**Submitter :** Mr. Jack Cumming **Date:** 10/10/2006

**Organization :** Hologic, Inc.

**Category :** Device Industry

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-1321-P-930-Attach-1.TXT

CMS-1321-P-930-Attach-2.DOC

#930-1

HOLOGIC®

October 10, 2006

Dr. Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P
P.O. Box 8014
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

Comments on CPT Codes 76075 (Dual energy X-ray Absorptiometry), 76077 (Vertebral Fracture Assessment), 76082 (Computer Aided Detection, Diagnostic), 76083 (Computer Aided Detection, Screening) and 76095 (Stereotactic Guidance)

Dear Dr. McClellan:

**Summary**

In the Centers for Medicare and Medicaid Services' (CMS) recently- launched public campaign to highlight its shift of focus to preventive medicine, screening procedures for osteoporosis and breast cancer are recognized as key components of this initiative. Conversely, at the same time, CMS published proposed reimbursement cuts to the technical components of DXA (80%), Vertebral Fracture Assessment (49%), Computer Aided Detection (56%), and Stereotactic Guidance (77%). These cuts, if implemented, will have the effect of placing these important screening benefits out of the reach of many Medicare beneficiaries. To reconcile this apparent disharmony, we request that a moratorium be placed on these proposed reimbursement cuts until sufficient data can be collected to allow appropriate and accurate valuation of these critical services. Valuation of these services should take into account the differences between providing services in a screening environment versus a therapeutic setting, the extra efforts and resources needed to maintain a successful, high-quality screen program with optimal utilization rates, and the overall economic benefits to be gained from such programs.

**Introduction**

Hologic, Inc. is pleased to submit comments on the Medicare Program 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 and Medicaid Services (CMS)[1]. Hologic is a leading developer and manufacturer of premium diagnostic and medical imaging systems dedicated to serving the healthcare needs of women. Our core business units are focused on osteoporosis assessment, mammography and breast biopsy. Hologic is in a unique position to appreciate the critical importance of



**HOLOGIC, Inc.** ■ 35 Crosby Drive ■ Bedford, MA 01730 ■ Tel: 781.999.7300 ■ Fax: 781.280.0669 ■ www.hologic.com

early detection of osteoporosis and breast cancer and the responsibility our industry bears to provide technologically superior imaging systems to support high quality screening procedures. Our company and its representatives expend a substantial amount of time and resources each year in promoting public awareness of the need for and benefits of regular screening procedures.

Hologic commends initiatives by the Centers for Medicare and Medicaid Services (CMS) to shift its focus to preventive medicine and wellness programs and to reinforce this direction through appropriate and accurate reimbursement mechanisms. Successful implementation of this visionary direction for CMS will result in decreased morbidity and a better quality of life for Medicare beneficiaries, as well as an overall reduction in healthcare costs due to earlier detection of treatable diseases. Hologic believes this direction is synchronous with the message we promote and the screening services made available through the products we manufacture.

Critical to the successful implementation of this admirable direction is broad, convenient access to high quality screening procedures. We believe the significant cuts which CMS has proposed to the relative value units of the above referenced CPT codes would impede access to these screening and diagnostic services. The result would be outcomes completely contrary to the CMS directive to promote preventive medicine.

**Previous Comments**

Reference is made to Hologic's letter to Dr. Mark McClellan dated August 17, 2006, in response to CMS-1512-PN; Medicare Program Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology. This letter commented on the potential impact dramatic decreases in reimbursement could have on screening services for osteoporosis and breast cancer and for diagnostic procedures for breast biopsy. Osteoporosis and breast cancer are two diseases that become more prevalent as people age. The effects of both diseases can be minimized with early detection, when treatments are most effective, and least traumatic and costly.

Over 10 million Americans currently have osteoporosis and an additional 34 million are at risk for the disease. More than 1.5 million fragility fractures require treatment each year at an annual cost of greater than $18 billion. Despite the existence of high-quality screening technologies to detect the disease, and effective drug therapies to stop or reverse the effects of bone loss, more than 60,000 deaths/year are attributable to osteoporosis-related fractures. Over the last decade, the utilization rate of dual energy x-ray absorptiometry (DXA), the only clinically accepted test for diagnosis of osteoporosis, has risen substantially, due in large part to efforts to make screening equipment available to primary care physicians. Despite these efforts, the utilization rate for DXA is currently less than approximately 20% of the eligible Medicare population. Vertebral fracture assessment (VFA) combined with DXA has the potential to identify future fracture risk



**HOLOGIC, Inc.** ■ 35 Crosby Drive ■ Bedford, MA 01730 ■ Tel: 781.999.7300 ■ Fax: 781.280.0669 ■ www.hologic.com

and permit more effective and earlier pharmacological intervention. This procedure, which is performed in conjunction with DXA, is also considerably under-utilized.

Breast cancer is the most prevalent type of cancer among U.S. women, and is the second leading cause of cancer death in women; however, when detected early, the chance for a successful cure is nearly 100%. One of the newest and most successful technologies to enable earlier detection of breast cancers is computer aided detection (CAD), as an adjunct to screening and diagnostic mammography. CAD has been shown to increase the detection rate of breast cancers by 15% or more, making it possible to use less aggressive and less traumatic treatment while still achieving good clinical outcomes. Despite these known benefits, breast cancer screening rates are sub-optimal.

Once an abnormality in the breast is detected, minimally invasive breast biopsy technologies offer women a safer and less traumatic alternative to open surgical biopsy (OSB); however, more than 650,000 OSB procedures are performed each year, the vast majority of which are not clinically required and could be accomplished by a minimally invasive procedure. Unnecessary OSB procedures result in increased morbidity to the patient and substantially higher costs to the healthcare system.

**Requirements for Successful Screening Programs**

The goal of any screening program should be to achieve close to 100% participation of all eligible individuals. The greater the utilization rate, the more effective the program will be in the early detection of diseases, initiation of minimally traumatic treatment plans, restoration or maintenance of health, and overall long-term reduction of healthcare costs. Multiple components to a screening program must be enacted to achieve maximum compliance, including the following:

- Broad, convenient access to high-quality screening procedures across all geographic and socioeconomic strata. Quality cannot be sacrificed for any patient population;
- Continuous public awareness campaigns by government and public organizations, healthcare providers, and industry representatives;
- Extraordinary efforts by healthcare providers to expand participation to new patients and monitor ongoing compliance in existing patients; and
- Accurate and adequate reimbursement to ensure the availability of equipment and resources required to support high-quality screening procedures.

The above elements are unique to screening programs and require efforts and resources beyond those needed to provide therapeutic services to a typical patient population. Consideration must be given to the special, additional resources required to achieve a successful, nation-wide screening campaign serving the highest possible number of participants.



**HOLOGIC, Inc.** ■ 35 Crosby Drive ■ Bedford, MA 01730 ■ Tel: 781.999.7300 ■ Fax: 781.280.0669 ■ www.hologic.com

Current Utilization Rates for Osteoporosis and Breast Cancer Screening

As noted previously, the utilization rates for osteoporosis and breast cancer screening are sub-optimal and fall far below expectations for a successful screening program. Although bone density screening tests for Medicare recipients increased from 77,133 in 1994 to 2,555,727 in 2004, this number represents less than approximately 20% of the eligible Medicare population. A recent, random sampling of representative Medicare patients revealed that approximately 23% had received bone density screening in a two-year period, providing further validation that the current utilization rate for this screening procedure falls far below what would be considered adequate for a successful screening program.

In 2004, only 37.7% of eligible Medicare recipients in all age groups received screening mammograms[2], indicating that serious constraints exist within our current national breast cancer screening program. A report issued by the U.S. General Accounting Office (GAO) in July 2006 stated that "the loss or absence of mammography machines in certain locations may have resulted in access problems, consisting of lengthy travel distances or considerable wait times, including problems for women who are medically underserved[3]." Impeded access in these areas may be one contributing factor to low utilization of these services by Medicare beneficiaries.

A disturbing trend is also noted in the decreasing number of certified breast cancer screening facilities. In 1999, following enactment of the Mammography Quality Standards Act (MQSA), 9,998 certified mammography facilities existed in the U.S. Today, only 8,832 such facilities continue to exist, although minimal fluctuation is noted in the number of actual systems available[4]. These statistics indicate continuing consolidation of facilities, with ongoing closure of smaller facilities in remote locations.

Financial constraints may also be a key factor in the low utilization rates associated with these technologies. It is difficult to justify the purchase of a piece of equipment that may be used only 20% to 40% of the time, as the investment may take two to three times longer to recoup than that made for a piece of equipment used in a therapeutic setting. In addition, there are significant operational inefficiencies inherent in a screening environment, where patients require more tracking, counseling and follow-up. This becomes a highly significant factor in practices motivated to expand screening services to a larger population of eligible patients.

The current users of screening services are those individuals easiest to reach, who maintain fair to good compliance with screening guidelines. Substantial, additional efforts will be required to expand utilization to the harder to reach patient population, who, whether through geographical limitations or lack of awareness, do not take advantage of regular screening opportunities. Despite the effort involved, utilization rates must be increased to accomplish the commendable goals set forth in the CMS preventive medicine initiative.



**HOLOGIC, Inc.** ■ 35 Crosby Drive ■ Bedford, MA 01730 ■ Tel: 781.999.7300 ■ Fax: 781.280.0669 ■ www.hologic.com

**Effect of Proposed Decreases in Reimbursement on Screening and Diagnostic Services**

The proposed cuts to reimbursement for the technical component for DXA, VFA, CAD, and stereotactic guidance will make it more difficult for practices to justify the cost of purchasing new equipment. In many cases, the proposed cuts may make it impossible for practices with existing systems to continue providing these services. Access to crucial, high-quality screening services will be limited, driving utilization rates down from already unacceptably low levels.

It is well understood that the reimbursement rates for mammography have rendered it a financially marginal service. This circumstance was highlighted in the July 2006 GAO report that voiced serious concerns about the continuing decline in the number of radiologists and technologists entering the specialty, warning that the lack of trained specialists will hinder access to screening services, particularly in traditionally underserved areas[3]. Reasons for this decline include poor reimbursement, lack of financial incentives, and the high rate of malpractice claims brought against the specialty.

In addition, in a recent reader poll, over 80 percent of respondents said the plan by CMS to cut CAD reimbursement nearly in half by 2010 would have a dramatic impact on their decision to adopt the modality[5]. With CAD penetration currently below 50% of the existing mammography facilities, this decrease could cripple the ability of physicians to offer the highest quality screening services to the broadest patient population.

**Policy Considerations**

Traditionally, CMS has calculated payment rates based on an average mix of patients in a typical therapeutic setting, where it is possible for a moderately active practice to operate efficiently and cost-effectively. Based on the low utilization rates for screening services and the greater resource demands associated with a screening environment, consideration must be given to whether this is the most appropriate pricing model to use for these services.

Limited data have been collected to date which would accurately reflect the real costs associated with the delivery of these screening services. Likewise, no data exist to reflect the resources that will be required to accelerate widespread adoption of osteoporosis and breast cancer screening, and to increase utilization rates to a level that would ensure successful nationwide screening programs. It would be counter-productive to implement the currently proposed reimbursement cuts, which are based on data not reflective of the special resource requirement inherent in a screening environment, or of the objectives of CMS's fledgling preventive medicine program. The program might be better served by adopting a more moderate interim position.

There may be pathways that can be pursued to support the CMS preventive medicine movement without creating unintended consequences for other services. For instance,



**HOLOGIC, Inc.** ■ 35 Crosby Drive ■ Bedford, MA 01730 ■ Tel: 781.999.7300 ■ Fax: 781.280.0669 ■ www.hologic.com

CMS can announce publicly that reimbursement rates will be held at current levels for DXA, VFA, CAD, and stereotactic guidance, while data are collected to establish appropriate and accurate pricing models and formulas. A mechanism can be established to collect the needed data, either through an independent commission, a public advisory process, a collaboration between MedPac, RUC, and practicing physicians, or any other available process.

Relevant data to be collected may include:

- Actual equipment utilization rates in an established practice;
- Potential equipment utilization rates in sparsely populated locations;
- Additional staff time required to track compliance and counsel patients;
- Unavoidable inefficiencies associated with delivery of services in a screening environment;
- In mammography facilities, additional resources needed to achieve compliance to MQSA requirements; and
- Additional "value" factor associated with pursuit of preventive medicine initiatives.

**Conclusion**

We believe that public health is served by ensuring access to screening services for bone mass measurement, high quality mammography, and minimally invasive breast biopsy technologies. It is also in accord with the CMS initiative to focus on preventive medicine. We strongly encourage CMS to carefully analyze the impact these proposed decreases in reimbursement will have on the viability of its newly launched preventive medicine program and to consider placing a moratorium on these decreases until appropriate data can be collected to allow appropriate and accurate valuation of these critical services.

We trust that these comments will be useful to CMS as it considers revisions to the practice expense methodology of the MPFS. We look forward to further dialogue on this issue and encourage CMS to contact us promptly with any questions, comments, or requests for additional information. We will be pleased to cooperate with CMS and provide any assistance we can in helping to determine the most appropriate way to ensure these valuable screening services remain highly accessible.

Sincerely,

Jack Cumming
Chairman and CEO



**HOLOGIC, Inc.** ■ 35 Crosby Drive ■ Bedford, MA 01730 ■ Tel: 781.999.7300 ■ Fax: 781.280.0669 ■ www.hologic.com

**References**


1. 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 with comment period, 71 Fed. Reg. (August 22, 2006).

2. Centers for Medicare and Medicaid Services; Mammography Claims Data Tables; Calendar Year National and State Mammography Data by Age Group.

3. United States Government Accountability Office Report to Congress, "Mammography: Current Nationwide Capacity is Adequate, but Access Problems May Exist in Certain Locations." July 2006. GAO-06-724

4. U.S. Food and Drug Administration, Center For Devices and Radiological Health; MQSA National Statistics, updated October 1, 2006.

5. Health Imaging News; August 31, 2006; Headline News.




**HOLOGIC, Inc.** ■ 35 Crosby Drive ■ Bedford, MA 01730 ■ Tel: 781.999.7300 ■ Fax: 781.280.0669 ■ www.hologic.com

#930-2

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 :** **Ms. Dawn Hopkins** **Date: 10/10/2006**

**Organization :** **Multi-Specialty - ACC, ACR, SCAI, SIR**

**Category :** **Health Care Provider/Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-1321-P-931-Attach-1.PDF

CMS-1321-P-931-Attach-2.PDF

#931-1

# ACC ** ACR ** SCAI ** SIR

*Working collaboratively to assure patient access to minimally invasive interventional procedures.*

October 10, 2006

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

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

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

Dear Administrator McClellan/Norwalk:

In addition to comments submitted by each individual society regarding the "Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B [CMS-1321-P]" - proposed rule, the American College of Cardiology (ACC), American College of Radiology (ACR), Society for Cardiovascular Angiography and Interventions (SCAI), and Society of Interventional Radiology (SIR), representing more than 75,000 physicians, have come together in agreement to offer the following joint comments regarding CMS' proposed definition of imaging and identification of specific codes subject to the Deficit Reduction ACT (DRA) reimbursement cap.

For purposes of defining imaging services subject to the technical component payment cap of the lesser of the HOPPS APC rate or technical component Physician Fee Schedule reimbursement rate by the DRA, CMS has proposed defining imaging as "services provid[ing] visual information regarding areas of the body that are not normally visible, thereby assisting in the diagnosis or treatment of illness or injury." We find this proposed definition to be overly broad and, theoretically, even applicable to open surgical techniques. Believing further refinement is necessary, the ACC, ACR, SCAI, and SIR support that imaging should be defined as follows:

***Medical Imaging uses noninvasive techniques to view all parts of the body and thereby diagnose an array of medical conditions. These techniques include the use of ionizing radiation (x-rays and CT scans), Magnetic Resonance Imaging, ultrasound and scans obtained after the injection of radio nucleotides (bone scans, PET imaging etc).***

Another type of distinctly different "imaging" is the use of real-time, imaging guidance to guide minimally invasive diagnostic and therapeutic procedural interventions such as percutaneous angioplasty, hepatic embolization or cardiac catheterization. In these types of procedures, imaging is essential in that it is used to guide the placement of catheters, balloons, stents, and other medical devices. Such imaging would never be provided in the absence of minimally invasive diagnostic procedures and interventions and without this type of imaging only open surgical procedures would be possible.

The ACC, ACR, SCAI, and SIR do not believe that this type of real-time, imaging guidance was the intended focus of the DRA imaging reimbursement cap. These imaging guidance services are differentiated within CPT by the inclusion of the nomenclature "radiological supervision and interpretation" or "imaging supervision and interpretation" within the code descriptors and we assert that these services are not subject to the DRA reimbursement cap.

We appreciate the opportunity to provide comment on this issue. If you have any questions regarding the practical application of radiological supervision and interpretation (RS&I) and imaging supervision and interpretation (IS&I) services provided in direct support of the performance of interventional procedures, please feel free to contact any of our staff members to facilitate a meeting and/or teleconference to discuss with any of the society representatives endorsing this document. Staff contact information is as follows:

Denise Garris, Associate Director, Regulatory and Legal Affairs
American College of Cardiology
Phone: (202) 375-6496; Email: dgarris@acc.org

Angela J. Choe, Senior Analyst, ACR
American College of Radiology
Phone: (703) 648-8900, ext. 4556; Email: AChoe@acr.org

Wayne Powell, Sr. Director for Advocacy and Guidelines
Society for Cardiovascular Angiography and Interventions
Phone: (202) 375-6341; Email: wpowell@scai.org

Dawn R. Hopkins, Director of Reimbursement & Health Policy
Society of Interventional Radiology
Phone: (703) 691-1805; Email: Hopkins@SIRweb.org.

Sincerely,

*[Endorsed copy mailed this day]*

Steven E. Nissen, MD, FACC
President,
American College of Cardiology

*[Endorsed copy mailed this day]*

John A. Patti, MD, FACR
Chair, Commission on Economics
American College of Radiology

*[Endorsed copy mailed this day]*

Gregory J, Dehmer, M.D., FSCAI
President
Society for Cardiovascular Angiography and Interventions

*[Endorsed copy mailed this day]*

Richard A. Baum, MD
IR CAC Network Chair
Society of Interventional Radiology

*[Endorsed copy mailed this day]*

Gary P. Siskin, MD
Economics Committee Chair
Society of Interventional Radiology

*[Endorsed copy mailed this day]*

Sean M. Tutton, MD
Economics Chair
Society of Interventional Radiology

CC: Kenneth Simon, MD, CMS
Edith Hambrick, MD, CMS
Katharine L. Krol, MD, SIR
Michael E. Edwards, MD, SIR
Bibb Allen, MD, FACR, ACR
Denise Garris, ACC
Angela Choe, ACR
Wayne Powell, SCAI
Dawn R. Hopkins, SIR

*American College of Cardiology*
*9111 Old Georgetown Road*
*Bethesda, MD 20814-1699*

*American College of Radiology*
*1891 Preston White Drive*
*Reston, VA 20191-4397*

*Society for Cardiovascular Angiography and Interventions*
*9111 Old Georgetown Road*
*Bethesda, MD 20814-1699*

*Society of Interventional Radiology*
*3975 Fair Ridge Drive, Suite 400 North*
*Fairfax, VA 22033*

#931 - 2

# ACC ** ACR ** SCAI ** SIR

***Working collaboratively to assure patient access to minimally invasive interventional procedures.***

October 10, 2006

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

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

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

Dear Administrator McClellan/Norwalk:

In addition to comments submitted by each individual society regarding the "Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B [CMS-1321-P]" - proposed rule, the American College of Cardiology (ACC), American College of Radiology (ACR), Society for Cardiovascular Angiography and Interventions (SCAI), and Society of Interventional Radiology (SIR), representing more than 75,000 physicians, have come together in agreement to offer the following joint comments regarding CMS' proposed definition of imaging and identification of specific codes subject to the Deficit Reduction ACT (DRA) reimbursement cap.

For purposes of defining imaging services subject to the technical component payment cap of the lesser of the HOPPS APC rate or technical component Physician Fee Schedule reimbursement rate by the DRA, CMS has proposed defining imaging as "services provid[ing] visual information regarding areas of the body that are not normally visible, thereby assisting in the diagnosis or treatment of illness or injury." We find this proposed definition to be overly broad and, theoretically, even applicable to open surgical techniques. Believing further refinement is necessary, the ACC, ACR, SCAI, and SIR support that imaging should be defined as follows:

***Medical Imaging uses noninvasive techniques to view all parts of the body and thereby diagnose an array of medical conditions. These techniques include the use of ionizing radiation (x-rays and CT scans), Magnetic Resonance Imaging, ultrasound and scans obtained after the injection of radio nucleotides (bone scans, PET imaging etc).***

Another type of distinctly different "imaging" is the use of real-time, imaging guidance to guide minimally invasive diagnostic and therapeutic procedural interventions such as percutaneous angioplasty, hepatic embolization or cardiac catheterization. In these types of procedures, imaging is essential in that it is used to guide the placement of catheters, balloons, stents, and other medical devices. Such imaging would never be provided in the absence of minimally invasive diagnostic procedures and interventions and without this type of imaging only open surgical procedures would be possible.

The ACC, ACR, SCAI, and SIR do not believe that this type of real-time, imaging guidance was the intended focus of the DRA imaging reimbursement cap. These imaging guidance services are differentiated within CPT by the inclusion of the nomenclature "radiological supervision and interpretation" or "imaging supervision and interpretation" within the code descriptors and we assert that these services are not subject to the DRA reimbursement cap.

