. In some cases, these radiation oncologists are located in freestanding centers, not the hospitals and therefore, the only option a woman has to receive breast brachytherapy is in the freestanding radiation center.

The proposed reductions are quite dramatic for the RVUs associated with planning and delivering partial breast irradiation and are scheduled to reduce by almost 20% during the transition period. These reductions are illustrated in the table below:

CPT Code	Description	Units	2006 RVU	2010 RVU	Variance 2010 to 2006
99245	office consult, comprehensive	1	5.91	6.25	0%
77263	physician treatment planning, complex	1	4.41	4.16	**-10%**
77470	special treatment procedure	1	14.64	4.55	**-71%**
76370	CT for planning	1	4.29	5.48	21%
77370	special medical	1	3.68	2.51	**-35%**



	physics consult				
77290	simulation, complex (contour volumes)	1	9.02	15.22	60%
77326	Brachytherapy isodose plan	1	3.78	3.89	**-2%**
77300	dose calc	10	2.26	1.80	**-24%**
77336	weekly medical physics consult	1	3.15	1.08	**-67%**
77280	simulation, simple	5	4.62	5.27	8%
77781	Afterloading HDR brachy (1-4 source positions)	10	23.69	6.58	**-74%**
					-18

While some of the proposed RVUs actually increase, the bottom line indicates an overall decrease of almost 20%. These proposed reductions actually translate to a greater than 50% reduction in payment for breast brachytherapy without any anticipated reduced changes in the conversion factor, well below the costs required to purchase the necessary equipment, sources and the required time for the radiation oncologist.

The combined impact of the proposed changes for the surgical RVUs as well as the RVUs for the radiation oncologist is quite severe and will impact the ability to provide breast conservation treatment and therapy to Medicare eligible women who meet the strict patient selection criteria. Women already face access issues as it relates to breast care, and these proposed reductions will further aggravate the ability to access technologies that are available to women with private insurance and may result in compromised care for Medicare eligible women. These proposed reductions in combination with reductions being proposed in the OPPS rule will significantly limit access to breast brachytherapy and possibly will drive treatment towards a more invasive and time consuming therapies. We have submitted comments regarding the OPPS rule separately.

We do not believe it was the intent of CMS to reduce overall payment in the area of breast cancer screening, surgery and treatment. However, as a company dedicated to women's health we are quite concerned about the proposed reductions in RVUs associated with numerous areas of breast care. In addition to the proposed changes for breast brachytherapy, we understand that there are also significant decreases in the physician fee schedule in the area of breast cancer screening and other areas of breast surgery supporting the latest technology and less invasive technologies.

Understanding the requirement for CMS to remain budget neutral when publishing the Final Rule, Cytyc performed an exercise to see what would the impact be to the Physician Fee Schedule if there was a maximum of 10% reductions. The total impact on the budget is 0.5% when freezing any RVU reduction at no more than 10%. As a possible solution, the 0.5% impact on the budget could be subsidized via the conversion factor.

Recommendations

Cytyc respectfully requests that CMS consider and implement the following recommendation:

- For RVUs decreasing by more than 10%, we recommend that CMS implement a maximum decrease of no more than 10%. This temporary freeze should remain in effect during the required time for CMS and the RUC to re-evaluate the data applicable to breast brachytherapy.

Cytyc appreciates the opportunity to provide comments during this proposed rule period as well as the opportunity to meet with your office and discuss our concerns about brachytherapy. Should you have any questions or need additional information, please do not hesitate to contact me at 508-263-8958 or via email at margaret.eckenroad@ cytyc.com.

Sincerely,

Margaret Eckenroad

Margaret Eckenroad
Senior Director, Women's Health
and Professional Relations

cc: Carolyn Mullen, Deputy Director, Division of Practitioner Services
Edith Hambrick, M.D., J.D., CMS Medical Officer; Chair, Advisory Panel on APC Groups
Robert Lee, MD, President American Brachytherapy Society
Douglas W. Laube, MD, President, American College of Obstetrics and Gynecology
Helen Pass, MD, President, American Society of Breast Surgeons

Submitter : **Dr. Yudhish Markan** **Date: 10/10/2006**

Organization : **Tate Cancer Center**

Category : **Physician**

Issue Areas/Comments

Impact

Impact

Regarding the ASP issue I request maintaining a specific J code for Aranesp. Amgen Portfolio Contract allows me to obtain different Amgen products at additional discounts irrespective of the quantity. This contract seems to benefit the patients as well since Amgen products Aranesp and Neulasta both allow patients increased convenience of fewer visits to our office and fewer copays. This contract does not force me to use other Amgen products rather it gives me a chance to obtain additional discounts if I choose to buy other Amgen products. Proposed change to the ASP using theoretical discount allocations, instead of markat prices could push the reimbursement down than the actual available prices affecting our ability to deliver these expensive treatments in our office pushing these patients to the hospital at increased inconvenience to patients and increased cost to medicare. More options and buying bulk to reduce cost should be rewarded not punished like in any other industry in this country. Procrit has enjoyed its monopoly in the marketplace before the arrival of Aranesp and the patients have benefited greatly with additional choices and new oncology supportive care products introduced by Amgen.

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

Organization : **Indiana Association of Pathologists**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment - 2007 Physician Fee Schedule Comments IAP.

CMS-1321-P-803-Attach-1.PDF

#803

Indiana Association of Pathologists, Inc.
9959 Allisonville Road ♦ Fishers, IN 46038
(317) 813-3147 ♦ Fax (317) 578-7718

Comments of the Indiana Association of Pathologists, Inc.

on the Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007

[CMS–1321–P]

The Indiana Association of Pathologists, Inc., (IAP) 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). The IAP is a professional society of pathologists practicing in the state of Indiana. IAP members perform a variety of services that are reimbursed under the physician fee schedule. Thus, IAP members will be significantly affected by the changes in the Proposed Rule. IAP'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 IAP 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, the IAP 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, the IAP 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.

  IAP position: **supports** applying current purchased-service limitations in situations of reassignment

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

  IAP 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

- 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.

  IAP 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. The IAP 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. The IAP 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.

<u>Part-Time Employment of Pathologists</u>

The IAP 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, the IAP considers it to be essential that CMS address both structures in its rulemaking.

The IAP 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 IAP 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 IAP 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.

INDEPENDENT LAB BILLING

In the Proposed Rule, CMS states, "We continue to believe, however, that hospital prospective payment amounts already compensate hospitals for the TC of physician pathology tests and that additional payment under the PFS is inappropriate." *Id.* Therefore, CMS is proposing to amend § 415.130 to provide that, for services furnished after December 31, 2006, an independent laboratory may not bill the carrier for physician pathology services furnished to a hospital inpatient or outpatient.

The IAP believes that the proposed rule misstates the intention of the proposal to discontinue the Grandfather provision, where it states "For services furnished after December 31, 2006, an independent laboratory may not bill the carrier for physician pathology services furnished to a hospital inpatient or outpatient." We believe the intent was to state that "For services furnished after December 31, 2006, an independent laboratory may not bill the carrier for the technical component of physician pathology services furnished to a hospital inpatient or outpatient." We urge CMS to correct this language if this concept is to appear in the final rule.

Given this major change to these historical billing rules, we strongly urge CMS to help hospitals understand their new obligations and move forward to address them to ensure that Medicare beneficiaries have full access to necessary clinical laboratory testing services.

CONCLUSION

Thank you for the opportunity to submit these comments. We look forward to working with CMS to finalize and implement the proposed changes to the physician fee schedule. Please do not hesitate to contact us should you have any questions about this information or need any further information.

Respectfully submitted,

Pieter Wiersema, M.D.
President, Indiana Association of Pathologists, Inc.
October 10, 2006

Submitter : Mr. David Brown **Date:** 10/10/2006

Organization : GlaxoSmithKline

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-804-Attach-1.DOC

#804

GlaxoSmithKline
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Tel. 919 483 2100
www.gsk.com

October 10, 2006

BY ELECTRONIC DELIVERY

Mark 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 (Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B): ASP Issues

Dear Administrator McClellan:

GlaxoSmithKline ("GSK") appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' ("CMS") Proposed Rule regarding revisions to payment policies under the physician fee schedule for calendar year 2007 (the "Proposed Rule").[1] GSK is a world leading research-based pharmaceutical company with a mission to improve the quality of human life by enabling people to do more, feel better, and live longer.

As a result of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), the reimbursement for most Medicare Part B drugs not paid on a cost or prospective payment basis is based on average sales

1 71 Fed. Reg. 48,982 (Aug. 22, 2006).

price ("ASP"), a pricing point calculated by pharmaceutical manufacturers and reported to CMS. Given that payment rates to providers depend largely on the reported ASP, GSK believes it is essential that the methodology used to determine ASP accurately incorporate the costs to a provider or supplier (hereafter "provider") for our products. Moreover, the ASP calculation and reporting requirements should be clearly articulated because manufacturers are subject to significant penalties for the submission of incorrect ASP data, even when inadvertent. Accordingly, given that even a minor change in the way ASP is calculated can have significant ramifications, GSK urges CMS to issue any new policies in a formal rulemaking rather than through informal program guidance in order to allow all stakeholders to comment.

GSK is pleased that CMS has chosen to further clarify the rules surrounding the ASP calculation, and we agree with many of CMS' proposals. We support CMS' proposal to continue to use the Medicaid definition for purposes of determining nominal sales. We also support the proposed amendment to the ASP regulations to clarify that, where a product has been sold for less than 12 months, the period used to estimate lagged price concessions is the total number of months the national drug code ("NDC") has been sold. Moreover, we agree with the proposal to require manufacturers to combine price concession data for those NDCs that are changed based upon a non-drug feature where the lagged price concessions for the prior NDC remain in effect for the redesignated NDC.

We ask, however, that CMS revise the Proposed Rule to clarify that fees paid to non-purchasers, such as group purchasing organizations ("GPOs"), are not discounts. We also ask that CMS specify the basis of its proposed application of the bona fide service fee standard to pharmacy benefit managers ("PBMs"). In the event CMS decides to apply the bona fide service fee standard to non-purchasers, GSK asks that CMS exclude from the ASP calculation all fees paid that are consistent with the GPO safe harbor to the anti-kickback statute. With respect to the bona fide service fee standard, GSK asks that CMS eliminate the requirement that no portion of the fees paid be passed on to a client or customer of the entity. Moreover, we urge CMS to clarify that any industry accepted methodology for determining fair market value be permitted.

While GSK generally supports the Proposed Rule's specification of a rolling average for purposes of calculating lagged exempt sales, we believe CMS should clarify that sales to ASP-ineligible entities that are not possession-takers need not be removed from the calculation. GSK also appreciates that CMS has asked for comments regarding bundled sales, but asks that any changes be made through a formal rulemaking so that all stakeholders have an opportunity to comment meaningfully, before any such changes are effective. We also ask that

CMS specify that providing a discount on one product in order to obtain a favorable formulary status on another product does not constitute a bundled sale. Moreover, any arrangement that meets a safe harbor to the anti-kickback statute, and which provides separately identifiable prices for the products included in the arrangement, should not be considered a bundled sale and the discounts offered on such products need not be reallocated.

Although not specifically addressed in the Proposed Rule, if CMS ultimately determines that all ASP-ineligible entity utilization must be removed from the calculation, we also ask that CMS specify that a manufacturer need not exclude sales from qualified retiree prescription drug plans from the ASP calculation where it is unable to identify them. We also ask that CMS seek legislation to amend the ASP statute to exempt prompt payment discounts from inclusion in the ASP calculation as price concessions. Finally, we ask that CMS amend its own regulations to include an intent requirement for purposes of the ASP certification and civil monetary penalty provisions. We discuss each of these comments in more detail below.

I. CMS Should Revise Its Proposal to Clarify that Fees Paid to Non-Purchasers Are Not Discounts.

GSK opposes CMS' revision of its current guidance on the proper treatment of administrative and service fees in the ASP calculation. In the Proposed Rule, CMS states that fees paid by manufacturers to an entity, *whether or not that entity takes title to the product*, must be considered price concessions for purposes of the ASP calculation, unless those fees meet the bona fide service fee standard.[2] In the preamble discussion to the Proposed Rule, CMS specifically states that service fees to GPOs and PBMs can constitute price concessions.

GSK opposes CMS' proposal to expand the application of the bona fide service fee definition to fees paid to non-purchasers, such as GPOs, because the statutory definition of ASP does not support such an expansion. The ASP calculation is meant to approximate acquisition cost because it is utilized by Medicare to set provider payment rates. The ASP statute therefore defines ASP as the measure of "the manufacturer's sales to all purchasers . . ."[3] The inclusion of non-purchaser transactions in ASP will broaden the calculation beyond the statute's definition and artificially lower ASP based on "discounts" that are not available to

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2 Id. at 49,001.

3 Social Security Act (SSA) § 1847A(c)(1).

purchasers from the manufacturer. This, in turn, will lower provider reimbursement rates and harm beneficiary access to important drug therapies.

As CMS likely knows, GPOs are not themselves purchasers, but instead negotiate contracts with pharmaceutical manufacturers on behalf of their health care provider members. Given that GPOs are not purchasers, and ASP is a measure of average *purchaser* price, fees paid to GPOs should not be included in the ASP calculation. GSK recognizes that GPOs may choose to share with their members some portion of the fees paid by manufacturers.[4] This does not, however, make the GPO itself a purchaser or transform the fee paid into a discount.[5] In either situation, the manufacturer has no control over whether the fee is shared with the GPO's members, nor is the manufacturer typically aware of the GPO's arrangements with its members in this regard.[6] Accordingly, even in these situations, administrative fees paid to the GPO should not be counted as a discount.[7]

GSK also asks that CMS clarify its rationale behind its statement that the bona fide service fee standard is applicable not only to GPOs, but to PBMs as well.[8] If the basis for this statement is that the bona fide service fee standard is applicable to entities that do not take title to the product, then GSK again asks CMS to reconsider this proposal for the reasons stated above. If, on the other hand, the basis for this statement is that CMS considers PBMs to be purchasers, GSK requests that CMS clarify whether this position is applicable to fees paid to PBMs that are not associated with product purchased by the PBM.

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4 In an audit conducted by the Office of Inspector General ("OIG"), it noted that GPO practices differed regarding the passing on of administrative fees. See Review of Revenue from Vendors at Three Additional Group Purchasing Organizations and Their Members, OIG Report A-05-04-00073 (May 2005).

5 Importantly, member-owned GPOs can satisfy the GPO definition found in the safe harbor to the anti-kickback statute. See 42 C.F.R. § 1001.952(j). The safe harbor excludes from its definition of a GPO those entities that own their members, but it has no similar prohibition against members owning the GPO. Id.

6 Indeed, as discussed below in Section II.A, it is because manufacturers have no knowledge or control over an entity's arrangements with its own customers that CMS should revise the bona fide service fee standard to eliminate the requirement that the fee not be passed on.

7 Such a proposal also would be unworkable. Manufacturers do not know when/whether the GPO has passed on the fee, the amount of any fee passed on, or as to which product the fee was generated. Such data is required if manufacturers are to include such transactions in the ASP calculation.

8 71 Fed. Reg. at 49,001.

Finally, if CMS moves forward with its proposal to include administrative fees paid to entities that do not take title to product as discounts, except where those fees meet the bona fide service fee standard, GSK asks that those fees paid that are consistent with the GPO safe harbor to the anti-kickback law be excluded from the ASP calculation.[9] The safe harbors were developed by the OIG to encourage competition in the industry, thus lowering prices, while at the same reducing the potential for abuse.[10] The OIG already has recognized that payment arrangements consistent with the GPO safe harbor are acceptable and non-abusive. Accordingly, CMS should not include as a price concession administrative and service fees that are compliant (in the case of GPOs) or consistent (in the case of PBMs) with the GPO safe harbor.

II. Bona Fide Service Fee Standard

A. CMS Should Amend the Bona Fide Service Fee Standard to Eliminate the Requirement that the Fee Not Be Passed On to a Client or Customer of an Entity.

GSK asks that CMS reconsider its definition of a bona fide service fee to eliminate the requirement that the fee not be passed on, in whole or in part, to a client or customer of an entity.[11] This requirement is unworkable because manufacturers do not have knowledge of, nor control over, the fee recipient's relationship with its own customers. On the other hand, where a manufacturer pays a service fee to a distributor for bona fide services, and it does not direct the distributor to pass that fee on to its customers, the fact that the distributor ultimately decides to pass on some portion of the fee does not transform it into a price concession provided by the manufacturer. The manufacturer has no control over, and likely no knowledge of, the distributor's arrangements with its own customers. Accordingly, CMS should revise the definition of bona fide service fee to remove the requirement that no portion of the fee be passed on to the entity's clients or customers.

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9 See 42 C.F.R. § 1001.952(j). The OIG, in its Compliance Program Guidance for Pharmaceutical Manufacturers, has explained that manufacturers can protect payment arrangements made with PBMs by structuring them so that they are consistent with the GPO safe harbor. See OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731, 23,736 (May 5, 2003).

10 See 54 Fed. Reg. 3088 (Jan. 23, 1989).

11 See 71 Fed. Reg. at 49,001.

B. CMS Should Provide Additional Guidance on the Appropriate Fair Market Value Methodology.

GSK urges CMS to provide more detailed guidance on acceptable methods for demonstrating fair market value. The agency's current guidance is vague, failing to specify any appropriate methodology for determining fair market value. To the extent any guidance is given, it states that the fees must be paid "at the same rate had [the] services been performed by other entities."[12] This seems to assume that manufacturers are in a position to choose a non-purchaser to perform these services when, in many instances, that is not the case. Certain services must be performed by a purchaser, such as data transfers that relate to end-user purchases, because some of that data is available only from a distributor that purchases our product. Accordingly, GSK requests that CMS specify that a manufacturer need not demonstrate fair market value by determining the cost of obtaining the service from a non-purchaser. GSK also asks that CMS clarify that any industry-accepted methodology for establishing fair market value be considered acceptable.

III. CMS Should Specify That Only Units Purchased By Possession-Taking ASP-Ineligible Entities Need Be Removed From the ASP Calculation.

While GSK generally supports the methodology proposed by CMS for estimating lagged exempt sales, we think it is important that CMS first make clear that manufacturers need not apply that methodology to ASP-ineligible entities that are not purchasers. ASP-ineligible entities include both possession-taking entities, such as the Veterans Administration and 340B entities, and non-possession taking entities, such as Part D plans and state pharmaceutical assistance plans.[13] The definition of ASP found in the statute describes ASP as the measure of the average price to ASP-eligible purchasing entities. With this as the definition, it should follow that the only transactions that are to be removed from the ASP calculation are those involving ASP-ineligible entities that are purchasers.

The inclusion in the lagged estimation methodology of ASP-ineligible entities that are not possession-takers will have the result of removing units that

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12 Question and Answer (Q&A) #4136, located at http://questions.cms.hhs.gov.

