Submitter : **Heide Bajnrauh** **Date: 10/09/2006**

Organization : **Arnold and Porter LLP**

Category : **Attorney/Law Firm**

Issue Areas/Comments

Background

Background

See Attachment

GENERAL

GENERAL

Arnold and Porter LLP is filing comments on behalf of the National Electrical Manufacturers Association (NEMA). For full description of comments, please see attachment.

Impact

Impact

See Attachment

Provisions of the Proposed Rule

Provisions of the Proposed Rule

See Attachment

CMS-1321-P-672-Attach-1.PDF

#672

Setting Standards for Excellence

Andrew Whitman
Vice President, Medical Products

NATIONAL ELECTRICAL MANUFACTURERS ASSOCIATION
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October 6, 2006

Mark McClellan, M.D., Ph.D.
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, 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 Under Part B

Dear Administrator McClellan:

The National Electrical Manufacturers Association (NEMA) is pleased to submit comments regarding proposed rule *Medicare Program; Revisions to Payment Policies Under the Medicare Physician Fee Schedule (MPFS) for Calendar Year 2007 and Other Changes to Payment Under Part B.*[1] As the leading trade association representing companies whose sales comprise over 90 percent of the global market for medical imaging, we are pleased to provide the Centers for Medicare and Medicaid Services (CMS) with our perspective on medical imaging policies proposed in this rule. Our goal is to ensure that Medicare beneficiaries continue to have access to the best care available.

Medical imaging encompasses X-ray imaging, computed tomography (CT) scans, radiation therapy, diagnostic ultrasound, nuclear medical imaging including positron emission tomography (PET) and magnetic resonance imaging (MRI). Imaging is used both to diagnose and treat patients with disease and offers physicians the ability to view soft tissue and organs, often reducing the need for costly and invasive medical and surgical procedures.[2] In addition, imaging equipment is used in some procedures to guide physicians as they carry- out a medical or surgical intervention to ensure high-quality clinical results for the patient.[3]

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

[2] Multidetector-Row Computed Tomography in Suspected Pulmonary Embolism," Perrier, et. al., New England Journal of Medicine, Vol 352, No 17; pp1760-1768, April 28, 2005.

[3] Jelinek, JS et al. "Diagnosis of Primary Bone Tumors with Image-Guided Percutaneous Biopsy: Experience with 110 Tumors." *Radiology*. 223 (2002): 731 - 737.

Imaging has become a standard of modern care for virtually all major medical conditions and diseases, including cancer, stroke, heart disease, trauma, and abdominal and neurological conditions. That role is reflected in the reliance of physicians upon imaging in everyday practice and its prominence in physician-developed practice guidelines across a broad range of medical conditions. Because of its dependence by practicing physicians today as well as its substantiation for increasing health outcomes and prolonging lives of beneficiaries, it is important for CMS to understand the adverse effect on patient access to imaging services if certain provisions in this proposed rule were implemented.

NEMA is also the world's primary voluntary standards-development organization for medical imaging equipment. Such standards establish commonly-accepted methods of design, production, and distribution for medical imaging products. Sound technical standards benefit the user and patient, as well as the manufacturer, by improving safety, fostering efficiencies, and assisting the purchaser in selecting and obtaining the appropriate product. We have been setting standards for 75 years. The following sections are designated by the headings CMS asked commenters to use.

I. Deficit Reduction Act (DRA) Proposals

As any new procedure or service integrates itself into the healthcare system, utilization and costs will rise. NEMA understands CMS's concerns regarding the increased use of imaging modalities but feels this is a logical consequence of integration as imaging becomes a standard in the diagnosis and treatment of patients. Congress has chosen to limit reimbursement for imaging modalities based solely on increased utilization, arguing this has led to higher costs. Our data show this argument to be overstated. A 2005 study by the Lewin Group found that when growth in imaging costs is compared to growth in all Medicare Part B services, imaging grew at roughly the same rate. From 1999-2003, the average annual growth in all Medicare Part B services across providers was 7.8 percent, while the comparable growth in imaging was 8.7 percent -- only about 0.9 percentage points faster.[4]

This study shows, while it is true imaging use is on the rise, it is not the sole contributor to increasing health care expenditures. While we understand that the law[5] specifies certain reductions, it is equally clear that CMS has considerable discretion in defining which specific services and associated codes are reasonably encompassed within the general intent of the statute.

a. Payment for Multiple Imaging Procedures for 2007

NEMA agrees with CMS that maintaining the multiple imaging payment reduction at the current 25 percent level for second and subsequent diagnostic imaging procedures when performed on the same day on contiguous body parts is reasonable. NEMA encourages CMS to continue obtaining and evaluating data relating to the costs of these procedures so that the most accurate cost information can be used in making any future determinations regarding reductions in the price of imaging services.

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[4] "Issues in the Growth of Diagnostic Imaging Services: A Case Study of Cardiac Imaging," The Lewin Group, May 3, 2005, p. 20.

[5] DRA § 1502

b. Reduction in Technical Component (TC) for Imaging Services Under the MPFS to Outpatient Department (OPD) Payment Amount

NEMA understands the importance of cost-containment in health care and supports keeping costs at appropriate levels. However, we have serious concerns with the severe reductions in the TC for imaging services proposed for 2007. In the proposed rule, CMS discussed the criteria used to determine suitable codes to include within the series of codes eligible for imposition of the so-called cap on the technical component as specified in the DRA[6]. NEMA fears these strict cuts will limit patient access and further reduce physician use of these imaging modalities.

According to a recent report performed by The Moran Company[7], in which the impact of the DRA provisions was analyzed, 87 percent of procedures affected by the DRA caps would be paid at an amount less than the cost of performing the procedure in a physician office setting. The Moran report also concluded that several procedures including PET/CT exams used to diagnose patients with otherwise undetectable cancer cells, image guided ultrasound procedures used to biopsy women with breast cancer, and bone density studies used to screen patients with osteoporosis will be cut from between 35 and 50 percent if the DRA provisions are enacted. If the DRA cuts are implemented as proposed, health care costs could rise dramatically as physicians would be forced to perform more costly alternative diagnostic and therapeutic procedures. More importantly, millions of Medicare beneficiaries could be deprived of beneficial therapies.

NEMA strongly urges that Category III CPT[8] codes be excluded from CMS's proposed list of codes affected by the DRA cap. Category III CPT codes are assigned to emerging technologies for which a fee has not been established in the Medicare physician fee schedule and are intended for tracking purposes only. Such codes are not assigned RVU values, and consequently there is no true technical component attached to these codes. We urge CMS to remove Category III CPT codes from the proposed CPT/HCPCS imaging codes list.