We appreciate the opportunity to provide comment on this issue. If you have any questions regarding the practical application of radiological supervision and interpretation (RS&I) and imaging supervision and interpretation (IS&I) services provided in direct support of the performance of interventional procedures, please feel free to contact any of our staff members to facilitate a meeting and/or teleconference to discuss with any of the society representatives endorsing this document. Staff contact information is as follows:

Denise Garris, Associate Director, Regulatory and Legal Affairs
American College of Cardiology
Phone: (202) 375-6496; Email: dgarris@acc.org

Angela J. Choe, Senior Analyst, ACR
American College of Radiology
Phone: (703) 648-8900, ext. 4556; Email: AChoe@acr.org

Wayne Powell, Sr. Director for Advocacy and Guidelines
Society for Cardiovascular Angiography and Interventions
Phone: (202) 375-6341; Email: wpowell@scai.org

Dawn R. Hopkins, Director of Reimbursement & Health Policy
Society of Interventional Radiology
Phone: (703) 691-1805; Email: Hopkins@SIRweb.org.

Sincerely,

*[Endorsed copy mailed this day]*

Steven E. Nissen, MD, FACC
President,
American College of Cardiology

*[Endorsed copy mailed this day]*

John A. Patti, MD, FACR
Chair, Commission on Economics
American College of Radiology

*[Endorsed copy mailed this day]*

Gregory J, Dehmer, M.D., FSCAI
President
Society for Cardiovascular Angiography and Interventions

*[Endorsed copy mailed this day]*

Richard A. Baum, MD
IR CAC Network Chair
Society of Interventional Radiology

*[Endorsed copy mailed this day]*

Gary P. Siskin, MD
Economics Committee Chair
Society of Interventional Radiology

*[Endorsed copy mailed this day]*

Sean M. Tutton, MD
Economics Chair
Society of Interventional Radiology

CC: Kenneth Simon, MD, CMS
Edith Hambrick, MD, CMS
Katharine L. Krol, MD, SIR
Michael E. Edwards, MD, SIR
Bibb Allen, MD, FACR, ACR
Denise Garris, ACC
Angela Choe, ACR
Wayne Powell, SCAI
Dawn R. Hopkins, SIR

*American College of Cardiology*
*9111 Old Georgetown Road*
*Bethesda, MD 20814-1699*

*American College of Radiology*
*1891 Preston White Drive*
*Reston, VA 20191-4397*

*Society for Cardiovascular Angiography and Interventions*
*9111 Old Georgetown Road*
*Bethesda, MD 20814-1699*

*Society of Interventional Radiology*
*3975 Fair Ridge Drive, Suite 400 North*
*Fairfax, VA 22033*

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

**Organization :** American Society of Clinical Oncology

**Category :** Physician

**Issue Areas/Comments**

**GENERAL**

GENERAL

See attachment

CMS-1321-P-932-Attach-1.DOC

CMS-1321-P-932-Attach-2.DOC

#932-1

ASCO®
AMERICAN SOCIETY OF CLINICAL ONCOLOGY



October 10, 2006

Mark McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

**Re: CMS-1321-P Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for CY 2007**

Dear Dr. McClellan:

These comments are submitted by the American Society of Clinical Oncology (ASCO) in response to the proposed changes to the Medicare physician fee schedule and other proposed changes to payment under Part B that were published in the Federal Register on August 22, 2006. ASCO is the national organization representing physicians who specialize in the treatment of cancer.

## DRA Proposals – Multiple Imaging Procedures

CMS previously adopted a policy of reducing payment for the technical component of the second and subsequent procedures in each of eleven families of imaging procedures. The reduction was 25% in 2006, and CMS had announced that the reduction would increase to 50% for 2007. CMS is proposing to maintain the current reduction at 25% in 2007, rather than moving to a 50% reduction as previously announced. Any reduction exceeding the current 25% would be preceded by further rulemaking.

ASCO supports the proposal to refrain from further reductions in the payment amounts for multiple imaging procedures. If CMS proposes additional reductions in the future, any such proposal should be supported by definitive data demonstrating the actual amount of cost savings incurred in providing multiple imaging procedures in the same encounter.

## ASP Issues

- **Additional Comment**

CMS is seeking additional comment on all aspects of the policy governing manufacturers reporting the average sales price (ASP) for their products. While

ASCO does not have comments on specific ASP reporting issues, we encourage CMS to provide extensive guidance on the proper method of calculating ASP. We are concerned that the current lack of instructions on many ASP reporting issues may cause manufacturers, acting conservatively, to report ASPs that are inaccurately low. Any such behavior would result in inappropriately low Medicare payment amounts that do not adequately reflect the prices that physicians pay for drugs. Proposed guidance should be subject to public comment before it is adopted.

- **Fees Not Considered To Be Price Concessions**

The notice addresses the issue of including administrative fees, service fees, and fees paid to pharmacy benefit managers in the ASP calculation. CMS proposes that a fee would not be considered a price concession if it meets the following criteria:

  - The fee must "represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement."
  - The fee must not be "passed on in whole or in part to a client or customer" of the entity furnishing the service, "whether or not the entity takes title to the drug."
  - In determining the fair market value for the service, CMS would continue its current policy that it generally means the same amount that the drug manufacturer would have paid if the services had been furnished by other entities.

ASCO is concerned that this proposed definition of a service fee could cause legitimate service fees to be regarded as price concessions, thereby lowering the ASP and the Medicare payment amount. In particular, the requirement that the fee must be for a service that "the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement" seems inappropriate. A service furnished by a drug purchaser, pharmacy benefit manager, or other entity could be wholly legitimate even if the drug manufacturer would not otherwise have performed the service. Characterizing the fee for a legitimate service as a discount, thus lowering the Medicare payment amount, would not result in accurate ASPs.

- **Bundled sales**

When two products are sold for a single price, or the price of one product is contingent on the purchase of a different product, it is considered a bundled sale. CMS states that it has provided no guidance on bundled sales in the context of calculating ASP and asks for comments on the issue.

ASCO's primary concern is that the ASP reported to CMS for Part B drugs should be an accurate reflection of the prices paid by physicians. For example, if a Part B drug is sometimes bundled in a sale with an item other than a Part B drug, attributing any discount on the non-Part B drug to the ASP of the Part B drug would lower the Medicare payment amount and would be especially unfair to physicians who did not purchase the Part B drug in the bundled arrangement.

ASCO®
AMERICAN SOCIETY OF CLINICAL ONCOLOGY

ASCO urges CMS to adopt rules on including bundled sales in ASP calculations that result in accurate payment amounts for each Part B drug involved and that do not adversely affect physicians who purchase the drugs involved but not through the bundled sale arrangements. These rules should be subject to public comment before they become final.

**Proposed Reduction to 2007 Conversion Factor**

CMS announces in this rule that the physician fee schedule conversion factor will be reduced by 5.1% in 2007.

ASCO understands that CMS is constrained in its ability to make changes to the conversion factor, which is statutorily determined by the sustainable growth rate formula. However, we are extremely concerned that this planned reduction in Medicare payments does not account for the increasing costs of providing health care to Medicare beneficiaries. We fear that this significant payment cut will have an adverse effect on beneficiary access to high quality cancer care.

* * * * *

ASCO appreciates the opportunity to comment on the proposals.

Sincerely,

Joseph S. Bailes

Joseph S. Bailes, MD
Co-Chair, Government Relations Council

#932-2

ASCO®
AMERICAN SOCIETY OF CLINICAL ONCOLOGY



October 10, 2006

Mark McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

**Re: CMS-1321-P Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for CY 2007**

Dear Dr. McClellan:

These comments are submitted by the American Society of Clinical Oncology (ASCO) in response to the proposed changes to the Medicare physician fee schedule and other proposed changes to payment under Part B that were published in the Federal Register on August 22, 2006. ASCO is the national organization representing physicians who specialize in the treatment of cancer.

## DRA Proposals – Multiple Imaging Procedures

CMS previously adopted a policy of reducing payment for the technical component of the second and subsequent procedures in each of eleven families of imaging procedures. The reduction was 25% in 2006, and CMS had announced that the reduction would increase to 50% for 2007. CMS is proposing to maintain the current reduction at 25% in 2007, rather than moving to a 50% reduction as previously announced. Any reduction exceeding the current 25% would be preceded by further rulemaking.

ASCO supports the proposal to refrain from further reductions in the payment amounts for multiple imaging procedures. If CMS proposes additional reductions in the future, any such proposal should be supported by definitive data demonstrating the actual amount of cost savings incurred in providing multiple imaging procedures in the same encounter.

## ASP Issues

- **Additional Comment**

CMS is seeking additional comment on all aspects of the policy governing manufacturers reporting the average sales price (ASP) for their products. While

ASCO does not have comments on specific ASP reporting issues, we encourage CMS to provide extensive guidance on the proper method of calculating ASP. We are concerned that the current lack of instructions on many ASP reporting issues may cause manufacturers, acting conservatively, to report ASPs that are inaccurately low. Any such behavior would result in inappropriately low Medicare payment amounts that do not adequately reflect the prices that physicians pay for drugs. Proposed guidance should be subject to public comment before it is adopted.

- **Fees Not Considered To Be Price Concessions**

The notice addresses the issue of including administrative fees, service fees, and fees paid to pharmacy benefit managers in the ASP calculation. CMS proposes that a fee would not be considered a price concession if it meets the following criteria:

  - The fee must "represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement."
  - The fee must not be "passed on in whole or in part to a client or customer" of the entity furnishing the service, "whether or not the entity takes title to the drug."
  - In determining the fair market value for the service, CMS would continue its current policy that it generally means the same amount that the drug manufacturer would have paid if the services had been furnished by other entities.

ASCO is concerned that this proposed definition of a service fee could cause legitimate service fees to be regarded as price concessions, thereby lowering the ASP and the Medicare payment amount. In particular, the requirement that the fee must be for a service that "the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement" seems inappropriate. A service furnished by a drug purchaser, pharmacy benefit manager, or other entity could be wholly legitimate even if the drug manufacturer would not otherwise have performed the service. Characterizing the fee for a legitimate service as a discount, thus lowering the Medicare payment amount, would not result in accurate ASPs.

- **Bundled sales**

When two products are sold for a single price, or the price of one product is contingent on the purchase of a different product, it is considered a bundled sale. CMS states that it has provided no guidance on bundled sales in the context of calculating ASP and asks for comments on the issue.

ASCO's primary concern is that the ASP reported to CMS for Part B drugs should be an accurate reflection of the prices paid by physicians. For example, if a Part B drug is sometimes bundled in a sale with an item other than a Part B drug, attributing any discount on the non-Part B drug to the ASP of the Part B drug would lower the Medicare payment amount and would be especially unfair to physicians who did not purchase the Part B drug in the bundled arrangement.

ASCO urges CMS to adopt rules on including bundled sales in ASP calculations that result in accurate payment amounts for each Part B drug involved and that do not adversely affect physicians who purchase the drugs involved but not through the bundled sale arrangements. These rules should be subject to public comment before they become final.

**Proposed Reduction to 2007 Conversion Factor**

CMS announces in this rule that the physician fee schedule conversion factor will be reduced by 5.1% in 2007.

ASCO understands that CMS is constrained in its ability to make changes to the conversion factor, which is statutorily determined by the sustainable growth rate formula. However, we are extremely concerned that this planned reduction in Medicare payments does not account for the increasing costs of providing health care to Medicare beneficiaries. We fear that this significant payment cut will have an adverse effect on beneficiary access to high quality cancer care.

* * * * *

ASCO appreciates the opportunity to comment on the proposals.

Sincerely,

Joseph S. Bailes

Joseph S. Bailes, MD
Co-Chair, Government Relations Council

**Submitter :** Mr. Jack Cumming **Date:** 10/10/2006

**Organization :** Hologic, Inc.

**Category :** Device Industry

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-1321-P-933-Attach-1.DOC

#933

HOLOGIC®

October 10, 2006

Dr. Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P
P.O. Box 8014
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

Comments on CPT Codes 76075 (Dual energy X-ray Absorptiometry), 76077 (Vertebral Fracture Assessment), 76082 (Computer Aided Detection, Diagnostic), 76083 (Computer Aided Detection, Screening) and 76095 (Stereotactic Guidance)

Dear Dr. McClellan:

**Summary**

In the Centers for Medicare and Medicaid Services' (CMS) recently- launched public campaign to highlight its shift of focus to preventive medicine, screening procedures for osteoporosis and breast cancer are recognized as key components of this initiative. Conversely, at the same time, CMS published proposed reimbursement cuts to the technical components of DXA (80%), Vertebral Fracture Assessment (49%), Computer Aided Detection (56%), and Stereotactic Guidance (77%). These cuts, if implemented, will have the effect of placing these important screening benefits out of the reach of many Medicare beneficiaries. To reconcile this apparent disharmony, we request that a moratorium be placed on these proposed reimbursement cuts until sufficient data can be collected to allow appropriate and accurate valuation of these critical services. Valuation of these services should take into account the differences between providing services in a screening environment versus a therapeutic setting, the extra efforts and resources needed to maintain a successful, high-quality screen program with optimal utilization rates, and the overall economic benefits to be gained from such programs.

**Introduction**

Hologic, Inc. is pleased to submit comments on the Medicare Program 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 and Medicaid Services (CMS)[1]. Hologic is a leading developer and manufacturer of premium diagnostic and medical imaging systems dedicated to serving the healthcare needs of women. Our core business units are focused on osteoporosis assessment, mammography and breast biopsy. Hologic is in a unique position to appreciate the critical importance of



HOLOGIC, Inc. ■ 35 Crosby Drive ■ Bedford, MA 01730 ■ Tel: 781.999.7300 ■ Fax: 781.280.0669 ■ www.hologic.com

early detection of osteoporosis and breast cancer and the responsibility our industry bears to provide technologically superior imaging systems to support high quality screening procedures. Our company and its representatives expend a substantial amount of time and resources each year in promoting public awareness of the need for and benefits of regular screening procedures.

Hologic commends initiatives by the Centers for Medicare and Medicaid Services (CMS) to shift its focus to preventive medicine and wellness programs and to reinforce this direction through appropriate and accurate reimbursement mechanisms. Successful implementation of this visionary direction for CMS will result in decreased morbidity and a better quality of life for Medicare beneficiaries, as well as an overall reduction in healthcare costs due to earlier detection of treatable diseases. Hologic believes this direction is synchronous with the message we promote and the screening services made available through the products we manufacture.

Critical to the successful implementation of this admirable direction is broad, convenient access to high quality screening procedures. We believe the significant cuts which CMS has proposed to the relative value units of the above referenced CPT codes would impede access to these screening and diagnostic services. The result would be outcomes completely contrary to the CMS directive to promote preventive medicine.

**Previous Comments**

Reference is made to Hologic's letter to Dr. Mark McClellan dated August 17, 2006, in response to CMS-1512-PN; Medicare Program Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology. This letter commented on the potential impact dramatic decreases in reimbursement could have on screening services for osteoporosis and breast cancer and for diagnostic procedures for breast biopsy. Osteoporosis and breast cancer are two diseases that become more prevalent as people age. The effects of both diseases can be minimized with early detection, when treatments are most effective, and least traumatic and costly.

Over 10 million Americans currently have osteoporosis and an additional 34 million are at risk for the disease. More than 1.5 million fragility fractures require treatment each year at an annual cost of greater than $18 billion. Despite the existence of high-quality screening technologies to detect the disease, and effective drug therapies to stop or reverse the effects of bone loss, more than 60,000 deaths/year are attributable to osteoporosis-related fractures. Over the last decade, the utilization rate of dual energy x-ray absorptiometry (DXA), the only clinically accepted test for diagnosis of osteoporosis, has risen substantially, due in large part to efforts to make screening equipment available to primary care physicians. Despite these efforts, the utilization rate for DXA is currently less than approximately 20% of the eligible Medicare population. Vertebral fracture assessment (VFA) combined with DXA has the potential to identify future fracture risk



**HOLOGIC, Inc.** ■ 35 Crosby Drive ■ Bedford, MA 01730 ■ Tel: 781.999.7300 ■ Fax: 781.280.0669 ■ www.hologic.com

and permit more effective and earlier pharmacological intervention. This procedure, which is performed in conjunction with DXA, is also considerably under-utilized.

Breast cancer is the most prevalent type of cancer among U.S. women, and is the second leading cause of cancer death in women; however, when detected early, the chance for a successful cure is nearly 100%. One of the newest and most successful technologies to enable earlier detection of breast cancers is computer aided detection (CAD), as an adjunct to screening and diagnostic mammography. CAD has been shown to increase the detection rate of breast cancers by 15% or more, making it possible to use less aggressive and less traumatic treatment while still achieving good clinical outcomes. Despite these known benefits, breast cancer screening rates are sub-optimal.

Once an abnormality in the breast is detected, minimally invasive breast biopsy technologies offer women a safer and less traumatic alternative to open surgical biopsy (OSB); however, more than 650,000 OSB procedures are performed each year, the vast majority of which are not clinically required and could be accomplished by a minimally invasive procedure. Unnecessary OSB procedures result in increased morbidity to the patient and substantially higher costs to the healthcare system.

**Requirements for Successful Screening Programs**

The goal of any screening program should be to achieve close to 100% participation of all eligible individuals. The greater the utilization rate, the more effective the program will be in the early detection of diseases, initiation of minimally traumatic treatment plans, restoration or maintenance of health, and overall long-term reduction of healthcare costs. Multiple components to a screening program must be enacted to achieve maximum compliance, including the following:

- Broad, convenient access to high-quality screening procedures across all geographic and socioeconomic strata. Quality cannot be sacrificed for any patient population;
- Continuous public awareness campaigns by government and public organizations, healthcare providers, and industry representatives;
- Extraordinary efforts by healthcare providers to expand participation to new patients and monitor ongoing compliance in existing patients; and
- Accurate and adequate reimbursement to ensure the availability of equipment and resources required to support high-quality screening procedures.

The above elements are unique to screening programs and require efforts and resources beyond those needed to provide therapeutic services to a typical patient population. Consideration must be given to the special, additional resources required to achieve a successful, nation-wide screening campaign serving the highest possible number of participants.



**HOLOGIC, Inc.** ■ 35 Crosby Drive ■ Bedford, MA 01730 ■ Tel: 781.999.7300 ■ Fax: 781.280.0669 ■ www.hologic.com

Current Utilization Rates for Osteoporosis and Breast Cancer Screening

As noted previously, the utilization rates for osteoporosis and breast cancer screening are sub-optimal and fall far below expectations for a successful screening program. Although bone density screening tests for Medicare recipients increased from 77,133 in 1994 to 2,555,727 in 2004, this number represents less than approximately 20% of the eligible Medicare population. A recent, random sampling of representative Medicare patients revealed that approximately 23% had received bone density screening in a two-year period, providing further validation that the current utilization rate for this screening procedure falls far below what would be considered adequate for a successful screening program.

In 2004, only 37.7% of eligible Medicare recipients in all age groups received screening mammograms[2], indicating that serious constraints exist within our current national breast cancer screening program. A report issued by the U.S. General Accounting Office (GAO) in July 2006 stated that "the loss or absence of mammography machines in certain locations may have resulted in access problems, consisting of lengthy travel distances or considerable wait times, including problems for women who are medically underserved[3]." Impeded access in these areas may be one contributing factor to low utilization of these services by Medicare beneficiaries.

A disturbing trend is also noted in the decreasing number of certified breast cancer screening facilities. In 1999, following enactment of the Mammography Quality Standards Act (MQSA), 9,998 certified mammography facilities existed in the U.S. Today, only 8,832 such facilities continue to exist, although minimal fluctuation is noted in the number of actual systems available[4]. These statistics indicate continuing consolidation of facilities, with ongoing closure of smaller facilities in remote locations.

Financial constraints may also be a key factor in the low utilization rates associated with these technologies. It is difficult to justify the purchase of a piece of equipment that may be used only 20% to 40% of the time, as the investment may take two to three times longer to recoup than that made for a piece of equipment used in a therapeutic setting. In addition, there are significant operational inefficiencies inherent in a screening environment, where patients require more tracking, counseling and follow-up. This becomes a highly significant factor in practices motivated to expand screening services to a larger population of eligible patients.

The current users of screening services are those individuals easiest to reach, who maintain fair to good compliance with screening guidelines. Substantial, additional efforts will be required to expand utilization to the harder to reach patient population, who, whether through geographical limitations or lack of awareness, do not take advantage of regular screening opportunities. Despite the effort involved, utilization rates must be increased to accomplish the commendable goals set forth in the CMS preventive medicine initiative.



**HOLOGIC, Inc.** ■ 35 Crosby Drive ■ Bedford, MA 01730 ■ Tel: 781.999.7300 ■ Fax: 781.280.0669 ■ www.hologic.com

**Effect of Proposed Decreases in Reimbursement on Screening and Diagnostic Services**

The proposed cuts to reimbursement for the technical component for DXA, VFA, CAD, and stereotactic guidance will make it more difficult for practices to justify the cost of purchasing new equipment. In many cases, the proposed cuts may make it impossible for practices with existing systems to continue providing these services. Access to crucial, high-quality screening services will be limited, driving utilization rates down from already unacceptably low levels.

It is well understood that the reimbursement rates for mammography have rendered it a financially marginal service. This circumstance was highlighted in the July 2006 GAO report that voiced serious concerns about the continuing decline in the number of radiologists and technologists entering the specialty, warning that the lack of trained specialists will hinder access to screening services, particularly in traditionally underserved areas[3]. Reasons for this decline include poor reimbursement, lack of financial incentives, and the high rate of malpractice claims brought against the specialty.

In addition, in a recent reader poll, over 80 percent of respondents said the plan by CMS to cut CAD reimbursement nearly in half by 2010 would have a dramatic impact on their decision to adopt the modality[5]. With CAD penetration currently below 50% of the existing mammography facilities, this decrease could cripple the ability of physicians to offer the highest quality screening services to the broadest patient population.