13 SSA §§ 1847A(c)(1), 1927(c)(1)(C).

initially were sold by the manufacturer (directly or indirectly) to an ASP-eligible entity that is a possession taker. For example, a manufacturer may sell units of its products to a long term care facility, which is an ASP-eligible entity. That entity may then dispense or administer those units to a Medicare beneficiary and be reimbursed by a Part D plan. The removal of the Part D utilization from the ASP calculation (through their inclusion in the lagged ineligible sales estimation methodology) will have the distorting result of removing units that were purchased by the long term care facility, an ASP-eligible entity. Accordingly, GSK urges CMS to specify in the final rule that the estimation methodology for lagged ineligible sales is not to be applied to transactions involving ASP-ineligible entities that do not purchase and take possession of product.

GSK endorses CMS's proposed methodology for estimating lagged exempt sales. In particular, in the event CMS determines that the lagged estimation methodology should be applied to ASP-ineligible entities that are not purchasers, GSK believes that the proposed units-based estimation methodology is the best approach. A sales-based approach would require the manufacturer to value the units attributable to non-purchaser entities, which would prove difficult because the manufacturer would have no purchase transactions to use as a basis for that valuation. This difficulty does not arise with an estimation methodology that is units-based.[14]

Should CMS determine that the estimation methodology applies to ASP-ineligible purchasers only, and not to entities that do not take possession of product, GSK believes that either a sales-based or units-based estimation methodology would be appropriate. Sales valuation does not present a hurdle in relation to ASP-ineligible purchasers because the manufacturer will have a sales transaction on which to base the valuation, i.e. the direct sale price in the case of a direct sale or the Wholesale Acquisition Cost referenced on the chargeback in the case of an indirect, chargeback-based sale.

IV. Any Additional Guidance Issued by CMS On Bundled Sales Should Be in the Form of a Proposed Rule.

GSK appreciates that CMS is attempting to better understand bundled sales by seeking comments from the industry on these type of sales arrangements. Because of the complexity involved in both defining a bundled sale, as well as re-allocating discounts between products, we ask that the agency issue a proposed rule

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14 If CMS were to permit a sales-based ratio in these circumstances, GSK suggests that the units attributed to ineligible non-purchasers be valued at the weighted average Wholesale Acquisition Cost for the 12 month period employed in the methodology.

prior to acting in order to allow all stakeholders to comment meaningfully. In general, however, GSK asks that any definition of a bundled sale have a basis in the statutory language of the MMA, and that specific guidance be provided on the proper reallocation methodology to be utilized if CMS decides to propose a change in this area.

More specifically, GSK asks that CMS specify in its proposed rule that formulary requirements do not constitute a bundle (in fact, formulary status does not even require a purchase of the product). Therefore, GSK recommends that any proposed rule that CMS issues specifically state that formulary requirements do not constitute a bundle that triggers an obligation to re-allocate discounts among the products involved.

GSK recommends that CMS define a bundled sale for purposes of the ASP calculation as the sale of at least two products where the products involved do not have a separately identified price or discount. For example, where a manufacturer sells Products A and B for $10, and does not separately identify the price for each product, this would constitute a bundle. However, where a manufacturer provides a discount percentage on multiple products and that percentage increases with the number of distinct manufacturer products purchased by the buyer, but each product has its own separately identified price or discount amount, the bundled sale definition would not apply. If one were to consider the latter situation a bundled sale and require reallocation, the discount from some products would need to be apportioned to others, which would serve to increase the ASPs of some products and decrease the ASPs of others, distorting the ASPs of all products involved. This distortion will lead to providers being under-reimbursed for certain products, particularly those providers who are not in a position to purchase all products included in the discounting arrangement. Accordingly, these types of arrangements should be excluded from the definition of a bundled sale for purposes of the ASP calculation.

In addition to the above, with respect to reapportionment, we ask that the proposed rule specify that any discounts that meet a safe harbor to the anti-kickback statute be exempt from any reapportionment requirement. The OIG has determined that arrangements that fully satisfy any one of the safe harbors are non-abusive and do not injure the Government. For example, in order for a contingent discount to meet the discount safe harbor, "the goods and services [must be] reimbursed by the same Federal health care program using the same methodology . . ."[15] The OIG has determined that discounts given in this situation

15 42 C.F.R. § 1001.952(h)(5)(ii).

are not abusive because the Government is given the full benefit of the discount. Accordingly, where a discount provided meets a safe harbor, no reapportionment of the discount should be required. Further, recognizing that the safe harbors are narrowly drafted and that a discount is not necessarily impermissible simply because it does not meet the strict parameters of a safe harbor, GSK recommends that any proposed rule that CMS issues state that where a discount may be outside of the parameters of a safe harbor, reallocation is not automatically required and manufacturers are permitted to use reasonable assumptions as to whether and how to reallocate any such discounts.

V. CMS Should Clarify that a Manufacturer Need Not Remove Qualified Retiree Prescription Drug Plan Utilization From the ASP Calculation Where It Is Unable to Identify It.

If CMS determines that the ineligible sales estimation methodology does need to be applied to ASP-ineligible entities that are not purchasers, GSK believes that special consideration should be afforded to qualified retiree prescription drug plans because of the difficulty in identifying these sales. The ASP statute provides that manufacturers are required to exclude from the ASP calculation all best price exempt sales and units.[16] Included in the best price exemptions are "any prices charged which are negotiated by a qualified retiree prescription drug plan (as defined in section 1860D-22(a)(2)) with respect to such drugs on behalf of individuals entitled to benefits under part A or enrolled under part B of such title."[17] Identifying sales to qualified retiree plans is, however, not always possible.

Manufacturers, including GSK, identify most ASP-ineligible sales through rebate and chargeback data. For instance, when a state pharmaceutical assistance program reimburses a provider for a drug, it subsequently requests a rebate from the manufacturer. This rebate claim allows the manufacturer to identify the ineligible transaction and remove it from the ASP calculation. Such separate quantification of utilization often is not available for qualified retiree plans. GSK contracts for rebates on qualified retiree plan utilization through its commercial PBM agreements. The rebate claims submitted by the PBM currently do not separately quantify the utilization for the qualified retiree plans, and, accordingly, manufacturers are usually unable to identify this utilization in order to remove it from the ASP calculation. GSK asks that CMS clarify that the failure to

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16 See SSA § 1847A(c)(2).

17 SSA § 1927(c)(1)(C).

exclude these sales from the ASP calculation because of an inability to identify them will not render the submitted ASP inaccurate for purposes of the certification or civil monetary penalties.

Importantly, the qualified retiree plan exemption can be interpreted to apply only to qualified retiree utilization, and not to utilization of dependents also covered by the qualified retiree plan.[18] Even in situations where GSK is able to identify qualified retiree plan utilization, that identification likely will not extend to distinguishing between retiree and dependent utilization. GSK urges CMS to specify that, in situations where the manufacturer is able to identify qualified retiree plan utilization, it need not separate out the dependent data and may instead exclude all such utilization from the ASP calculation.

VI. CMS Should Urge Congress To Amend the ASP Statute to Exclude Prompt Payment Discounts from the ASP Calculation.

The ASP statute currently requires manufacturers to include prompt payment discounts as price concessions in the ASP calculation.[19] As discussed, ASP is utilized to set payment rates and it is therefore meant to approximate provider acquisition costs.[20] Importantly, however, the prompt payment discount given by manufacturers is typically available only to direct purchasers, which usually does not include providers. To include prompt payment discounts as price concessions in the ASP calculation serves to artificially lower ASP rather than approximate provider acquisition costs.

Congress itself recognized this distinction in the Deficit Reduction Act ("DRA"). The DRA amended the Medicaid statute to utilize average manufacturer price ("AMP") to set payment rates,[21] and, as a result, it also amended the statute so

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18 As mentioned above, the best price exemption includes prices charged which are negotiated by a qualified retiree prescription drug plan "with respect to such drugs on behalf of individuals entitled to benefits under part A or enrolled under part B." Id. It is possible that certain dependents covered under the plan will not be entitled to benefits under part A or enrolled under part B, and, therefore, the statute could be interpreted not to exclude prices charged for the utilization of dependents covered under the qualified retiree plan.

19 See id. § 1847A(c)(3).

20 The ASP statute explains that ASP is calculated utilizing "a manufacturer's sales to all purchasers . . ." Id. § 1847A(c)(1)(A).

21 See DRA, § 6001(a)(2), Pub. L. No. 109-171 (2005) (utilizing AMP in federal upper payment limits).

GSK appreciates the opportunity to comment on these issues, and we look forward to working with CMS to ensure that the ASP reporting system is fair and accurate, and that it protects Medicare beneficiaries' access to critical drug therapies. Please feel free to contact me at (919) 483-2353 if you have any questions regarding these comments. Thank you for your attention to this very important matter.

Respectfully submitted,

David Brown

David B. Brown
Director, Government Contracts and
Pricing Programs

Submitter : Mr. Holger Schmidt **Date:** 10/10/2006

Organization : Siemens Medical Solutions-Oncology Care Systems

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1321-P-805-Attach-1.PDF

SIEMENS

October 2, 2006

Honorable Mark B. McClellan, M.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8010
Baltimore, MD 21244-8018

RE: Proton Therapy Payment Rates

Dear Dr. McClellan:

We are writing to you on a matter of great importance to the proton therapy community. More than 40,000 cancer patients have been treated with proton therapy in many institutions in the United States and across the world. Proton beam therapy, due to its recognized and desired biological effect on malignant tissue, has the clinical advantage of being significantly more precise in delivery. Positive clinical results at these facilities have stimulated worldwide interest in the clinical applications of proton therapy and consequently two additional facilities opened in the United States this calendar year.

STATEMENT OF SUPPORT FOR THE PROPOSED CALENDAR 2007 HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT RATES FOR PROTON THERAPY.

We fully support the Proposed Calendar Year 2007 (CY'07) Hospital Outpatient Prospective Payment System (OPPS) Payment Rates for proton beam therapy, which is as follows:

APC	CPT	CY'07 Proposed Payment Rate	CY'06 Payment Rate
0664	77520 and 77522	$1,136.83	$947.93
0667	77523 and 77525	$1,360.10	$1,134.08

These payment rates will ensure that further development of proton therapy continues as the clinical demand for this technology rises around the country.

As you know, the National Payment rates for proton therapy are determined based upon submitted claims and cost data received by CMS from centers delivering proton therapy in the United States. Rate setting is a challenging and difficult task. We appreciate the diligence with which you have set the CY'07 proposed payment rates for proton therapy.

STATEMENTS OF CONCERN REGARDING FREESTANDING FACILITIES

For freestanding proton therapy centers the CMS has given its contracted Carriers significant latitude but limited guidance from which to determine payment rates for proton therapy.

We remain concerned with the manner in which contracted Carriers of the Centers have managed freestanding Proton Therapy Centers for Medicare and Medicaid Services in the State of Texas, Florida and Indiana. The existing or proposed proton therapy payment rates by State are as follows:

Siemens Medical Solutions USA, Inc.

Oncology Care Systems Group
4040 Nelson Avenue
Concord, CA 94520
Tel: (925) 246-8200
Fax: (925) 246-8284
www.siemensmedical.com/oncology

SIEMENS

Comparison of Freestanding Centers' Proton Therapy Rates by State			
	Indiana – Current	Florida – Proposed 9/11/06	Texas – 9/1/06
77520	—	$750.63	$652.75
77522	$496.83	$776.90	$653.90
77523	$811.33	$806.93	$783.79
77525	$856.12	$900.76	$954.41

As each State has its own CMS contracted Carrier, variations in existing CY'06 and proposed CY'07 proton therapy coverage and payment rates are occurring and are significant by comparison to CMS's National Payment Policy for protons as expressed in the OPPS rules.

Curtailing the development of proton beam therapy centers now through inadequate payment may have the negative long-term effect of precluding future cost reductions provided by proton beam therapy and not having this important therapy available to patients.

We are requesting that CMS direct its Carrier's on issues of payment proton therapy for Free-Standing centers so that their decisions are consistent with that of the CMS for HOPD.

It should be noted that due to the capital cost of proton therapy, both freestanding and HOPD centers have similar costs for patient treatments. The cost of treatment per fraction is consistent, if not higher, in both hospital based and freestanding facilities than the current 2006 APC payment rate. Given the great similarity of capital investment and operating costs of proton beam therapy centers, whether hospital-based or freestanding, this is an appropriate recommendation for CMS given the number of operating centers and patient demand for this valuable therapy.

In addition, we agree with the CMS that it is not appropriate for freestanding facilities to pursue a relative value unit (RVU) from the RUC for proton beam therapy. Due to the limited availability of this technology in the freestanding setting and the established coverage and payment policy established by CMS for hospital outpatient departments, we feel it is more appropriate to leverage the considerable work performed by CMS to establish payment for these setting across both hospital outpatient and freestanding facilities. The risk of not doing so may in effect limited the access of this technology to cancer patients around the country.

CONCLUSIONS

In conclusion, proton beam therapy has a recognized and desirable radiobiological effect on malignant tissue with the clinical advantage of being significantly more precise in the delivery, resulting in better health outcomes and fewer or less significant adverse side effects than other forms of radiation therapy.

We strongly agree with CMS's proposed CY'07 payment rule for proton beam therapy for Hospital Outpatient Departments.

We strongly urge CMS to direct its Carriers on matters concerning proton therapy payment so that CMS contracted Carriers determinations regarding proton therapy payment rates are in keeping with National Payment policy decisions, currently in effect for Hospital Outpatient Departments.

CMS thoroughly analyzes proton beam therapy claims and cost data in establishing payment rates for Hospital Outpatient Departments. CMS contracted Carriers should take advantage of vast work already performed on the part of the CMS when determining payment rates.

Holger Schmidt
President & CEO
Siemens Medical Solutions – Oncology Care Systems

Submitter : Robert Knorr **Date:** 10/10/2006

Organization : Tapestry Medical

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

We are attaching a Word version of the pdf file that was attached to our previous comment #92511.

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

Organization : **Immune Deficiency Foundation**

Category : **Consumer Group**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-807-Attach-1.DOC

#807

IMMUNE DEFICIENCY FOUNDATION

October 9, 2006

Mark McClellan, M.D., Ph. D
Administrator
Centers for Medicare and Medicaid Services
200 Independence Ave., SW
Washington, D.C. 20201

Re: CMS-1321; Comments on Revisions to Payment Policies under the Physician Fee Schedule for CY 2007 and Other Changes to Payment under Part B

Dear Dr. McClellan:

The Immune Deficiency Foundation (IDF), founded in 1980, is the national patient organization dedicated to improving the diagnosis and treatment of patients with primary immune deficiency diseases through research, education, and advocacy. Thousands of individuals and their families who live with primary immune deficiency diseases count on IDF for (1) education programs and materials that focus on the recognition and diagnosis of primary immune deficiency diseases, important life management, patient care resources, and support for patients and family members, (2) research and medical education programs that improve diagnosis and treatment of primary immune deficiency diseases, and (3) advocacy to promote policies that positively affect the primary immune deficiency community.

We are providing our comments on the August 22, 2006, Federal Register proposed rule regarding elimination of the preadministration-related services payment for IVIG in physicians' offices. Our comments below supplement others submitted by a group of IVIG stakeholders of which IDF is a part for purposes of responding to the August 22 proposed rule.

Comments on Proposed Elimination of the Preadministration-Related Services Payment for IVIG Infusion in Physicians' Offices

Addendum B of the August 22, 2006 proposed rule on changes in Medicare's payments for physician and other Part B services appears to eliminate for 2007 the preadministration-related services payment for IVIG. IDF is concerned that this change will further compromise access of patients with primary immune deficiency disease (PI) to infusion of this life-saving product in a doctor's office. Access to IVIG is critical to patients with PI. At least 7 of every 10 PI patients have diagnoses for which IVIG is the only effective treatment. About 20% of these patients are on Medicare. This translates into at least 10,000 persons, nationwide, who are being treated with

IVIG under Medicare. Since January 2005 when Medicare reimbursement for IVIG changed for physicians providing IVIG infusion in their offices, IDF has received thousands of phone calls and emails from patients and physicians who have had serious issues of access to IVIG.

In order to provide hard data on the impact of Medicare reimbursement's changes on treatment with IVIG in the PI community, IDF has undertaken three national surveys in partnership with the American Academy of Asthma, Allergy, and Immunology (AAAAI): a survey of patients with PI, a survey of physicians treating patients with PI, and a survey of hospital pharmacists dispensing IVIG. Only the patient survey is sufficiently advanced at this time to present preliminary findings of the impact of the 2005 change in reimbursement on Medicare patients with PI.

Findings from our patient survey show that access to IVIG has been affected by the changes in reimbursement and these findings point to a possible exacerbation of access problems for PI patients receiving IVIG in physicians' offices as a result of the proposed elimination of the preadministration-related services add-on. When taken together with other proposed reductions in Medicare payment for IVIG infusion in hospital outpatient settings, as enumerated in an August 23 proposed rule, PI patient access to IVIG will be seriously jeopardized in 2007.

Methodology of Patient Survey. IDF drew the sample for the national patient survey from the Foundation's database of PI patients. Although it is impossible to draw a strictly random sample of this very low-incidence population, no other organization maintains a list of PI patients as large as IDF's, so that the data should be as accurate as can be practically obtained. The survey was mailed to a random sample of 3,000 households from IDF's list, which we believe represents a cross-section of patients nationwide, as well as a supplemental sample of 135 households whom we believe to include PI patients on Medicare. IDF included the supplemental sample of Medicare patients in order to have a sufficient number of responses from Medicare patients to be able to analyze that key segment separately, in order to evaluate what impact the change in reimbursement policy has had on that group.

To date, IDF has received nearly 800 completed questionnaires from the first mailing of the survey. After deducting bad addresses and deceased responses, we have a response rate of approximately 25% to the first mailing. A second mailing has just been done. IDF's objective is to have a completed sample of approximately 1,000 patients with PI. Our preliminary findings presented in these comments on the August 22 Federal Register proposed rule are from the first 763 completed surveys from adult patients or parents of children with PI. This includes a national sample of 268 Medicare patients with PI.

Findings. Approximately 70% of respondents are currently being treated with IVIG. Specifically, 532 patients of the 763 total respondents are currently being treated with IVIG, 206 of which are Medicare patients. Another 41 stopped being treated since the beginning of 2005. Of these who stopped receiving treatment, 11 cited inadequate insurance coverage or higher expenses and 3 mentioned difficulty in obtaining IVIG.

One of the impacts of Medicare reimbursement has been to force patients from their usual site of service for infusions to other sites of service where payment rates were higher and/or Medicare

patients were still accepted. More than a third of Medicare patients (34%) reported that they are now being treated at a different site since December 2004, compared to about one-fifth (21%) of non-Medicare patients. Moreover, when asked the reason for the change in site of infusion, 38% of Medicare patients said that the change was due to insurance reimbursement reductions/inadequate insurance, as compared to 9% of non-Medicare patients. More than a quarter of Medicare patients (27%) who had changed site of infusion said it was because IVIG was no longer available at the previous site, compared to 6% of non-Medicare patients.