Also, vascular duplex and transcranial Doppler procedures are not appropriately included in the definition of imaging services. These codes should be excluded from the list of procedures covered under the DRA caps for the same reason that CMS excluded other CPT codes that have both an imaging and a non-imaging component. The reasoning is the majority of the work of the above-mentioned services involves the use of spectral Doppler, which does not provide an image of the areas of the body that are not normally visible. This information is provided in a waveform, not an image, from which the velocity information is then ascertained. In these cases, it is not possible to distinguish the imaging from the non-imaging components of the services.

NEMA asks CMS to remove transcranial Doppler procedures (CPT codes 93886 – 93893) and Duplex procedures of veins or arteries (CPT codes 93880, 93882, 93925 – 93931, 93970, 93970 – 93990, and G0365) for the list of services subject to payment caps under DRA.

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[6] DRA § 1502

[7] "Assessing the Deficit Reduction Act Limits on Image Reimbursement: Cross-Site Comparisons of Cost and Reimbursement," The Moran Company, September 2006. For a complete copy of this report please visit http://www.imagingaccess.org/reports/index.cfm.

[8] CPT® codes and descriptions are copyright 2005 American Medical Association.

Finally, we urge CMS to not include ultrasound guidance procedures under the DRA cap. Ultrasound guidance is an integral part of many cost saving minimally invasive surgical procedures. Due to changing coding conventions, some CPT codes for procedures are written to include the ultrasound guidance while other CPT codes for procedures are written so that the ultrasound is reported separately. Thus to include ultrasound guidance codes in DRA implementation is to apply cuts unevenly across similar types of services. This assertion is supported by the fact that in processing claims Medicare confirms coverage for both the surgical or interventional procedure and the ultrasound guidance code based on a single or the same ICD-9-CM diagnosis code. This is not the case for diagnostic imaging studies. Therefore including ultrasound guidance codes within the cap subjects a number of minimally invasive surgical procedures that are less costly to the Medicare program than the open surgical alternatives to cuts that other procedures avoid due only to coding convention.

c. Interaction of the Multiple Imaging Payment Reduction and the Hospital Outpatient Prospective Payment System (HOPPS) Cap

CMS proposes to maintain its policy of multiple procedure discounting at the 25 percent level in CY 2007. CMS would first apply the discount, then apply the DRA cap to payment levels for imaging services. We appreciate the CMS decision to first apply any multiple procedure discount prior to the DRA cap, as this will lessen the impact of DRA payment reductions on providers. More generally, however, we believe that the multiple procedure discount policy is redundant in light of the impending DRA payment caps and should be discontinued at the time when the DRA cap is implemented in CY 2007.

DRA specifies that payments for imaging services subject to the Medicare physician fee schedule will be capped at the CY 2007 hospital outpatient prospective payment system (HOPPS) payment amount (prior to geographic adjustment). Currently, there is no multiple procedure discount policy for HOPPS. CMS has determined that, at this time, there is insufficient evidence to warrant such a cap under this payment system. Specifically, in its proposed rule for HOPPS, CMS notes that it does not intend to implement such a policy in CY 2007, stating that the agency's analysis to date support continued deferral of such a policy. Specifically, CMS notes that its analysis does not disprove commenters' assertions that there are efficiencies already reflected in hospital costs and, therefore, in existing HOPPS payment rates.

We believe that application of the multiple procedure discount policy in the MPFS is redundant and excessive in light of the DRA cap. HOPPS rates serve as the basis for the cap, and these rates already factor in the effects and economies of performing multiple imaging procedures during the same session. To apply the multiple procedure discount (MPD) policy in the MPFS, and then to apply the cap, would essentially "over-adjust" payment levels to account for economies in multiple procedure imaging. We urge CMS to remove the MPD policy from the Medicare physician fee schedule and, instead, to rely on the DRA cap to accurately account for cost effects of multiple procedure imaging during the same session.

d. Addition of Ultrasound Screening for Abdominal Aortic Aneurysm (AAA)

NEMA takes pride in the fact that we represent manufacturers of products that provide high-quality, cost-effective, and clinically-proven screening services, providing physicians with superior tools for early disease detection. In the past, abdominal aortic aneurysms were rarely identified until they ruptured and patients died. Today, physicians are able to utilize ultrasound

scans to detect these life-threatening aneurysms reducing the risk of death by more than 40 percent.[9] We thank CMS for its proposals offering appropriate and reasonable coverage and payment for a preventive service that will save beneficiaries' lives. We also appreciate the proposal to evaluate future coverage considerations through the NCD process.

II. Reassignment and Physician Self-Referral

There are laws in place to prohibit abuses against the Medicare program, and they provide a framework for detection of and enforcement against inappropriate practices. However, the intention of this provision should not be to create rules that limit access to innovative technologies for patients, nor should it foreclose reasonable methods of developing efficiencies in how technology is made available to support physicians.

NEMA is encouraged by CMS's intentions of preventing abuse within the Medicare system but feels the definition of a "centralized building" needs to be outlined in a more concise manner to ensure that mobile radiology services and teleradiology services are not disrupted. It is our view that if CMS has identified one or two clearly questionable situations, the Agency should act on those specific matters rather than propose broader-scope rules that may inadvertently disrupt legitimate service arrangements in imaging.

III. Bone Mass Measurement Tests

a. Coverage of Bone Mass Measurement (BMM) Tests

As stated above, NEMA supports expanded coverage of screening services that give physicians the ability to diagnose disease in patients at earlier and more treatable stages. In the case of BMM, CMS proposes expanded coverage to include screening more women who have the potential for developing osteoporosis. While we strongly support CMS's coverage expansion, it is deeply counterproductive to the shared public health objectives of significantly reducing payment, through this proposed rule, for the very equipment which provides these life-saving techniques. We note major payment decreases occurring under the proposed relative value units in the following codes: 76075, 76977, and 76077. As CMS is aware, providers will simply resist purchasing or upgrading essential screening equipment if it shows little or no return on investment. If this adverse scenario is implemented, crucial screening services for this painful, debilitating, and ultimately costly condition will be ever harder to access. The medical toll will be great, and since this is a condition that in aging can lead to collapsed vertebrae, broken hips and other complications, the Medicare program especially will experience a disproportionate share of the economic costs.

NEMA suggests that CMS investigate whether it has the legal discretion to categorically exempt at least statutorily mandated Medicare screening services from imaging-related DRA reductions.