**Policy Considerations**

Traditionally, CMS has calculated payment rates based on an average mix of patients in a typical therapeutic setting, where it is possible for a moderately active practice to operate efficiently and cost-effectively. Based on the low utilization rates for screening services and the greater resource demands associated with a screening environment, consideration must be given to whether this is the most appropriate pricing model to use for these services.

Limited data have been collected to date which would accurately reflect the real costs associated with the delivery of these screening services. Likewise, no data exist to reflect the resources that will be required to accelerate widespread adoption of osteoporosis and breast cancer screening, and to increase utilization rates to a level that would ensure successful nationwide screening programs. It would be counter-productive to implement the currently proposed reimbursement cuts, which are based on data not reflective of the special resource requirement inherent in a screening environment, or of the objectives of CMS's fledgling preventive medicine program. The program might be better served by adopting a more moderate interim position.

There may be pathways that can be pursued to support the CMS preventive medicine movement without creating unintended consequences for other services. For instance,



**HOLOGIC, Inc.** ■ 35 Crosby Drive ■ Bedford, MA 01730 ■ Tel: 781.999.7300 ■ Fax: 781.280.0669 ■ www.hologic.com

CMS can announce publicly that reimbursement rates will be held at current levels for DXA, VFA, CAD, and stereotactic guidance, while data are collected to establish appropriate and accurate pricing models and formulas. A mechanism can be established to collect the needed data, either through an independent commission, a public advisory process, a collaboration between MedPac, RUC, and practicing physicians, or any other available process.

Relevant data to be collected may include:

- Actual equipment utilization rates in an established practice;
- Potential equipment utilization rates in sparsely populated locations;
- Additional staff time required to track compliance and counsel patients;
- Unavoidable inefficiencies associated with delivery of services in a screening environment;
- In mammography facilities, additional resources needed to achieve compliance to MQSA requirements; and
- Additional "value" factor associated with pursuit of preventive medicine initiatives.

**Conclusion**

We believe that public health is served by ensuring access to screening services for bone mass measurement, high quality mammography, and minimally invasive breast biopsy technologies. It is also in accord with the CMS initiative to focus on preventive medicine. We strongly encourage CMS to carefully analyze the impact these proposed decreases in reimbursement will have on the viability of its newly launched preventive medicine program and to consider placing a moratorium on these decreases until appropriate data can be collected to allow appropriate and accurate valuation of these critical services.

We trust that these comments will be useful to CMS as it considers revisions to the practice expense methodology of the MPFS. We look forward to further dialogue on this issue and encourage CMS to contact us promptly with any questions, comments, or requests for additional information. We will be pleased to cooperate with CMS and provide any assistance we can in helping to determine the most appropriate way to ensure these valuable screening services remain highly accessible.

Sincerely,

Jack Cumming
Chairman and CEO



**HOLOGIC, Inc.** ■ 35 Crosby Drive ■ Bedford, MA 01730 ■ Tel: 781.999.7300 ■ Fax: 781.280.0669 ■ www.hologic.com

**References**


1. 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 with comment period, 71 Fed. Reg. (August 22, 2006).

2. Centers for Medicare and Medicaid Services; Mammography Claims Data Tables; Calendar Year National and State Mammography Data by Age Group.

3. United States Government Accountability Office Report to Congress, "Mammography: Current Nationwide Capacity is Adequate, but Access Problems May Exist in Certain Locations." July 2006. GAO-06-724

4. U.S. Food and Drug Administration, Center For Devices and Radiological Health; MQSA National Statistics, updated October 1, 2006.

5. Health Imaging News; August 31, 2006; Headline News.




**HOLOGIC, Inc.** ■ 35 Crosby Drive ■ Bedford, MA 01730 ■ Tel: 781.999.7300 ■ Fax: 781.280.0669 ■ www.hologic.com

CMS-1321-P-934

**Submitter :** **Ms. Laura Loeb** **Date: 10/10/2006**

**Organization :** **Dornier Med Tech**

**Category :** **Health Care Provider/Association**

**Issue Areas/Comments**

**Background**

Background

Physician Fee 1321

**GENERAL**

GENERAL

Comments filed by Dornier Med Tech regarding Schedule Physician Fee

CMS-1321-P-934-Attach-1.DOC

CMS-1321-P-934-Attach-2.DOC

#934-1

**Dornier** *MedTech*

October 10, 2006

Leslie Norwalk, Acting Administrator Centers
for Medicare and Medicaid Services 7500
Security Boulevard
Baltimore, Maryland 21244

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

Dear Acting Administrator Norwalk:

Thank you for this opportunity to comment on the Proposed Rule for the Medicare Physician Fee Schedule for Calendar Year 2007, as published in the August 22, 2006 Federal Register. Domier is a manufacturer of medical equipment, including equipment for extracorporeal shock wave therapy (ESWT) for the treatment of plantar fascia. We are commenting only on one issue, which is the significant undervaluing of CPT code 28890, which was first issued for January 1, 2006 - ESWT, high energy, performed by a physician, requiring anesthesia other than local, including ultrasound guidance, for plantar fascia.

This is a service which has been safely performed in physician's offices. However, because of the extremely low and unjust reimbursement amount that CMS has established for 28890, the Medicare reimbursement no longer covers the physician's costs of providing this care. Therefore, this reimbursement rate has effectively forced the physician to treat in a hospital setting. This removes a critical aspect of the patient care equation. The physician can no longer decide what is in the best interest of the patient, but must treat according to where he or she will receive appropriate reimbursement for medical services. As an equipment provider, we do not tell nor do we favor one treatment location over the other. We do favor the right for a patient in conjunction with his or her physician to make an infoiified choice on what is best in the individual's case. That choice is removed under your proposed reimbursement rates.

CMS is proposing in the hospital outpatient rule to pay the hospital $1,542.47 for ESWT for plantar fascia. Meanwhile, under the proposed rule for the physician fee schedule, in 2010, when the changes are fully phased in, a physician would be paid approximately $302 for providing the service in the physician's office (8.36 total RVUs non-facility x $36.1770, last year's conversion factor). That in-office fee simply cannot be right. We respectfully urge CMS to correct this reimbursement amount for 2007, so that this treatment will continue to be offered to patients in the office setting.

***DornierMedTech America, Inc.***

**1155 Roberts Boulevard**
Kennesaw, Georgia 30144

Telephone (770)514-6100
Toll Free (800)367-6437
Fax (770)426-6115

www.dornier.co

**Dornier *MedTech***



Per a copy of an invoice attached, the ESWT equipment for plantar fascia costs physicians approximately $350,000 and the equipment has a useful life of 5 to 7 years. This equipment would be sold to a hospital at the same price. The supply cost would be the same across settings. In the hospital outpatient department, general anesthesia could be administered, where it typically is not in a physician's office. However, a regional block is usually used in the physician office setting. Additional staff is usually needed to assist the doctor with the regional block. Further, ultrasound guidance is bundled into the payment.

Similar procedures are reimbursed at higher amounts in the physician office. For example, CPT Code 29893, endoscopic plantar fasciatomy, is reimbursed at $559 (15.45 RVUs x $36.1770). CPT Code 28250, Revision of foot fascia, is reimbursed at $514, (14.22 RVUs x $36.1770). Even those values appear to be out of line with the hospital outpatient payment of $1,542.

We believe that the hospital outpatient payment is appropriate. It is simply the physician office setting that is valued far too low. Since we understand that CMS desires to make the payments more equitable across sites of service, we urge CMS to increase significantly the Medicare payment for ESWT for the treatment of plantar fascia provided in the office setting. The costs of performing this particular procedure are very similar in comparing the hospital outpatient department to the physician office.

We are also concerned about the ASC rates and believe they should be increased; we will comment on that issue in a separate letter.

We look forward to working with CMS to more appropriately value this service in the office setting. If you have any questions, please contact Tim Thomas at 770-514-6163.

Sincerely,

Brian Walsh
President

Dornier MedTech America

BWljp

Attachment

Dornier MedTech America, Inc.

## QUOTATION AND SALES CONTRACT

Customer Name and Address:
XYZ Company
123 TBD
TBD, GA 12345

Quotation No: S065871
Regional Account Manager: Corporate Account
Order No: _____
Date: 10/10/2006

Contact: TBD -

Dornier MedTech America, Inc. ("DMTA") is pleased to submit the following Quotation. DMTA offers to sell the product(s) listed below ("Product or Products") subject to your acceptance of the terms and conditions written below and attached hereto.

| Qty | Description | | Price |
|---|---|---|---|
| 1 | **DORNIER EPOS ULTRA ESWT ORTHOPEDIC DEVICE** | | $437,500 |
| | **Included with System:** | | |
| 1 | Ultrasound Scanner with Black/White Monitor | | Included |
| 1 | 1 Day On-site Applications Training | | Included |
| 1 | Transport Kit | | Included |
| 1 | Operator's Manual | | Included |
| | | **Special Discount:** | (87,500) |
| | | **System Sub Total:** | $350,000 |
| | **Options:** (Indicate quantity of each desired option.) | | |
| 1 | Shipping & Handling | $2,000 | $2,000 |
| | | **Options Sub Total:** | $2,000 |
| | (Sub Total + Options) | **PURCHASE PRICE:** | $352,000 |
| | | | *Plus Applicable Taxes |

**Delivery: 90 - 120 Days ARO FOB Point: Kennesaw, GA**

**NOTE: Quotation valid for 60 days**
Delivery Instructions: _____

Purchase Price: $352,000 (US) Payment Terms: 25% Down; 65% on Delivery; 10% Net 30

Down Payment required with order: $88,000 (US)
Length of Warranty: 12 Months

Please return quote and payment to the attention of Pam Stromberg at the address given below.

| Customer | Dornier MedTech America, Inc. |
|---|---|
| By: | By: |
| Name: | Title: |
| Please Print | By: |
| Title: | Title: |
| Date: | Date: |

#934-2

**Dornier** *MedTech*

October 10, 2006

Leslie Norwalk, Acting Administrator Centers
for Medicare and Medicaid Services 7500
Security Boulevard
Baltimore, Maryland 21244

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

Dear Acting Administrator Norwalk:

Thank you for this opportunity to comment on the Proposed Rule for the Medicare Physician Fee Schedule for Calendar Year 2007, as published in the August 22, 2006 Federal Register. Domier is a manufacturer of medical equipment, including equipment for extracorporeal shock wave therapy (ESWT) for the treatment of plantar fascia. We are commenting only on one issue, which is the significant undervaluing of CPT code 28890, which was first issued for January 1, 2006 - ESWT, high energy, performed by a physician, requiring anesthesia other than local, including ultrasound guidance, for plantar fascia.

This is a service which has been safely performed in physician's offices. However, because of the extremely low and unjust reimbursement amount that CMS has established for 28890, the Medicare reimbursement no longer covers the physician's costs of providing this care. Therefore, this reimbursement rate has effectively forced the physician to treat in a hospital setting. This removes a critical aspect of the patient care equation. The physician can no longer decide what is in the best interest of the patient, but must treat according to where he or she will receive appropriate reimbursement for medical services. As an equipment provider, we do not tell nor do we favor one treatment location over the other. We do favor the right for a patient in conjunction with his or her physician to make an infoiified choice on what is best in the individual's case. That choice is removed under your proposed reimbursement rates.

CMS is proposing in the hospital outpatient rule to pay the hospital $1,542.47 for ESWT for plantar fascia. Meanwhile, under the proposed rule for the physician fee schedule, in 2010, when the changes are fully phased in, a physician would be paid approximately $302 for providing the service in the physician's office (8.36 total RVUs non-facility x $36.1770, last year's conversion factor). That in-office fee simply cannot be right. We respectfully urge CMS to correct this reimbursement amount for 2007, so that this treatment will continue to be offered to patients in the office setting.

***DornierMedTech America, inc.***

**1155 Roberts Boulevard**
Kennesaw, Georgia 30144

Telephone (770)514-6100
Toll Free (800)367-6437
Fax (770)426-6115

www.dornier.co

Per a copy of an invoice attached, the ESWT equipment for plantar fascia costs physicians approximately $350,000 and the equipment has a useful life of 5 to 7 years. This equipment would be sold to a hospital at the same price. The supply cost would be the same across settings. In the hospital outpatient department, general anesthesia could be administered, where it typically is not in a physician's office. However, a regional block is usually used in the physician office setting. Additional staff is usually needed to assist the doctor with the regional block. Further, ultrasound guidance is bundled into the payment.

Similar procedures are reimbursed at higher amounts in the physician office. For example, CPT Code 29893, endoscopic plantar fasciatomy, is reimbursed at $559 (15.45 RVUs x $36.1770). CPT Code 28250, Revision of foot fascia, is reimbursed at $514, (14.22 RVUs x $36.1770). Even those values appear to be out of line with the hospital outpatient payment of $1,542.

We believe that the hospital outpatient payment is appropriate. It is simply the physician office setting that is valued far too low. Since we understand that CMS desires to make the payments more equitable across sites of service, we urge CMS to increase significantly the Medicare payment for ESWT for the treatment of plantar fascia provided in the office setting. The costs of performing this particular procedure are very similar in comparing the hospital outpatient department to the physician office.

We are also concerned about the ASC rates and believe they should be increased; we will comment on that issue in a separate letter.

We look forward to working with CMS to more appropriately value this service in the office setting. If you have any questions, please contact Tim Thomas at 770-514-6163.

Sincerely,

Brian Walsh
President

Dornier MedTech America

BWljp

Attachment

Dornier MedTech America, Inc.

## QUOTATION AND SALES CONTRACT

Customer Name and Address:
XYZ Company
123 TBD
TBD, GA 12345

Quotation No: S065871
Regional Account Manager: Corporate Account
Order No: _____
Date: 10/10/2006

Contact: TBD -

Dornier MedTech America, Inc. ("DMTA") is pleased to submit the following Quotation. DMTA offers to sell the product(s) listed below ("Product or Products") subject to your acceptance of the terms and conditions written below and attached hereto.

| Qty | Description | | Price |
|---|---|---|---|
| 1 | **DORNIER EPOS ULTRA ESWT ORTHOPEDIC DEVICE** | | **$437,500** |
| | **Included with System:** | | |
| 1 | Ultrasound Scanner with Black/White Monitor | | **Included** |
| 1 | 1 Day On-site Applications Training | | **Included** |
| 1 | Transport Kit | | **Included** |
| 1 | Operator's Manual | | **Included** |
| | | **Special Discount:** | **(87,500)** |
| | | **System Sub Total:** | **$350,000** |
| | **Options:** (Indicate quantity of each desired option.) | | |
| 1 | Shipping & Handling | $2,000 | $2,000 |
| | | **Options Sub Total:** | **$2,000** |
| | | (Sub Total + Options) **PURCHASE PRICE:** | **$352,000** *Plus Applicable Taxes |

**Delivery: 90 - 120 Days ARO FOB Point: Kennesaw, GA**

**NOTE: Quotation valid for 60 days**
Delivery Instructions: _____

Purchase Price: $352,000 (US) Payment Terms: 25% Down; 65% on Delivery; 10% Net 30

Down Payment required with order: $88,000 (US)
Length of Warranty: 12 Months

Please return quote and payment to the attention of Pam Stromberg at the address given below.

| Customer | | Dornier MedTech America, Inc. | |
|---|---|---|---|
| By: | | By: | |
| Name: | | Title: | |
| Please Print | | By: | |
| Title: | | Title: | |
| Date: | | Date: | |

**Submitter :** Dr. Sandeep Bajaj **Date:** 10/10/2006

**Organization :** Florida Cardiology

**Category :** Physician

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attatchment

CMS-1321-P-935-Attach-1.PDF

Cardiovascular disease is the #1 killer in the United States. Given the magnitude of cardiovascular morbidity and mortality, a reasonable person would expect medicare to make it a priority to support cardiovascular specialists who lead the way in the battle against this dreaded disease. Instead, medicare plans to make crippling cuts in the reimbursement we receive for diagnostic procedures in our office practices. The current range of cuts is from 40%-62%, and involve essential diagnostic procedures including echocardiography, nuclear stress testing and outpatient diagnostic cardiac catheterization. Over the last several years, medicare reimbursements to physicians have failed to keep pace with medical inflation and cost of living increases. Nonetheless cardiologists have managed to maintain high levels of care for both medicare and non-medicare patients alike, including those patients who have no health insurance and receive care for free. Current medicare proposals that will take effect in January 2007 threaten our ability to deliver care to these patients. The net results of these cuts will be that the cost of providing cardiovascular services in the office setting will actually be greater than the reimbursement. Compounding the problem is the fact that private insurance companies use medicare as a guideline and this reduction in fees will impact our ability to deliver care to non-medicare patients as well. The magnitude and depth of these cuts will have a rippling catastrophic effect on cardiovascular care throughout Central Florida. It is unlikely that physicians will be able to afford to make new medical and information technologies available through their office practices. I anticipate many cardiologists will be forced to close their practices in the State of Florida and move to other states with a smaller medicare population. The remaining practices will have no choice but to reduce office staff substantially, and reduce or eliminate services in order to survive in this environment. Many cardiologists may find that they are unable to see new medicare patients; others will have no choice but stop seeing medicare patents at all.

In an effort to reverse these unfair cuts, the major cardiology groups in Central Florida have been meeting to discuss possible solutions. These cardiac groups include Cardiology Consultants, Florida Heart Group, Central Florida Cardiology, Mid Florida Cardiology, Orlando Heart Center, Florida Cardiology, Cardiac Care Specialists and Cardiovascular Associates. These groups together comprise 120 cardiologists who provide care for greater than 80% of the cardiac patient's in Central Florida. We have been meeting with our representatives who include Senator Bill Nelson and Congressmen Ric Keller and Thomas Feeney. In addition we have met without representatives from the Florida Medical Association and the Florida chapter of the American College of Cardiology. We are all in agreement that the proposed cuts will destroy our practices, and force many of us out of business. The lack of reimbursement will have a crippling negative effect and, therefore, physicians will not be able to install electronic medical records in the office. They will not invest in further imaging solutions. They will be forced to have employee cuts or wage freezes, in addition to not taking new Medicare patients. The end result will be that most patients will have to go to the hospital for these services. The hospitals, at the present time, have no capacity to take care of these patients. Additionally, the hospitals for outpatient services work at a much higher cost to the payers. There is going to be a delay in patient access for these services and, therefore, a gross decrease in patient satisfaction with overall health care delivery system. Therefore, we would ask that you freeze the reimbursement rates for the current office diagnostic procedures which include echocardiography, carotid ultrasound, Nuclear stress testing and diagnostic cardiac catheterization at the current levels.

We would ask that you develop a fair solution that addresses the issues of compensation for these services. Any solution that is fair should include the participation of clinical cardiologists like ourselves who have a vital stake in this process and actually take care of the patients.

Thank you so much for considering these comments.

Sincerely,

Sandeep Bajaj, M.D.

**Submitter :** **Ms. Juliana Reed** **Date: 10/10/2006**

**Organization :** **Hospira, Inc.**

**Category :** **Drug Industry**

**Issue Areas/Comments**

**Background**

Background

See Attachment

**GENERAL**

GENERAL

See Attachment

**Impact**

Impact

See Attachment

**Provisions of the Proposed Rule**

Provisions of the Proposed Rule

See Attachment

CMS-1321-P-936-Attach-1.PDF

CMS-1321-P-936-Attach-2.PDF

included in these agreements, including rebates that are paid to the GPO for redistribution to the GPO's participating members. Any GPO rebates intended for distribution to GPO members should be clearly defined as such in the GPO contractual agreements and distinguished from payments of administrative fees. These GPO payments are intended to be passed on to the healthcare provider as a discount and should be included in any ASP calculation.

The administrative fees paid by a manufacturer to a GPO are intended as payment for "bona fide services" delivered in the contract lifecycle process by the GPO. Several, but not all, GPOs have published that they redistribute some portion of these fees back to their membership after the deduction of GPO operating costs. Any such redistribution is likely based on the total annual revenue of the GPO, which may constitute fees from all types of manufacturers or distributors covering a broad range of products – drugs, medical/surgical supplies, food, capital equipment, etc. The amount of each manufacturer's individual fees that may be included in this redistribution amount is unknown to the manufacturer. These fees are negotiated by the manufacturer in good faith based upon the standards in the marketplace (all GPOs require some level of fee payments) for the intent of covering GPO expenses, not as an added discount for the healthcare provider. GPOs do not provide any report to manufacturers as to the allocation and distribution of any of these distributions. Therefore, those administrative fees included under the GPO Safe Harbor should **not** be included in the ASP calculation. If CMS is proposing to change the way these fees are applied in the ASP calculation, we ask that CMS analyze the impact the changes would have on the manufacturer's compliance with the GPO safe harbor to the anti-kickback statute found at 42 C.F.R. §1001.952(j).

Some manufacturers also have contracts with trading partners (drug wholesalers and distributors) that include payment of fees to cover the distribution and promotional services of these trading partners. These fees are negotiated to cover the expenses of the trading partner in the provision of the services for the manufacturer and are not intended for redistribution by the trading partner to the healthcare provider. These are "bona fide service fees" that also should **not** be included in the ASP calculations.

**II. The appropriate method for determining whether a fee is passed on in whole or part to the end-user:**

The process for determining whether a GPO or trading partner payment is passed on in whole or in part to the end-user for the purposes of the quarterly calculation of ASP should be determined based on the contractual arrangement between the manufacturer and the GPO.