Among Medicare patients who are currently infusing IVIG, the proportion infusing in physician private offices has dropped from 21.1% prior to 2005 to 9.1% today. The shift away from the doctor's office has moved many Medicare infusers to hospital outpatient or hospital infusion clinics. Prior to 2005, only 47.5% of Medicare patients reported usually getting their infusions in hospital outpatient or hospital infusion clinics, and currently, 55.6% of Medicare patients are receiving their infusions in hospital outpatient or infusion clinics. For non-Medicare patients, there was no corresponding shift away from the doctor's office. Proportions remained at 13.3% both before and after 2005. The proportions using hospital outpatient or infusion clinics actually declined for non-Medicare patients from 36% to 31.5%, with more non-Medicare patients shifting to home health care for their infusions. Since these dramatic shifts in site of infusion occur only for Medicare patients, Medicare reimbursement is the likely cause. The consequence is that Medicare patients are being shifted into hospitals where they are at greater risk for disease transmission, and this is transforming the patient mix in hospitals. IDF believes that it does not make sense to move a PI patient out of a physician's office to a hospital where an immune-compromised patient can be exposed to an opportunistic infection.

What are the consequences for Medicare as well as non-Medicare PI patients who experience access problems for IVIG? Our 2006 patient survey shows that Medicare (31%) and non-Medicare patients (29%) were about as likely to say that they had to switch to another brand of IVIG since the beginning of 2005. This is problematic because patients with immune problems require brand-specific IVIG, since each product is different. Patients treated with brands their bodies do not tolerate can suffer life-threatening anaphylactic reactions. In fact, in a 2005 survey, IDF documented that many Medicare PI patients moving to hospital outpatient sites suffered serious reactions to the brands of IVIG that were used by hospitals and that were different from the ones they had been using in their physicians' offices. Some were hospitalized and many had increased infections. Product choice is critical for PI patients.

In addition, Medicare (17%) and non-Medicare (18%) were about equally likely to say that they had to pay more for IVIG since the beginning of 2005. These two findings together suggest that a tight market has affected product availability, product choice, and product price over the past 2 years for IVIG users regardless of type of insurance coverage.

Furthermore, Medicare patients (25%) were twice as likely as non-Medicare patients (13%) to report that their treatments had to be postponed since the beginning of 2005. Medicare patients (13%) were also twice as likely as non-Medicare patients (6%) to report that the time intervals between infusions had been increased since the beginning of 2005. Finally, Medicare patients (8%) were seven times as likely as non-Medicare (1%) patients to report that their dosage had been reduced since 2005. These differences between Medicare and non-Medicare users of IVIG

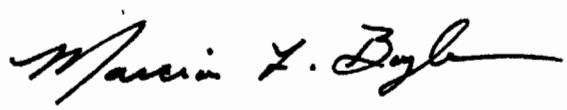
are statistically significant. Since the main difference between the two populations is their type of insurance coverage, the survey findings demonstrate a serious reimbursement impact on the treatment of Medicare patients needing IVIG.

IDF's patient survey also asked users of IVIG if they had experienced any negative health effects as a result of problems in getting or paying for IVIG since the beginning of 2005. Once, again, Medicare patients (27%) were nearly three times as likely as non-Medicare patients (10%) to report having negative health effects as a result of problems in getting or paying for IVIG. Those experiencing problems reported more infections, bronchitis, pneumonia, and increased use of antibiotics. For more than one in 9 (11%) of Medicare patients reporting negative health effects (about 3% of all Medicare patients using IVIG), the health consequences were severe enough to require hospitalization.

Conclusion. IDF's survey of PI patients suggests a substantial minority of patients is experiencing limited product choice and increased product cost regardless of insurance status. However, serious problems of dislocations that have come with many PI patients having to leave the physician's office for infusion, as well as postponed infusions, increased intervals between infusions and reduced dosage have fallen disproportionately on Medicare patients. The significant difference in these treatment experiences and changes in site of care, by Medicare status, along with higher rates of negative health outcomes, is clearly a reimbursement problem that began in January, 2005, with the change to ASP+6 methodology. IDF is concerned that these problems are likely to continue, without a change in reimbursement for care in physicians' offices, and will likely be magnified with the elimination of the preadministration-related services payment for IVIG in the physician office, as proposed in the August 22 rule, creating even more dislocations for PI patients requiring IVIG.

Thank you for your consideration of these issues of tremendous importance to the access of primary immune deficient patients to their life-saving therapy of IVIG. We look forward to sharing the final findings of the IDF patient survey with you shortly.

Sincerely yours,



Marcia Boyle
President

Submitter : Dr. Leonard Wartofsky **Date:** 10/10/2006

Organization : The Endocrine Society

Category : Physician

Issue Areas/Comments

Background

Background

On behalf of The Endocrine Society, representing more than 13,000 physicians and scientists in the field of endocrinology, we appreciate the opportunity to provide comments on the Centers for Medicare & Medicaid Services' (CMS) proposed revisions to the Medicare payment policies under the Physician Payment Schedule for calendar year 2007.

GENERAL

GENERAL

See attachment

Impact

Impact

The Society is sensitive to the statutory limitations imposed on CMS with regard to the DRA imaging cuts. However, we believe CMS has the authority to exempt the following HCPCS/CPT imaging code from inclusion in the proposed list of codes to be reduced to the OPPS payment rate, as identified in Addendum F of the Proposed Rule:

" 76075 DXA bone density, axial

Dual energy X-ray absorptiometry (DXA, or DEXA) is now widely accepted as the single most accurate screening method for identifying patients with low bone mineral density. DXA is crucial for the detection of osteoporosis and identification of those at highest fracture risk before a fracture occurs. It has become the clinical standard for osteoporosis screening due to its accuracy. While other osteoporosis screening procedures are scheduled to be cut by the proposed rule, no other single procedure is as important as 76075, or will see as dramatic a cut, about 41 percent. The DRA cuts do not even factor in the cuts to screening procedures proposed in the 2007 Medicare Physician Fee Schedule.

Provisions of the Proposed Rule

Provisions of the Proposed Rule

Physician Fee Schedule Across-the-Board Cuts The Endocrine Society again states its opposition to the proposed 5.1 percent across-the-board cut to the fee schedule due to the flawed Medicare sustainable growth rate (SGR) physician payment formula. As you are no doubt aware, the SGR does not accurately reflect the cost of caring for Medicare patients and must be replaced. We urge CMS to take administrative action to increase funding for physicians services and facilitate enactment of legislation to replace the SGR with payment updates based on physicians practice cost increases. Further, we ask that CMS continue to work diligently with Congress and physician groups to avert the proposed 5.1 percent payment cut for 2007, and to find a long-term solution to the flawed payment formula. DRA Proposals The Society remains very concerned about the congressionally mandated cuts to imaging services as directed by the Deficit Reduction Act (DRA). By capping payment for the technical component of these imaging procedures, as directed by the DRA, to the Outpatient Prospective Payment System (OPPS) payment amount you will be reducing patient access to these important diagnostic procedures.

CMS-1321-P-808-Attach-1.PDF

#808

THE ENDOCRINE SOCIETY

8401 CONNECTICUT AVENUE, SUITE 900 ■ CHEVY CHASE, MARYLAND ■ 20815-5817 ■ TELEPHONE 301.941.0200 ■ FAX 301.941.0259 ■ www.endo-society.org

October 10, 2006

The Honorable Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard, C4-26-05
Baltimore, MD 21244-8014

RE: CMS-1321-P Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B; Proposed Notice August 22, 2006 Federal Register

Dear Administrator McClellan:

On behalf of The Endocrine Society, representing more than 13,000 physicians and scientists in the field of endocrinology, we appreciate the opportunity to provide comments on the Centers for Medicare & Medicaid Services' (CMS) proposed revisions to the Medicare payment policies under the Physician Payment Schedule for calendar year 2007.

Physician Fee Schedule Across-the-Board Cuts

The Endocrine Society again states its opposition to the proposed 5.1 percent across-the-board cut to the fee schedule due to the flawed Medicare sustainable growth rate (SGR) physician payment formula. As you are no doubt aware, the SGR does not accurately reflect the cost of caring for Medicare patients and must be replaced. We urge CMS to take administrative action to increase funding for physicians' services and facilitate enactment of legislation to replace the SGR with payment updates based on physicians' practice cost increases. Further, we ask that CMS continue to work diligently with Congress and physician groups to avert the proposed 5.1 percent payment cut for 2007, and to find a long-term solution to the flawed payment formula.

DRA Proposals

The Society remains very concerned about the congressionally mandated cuts to imaging services as directed by the Deficit Reduction Act (DRA). By capping payment for the technical component of these imaging procedures, as directed by the DRA, to the Outpatient Prospective Payment System (OPPS) payment amount you will be reducing patient access to these important diagnostic procedures.

Osteoporosis is a major health care issue in the United States costing more than $18 billion annually. Recent federal initiatives to identify patients with osteoporosis have led to the increased utilization of osteoporosis screening procedures (bone mass measurement tests); however, the vast majority of affected individuals continue to remain undiagnosed and untreated.

An estimated 10 million Americans over age 50 have osteoporosis, while another 34 million are at risk. Each year an estimated 1.5 million people suffer an osteoporotic-related fracture.

The Society is sensitive to the statutory limitations imposed on CMS with regard to the DRA imaging cuts. However, we believe CMS has the authority to exempt the following HCPCS/CPT imaging code from inclusion in the proposed list of codes to be reduced to the OPPS payment rate, as identified in Addendum F of the Proposed Rule:

- 76075 – DXA bone density, axial

Dual energy X-ray absorptiometry (DXA, or DEXA) is now widely accepted as the single most accurate screening method for identifying patients with low bone mineral density. DXA is crucial for the detection of osteoporosis and identification of those at highest fracture risk before a fracture occurs. It has become the clinical standard for osteoporosis screening due to its accuracy. While other osteoporosis screening procedures are scheduled to be cut by the proposed rule, no other single procedure is as important as 76075, or will see as dramatic a cut, about 41 percent. The DRA cuts do not even factor in the cuts to screening procedures proposed in the 2007 Medicare Physician Fee Schedule.

We recognize the dramatic growth in usage for DXA scans but find its usage trends reasonable considering its reliability and relatively low cost when compared to other bone mass measurement screening tests. Couple an aging population with increased usage of these more accurate osteoporosis screening methods, and growth seems inevitable.

The reduced access to in-office DXA scanning resulting from these cuts would also directly conflict with federal initiatives such as the 2004 Surgeon General's Report on Bone Health and Osteoporosis, which supports increasing bone density screening for at-risk groups including patients with fractures, women aged 65 and older, patients on glucocorticoids, and other high risk groups. In viewing this recommendation, in conjunction with those from the National Osteoporosis Foundation and other clinical recommendations noted in the Surgeon General's Report, it is easy to identify the legitimate growth factors associated with DXA screening.

In reviewing the DRA it would seem that Congress' intent was not to compromise access to preventive medicine, as seen in its exemption of diagnostic and screening mammography procedures. Therefore, CMS should exempt vital screening procedures, such as DXA scans, from the DRA imaging cuts. We believe the cuts in the DRA would profoundly impact patient access to osteoporosis screening imaging procedures and ask that CMS intervene to prevent the unintended consequences that would result.

Bone Mass Measurements Tests

The Society would like to commend CMS for expanding the number of beneficiaries who qualify for bone mass measurement (BMM) tests by reducing the dosage requirements for steroid therapy in order to meet the eligibility requirements. This heightened awareness by CMS of the need for additional screening in the aging population provides additional credence to the argument that patient access to BMM tests should be increased--not decreased--as would be the consequence of the DRA imaging cuts to BMM tests.

In addition, the Society supports CMS' proposal to redefine the definition of "bone mass measurement" to remove coverage for the use of single-photon absorptiometry (SPA). As previously mentioned, we share CMS' assertion in the proposed rule that DXA is the superior clinical tool for bone mass measurement. SPA does not directly measure **vertebral** or **femoral** bone density. Instead, bone density in the lower leg bones or heel is measured, and the results are applied to the rest of the skeleton using assumptions. DXA can measure bone density in the lower leg bones, the spine, the femur, and over the entire body. DXA exposes the patient to less radiation, shorter scanning time, and is very precise. DXA measurement at the hip bone also provides the best predictor of hip fractures. There are relevant clinical data to support these assertions.[1,2,3] However, we are concerned that CMS proposes to drastically cut access to newer technologies (such as DXA), while simultaneously eliminating coverage for older diagnostic technologies. The Society would only support repealing coverage for SPA based on the assumption that coverage for newer screening procedures would not be reduced.

In conclusion, the Society appreciates the opportunity to submit these brief comments regarding the proposed revisions to payment policies under the Physician Fee Schedule for 2007. As always, the Society is grateful to CMS staff for all the hard work that went into drafting this proposed rule. Please do not hesitate to contact Janet Kreizman, Senior Director of Government & Public Affairs, at jkreizman@endo-society.org, if we may provide any additional information or assistance as CMS moves forward in developing this rule.

Sincerely,

Leonard Wartofsky, MD
President
The Endocrine Society

---

[1] Clinical Applications of Vertebral Fracture Assessment by Dual-energy X-ray Absorptiometry. E. Michael Lewiecki and Andrew J. Laster. *Journal of Clinical Endocrinology & Metabolism*. Aug 2006; 10.1210/jc.2006-1178.

[2] Dual-energy X-ray absorptiometry versus single photon absorptiometry of the radius. R.S. Weinstein, K.D. New, L.J. Sappington. *Calcified Tissue International*. Nov 1991; 49(5):313-6.

[3] An evaluation of forearm bone mineral measurement with dual-energy X-ray absorptiometry. G. Larcos and H.W. Wahner. *Journal of Nuclear Medicine*. 1991; 32: 2101-2106.

Submitter : **Dr. Terry Zellmer** **Date: 10/10/2006**

Organization : **Dr. Terry Zellmer**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1321-P-809-Attach-1.DOC

#809

BATON ROUGE CARDIOLOGY CENTER

Boyd E. Helm, M.D., F.A.C.C., F.S.C.A
Joseph M. Cefalu, M.D., F.A.C.
Kevin L. Kilpatrick, M.D., F.A.C.
Terry L. Zellmer, M.D., F.A.C.
Daniel T. Fontenot, M.D., F.A.C.
Harold G. Clausen, Jr., M.D., F.A.C.C., F.S.C.A
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Venkat R. Surakanti, M.D., F.A.C.
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Coronary Atherectomy & Stents

Cardiac Rehabilitation

Pacemaker Implantation & Follow-up

Lipid Management

Syncope Evaluation

Electrophysiologic Studies

Radiofrequency Catheter Ablation

Defibrillation Implantation & Follow-up

October 9, 2006

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

Dear Dr. McClellan:

On behalf of Baton Rouge Cardiology Center and our 11 individual practicing cardiologists, we appreciate the opportunity to submit these comments to the Centers for Medicare & Medicaid Services ("CMS") regarding the above proposed Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B; Proposed Rule ("Proposed Rule"). We are concerned about several provisions that will impact Medicare beneficiaries' access to services in outpatient cardiac centers, particularly those related to cardiac catheterizations. Specifically, we are concerned about the payment method proposed for cardiac catheterization related procedures. The Cardiovascular Outpatient Center Alliance ("COCA"), of which we are a member, will address the CMS proposal to require standards for Independent Diagnostic Testing Facilities ("IDTFs"). Our concerns related to the payment method are outlined below.

Payment Method

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

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

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

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

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

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

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

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

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

Sincerely,

Terry Zellmer, M.D., F.A.C.C.

Submitter : **Dr. Michael Repka** **Date: 10/10/2006**

Organization : **American Academy of Ophthalmology**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1321-P-810-Attach-1.PDF

#810

AMERICAN ACADEMY OF OPHTHALMOLOGY
The Eye M.D. Association

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1101 Vermont Avenue NW
Washington, DC 20005-3570

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Federal Affairs Department

October 10, 2006

via Electronic Mail
Mark McClellan, M.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-P
P.O. Box 8017
Baltimore, MD 21244-8017

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

Dear Dr. McClellan:

On behalf of the American Academy of Ophthalmology (Academy) I am writing to comment on the proposed Medicare Program Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007. The Academy is the world's largest organization of eye physicians and surgeons, with more than 27,500 members. Over 16,000 of our members are in active practice in the United States. We appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule.

First and foremost, the Sustainable Growth Rate (SGR) utilized in the physician fee schedule is fundamentally flawed as is reflected by the revised 2007 update which results in a reduction of 5.1%. This comes at a time when ophthalmologists and all physicians are facing increasing costs to maintain their quality of care provided in their practices. **Under the current SGR formula, physicians will receive negative updates between 5 and 7 percent each year from 2007 until 2013 and rates will not return to their 2002 level until well after 2013.** Thus physicians will receive less reimbursement in 2013 than they did in 2002 for the same procedure, regardless of inflation and increases in practice costs. We realize that statutory changes are needed for a comprehensive fix to the SGR problem but CMS can take steps now to improve the environment for needed reform including removing Medicare-covered outpatient drugs and other incident-to services from the expenditure target. The Congressional Budget Office has predicted that spending for outpatient drugs and other incident-to services will grow faster, on a per-beneficiary basis, than allowed by the expenditure target. This highlights the urgency of CMS administrative action.

Each year outpatient drugs and incident-to services will consume a greater portion of the expenditure target, rising from $12 billion (20 percent of the $62 billion expenditure target) in 2004 to $28 billion ($23 billion of the $121 billion expenditure target) in 2014. The agency has acknowledged that it has the authority to take drugs out prospectively. While removing drugs from the pool of physician services will not have an immediate substantial impact on predicted cuts, it will shorten the number of years of negative updates, stabilizing the system in the long run.

AAO Proposed Fee Schedule Comments

In general, changes proposed for 2007 continue to raise the utmost concern for our specialty because of the detrimental impact on the effective practice of ophthalmology with the impending changes to the practice expense (PE) methodology and continuing problems with the SGR. Additionally, the actions taken by the agency regarding applications of budget neutrality adjustments are raising significant concerns throughout the practice of medicine about the viability of our current payment system. The Academy urges CMS to consider and subsequently adopt the recommendations included in this comment letter on these and other areas.

- **Provisions: Specific Items from the NPRM 2007 on the physician fee schedule**

90-Day Global Procedures

The Academy has reviewed the 90-day global procedures for ophthalmology throughout the transition to a practice expense relative value system. Most recently at the April 2006 AMA Relative Value Update Committee (RUC) the Academy again submitted detailed information about the supplies and equipment involved with these and other ophthalmologic procedures because of inconsistencies and mistakes we found in the CMS database. These standard supplies and equipment packages were reviewed and accepted by the RUC. We urge CMS to incorporate those recommendations in order to ensure that all ophthalmologic codes have the correct practice expense inputs.

Supply and Equipment Items Needing Specialty Input

The Academy acknowledges the acceptance and pricing of the radiuscope used in the services to prescribe and fit contact lenses. We appreciate the updating of this equipment by CMS.