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[9] "Screening for Abdominal Aortic Aneurysm: A Best-Evidence Systematic Review for the U.S. Preventive Services Task Force," Fleming C, Whitlock EP, Beil TL, Lederle FA; *Annals of Internal Medicine*, Feb 2005, Vol 142, No 3; 203-211. Also, "Screening for Abdominal Aortic Aneurysm: Recommendation Statement, U.S. Preventive Services Task Force, *Annals of Internal Medicine*, Feb 2005, Vol 142, No 3; 198-202.

IV. IDTF Issues

a. Proposed Performance Standards for Independent Diagnostic Testing Facilities (IDTFs)

In the course of diagnostic patient care, physicians from many specialties rely on imaging tools and techniques to help determine a patient's diagnosis and establish appropriate treatment. It is neither feasible nor cost-effective for all physicians to maintain all types of sophisticated medical equipment in their offices. In order to provide the best possible care, physicians engage in relationships with IDTFs. These facilities provide patients with access to testing and diagnostic equipment, while lowering health care costs due to efficiencies of scale. As these arrangements have developed, CMS has identified a need to ensure consistent, appropriate operational practices across the U.S., including standards to ensure the safe operation of major medical equipment.

As we noted earlier, NEMA is the premier, global standard-setting organization for electrical equipment, including medical imaging and therapy machines. We would appreciate the opportunity to offer our expertise to CMS in its efforts to devise appropriate standards for such equipment in the IDTF setting, as well as any other setting for patient care.

CMS proposes to implement Medicare operational standards for IDTFs. Of the standards proposed, Number 11 is of great interest to NEMA. It states that an IDTF should, "Have its testing equipment calibrated per equipment instructions and in compliance with applicable national standards".[10] NEMA is not aware of current national standards surrounding testing equipment, and has noted recently with some concern that many Medicare Local Carriers have published highly divergent policies outlining proper equipment standards. Accurate equipment calibration and testing, including defining appropriate periodicity schedules for these activities (which vary significantly across types of equipment and across manufacturers), is a high priority for NEMA. NEMA has a strong background in developing these types of guidelines for industry and we propose to work with CMS to develop guidelines to warrant patient access to these life-saving technologies.

V. Health Care Information Transparency Initiative

CMS has successfully focused the attention of policy-makers in healthcare on the importance and potential benefits to patients, caregivers and payers of health care transparency -- that is, providing the public with health care cost and quality information about medical services that has been difficult, if not impossible, for consumers to find and use appropriately. Through the Internet and other public postings, the federal government is putting considerable resources into organizing and placing information into consumer's hands. These efforts help empower consumers to make thoughtful clinical and economic decisions about their health care choices.

In order to properly evaluate and exercise these choices, accurate information must be provided and be organized in a clear, accessible and meaningful format. We appreciate CMS's recent efforts to display Medicare data, such as in the Hospital Compare program, and in the recent release on Ambulatory Surgery Center Services.

[10] 71 Fed. Reg. 49060 (August 22, 2006)

As the largest association representing medical imaging manufacturers, NEMA has the ability to work with CMS to ensure imaging services and costs are being captured and reflected properly, and to help determine useful data elements and display options that will contribute to beneficiaries' understanding and use of such data. We support your efforts to improve health outcomes and patient satisfaction, and to manage costs. As with the IDTF standard setting initiative, NEMA would like to offer the expertise of the organization and our members to assist in CMS's transparency efforts as they relate to imaging services.

VI. Conclusion

NEMA respects the importance and necessity of implementing sound fiscal healthcare policies. With healthcare budgets under continuous pressure, cost-effective treatments are paramount to payers, providers and patients. Our goal is to ensure that Medicare beneficiaries retain access to the significant clinical benefits of high-quality imaging products and services.

We ask CMS to develop policy decisions intended to recognize that much of the growth within the imaging environment emerges from the off-setting savings created by these innovative procedures- through less-invasive care, quicker recovery and fewer complications and are often overlooked in assessments of growth in imaging spending. A better approach to managing this increased utilization is to rely upon sound evidence and practice guidelines developed by physician groups so proper standards are in place. Imaging advocacy groups, such as NEMA, also feel it is necessary to instill guidelines to promote proper equipment maintenance and utilization. NEMA looks forward to sharing its ideas with CMS in the upcoming months. Finally, we urge CMS to look to the future, as developments in molecular, cellular, functional and genetic imaging promise a new era of prediction and prevention of disease, not just diagnosis and treatment.[11]

We strive to continue working with CMS on these matters under the Medicare Physician Fee Schedule. If you have any questions or would like to discuss these matters further, please contact me at 703-841-3279.

Respectfully Submitted,

Andrew Whitman
Vice-President, Medical Products

CC: Amy Bassano
August Nemec

[11] "Advances in Biomedical Imaging," Tempany MC, McNeil BJ, *Journal of the American Medical Association,* 2001, Vol. 285: 562-567

Submitter : **Ms. Irene Plenefisch** **Date: 10/09/2006**

Organization : **SonoSite, Inc.**

Category : **Device Industry**

Issue Areas/Comments

GENERAL

GENERAL

SonoSite, Inc. comments on DRA Proposals and IDTF Issues. "See Attachment."

CMS-1321-P-673-Attach-1.DOC

#673

SonoSite

October 10, 2006

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

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

Dear Dr. McClellan:

SonoSite, Inc., appreciates the opportunity to comment on CMS-1321-P, the Proposed Rule for the 2007 Medicare Physician Fee Schedule (MPFS). SonoSite is a manufacturer of high quality, portable ultrasound systems located in Bothell, Washington. SonoSite manufactures and markets ultrasound systems that provide complete diagnostic ultrasound studies that are optimized for use at the point of care. SonoSite's products are used in physician offices and other sites of care, such as hospitals and free-standing imaging labs, to provide a wide variety of diagnostic and guidance ultrasound services.

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DRA Proposals

I. Issue: Non-Invasive Vascular Duplex and Transcranial Doppler Studies Should be Excluded from the List of Services Subjected to DRA Imaging Caps

In the proposed MPFS rule, the Centers for Medicare and Medicaid Services (CMS) interprets the term "imaging services" from Section 5102(b)(1) of the DRA to include vascular duplex and transcranial Doppler services, thus making those services eligible for payment caps under DRA.

A. Supporting Information

Including the vascular duplex and transcranial Doppler services under the DRA imaging provision is in direct conflict with CMS' own rationale for excluding other codes from DRA implementation because they contain an imaging and a non-imaging component.