Hospira

Hospira recommends that the contract between the manufacturer and the GPO or trading partner should specify if the administrative fee is passed on in whole or in part to the end-user. If the contract does not specify a member redistribution of a payment, the manufacturer has negotiated the payment as an administrative fee and not as a discount for the final customer. Any redistribution of excess fees by a GPO is governed by the agreements between the GPO and its members, not by the manufacturer. The volume of any such redistribution may vary year-to-year and is not within the control of the manufacturer or disclosed to the manufacturer. Since the excess fees redistributed by the GPO are an aggregation over all GPO suppliers, the manufacturer has no knowledge of how its fee payments contributed or detracted from the excess value; nor does the manufacturer have knowledge of whether the value was generated by the manufacturer's drugs, by the manufacturer's non-drug products, or by other manufacturer's products. Therefore, any estimation of this redistribution would have no basis with regard to the actual price paid by the healthcare provider for the products reported and should not be included in any ASP calculation.

Hospira thanks CMS for the opportunity to comment on the CMS-1321-P, CMS-1321-P, Medicare Physician Fee Schedule Calendar Year 2007, Section F. Proposed Payment for Covered Drugs and Biologicals: ASP Issues. We applaud CMS in continuing to reach out to all stakeholders throughout this process and we look forward to ongoing dialogue and clarification of the regulations. We invite CMS to contact us in the future for any additional information or feedback.

Respectfully submitted,

Juliana M. Reed
Director, Health Policy
Hospira, Inc.
275 N. Field Drive
Bldg. H1, Dept. 36V
Lake Forest, IL. 60045
224-212-2333
juliana.reed@hospira.com

**Submitter :** **Mr. Guy Beaumont** **Date: 10/10/2006**

**Organization :** **American College of Osteopathic Surgeons**

**Category :** **Health Care Professional or Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See attachment

**Impact**

Impact

Physician Self-Referral/Stark Changes

CMS-1321-P-937-Attach-1.DOC

937



October 10, 2006

Leslie Norwalk
Acting Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

RE: CMS – 1321 – P; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes To Payment Under Part B

Dear Acting Administrator Norwalk:

The American College of Osteopathic Surgeons (ACOS) and the American Osteopathic Academy of Orthopedics (AOAO) appreciate the opportunity to comment on the Proposed Rule for the Medicare Physician Fee Schedule for Calendar Year 2007, as published in the August 22, 2006 Federal Register. Specifically, we will comment on the proposed changes to the existing physician self-referral rule (the "Self-Referral" or "Stark" Rule).

Issue Identifier: *Reassignment and Physician Self-Referral Definitions: Centralized Buildings*

ACOS and AOAO agree with most of the proposed regulation as it affects the reassignment rules. In particular, we believe that the clarifications CMS offers with respect to the billing of technical components ("TC") of diagnostic tests and the clarification regarding "leased employees and purchased tests" are helpful.

However, ACOS and AOAO disagree with the two recommendations that would clarify the definition of a "centralized building," relied upon in the Stark legislation by (i) establishing a square footage minimum of 350 square feet and (ii) requiring that the group practice must staff the centralized building with at least one non-physician employee who performs services in that space not less than 35 hours per week.

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

**Organization :** CAPU

**Category :** Physician

**Issue Areas/Comments**

**GENERAL**

GENERAL

Please See Attachment

CMS-1321-P-938-Attach-1.DOC

938

**The Coalition for the Advancement of Prosthetic Urolog**
**1301 K Street, N.W., Suite 110**
**Washington, DC. 2000**
**202-414-924**



October 10, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P
P.O. Box 8010
Baltimore, MD 21244-8010

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

**RE:** CMS-1321-P: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for CY 2007 and Other Changes to Payment, Specifically **Provisions Regarding Standard Supplies & Equipment for Procedures with a 90 day Global Period and Resource-Based Practice Expense (PE) RVU Proposals for CY 2007**

Dear Dr. McClellan:

On behalf of the Coalition for the Advancement of Prosthetic Urology (CAPU), we are pleased to submit comments in response to Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule for CY 2007 and other Changes to Payment under Part B. CAPU is a national organization that includes leading clinical experts and researchers in prosthetic urology and the nation's leading manufacturers and developers of innovative prosthetic urology devices. As the leading representative of the prosthetic urology community, CAPU's mission is to ensure that the issues affecting this community are given appropriate consideration in the formation of federal health care and reimbursement policy.

Over the past few years, CAPU has been concerned regarding the Relative Value Units (RVUs) assigned to prosthetic urology procedures. We are encouraged by CMS' actions regarding some of the elements of the proposed practice expense methodology; however, there is still more that can be done to ensure future access for Medicare beneficiaries to prosthetic urology procedures. Therefore, as explained in greater detail below, CAPU has the following recommendations:

## I. Summary

- Standard Supplies and Equipment for CPT Codes with 90 day Global Periods:
    - Many of the prosthetic urology procedures have been negatively impacted by the use of standard packages for various practice expense inputs, partly because of the assertion by CMS that most 90 day global period codes only contain three post-operative (post-op) visits. This is not the case with prosthetic urology procedures where the average number of post-op visits is five. Thus we recommend that CMS re-evaluate the number of post-op visits packaged into each 90 day global period code.

**The Coalition for the Advancement of Prosthetic Urology**
**1301 K Street, N.W., Suite 1100**
**Washington, DC. 20005**
**202-414-9241**

- We appreciate CMS soliciting comments regarding standard packages of supplies and equipment for post-operative visits associated with a 90 day global period procedure. With regard to standard supply inputs, CAPU would recommend to CMS that for each post-op visit standard supplies should include the following:
  - Office visit supply package
  - Post-surgical incision care kit

- Two sets of gloves
- Exam table paper
- Drape, non-sterile sheet
- Additional items recommended by the RUC/PERC.

- With regard to standard equipment inputs, CAPU would recommend to CMS that for each post-op visits that standard equipment should include the following:

  - Exam Table
  - Exam Light
  - Additional equipment recommended by the RUC/PERC.

- Proposed Changes to Practice Expense Methodology:

  - CAPU strongly supports switching to a bottom-up methodology for calculating PE RVUs and believes that it meets CMS's stated goals of using the most appropriate data, simplifying the practice expense methodology and increasing the stability of the practice expense payments.

  - In general, CAPU is concerned that compared to last year's "bottom-up" methodology for calculating PE RVUs, this year's method proposes to use budget neutrality adjustors in three separate steps. Physicians cannot continue to absorb these under-valuations, especially as they face 37% in Medicare payment cuts over the next nine years, as projected by the Medicare Trustees. There are steps that the CMS and the Administration could take, even without legislative action, to improve this dire financial picture. CAPU urges CMS to investigate these steps.

  - CAPU appreciates CMS using the American Urological Association's supplemental survey data as part of the process of creating a more accurate, intuitive and stable Practice Expense (PE) methodology.

## II. Detailed Discussion

### A. Provisions - Standard Supplies and Equipment for CPT Codes with 90 Day Global Periods

#### 1. Number of Post-Operative Visits Packaged in Codes with 90 Day Global Periods

The results of the CAPU Survey of Post-Operative Office Visits and Clinical Staff Time demonstrate that the number of post-operative visits in the Centers for Medicare and Medicaid Services (CMS) Practice Expense (PE) Inputs Database are not representative of a typical prosthetic urology practice.

In general, the total number of visits in the CMS PE database for prosthetic urology procedures is three (3). The results of the CAPU survey demonstrate an average of four (4) to five (5) and, in some cases, six (6) post-operative visits depending on the CPT code.

**Created Pre- 1990 - Prosthetic Urology CPT Codes 53445, 53447, & 54405:**

The CAPU survey results for three CPT codes (53445, 53447, & 54405) created before 1990 reflect that the use of the 90-day global period standardized package of three (3) post-operative visits for most surgical CPT codes as the PE input is not representative of actual prosthetic urology practice.

**The Coalition for the Advancement of Prosthetic Urology**
**1301 K Street, N.W., Suite 1100**
**Washington, DC. 20005**
**202-414-9241**

In conjunction with the 2003 PEAC review, the PEAC recommended a standardized package of three (3) post-operative visits for "all" surgical procedures with a 90-day global period. However, the results of this survey show that three (3) post-operative visits is not representative of actual prosthetic urology practice.

The CAPU survey results demonstrate that for all three of these CPT codes the mean number of post-operative visits is five (5). The median is also at least five (5) visits, with one exception. For CPT code 53445, the median is six (6) office visits.

**Created in 2002 - Prosthetic Urology CPT Codes 53444, 54410, 54411, 54416, & 54417:**

While the differences between the CAPU aggregate results for this group of CPT codes and the clinical staff inputs in the CMS PE database are not as wide as the group of CPT codes discussed above, the survey results of prosthetic urology codes created in 2002 also confirm that using standard packages for 90 global period codes is not representative of typical prosthetic urology practice.

The CAPU survey results for the CPT codes in this group, with the exception of CPT code 54417, demonstrate that mean and median number of post-operative visits in a typical practice is four (4) – five (5). This is one -two visits more than the standard of 3 post- operative visits for a 90-day global CPT code.

2. Standard Supplies and Equipment for 90 day Global Period Codes:

A review of the CPEP data used to calculate the proposed 2007 PE RVUs for PU codes revealed that most of the CPT codes have an office visit package and a post-surgical incision care kit assigned to them. However, the number of visit packages and the number of incision care kits in the CPEP data base is three versus the typical number of post-operative visits which is five. CMS needs to update the number of packages and kits based on the results of the CAPU survey, stated above.

Also, CMS needs to include as "standard" supplies that are used to prevent any risk of infection or for patient comfort, such as gloves for the physician and clinical staff, exam table paper, gowns, and drapes.

With regard to equipment, all of these CPT codes were assigned an exam table under the CPEP data for equipment. This is appropriate; however, we would also recommend that an exam light be included as this is standard equipment in an exam room and can be used to illuminate the wound site for greater inspection by the physician.

**B. Practice Expense (PE)**

1. Bottom-Up Methodology

CAPU strongly supports switching to a bottom-up methodology for calculating PE RVUs and believes that it meets CMS's stated goals of using the most appropriate data, simplifying the practice expense methodology and increasing the stability of the practice expense payments. CAPU is pleased that CMS is seeking ways to provide more stability to the practice expense RVUs now that the AMA and the specialty societies have completed refinement of the original CPEP-collected data. For calculating the direct cost portion of PE RVUs, relying on the direct cost inputs (clinical labor, supplies and equipment) for urology procedures, as refined by the AUA, is an improvement over the previous methodology, which scaled direct cost inputs to a pool of money that was developed based on AMA SMS survey data. The scaling factors in the previous methodology led to inaccurate distribution of PE RVUs among urology's codes, and CAPU strongly supports the change in methodology that does away with the need for scaling factors.

**The Coalition for the Advancement of Prosthetic Urology**
**1301 K Street, N.W., Suite 1100**
**Washington, DC. 20005**
**202-414-9241**

2. Budget Neutrality

In the newly-proposed PE methodology discussed in the proposal, CMS applies a budget neutrality adjustment three times – to the direct inputs, to the indirect allocators and also as a final step. It is unclear why CMS does not apply budget neutrality just once as a final step in the methodology, and we seek clarification on the impacts of applying three separate budget neutrality adjustments in the new methodology. We are concerned that physicians are being forced to "pay" CMS a 30% discount on all of their direct costs because those direct costs are being subjected to a greater than 30% budget neutrality adjustment.

3. Use of Supplemental Survey Data

CAPU applauds CMS for proposing to use the urology supplemental survey data that AUA submitted originally for use in calculating PE RVUs for the 2006 fee schedule. We were disappointed that although CMS accepted AUA's data last year based on Lewin's recommendation that the data met all of the necessary criteria; an error in the proposed rule's list of 2006 PE RVUs caused CMS to withdraw its proposal to actually use the data in calculating the PE RVUs for 2006. Nevertheless, CAPU strongly support the use of AUA's supplemental data in 2007 and beyond (until a new multi-specialty survey is conducted) for calculating the indirect portion of urology PE RVUs.

***

As always, we look forward to working with CMS to address these important issues. If CAPU can provide CMS with additional information, please do not hesitate to contact Jill Rathbun, at 703-486-4200 or Gail Daubert at 202.414.9241.

Sincerely,

*John J. Mulcahy, MD*

John J. Mulcahy, M.D., Ph.D., F.A.C.S.
Chair

cc: Dr. Jim Regan, Chairman of Health Policy Council, AUA
Robin Hudson, AUA
CAPU Board Members (via email only)

**Submitter :** **Ms. Pamela Marrs** **Date: 10/10/2006**

**Organization :** **Dey, L.P.**

**Category :** **Drug Industry**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-1321-P-939-Attach-1.PDF

#939

Dey, L.P.
2751 Napa Valley Corporate Drive
Napa, CA 94558

October 10, 2006

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

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

Dear Sir or Madam:

Dey, L.P. (Dey) is pleased to submit the following comments on the above-referenced proposed rule, which was published by the Centers for Medicare & Medicaid Services (CMS) in the Federal Register of August 22, 2006.[1] Dey develops, manufactures, and markets prescription pharmaceuticals for the treatment of respiratory illnesses and other conditions. Several of Dey's products are reimbursed under Medicare Part B. Below, we provide comments on provisions of the Proposed Rule that pertain Average Sales Price (ASP).

1. Administration Fees Paid to GPOs and PBMs Should Not Be Considered Price Concessions

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

CMS proposes to add to 42 C.F.R. § 414.804 (the "ASP rule") a provision that "bona fide service fee are not considered price concessions" for purposes of the ASP calculation. "Bona fide service fees" would be defined as

> fees paid by a manufacturer to an entity, that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.[2]

CMS explains that the agency is considering providing guidance on the types of services that may qualify as bona fide services, and seeks comments on, among other things, activities that should be considered bona fide services for all types of products.[3]

Although CMS notes in the preamble that it has received requests for clarification on how fees paid to group purchasing organizations (GPOs) and pharmacy benefit managers (PBMs) should be treated for purposes of ASP, neither the proposed rule nor the preamble addresses such fees specifically. However, under the last phrase of the proposed definition of bona fide service fees, administrative fees paid to GPOs and PBMs presumably would be eligible to be considered bona fide service fees, even though neither of these entities typically takes title to drugs.

Dey recommends that CMS provide explicit guidance on the treatment of administrative fees paid to GPOs and PBMs. We further propose that administrative fees that are paid to GPOs and PBMs based on purchase volume or utilization should automatically be considered bona fide service fees, and accordingly ignored in ASP. GPOs have a long history of receiving administrative fees from suppliers (including drug companies) based on a percentage of the purchases of the supplier's products by the

---

2 Prop. §§ 414.802 and 414.804(a)(2)(ii).

3 71 Fed. Reg. at 49001.

GPO's members. The fee compensates the GPO for the services of aggregating multiple buyers so that the manufacturer does not have to negotiate a price with each one, of publicizing the manufacturer's contracted products to its members, and of performing other promotional activities. Accordingly, in 1977, when Congress added exemptions for price reductions and GPO administrative fees to the Medicare/Medicaid antikickback law, Congress did not treat GPO fees as a price reduction, but addressed them in a separate exemption.[4] Presumably, if Congress considered GPO fees to be a price reduction, a separate exemption for GPO fees would have been unnecessary. Accordingly, Dey recommends that CMS adopt an approach under which administrative fees paid to GPOs that comply with the GPO exception and safe harbor under the antikickback law are automatically deemed to be bona fide service fees excludable from ASP.

Manufacturers may also pay administrative fees to PBMs. PBMs act on behalf of their client health plans to negotiate discounts on drugs dispensed to health plan beneficiaries. They also implement formularies and may administer the drug benefit for their client health plans. The administrative fee helps defray the PBM's cost of implementing formularies, providing prescribing data to manufacturers, notifying prescribers about the formulary status of the manufacturer's drugs, and other activities. To the best of our knowledge, administrative fees received by PBMs are not passed on to the health plan clients of the PBM.

The OIG has advised that drug manufacturer payments to PBMs may be structured to comply with the safe harbor for GPO administrative fees under the antikickback law.[5]

---

4 Pub. L. No. 95-142, § 4(b), 91 Stat. 1175, 1182 (1977), codified at 42 U.S.C. § 1320a-7b)(b)(3)(A) and (C). GPO fees are also treated as distinct from price reductions in implementing safe harbor regulations issued by the Office of the Inspector General (OIG) of the Department of Health and Human Services. See 42 C.F.R. § 1001.952(h) and (j).

5 68 Fed. Reg. 23731, 23736 (May 5, 2003) (compliance program guidance for drug

If a PBM is a GPO (i.e., if it is acting as an agent on behalf of health plans to negotiate pharmaceutical discounts), administrative fees paid to the PBM should be treated the same as administrative fees paid to other GPOs. Therefore, for reasons explained above in connection with GPOs, Dey recommends that administrative fees paid to PBMs be automatically deemed to be bona fide service fees excludable from ASP, if the PBM meets the conditions of the GPO safe harbor.

2. Service Fees Paid to Wholesalers and Distributors Should Not be Considered Price Concessions

In the preamble, CMS seeks comments on the specific types of services entities perform on behalf of manufacturers that a manufacturer would otherwise perform (or contract for) and the necessity of those services in the efficient distribution of drugs.[6] Many wholesalers and distributors now seek service fees from drug manufacturers. These fees are variously described as inventory management fees, core distribution fees, handling fees, or in other terms. They are typically based on a percentage of the wholesaler's or distributor's purchases from the manufacturer. Our understanding is that they are not passed on to the customers of the wholesaler or distributor.

These fees compensate wholesalers and distributors not only for the traditional distribution activities of storing, picking orders, packing, and shipping pharmaceuticals, but also for handling chargebacks for contract sales, managing inventory levels in different geographical locations to match demand, providing special handling (e.g., refrigeration), managing returns, providing promotional services, and other activities. These are activities that benefit drug manufacturers, and that a drug manufacturer, in the absence of the wholesaler or distributor, would have to perform itself. Dey urges CMS to

---

manufacturers).

[6] 71 Fed. Reg. at 49001.

clarify in the final rule or in guidance that service fees paid to wholesalers and distributors should not be considered price reductions for purposes of ASP, where the amount is within the range of fees generally paid to wholesalers for such services.

3. CMS Should Provide Guidance on the Treatment in ASP of Rebates to PBMs and Other Managed Care Organizations

In addition to administrative fees discussed in section 1, above, manufacturers also pay rebates to PBMs based on formulary status, the volume or market share of the manufacturer's products dispensed by health plan network pharmacies, or other factors. Manufacturers also pay similar rebates to other managed care organizations (MCOs) besides PBMs. Neither the proposed rule nor its preamble addresses rebates paid by manufacturers to PBMs and other MCOs. This is a serious omission. Because PBMs and MCOs do not pay prices to (i.e., purchase product from) manufacturers, it is uncertain whether these rebates can be considered a price reduction. As CMS is aware, the treatment of PBM and MCO rebates in Medicaid Rebate Average Manufacturer Price (AMP) and best price has been a source of confusion in the industry for over a decade, and the General Accountability Office (GAO) as been critical of CMS's failure to provide guidance in this area.[7]

This rulemaking provides CMS an opportunity to provide clarity on the treatment of PBM and MCO rebates in ASP. Alternatively, if CMS determines that this subject is outside the scope of this rulemaking, CMS should issue guidance in another form. In any event, Dey strongly urges CMS to address this ASP issue through public guidance at the earliest possible time, in order to avoid the disparate methodologies and the confusion that have troubled the Medicaid Rebate Program.

---

7 GAO, Medicaid Drug Rebate Program: Inadequate Oversight Raises Concerns About Rebates Paid to States (GAO-05-102) ("GAO Report"), at 19-23 (Feb. 2005), available at http:/www.gao.gov/new.items/d05102.pdf.

We believe that rebates to PBMs and other MCOs cannot reasonably be treated as a price concession. Since these entities do not purchase drugs,[8] they do not pay any price to a manufacturer. Where there is no price, there cannot be a price concession. Moreover, PBM/MCO rebates are not passed through to wholesalers or pharmacies, so they cannot be considered a reduction in price paid by a wholesaler or pharmacy to the manufacturer. Accordingly, PBM/MCO rebates should be ignored for purposes of ASP.

4. The Estimation Methodology for Lagged Exempted Sales Should Be Optional

The proposed rule would require all manufacturers to use a 12-month rolling average ratio methodology to estimate ASP-exempt sales that become known on a lagged basis (for example, through chargeback notices or rebate invoices).[9] As a rationale for imposing this new layer of complexity in the ASP calculation, CMS explains that it would reduce potential errors (though the agency does not explain what types of errors would be reduced or why), and would reduce quarter-to-quarter variations in the ASP.[10] Dey agrees that the proposed "smoothing" methodology would help reduce quarterly variations in ASP. However, many manufacturers (Dey among them) do not have significant variations in quarterly excludable sales. For these manufacturers, the new methodology would introduce further complexity into the calculation, and require additional time and resources, for little or no benefit. Therefore, Dey recommends that the final rule provide that the smoothing methodology for lagged exempt sales be optional, so that an additional burden is not imposed where it is unnecessary and unhelpful.

---

8 Certain PBMs operate mail order pharmacies. This discussion does not pertain to sales to a PBM's mail order pharmacy.

9 Prop. § 414.804(a)(4).

10 71 Fed. Reg. at 49002.

In addition, for the benefit of manufacturers who wish to use the smoothing methodology, CMS should clarify the final stage of the methodology. The proposed rule would require that, after the manufacturer uses the 12-month ratio methodology to estimate the lagged quarterly exempted sales in units, the manufacturer must make an adjustment to the numerator of the ASP calculation to remove the sales dollars associated with the excluded units.[11] However, the proposal does not explain what dollar value to attribute to each unit in order to perform this operation. Non-lagged sales units can usually be excluded from ASP based on the actual sale price of the unit, which is available to the manufacturer because the sale was a direct sale. However, lagged units are typically associated with indirect sales. The manufacturer becomes aware of the unit though a chargeback notice or rebate utilization report, but these sources may not identify the price at which the unit was originally sold. In such instances, CMS should clarify that the manufacturer should value an excluded unit at the current wholesale acquisition cost[12].