- **From the "Background" Section: Budget Neutrality from 5 Year Review**

The Academy reiterates its concerns about the inconsistency of applying the budget neutrality adjustment to the work relative value units (RVUs) for 2007 instead of to the conversion factor as has been done previously. The Omnibus Budget Reconciliation Act of 1989 requires that increases or decreases in relative value units (RVUS) for a year may not cause the amount of expenditures for the year to differ more than $20 million from the expected expenditures without the new RVU changes. For 2007, CMS is proposing to effect the statutorily mandated budget neutrality adjustment by developing a new work adjuster. **The AAO strongly objects to this approach and recommends that budget neutrality be applied to the final conversion factor and not solely to work relative value units.**

We have agreed with the previous CMS decision that applied budget neutrality to the conversion factor and believe this CMS proposed policy change is inconsistent and inequitable. CMS states in the June 29, 2006 Federal Register that they are adopting a work RVU adjuster because they believe it is more equitable to apply budget neutrality reduction in the fee schedule directly to codes code involved in the Five Year of Work Values. The Academy disagrees. Fewer than 500 codes were involved in the Five Year Review and the other 7,000 codes will be penalized specifically because they have WRVUs. We understand CMS's consideration of codes with no or low WRVUs, but these are mostly technical services which are part of imaging codes which are among the fastest growing in terms of volume in the Medicare fee schedule, which previously had been targeted for reduction by policymakers under DRA.

In addition, the decision to adopt a work adjustment for budget neutrality will adversely affect codes with a higher ratio of work to practice expense and PLI RVUs. By protecting codes with little or no physician work, CMS is further reducing payment for those services felt by the RUC and other health policy decision makers to be currently undervalued: E/M codes and complex surgical procedures. By applying the work adjuster, only 23 of 35 cognitive codes recommended for increases will actually see an increase. This negates the RUC recommended increases to another dozen E&M codes. We do not believe this is good public policy to deny increased payment to services felt to be undervalued.

The Academy strongly objects to CMS using the decreased work RVUs to in turn determine the indirect practice expenses proposed for its new PE formula. This allows CMS to cut physicians twice. We feel the full value of the WRVUs should be used in the practice expense calculations.

- **Further "Background" Comments: PE Methodology Changes**

The Academy reiterates its strong opposition to the proposed adoption of the policies outlined in the June 29, 2006 rule as inequitable and poor policy. Obtaining current and accurate indirect practice expense data is a crucial issue facing Medicare and we applaud CMS' goal of simplification and transparency. MedPAC, however, has consistently raised equity concerns about using the new specialty data for only some specialties, while 1999 SMS survey data are used for others. We are optimistic that CMS and AMA are exploring the development of a new survey and would hope that such new data could be incorporated as soon as 2008. With an equitable approach in sight, CMS must not proceed with missing data at this time. If new specialty wide survey data is not available for 2008, we recommend that specialties be able to continue to submit new data.

We will focus our comments on four aspects of the new practice expense methodology. These comments deal with the adoption of supplemental survey data, the calculation of equipment expense, the use of clinical labor costs for indirect practice expense allocation for codes with low or no physician work and the use of the discounted WRVUs for indirect practice expense calculations.

1) *Use of Supplemental Survey Data*:

The Academy continues to be concerned with the distortions introduced into the Medicare fee schedule by the adoption of supplemental survey from several specialties. The validity of the method used by CMS to integrate these new values with the current SMS data used by the remaining specialties is suspect. The supplemental survey data submitted by radiology, cardiology, radiation oncology, dermatology, allergy, and gastroenterology increased the PE/HR values of those specialties between 83% and 202%. **It is unreasonable to assume that only these specialties had a significant increase in PE and therefore inappropriate to allow these new data to be considered for some specialties in computing the PE values when the practice expense payments of all other physicians are based on the original SMS survey data from 1999.**

We urge CMS to not utilize these data until the data from the planned AMA Multi-Specialty Practice Expense Survey are gathered. If the data must be used for the 2007 fee schedule, the AAO urges a blending of the new and old SMS data for these specialties to minimize the

distortions in the Medicare fee schedule in 2007 that would otherwise result. With practice expenses accounting for over 40% of physician payments and CMS acknowledging that it is only paying a fraction of physician's overhead it is important that the practice expense distribution be done equitably.

2) *Equipment Assumptions:*
CMS currently assumes that all equipment is utilized 50% of the time. We believe that CMS must select utilization figures that are more closely related to the type of equipment. The 50% figure does not reflect the current utilization of expensive imaging equipment as pointed out by MedPAC and others. We urge CMS to consider a higher utilization rate of 75% as proposed in the past. For other categories of equipment such as lasers, a much lower utilization rate of 10-20% is justifiable. **CMS should develop a variety of equipment utilization categories and provide a mechanism for specialties to provide data to justify the most accurate rate for each category.**

3) Use of Discounted Work RVUs in Indirect Practice Expense Calculations
CMS has used WRVUs calculated after budget neutrality adjustments. This would lead to inaccurate payments of practice expenses and is just another reason not to apply budget neutrality as a work adjuster. We urge CMS to use correct work RVUs that have not undergone budget neutrality adjustments. We suggest that CMS use current RUC and CMS values to include the results of the third Five Year Review.

4) Specialty weighting of PCI
The Proposed Notice states that the Secretary has determined that PE RVUs should reflect the resources required to perform a service for a "typical" patient. Therefore, we suggest that the approach of basing the specialty adjusted weight on a weighted average of all specialties providing a service is flawed. Rather, we suggest that the weight should be based on the weight of the specialty or specialties that represent 95 percent of the total utilization of the appropriate CPT code and modifier. Otherwise, the practice expense (PE) related payment is impacted by the practice costs of specialties who do not represent the "typical" patient.

We believe that this adjustment will be particularly important for codes that are billed by a wide range of specialties that typically are not performing the entirety of the service. For example, CPT code 66894 which describes cataract surgery is billed by 19 specialties, even though almost all of the procedures (99%) are actually billed for and performed by ophthalmologists.

The specialty-based weights impact the PE RVU calculation because the indirect costs are determined based on the direct cost estimate at the procedure level and the ratio of direct and indirect costs at the practice level. AAO has analyzed the proposed PE RVUs and determined that an alternative approach described below would correct some of the anomalies that result from the inclusion of specialties that are not directly or typically related to a procedure code. In addition, we believe that the utilization data used in calculating the weighted values for CPT 66984 are incorrect and do not reflect the clinical reality and the non-surgical role of optometrists in the service.

The utilization data contained on the CMS website and made available at the February 2006 Town Hall meeting indicate that 85.4 percent of the allowed PE charges of CPT 66984 are associated with an ophthalmologist while another 14.2 percent of those charges are associated with an optometrist and 0.4 percent stems from some 17 other specialties. The Academy

believes that many of these claims must be due to coding error because this belies the clinical reality that the surgery is exclusively provided by ophthalmologists.

Optometrists are involved only during the post-procedure period for a limited number of post-operative visits and not involved in the pre-service, intra-service, and day of service discharge portions of the procedure. CMS limits this co-management fee to 20% of the full procedure payment. The clinical reality could be confirmed if the utilization data at the CPT code level also included modifiers since most optometrists will bill for CPT code 66984 with the "54" modifier to indicate the care associated with the post- operative period. The published PE RVU appears to reflect the 0.854 and 0.142 for ophthalmology and optometry, respectively with an additional small weight used to distribute the 0.4 percent associated with the other 17 specialties.

According to calculations determined by the Academy, if CMS utilizes the correct proportion of ophthalmology's percentage of care in weighting for code 66984, the payment would be as follows:

Proposed PE RVU for CPT 66984
Should Be Increased To Reflect Surgical Nature of Procedure

CPT Code 66984 (extracapsular cataract removal with insertion of intraocular lens)	**Clinical Reality (Optometry Services Limited to Post-Procedure Follow-up)**	**100% Ophthalmology**	**Proposed Value for 2010 (Based on a blended 86% Ophthalmology and 14% Optometry Utilization)**
PE RVU	**6.84**	**6.89**	**6.62**
% Change from Proposed Value for 2010	**+3.3 %**	**+4.1 %**	
Payment Impact	**$14.6 million**	**$17.4 million**	

This chart shows the impact of correcting the RVU for CPT code 66984 to reflect the surgical nature of the procedure. The RVU shown in Addendum B of the August 22nd NPRM inaccurately reflects the role of optometry in cataract surgery, which is limited to follow-up care. The surgical procedure is performed only by ophthalmologists. Therefore, the RVU should be 4.1 percent higher. The proposed RVU deflates the practice costs associated with this procedure by 14 percent because the final value is a blend of the practice costs of both specialties. The 14 percent utilization estimate is based on inaccurate data that does not distinguish between the various modifiers used in conjunction with CPT 66984. When billed correctly, optometrists should use a "55" modifier to indicate the service is for post-operative management only, when one physician performs the post-operative management and another physician performs the surgical procedure.

If CMS were to base the practice expense calculation to reflect the clinical reality where the optometrist role is limited to post-operative care, the PE RVU would be 6.84, or 3.3 percent higher than the proposed RVU for cataract surgery. The two alternatives that

AAO Proposed Fee Schedule Comments

AAO proposes does not increase the PE RVU by a significant percentage change and the budget impact may not seem significant in the context of the budget impact of the change to a bottom-up methodology. Nonetheless, the change can have a dramatic impact at the individual practice level and will ensure that the PE RVU reflects the costs that ophthalmologists incur as they provide services related to cataract surgery.

AAO suggests that the PE RVU for CPT 66984 be based solely on ophthalmology utilization, or if a weighting of the optometry practice costs is necessary, that the weight assigned reflect either the clinical reality of the service provided by optometry affect only a portion of the postoperative service. The result will be a PE RVU which better approximates the resources needed to perform this service.

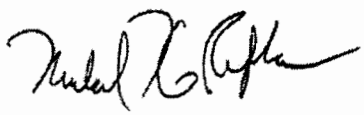
We urge CMS to respond affirmatively to our comments and to delay implementation of changes in the PE methodology for one year or until new data can be submitted or all specialties.

Conclusion

The Academy urges CMS to seriously consider the comments raised in this letter. Approximately one million health care providers, including ophthalmologists, have called on CMS to apply its budget neutrality adjustment to the conversion factor as had been the precedence for the previous 5-Year Review and the Academy strongly urges CMS to make that change. We once again strongly urge CMS to consider delaying implementation of the proposed change in PE methodology for one year. The Academy also encourages CMS to accept the supply and equipment pricing information solicited in the proposed rule and to incorporate this data into the PE database. Lastly, we continue to urge CMS to make appropriate adjustments to the PE methodology that would correctly weigh the practice cost index for provision of cataract surgery (66984) to reflect the co-management of post surgical care. Ophthalmologists are being unfairly penalized in their practice expense payments for this surgical procedure by the inclusion of optometry practice cost index in calculation of the PCI.

The Academy appreciates the opportunity to comment on the proposed rule. If there are additional questions and/or comments regarding the cost of ophthalmology code inputs we encourage CMS to contact us. Again, the Academy would like to thank you for providing us with the opportunity to comment and looks forward to CMS's response to our comments in the final rule.

Sincerely,



Michael X. Repka, M.D.
Secretary of Federal Affairs

Submitter : **Dr. Daniel Fontenot** **Date: 10/10/2006**

Organization : **Dr. Daniel Fontenot**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1321-P-811-Attach-1.DOC

#811

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Defibrillation Implantation & Follow-up

October 9, 2006

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

Dear Dr. McClellan:

On behalf of Baton Rouge Cardiology Center and our 11 individual practicing cardiologists, we appreciate the opportunity to submit these comments to the Centers for Medicare & Medicaid Services ("CMS") regarding the above proposed Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B; Proposed Rule ("Proposed Rule"). We are concerned about several provisions that will impact Medicare beneficiaries' access to services in outpatient cardiac centers, particularly those related to cardiac catheterizations. Specifically, we are concerned about the payment method proposed for cardiac catheterization related procedures. The Cardiovascular Outpatient Center Alliance ("COCA"), of which we are a member, will address the CMS proposal to require standards for Independent Diagnostic Testing Facilities ("IDTFs"). Our concerns related to the payment method are outlined below.

Payment Method

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

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

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

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

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

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

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

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

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

Sincerely,

Daniel Fontenot, M.D., F.A.C.C.

Submitter : **Ms. Andree Gardner** **Date: 10/10/2006**

Organization : **National Renal Administrators Association**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-812-Attach-1.PDF

#812

National Renal Administrators Association

October 10, 2006

The Honorable Mark McClellan
Administrator
Centers for Medicare and Medicaid Services
U. S. Department of Health and Human Services
Hubert H. Humphrey Building
Room 445-G
200 Independence Ave., S. W.
Washington, D. C. 20201

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

Dear Administrator McClellan:

The National Renal Administrators Association (NRAA) welcomes the opportunity to comment on the "Proposed Rule for Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B." We will focus our comments on the "End Stage Renal Disease Related Provisions" of the proposed regulation.

The NRAA is a voluntary organization representing professional managers of dialysis facilities and centers throughout the United States. Our Association represents free-standing and hospital-based facilities, which are for-profit and non-profit providers located in urban, rural, and suburban areas and serving dialysis patients in all settings. The NRAA is the only organization that represents the full spectrum of dialysis providers.

Before addressing the specific provisions in the proposed regulation, we want to again emphasize that, unlike most providers participating in the Medicare program, those who care for dialysis patients do not have a statutory mechanism to update their reimbursement on an annual basis. As you know, we must seek Congressional action in order to gain an increase in the composite rate. Currently, Medicare payments do not cover the patient's dialysis treatment costs. MedPAC has recommended that the composite rate be increased by 2.65 percent in 2007.

NRAA members are committed to providing their patients with the best possible care. But the current reimbursement system makes it difficult to fulfill this commitment. To ensure the quality of care that Medicare beneficiaries deserve and to guarantee reasonable access to dialysis services, it is essential that Congress provide an annual update mechanism. We ask the Administration to join with us in urging the Congress to move expeditiously on enacting appropriate legislation that will place our members on an equal footing with other providers under the Medicare program.

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Turning to the proposed regulation, we would urge the Centers for Medicare and Medicaid Services (CMS) to **consider adopting a proxy to estimate the update to the drug add-on adjustment for Calendar Year 2007 and allow for forecast error adjustments to ensure that the estimates are correct.**

NRAA supports the use of an index to establish the update to the drug add-on adjustment. However, we are concerned that the proposed Rule's methodology does not provide an accurate estimate of either 2007 prices or utilization of End Stage Renal Disease (ESRD) separately billable drugs. We endorse the recommendations outlined in The Moran Company's report "The Proposed ESRD Prospective Payment System Update for CY 2007: Evaluating Technical Options for Improved Payment Accuracy," conducted on behalf of, and submitted to you by, the Kidney Care Council. The Report recommends that CMS (1) use a proxy for CY 2007 to calculate the update and (2) establish a mechanism that would allow for forecast error adjustments if the estimates are incorrect.

Given The Moran Company's valid concerns about the data and methodology regarding the price and utilization estimates used to calculate the update to the drug add-on adjustment in the proposed Rule, we encourage CMS to clarify how it developed its estimates. NRAA further encourages CMS to re-examine its estimates of price and utilization for purposes of calculating the update to the drug add-on adjustment.

Because the payment to cost ratio for dialysis payment, including separately billable drugs, remains negative (MedPAC "Report to the Congress, 2006"), it is important that the method used to calculate the update results in an accurate assessment of the price and utilization changes to ensure economic stability for kidney care providers.

Regarding the price estimate, NRAA appreciates the value of using the Producer Price Index (PPI). However, we are concerned that the forecast outlined in the proposed Rule is significantly lower than it should be. The proposed Rule states that CMS estimates the PPI to be 4.9 percent. The current reported PPI for 2006 is 6.3 percent. Looking at the 2004/2005 PPI would result in 5.1 percent. If CMS determines it is appropriate to continue to use the PPI to estimate price changes, we request that you review the 2006 PPI and other data to ensure that in the final Rule the PPI estimate reflects the most current data available.

NRAA is also concerned about the data and methodology CMS uses in the proposed Rule to estimate utilization changes. We agree that CMS's current volume data are not stable and, as such, cannot be used to estimate accurately changes in volume. Without accurate data, CMS proposes a methodology that relies on less than complete data and results in a conclusion that utilization is flat. NRAA is concerned that this analysis does not accurately reflect the true trends in drug utilization.

Although it is unlikely that there has been double-digit growth in utilization for separately billable drugs, the analysis conducted by The Moran Company suggests that utilization is slightly higher and not flat. The data upon which CMS bases its estimate are not the most recent data available about separately billable drugs. Additionally, we are concerned that CMS has assumed, without having data to confirm its conclusion, that the new EPO Monitoring Policy will result in a significant decrease in the utilization of EPO. Respectfully, CMS should not incorporate unsubstantiated assumptions into a calculation as complex as estimating utilization. Because of these problems and based upon its review of the proposed Rule and CMS data, The Moran Company concludes that the use of the proposed methodology is flawed. These flaws make it difficult to ensure that any utilization estimate accurately reflects reality.

NRAA agrees with The Moran Company's suggestion that CMS **use the National Health Expenditure (NHE) index for purposes of determining the update to the drug add-on adjustment**. The benefit of the NHE index is that, unlike the PPI, it includes both price and utilization changes. We appreciate the concerns about Part D data distorting the NHE. However, as The Moran Company discusses, CMS can easily separate the Part D and Part B data so that the update would be determined looking only at trends in Part B drugs. Therefore, NRAA urges CMS to use the NHE as a proxy for price and utilization changes until CMS has credible data that will allow it to estimate price and utilization more accurately.

In addition to using the correct proxy in the short-term, CMS should also **establish a mechanism that will allow it to check and, if necessary, correct its estimates on a prospective basis until it has stable data** with which to estimate price and utilization changes. We agree with the suggestion outlined in The Moran Company report that CMS should temporarily adopt a mechanism that would allow it to forecast error adjustments of prior price and utilization estimates before calculating the next year's update to ensure that any estimating errors do not accumulate. This approach is consistent with CMS policies in other parts of the Medicare program, most notably in the MedicareAdvantage program payments to health plans. For example, if the estimates were incorrect for 2007, CMS could use the correct numbers to adjust the 2007 update before calculating the 2008 update. This mechanism would be necessary only until CMS has accurate volume data for ESRD drugs. NRAA encourages CMS to adopt such a mechanism for a limited time in addition to using an adjusted NHE as a proxy to ensure that updating the drug add-on adjustment is done in as accurate a manner as possible.

We would urge that the final Rule expressly state that **CMS will reimburse separately billable drugs at ASP+6 percent in 2007.** Given the importance of separately billable drugs to the reimbursement for dialysis services, it is vital that the rates be stable and predictable. We appreciate CMS noting that separately billable drugs will be reimbursed "based on section 1847A of the Act." However, we would encourage CMS to be more direct in the final Rule and to state expressly that for CY 2007, the Secretary will reimburse separately billable drugs at ASP+6 percent. This statement would be consistent with the statutory mandate and provide needed clarity. We urge that the preamble and the text of the Rule make it clear that the reimbursement rate is ASP+6 percent.