CMS Rationale from the MPFS:

> *We [CMS] excluded any service where the CPT code describes a procedure for which fluoroscopy, ultrasound, or another imaging modality is either included in the code whether or not it is used or is employed peripherally in the performance of the main procedure, for example, 31622 for bronchoscopy with or without fluoroscopic guidance and 43242 for upper gastrointestinal endoscopy with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s). In these cases, we are unable to clearly distinguish imaging from non-imaging services because, for example, a specific procedure may or may not utilize an imaging modality, or the use of an imaging technology cannot be segregated from the performance of the main procedure.* [1]

We agree with this rationale for excluding codes that contain an imaging and a non-imaging component, and assert that under this same rationale, the vascular duplex and transcranial Doppler codes should also be excluded. In the performance of these services, the majority of the work and practice expense involves the use of spectral Doppler, which does not provide an image of the areas of the body that are not normally visible (CMS' definition of an imaging service for coverage under the DRA provision). This information is provided in a waveform, not an image, from which the velocity information is then derived. In these cases, as in the case of the other hybrid services CMS excluded, it is not possible to separate the imaging from the non-imaging components of the services.

Additionally, we believe that it was Congress' intent to exclude these services from the DRA caps. Statutory language from the section entitled "Imaging Services Described[2]" does not specifically state that non-invasive vascular procedures are to be included as was noted in the case of echocardiography. Both echocardiography and non-invasive vascular studies are in the "Medicine" section of CPT rather than the "Radiology" section of CPT. Had Congress intended for the non-invasive vascular procedures to be included, they would have been listed separately in the statute as is done with echocardiography services.

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

[2] Deficit Reduction Act, §1502 (b)(1)(4)(B)

B. Recommendation for Duplex Procedures and Transcranial Doppler Procedures

SonoSite, Inc. asks CMS to remove duplex procedures of veins or arteries (CPT codes 93880, 93882, 93925 - 93931, 93970, 93970 - 93990, and G0365) and transcranial Doppler procedures (CPT codes 93886 - 93893) from the list of services considered eligible for payment caps imposed by DRA 5102.

II. Issue: Ultrasound Guidance Services Should be Excluded from DRA Imaging Caps.

In the proposed PFS rule, the Centers for Medicare and Medicaid Services (CMS) interprets the term "imaging services" from Section 5102(b)(1) of the DRA to include ultrasound guidance services.

A. Supporting Information.

We believe that these services are inappropriately included as it is due only to a temporarily used coding methodology that ultrasound guidance is reported separately from the surgical procedures for which the guidance is utilized. Prior to 1992 and following 2004, ultrasound guidance is included in the CPT code for which the guidance is utilized. Thus, including ultrasound guidance procedures in the DRA caps causes those surgical procedures that, due only to a temporary coding convention are reported without the imaging used to guide them, to experience reductions in payments that other surgical procedures that are different only in their coding descriptors avoid.

- Prior to 1992, surgical procedures using imaging guidance were reported using so-called "complete" procedure codes. These codes described both the surgical procedure and the necessary imaging guidance. An example of this coding methodology is the now deleted, 76943 for ultrasound guided prostate biopsies.
- Beginning January 1, 1992 "component coding" was introduced and the surgical procedures and the imaging guidance procedures were made into separate codes. An example of this transition is discussed in a CPT Assistant Coding Communication entitled, "Coding for Needle Biopsies and Ultrasound of the Prostate.[3]"
- More recently, coding conventions are returning to the original CPT method of incorporating the ultrasound guidance into the surgical procedure itself. An example of the return to this coding methodology is CPT code 19296 - *Placement of radiotherapy afterloading balloon catheter, including imaging guidance* that was created in 2005.

The claim that the surgical procedures and the ultrasound guidance are separated only by coding convention, that is not uniform, is supported by the fact that for ultrasound guidance studies, it is the medical necessity of the underlying surgical procedure, whether that is a suspicious lesion in a certain part of the anatomy requiring a

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[3] CPT Assistant, American Medical Association, May 1996, page 3

biopsy or a complication during a pregnancy that requires further tests such as an amniocentesis, that determines the coverage for both procedures. In processing claims, Medicare confirms coverage for both the surgical or interventional procedure and the ultrasound guidance code based on a single or the same ICD-9-CM diagnosis code. This is not the case for imaging studies that are categorized as diagnostic.

B. Recommendation for Ultrasound Guidance Procedures

SonoSite asks CMS to exclude ultrasound guidance codes (CPT codes 76930 - 76956) from the list of procedures that are eligible for reductions under DRA Section 5102.

III. Addition of Ultrasound Screening for Abdominal Aortic Aneurysm (AAA)

SonoSite wishes to express support and appreciation for CMS' proposals regarding the definition of eligible beneficiaries, the proposed payment level associated with the screening service, and the intent to use the NCD process to evaluate other risk factors for coverage in the future.

We note that part of the definition of "eligible beneficiary" requires beneficiaries to receive referrals for ultrasound screenings as a result of IPPEs. However, the Proposed Rule does not provide additional guidance on the meaning of "referral." Based upon its customary usage, we believe that the term "referral" should mean "a direction to receive care from a qualified provider." This referral may be provided orally or in written form during or after the eligible beneficiary receives his/her Welcome to Medicare physical examination.

We would be concerned if CMS used the word "referral" to create an onerous or restrictive coverage process. A burdensome referral process would undoubtedly limit the number of referrals for screenings and fail to serve the best interest of Medicare beneficiaries. Equally important, it would contravene the intent of Congress, which was to facilitate a smooth implementation process and beneficiary access.

To complement CMS' reimbursement proposal, SonoSite recommends that the agency monitor the utilization of the new AAA screening benefit. If fewer than fifty percent of eligible beneficiaries receive access to this service within two years, the agency should work to increase awareness and utilization.

IDTF Issues

In its discussion of place of service, CMS has requested comments regarding the types of services that can be safely and appropriately performed in a residential setting.

SonoSite appreciates CMS' interest in this question. Ultrasound services, because they do not use ionizing radiation and do not require special rooms for safe provision, can be safely provided in a residential setting. Furthermore, SonoSite ultrasound systems, which are portable, contain all the imaging modes, software, and documentation

capabilities required to perform complete ultrasound services as described in the CPT codes for ultrasound, echocardiography and non-invasive vascular studies.

The costs to the Medicare program for financing the provision of this service in the patient's residence are no greater than the costs of providing that service in the physician office or freestanding imaging clinic. Yet for homebound patients or patients of limited mobility payment for these services in the patient's residence helps to maintain access to important diagnostic services.

SonoSite urges CMS to allow for payment of ultrasound services provided in the patient's residence.