5. CMS Should Not Implement ASP-AMP Comparisons Until an AMP Rule is Finalized

In the preamble, CMS solicited comments on a number of issues regarding its authority to substitute a lower payment amount where the OIG informs the Secretary that ASP exceeds the AMP or the widely available market price (WAMP) by more than a specified percentage (proposed to be five percent for 2007). CMS seeks comment on the timing and frequency of ASP, AMP and WAMP comparisons, and the effective date and duration of the rate substitutions.

---

11 Prop. § 414.804(a)(4)(iii)(A).

12 See the definition of WAC at 42 U.S.C. § 1395w-3a(c)(6)(B).

Dey believes it is premature for the OIG to conduct, and for CMS to use, comparisons between ASP and AMP. Although the Medicaid Rebate Program has been in effect for over 15 years, CMS has never issued a final regulation describing how AMP should be calculated. There are numerous facets of the AMP calculation that are subject to differing interpretations and methodologies on the part of manufacturers.[13] Administrator Mark McClellan recently remarked that CMS is not confident that AMPs are being calculated accurately, and for this reason, CMS has postponed implementation of a new statutory requirement that the agency publish AMPs on a public web site, and is temporarily prohibiting states from using AMPs to establish Medicaid reimbursement rates.[14] Because CMS rightly does not have confidence in the accuracy of AMPs, AMP should not be used as a benchmark for comparison with ASP, and implementation of the statutory provision authorizing Part B payment rate substitutions based on AMP should similarly be delayed. CMS is obligated to publish a regulation regarding AMP by July 1, 2007.[15] Dey strongly urges CMS to wait until after that regulation has been finalized and taken effect before lowering any Part B drug payment amount based on a comparison between AMP and ASP.

6. Payment Rate Substitutions Should Not Be Based on an ASP-AMP or ASP-WAMP Comparison for a Single Quarter

The OIG is mandated by statute to conduct surveys of AMP and WAMP, and to compare ASPs with these prices.[16] However, the statute does not specify the frequency

---

13 See GAO Report.

14 See 42 U.S.C. § 1396r-8(b)(3)(A)(i), as amended by the Deficit Reduction Act of 2005 ("DRA"), § 6001(b), Pub. L. No. 109-171, 120 Stat. 4 (2006). See Remarks of Mark B. McClellan, M.D., delivered to the NCPA 38th Legislation and Government Conference, at 8 (May 22, 2006).

15 DRA § 6001(c)(3)(B).

16 42 U.S.C § 1395w-3a(d)(1) and (d)(2)(A).

of such surveys, nor the duration of a rate substitution that may be implemented by CMS when ASP exceeds ASP or WAMP by more than five percent. For the reasons explained below, Dey believes that an OIG report providing a comparison between AMP or WAMP on one hand and ASP on the other in a single quarter "snapshot" is an insufficient basis on which to reduce payment rates.

Differences in calculation methodology make AMP an untrustworthy comparator for ASP in any single quarter. AMP may vary widely from quarter to quarter, based not only on actual price changes but differences in the relative volume of sales and chargebacks, inordinate numbers of returns, large numbers of rebate payments, and other factors. CMS does not require or recommend smoothing methodologies for AMP, and manufacturers typically do not use it. Recognizing the wide variability in AMP from quarter to quarter, the Center for Medicaid and State Operations does not send inquiries to manufacturers about the accuracy of their AMPs unless the variation in the current quarter AMP is so great that it causes the new unit rebate amount to be more than 400% greater than, or 100% less than, that of the previous quarter.

ASP is much less variable than AMP because smoothing is used for lagged price concessions, and because returns are ignored. If CMS's proposal to extend smoothing to lagged excluded sales in the ASP calculation is finalized, this will increase the difference between AMP and ASP. As a result of these differences, AMP may be substantially lower (or higher) than ASP in any single quarter, even for a drug whose AMP and ASP are very similar when looked at over a longer period. For this reason, a single quarter comparison between AMP and ASP is a poor indicator of a payment rate that is too high. In order to take into account the absence of smoothing methodologies in AMP, any valid comparison between AMP and ASP must be made be over a relatively long term – at least 12 months. For this reason, Dey believes that the OIG must compare the AMP and ASP of a drug for at least four consecutive quarters before CMS could have confidence in

any conclusion that an ASP is actually five percent higher than AMP. A single quarter snapshot is clearly inadequate.

The same is true, though perhaps to a lesser extent, with WAMP. An OIG survey of WAMP at a single point in time is a poor indicator that ASP-based payment is generally too high. Neither the WAMP snapshot survey nor the quarterly ASP (even with smoothing) may reflect the true relationship between the WAMP and the ASP over the longer term. Therefore, our recommendation with regard to AMP-ASP surveys applies also to WAMP-ASP surveys. No rate substitution should be made on the basis of a WAMP survey that covers only a single quarter.

Even if a longer term (e.g., 12-month) comparison between ASP and AMP or between ASP and WAMP results in a conclusion that ASP-based payment has been too high, this does not mean that ASP-based payment will *remain* too high. Prices of manufacturers, wholesalers, specialty pharmacies, and physician supply houses change constantly. For this reason, a rate substitution should be of relatively short duration (for example, two quarters), unless a continuing substitution is supported by a follow-up survey by the OIG.* * *

Dey appreciates this opportunity to provide input on the ASP calculation and Part B payment process, and we urge CMS to seriously consider the above recommendations and comments.

Respectfully submitted,

_____

Pamela Marrs
Senior Vice President and CFO

**Submitter :** Dr. Pacita Colanta **Date:** 10/10/2006

**Organization :** Colanta Hematology & Oncology Center

**Category :** Physician

**Issue Areas/Comments**

**GENERAL**

GENERAL

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

**Submitter :** **Mr. Michael Parini** **Date: 10/10/2006**

**Organization :** **Pfizer Inc**

**Category :** **Drug Industry**

**Issue Areas/Comments**

**Background**

Background

See attachment

**GENERAL**

GENERAL

See attachment

**Impact**

Impact

See attachment

**Provisions of the Proposed Rule**

Provisions of the Proposed Rule

See attachment

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

941

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

October 10, 2006

**BY ELECTRONIC DELIVERY**

Honorable Mark B. McClellan
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

**Re: CMS-1321-P; Medicare Program, Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Policy Under Part B**

Dear Administrator McClellan:

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

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

## I. General Comments

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

## II. Reductions in Physician Payments

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

[2] Id. at 49,077.

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

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

---

[3] 42 U.S.C. 1935w-4(f).

[4] Id.

[5] 42 U.S.C. 1935w-4(f)(2).

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

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

---

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

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

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

## III. ASP Issues

### A. Fees Not Considered Price Concessions

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

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

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

**B. Estimation Methodology for Lagged Exempted Sales**

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

**C. Widely Available Market Prices and the AMP Threshold**

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

[8] 42 U.S.C. § 1395w-3a(c)(2).

[9] 71 Fed. Reg. at 49,002.

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

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

---

[10] 42. U.S.C. § 1395w-3a(d)(3).

[11] 71 Fed. Reg. at 49,004.

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

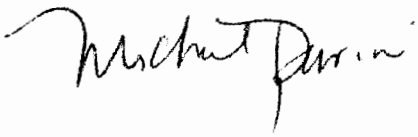
## IV. Conclusion

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

---

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

Sincerely,



Michael J. Parini
Sr. Corporate Counsel

**Submitter :** **Ms. Dawn Hopkins** **Date: 10/10/2006**

**Organization :** **Society of Interventional Radiology**

**Category :** **Health Care Professional or Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

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

CMS-1512-PN 942

SOCIETY OF INTERVENTIONAL RADIOLOGY
*Enhanced care through advanced technology™*

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

October 10, 2006

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

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

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

Dear Administrator McClellan/Norwalk:

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

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

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

**Ultrasound Screening for Abdominal Aortic Aneurysm (AAA)**

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

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

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

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

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

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

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

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

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

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

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

Sincerely,

[Endorsed copy mailed this day]

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

[Endorsed copy mailed this day]

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

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

## Attachment A -

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

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

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

**Submitter :** Mr. Steve Kowske **Date:** 10/10/2006

**Organization :** Aurora Health Care

**Category :** Hospital

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

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

#943

Aurora Health Care

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

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

October 10, 2006

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

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

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

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

## New Technology APC's

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

## Hospital Quality Data

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

1. Having to send out a second survey is prohibitively expensive should the patient not send back the first survey.
2. The length of the survey is too long, lessening our ability to add in our own questions, and taking away from our historical measures that we have tracking for the last six years. If the survey is too long the patient will not fill it out, and require us to send out another one. Please see first comment regarding the second survey.
3. The required sample size of 300 per year is too many for the smaller hospitals to get enough responses. As a result, we will be unable to utilize our existing survey because there is not a sample of patients left after complying with the HCAHPS Protocol. In effect, to be compliant with HCAHP Protocol in order to receive the proposed market basket update, assuming the rule is passed, our hospitals, especially our smaller ones, have little choice but to abandon our present methodology, in lieu of the more expensive HCAHPS methodology.

4. For the facilities, participating in the national rollout, it takes too long for the benchmark data to be returned (one year). The data is not very meaningful when it takes that long to obtain the results.

5. Participating in HCAHPS is going to require expensive remodeling of our current custom web-based reporting system.

6. Hospitals that participated in the 2006 dry-run should be allowed to join the national implementation in 2007 without having to go through the dry-run again

## Device Dependant APC's

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

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

Sincerely,

Steve Kowske
Regulatory and Reimbursement Manager
Aurora Health Care

**Submitter :** **Daniel Dowdy** **Date: 10/10/2006**

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

**Category :** **Physician**

**Issue Areas/Comments**

**GENERAL**

GENERAL

Please see attachment. Thanks, Dan Dowdy

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

#944

# AMARILLO UROLOGY ASSOCIATES, L.L.P.

RICHARD G. KIBBEY III, M.D.
JACK C. LONG, M.D.
VIRGIL A. PATE III, M.D.
GARY L. BROWN, M.D.
MICHAEL D. WILKERSON, M.D.
RONALD W. FORD, M.D.
DAVID M. WILHELM, M.D.
C. SLOAN TEEPLE, M.D.

1900 MEDI PARK DRIVE
AMARILLO, TX 79106
P.O. BOX 51800
AMARILLO, TX 79159-1800
PHONE: 806.355.9447
FRONT FAX: 806.354.8662
BACK FAX: 806.356.9251

Writer's e-mail address: dand@amarillourology.com

TO: Centers for Medicare & Medicaid Services

FROM: Daniel A. Dowdy, Chief Operating Officer

SUBJECT: File Code CMS-1321-P
Reassignment and Physician Self-Referral

DATE: October 10, 2006

Ladies and Gentlemen:

Please accept these comments respecting your Proposed Changes to Reassignment and Physician Self-Referral Rules Relating to Diagnostic Tests.

Amarillo Urology Associates, L.L.P. is comprised of 8 urologists, all of whom are specialists who offer surgical and medical services, including the diagnosis and treatment of prostate cancer. Our practice provides a full array of urological care to men, women and children. Approximately 48% of our practice is devoted to the care of Medicare beneficiaries.

In order to assure that we can provide the best and most cost efficient laboratory services, in 2004, our practice engaged the services of Uropath, a company that develops, implements and manages our specialized urological laboratory facility, located in San Antonio, Texas. We wish to maintain our pathology laboratory facility and we make the following comments:

- In the opinions of our doctors, adequate specialized uro-pathology services were not available in Amarillo, Texas in 2004 and are still not available in Amarillo in 2006.
- Prior to opening our own pathology lab, we were sending 100% of our human tissue and specimens to outside reference labs, primarily in Oklahoma City, OK. Now, our internal pathological laboratory provides quick, reliable, accurate and superior service, resulting in better patient care, without additional cost to CMS.
- A single, trained pathologist reviews all of our tissue and specimen samples. We are not relying on the "luck of the draw" at a reference lab. Our pathologist provides accurate results and she is available for one-on-one consultations with the urologists in our group.
- Our pathologist has at least 1 and typically 2 full time, trained urologic pathologists who provide backup and serve as professional on-site consultants on difficult interpretations. Our doctors informally consult with each other on other cases and we appreciate the "2 heads are better than 1" concept that the Uropath pathology model allows.

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

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

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

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

**Organization :**

**Category :** **Attorney/Law Firm**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

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 :** **Ms. Jaime Mulligan** **Date: 10/10/2006**

**Organization :** **American Chiropractic Association**

**Category :** **Chiropractor**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment.

CMS-1321-P-946-Attach-1.PDF

H 946

American Chiropractic Association

October 10, 2006

RE: CMS-1321-P
Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and other Changes to Payment Under Part B
CHIROPRACTIC SERVICES DEMONSTRATION, PROVISIONS: RESOURCE-BASED PRACTICE EXPENSE RELATIVE VALUE UNIT PROPOSALS

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

**CHIROPRACTIC SERVICES DEMONSTRATION**

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

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

**PROVISIONS: RESOURCE-BASED PRACTICE EXPENSE RELATIVE VALUE UNIT PROPOSALS**

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

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

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

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

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

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

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

Sincerely,

Kevin Corcoran
Executive Vice President

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

---

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

Sincerely,

John Lyman, MD, FACEP
Chair, Board of Directors

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

**Organization :**

**Category :** **Nurse Practitioner**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

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

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

#949-1
October 9, 2006

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

Re: File code CMS-1321-P Criteria for National Certifying Bodies- Advanced Practice Nurses

To Whom It May Concern:

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

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

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

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

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

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

Sincerely:

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

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

National Certification Corporation
Betty Burns 312-951-0207

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

Pediatric Nursing Certification Board
Janet Wyatt 301-330-2921

#949-2
October 9, 2006

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

Re: File code CMS-1321-P Criteria for National Certifying Bodies- Advanced Practice Nurses

To Whom It May Concern:

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

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

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

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

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

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

Sincerely:

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

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

National Certification Corporation
Betty Burns 312-951-0207

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

Pediatric Nursing Certification Board
Janet Wyatt 301-330-2921

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

**Organization :**

**Category :** **Attorney/Law Firm**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

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

#950

ReedSmith

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

October 10, 2006

BY ELECTRONIC MAIL

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

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

Dear Ms. Greenberg:

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

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

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

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

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

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

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

### A. Procedural History

---

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

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

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

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

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

---

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

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

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

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

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

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

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

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

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

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

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

Id. (emphasis added).

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

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

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

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

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

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

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

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

## II. The Proposed Rule Is Inconsistent with Applicable Legal Authorities

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

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

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

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

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

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

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

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

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

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

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

---

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

scientific articles, technology assessments, clinical guidelines, statements from clinical experts, medical textbooks, claims data, or other indication of medical standards of practice that CMS considered before issuing the Proposed Rule. The Proposed Rule is also wholly inconsistent with the diabetes care initiatives established and promoted by the U.S. Department of Health and Human Services ("HHS"), as discussed further below. In sum, CMS has failed to articulate any rationale for its rule, the alternatives considered and ruled out, and, fundamentally, why such a restrictive policy is consistent with the statutory mandate that blood glucose testing services be "reasonable and necessary."

The complete absence of medical evidence or claims data to support the proposed regulation means that interested parties cannot offer meaningful comments to the substance of the Proposed Rule. Pursuant to the Administrative Procedures Act (the "APA"), federal agencies must "give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments." 5 U.S.C. 553(c). Courts have consistently held that the public's right to participate in the rulemaking process requires an agency to "provide sufficient factual detail and rationale for the rule to permit interested parties to comment meaningfully." Florida Power & Light Co. v. United States, 846 F.2d 765, 771 (D.C. Cir. 1988). See also Home Box Office, Inc. v. FCC, 567 F.2d 9, 35 (D.C. Cir. 1977); United States v. Nova Scotia Food Products Corp., 568 F.2d 240, 251-52 (2nd Cir. 1977).

In order for parties to offer meaningful support or criticism under the APA's notice-and-comment rulemaking process, "it is especially important for the agency to identify and make available technical studies and data that it has employed in reaching the decisions to propose particular rules." Connecticut Light & Power Co. v. Nuclear Regulatory Com., 673 F.2d 525, 530-31 (D.C. Cir. 1982). See also Sierra Club v. Costle, 657 F.2d 298 (D.C. Cir. 1981). If the federal agency relies on an outside study in promulgating a rule, the agency itself must first examine the methodology used to conduct the study. City of New Orleans v. SEC, 969 F.2d 1163, 1167 (D.C. Cir. 1992). Furthermore, the technical complexity of the analysis does not relieve the agency of the burden to consider all relevant factors and there "must be a rational connection between the factual inputs, modeling assumptions, modeling results and conclusions drawn from these results." Sierra Club, 657 F.2d at 333. In Portland Cement Ass'n v. Ruckelshaus, 486 F.2d 375 (D.C. Cir. 1973), the D.C. Circuit invalidated a final EPA regulation because

---

program recognizes that "administration of the [blood glucose testing] service several times a day is common in order to maintain tight control of glucose to prevent heart disease, blindness, and other complications of diabetes." Program Memorandum AB-00-108 (Dec. 1, 2000), pg. 1. The Program Memorandum also discusses blood glucose testing services for Medicare Part B nursing home patients and states that payment cannot be denied on the basis that the service is routine care, which is only a consideration for Part A nursing home services. See id., pg. 3

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

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

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

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

### A. Blood Glucose Testing is a Cornerstone of Diabetes Care

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

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

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

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

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

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

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

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

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

been shown to be cost-effective. See id. Regular blood glucose testing with home use devices is less expensive in the long run than the costs of surgery and other treatments for patients who develop complications due to poor glycemic control. However, despite the advances in monitoring devices and therapeutic agents, at least one study suggests that there has not been a corresponding improvement in glycemic control for diabetic patients. See id. The likely explanations for this include "lack of time and resources due to reimbursement considerations, for physicians to treat patients with diabetes," provide needed education, and other factors. Id.

CMS has a clear opportunity to place itself at the forefront of combating diabetes in the nursing home population. However, the Proposed Rule is precisely the type of reimbursement policy that discourages regular blood glucose testing. Rather than encourage the necessary monitoring of blood glucose levels in Part B SNF residents by covering these tests, the Proposed Rule establishes administrative burdens that would effectively deny coverage, creating a disincentive to perform these tests. Moreover, the Proposed Rule directly contradicts best practices and instead calls for an unworkable, misguided and impractical approach to treating diabetes. Although physicians and nursing homes will continue to use their best efforts to treat Medicare beneficiaries, the treatment protocol advocated by the Proposed Rule would be less effective than current best practices in preventing institutionalized diabetics from suffering heart attacks and strokes, developing blindness, requiring the amputation of limbs, and experiencing other complications that require costly medical intervention. The preamble to the Proposed Rule also includes no comparisons of the costs of regular blood glucose monitoring without the proposed physician certification requirement with the costs of hospital and rehabilitative care for these severe complications. CMS should withdraw the Proposed Rule for precisely these reasons and, instead, develop blood glucose monitoring policies that comport with current best practices in treating and preventing diabetes.

B. Requiring Orders for Each Individual Blood Glucose Test is Not Best Medical Practices

The established best practice is for the physician to set the frequency of the testing and a range for the blood glucose values of the specific patient. Physicians are notified when glucose values go above or below the specified parameters. Adjustments are made to the base (and supplemental) insulin dose when necessary. This treatment protocol is essentially the same whether the patient is being treated at home, as a hospital inpatient, or in a SNF, and is consistent with existing Medicare requirements and the policy of many fiscal intermediaries. As discussed below, there is no rational basis to apply a more restrictive policy to the administration of blood glucose testing to SNF residents than to ambulatory beneficiaries performing self-testing at home, particularly considering that SNF residents are less capable of such tasks – as reflected in the fact that they require 24-hour care in nursing homes that offer skilled nursing care and other services.

Adherence to the current best practices for glucose testing is particularly important in elderly patients whose age has compromised the body's ability to maintain stability and uniformity on its own. To help elderly diabetics maintain a homeostatic state, the clinical practice model of the AMDA recommends a blood glucose test on admission, bedside glucose testing several times a day (more frequently if the patient's glucose level is poorly controlled), daily blood glucose review, and physician alert when values fall below or above the recommended range or a range indicated in the physician's order. See Managing Diabetes in the Long-Term Care Setting: Clinical Practice Guideline, American Medical Directors Association (AMDA) (2002), pgs. 11, 27-28, 39-42. These carefully designed clinical practices are clearly "reasonable and necessary" for the ongoing diagnosis and treatment of diabetes in institutionalized beneficiaries.

Clearly, physicians will and should follow the best practice in this area. Thus, compelling SNFs to phone a physician for each patient, sometimes up to three and four times a day, for an order for the next test to be done in a few hours (in order to achieve coverage under the rubric of the Proposed Rule) is in actuality telling physicians how to practice medicine, and more importantly, telling them how to practice it inappropriately and badly.[4] This is not acceptable. Accordingly, CMS should withdraw the Proposed Rule because it is contrary to the best practices of medicine, it is not patient-centered, contradicts the plain requirements of the Act, and is a marked departure from the long-standing policy of the agency.

C. The Proposed Rule is Inconsistent with Federal Initiatives to Treat and Prevent Diabetes

The Proposed Rule not only ignores current medical literature and clinical authorities, it is inconsistent with numerous federal initiatives to combat diabetes and prevent complications of the disease. A number of these programs recognize the value of having the physician prescribe supplies and document the frequency of self-testing, without requiring physician review before each testing event. Some of the key programs sponsored by the federal government include:

- The Centers for Disease Control and Prevention ("CDC") National Public Health Initiative on Diabetes and Women's Health (see http://www.cdc.gov/diabetes/projects/women.htm);
- The HHS Council on Health Disparities, which sponsors a number of programs designed to improve the health of minorities and underserved populations, including diabetes detection and prevention (see http://raceandhealth.hhs.gov); and

4 The Social Security Act expressly mandates that federal agencies are not authorized to "exercise any supervision or control over the practice of medicine or the manner in which medical services are provided." Social Security Act § 1801 (codified at 42 U.S.C. § 1395).