As CMS continues to implement the geographic wage index, **the budget neutrality calculation should be clarified and the methodology clearly explained.** We are concerned that the proposed regulation does not have the necessary transparency. The modifications to the geographic wage index have an enormous impact on small providers. Erroneous calculations that reduce the composite rate can force these providers to close their doors or forego improvements that can lead to better quality of care for their patients. To have faith in the new wage index, they need to understand that the budget neutrality factor is being calculated correctly. NRAA urges CMS to provide the data and methodology it used to calculate the budget neutrality factor in the final Rule to allow our membership to assess the impact of the proposed changes and confirm their accuracy.

We firmly believe that **CMS should encourage patient services such as self-management for diabetes, blood flow monitoring and nutritional therapy through appropriate reimbursement.** We are pleased that CMS recognizes that these services can improve care for patients and encourage them to learn to better manage their disease. NRAA encourages CMS to continue its efforts to provide coverage for these and other services that can assist in slowing the progression of kidney disease and help patients who have kidney failure achieve a better quality of life.

One precursor to chronic kidney disease is diabetes. Patients who manage their diabetes effectively will slow the progression or prevent the onset of chronic kidney disease. The more opportunities patients have to learn how to manage their disease, the less likely they will need dialysis services. We enthusiastically support the proposal regarding diabetes self-management services. Patient education and training is critical and we applaud CMS for recognizing its importance in the proposed Rule.

It is generally recognized that for most hemodialysis patients, an AV fistula is the best type of access. Monitoring a patient's access, whether fistula, graph, or catheter, is crucial to assuring that the patient can receive the appropriate treatments. **NRAA strongly supports additional resources for blood flow monitoring services.** These services allow dialysis professionals to assess a patient's blood flow rate and vascular access and determine whether additional maintenance services are required before a problem occurs. By enhancing the accuracy of the services, blood flow monitors improve the quality of care that patients receive and eliminate indirect costs by reducing patient morbidity and the number of required hospital tests. CMS should recognize the importance of providing patients with flow monitoring services and ensure coverage with appropriate payment for these services.

We fully support expanding coverage for medical nutritional therapy to non-diabetic patients. Limited access to nutritional therapists denies patients with Stage 3 and 4 kidney disease important information and education in better managing their disease. Medical nutritional therapy and counseling are important services to assist patients in improving their nutritional status and to control several critical electrolytes, such as potassium and phosphorous. The availability of nutritional therapy will help non-diabetic patients learn how to better manage their disease.

NRAA is extremely pleased that CMS recognizes in the proposed Rule these important preventive services. These types of programs not only help to prevent the onset of chronic kidney disease, but also help dialysis professionals better manage their patients. We encourage CMS to continue to provide incentives for improved educational and preventive services.

The NRAA greatly appreciates the opportunity to comment on the proposed Rule. We would be pleased to respond to any questions you may have and to work with you to assure appropriate implementation of the final Rule. We look forward to continuing to work with CMS on all issues affecting the dialysis community.

Sincerely,

Andree Gardner
President
National Renal Administrators Association

1904 Naomi Place • Prescott, AZ 86303
(928) 717-2772 • Fax (928) 441-3857 • email nraa@nraa.org • www.nraa.org

Submitter : Dr. Alfred R. Smith, Ph.D. **Date:** 10/10/2006

Organization : Particle Therapy Cooperative Group

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Submitter : Dr. Harold Clausen, Jr. **Date:** 10/10/2006

Organization : Dr. Harold Clausen, Jr.

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1321-P-814-Attach-1.DOC

814

BATON ROUGE CARDIOLOGY CENTER

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Syncope Evaluation

Electrophysiologic Studies

Radiofrequency Catheter Ablation

Defibrillation Implantation & Follow-up

October 9, 2006

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

Dear Dr. McClellan:

On behalf of Baton Rouge Cardiology Center and our 11 individual practicing cardiologists, we appreciate the opportunity to submit these comments to the Centers for Medicare & Medicaid Services ("CMS") regarding the above proposed Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B; Proposed Rule ("Proposed Rule"). We are concerned about several provisions that will impact Medicare beneficiaries' access to services in outpatient cardiac centers, particularly those related to cardiac catheterizations. Specifically, we are concerned about the payment method proposed for cardiac catheterization related procedures. The Cardiovascular Outpatient Center Alliance ("COCA"), of which we are a member, will address the CMS proposal to require standards for Independent Diagnostic Testing Facilities ("IDTFs"). Our concerns related to the payment method are outlined below.

Payment Method

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

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

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

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

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

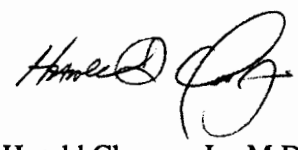
We believe that the development of unique standards for each type of diagnostic testing facilities will facilitate the development of a consistent Medicare policy for outpatient cardiac catheterization services. The standards will provide a solution to the issue that cardiac catheterization labs faced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

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

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

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

Sincerely,



Harold Clausen, Jr., M.D., F.A.C.C.

setting for 90-day global services to the remaining unrefined 90-day global procedures. As recommended by the RUC, this will include one minimum supply visit package for each post-operative visit assigned to each code and a post-surgical incision care kit where appropriate, along with additional items recommended by the RUC for certain procedures. For equipment, CMS is proposing to include an exam table and light.

The AUA performed an initial review through the RUC process and recommended that certain supply items be retained. These were reviewed at the April, 2006 PERC meeting and accepted. However, our review of the CMS database indicates that all of our recommendations were not incorporated. For your information, we have attached the list of codes and the supplies that the AUA recommended to be retained and/or added (**see Attachment 1**). **We urge CMS to assure that these items are properly recorded in the practice expense direct cost input database.**

Supply for CPT Code 50384

According to CMS, upon review of the RUC-recommended direct PE inputs for CPT code 50384, *Removal (via snare/capture) of internally dwelling ureteral stent via percutaneous approach, including radiological supervision and interpretation*, a new procedure for CPT 2006, it identified the inappropriate inclusion of a ureteral stent that it is proposing to delete for CY 2007. **The AUA agrees with CMS that the ureteral stent should be deleted from the supply inputs for CPT code 50384, because it is not appropriate to list the stent as a supply item for this procedure as the procedure involves stent removal only**. The inclusion of this supply item was inadvertent, as the other codes that were reviewed included removal and reinsertion.

Miscellaneous Coding Issues

Global Period for Remote Afterloading High Intensity Brachytherapy Procedures

Due to an increasing variability in the treatment of patients with prostate cancer, breast cancer, and sarcoma, CMS proposes to assign codes 77781-77784, within the Clinical Brachytherapy family, a global period of XXX, rather than 090. CMS also proposes interim work RVUs of 1.21, 2.04, 3.27, and 5.15, respectively, lowering each by 0.45 RVUs commensurate with the removal of the single 99212 postoperative visit. **The AUA agrees that the global period should be changed to XXX, but recommends that the RUC review the work RVUs for these procedures before any changes are made to their work RVUs**. The RUC has agreed to include a review of these codes on its April 2007 meeting agenda if the change in the global period is finalized.

II. DRA PROPOSALS

Section 5102 of the Deficit Reduction Act (DRA) of 2005 includes two provisions that affect payment of imaging services under the Medicare physician fee schedule. The first provision addresses payment for certain multiple imaging procedures for 2007 and application of budget neutrality and the second provision addresses limiting the payment amount under the physician fee schedule to the outpatient department payment amount for the technical component (TC) of certain imaging services.

Payment for multiple imaging procedures for 2007

In the 2006 physician fee schedule proposed rule, CMS proposed to reduce by 50 percent the payment for the TC of selected diagnostic imaging procedures belonging to one of eleven imaging families when the procedures are performed on contiguous body areas. In the 2006 physician fee schedule final rule, CMS stated that it would phase-in the 50 percent payment reduction over two years, beginning with a 25 percent reduction in 2006. CMS also sought

contractual reassignments to the extent that the arrangement meets program integrity and other standards as determined by the Secretary, Congress surely did not mean that this statutory provision could be administratively repealed by merging it into the already existing purchased diagnostic test rules.

The deletion of the reassignment rules has far-reaching and, we believe, unintended consequences. CMS has stated that in order for a physician group to bill for the technical component of a diagnostic test where there has been a reassignment under the contractual arrangement, there can be no mark-up by the physician group. In addition, the physician group would only be able to bill for the technical component of the test if it also performed the interpretation. Finally, CMS is considering amendments that impose certain conditions on when a physician or medical group can bill for a reassigned professional component of the diagnostic test. These conditions do not allow for a group to bill for a professional component from a reassigned physician if that physician has a financial relationship with the ordering physician, the physician performing the interpretation can not see the patient, and a physician or group must have performed the technical component of the test.

The outcome of these rules together is that a technical component of a diagnostic test performed by an independent contractor physician to a physician group would not be able to be "marked up" by the physician group. This concept of a mark-up is misplaced where a physician contracts with a group, and works in the group's location. In this situation, the physician may be paid for many services, not just diagnostic testing and may be paid a salary, hourly or other rate that does not take into account the number of tests performed or the reimbursement for such tests. Further, under the proposed rule, the group would also need to provide the professional component.

However, that professional component could not be provided by an independent contractor physician who has reassigned his/her rights to payment. The only physicians that could perform the interpretation would be owners or employees of the group practice. By way of example, a urology group that has an independent contract with a particular urologist, rather than an employment agreement, would need to comply with these requirements. Accordingly, the technical component of an ultrasound performed by the independent contractor urologist during a patient's visit to the urologist would not be able to be marked up by the physician group. As stated above, it is potentially impossible to calculate any mark-up because there is no per-test charge by the independent contractor physician. More importantly, CMS has not identified any abuse in such an arrangement.

An additional problem highlighted by this scenario is that the independent contractor physician would not be able to perform the interpretation of that ultrasound. Due to the proposed confines of reassigned billing rights for the professional component of a diagnostic test, only an employee or owner of the group practice could perform the interpretation. Quality of care issues and inconvenience to the patient will stem from this rule if a patient who is receiving services from a urologist who is an independent contractor, must wait for an employee or owner of the physician group to come and perform the ultrasound during the patient's physician visit due to the imposition of these rules. We are hard pressed to understand any principled basis for such a result.

Further, this proposed rule would prevent a physician group from performing the technical component of a diagnostic test for a patient in their office and sending the results to a specialist who would perform and bill for the interpretation of the test. This common practice is beneficial for patients. It is convenient for patients to have tests performed in their physician's office, which is specifically acknowledged by Congress and CMS by the creation of the in-office ancillary services exception under the Stark Law and regulations.

The AUA strongly disagrees with any attempt by CMS to eliminate the reassignment rules by collapsing them into the purchased diagnostic test rules. These are two separate modes of providing services for patients and each has its own purpose. Such requirements are overly broad. The AUA opposes any requirement by CMS to apply the purchased technical component anti-mark-up rules in situations where a physician reassignment meets the independent contractor exception and the contracted physician performs his or her services for a group practice on the group practice's premises. The AUA further opposes any requirement that limits a physician group's ability to bill for the technical component of a service provided by that physician group when the professional component is provided and billed separately by a physician who is not either a member or a physician in the group. Finally, the AUA opposes incorporating the limitations for purchased interpretations to interpretations provided by a physician in a group who meets the contractual reassignment exception and provides those interpretations on the premises of the physician group.

I. Limitation of Rules to Pathology Services

CMS has requested comments as to whether diagnostic tests in the DHS category of radiology and certain other imaging services should be excepted from these provisions, and whether the proposal in whole or in part should apply only to pathology services. As stated above, the AUA supports a clear distinction between the reassignment and the purchased diagnostic testing rules. **The AUA believes that the purchased diagnostic testing rules and any changes to the contractual reassignment rule be drafted as narrowly as possible.**

II. Exception to Rules for Services Performed on Premises.

CMS has asked for comments as to whether the provisions should apply to services performed on the "premises" of the billing entity and if so, how to define the "premises" appropriately. The AUA strongly advocates the position that the proposed rule should not apply to services performed on the premises of the billing entity. Notably, an exception for services performed on the "premises" will permit physicians and specialists to perform and interpret tests in a physician group's office. The exception would allow the physicians to continue to interact and collaborate face-to-face, thus improving the quality of the testing and the healthcare services to the patients. CMS has not shown that there is any abuse in independent contractor relationships where services are performed on the "premises" of a physician group. **The AUA supports an exception from the proposed rules for diagnostic tests performed on the premises of the billing entity as a means to provide appropriate and quality patient care**.

III. Anti-Markup of Professional Component.

CMS has solicited comments on whether an anti-mark-up provision should apply to the reassignment of the professional component of diagnostic tests performed under a contractual

arrangement, and if so, how to determine the correct amount that should be billed to the Medicare program. There is no need to require an anti-markup provision for the professional component of diagnostic tests. The Office of Inspector General (OIG) has addressed the same issue in the context of its proposed exclusion rule regarding claims that are substantially in excess of a practitioner's usual charges. See 68 Fed. Reg. 53,939 (September 15, 2003). In that proposed rule, the OIG concluded that physician services should be excluded from the scope of the substantially in excess rule because of the physician fee schedule, which is updated regularly and provides adequate protection against the government overpaying for physician services.

> We are excluding from the scope of the proposed regulation claims for physician services reimbursed under the Medicare physician fee schedule . . . While reimbursement for physician services under section 1848(a) of the Act is the lower of the actual charge or the fee schedule amount, the Medicare fee schedule for physician services is developed independently by the Centers for Medicare and Medicaid Services based on a review of actual costs of delivering such services, updated annually, and subject to public notice and comment. Given that the physician fee schedule is subject to detailed statutory direction as to the components and the method of calculation, which include relative value units (RVUs) and empirical market data, we have determined that the fee schedule amounts for physician services under section 1848(a) of the Act are functionally equivalent to a prospective payment methodology and should be treated accordingly for purposes of section 1128(b)(6)(A) of the Act. . . .The principal protection against overpaying for services to Federal health care program beneficiaries is timely and accurate updating of the various fee schedules used by Federal health care programs.

Since the physician fee schedule provides adequate protection against overcharging Medicare, there is no need to require an anti-markup provision for the professional component of a diagnostic test. Furthermore, as stated above, it would be difficult if not impossible, to determine the correct amount to be billed to Medicare for interpretations that are performed by contracting physicians who are not paid on a per-test basis.

The AUA requests that CMS not impose an anti-markup provision for the professional component of diagnostic test and again seeks that CMS retain the clear distinction between the reassignment provisions and the purchased diagnostic testing provisions.

IV. Equipment Located in Centralized Building on Permanent Basis.

CMS has sought comments on whether the space located in a centralized building must contain, on a permanent basis, the necessary equipment to perform substantially all of the designated health services that are performed in the space. The AUA believes that such a requirement would be unduly restrictive, especially with respect to new technology. When new technology appears, its early adapters do not always have the need to use such equipment on a full-time basis. Accordingly, such new equipment is often not permanently located on the premises of the physician group. Creation of a requirement that such equipment be located permanently in a centralized building may lengthen the time it takes for such new technology to reach patients, thus impacting potentially on the quality of the care patients receive.

V. Employment of Individuals for Centralized Location.

CMS asked whether they should include a requirement that for space to qualify as a centralized building, the group practice would employ, in that space, a non-physician employee or independent contractor who will perform services exclusively for the group for at least 35 hours per week. Specifically, they have asked whether this will be unduly burdensome on small group practices. The AUA believes strongly that such a restriction is not necessary. Currently, there is no requirement that a centralized building be open to the public for any length of time. Some physician practices do not open their centralized building 35 hours per week although it is leased on a full time basis. **This requirement is unduly restrictive and would be very burdensome for small practices. It may force certain groups to close their centralized buildings and thus, could lead to restriction of access for patients.**

VII. Centralized Building in a Separate State.

CMS has asked whether a group practice should be allowed to maintain a centralized building in a state different from the state in which it has an office that meets the in-office ancillary services exception, and if so, must the centralized building be within a certain number of miles from an office of the group practice that meets the ancillary services exception. **The AUA supports a definition of centralized building that allows group practices to maintain such building in a state different than its office that meets the criteria for the same building test under the in-office ancillary services exception**. In many areas of the country, patients may travel across state lines to see their physician for both non-DHS and DHS services. In many areas of the country proximate to state borders, it is common for a group practice to have locations that meet the same building requirement across state lines.

The Stark regulations themselves permit a "single legal entity" to have locations across state lines. Because one of the purposes of the centralized building location is to allow patient access and patient convenience, we believe that centralized buildings that are in a different state should be permitted as long as they are located within the catchment areas of the patients that the group practice generally treats. Such a requirement would prevent physician groups from establishing centralized buildings, which have no nexus with the patients, while permitting the flexibility of having centralized buildings in areas that are convenient to the patients. In this instance, a bright line rule would not be helpful. In areas of greater population density, a patient catchment area may be much smaller than in rural areas where patients often travel further to reach their physicians, as well as the centralized buildings.

Supplier access to claims billed on reassignment

The AUA supports CMS's proposal to amend the regulations to state that the supplier who reassigns his or her right to bill and receive Medicare payment to an entity has unrestricted access to claims information submitted by that entity for services supposedly furnished by the individual supplier, irrespective or whether the supplier is an employee or independent contractor of the entity.

V. ADDENDUM B CLARIFICATION

Clarification of N/A for radiology codes
For CPT code 74420 and some other codes in that family, N/A is listed for non-facility as well as facility settings. N/A in the non-facility PE RVUs column means that CMS has not developed a PE RVU in the non-facility setting for the service because it is typically performed in the hospital. An N/A in the facility PE RVUs column indicates that the service is typically not paid using the fee schedule when provided in a facility setting. These services (which include incident to services and the technical portion of diagnostic tests) are generally paid under either the outpatient hospital prospective payment system or bundled into the hospital inpatient prospective payment system payment. We seek clarification on why there are N/As listed for both settings for these codes, as they are generally performed in the office.

Thank you for considering our comments. If you have any questions or need additional information, contact Robin Hudson, Manager of Regulatory Affairs, at 410-689-3762 or rhudson@auanet.org.