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SonoSite, Inc. appreciates the opportunity to provide comments on this proposed rule. If SonoSite can provide CMS with additional information regarding this matter, please do not hesitate to contact me at 425-951-1205 or irene.plenefisch@sonosite.com.

Sincerely,

Irene Plenefisch
Director, Payer and External Relations

[redacted]

Submitter : Dr. David Bryant **Date:** 10/09/2006

Organization : St.Catherine Hospital, Cyberknife Center

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1321-P-674-Attach-1.PDF

Submitter : **Dr. Dudley Anderson** **Date: 10/09/2006**

Organization : **Dudley B Anderson, MD PA**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

On behalf of my practice I would like to express concern over the proposed changes affecting Medicare payment for Part B covered drugs and biologicals in 2007. We currently use the products Aranesp, Neulasta, and Neupogen and strongly disagree with any changes that could potentially lower the reimbursement for these three products.

To start, this practice finds a great deal of value in using Aranesp for the treatment of chemotherapy induced anemia. Clinically it is the best and only agent that we use due to the benefits of more convenient dosing and proven efficacy. The less-frequent injections significantly reduce the time burden for both the patients and the staff, which is a great value to the office. Also, we have had a lot of experience with Aranesp and Neulasta and feel that they offer the optimal care for the supportive care needs of cancer patients.

This office sees no added benefit to the proposed changes for the ASP calculation on these products. For over ten years this office had used Procrit while there was no other competition, and with the release of Aranesp it was decided that the clinical benefits were superior and therefore we instituted a switch. Before Aranesp brought competition to the market, there was very little discounting given on the part of Procrit. The release of Aranesp and Neulasta brought not only more choices for treatment, but also heavy discounting from both companies.

The contract that Amgen offers allows for rebates on all of their products, but does not in any way deny our office the ability to use any other products. We simply choose not to use Procrit due to the reasons stated above. Therefore, we feel that any change that does not reflect the ASP of the current market purchases will unfairly lower the reimbursement and limit access to our best products.

Submitter : **Dr. James Orr** **Date: 10/09/2006**

Organization : **Florida Gynecologic Oncology**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

INDEPENDENT LAB BILLING - Also attached

I have recently been informed that CMS is re-interpreting an existing policy which would likely have a harmful effect on women with Gynecologic Cancer. As I understand this re-interpretation would require Oncotech to bill their services(when providing valuable drug resistance data) to a hospital as part of the Medicare Part A program, instead of as an outpatient service, being directly to Medicare part B. As a result their Extreme Drug Resistance assay would fall under current DRG's and hospitals would be responsible for the cost of the assay and would not be reimbursed for the payment to Oncotech. Please be reminded that Oncotech provides a very effective drug resistance assay, designed to identify patients who are resistant to a chemotherapy drug and therefore would be highly unlikely to (<1%as reported in published literature) to respond to those specific drugs deemed resistant in a clinical setting. I personally use this test to assist me in the management of my cancer patients and have reported as to the cost effectiveness of this approach (Orr Jr JW, Orr P, Kern DH. Cost-Effective treatment of women with advanced ovarian cancer by cytoreductive surgery and chemotherapy directed by an in vitro assay for drug resistance. The Cancer Journal from Scientific Amerinca 5:174-178, 1999).By utilizing the EDR Assay, both the patient and Medicare are spared the side effects and expense of treatmetn with ineffective chemotherapy. As I mentioned above, their EDR Assay is currently eligible for Medicare Part B reimbursement as a physician provided laboratory test which is performed out of the hospital, however this new interpretation would force their services into Part A. The consequence is a result of the EDR Assay laboratory procedures requiring living tumor tissue which must be collected at the time of the patient's surgery (obtained during the patient's surgery (obtained during the patient's hospital stay);linking the service to the Part A program. While I do not believe the new interpretation was not directed specifically at Oncotech or similar laboratories, these labs are being affected as a unintended consequence. Patients and physicians may be unduly denied the ability to utilize Oncotech's valuable cancer treatment tool because these services will be unfairly classified as a Medicare Part A procedure. I respectfully request a review of the re-interpretation of this federal regulation which directly affects Oncotech's EDR Assay procedure.

CMS-1321-P-676-Attach-1.PDF

#676

FLORIDA GYNECOLOGIC ONCOLOGY

James W. Orr, Jr., M.D.
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October 3, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Dr. McClellan:

I have recently been informed that CMS is re-interpreting an existing policy which would likely have a harmful effect on women with Gynecologic Cancer. As I understand this re-interpretation would require Oncotech to bill their services(when providing valuable drug resistance data) to a hospital as part of the Medicare Part A program, instead of as an outpatient service, being directly to Medicare Part B.As a result, their Extreme Drug Resistance EDR Assay would fall under current DRG's and Hospitals would be responsible for the cost of the Assay and would not be reimbursed for the payment to Oncotech.

Please be reminded that Oncotech provides a very effective drug resistance assay, designed to identify patients who are resistant to a chemotherapy drug and therefore would be highly unlikely (< 1% as reported in published literature) to respond to those specific drugs deemed resistant in a clinical setting. I personally use this test to assist me in the management of my cancer patients and have reported as to the cost effectiveness of this approach (*Orr Jr JW, Orr P, Kern DH Cost-effective treatment of women with advanced ovarian cancer by cytoreductive surgery and chemotherapy directed by an in vitro assay for drug resistance. The Cancer Journal from Scientific American 5:174-178, 1999*). By utilizing the EDR Assay, both the patient and Medicare are spared the side effects and expense of treatment with ineffective chemotherapy. As I mentioned above, their EDR Assay is currently eligible for Medicare Part B reimbursement as a physician provided laboratory test which is performed out of the hospital, however this new interpretation would force their services into Part A. The consequence is a result of the EDR Assay laboratory procedures requiring living tumor tissue which must be collected at the time of the patient's surgery (obtained during the patients' hospital stay); linking our services to the Part A program.

FLORIDA GYNECOLOGIC ONCOLOGY

While I do not believe the new interpretation was not directed specifically at Oncotech or similar laboratories, these labs are being affected as an unintended consequence. Patients and physicians may be unduly denied the ability to utilize Oncotech's valuable cancer treatment tool because these services will be unfairly classified as a Medicare Part A procedure. I respectfully request a review of the re-interpretation of this federal regulation which directly affects Oncotech's EDR Assay procedure.