- The National Diabetes Education Program ("NDEP") (see http://www.cdc.gov/diabetes/ndep/index.htm).

When HHS launched NDEP in 2001, a joint federal program run by the National Institutes of Health and the CDC, the Secretary emphasized the importance of informing Medicare beneficiaries that they "can use their benefits to better monitor and manage their diabetes." See "HHS Launches Diabetes Education Program for Older Americans," HHS Press Release (May 3, 2001), reprinted at http://www.hhs.gov/news/press/2001pres/20010503.html, pg. 1. The NDEP supports routine monitoring of blood sugar levels by diabetics and their health care providers for use in an effective treatment plan for managing their disease. See id. These policies are even more important for diabetic patients residing in nursing homes considering the significant impact that diabetes can have on this vulnerable Medicare population.

Nonetheless, the Proposed Rule would frustrate the objectives of these vital federal initiatives by imposing additional hurdles to regular blood glucose testing in SNF residents. The Proposed Rule also runs counter to the recommendations of the American Diabetes Association that, given the importance of blood glucose testing to diabetes care, government and third-party payers "should strive to make the procedure readily accessible and affordable for all patients who require it." See Position Statement: Tests of Glycemia In Diabetes, American Diabetes Association, Diabetes Care 25:S97-S99, Supp. 1 (Jan. 2002), pg. S97. CMS should remain cognizant of the significant efforts that the federal government has undertaken to prevent and combat diabetes. Accordingly, the Proposed Rule should be withdrawn.

D. A Physician's Treatment Protocol Does Not Constitute a "Standing Order"

The proposed regulation would deem that a physician's "standing order" is not sufficient to order a series of blood glucose testing services. We are concerned that CMS is improperly interpreting a physician-prescribed protocol of blood glucose monitoring, including sliding scale insulin dosage determination by glucose monitoring, as a "standing order" or as "routine testing." If these general principles are misunderstood or misapplied, SNFs would be required to obtain a new physician order for each blood glucose test, which in many cases is done two to three times a day. In short, we believe that any interpretation of physician-prescribed protocols of blood glucose monitoring as "standing orders" is in error. Moreover, we are extremely troubled that CMS is not correcting this misunderstanding and, as indicated by the Proposed Rule, may indeed be supporting it.

In diabetes management, "standing order prescriptions" are designed to control unplanned conditions. Conversely, prescriptions for glucose monitoring are patient-specific and are designed to maintain a homeostasis (to maintain stability/uniformity in the normal body state of the particular patient). The difference between these two medical treatment strategies is medical event management

(standing orders) versus medical diagnosis and maintenance (glucose monitoring via sliding scale to determine insulin dose). Unlike "standing orders" aimed at management to control unplanned/acute conditions, glucose monitoring strives to maintain a homeostatic state which is particularly important in elderly patients where their age has compromised the body's ability to maintain stability. Moreover, a physician's determination that a series of blood glucose tests administered over a limited period time is reasonable and necessary to detect and treat glucose abnormalities should not be discounted as a "standing order" that would not qualify for reimbursement of the testing services.

The American Healthways, Inc. (formerly the Diabetes Treatment Centers of America) developed best practice guidelines for the inpatient management of patients with diabetes. In this model, "standing orders" consist of developing protocols for responding to hypoglycemia, intravenous insulin infusion instructions, perioperative diabetic assessments and insulin pump management. These standing orders are needed to address situations where abrupt or unplanned conditions precipitate deterioration of metabolic glucose control, resulting in acute complications like diabetic ketoacidosis, hypoglycemia, and other adverse outcomes. As is evident, there is significant difference between "standing orders" and a beneficiary-specific blood glucose monitoring and treatment protocol, yet CMS fails to recognize such a distinction in the Proposed Rule.

Even if CMS considers a blood glucose monitoring protocol to be a "standing order," such an order would continue to reflect a physician's independent judgment that the prescribed tests are "reasonable and necessary" to diagnose and treat diabetes and therefore covered under Medicare Part B. In its Compliance Program Guidance for Clinical Laboratories, the Office of Inspector General (the "OIG") for HHS clearly states that "standing orders are not prohibited in connection with an extended course of treatment . . . ." 63 Fed. Reg. 45,076, 45,081. The OIG does not suggest that laboratory testing performed pursuant to a "standing order", including blood glucose testing, is itself not reasonable and necessary. Rather, the OIG's concern is that, in some cases, a physician's initial determination that testing is medically necessary may not be adequately updated or reviewed. In the context of blood glucose monitoring in SNFs, it is our experience that physicians who order glucose monitoring in connection with an extended course of treatment for diabetic nursing home beneficiaries <u>are</u> periodically monitoring those "standing orders." Thus, a carefully planned protocol for blood glucose testing, reviewed periodically by the treating physician, does not present the potential concerns highlighted by the OIG and, accordingly, would satisfy the "reasonable and necessary" requirements of the Medicare statute and regulations. Therefore, the Proposed Rule should be withdrawn or, at a minimum, amended to clarify that a protocol of blood glucose monitoring for a SNF resident may itself be reasonable and necessary, not just the individual tests that are administered pursuant to the prescribed plan of treatment.

E. CMS Should Adopt the AHCA or Highmark Protocol for the Administration of Blood <u>Glucose Testing</u>

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

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

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

---

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

for individual test certifications would impose. We invite CMS to review and comment on the proposed AHCA and Highmark protocols.

## V. The Proposed Rule Would Place Unnecessary Administrative Burdens On Providers And Physicians

The Proposed Rule's requirement that treating physicians certify each individual blood glucose test prescribed for a SNF beneficiary would undoubtedly create unnecessary administrative burdens for both physicians and SNF personnel. Treating diabetes using blood glucose testing in a hospital, SNF, or home, is best managed by trend analysis, not test-to-test adjustments. It is generally of little use to provide individual test results to, and obtain a new order from, the physician after each test, except when the results are outside the parameters set by the physician; in such cases, as with any significant change in condition, the physician would be promptly notified. Under current best practices, it is most useful for the physician to see trends of test results in order to determine whether dosage modification is medically necessary. See Managing Diabetes in the Long-Term Care Setting: Clinical Practice Guideline, American Medical Directors Association (AMDA) (2002), pgs. 28.

Nevertheless, the Proposed Rule would impose additional, unreasonable requirements that would not serve to improve the health of Medicare beneficiaries. Instead of adhering to current best practices, the Proposed Rule would require repeat communications between the SNF and the physician, as many as three or four times per day, for each diabetic SNF resident whose physician has prescribed a protocol of ongoing blood glucose monitoring. As one physician that treats diabetic Medicare SNF residents observes, it "would be impractical and, in my opinion, unnecessary for me to write a separate order for each blood glucose test to be administered to [my patient], or to be notified of the results of each test. It is my professional opinion, in keeping with standard medical practice, to review [my patient's] blood glucose test results on a bi-monthly basis and make appropriate adjustment to her plan of care."

The Proposed Rule would also create a tremendous burden on SNFs and their nursing staff and fails to take into consideration the realities of caring for Medicare beneficiaries who suffer from this common and debilitating disease. Most SNF residents have blood glucose testing schedules that follow similar time frames and, thus, the Proposed Rule would require nurses to call physicians for every diabetic patient at the same time. In other words, even if SNFs reported each individual test result to each diabetic resident's physician – and then waited for the physician to certify the next scheduled test – it is doubtful that this process would further the agency's ostensible goal of increasing physician involvement in diabetes management. Time taken to report individual tests also impedes necessary consultation and input from interdisciplinary care team members that have a critical role in the patient's diabetes management. Moreover, as discussed below, the requirement that each blood glucose test be supported by an individual physician order would impose a significant paperwork burden on providers and fiscal intermediaries. Consequently, the Proposed Rule would not serve to further the health needs

of Part B beneficiaries, but would merely impose additional burdens on those practitioners and SNF personnel currently following best practices in treating diabetes in nursing home residents. CMS should encourage physicians and SNFs to continue using current best practices in treating Medicare Part B beneficiaries, not frustrate such efforts by imposing unnecessary administrative burdens on these providers.

## VI. The Proposed Rule Disparately Impacts Part B Beneficiaries Residing in SNFs

The Proposed Rule also improperly distinguishes between Medicare Part B beneficiaries based solely on their place of residence, and does not take into consideration the inherent differences in the medical needs of ambulatory diabetics and those who reside in nursing homes. As noted, blood glucose testing with a device approved for home use is covered under Medicare Part B as a "diagnostic laboratory test" when reasonable and necessary to diagnose and treat illness or injury. See 42 U.S.C. § 1395y(a)(1)(A); 42 C.F.R. § 493.15. In order to be covered by Medicare, therefore, a physician must certify that blood glucose monitoring is reasonable and necessary based upon the circumstances and needs of the individual beneficiary. However, the Proposed Rule attempts to create an arbitrary distinction between diabetic beneficiaries that reside in SNFs, and ambulatory beneficiaries that are capable of performing their own tests at home on a device similar, or even identical to, the device used by a nursing home to perform blood glucose monitoring. As such, the Proposed Rule would allow physicians to prescribe an ongoing blood glucose treatment monitoring plan for ambulatory Part B beneficiaries, but not for more vulnerable nursing home residents - who clearly require substantially more attention and care. This disparate impact on institutionalized Part B beneficiaries would be untenable.

In general, nursing home patients have a high incidence of cognitive and physical impairment and need help in daily activities. The prevalence of these impairments is higher among diabetic nursing home patients than in the nursing home population as a whole, which increases the complexity of diabetes management, and makes it unlikely that these patients can independently manage their diabetes. Diabetic nursing home residents are susceptible to hyperglycemia and hypoglycemia, and are frequently unable to perceive or communicate hypoglycemic symptoms to their caregivers. Nevertheless, CMS would impose additional administrative requirements – unwarranted by current clinical evidence and industry practices – on nursing homes and physicians that provide such critical services to Medicare beneficiaries. Given the increased vulnerability of diabetic nursing home residents, there is simply no rational basis for making it more difficult for such individuals to receive adequate blood glucose monitoring services than for those that can perform such services at home, without assistance. In the event that a physician fails to certify an individual blood glucose test for a nursing home resident, the Proposed Rule would effectively penalize the beneficiary for obtaining the necessary supervision and care that a Medicare-certified SNF can provide. Because the Proposed Rule presents an issue of

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

## VII. CMS Failed to Adequately Perform the Regulatory Impact Analysis

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

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

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

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

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

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

Respectfully submitted,

Thomas C. Fox
Jason M. Healy
REED SMITH LLP

**er :** **Ms. Margaret Boiano** **Date: 10/10/2006**

**ation :** **VNUS Medical Technologies, Inc.**

**y :** **Private Industry**

**eas/Comments**

**RAL**

RAL

ee attached comments. Thank you.

21-P-951-Attach-1.DOC

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

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

Sincerely,

Margaret Boiano
Director of Reimbursement
VNUS Medical Technologies, Inc.

Reliant...
HEALTHCARE SOLUTIONS

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

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

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

Sincerely,

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

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

**itter :** **Dr. Stanton Champion** **Date: 10/10/2006**

**nization :** **Urology Tyler, PA**

**gory :** **Physician**

**Areas/Comments**

**NERAL**

IERAL

Attachment

**Submitter :** **Mrs. Tamara Schwartz** **Date: 10/10/2006**

**Organization :** **BioTech Laboratory, Inc.**

**Category :** **Other Health Care Professional**

**Issue Areas/Comments**

**Background**

Background

Diabetic patients health jeapardized.
RE: Revisions to 42 CFR 424.24(f) BLOOD GLUCOSE MONITORING IN A SNF

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

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

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

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

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

**Submitter :** **Ms. Maya Bermingham** **Date: 10/10/2006**

**Organization :** **Pharmaceutical Research and Manufacturers Associat**

**Category :** **Drug Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

"See Attachment"

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

Conan P. Grames
Senior Vice President
General Counsel

PhRMA

October 10, 2006

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

Dear Dr. McClellan:

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

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

Sincerely,

Conan P. Grames

Conan P. Grames

Enclosure

PhRMA

October 10, 2006

**VIA HAND DELIVERY AND E-MAIL**
***http://www.cms.hhs.gov/eRulemaking***

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

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

Dear Dr. McClellan:

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

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

---

[1] Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B; Proposed Rule, 71 Fed. Reg. 48982 (Aug. 22, 2006).

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

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

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

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

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

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

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

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

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

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

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

### 2. Estimation Methodology for Lagged Exempted Sales

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

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

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

---

[4] Id.

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

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

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

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

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

---

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

8 Id. at 49003.

9 Id.

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

### 6. Widely Available Market Prices and AMP Threshold

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

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

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

---

10 See SSA § 1847A(d)(3).

11 71 Fed. Reg. at 49004.

12 Id.

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

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

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

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

---

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

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

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

### 8. Medicare Part B Coverage

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

## B. DRA Proposals

The proposed rule would amend 42 C.F.R. § 410.160 to implement the DRA provision concerning payment for colorectal cancer screening tests. That provision exempts such tests from the Part B deductible, effective 2007.[16] PhRMA supports this provision and the corresponding proposed change in the regulation, which will increase the availability of these tests to Medicare beneficiaries and thank CMS for revising the regulations to make the policy clear.

## C. Payment for Administration Fees for Part D Vaccines

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

---

15 Id. at 49000.

16 See 71 Fed. Reg. at 48999.

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

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

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

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

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

---

18 SSA, § 1860D-2(e).

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

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

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

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

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

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

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

---

22 70 Fed. Reg. at 4231.

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

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

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

### D. Echocardiography Imaging Drug Administration Issue

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

* * *

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

Sincerely,

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

Maya J. Bermingham
Assistant General Counsel

**Submitter :** Dr. Kent Webb **Date:** 10/10/2006

**Organization :** Trinity Vascular Institute

**Category :** Physician

**Issue Areas/Comments**

**Background**

Background

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

**GENERAL**

GENERAL

CMS-1321-P

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

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

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

3. The values for radiofrequency vein ablation (36475 & 36476) have been consisiently higher than endovenous laser ablation despite the higher acquisition cost for the Laser Generator, which raises the cost of laser ablation (36478) to equal or higher than radiofrequency ablation (36475).
I am requesting that the fully implemented, non-facility practice expense RVU remain at the 2006 rate for 36475 of 51.5 and that the RVU for 36478 be increased to this same level.

4. I should add that if the RVU levels continue to drop, it may not be economically feasible to continue these minimally invasive procedures in our office. The alternative would include going back to old-fashioned surgical saphenous vein stripping in the hospital, with the attendant costs of hospital, operating room, anesthesia, recovery room, etc, etc.
Several of my patients have had a vein stripping operation on one leg years ago, and then have endovenous laser ablation of the other leg. Without question they always tell me that the laser ablation was much easier on them, with decreased pain, morbidity, and faster return to work and activities of daily living when compared to the vein stripping.

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

Sincerely,

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

**Impact**

Impact

See General Comment Statement below

**Provisions of the Proposed Rule**

Provisions of the Proposed Rule

See General Comment Statement below

**Submitter :** Mr. Santiago Mu?oz **Date:** 10/10/2006

**Organization :** University of California Health System

**Category :** Hospital

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

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

UNIVERSITY OF CALIFORNIA

BERKELEY • DAVIS • IRVINE • LOS ANGELES • MERCED • RIVERSIDE • SAN DIEGO • SAN FRANCISCO

SANTA BARBARA • SANTA CRUZ

OFFICE OF THE PRESIDENT --
CLINICAL SERVICES DEVELOPMENT

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

October 10, 2006

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

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

Dear Administrator McClellan:

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

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

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

effort to protect access for Medicare beneficiaries. The SGR payment formula unfairly cuts physician payments if growth in Medicare patients' use of services exceeds the growth in t he g ross do mestic p roduct ( GDP). T his l ink is inappropriate b ecause the medical needs of patients do not decline during economic downturns.

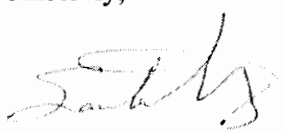
While we understand that structural changes to the flawed SGR payment formula will require Congressional action, we believe that CMS has the authority to amend the 2007 payment rule and address issues created by the SGR payment formula. In particular, CMS can remove drugs from the growth target that trigger the negative update. Drugs were included in the growth target in order to reduce over-utilization. However, much of the expenses associated with drugs are related to oncology treatments, where the physician has little utilization discretion. As such, we respectfully request that CMS remove drugs from the SGR system in the CY 2007 Physician Fee Schedule Rule.

Absent CMS and Congressional action on the flawed SGR mechanism, Medicare payment rates for physicians will be cut by 5.1 percent beginning January 1, 2007; reductions are projected to total 34 percent through calendar year 2015. For UC faculty physicians, the direct effect of these pending payment reductions is substantial; the cuts will total over $8 million in 2007. Since many other professional agreements are tied to Medicare rates, indirect losses are estimated at an additional $4-6 million for a total 2007 financial impact of approximately $12-14 million. Moreover, while Medicare payment rates plummet, practice costs continue to increase at a significant rate.

Declining Medicare payments greatly affect UC physicians as they provide medical education and care for extremely high-cost Medicare beneficiaries. Medicare beneficiaries rely on academic physicians and health systems like the University of California to provide high quality, innovative, and accessible healthcare. Absent leadership from CMS and Congress, the University's ability to continue to meet the diverse clinical needs of a growing Medicare population will be severely compromised.

Thank you for the opportunity to comment on the Medicare Physician Fee Schedule for CY 2007. If there are questions or if I can provide any additional information or input, please contact me at 510-987-9062 or santiago.munoz@ucop.edu.

Sincerely,



Santiago Muñoz, Executive Director
Clinical Services Development

**Submitter :** **Mr. Matthew Eyles** **Date: 10/10/2006**

**Organization :** **Wyeth Pharmaceuticals**

**Category :** **Drug Industry**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See attachment

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

#95 B

**Wyeth Pharmaceuticals**
500 Arcola Road
Collegeville, PA 19426

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

**Wyeth**

**BY ELECTRONIC DELIVERY**

October 10, 2006

Mark McClellan, M.D., Ph.D.
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Ave., SW
Washington, DC 20201

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

Dear Dr. McClellan:

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

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

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

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

**Colorectal Screening Deductible**

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

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

**ASP-Related Issues**

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

Bona Fide Service Fees

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

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

[1] See 71 Federal Register at 48999.

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

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

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

ASP Payment Calculations

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

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

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

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

Fair Market Value

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

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

Estimation Methodology for Lagged Exempt Sales

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

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

---

[2] 71 Federal Register at 49,001

[3] 71 Federal Register at 49,001

[4] Id

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

Nominal Sales

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

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

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

Bundled Price Concessions

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

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

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

Other Price Concessions - Redesignated NDCs

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

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

**Clotting Factor Furnishing Fee**

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

CMS proposes to increase the furnishing fee by the percentage increase in the CPI for medical care for the twelve-month period ending June 2006.[7] Without an increase in the clotting factor furnishing fee, providers of clotting factor—especially hemophilia home care companies—could eventually be forced to withdraw from the Medicare market. If that occurs, hemophilia patients could be denied clinically appropriate access and may not receive prompt treatment for bleeds associated with their disease. In addition to the significant physical and emotional harm to hemophilia patients, it could result in a shifting of care to other

---

[5] 71 Federal Register at 49003

[6] 71 Federal Register at 49003

[7] 71 Federal Register at 49004

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

**ESRD Provisions**

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

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

**Drug Administration Services**

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

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

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

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

**Conclusion**

Wyeth appreciates the opportunity to comment on the issues outlined in the CMS-1321-P (Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B) proposed rule. We look forward to our continued work with CMS to ensure that Medicare beneficiaries receive appropriate access to vital drug and biological therapies covered under the Medicare program. If you have any questions about Wyeth's comments, please do not hesitate to contact me.

Sincerely,

Matthew D. Eyles

Matthew D. Eyles

**Submitter :** **Date: 10/11/2006**

**Organization :**

**Category :** **Physician**

**Issue Areas/Comments**

**Background**

Background

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

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

**Impact**

Impact

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

**Provisions of the Proposed Rule**

Provisions of the Proposed Rule

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

**Submitter :** Ms. Lourdes Hernandez **Date:** 10/10/2006

**Organization :** Michael S. Buchholtz, MD, PC

**Category :** Physician

**Issue Areas/Comments**

**GENERAL**

GENERAL

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

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

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

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

**Submitter :** **Dr. Stanton Champion** **Date: 10/10/2006**

**Organization :** **Urology Tyler, PA**

**Category :** **Physician**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID 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. Craig Schwartz **Date:** 10/10/2006

**Organization :** Vein Centers for Excellence of KC

**Category :** Physician

**Issue Areas/Comments**

**Background**

Background

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

**GENERAL**

GENERAL

General Comment

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

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

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

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

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

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

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

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

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

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

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

Respectfully submitted,

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

**Impact**

Impact

Provisions of the Proposed Rule
See General Comment below.