Sincerely,

Lawrence S. Ross, M.D.
President

Attachment 1

List of Supplies to be Included or Added to 90-Day Global Codes

Specialty	Reason for Inclusion (reason for the supply not to be deleted)	CPT Code	Item is scheduled for Deletion?	Supply Code	Description	Quantity of Standardized Supply Units Out of Office	Post-Op Visits
AUA/ACOG		57310	No	SA048	pack, minimum multi-specialty visit	2	2
AUA/ACOG	Delete one minimum multi-specialty visit pack (x2) as it is duplicative	57310	No	SA048	pack, minimum multi-specialty visit	2	2
AUA/ACOG	Standard ob/gyn supply	57310	Yes	SB006	drape, non-sterile, sheet 40in x 60in	3	
AUA/ACOG	Used post op/specific to procedure	57310	Yes	SC051	syringe 10-12ml	1	
AUA/ACOG	Standard ob/gyn post-op visit supply	57310	Yes	SJ046	silver nitrate applicator	5	
AUA/ACOG	Pt has post op discharge	57310	No	SK054	pad, urinary incontinence (Depends)	2	
AUA/ACOG	Pt has post op discharge	57310	Yes	SM021	sanitizing cloth-wipe (patient)	20	
AUA/ACOG	**ADD**	57310		SA051	pack, pelvic exam	2	
AUA/ACOG	**ADD**	57310		SA052	pack, post-op incision care (staple)		
AUA/ACOG		57311	No	SA048	pack, minimum multi-specialty visit	2	2
AUA/ACOG	Delete one minimum multi-specialty visit pack (x2) as it is duplicative	57311	No	SA048	pack, minimum multi-specialty visit	2	2
AUA/ACOG	Standard ob/gyn supply	57311	Yes	SB006	drape, non-sterile, sheet 40in x 60in	3	
AUA/ACOG	Used post op/specific to the procedure	57311	Yes	SC051	syringe 10-12ml	1	
AUA/ACOG	Standard ob/gyn post-op visit supply	57311	Yes	SJ046	silver nitrate applicator	5	
AUA/ACOG	Pt has post op discharge	57311	Yes	SK054	pad, urinary incontinence (Depends)	1	
AUA/ACOG	Pt has post op discharge	57311	Yes	SM021	sanitizing cloth-wipe (patient)	20	
AUA/ACOG	**ADD**	57311	**ADD**	SA052	pack, post-op incision care (staple)	1	

Specialty	Reason for Inclusion (reason for the supply not to be deleted)	CPT Code	Item is scheduled for Deletion?	Supply Code	Description	Quantity of Standardized Supply Units Out of Office	Post-Op Visits
AUA/ACOG	**ADD**	57311	**ADD**	SA051	pack, pelvic exam	2	
AUA/ACOG		57320	**No**	SA048	pack, minimum multi-specialty visit	2	2
AUA/ACOG	Need to delete one minimum multi-specialty visit pack (x2) as it is duplicative	57320	**No**	SA048	pack, minimum multi-specialty visit	2	2
AUA/ACOG	Standard ob/gyn supply	57320	**Yes**	SB006	drape, non-sterile, sheet 40in x 60in	1	
AUA/ACOG	Used post op/specific to the procedure	57320	**Yes**	SC051	syringe 10-12ml	1	
AUA/ACOG	Standard ob/gyn post-op visit supply	57320	**Yes**	SJ046	silver nitrate applicator	5	
AUA/ACOG	Pt has post op discharge	57320	**NO**	SK054	pad, urinary incontinence (Depends)	1	
AUA/ACOG	Pt has post op discharge	57320	**Yes**	SM021	sanitizing cloth-wipe (patient)	20	
AUA/ACOG	**ADD**	57320	**ADD**	SA052	pack, post-op incision care (staple)	1	
AUA/ACOG	**ADD**	57320	**ADD**	SA051	pack, pelvic exam	2	
AUA/ACOG		57330	**No**	SA048	pack, minimum multi-specialty visit	2	2
AUA/ACOG	Need to delete one minimum multi-specialty visit pack (x2) as it is duplicative	57330	**No**	SA048	pack, minimum multi-specialty visit	2	2
AUA/ACOG	Standard ob/gyn post-op visit supply	57330	**Yes**	SB006	drape, non-sterile, sheet 40in x 60in	3	
AUA/ACOG	Used post -op/specific to this procedure	57330	**Yes**	SC051	syringe 10-12ml	1	
AUA/ACOG	Standard ob/gyn post-op visit supply	57330	**Yes**	SJ046	silver nitrate applicator	5	
	Pt has post op discharge	57330	**Yes**	SK054	pad, urinary incontinence (Depends)	1	
AUA/ACOG	Pt has post op discharge	57330	**Yes**	SM021	sanitizing cloth-wipe (patient)	20	
AUA/ACOG	**ADD**	57330	**ADD**	SA051	pack, pelvic exam	2	
AUA/ACOG	**ADD**	57330	**ADD**	SA052	pack, post-op incision care (staple)	1	

Submitter : Dr. Corey Johnson **Date:** 10/10/2006

Organization : Cache Vein Care

Category : Physician

Issue Areas/Comments

Background

Background

Refer to General Comment below.

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 employee a Registered Vascular Technologist (RVT) to provide imaging services. These highly skilled technologists are in drastic shortage and therefore are in high demand and as such command extremely high salaries in excess of $70,000 per year plus benefits. Given the limited number of these procedures that the average physician performs per year it is impossible to comply with CMS guidelines if the RVUs and subsequent reimbursements continue to drop!

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

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

3. Values for codes 36475 and 36476, radiofrequency vein ablation have been consistently higher that those for laser ablation:
a. 2006: 51.5
b. 2007: 47.77
c. 2008: 44.52

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

Decreasing reimbursement for physicians now may have the desired effect in the short run of limiting Medicare expenditures. However, the long term consequences should be carefully examined. There was a time in this country when medicine was reserved for the best and brightest. The ratio of medical school applicants to class positions was dramatically higher than it is now. Young people making career decisions are keenly aware of tumbling physician reimbursements in the face of mounting education and practice expenses. Consequently the best and brightest are choosing engineering, computer science, business and other fields. In many areas of the country we already have a primary care erisis--which will inexorably deepen and ultimately spread to other specialties as reimbursements fall.

Respectfully submitted,

Corey B. Johnson M.D.
1219 North 400 East
Logan, Utah 84341
cjtj@sourceoneinternet.com

Impact

Impact

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

Provisions of the Proposed Rule

Provisions of the Proposed Rule

Refer to General Comment below.

Submitter : Dr. Fred Petty **Date:** 10/10/2006

Organization : Dr. Fred Petty

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1321-P-817-Attach-1.DOC

817

BATON ROUGE CARDIOLOGY CENTER

Boyd E. Helm, M.D., F.A.C.C., F.S.C.A.I.
Joseph M. Cefalu, M.D., F.A.C.C.
Kevin L. Kilpatrick, M.D., F.A.C.C.
Terry L. Zellmer, M.D., F.A.C.C.
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Henry C. Patrick, M.D., F.A.C.C.
Venkat R. Surakanti, M.D., F.A.C.C.
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Darrin M. Breaux, M.D., F.A.C.C.
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James R. Calvin, M.D., F.A.C.C., Emeritus

5231 Brittany Drive, Baton Rouge, Louisiana 70808, Phone: 225/769-0933, Fax: 225/769-6255

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Post Heart Surgery Cardiac Management

Balloon & Laser Coronary Angioplasty

Coronary Atherectomy & Stents

Cardiac Rehabilitation

Pacemaker Implantation & Follow-up

Lipid Management

Syncope Evaluation

Electrophysiologic Studies

Radiofrequency Catheter Ablation

Defibrillation Implantation & Follow-up

October 9, 2006

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

Dear Dr. McClellan:

On behalf of Baton Rouge Cardiology Center and our 11 individual practicing cardiologists, we appreciate the opportunity to submit these comments to the Centers for Medicare & Medicaid Services ("CMS") regarding the above proposed Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B; Proposed Rule ("Proposed Rule"). We are concerned about several provisions that will impact Medicare beneficiaries' access to services in outpatient cardiac centers, particularly those related to cardiac catheterizations. Specifically, we are concerned about the payment method proposed for cardiac catheterization related procedures. The Cardiovascular Outpatient Center Alliance ("COCA"), of which we are a member, will address the CMS proposal to require standards for Independent Diagnostic Testing Facilities ("IDTFs"). Our concerns related to the payment method are outlined below.

Payment Method

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

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

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

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

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

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

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

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

Sincerely,

Fred Petty, M.D., F.A.C.C.

Please see below.

Provisions of the Proposed Rule

Provisions of the Proposed Rule

Please see below.

Submitter : **Dr. Henry Patrick** **Date: 10/10/2006**

Organization : **Dr. Henry Patrick**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1321-P-819-Attach-1.DOC

819

BATON ROUGE CARDIOLOGY CENTER

Boyd E. Helm, M.D., F.A.C.C., F.S.C.A.I.
Joseph M. Cefalu, M.D., F.A.C.C.
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October 9, 2006

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Payment Method

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

Sincerely,

Henry Patrick, M.D., F.A.C.C.

Submitter : Dr. Alfred R. Smith, Ph.D. **Date:** 10/10/2006

Organization : Particle Therapy Cooperative Group

Category : Health Care Professional or Association

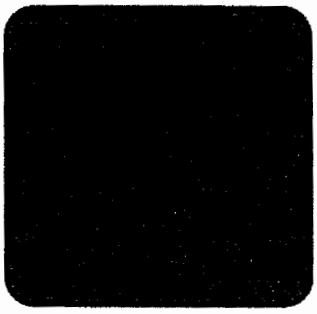
Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-820-Attach-1.PDF



September 30, 2006

Honorable Mark B. McClellan, M.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8010
Baltimore, MD 21244-8018

RE: Proton Therapy Payment Rates

Dear Dr. McClellan:

We are writing to you on a matter of great importance to the proton therapy community. More than 40,000 cancer patients have been treated with proton therapy in institutions in the United States and across the world. Proton beam therapy, due to its recognized and desired physical properties, has the clinical advantage of being significantly more precise in treatment delivery. Therefore, higher radiation doses can be delivered to malignant tissues, leading to higher rates of local control. Positive clinical results achieved with proton beams have stimulated worldwide interest in the clinical applications of proton therapy and, consequently, two additional facilities opened in the United States this calendar year.

STATEMENT OF SUPPORT FOR THE PROPOSED CALENDAR 2007 HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT RATES FOR PROTON THERAPY.

We fully support the Proposed Calendar Year 2007 (CY'07) Hospital Outpatient Prospective Payment System (OPPS) Payment Rates for proton beam therapy, which is as follows:

APC	CPT	CY'07 Proposed Payment Rate	CY'06 Payment Rate
0664	77520 and 77522	$1,136.83	$947.93
0667	77523 and 77525	$1,360.10	$1,134.08

These payment rates will ensure that further development of proton therapy continues as the clinical demand for this technology rises around the country.

As you know, the National Payment rates for proton therapy are determined based upon submitted claims and cost data received by CMS from centers delivering proton therapy in the United States. Rate setting is a challenging and difficult task. We appreciate the diligence with which you have set the CY'07 proposed payment rates for proton therapy.

STATEMENTS OF CONCERN REGARDING FREESTANDING FACILITIES

For freestanding proton therapy centers the CMS has given its contracted Carriers significant latitude but limited guidance from which to determine payment rates for proton therapy.

We remain concerned with the manner in which contracted Carriers of the Centers have managed freestanding Proton Therapy Centers for Medicare and Medicaid Services in the State of Texas, Florida and Indiana. The existing or proposed proton therapy payment rates by State are as follows:

Comparison of Freestanding Centers' Proton Therapy Rates by State			
	Indiana – Current	**Florida – Proposed 9/11/06**	**Texas – 9/1/06**
77520	—	$750.63	$652.75
77522	$496.83	$776.90	$653.90
77523	$811.33	$806.93	$783.79
77525	$856.12	$900.76	$954.41

As each State has its own CMS contracted Carrier, variations in existing CY'06 and proposed CY'07 proton therapy coverage and payment rates are occurring and are significant by comparison to CMS's National Payment Policy for protons as expressed in the OPPS rules.

Curtailing the development of proton beam therapy centers now through inadequate payment may have the negative long-term effect of precluding future cost reductions provided by proton beam therapy and not having this important therapy available to patients.

We are requesting that CMS direct its Carrier's on issues of payment of or for proton therapy for Free-Standing centers so that their rate setting approach is consistent with that of the CMS for HOPD.

It should be noted that due to the capital cost of proton therapy, both freestanding and HOPD centers have similar costs for patient treatments. The cost of treatment per fraction is consistent, if not higher, in both hospital based and freestanding facilities than the current 2006 APC payment rate. Given the great similarity of capital investment and operating costs of proton beam therapy centers, whether hospital-based or freestanding, this is an appropriate recommendation for CMS given the number of operating centers and patient demand for this valuable therapy.

In addition, we believe that it is not appropriate for freestanding facilities to pursue a relative value unit from the RUC for proton beam therapy. Due to the limited availability of this technology in the freestanding setting and the established coverage and payment policy established by CMS for hospital outpatient departments, we feel it is more appropriate to leverage the considerable work performed by CMS to establish payment for these procedures across both hospital outpatient and freestanding facilities. The risk of not doing so may, in effect, limit the access of this technology to cancer patients around the country.

CONCLUSIONS

In conclusion, proton beam therapy has a recognized and desirable effect in cancer treatment with the clinical advantage of being significantly more precise in the delivery of treatment, resulting in better clinical outcomes and fewer or less significant adverse side effects than other forms of radiation therapy.

We strongly agree with CMS's proposed CY'07 payment rule for proton beam therapy for Hospital Outpatient Departments.

We are requesting that CMS direct its Carriers on issues of payment of or for proton therapy for Free-Standing centers so that their rate setting approach is consistent with that of the CMS for HOPD.

CMS thoroughly analyzes proton beam therapy claims and cost data in establishing payment rates for Hospital Outpatient Departments. CMS contracted Carriers should take advantage of vast work already performed on the part of the CMS when determining payment rates.

Sincerely,

Alfred R. Smith

Alfred R. Smith, Ph.D.
Chairman, Particle Therapy Co-Operative Group (PTCOG)

Submitter : **Dr. Venkat Surakanti** **Date: 10/10/2006**

Organization : **Dr. Venkat Surakanti**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1321-P-821-Attach-1.DOC

821

BATON ROUGE CARDIOLOGY CENTER

Boyd E. Helm, M.D., F.A.C.C., F.S.C.A.I.
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October 9, 2006

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Sincerely,

Venkat Surakanti

Venkat Surakanti, M.D., F.A.C.C.

Submitter : Mr. Len Arzt **Date:** 10/10/2006

Organization : The National Association for Proton Therapy

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-822-Attach-1.PDF

822

The National Association for Proton Therapy

August 18, 2005

Honorable Mark B. McClellan, M.D.
Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Room 314G
Washington, D.C. 20201

Re: CMS-1501-P –Proton Beam Therapy

Dear Dr. McClellan:

The National Association for Proton Therapy (NAPT), founded in 1990, completely supports the classification and payment rates for simple, intermediate, and complex proton therapies as proposed in the CMS CY 2006 OPPS rule and strongly recommends that CMS make the proposed rule **final for CY 2006.**

This action will ensure that the nation's proton centers will continue to have the capability to provide cancer patients with this proven non-invasive radiation treatment.It will also ensure the sustainability and future growth of proton treatment at premier regional cancer centers currently in development and scheduled to open in 2006.

As you know, proton beam therapy is in an early stage of clinical adoption. The new proposed ruling will enhance the possibility of establishing more proton therapy facilities, and/or allow for expansion of current proton centers in order to keep pace with the clinical demand by thousands of cancer patients across the country.

We appreciate the complexities of the hospital payment system and the challenges faced by CMS in developing the proposed rule. We are aware that CMS OPPS works closely with the hospital providers of proton therapy in order to understand and analyze data for payment classification purposes. That is reflected in the CY 2006 proposed rule that ensures the economic viability of both existing proton facilities and those in various stages of construction and development.

We are excited about the future of proton therapy for improving patient outcomes and quality-of-life. As Dr. James Cox, chairman of radiation oncology at the M.D. Anderson Cancer Center, said: *"Oncologists have long known that substituting proton beam radiation for X-rays now used to treat cancer patients would do less harm to normal tissues and organs and more damage to malignant growths. That means more cures."*

The National Association for Proton Therapy 1301 Highland Drive Silver Spring, MD 20910
Tel 301 587 6100 Fax 301 565 0747 www.proton-therapy.org

On behalf of the proton therapy industry, as well as the many thousands of cancer patients in the U.S. who seek proton radiation treatment, we thank you and your very capable CMS staff for the government's role in providing support for this leading-edge cancer therapy.

In conclusion, we agree with CMS's CY 2006 proposed payment rule for proton therapy and strongly support it being included in the final rule.

Thank you for your attention to this important matter. If you have any questions, I can be reached at 301-587-6100 or via email: lenarzt@proton-therapy.org.

Sincerely yours,

Leonard J. Arzt
Executive Director
NAPT

lenarzt@proton-therapy.org

823 -

Patient Selfcare Providers Association
2020 Pennsylvania Ave NW Suite 863
Washington DC 20006

October 9, 2006

Hon. Leslie Norwalk, Esq.
Acting 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: "Provisions Issues"

SUMMARY: We believe that the RVUs for G-0248 and G-0249 included in the Proposed Rule § II.A.5.(k) do not reflect the cost of providing these services. We recommend that the PE RVUs be set at 7.63 and 5.99 for G-0248 and G-0249 respectively. Our recommendation is based on an updated version of the detailed analysis that was presented to CMS in 2002 when the original payment rates for this code were first established. The original analysis was based on input provided by several product manufacturers and experienced Medicare providers of diagnostic services. In addition, the resource requirements were based on best estimates of what it should take to perform the activities according to best practice guidelines. For this we used the second edition of "Managing Oral Anticoagulation Therapy", the recognized best care practice guide for Home INR Monitoring. The updated version of the original analysis has been updated for changes in product prices and other variables based on field experience over the past several years. The updated version of this original analysis is attached.

Dear Ms. Norwalk:

Patient Selfcare Providers Association (PSP) 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"). We wish to comment specifically on proposed § II.A.5.(k) as it relates to the Resource-Based Practice Expense (PE) RVU Proposals for CMS Billing Codes G-0248 and G-0249. PSP is a non-profit association organized under section 501(c)(3) of the Internal Revenue Code, with a mission to promote quality standards and patient self care treatment options including Home INR Monitoring for patients on anticoagulation therapy.

In a former capacity with a major manufacturer, I was personally involved in the original estimation of resources requirements when the Home INR Monitoring Program was first

implemented. At the time, we provided CMS with a comprehensive analysis which was based on our best estimate of the resources requirements needed to fulfill the activities outlined in the second edition of "Managing Oral Anticoagulation Therapy". This book, written by Jack Ansell, M.D. from Boston University School of Medicine and others, is recognized as the best practice guide for Home INR Monitoring. The updated version of our original analysis remains consistent with these best care guidelines and the experience we have collected from PSP members who have serviced Medicare beneficiaries over the past three years.

The updated analysis that we have prepared to support these recommendations evaluates four variables for each code; Clinical Labor, Administrative Labor, Supplies and Equipment. Each variable was cross-referenced to the relevant section of best care guidelines and then analyzed according to assumptions that have been drawn from our previous or other publicly available data. The 14-page analysis, which is summarized on page 1, shows that the updated resource requirements for G-0248 are $351.09 and for G-0249 are $275.83. We recognize that these codes are atypical and therefore have calculated these resource requirements based on the direct practice expenses plus an additional 25% for indirect practice expenses. Our recommended PE RVUs have been calculated by dividing the dollar-based resource requirements by the proposed 2007 conversion factor of 37.8975. The minimums and maximums are in turn calculated by the range of GPCIs used by CMS. Based on our analysis, we believe that the proposed reductions in PE RVUs for these two codes will be inadequate for providers to offer these services. Our updated analysis shows that a more appropriate PE RVU level for:

1. **G-0248** should be in the range of 5.99 (minimum) and 9.26 (maximum). Our recommendation of 7.63 is based on a simple average of the minimum and maximums supported by our analysis.
2. **G-0249** should be in the range of 4.71 (minimum) and 7.28 (maximum). Our recommendation of 5.99 is based on a simple average of the minimum and maximums supported by our analysis.