Sincerely,

James W. Orr, Jr. M.D., FACOG, FACS
President Florida Obstetric and Gynecologic Society
Medical Director, Florida Gynecologic Oncology &
Lee Cancer Care
Phone: 239.334.6626
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Submitter : **Dr. Mark Fesen** **Date: 10/09/2006**

Organization : **Hutchinson Clinic**

Category : **Physician**

Issue Areas/Comments

Background

Background

We at the Hutchinson Clinic base our choice of therapeutics on clinical outcomes. Changing reimbursement on those products would reduce our choices available to our patients. The current payment system accurately captures the true cost of our drugs. By tampering with the payment system we have become used to, you will take away clinical options available to us. With regards to Amgen's portfolio contract, it provides us with the choice of purchasing as little or as much product as we need. As for as our Aranesp or Procrit purchases, we use both products at our facility. We choose to use more Aranesp because of its flexible dosing schedules which free our patients from unnecessary office visits. We are free to use either Procrit or Aranesp and we use Procrit when we feel it is clinically appropriate. Procrit was the only growth factor on the market for many years and provided very few discounts. Since Amgen brought Aranesp to market, our discounts on both drugs have increased dramatically. This, in turn, should be saving the entire system money. Amgen's lineup of oncology products has provided us with many more choices in supportive care tharapies. In conclusion, we feel that changing reimbursement would drastically reduce our choices to use the best products for our patients.

Submitter : **Dr. Peter Burke** **Date: 10/09/2006**

Organization : **Vermont Society of Pathologists**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Impact

Impact

See Attachment

Provisions of the Proposed Rule

Provisions of the Proposed Rule

See Attachment

CMS-1321-P-678-Attach-1.DOC

#678

Northwestern Medical Center
Department of Laboratory Services
133 Fairfield Street
Saint Albans, Vermont 05478-1013
802-524-1074

Comments of the Vermont Society of Pathologists on the Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007

[CMS–1321–P]

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

VSP 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, VSP 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, VSP 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.

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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.

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

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

VSP position: **no additional limitations** are necessary on PC purchase, beyond the need to apply the purchased-service rules that already exist and clarifying that they apply in the contracted reassignment setting

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

VSP 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. VSP 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. VSP 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

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VSP 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, VSP considers it to be essential that CMS address both structures in its rulemaking.

VSP 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. VSP 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. VSP 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

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furnished after December 31, 2006, an independent laboratory may not bill the carrier for physician pathology services furnished to a hospital inpatient or outpatient.

VSP 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,

Peter R. Burke, MD, FCAP
President, Vermont Society of Pathologists
October 9, 2006

Submitter : **Date: 10/09/2006**

Organization : **Marshfield Clinic**

Category : **Other Health Care Provider**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Impact

Impact

B. GPCI
C. Telehealth
D. Miscellaneous Coding Issues
L. IDTF Issues
M. Independent Lab Billing
N. Clinical Diagnostic Lab Comments
Q. Promoting Effective Use of HIT
R. Health Care Information Transparency Initiative

CMS-1321-P-679-Attach-1.DOC

MARSHFIELD CLINIC

CMS-1321-P Comments

GPCI

In the proposed rule CMS indicates that it is interested in receiving suggestions on alternative ways to administratively reconfigure payment localities that could be developed and proposed in future rulemaking. CMS states that it does not anticipate proposing significant changes to the GPCIs in response to changes in the source data. In the following comments we demonstrate that the source data utilized to apportion payments in the localities inaccurately represents the cost of providing Medicare services. We urge CMS to revise obsolete and incomplete measures of practice cost to assure a fair allocation of payments in all localities.

We have a number of concerns related to the practice expense (PE) GPCI that have direct implications for equitable compensation of physicians under the Medicare fee schedule. We are concerned that the source data used to estimate non-physician wages in the current PE GPCI do not properly reflect prevailing relative wage rates for the index occupational groups. We are also concerned that the composition of the PE GPCI, especially the non-physician wage component, is outdated and does not adequately reflect prevailing practice organization realities. Both of these have the potential to distort practice-related expense payments across localities, resulting in the Medicare program paying too much in some localities and too little in others.

The PE GPCI for 2005 accounted for 43.7% of Medicare physician fee schedule payments. It is composed of non-physician wages, office space costs, and equipment and supplies. The largest component of the PE GPCI is non-physician employee wages. Non-physician wages, which are based on U.S. census wage data, account for slightly over 40 percent of the practice expense GPCI. CMS uses the median hourly earnings of only four occupational classes to compute local wage effects on payments: clerical workers, registered nurses, licensed practical nurses, and medical technicians.

Recent studies conducted by multi-specialty group practices in Montana, Iowa and Wisconsin have examined elements of the non-physician wage component in the PE GPCI. The results of these investigations raise questions about the validity of data used in the non-physician wage component of the PE GPCI and also about the validity of the wage component's structure. With respect to the latter, the practice of medicine has evolved dramatically since the PE resource input measures were proposed in the early 1980's and current staffing mix, especially in large group practices, appears to be distinctly different in composition than that reflected in the current PE GPCI.

One analysis conducted at Marshfield Clinic found that median current occupational wages for health care employees in Wisconsin were consistently higher than national median wages for the same occupational category. The study focused on 10 occupational groups that mapped directly to the health care occupational categories included in the current PE GPCI. In 9 of 10 occupational categories examined, Wisconsin health care employees' median current wages exceeded national median wages, although the wage differences in many of these categories were relatively small as it was for the one occupation where national median wages were higher. (See attached table.)

These findings gain potential importance when they are considered in the context of the PE GPCI for Wisconsin, which has a value of 0.927 for 2005. With Wisconsin health care employee wage rates near or above national levels for health care occupational categories that align closely with CMS PE GPCI wage categories, and considering that the medical equipment and supplies category in the PE GPCI is fixed at the national average, it would seem that either Wisconsin rents are extraordinarily low (i.e., about 38-40% of the national average) and/or that the wage data used by CMS in the PE GPCI differs substantially from that used as benchmarks by a wide range of health care systems and physician practices. While differences would be expected in wage estimates from private and government sources, differences as large as those suggested by these data raise additional questions about the validity of the data used currently to estimate PE GPCIs and the potential distributional effects associated with using alternative wage data sources in the PE GPCI.

Marshfield Clinic also recently conducted an internal analysis of 2004 data to determine the percentage of its employees that were classified in one of the four PE GPCI occupational wage groups and their average wages for that year. These data and comparable wage data for major occupational groups employed in the Clinic but not included in the PE GPCI wage component are reported below. Both occupational groups were constructed using Medicare cost principles to facilitate comparisons with other data sources available to CMS.