**Provisions of the Proposed Rule**

Provisions of the Proposed Rule

Background
See General Comment Below

**Submitter :** Dr. Stanton Champion **Date:** 10/10/2006

**Organization :** Urology Tyler, PA

**Category :** Physician

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

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

#961
Department of Health and Human Services
Centers for Medicare and Medicaid Services, HHS

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

Dear Sir or Madam:

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

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

**I. Unsupported Rationale for the Elimination of Centralized Pathology Laboratories**

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

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

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

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

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

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

## II. Benefits of Path Lab Arrangements

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

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

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

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

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

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

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

### III. Controlling the Risk of Over-utilization

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Respectfully submitted,

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

**Submitter :** Dr. Lee Adler **Date:** 10/10/2006

**Organization :** AIAI

**Category :** Physician

**Issue Areas/Comments**

**Impact**

Impact

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

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

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

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

**Organization :** Arizona Oncology

**Category :** Physician

**Issue Areas/Comments**

**GENERAL**

GENERAL

"See Attachment"

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

#963
September 8, 2006

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

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

Dear Administrator:

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

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

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

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

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

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

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

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

Sincerely,

*Robert Kuske, MD*

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

cc: Senator John Kyl, AZ, (R)

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

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

**Submitter :** Dr. David Huang **Date:** 10/10/2006

**Organization :** Dr. David Huang

**Category :** Physician

**Issue Areas/Comments**

**GENERAL**

GENERAL

"See Attachments"

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

#964

September 8, 2006

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

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

Dear Administrator:

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

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

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

Sincerely,

*David Huang, MD*

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

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

Congresswoman Lois Cappas, CA, (D)

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

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

**Submitter :** Dr. J Leonard DeCarlo **Date:** 10/10/2006

**Organization :** Urology Tyler, PA

**Category :** Physician

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

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

#965

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

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

Dear Sir or Madam:

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

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

**I. Unsupported Rationale for the Elimination of Centralized Pathology Laboratories**

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

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

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

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

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

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

## II. Benefits of Path Lab Arrangements

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

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

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

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

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

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

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

### III. Controlling the Risk of Over-utilization

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Respectfully submitted,

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

**Submitter :** Ms. Mary Ann Shacklett **Date:** 10/10/2006

**Organization :** Community Foundation of Northwest Indiana, Inc

**Category :** Hospital

**Issue Areas/Comments**

**Background**

Background

See attachment

**GENERAL**

GENERAL

See Attachment

**Impact**

Impact

See Attachment

**Provisions of the Proposed Rule**

Provisions of the Proposed Rule

See Attachment

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

#966

*Community Healthcare System*

# Community Foundation Of Northwest Indiana, Inc.

Community Hospital
St. Catherine Hospital
St. Mary Medical Center

October 6, 2006

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

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

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

New Technology APCs

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

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

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

CY 2002

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

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

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

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

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

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

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

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

CY 2003

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

CY 2004

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

CY 2005

---

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

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

CY 2006

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

Proposed CY 2007 APC Changes

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

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

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

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

centers (67%) beginning operations during the calendar year and submitting claims to CMS for less than a full year.

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

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

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

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

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

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

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

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

Historical Precedent - Gamma Knife New Technology Codes

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

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

CY 2004 and CY 2005 Data Variability Summary

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

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

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

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

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

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

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

Conclusion

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

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

Recommendations

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

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

Sincerely,

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

**Submitter :** A B **Date:** 10/10/2006

**Organization :** A B

**Category :** Individual

**Issue Areas/Comments**

**Background**

Background

TEST

**Submitter :** **Mr. Mitchel Williams** **Date: 10/10/2006**

**Organization :** **Palmetto GBA**

**Category :** **Health Care Industry**

**Issue Areas/Comments**

**GENERAL**

GENERAL

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

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

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

**Submitter :** **Dr. Juan Agostini** **Date: 10/10/2006**

**Organization :** **Vein& Laser specialists PC**

**Category :** **Physician**

**Issue Areas/Comments**

**Background**

Background

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

**GENERAL**

GENERAL

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

**Impact**

Impact

Reduction of RVU for CPT codes 34478 and 34479 .

**Provisions of the Proposed Rule**

Provisions of the Proposed Rule

See general comment

**Submitter :** Dr. Astrid Morrison **Date:** 10/10/2006

**Organization :** St. Anthony Hospital Cyberknife Center

**Category :** Physician

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

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

#970

October 4, 2006

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

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

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

New Technology APCs

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

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

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

CY 2002

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

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

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

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

---

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

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

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

CY 2003

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

CY 2004

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

CY 2005

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

---

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

CY 2006

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

Proposed CY 2007 APC Changes

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

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

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

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

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

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

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

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

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

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

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

Historical Precedent – Gamma Knife New Technology Codes

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

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

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

CY 2004 and CY 2005 Data Variability Summary

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

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

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

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

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

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

Conclusion

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

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

Recommendations

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

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

Sincerely,

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

**Submitter :** **Dr. Janet Durham** **Date: 10/10/2006**

**Organization :** **Wisconsin Society of Pathologists, Inc.**

**Category :** **Physician**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

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

#971

# Comments of the Wisconsin Society of Pathologists, Inc on the Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007

**[CMS–1321–P]**

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

## PROVISIONS

## REASSIGNMENT AND PHYSICIAN SELF-REFERRAL

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

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

***Changes to the Reassignment Rule***

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

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

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

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

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

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

  **WSP position: no comment**

***Stark Self Referral Provisions***

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

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

Part-Time Employment of Pathologists

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

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

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

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

**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 Wisconsin Society of Pathologists, Inc. 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,

Janet R. Durham, MD
President, Wisconsin Society of Pathologists, Inc.
October 10, 2006

**Submitter :** Mr. Douglas Fesler **Date:** 10/10/2006

**Organization :** ASBMR

**Category :** Other Association

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-1321-P-972-Attach-1.PDF

#972

ASBMR
The American Society for Bone and Mineral Research

October 10, 2006

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

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

Dear Dr. McClellan:

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

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

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

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



2025 M Street, NW · Suite 800 · Washington, DC 20036-3309, USA · Tel: (202) 367-1161 · Fax: (202) 367-2161
E-mail: asbmr@asbmr.org · Internet: www.asbmr.org

Respectfully,

Steven R. Goldring, M.D.
*ASBMR President*

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

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

**Submitter :** **Mr. Thomas Bartrum** **Date: 10/10/2006**

**Organization :** **Waller Lansden Dortch & Davis**

**Category :** **Attorney/Law Firm**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

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

#973

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

October 10, 2006

**VIA ELECTRONIC SUBMISSION**

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

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

Dear Dr. McClellan:

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

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

.0

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

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

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

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

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

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

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

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

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

.0

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

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

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

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

.0

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

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

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

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

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

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

apply only when "a physician or medical group can bill for a reassigned professional component of a diagnostic test." 71 Fed. Reg. at 49056.

However, it is not clear whether such a limitation was intended or whether Medicare contractors would make such a distinction. Accordingly, if the amendment is eventually adopted, such a cardiologist would most likely be unable to furnish interpretations for his or her patients and allow the imaging center to bill globally. While one could argue that the arrangement poses Anti-Kickback Statute and Stark risks, mechanisms are already in place to address these concerns. Further, there would be no prohibition on the cardiologist billing directly for such interpretations or for building the capacity directly and billing globally for the service. Hence, if CMS' concern is inappropriate utilization such a risk is present so long as the physician can bill directly for the service. One could also argue that the purpose of the reassignment prohibition is not to cure all possible risks of program abuse and that CMS already has sufficient means to prevent such abuse.

If CMS simply wants a means to identify situations where a referring physician is also furnishing interpretations, a modifier could be established to identify that the interpretation was furnished by the referring physician. This would give which CMS the means to look behind some of these arrangements to determine their merits, whether the arrangements comply will all applicable laws, and the risks of program abuse of the particular arrangement.

Other legitimate relationships that would be affected if CMS amended the independent contractor exception to incorporate the purchased interpretation rule would include:

- Situations where a radiology group reads for an IDTF and separately bills for the professional component but uses independent contractor radiologists to meet capacity demands because in such situation the IDTF would bill the technical component so the purchased interpretation rule would not be available to allow the radiology group to bill for the professional component furnished by the independent contractor radiologists;

- Situations where a hospital-based radiology group separately bills for the professional component but uses an independent teleradiology service to provide some interpretations because in such event the hospital would bill for the technical component so the purchased interpretation rule would not be available to allow the radiology group to bill for the professional component furnished by the teleradiologists; and

- Situations where a physician group (e.g., orthopedic group) contracts with a radiology group to furnish interpretations on imaging services furnished in the physician group's practice because the ordering physician group would be both ordering and performing the technical component of the imaging service.

These arrangements would appear to pose very little risk of program abuse. Unlike pod lab arrangements, these arrangements are not structured primarily to capture an ancillary revenue stream. Instead, they are intended to address specific needs so as to ensure the seamless delivery of services to the patient. Nonetheless, each of the situations described above would have to be restructured if CMS decides to incorporate the purchased interpretation rule into the independent contractor exception to the reassignment prohibition. It has been my experience in representing IDTFs nationally that patients generally prefer to receive a single bill for most diagnostic tests as opposed to receiving separate bills for the technical component and the professional component. Likewise, a single bill reduces the likelihood that CMS would be double billed for the service (either intentionally or unintentionally). For these reasons, I urge CMS not to incorporate the purchased interpretation rule into the independent contractor exception to the reassignment prohibition.

I would also like to raise a related issue to your attention and would specifically request that you address this issue in the final rule. Some of my clients have recently been advised by a Carrier that CMS has updated its IDTF rules to prohibit off-site interpretations. Upon investigation of this issue, it appears that the rule in question is the Section 4.19.8.C of the revised Chapter 10 of the Program Integrity Manual (Pub. 100-08). Specifically, the Carrier interpreted Transmittal 150, which was published on June 30, 2006 with an effective date of July 3, 2006 as a new rule when, in fact, this provision was in prior versions of the manual that predated Congress' adoption of the independent contractor exception to the reassignment prohibition.

Since the language of Section 4.19.8.C predates the reassignment prohibition and makes a distinction between interpretation services of an independent contractor furnished on the IDTF's premises and the same services furnished off the IDTF's premises, I have taken the position that the Section is not applicable and does not reflect current law.

This position would appear to be supported by your current consideration of incorporating the purchased interpretation rule into the independent contactor exception to the reassignment prohibition. If Section 4.19.8.C is a valid provision, with respect to IDTFs, CMS has already incorporated the purchased interpretation rule into the independent contractor exception to the reassignment prohibition. Likewise, the on premises/off premises distinction only makes sense in light of the

pre-MMA reassignment exception for organized health care delivery systems, which would have allowed an IDTF to bill for professional services furnished on premises. See Medicare Carriers Manual, Part III, § 3060.3 (Feb. 1993) (Rev. 1445). Given that CMS did away with this exception at the beginning of Fiscal Year 2005, such distinction no longer makes sense.

Accordingly, I ask that clarification be provided to the Medicare contractors with respect to Section 4.19.8.C and that this issue be specifically addressed in the final rule so that, from CMS' perspective, there is a single, consistent approach as to whether the purchased interpretation rule will be incorporated into the independent contractor exception to the reassignment prohibition.

**Section II. L. Proposed Changes to the Independent Diagnostic Testing Facility ("IDTF") Standards (42 C.F.R. § 410.33(g)).**

I would ask that further consideration be given to the following with respect to the proposed addition of IDTF performance standards:

- With respect to the proposed requirement that the IDTF must have a comprehensive liability insurance policy that covers both the place of business and all customers and employees of the IDTF in an amount that is equal to the greater of $300,000 or 20 percent of the average annual Medicare billings, I would recommend that CMS only impose a minimum in those states that do not specifically have malpractice caps applicable to radiologists and/or IDTFs. It would appear that state legislatures are in a better position than CMS to evaluate the insurance market and any malpractice caps to determine appropriate insurance coverage. In those situations, where CMS' standard is applicable, I question whether 20% of billing is the appropriate threshold standard. As you are aware, billings may be significantly higher than collections. Also, in those situations where multiple locations are enrolled as a single IDTF, a 20% standard of billings or collections may result in over insurance. It has been my experience that over insurance in the health care context often leads to nuisance type malpractice claims.
- With respect to the proposed requirement that the IDTF must maintain a primary business phone at the physical facility and under the name of the designated business and that such telephone number must be available in a local directory and through directory assistance in the name of the IDTF. This requirement would seem to impose an added layer of costs for physician practices that operate an IDTF along side their practice. In many of these situations, the phone number is held in the name of the practice, not the IDTF. I am not sure the benefit of this proposed standard outweigh the costs in the physician practice setting.
- With respect to the requirement that a supervising physician can provide supervision at no more than three (3) IDTFs, I would recommend that a

distinction be drawn between physicians providing general supervision, which could merit such restriction and physicians providing direct or personal supervision. It is not unusual in an IDTF setting to enroll every interpreting physician as a supervising physician for purposes of furnishing personal and direct supervision of tests. Such enrollment allows the interpreting physician to provide the on-site supervision for tests he or she is interpreting regardless of whether the physician providing general supervision is on site.

If you have any questions or require clarification of these comments, please feel free to contact me at either (615) 850-8705 or Thomas.Bartrum@wallerlaw.com.

Sincerely,

**/s/ Thomas E. Bartrum**

Thomas E. Bartrum

.0

**Submitter :** Dr. dennis olson **Date:** 10/10/2006

**Organization :** solo practice

**Category :** Physician

**Issue Areas/Comments**

**GENERAL**

GENERAL

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

**Provisions of the Proposed Rule**

Provisions of the Proposed Rule

cpt 36478 cpt36479

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

**Organization :** Renewal Medical Specialists

**Category :** Physician

**Issue Areas/Comments**

**Background**

Background

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

**GENERAL**

GENERAL

General Comment

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

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

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

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

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

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

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

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

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

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

Respectfully submitted,
Michael J. Aruta, MD

**Impact**

Impact

Provisions of the Proposed Rule
See General Comment below.

**Provisions of the Proposed Rule**

Provisions of the Proposed Rule

#984
Saint Louis University Hospital

October 9, 2006

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

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

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

New Technology APCs

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

**Submitter :** **Dr. Lawrence Fanelly** **Date: 10/10/2006**

**Organization :** **The Ohio Society of pathologists**

**Category :** **Physician**

**Issue Areas/Comments**

**GENERAL**

GENERAL

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

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

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

**Organization :**

**Category :** **Nurse Practitioner**

**Issue Areas/Comments**

**GENERAL**

GENERAL

see attachment

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

#979
October 9, 2006

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

Re: File code CMS-1321-P Criteria for National Certifying Bodies- Advanced Practice Nurses

To Whom It May Concern:

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

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

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

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

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

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

Sincerely:

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

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

National Certification Corporation
Betty Burns 312-951-0207

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

Pediatric Nursing Certification Board
Janet Wyatt 301-330-2921

**mitter :** **Dr. Bruce Hoyle** **Date: 10/10/2006**

**ganization :** **Dr. Bruce Hoyle**

**tegory :** **Physician**

**ue Areas/Comments**

**Background**

Background

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

**GENERAL**

GENERAL

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

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

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

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

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

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

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

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

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

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

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

**Impact**

Impact

See General Comment below.

**ovisions of the Proposed Rule**

ovisions of the Proposed Rule

e General Comment below.

**mitter :** **Dr. Wayne Gradman** **Date: 10/10/2006**

**ganization :** **Beverly Hills Vein Center**

**tegory :** **Physician**

**ue Areas/Comments**

**Background**

Background

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

**GENERAL**

GENERAL

I am responding to proposed changes to codes 36475 and 36478. Please note that the RVUs for these codes are to be consistently reduced from 2005 levels, when the codes were introduced.
2006: 46.91
2007: 43.53
2008: 40.84
The cost of providing these services have actually increased, particularly when one realizes that an ultrasound technition and two nurses are typically necessary to complete the procedure. These costs are increasing, not decreasing. When added to the proposed 5.1% overall cut in reimbursement and the proposed reuction for all imaging procedures, the final reimbursement will not cover the substantial fixed costs of the procedures. If physicians cannot cover their office costs, they will be obliged to treat their patients in the hospital, where the costs to CMS are substantially higher, and where the elderly are understandably reluctant to go. If the disease process is ignored, the eventual cost of treatment rises exponentially, at even greater cost to CMS (tens of thousands are hospitalized each year to treat the consequences of late stage venous disease.) I urge CMS to keep the fully implements, non-facility practice expense RVU to remain at the 2006 level for code 36475 and to increase the RVU for 36478 to his level as well.

**Impact**

Impact

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

**Provisions of the Proposed Rule**

Provisions of the Proposed Rule

See Provisions and Impact

**ımitter :** **Dr. michael arata** **Date: 10/10/2006**

**ganization :** **Dr. michael arata**

**tegory :** **Physician**

**ıue Areas/Comments**

**lackground**

3ackground

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

**GENERAL**

GENERAL

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

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

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

2. Values for codes 36475 and 36476, radiofrequency vein ablation have been consistently higher that those for laser ablation. These technologies are comparable especially when we look at both the initial capital acquisition cost ($37,900 for laser and $25,000 for RF) and the, per patient supply costs ($360 for laser and $750 for radiofrequency for the procedure kits PLUS disposable sterile supplies such as drapes, gowns, Anesthetic solution, IV bags and tubing to name just a few). While the per patient supply cost may be slightly higher for 36475 (radiofrequency ablation), the significantly higher acquisition cost for 36478 (laser ablation) raises the overall physician s cost of delivering the service to the same level (possibly even higher).

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

**mitter :** **Mr. Simon Abrahms** **Date: 10/10/2006**

**ganization :** **Saint Louis University Hospital**

**tegory :** **Hospital**

**ue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

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

# #983
# Saint Louis University Hospital

October 9, 2006

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

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

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

New Technology APCs

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

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

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

CY 2002

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

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

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

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

---

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

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

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

CY 2003

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

CY 2004

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

CY 2005

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

---

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

CY 2006

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

Proposed CY 2007 APC Changes

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

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

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

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

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

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

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

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

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

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

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

Historical Precedent – Gamma Knife New Technology Codes

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

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

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

CY 2004 and CY 2005 Data Variability Summary

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

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

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

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

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

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

Conclusion

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

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

Recommendations

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

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

Sincerely,

Simon Abrahms
Saint Louis University Hospital
Strategic Business Development
3635 Vista Ave.
Saint Louis, MO 63110

**nitter :** **Mr. Ryan Nestrick** **Date: 10/10/2006**

**anization :** **Saint Louis University Hospital**

**egory :** **Hospital**

**ıe Areas/Comments**

**ENERAL**

ENERAL

:e Attachment

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

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

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

CY 2002

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

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

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

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

---

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

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

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

CY 2003

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

CY 2004

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

CY 2005

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

---

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

CY 2006

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

Proposed CY 2007 APC Changes

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

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

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

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

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

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

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

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

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

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

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

Historical Precedent - Gamma Knife New Technology Codes

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

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

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

CY 2004 and CY 2005 Data Variability Summary

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

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

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

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

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

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

Conclusion

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

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

Recommendations

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

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

Sincerely,

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

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

**Organization :** CAPU

**Category :** Physician

**Issue Areas/Comments**

**GENERAL**

GENERAL

Please See Attachment

CMS-1321-P-938-Attach-1.DOC

938

**The Coalition for the Advancement of Prosthetic Urology**
**1301 K Street, N.W., Suite 1100**
**Washington, DC. 20005**
**202-414-9241**



October 10, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P
P.O. Box 8010
Baltimore, MD 21244-8010

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

**RE:** CMS-1321-P: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for CY 2007 and Other Changes to Payment, Specifically **Provisions Regarding Standard Supplies & Equipment for Procedures with a 90 day Global Period and Resource-Based Practice Expense (PE) RVU Proposals for CY 2007**

Dear Dr. McClellan:

On behalf of the Coalition for the Advancement of Prosthetic Urology (CAPU), we are pleased to submit comments in response to Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule for CY 2007 and other Changes to Payment under Part B. CAPU is a national organization that includes leading clinical experts and researchers in prosthetic urology and the nation's leading manufacturers and developers of innovative prosthetic urology devices. As the leading representative of the prosthetic urology community, CAPU's mission is to ensure that the issues affecting this community are given appropriate consideration in the formation of federal health care and reimbursement policy.

Over the past few years, CAPU has been concerned regarding the Relative Value Units (RVUs) assigned to prosthetic urology procedures. We are encouraged by CMS' actions regarding some of the elements of the proposed practice expense methodology; however, there is still more that can be done to ensure future access for Medicare beneficiaries to prosthetic urology procedures. Therefore, as explained in greater detail below, CAPU has the following recommendations:

## I. Summary

- Standard Supplies and Equipment for CPT Codes with 90 day Global Periods:
    - Many of the prosthetic urology procedures have been negatively impacted by the use of standard packages for various practice expense inputs, partly because of the assertion by CMS that most 90 day global period codes only contain three post-operative (post-op) visits. This is not the case with prosthetic urology procedures where the average number of post-op visits is five. Thus we recommend that CMS re-evaluate the number of post-op visits packaged into each 90 day global period code.

**The Coalition for the Advancement of Prosthetic Urology**
**1301 K Street, N.W., Suite 1100**
**Washington, DC. 20005**
**202-414-9241**

- We appreciate CMS soliciting comments regarding standard packages of supplies and equipment for post-operative visits associated with a 90 day global period procedure. With regard to standard supply inputs, CAPU would recommend to CMS that for each post-op visit standard supplies should include the following:
  - Office visit supply package
  - Post-surgical incision care kit

**The Coalition for the Advancement of Prosthetic Urology**
**1301 K Street, N.W., Suite 1100**
**Washington, DC. 20005**
**202-414-9241**

- Two sets of gloves
- Exam table paper
- Drape, non-sterile sheet
- Additional items recommended by the RUC/PERC.

- With regard to standard equipment inputs, CAPU would recommend to CMS that for each post-op visits that standard equipment should include the following:

  - Exam Table
  - Exam Light
  - Additional equipment recommended by the RUC/PERC.