We believe that maintaining appropriate PE RVU levels are particularly important for G-0248 and G-0249 because of the significant supply and equipment component in each code. Therefore, we request that CMS reevaluate the proposed PE RVUs included in the Proposed Rule and consider the updated analysis that we have provided. If needed, I would welcome the opportunity to provide you further information.

Sincerely,

Shari Kipp
Executive Director
skipp@inrcare.com

CMS
Home INR Monitoring
Practice Expense RVU's

			Page #	Resource Requirements: $ Per Unit of Service	PE RVU: Min.	PE RVU: Max.	PE RVU: Avg.
G-0249	**Recurring Technical (RT)**						
	Clinical Labor	RT - C	2	$ 20.38	0.35	0.54	0.44
	Adminstrative Labor	RT - A	3	$ 24.35	0.42	0.64	0.53
	Supplies	RT - S	4	$ 114.22	1.95	3.01	2.48
	Equipment	RT - E	5	$ 116.88	1.99	3.08	2.54
	Summary	RT	6	$ 275.83	4.71	7.28	5.99
G-0248	**Initiation Technical (IT)**						
	Clinical Labor	IT - C	7	$ 93.33	1.59	2.46	2.03
	Adminstrative Labor	IT - A	8	$ 10.45	0.18	0.28	0.23
	Supplies	IT - S	9	$ 224.65	3.83	5.93	4.88
	Equipment	IT - E	10	$ 22.65	0.39	0.60	0.49
	Summary	IT	11	$ 351.09	5.99	9.26	7.63
	Best Care Guidelines		12				
	Supply & Equipment Data		13-14				

CMS
Home INR Monitoring
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Recurring Technical - Clinical (RT-C)	Assumptions				Clinical Labor	
(G0248) Home prothrombin time (INR) monitoring for anticoagulation management, receipt of results and report only.	Staff Type	Time in Minutes	PM Event	Occurrence Rate	Labor $/Hr: $ 19.02	
Care Guidelines / Steps					Time/Unit Value	Cost/Unit Value
1 Process Order						
2 Dispense Supplies & Equipment for Monitoring INR						
a) Fulfill Prescription According to Physician Orders	Pharmacist	10.00	Prescription		0.95	$ 0.30
3 Manage Patient Compliance / Provide Consultation						
a) Receive and review INR values	RN/LPN/MA	5.00	Reported Test	1.00	5.00	$ 1.59
b) Follow-up with patient to ensure INR values reported as prescribed	RN/LPN/MA	5.00	Missed Test	20%	1.00	$ 0.32
c) Follow-up with patient to ensure re-testing following Physician-directed dosing change	RN/LPN/MA	10.00	Dosing Change	4.00	0.95	$ 0.30
d) Provide ongoing technical support for use of equipment.	RN/LPN/MA	20.00	Call	2.00	0.95	$ 0.30
e) Provide technical support related to specific test errors	RN/LPN/MA	20.00	Call	2.00	0.95	$ 0.30
f) Update Changes to Patient Clinical Profile	RN/LPN/MA	20.00	Year	20%	0.10	$ 0.03
4 Manage Anticipated Changes in Anticoagulant Change						
a) Follow-up with patient to ensure INR values reported prior to invasive procedure	RN/LPN/MA	10.00	Procedure	20%	0.05	$ 0.02
5 Communication & Documentation						
a) Contact physician directly regarding out of range INR Values	RN/LPN/MA	2.00	Out of Range INR	20%	0.40	$ 0.13
b) Contact physician directly regarding non-adherent patients	RN/LPN/MA	10.00	Year	17%	1.70	$ 0.54
6 Claim filing with Medicare						
7 Accounts receivable mgmt. & collection						
Total Clinical Costs to Generate:						
1 Controlled, Billable INR Value					**12.05**	**$ 3.82**
4 Controlled, Billable INR Values					**48.21**	**$ 15.28**

		Comments	Reference	Best Care Guidelines
2	a)	Quarterly Rx for 8-13 INR Values	Per CMS Meeting 2/28/02	5.1
3	a)	Information provided to ensure physician that patient's condition is properly managed	Estimation by Raytel Medical Inc.	10.3
3	b)	% Patients fail to report INR value without reminder	Estimation based on '2 Year Transitional Study @ Loma	10.3
3	c)	# Times physician changes warfarin dose during course of year	Linda VA Medical Center:	8.2
3	d)	# Times patients call during course of year	" "	8.1
3	e)	# Times patients call during course of year	" "	8.1
3	f)	% Patients who have some form of clinical change during course of year	" "	8.3
4	a)	% Patients who undergo some invasive procedure each year	" "	10.2
5	a)	% INR results outside of target range	" "	4.1
5	b)	% Patients who will be repeatedly non-compliant during course of year.	" "	

CMS
Home INR Monitoring
Practice Expense RVU's

Recurring Technical - Administrative (RT-A) (G-0249) Home prothrombin time (INR) monitoring for anticoagulation management, receipt of results and report only. Care Guidelines / Details	Assumptions Staff Type	Time in Minutes	Per Event	Occurrence Rate	Administrative Labor Labor Rate/Hr $ 14.60 Time/INR Value	Cost/INR Value
1 Process Order						
a) Receive and enter order	Admin Staff	7.50	Prescription	4.00	0.71	$ 0.17
2 Dispense Supplies & Equipment for Monitoring INR						
3 Manage Patient Compliance / Provide Consultation						
a) Update Changes to Patient Data Profile	Admin Staff	15.00	Year	20%	0.07	$ 0.02
4 Manage Anticipated Changes in Anticoagulant Change						
5 Communication & Documentation						
a) Send report of patient's INR Value to physician	Admin Staff	2.00	Test Reported	1.00	2.00	$ 0.48
b) Send report of patient's INR trends for past quarter to support physician's evaluation	Admin Staff	3.00	Quarter	4.00	0.29	$ 0.07
c) Document & Archive all INR Results & patient interaction	Admin Staff	5.00	Test Reported	1.00	5.00	$ 1.21
d) Send report of annual report to support physician's annual outcomes assessment	Admin Staff	3.00	Year	1.00	0.07	$ 0.02
6 Claim filing with Medicare						
a) Submit claims for New & Re-Initiated Patients	Admin Staff	5.00	Per Month	1.00	5.00	$ 1.21
7 Accounts receivable mgmt. & collection				1.00		
a) Bill Patient Co-Pay	Admin Staff	5.00	Month	1.00	1.43	$ 0.35
b) Follow-up on Past Due Accounts	Admin Staff	5.00	Month	16%	0.23	$ 0.06
c) Write-off for Non-collectable Accounts	Admin Staff			8%		$ 1.01
Total Clerical Costs to Generate:						
1 Controlled, Billable INR Value					**14.80**	**$ 4.58**
4 Controlled, Billable INR Values					**59.20**	**$ 18.33**

	Comments	Reference	Best Care Guidelines
1	a) Quarterly Rx for 8-13 INR Values	Per CMS Meeting 2/28/02	5.1
3	a) 20% of Patients have some element of demographic or insurance change	Estimation by Raytel Medical Inc.	4.1
5	a) Assumes semi-automated data handling systems	Estimation by Raytel Medical Inc.	4.1
5	b) Assumes semi-automated data handling systems	Estimation by Raytel Medical Inc.	12.1
5	c) Assumes semi-automated data handling systems	Estimation by Raytel Medical Inc.	4.1
5	d) Assumes semi-automated data handling systems	Estimation by Raytel Medical Inc.	12.1
6	a) IDTF submits monthly claims for INR Values reported in month	Proposed Gxxx4 work instructions	5.1
7	a) IDTF bills patient co-pay for INR Values reported in month	Proposed Gxxx4 work instructions	5.1
7	b) % Patients who are diligent in co-pay payment	Estimation by Raytel Medical Inc.	5.1
7	c) % of Non-collectable Co-Pay Amounts	Estimation by Raytel Medical Inc.	5.1

CMS
Home INR Monitoring
Practice Expense RVU's

Recurring Technical - Supplies (RT-S) (G0248) Home prothrombin time (INR) monitoring for anticoagulation management, receipt of results and report only. Care Guidelines / Details	Assumptions Unit Value	Per Event	Occurrence Rate	Supplies Units/INR	Cost/INR Value
Average					
1 Process Order					
2 Dispense Supplies & Equipment for Monitoring INR					
a) Test Strips to Generate 1 Controlled INR Value	$ 16.39	Per Strip	1.0	1.0	$ 16.39
b) Re-test due to Reconfirm Extreme Out of Ranges	$ 16.39	Year	4.0	0.1	$ 1.56
c) Product Spoilage	$ 16.39	Year	3.5	0.1	$ 1.44
d) Re-test due to Testing Errors (e.g.. Insufficient Blood,Temperatures, Insertion, QC Checks, etc.)	$ 16.39	Year	2.8	0.1	$ 1.02
e) Express ship strips to patients	$ 10.00	Prescription	4.0	0.1	$ 0.95
f) Insurance on Product Shipments	$ 0.50	Prescription	4.0	0.1	$ 0.05
3 Manage Patient Compliance / Provide Consultation				-	$ -
4 Manage Anticipated Changes in Anticoagulant Change				-	$ -
5 Communication & Documentation				-	$ -
6 Claim filing with Medicare				-	$ -
7 Accounts receivable mgmt. & collection				-	$ -
Total Supply Costs to Generate:					
1 Controlled, Billable INR Value				**1.4**	**$ 21.42**
4 Controlled, Billable INR Values				**5.7**	**$ 85.66**

	Comments	Reference	Best Care Guidelines
2 a)	Adjusted to account for QC controls	Roche, ITC & LifeScan Estimated Averages	5.1
2 a)	Expected # of INR Values Reported Per Year (Avg. of 8-13 Values / Prescription)	42 Per CMS Meeting 2/28/02	5.1
2 b)	Patients instructed to re-test prior to physician action whenever INR significantly out of range	Estimation based on 2 Year Transitional	10.1
2 c)	Accidental product spoilage due to abuse, storage, environmental conditions, etc.	Study @ Loma Linda VA Medical Center:	5.1
2 d)	Patients instructed to re-test whenever error is generated (e.g. insufficient blood, temperature)	" "	5.1
2 e)	Quarterly Rx for 8-13 INR Values	Per CMS Meeting 2/28/02	5.1
2 f)	Quarterly Rx for 8-13 INR Values	Per CMS Meeting 2/28/03	5.1
7 a)	% of Non-collectable Co-Pay Amounts	Estimation by Raytel Medical Inc.	5.1

CMS
Home INR Monitoring
Practice Expense RVU's

Recurring Technical - Equipment (RT-E) (G-0249) Home prothrombin time (INR) monitoring for anticoagulation management, receipt of results and report only. Care cuidelines / Details	Assumptions Unit Value	Per Event	Occurrence Rate	Equipment Units/Visit	Cost/Unit	Value
Est. Avg.						
1 **Process Order**						
2 **Dispense Supplies & Equipment for Monitoring INR**						
a) Provide Home INR Monitoring Equipment	$2,341.67	Per New or Re-Initiated Patient	48	0.006	$	14.74
b) Adjustment for Patient Fall-Out	$2,341.67	Year	15.3%	0.001	$	2.25
c) Financing Cost of Meter	16%	Year			$	4.93
3 **Manage Patient Compliance / Provide Consultation**				-	$	-
4 **Manage Anticipated Changes in Anticoagulant Change**				-	$	-
5 **Communication & Documentation**				-	$	-
6 **Claim filing with Medicare**				-	$	-
7 **Accounts receivable mgmt. & collection**				-	$	-
				-	$	-
Total Equipment Costs to Generate:				-	$	-
1 Controlled, Billable INR Value				**0.007**	$	**21.92**
4 Controlled, Billable INR Values				**0.029**	$	**87.66**

Comments		Reference	Best Care Guidelines
2 a) Expected useful life of equipment		Roche, ITC & LifeScan Estimated Averages	5.1
2 b) Patient Fall-Out :			5.1
Mortality	2.5%	St. Jude Medical: 5% 1st Year, 1.25% Years 2 -3	
Other (Incapacitation/Relocation/Etc.)	12.8%	Ann Thorac Surg 2001;72:1523-7	
Total % Meters Whose Acquisition Costs Not Fully Recovered by IDTF	15.3%		
2 c) Average consumer credit charge			5.1
7 a) % of Non-collectable Co-Pay Amounts		Estimation by Raytel Medical Inc.	5.1

CMS
Home INR Monitoring
Practice Expense RVU's

	Recurring Technical - Summary (RT) (G-0249) Home prothrombin time (INR) monitoring for anticoagulation management, receipt of results and report only. Care coordinator/ nurse	Cost / INR Value Clinical RT - C	Admin RT - A	Supplies RT - S	Equipment RT - E	Summary RT	Required By Rest Practice	Required By 9/18/2001 Coverage Memorandum
RT-	1 **Process Order**	$ -	$ 0.17	$ -	$ -	$ 0.17	5	
RT-	2 **Dispense Supplies & Equipment for Monitoring INR**	$ 0.30	$ -	$ 21.42	$ 21.92	$ 43.63	5	√
RT-	3 **Manage Patient Compliance / Provide Consultation**	$ 2.84	$ 0.02	$ -	$ -	$ 2.86	8,10	√
RT-	4 **Manage Anticipated Changes in Anticoagulant Response**	$ 0.02	$ -	$ -	$ -	$ 0.02	8	√
RT-	5 **Communication & Documentation**	$ 0.67	$ 1.76	$ -	$ -	$ 2.43	4	√
RT-	6 **Claim filing with Medicare**	$ -	$ 1.21	$ -	$ -	$ 1.21	5	
RT-	7 **Accounts receivable mgmt. & collection**	$ -	$ 1.41	$ -	$ -	$ 1.41	5	
AVG Based	**Total Recurring Technical Costs to Generate 1 Controlled, Billable INR Value**	$ 3.82	$ 4.57	$ 21.42	$ 21.92	$ 51.72		
	+ Overhead @ 25%	$ 1.27	$ 1.52	$ 7.14	$ 7.31	$ 17.24		
	Total	$ 5.09	$ 6.09	$ 28.55	$ 29.22	$ 68.96		
	Total Recurring Technical Costs to Generate 4 Controlled, Billable INR Values	$ 15.28	$ 18.26	$ 85.66	$ 87.66	$ 206.87		
	+ Overhead @ 25%	$ 5.09	$ 6.09	$ 28.55	$ 29.22	$ 68.96		
	Total	$ 20.38	$ 24.35	$ 114.22	$ 116.88	$ 275.83		

CMS
Home INR Monitoring
Practice Expense RVU's

Initiation Technical - Clinical (IT-C)	Assumptions				Clinical Labor	
(G-0248) Home prothrombin time (INR) monitoring for anticoagulation management, provision of home monitor and initial test strips, with training and test transmissions.	Staff Type	Time in Minutes	Per Event	Occurrence Rate	Labor Rate/Hr	$ 30.00
Care Guidelines (Direct)					Unit/Duration	Cost/Initiation
1 Patient Selection & Assessment						
a) Verify & document Patient has received required training before releasing equipment & strips	Pharmacist	5.00	Per Initiation		5.00	$ 2.50
2 Initiation of Therapy						
a) Contact patient to explain IDTF service	RN/LPN/MA	10.00	Per Initiation		10.00	$ 5.00
b) Contact Physician Office to review patient instructions (Therapeutic Range & Notification)	RN/LPN/MA	5.00	Per Initiation		5.00	$ 2.50
3 Patient Education	RN/LPN/MA	120.00	Per Initiation		120.00	$ 60.00
4 Claim filing with Medicare						
5 Accounts receivable mgmt. & collection						
Total Initiation Technical - Clinical Costs for New or Re-Initiated Patient					**140.00**	**$ 70.00**

	Comments	References	Best Care Guidelines
1 a)	Prescription product required dispensing in accordance with FDA requirements.	510(k) Clearance	4.1
2 a)	Similar to Initiation of EKG & Holter Monitoring Services	Estimation by Raytel Medical Inc.	9.1
2 b)	Similar to Initiation of EKG & Holter Monitoring Services	Estimation by Raytel Medical Inc.	7.1

CMS
Home INR Monitoring
Practice Expense RVU's

Initiation Technical - Administrative (IT-A) (G-0248) Home prothrombin time (INR) monitoring for anticoagulation management, provision of home monitor and initial test strips, with training and transmission of results	Assumptions				Administrative Labor		
Care Guidelines Section	Staff Type	Time in Minutes	Per Event	Occurrence Rate	Labor Rate/hr $ 14.50 Units/minutes		Compensation
1 Patient Selection & Assessment							
2 Initiation of Therapy							
a) Create Patient Record (Demographic & Insurance Data)	Admin Staff	15.00	Per Initiation		15.00	$	3.63
b) Send copy of Patient Record to Physician's Office for final review & confirmation	Admin Staff	5.00	Per Initiation		5.00	$	1.21
3 Patient Education							
4 Claim filing with Medicare							
a) Submit claims for New & Re-Initiated Patients in month	Admin Staff	5.00	Per Initiation		5.00	$	1.21
5 Accounts receivable mgmt. & collection							
a) Bill Patient Co-Pay	Admin Staff	5.00	Per Initiation		1.43	$	0.35
b) Follow-up on Past Due Accounts	Admin Staff	5.00	Per Initiation	16%	0.23	$	0.06
c) Write-off for Non-collectible Accounts				8%		$	3.82
Total Initiation Technical - Administrative Costs for New or Re-Initiated Patient					**26.66**	**$**	**10.26**

	Comments	Reference	Best Care Guidelines
2	a) Process similar to other Cardiovascular Monitoring Services	Estimation by Raytel Medical Inc.	7.1
2	b) Process similar to other Cardiovascular Monitoring Services	Estimation by Raytel Medical Inc.	7.1
4	a) Process similar to other Cardiovascular Monitoring Services	Estimation by Raytel Medical Inc.	5.1
5	a) Process similar to other Cardiovascular Monitoring Services	Estimation by Raytel Medical Inc.	5.1
5	b) % of Patients who do not pay on schedule	Estimation by Raytel Medical Inc.	5.1
5	c) % of Non-collectible Co-Pay Amounts	Estimation by Raytel Medical Inc.	5.1