Total wages (5138 employees)	$177,347,115
Average wage (5138 employees)	$34,516/yr
Average wage (3351 PE GCPI employees)	$27,262/yr
Average wage (1787 non-PE GCPI employees)	$48,399/yr
Non-PE GCPI employee share of total wages	48.7%

Based on these data, it is clear that the CMS PE GPCI excludes occupational groups that account for about 35% of all non-physician Marshfield Clinic employees and that the wages of excluded group employees is, on average, nearly 27% higher than included occupational group average wages. It is also apparent that health care workers whose wages represent nearly one-half of Marshfield Clinic's non-physician wage bill are not represented in any systematic way in the current PE GPCI. The employees not included among the CMS proxies provide managerial and administrative support such as purchasing, business office or patient accounting/reimbursement, accounting and finance, legal services, human resources, medical records and information systems support.

These results are supported by similar findings from studies conducted at The Iowa Clinic in Des Moines and the Deaconess Billings Clinic in Montana. These findings raise questions about the validity of the current PE GPCI for today's physician practices and, specifically, whether other occupational groups should be included in the PE GPCI.

There may be other important reasons to consider revisions to the PE GPCI methodology as well. For example, to the extent that GPCIs are higher in high payment localities, is it possible that problems with the GPCIs contribute in a systematic way to the large variations in per capita expenditures observed across different geographic localities? A study published in 2003 looked at regional variations in the number of services received by Medicare patients who were hospitalized for hip fractures, colorectal cancer, and acute myocardial infarction. The researchers found that patients in higher spending areas received approximately 60 percent more care, but that quality

of care in those regions was no better on most measures and was worse for several preventive care measures. (Fisher, Elliott S., MD, MPH; David E. Wennberg, MD, MPH; Therese A. Stukel, Ph.D.; Daniel J. Gottlieb, MS; F.L. Lucas, Ph.D.; and Etoile L. Pinder, MS, "The Implications of Regional Variations in Medicare Spending. Part 1: The Content, Quality, and Accessibility of Care," in The Annals of Internal Medicine, February 18, 2003, Vol. 138, Issue 4.)

In previous versions of the Medicare physician fee schedule rule, CMS has stated that it intends to revise both the work and practice expense GPCIs based on updated U.S. Census and other data. While we support such updates and believe regular updates are important, we believe the base on which these updates are made can and should be improved. To that end, we recommend that CMS improve, refine, and validate the proxy measures utilized in determining the practice expense component resource inputs through a documented and transparent process. We also recommend that CMS should consult with appropriate stakeholders to determine if an appropriate set of resource inputs are being captured.

It is important for all physicians to be properly compensated for the services they provide. CMS must ensure that geographic disparities are not perpetuated due to inadequate and outdated data sources. Thank you for your consideration of this important issue.

Position Title	Wisconsin Median Current Hourly Wage	National Median Current Hourly Wage
1. Registered Nurse (staff)	25.41 (15019)	23.22 (219,251)
2. LPN	16.83 (1113)	16.15 (31,606)
3. Surgical Technologist	17.13 (975)	15.67 (6978)
4. Medical Technologist (ASCP)	21.99 (1560)	21.15 (16,447)
5. Medical Lab Technician	17.23 (570)	16.49 (4143)
6. Mammography Tech	22.66 (291)	22.60 (2580)
7. Radiologic Tech - ARRT	19.78 (1115)	19.90 (10,928)
8. Ultrasound Technologist	29.95 (342)	24.95 (3889)
9. Nuclear Medicine Tech	27.37 (175)	26.97 (1966)
10. Pharmacy Technician	12.47 (700)	12.36 (11,842)

The number in brackets( ) after the dollar figure is the number of employees in the job title reporting current wages paid.
Source: RSM McGladrey Inc., and Watson Wyatt Data Services

TELEHEALTH

The process for submitting and justifying requests for additional CPT codes outlines a process for quantifying whether a request for additional CPT codes meets the definition of telehealth services (Section 1834(m)(4)(F) of the Act) as professional consultations, office visits, and office psychiatry services (identified as of July 1, 2000 by CPT codes 99241 through 99275, 99201 through 99215, 90804 through 90809, and 90862) and any additional service specified by the Secretary (Fed Reg, Aug 22, 2006, p. 48994). In reviewing requests, CMS looks for similarities between the proposed and existing telehealth services for the roles of, and interactions among, the beneficiary, the physician (or other practitioner) at the distant site and, if necessary, the telepresenter as well as similarities in the telecommunications system used to deliver the proposed service, for example, the use of interactive audio and video equipment (Fed Reg, Aug 22, 2006, p. 48994).

Since establishing the regulatory process, CMS has added TeleHealth codes psychiatric diagnostic interview examination; ESRD services with two to three visits per month and four or more visits per month; and individual medical nutritional therapy. CPT codes for dialysis were added to the approved list of TeleHealth Services by CMS without a request to do so from the public through the process outlined in the December 31, 2002 Federal Register (67 CFR 79988), and without dialysis centers being an approved originating site. Psychiatric diagnostic interview examination also was not formally requested through the legislated process. In 2005, CMS added medical nutrition therapists and other nutrition professionals to the list of eligible practitioners without legislative mandate, and without any report from the Secretary suggesting or mandating that these health professionals be added.

The request for addition of the codes for approved TeleHealth services in 2005 for consideration in the 2006 Physician Fee Schedule were for speech therapy, audiology and physical therapy services. Those codes were denied based on the premise that physical therapists, speech language pathologists and audiologists are not permitted under current law to provide and receive payment for Medicare telehealth services at the distant site.

We would respectfully disagree with the position taken by CMS. The addition of CPT codes to the list of approved TeleHealth services is dependant on the regulatory process outlined in the Federal Register as being an assessment of whether or not services are those that are similar to office and other outpatient visits, consultation, and office psychiatry services. There is limited discretion in the regulatory process for CMS to disallow a CPT code based on whether or not the providers connecting to a distant site are eligible practioners under the law. The regulatory process allows CMS to look for similarities between the proposed and existing telehealth services within the criteria listed in the regulatory language.

We would propose that CMS either reverse its decision to disallow the speech pathology, audiology, and physical therapy codes, as CMS approved Medical Nutrition Therapy codes in 2005 without MNTs being eligible practitioners. If the codes are not added, we would request an explanation of the contradiction between the approval of non-eligible practioners' codes in 2005 and the denial in 2006.