- Proposed Changes to Practice Expense Methodology:

  - CAPU strongly supports switching to a bottom-up methodology for calculating PE RVUs and believes that it meets CMS's stated goals of using the most appropriate data, simplifying the practice expense methodology and increasing the stability of the practice expense payments.

  - In general, CAPU is concerned that compared to last year's "bottom-up" methodology for calculating PE RVUs, this year's method proposes to use budget neutrality adjustors in three separate steps. Physicians cannot continue to absorb these under-valuations, especially as they face 37% in Medicare payment cuts over the next nine years, as projected by the Medicare Trustees. There are steps that the CMS and the Administration could take, even without legislative action, to improve this dire financial picture. CAPU urges CMS to investigate these steps.

  - CAPU appreciates CMS using the American Urological Association's supplemental survey data as part of the process of creating a more accurate, intuitive and stable Practice Expense (PE) methodology.

## II. Detailed Discussion

### A. Provisions - Standard Supplies and Equipment for CPT Codes with 90 Day Global Periods

#### 1. Number of Post-Operative Visits Packaged in Codes with 90 Day Global Periods

The results of the CAPU Survey of Post-Operative Office Visits and Clinical Staff Time demonstrate that the number of post-operative visits in the Centers for Medicare and Medicaid Services (CMS) Practice Expense (PE) Inputs Database are not representative of a typical prosthetic urology practice.

In general, the total number of visits in the CMS PE database for prosthetic urology procedures is three (3). The results of the CAPU survey demonstrate an average of four (4) to five (5) and, in some cases, six (6) post-operative visits depending on the CPT code.

**Created Pre- 1990 - Prosthetic Urology CPT Codes 53445, 53447, & 54405:**

The CAPU survey results for three CPT codes (53445, 53447, & 54405) created before 1990 reflect that the use of the 90-day global period standardized package of three (3) post-operative visits for most surgical CPT codes as the PE input is not representative of actual prosthetic urology practice.

**The Coalition for the Advancement of Prosthetic Urology**
**1301 K Street, N.W., Suite 1100**
**Washington, DC. 20005**
**202-414-9241**

In conjunction with the 2003 PEAC review, the PEAC recommended a standardized package of three (3) post-operative visits for "all" surgical procedures with a 90-day global period. However, the results of this survey show that three (3) post-operative visits is not representative of actual prosthetic urology practice.

The CAPU survey results demonstrate that for all three of these CPT codes the mean number of post-operative visits is five (5). The median is also at least five (5) visits, with one exception. For CPT code 53445, the median is six (6) office visits.

**Created in 2002 - Prosthetic Urology CPT Codes 53444, 54410, 54411, 54416, & 54417:**

While the differences between the CAPU aggregate results for this group of CPT codes and the clinical staff inputs in the CMS PE database are not as wide as the group of CPT codes discussed above, the survey results of prosthetic urology codes created in 2002 also confirm that using standard packages for 90 global period codes is not representative of typical prosthetic urology practice.

The CAPU survey results for the CPT codes in this group, with the exception of CPT code 54417, demonstrate that mean and median number of post-operative visits in a typical practice is four (4) – five (5). This is one -two visits more than the standard of 3 post- operative visits for a 90-day global CPT code.

2. Standard Supplies and Equipment for 90 day Global Period Codes:

A review of the CPEP data used to calculate the proposed 2007 PE RVUs for PU codes revealed that most of the CPT codes have an office visit package and a post-surgical incision care kit assigned to them. However, the number of visit packages and the number of incision care kits in the CPEP data base is three versus the typical number of post-operative visits which is five. CMS needs to update the number of packages and kits based on the results of the CAPU survey, stated above.

Also, CMS needs to include as "standard" supplies that are used to prevent any risk of infection or for patient comfort, such as gloves for the physician and clinical staff, exam table paper, gowns, and drapes.

With regard to equipment, all of these CPT codes were assigned an exam table under the CPEP data for equipment. This is appropriate; however, we would also recommend that an exam light be included as this is standard equipment in an exam room and can be used to illuminate the wound site for greater inspection by the physician.

**B. Practice Expense (PE)**

1. Bottom-Up Methodology

CAPU strongly supports switching to a bottom-up methodology for calculating PE RVUs and believes that it meets CMS's stated goals of using the most appropriate data, simplifying the practice expense methodology and increasing the stability of the practice expense payments. CAPU is pleased that CMS is seeking ways to provide more stability to the practice expense RVUs now that the AMA and the specialty societies have completed refinement of the original CPEP-collected data. For calculating the direct cost portion of PE RVUs, relying on the direct cost inputs (clinical labor, supplies and equipment) for urology procedures, as refined by the AUA, is an improvement over the previous methodology, which scaled direct cost inputs to a pool of money that was developed based on AMA SMS survey data. The scaling factors in the previous methodology led to inaccurate distribution of PE RVUs among urology's codes, and CAPU strongly supports the change in methodology that does away with the need for scaling factors.

**The Coalition for the Advancement of Prosthetic Urology**
**1301 K Street, N.W., Suite 1100**
**Washington, DC. 20005**
**202-414-9241**

2. Budget Neutrality

In the newly-proposed PE methodology discussed in the proposal, CMS applies a budget neutrality adjustment three times – to the direct inputs, to the indirect allocators and also as a final step. It is unclear why CMS does not apply budget neutrality just once as a final step in the methodology, and we seek clarification on the impacts of applying three separate budget neutrality adjustments in the new methodology. We are concerned that physicians are being forced to "pay" CMS a 30% discount on all of their direct costs because those direct costs are being subjected to a greater than 30% budget neutrality adjustment.

3. Use of Supplemental Survey Data

CAPU applauds CMS for proposing to use the urology supplemental survey data that AUA submitted originally for use in calculating PE RVUs for the 2006 fee schedule. We were disappointed that although CMS accepted AUA's data last year based on Lewin's recommendation that the data met all of the necessary criteria; an error in the proposed rule's list of 2006 PE RVUs caused CMS to withdraw its proposal to actually use the data in calculating the PE RVUs for 2006. Nevertheless, CAPU strongly support the use of AUA's supplemental data in 2007 and beyond (until a new multi-specialty survey is conducted) for calculating the indirect portion of urology PE RVUs.

***

As always, we look forward to working with CMS to address these important issues. If CAPU can provide CMS with additional information, please do not hesitate to contact Jill Rathbun, at 703-486-4200 or Gail Daubert at 202.414.9241.

Sincerely,

*John J. Mulcahy, MD*

John J. Mulcahy, M.D., Ph.D., F.A.C.S.
Chair

cc: Dr. Jim Regan, Chairman of Health Policy Council, AUA
Robin Hudson, AUA
CAPU Board Members (via email only)

**Submitter :** **Ms. Pamela Marrs** **Date: 10/10/2006**

**Organization :** **Dey, L.P.**

**Category :** **Drug Industry**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-1321-P-939-Attach-1.PDF

#939

Dey, L.P.
2751 Napa Valley Corporate Drive
Napa, CA 94558

October 10, 2006

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

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

Dear Sir or Madam:

Dey, L.P. (Dey) is pleased to submit the following comments on the above-referenced proposed rule, which was published by the Centers for Medicare & Medicaid Services (CMS) in the Federal Register of August 22, 2006.[1] Dey develops, manufactures, and markets prescription pharmaceuticals for the treatment of respiratory illnesses and other conditions. Several of Dey's products are reimbursed under Medicare Part B. Below, we provide comments on provisions of the Proposed Rule that pertain Average Sales Price (ASP).

1. Administration Fees Paid to GPOs and PBMs Should Not Be Considered Price Concessions

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

CMS proposes to add to 42 C.F.R. § 414.804 (the "ASP rule") a provision that "bona fide service fee are not considered price concessions" for purposes of the ASP calculation. "Bona fide service fees" would be defined as

> fees paid by a manufacturer to an entity, that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.[2]

CMS explains that the agency is considering providing guidance on the types of services that may qualify as bona fide services, and seeks comments on, among other things, activities that should be considered bona fide services for all types of products.[3]

Although CMS notes in the preamble that it has received requests for clarification on how fees paid to group purchasing organizations (GPOs) and pharmacy benefit managers (PBMs) should be treated for purposes of ASP, neither the proposed rule nor the preamble addresses such fees specifically. However, under the last phrase of the proposed definition of bona fide service fees, administrative fees paid to GPOs and PBMs presumably would be eligible to be considered bona fide service fees, even though neither of these entities typically takes title to drugs.

Dey recommends that CMS provide explicit guidance on the treatment of administrative fees paid to GPOs and PBMs. We further propose that administrative fees that are paid to GPOs and PBMs based on purchase volume or utilization should automatically be considered bona fide service fees, and accordingly ignored in ASP. GPOs have a long history of receiving administrative fees from suppliers (including drug companies) based on a percentage of the purchases of the supplier's products by the

---

2 Prop. §§ 414.802 and 414.804(a)(2)(ii).

3 71 Fed. Reg. at 49001.

GPO's members. The fee compensates the GPO for the services of aggregating multiple buyers so that the manufacturer does not have to negotiate a price with each one, of publicizing the manufacturer's contracted products to its members, and of performing other promotional activities. Accordingly, in 1977, when Congress added exemptions for price reductions and GPO administrative fees to the Medicare/Medicaid antikickback law, Congress did not treat GPO fees as a price reduction, but addressed them in a separate exemption.[4] Presumably, if Congress considered GPO fees to be a price reduction, a separate exemption for GPO fees would have been unnecessary. Accordingly, Dey recommends that CMS adopt an approach under which administrative fees paid to GPOs that comply with the GPO exception and safe harbor under the antikickback law are automatically deemed to be bona fide service fees excludable from ASP.

Manufacturers may also pay administrative fees to PBMs. PBMs act on behalf of their client health plans to negotiate discounts on drugs dispensed to health plan beneficiaries. They also implement formularies and may administer the drug benefit for their client health plans. The administrative fee helps defray the PBM's cost of implementing formularies, providing prescribing data to manufacturers, notifying prescribers about the formulary status of the manufacturer's drugs, and other activities. To the best of our knowledge, administrative fees received by PBMs are not passed on to the health plan clients of the PBM.

The OIG has advised that drug manufacturer payments to PBMs may be structured to comply with the safe harbor for GPO administrative fees under the antikickback law.[5]

---

4 Pub. L. No. 95-142, § 4(b), 91 Stat. 1175, 1182 (1977), codified at 42 U.S.C. § 1320a-7b)(b)(3)(A) and (C). GPO fees are also treated as distinct from price reductions in implementing safe harbor regulations issued by the Office of the Inspector General (OIG) of the Department of Health and Human Services. See 42 C.F.R. § 1001.952(h) and (j).

5 68 Fed. Reg. 23731, 23736 (May 5, 2003) (compliance program guidance for drug

If a PBM is a GPO (i.e., if it is acting as an agent on behalf of health plans to negotiate pharmaceutical discounts), administrative fees paid to the PBM should be treated the same as administrative fees paid to other GPOs. Therefore, for reasons explained above in connection with GPOs, Dey recommends that administrative fees paid to PBMs be automatically deemed to be bona fide service fees excludable from ASP, if the PBM meets the conditions of the GPO safe harbor.

2. Service Fees Paid to Wholesalers and Distributors Should Not be Considered Price Concessions

In the preamble, CMS seeks comments on the specific types of services entities perform on behalf of manufacturers that a manufacturer would otherwise perform (or contract for) and the necessity of those services in the efficient distribution of drugs.[6] Many wholesalers and distributors now seek service fees from drug manufacturers. These fees are variously described as inventory management fees, core distribution fees, handling fees, or in other terms. They are typically based on a percentage of the wholesaler's or distributor's purchases from the manufacturer. Our understanding is that they are not passed on to the customers of the wholesaler or distributor.

These fees compensate wholesalers and distributors not only for the traditional distribution activities of storing, picking orders, packing, and shipping pharmaceuticals, but also for handling chargebacks for contract sales, managing inventory levels in different geographical locations to match demand, providing special handling (e.g., refrigeration), managing returns, providing promotional services, and other activities. These are activities that benefit drug manufacturers, and that a drug manufacturer, in the absence of the wholesaler or distributor, would have to perform itself. Dey urges CMS to

---

manufacturers).

6 71 Fed. Reg. at 49001.

clarify in the final rule or in guidance that service fees paid to wholesalers and distributors should not be considered price reductions for purposes of ASP, where the amount is within the range of fees generally paid to wholesalers for such services.

### 3. CMS Should Provide Guidance on the Treatment in ASP of Rebates to PBMs and Other Managed Care Organizations

In addition to administrative fees discussed in section 1, above, manufacturers also pay rebates to PBMs based on formulary status, the volume or market share of the manufacturer's products dispensed by health plan network pharmacies, or other factors. Manufacturers also pay similar rebates to other managed care organizations (MCOs) besides PBMs. Neither the proposed rule nor its preamble addresses rebates paid by manufacturers to PBMs and other MCOs. This is a serious omission. Because PBMs and MCOs do not pay prices to (i.e., purchase product from) manufacturers, it is uncertain whether these rebates can be considered a price reduction. As CMS is aware, the treatment of PBM and MCO rebates in Medicaid Rebate Average Manufacturer Price (AMP) and best price has been a source of confusion in the industry for over a decade, and the General Accountability Office (GAO) as been critical of CMS's failure to provide guidance in this area.[7]

This rulemaking provides CMS an opportunity to provide clarity on the treatment of PBM and MCO rebates in ASP. Alternatively, if CMS determines that this subject is outside the scope of this rulemaking, CMS should issue guidance in another form. In any event, Dey strongly urges CMS to address this ASP issue through public guidance at the earliest possible time, in order to avoid the disparate methodologies and the confusion that have troubled the Medicaid Rebate Program.

---

[7] GAO, Medicaid Drug Rebate Program: Inadequate Oversight Raises Concerns About Rebates Paid to States (GAO-05-102) ("GAO Report"), at 19-23 (Feb. 2005), available at http:/www.gao.gov/new.items/d05102.pdf.

We believe that rebates to PBMs and other MCOs cannot reasonably be treated as a price concession. Since these entities do not purchase drugs,[8] they do not pay any price to a manufacturer. Where there is no price, there cannot be a price concession. Moreover, PBM/MCO rebates are not passed through to wholesalers or pharmacies, so they cannot be considered a reduction in price paid by a wholesaler or pharmacy to the manufacturer. Accordingly, PBM/MCO rebates should be ignored for purposes of ASP.

4. The Estimation Methodology for Lagged Exempted Sales Should Be Optional

The proposed rule would require all manufacturers to use a 12-month rolling average ratio methodology to estimate ASP-exempt sales that become known on a lagged basis (for example, through chargeback notices or rebate invoices).[9] As a rationale for imposing this new layer of complexity in the ASP calculation, CMS explains that it would reduce potential errors (though the agency does not explain what types of errors would be reduced or why), and would reduce quarter-to-quarter variations in the ASP.[10] Dey agrees that the proposed "smoothing" methodology would help reduce quarterly variations in ASP. However, many manufacturers (Dey among them) do not have significant variations in quarterly excludable sales. For these manufacturers, the new methodology would introduce further complexity into the calculation, and require additional time and resources, for little or no benefit. Therefore, Dey recommends that the final rule provide that the smoothing methodology for lagged exempt sales be optional, so that an additional burden is not imposed where it is unnecessary and unhelpful.

---

8 Certain PBMs operate mail order pharmacies. This discussion does not pertain to sales to a PBM's mail order pharmacy.

9 Prop. § 414.804(a)(4).

10 71 Fed. Reg. at 49002.

In addition, for the benefit of manufacturers who wish to use the smoothing methodology, CMS should clarify the final stage of the methodology. The proposed rule would require that, after the manufacturer uses the 12-month ratio methodology to estimate the lagged quarterly exempted sales in units, the manufacturer must make an adjustment to the numerator of the ASP calculation to remove the sales dollars associated with the excluded units.[11] However, the proposal does not explain what dollar value to attribute to each unit in order to perform this operation. Non-lagged sales units can usually be excluded from ASP based on the actual sale price of the unit, which is available to the manufacturer because the sale was a direct sale. However, lagged units are typically associated with indirect sales. The manufacturer becomes aware of the unit though a chargeback notice or rebate utilization report, but these sources may not identify the price at which the unit was originally sold. In such instances, CMS should clarify that the manufacturer should value an excluded unit at the current wholesale acquisition cost[12].

5. CMS Should Not Implement ASP-AMP Comparisons Until an AMP Rule is Finalized

In the preamble, CMS solicited comments on a number of issues regarding its authority to substitute a lower payment amount where the OIG informs the Secretary that ASP exceeds the AMP or the widely available market price (WAMP) by more than a specified percentage (proposed to be five percent for 2007). CMS seeks comment on the timing and frequency of ASP, AMP and WAMP comparisons, and the effective date and duration of the rate substitutions.

---

11 Prop. § 414.804(a)(4)(iii)(A).

12 See the definition of WAC at 42 U.S.C. § 1395w-3a(c)(6)(B).

Dey believes it is premature for the OIG to conduct, and for CMS to use, comparisons between ASP and AMP. Although the Medicaid Rebate Program has been in effect for over 15 years, CMS has never issued a final regulation describing how AMP should be calculated. There are numerous facets of the AMP calculation that are subject to differing interpretations and methodologies on the part of manufacturers.[13] Administrator Mark McClellan recently remarked that CMS is not confident that AMPs are being calculated accurately, and for this reason, CMS has postponed implementation of a new statutory requirement that the agency publish AMPs on a public web site, and is temporarily prohibiting states from using AMPs to establish Medicaid reimbursement rates.[14] Because CMS rightly does not have confidence in the accuracy of AMPs, AMP should not be used as a benchmark for comparison with ASP, and implementation of the statutory provision authorizing Part B payment rate substitutions based on AMP should similarly be delayed. CMS is obligated to publish a regulation regarding AMP by July 1, 2007.[15] Dey strongly urges CMS to wait until after that regulation has been finalized and taken effect before lowering any Part B drug payment amount based on a comparison between AMP and ASP.

6. Payment Rate Substitutions Should Not Be Based on an ASP-AMP or ASP-WAMP Comparison for a Single Quarter

The OIG is mandated by statute to conduct surveys of AMP and WAMP, and to compare ASPs with these prices.[16] However, the statute does not specify the frequency

---

13 See GAO Report.

14 See 42 U.S.C. § 1396r-8(b)(3)(A)(i), as amended by the Deficit Reduction Act of 2005 ("DRA"), § 6001(b), Pub. L. No. 109-171, 120 Stat. 4 (2006). See Remarks of Mark B. McClellan, M.D., delivered to the NCPA 38th Legislation and Government Conference, at 8 (May 22, 2006).

15 DRA § 6001(c)(3)(B).

16 42 U.S.C § 1395w-3a(d)(1) and (d)(2)(A).

of such surveys, nor the duration of a rate substitution that may be implemented by CMS when ASP exceeds ASP or WAMP by more than five percent. For the reasons explained below, Dey believes that an OIG report providing a comparison between AMP or WAMP on one hand and ASP on the other in a single quarter "snapshot" is an insufficient basis on which to reduce payment rates.

Differences in calculation methodology make AMP an untrustworthy comparator for ASP in any single quarter. AMP may vary widely from quarter to quarter, based not only on actual price changes but differences in the relative volume of sales and chargebacks, inordinate numbers of returns, large numbers of rebate payments, and other factors. CMS does not require or recommend smoothing methodologies for AMP, and manufacturers typically do not use it. Recognizing the wide variability in AMP from quarter to quarter, the Center for Medicaid and State Operations does not send inquiries to manufacturers about the accuracy of their AMPs unless the variation in the current quarter AMP is so great that it causes the new unit rebate amount to be more than 400% greater than, or 100% less than, that of the previous quarter.

ASP is much less variable than AMP because smoothing is used for lagged price concessions, and because returns are ignored. If CMS's proposal to extend smoothing to lagged excluded sales in the ASP calculation is finalized, this will increase the difference between AMP and ASP. As a result of these differences, AMP may be substantially lower (or higher) than ASP in any single quarter, even for a drug whose AMP and ASP are very similar when looked at over a longer period. For this reason, a single quarter comparison between AMP and ASP is a poor indicator of a payment rate that is too high. In order to take into account the absence of smoothing methodologies in AMP, any valid comparison between AMP and ASP must be made be over a relatively long term – at least 12 months. For this reason, Dey believes that the OIG must compare the AMP and ASP of a drug for at least four consecutive quarters before CMS could have confidence in

any conclusion that an ASP is actually five percent higher than AMP. A single quarter snapshot is clearly inadequate.

The same is true, though perhaps to a lesser extent, with WAMP. An OIG survey of WAMP at a single point in time is a poor indicator that ASP-based payment is generally too high. Neither the WAMP snapshot survey nor the quarterly ASP (even with smoothing) may reflect the true relationship between the WAMP and the ASP over the longer term. Therefore, our recommendation with regard to AMP-ASP surveys applies also to WAMP-ASP surveys. No rate substitution should be made on the basis of a WAMP survey that covers only a single quarter.

Even if a longer term (e.g., 12-month) comparison between ASP and AMP or between ASP and WAMP results in a conclusion that ASP-based payment has been too high, this does not mean that ASP-based payment will *remain* too high. Prices of manufacturers, wholesalers, specialty pharmacies, and physician supply houses change constantly. For this reason, a rate substitution should be of relatively short duration (for example, two quarters), unless a continuing substitution is supported by a follow-up survey by the OIG.* * *

Dey appreciates this opportunity to provide input on the ASP calculation and Part B payment process, and we urge CMS to seriously consider the above recommendations and comments.

Respectfully submitted,

_____

Pamela Marrs

Senior Vice President and CFO