CMS
Home INR Monitoring
Practice Expense RVU's

Initiation Technical - Supplies (IT-S) (G-0248) Home prothrombin time (INR) monitoring for anticoagulation management, provision of home monitor and initial test strips, with training and test transmissions. Care Guidelines / Details	Assumptions Unit Value	Per Event	Occurrence Rate	Supplies Units/Initiation	Cost/Initiation
1 Patient Selection & Assessment					
a) Test Strips required to support & validate Patient Training	$ 16.39	Per Strip	4	4.00	$ 65.56
b) Express ship strips to patients	$ 29.00	Per Initiation	1	1.00	$ 29.00
2 Initiation of Therapy					
a) Provide Spring-Powered Device for Lancing	$ 17.21	Per Initiation	1	1.00	$ 17.21
b) Provide Lancets per Box of 200	$ 24.30	Per Initiation	1	1.00	$ 24.30
c) Provide Batteries	$ 0.64	Per Initiation	3	3.00	$ 1.92
d) Provide for Refurbishment & Re-qualification of Meters for Non-Compliant Patients	$ 250.00	Per Refurbishment	10.8%	0.11	$ 27.00
3 Patient Education					
a) Provide Printed Education & Training Materials	$ 1.00	Per Initiation	1	1.00	$ 1.00
b) Provide Video/CDRom Education & Training Materials	$ 2.50	Per Initiation	1	1.00	$ 2.50
4 Claim filing with Medicare					
5 Accounts receivable mgmt. & collection					
Total Initiation Technical - Supply Costs for New or Re-Initiated Patient				**12.11**	**$ 168.49**

Comments	Reference	Best Care Guidelines
1 a) 1 for trainer demo, 3 for patient confirmation	Roche, ITC & LifeScan	6.1
1 b) Quarterly Rx for 8-13 INR Values	Per CMS Meeting 2/28/02	6.1
2 a) Upfront materials needed to initiate therapy (can not be refurbished)	Cross-Walk to A4258	7.3
2 b) Upfront materials needed to initiate therapy (can not be refurbished)	Cross-Walk to A4259	7.3
2 c) Upfront materials needed to initiate therapy (can not be refurbished)	Cross-Walk to A4254	7.3
2 d) Meters Which Can Be Refurbished:		10.3
Failure to Complete Training	6.8% Ann Thorac Surg 2001;72:1523-7	
Non-Compliance (Meter Is Retrievable from Patient)	4.0% LifeScan Clinical Trials shows ~4% discontinuation.	
Allowance for Refurbishment	10.8%	
3 a) FDA Clearance requires appropriate training material	ITC & Roche	9.1
3 b) FDA Clearance requires appropriate training material	ITC & Roche	9.1

CMS
Home INR Monitoring
Practice Expense RVU's

Initiation Technical - Equipment (IT-E)	Assumptions			Equipment	
(G-0248) Home prothrombin time (INR) monitoring for anticoagulation management, provision of home monitor and initial test strips, with training test transmissions	Unit Value	Per Event	Occurrence Rate	Units/Occ.	Cost/INR Value
Care Guidelines / Details					
Est. Avg.					
1 Patient Education					
2 Initiation of Therapy					
a) Provide Home INR Monitoring Equipment	$2,341.67	Per New or Re-Initiated Patient	4	0.006	$ 14.74
b) Adjustment for Patient Fall-Out	$2,341.67	Year	15.3%	0.001	$ 2.25
3 Patient Selection & Assessment					
4 Care Guidelines / Details					
5 Patient Selection & Assessment					
Total Initiation Technical - Equipment Costs for New or Re-Initiated Patient				**0.007**	**$ 16.99**

Comments		Reference	Best Care Guidelines
2 a) Expected useful life of equipment		Roche, ITC & LifeScan Estimated Averages	5.1
2 b) Patient Fall-Out :			5.1
Mortality	2.5%	St. Jude Medical: 5% 1st Year, 1.25% Years 2 -3	
Other (Incapacitation/Relocation/Etc.)	12.8%	Ann Thorac Surg 2001;72:1523-7	
Total % Meters Whose Acquisition Costs Not Fully Recovered by IDTF	15.3%		
2 c) Average consumer credit charge			5.1
7 a) % of Non-collectable Co-Pay Amounts		Estimation by Raytel Medical Inc.	5.1

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Home INR Monitoring
Practice Expense RVU's

Initiation Technical - Summary (IT)		Cost / Initiation					Required By	
(G-0248) Home prothrombin time (INR) monitoring for anticoagulation management, provision of home monitor and initial test strips, with training, test transmissions.		Clinical	Admin	Supplies	Equipment	Summary	Best Care Guidelines	9/15/2001 Coverage Memorandum
Care Guidelines ("Visit"		IT - C	IT - A	IT - S	IT - E	IT		
IT - 1	**Patient Selection & Assessment**	$ 2.50	$ -	$ 94.56	$ -	$ 97.06	6	√
IT - 2	**Initiation of Therapy**	$ 7.50	$ 3.63	$ 70.43	$ 16.99	$ 98.54	7,10	√
IT - 3	**Patient Education**	$ 60.00	$ -	$ 3.50	$ -	$ 63.50	9	√
IT - 4	**Claim filing with Medicare**	$ -	$ -	$ -	$ -	$ -	5	
IT - 5	**Accounts receivable mgmt. & collection**	$ -	$ 4.22	$ -	$ -	$ 4.22	5	
	Total Initiation Technical Costs for New or Re-Initiated Patient	**$ 70.00**	**$ 7.84**	**$ 168.49**	**$ 16.99**	**$ 263.32**		
AVG Based	**Total Recurring Technical Costs to Generate 1 Controlled, Billable INR**	$ 70.00	$ 7.84	$ 168.49	$ 16.99	$ 263.32		
	+ Overhead @ 25%	$ 23.33	$ 2.61	$ 56.16	$ 5.66	$ 87.77		
	Total	$ 93.33	$ 10.45	$ 224.65	$ 22.65	$ 351.09		

CMS
Home INR Monitoring
Best Care Guidelines

1. Qualifications of Personnel					
1.1 Anticoagulation providers should meet minimum competencies and hold a license in a patient-oriented health-related field (e.g., medicine, nursing, pharmacy).	X				
2. Supervision					
2.1 The physician or health care provider with ultimate responsibility for therapeutic decisions should develop an agreed-upon policy and procedure for personnel supervision and oversight of those health care providers actually managing the anticoagulation therapy.	X				
3. Care Management and Coordination					
3.1 Written protocols for the management of anticoagulation should be established.	X				
3.2 The anticoagulation provider should have a systematic process to identify patients who need to be scheduled for a blood sample and/or medical assessment, to schedule the necessary appointments, to retrieve laboratory results, and to provide patient instruction and follow-up.	X				
4. Communication and Documentation					
4.1 The anticoagulation provider should have policies and procedures regarding communications with the patient, primary care physician or health care providers, laboratory, and designated pharmacy(ies). Documentation of these interactions, as well as documentation of outcomes assessment, should be recorded in the database of the patient.			X		X
5. Laboratory Monitoring					
5.1 The anticoagulation provider should use the INR to assess patient anticoagulation control.					X
6. Patient Selection and Assessment					
6.1 The referring physician or health care provider recommending anticoagulation therapy shall determine the appropriateness of anticoagulation therapy for a particular patient. The actual anticoagulation provider or director of the service, in order to manage the care, must agree on the appropriateness of the therapy.		X			
6.2 The anticoagulation provider should assess the patient's current medical, medication, dietary, and lifestyle history; level of understanding and literacy; health beliefs and attitudes; motivation for self-care behavior; and other environmental or behavioral barriers to learning and adherence when therapy is instituted.		X			
7. Initiation of Therapy					
7.1 A patient-specific INR range based on the medical literature and other patient specific-information, should be established.		X	X		
7.2 The anticoagulation provider should base dosage adjustments on INR and other pertinent laboratory results, individual assessment, patient-specific response, and guidelines approved by the anticoagulation service as part of its policies and procedures.				X	
7.3 Initial monitoring should occur every week or more frequently following initiation of therapy or hospital discharge, depending on the stability of the patient. After the patient's anticoagulation has been stabilized, follow-up evaluation should occur at least every four weeks.					X
8. Maintenance and Management of Therapy					
8.1 The anticoagulation provider should have a systematic process for follow-up evaluations focused on patient assessment for potential side effects of therapy; recurrent disease; hemmorrhagic complications; drug-drug/drug-disease state and drug-food interactions; lifestyle changes; review of laboratory results; adherence issues; and patient education.				X	X
8.2 The anticoagulation provider should have a policy on the interval for follow-up blood testing after a dosage adjustment has been made. The determination should consider the magnitude of the nontherapeutic INR and dosage change, as well as other variables influencing patient responsiveness and stability.				X	X
8.3 Anticoagulation providers should develop guidelines regarding management of anticipated changes in anticoagulant response that result from a change in patient status, medication use, diet, or other factors.				X	X
9. Patient Education					
9.1 The anticoagulation provider should have a policy and procedure pertaining to the desired goals and objectives of its educational program. Patient education should be individualized according to the initial assessment, based on the patient's level of understanding; be accompanied by written information as a reinforcement; and be reviewed on a regular basis.		X	X		
10. Management and Triage of Therapy-Related and Unrelated Problems					
10.1 Anticoagulation providers should have a policy and procedure for the management of major and minor bleeding episodes, signs and symptoms of thromboembolism, other potential anticoagulation side effects, or other medical problems not related to anticoagulation therapy. This should include the use of vitamin K or fresh-frozen plasma to correct an excessively prolonged INR or to treat serious hemorrhage.				X	
10.2 Anticoagulation providers should have a policy and procedure for the management of anticoagulation when the patient requires and invasive procedure.				X	X
10.3 Anticoagulation providers should have a policy and procedure for the management of patients who are nonadherent with therapy, appointments, or other aspects of anticoagulation treatment. This policy should include guidelines for termination of anticoagulation management by the anticoagulation service.					X
11. Organizational components					
11.1 The anticoagulation provider should perform a program evaluation of organizational components on an annual basis or more often as deemed necessary. Anticoagulation providers should analyze the contribution of various processes to patient outcomes.	X				
12. Patient Outcomes					
12.1 The anticoagulation provider should perform an outcomes evaluation on an annual basis or more often as deemed necessary. This outcome assessment should include, as a minimum, information pertaining to degree of therapeutic effectiveness as determined by the INR, hemorrhagic complication rates, thromboembolism rates, and other complications resulting from anticoagulant therapy.	X				X

CMS
Home INR Monitoring
Practice Expense RVU's

Recurring Technical Supervision (T1-3)	Assumptions				Supplies	
	Unit Cost	Per Period	Occurrence Rate	Comments	Quantities	Extended Value
Company Specific Assumptions						
Roche - CoaguChek						
1 Process Order						
2 Dispense Supplies & Equipment for Monitoring INR						
a) Test Strips to Generate 1 Controlled INR Value	$ 23.00	Per Strip	1.0		1.00	$ 23.00
b) Re-test due to Reconfirm Extreme Out of Ranges	$ 23.00	Year	4.0		0.10	$ 2.19
c) Re-test due to Testing Errors (e.g.. Insufficient Blood,Temperatures, Insertion, QC Checks, etc.)	$ 23.00	Year	4.3	Patient Error Rate during LifeScan 2 Yr. Transition Study	0.10	$ 2.37
d) Product Spoilage	$ 23.00	Year	2.0	Estimated waste due to spoilage	0.05	$ 1.10
e) Express ship strips to patients	$ 10.00	Prescription	4.0	Quarterly Rx for 8-13 INR Values	0.10	$ 0.95
f) Insurance on Product Shipments	0.50	Prescription	4.0	Quarterly Rx for 8-13 INR Values	0.10	$ 0.05
3 Manage Patient Compliance / Provide Consultation						
4 Manage Anticipated Changes in Anticoagulant Change						
5 Communication & Documentation						
6 Claim filing with Medicare						
7 Accounts receivable mgmt. & collection						
Total Supply Costs to Generate 1 Controlled, Billable INR Value					1.44	$ 29.65
ITC - ProTime						
1 Process Order						
2 Dispense Supplies & Equipment for Monitoring INR						
a) Test Strips to Generate 1 Controlled INR Value	$ 13.00	Per Strip	1.0		1.00	$ 13.00
b) Re-test due to Reconfirm Extreme Out of Ranges	$ 13.00	Year	4.0		0.10	$ 1.24
c) Re-test due to Testing Errors (e.g.. Insufficient Blood,Temperatures, Insertion, QC Checks, etc.)	$ 13.00	Year	4.3	Patient Error Rate during LifeScan 2 Yr. Transition Study	0.10	$ 1.34
d) Product Spoilage	$ 13.00	Year	2.0	Estimated waste due to spoilage	0.05	$ 0.62
e) Express ship strips to patients	$ 10.00	Prescription	4.0	Quarterly Rx for 8-13 INR Values	0.10	$ 0.95
f) Insurance on Product Shipments	0.50	Prescription	4.0	Quarterly Rx for 8-13 INR Values	0.10	$ 0.05
3 Manage Patient Compliance / Provide Consultation						
4 Manage Anticipated Changes in Anticoagulant Change						
5 Communication & Documentation						
6 Claim filing with Medicare						
7 Accounts receivable mgmt. & collection						
Total Supply Costs to Generate 1 Controlled, Billable INR Value					1.44	$ 17.19
HemoSense - INRatio						
1 Process Order						
2 Dispense Supplies & Equipment for Monitoring INR						
a) Test Strips to Generate 1 Controlled INR Value	$ 13.17	Per Strip	1.0		1.00	$ 13.17
b) Re-test due to Reconfirm Extreme Out of Ranges	$ 13.17	Year	4.0		0.10	$ 1.25
c) Re-test due to Testing Errors (e.g.. Insufficient Blood,Temperatures, Insertion, QC Checks, etc.)	$ 13.17	Year	4.3	Patient Error Rate during LifeScan 2 Yr. Transition Study	0.10	$ 1.35
d) Product Spoilage	$ 13.17	Year	2.0	Estimated waste due to spoilage	0.05	$ 0.63
e) Express ship strips to patients	$ 10.00	Prescription	4.0	Quarterly Rx for 8-13 INR Values	0.10	$ 0.95
f) Insurance on Product Shipments	0.50	Prescription	4.0	Quarterly Rx for 8-13 INR Values	0.10	$ 0.05
3 Manage Patient Compliance / Provide Consultation						
4 Manage Anticipated Changes in Anticoagulant Change						
5 Communication & Documentation						
6 Claim filing with Medicare						
7 Accounts receivable mgmt. & collection						
Total Supply Costs to Generate 1 Controlled, Billable INR Value					1.44	$ 17.40

CMS
Home INR Monitoring
Practice RVU's

Recurring Technical - Equipment (NTE)	Assumptions				Equipment			
	Unit Value	Per	Occurrence Rate					
Roche - CoaguChek								
1 Process Order								
2 Dispense Supplies & Equipment for Monitoring INR								
a) Provide Home INR Monitoring Equipment	$ 2,135.00	Per New or Re-Initiated Patient	60	Expected useful life of equipment	0.005	$	10.17	5.1
b) Adjustment for Patient Fall-Out	$ 2,135.00	Year	15.3%	Patients who discontinue each year.	0.001	$	1.55	5.1
c) Financing Cost of Meter	10%	Year	36	Expected useful life of equipment			$3.69	5.1
3 Manage Patient Compliance / Provide Consultation								
4 Manage Anticipated Changes in Anticoagulant Change								
5 Communication & Documentation								
6 Claim filing with Medicare								
7 Accounts receivable mgmt. & collection								
Total Equipment Costs to Generate 1 Controlled, Billable INR Value					0.005	$	15.40	
ITC - ProTime								
1 Process Order								
2 Dispense Supplies & Equipment for Monitoring INR								
a) Provide Home INR Monitoring Equipment	$ 2,495.00	Per New or Re-Initiated Patient	36	Expected useful life of equipment	0.008	$	19.80	5.1
b) Adjustment for Patient Fall-Out	$ 2,495.00	Year	15.3%	Patients who discontinue each year.	0.001	$	3.02	5.1
c) Financing Cost of Meter	10%	Year	36	Expected useful life of equipment			$4.31	5.1
3 Manage Patient Compliance / Provide Consultation								
4 Manage Anticipated Changes in Anticoagulant Change								
5 Communication & Documentation								
6 Claim filing with Medicare								
7 Accounts receivable mgmt. & collection								
Total Equipment Costs to Generate 1 Controlled, Billable INR Value					0.009	$	27.13	
HemoSense - INRatio								
1 Process Order								
2 Dispense Supplies & Equipment for Monitoring INR								
a) Provide Home INR Monitoring Equipment	$ 2,395.00	Per New or Re-Initiated Patient	48	Expected useful life of equipment	0.006	$	14.26	5.1
b) Adjustment for Patient Fall-Out	$ 2,395.00	Year	15.3%	Patients who discontinue use	0.001	$	2.17	5.1
c) Financing Cost of Meter	16%	Year	36	Expected useful life of equipment			$6.78	5.1
3 Manage Patient Compliance / Provide Consultation								
4 Manage Anticipated Changes in Anticoagulant Change								
5 Communication & Documentation								
6 Claim filing with Medicare								
7 Accounts receivable mgmt. & collection								
Total Equipment Costs to Generate 1 Controlled, Billable INR Value					0.007	$	23.21	

Submitter : Dr. Evens Rodney
Organization : Dr. Evens Rodney
Category : Physician

Date: 10/10/2006

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1321-P-824-Attach-1.DOC

BATON ROUGE CARDIOLOGY CENTER

Boyd E. Helm, M.D., F.A.C.C., F.S.C.
Joseph M. Cefalu, M.D., F.A.C
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Evens Rodney, M.D., F.A.C
Darrin M. Breaux, M.D., F.A.C
Boyd M. Helm, M
James R. Calvin, M.D., F.A.C.C., Emeri

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Cardiac Rehabilitation

Pacemaker Implantation & Follow-up

Lipid Management

Syncope Evaluation

Electrophysiologic Studies

Radiofrequency Catheter Ablation

Defibrillation Implantation & Follow-up

October 9, 2006

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

Dear Dr. McClellan:

On behalf of Baton Rouge Cardiology Center and our 11 individual practicing cardiologists, we appreciate the opportunity to submit these comments to the Centers for Medicare & Medicaid Services ("CMS") regarding the above proposed Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B; Proposed Rule ("Proposed Rule"). We are concerned about several provisions that will impact Medicare beneficiaries' access to services in outpatient cardiac centers, particularly those related to cardiac catheterizations. Specifically, we are concerned about the payment method proposed for cardiac catheterization related procedures. The Cardiovascular Outpatient Center Alliance ("COCA"), of which we are a member, will address the CMS proposal to require standards for Independent Diagnostic Testing Facilities ("IDTFs"). Our concerns related to the payment method are outlined below.

Payment Method

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

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

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

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

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

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

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

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

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

Sincerely,

Evens Rodney, M.D., F.A.C.C.

Submitter : **Dr. Darrin Breaux** **Date: 10/10/2006**

Organization : **Dr. Darrin Breaux**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1321-P-825-Attach-1.DOC

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Darrin Breaux, M.D., F.A.C.C.