In addition, CMS has stated that although speech language pathologists, audiologists and physical therapists are not permitted under current law to provide and receive payment for Medicare telehealth services at the distant site, CMS is

exploring this issue as part of a report to the Congress (required by section 223(d) of BIPA) on additional sites and settings, geographic areas, and types of non-physician practitioners that could be reimbursed for the provision of telehealth services. The report to Congress was due January 1, 2003. In lieu of the report being several years overdue, if indeed CMS is waiting for this report, we would ask for clarification of the expected date of release of the report.

In addition, codes for skilled nursing care (now called nursing facility care) were denied. We would again reiterate that the regulatory process does not require an originating site to be approved prior to the approval of the requested CPT codes. CMS approved dialysis codes in 2004 without dialysis centers being an originating site. We are confused by the contradiction in process from 2004 to 2006 and would request that CMS either add the requested nursing facility codes based on the required assessment for Category 1 services, or explain the contradiction in process.

We would also request that if indeed, no changes can be made to the approved list of CPT codes that would be used by non-eligible practitioners for the purposes of TeleHealth services reimbursement, until the two reports mentioned are completed and distributed, that CMS indicate when those reports will be available and when codes will be revised based on the reports (Federal Register, Vol. 71, No. 162, Aug 22, 2006, p. 48995) . The findings of the report are not required to add CPT codes as requested formally by the public, to the list of approved TeleHealth CPT codes. The report to Congress with recommendations on adding SNFs to the list of approved originating sites is mutually exclusive of the process for approving CPT codes. Although the report is currently under review in DHHS, we would request that CMS move forward with approval of the SNF code requests, as not to delay implementation of the recommendations that will be forthcoming from DHHS.

CMS has also indicated that they review and consider the recommendations of the report to the Congress once it is issued. If it is determined that SNFs should be added as an originating site, the change will be considered in future rulemaking (Federal Register, Vol. 71, No. 162, Aug 22, 2006, p. 48995). We would request clarification of what process is referred to in "future rulemaking"? Will the public be required to formally resubmit the SNF codes or will CMS take the lead and approve the codes at the same time that skilled nursing facilities are added as originating sites? We respectfully request clarification on this issue.

Miscellaneous Coding Issues

2. Section 5107 Payments for Therapy Services

The therapy cap is having a significant impact on beneficiaries in central Wisconsin and across the country. We are finding that patients must be discharged from therapy before they have completed their rehabilitation, due to the cap. We also do not have hospitals in the area that offer out patient therapy services. Medicare beneficiaries have no options once they have reached the cap.

The Medicare "therapy cap" went into effect on January 1, 2006 and a new therapy cap exceptions process started on March 13. The therapy cap limits Medicare rehabilitation coverage to $1,740 per beneficiary per year for physical therapy and speech language pathology combined and $1,740 for occupational therapy. The new exceptions process allows beneficiaries needing care above the cap to apply for an exception – but Congress only authorized exceptions through 2006. Without the

exceptions process, patients will have to either pay out of pocket or travel long distances to an outpatient hospital to see a physical therapist.

Congress should reauthorize this new exceptions process, so patients needing therapy services can continue to receive the care they need. A better solution for Medicare beneficiaries would be to repeal the therapy caps and pass the Medicare Access to Rehabilitation Services Act (HR 916/S 438).

IDTF Issues

We appreciate the fact that you are proposing to establish standards for IDTFs.

Several of the proposed standards relate to the physical facility of the IDTF. An IDTF may be a mobile unit, and we feel this must be taken into consideration in developing the standards. The mobile units would have a designated "home location" that should be taken into consideration for storing records, etc.

One of the proposed standards would require the IDTF to maintain documentation of beneficiary questions and complaints at the physical location of the IDTF. Because IDTFs can be mobile units, we hope that if the documentation were stored at the "home location" of the mobile unit, this requirement would be satisfied. The information could be accessed electronically.

Another standard would require the IDTF to maintain a primary business phone under the name of the business that would be located at the designated site of the business. Again, since an IDTF can be a mobile unit, the primary business phone may be at the "home location" of the mobile unit, with secondary communication to the mobile unit. We hope that this would satisfy the requirement.

You are considering designating the place of service (POS) as the actual point of delivery. In the past, we have been directed told that if services are furnished in a mobile unit, they are often provided to serve an entity for which another POS code exists. For example, a mobile unit may be sent to a physician's office or a skilled nursing facility. If the mobile unit is serving an entity for which another POS code already exists, providers should use the POS code for that entity. However, if the mobile unit is not serving an entity which could be described by an existing POS code, the providers are to use the Mobile Unit POS code 15. This may require some clarification if the mobile unit is an IDTF.

Independent Lab Billing

We agree with this change.

Clinical Diagnostic Lab Comments

2c. These procedures should receive acceptance in the laboratory community. In practice, CMS has been using procedures that permit public consultation for payment determinations for new tests for a number of years, including 2006. This proposal is codifying the existing procedures.

2d. These procedures should receive acceptance in the laboratory community. The proposal defines when crosswalking or gapfillling may be used to establish reimbursement. The proposal is changing how CMS pays for gap filled tests in the second year; Carriers will no longer be able to pay at the lower of their local rate or the NLA - carriers will have to pay at the NLA.

3a. The laboratory coalition societies of major reference laboratories and the professional societies will likely oppose this proposal due to the additional burden on laboratories and delays in payment. We will work with the Clinical Laboratory Management Association to provide such comments as:

- Laboratory Information systems will have to merge specimen types and test results data into a LOINC code. Operationally, the LOINC code will have to be assigned on an individual patient basis for each test performed. Such processes will cause delays in billing until results are available, therefore, causing delays in billing and payment.
- Not all LOINC assignment will be able to occur electronically. Billing Medicare for services performed by outside laboratories that do not bill Medicare themselves will cause manual LOINC assignment by internal billing staff that initiate such Medicare billings internally.
- Billing interfaces will have to be modified at additional cost to accept transfer of the LOINC field from the Laboratory Information system to the billing system for inclusion of the LOINC field on the claim.
- Information Systems staff will have to be trained on the LOINC system at additional cost to laboratories.
- LOINC assignment will have to be monitored from the compliance perspective at additional cost to laboratories.
- Implementation of LOINC code with the claim may result in additional payment denials that the laboratory cannot control yet will be the ones denied payment.
- If commercial carriers also start to require such coding for payment, the additional cost and delays in payment are compounded.

3b. We are in agreement with this change.

3c. We agree with this change. This change simplifies the decisions regarding assigning a date of service to the specimen on archived specimens.

Promoting Effective Use of HIT

This section seems to be focused on HIT technology in the hospitals and patient care areas, but we would also like to promote using scanning methods for other forms that are required to be retained and available - namely the Medicare Authorization forms and the Medicare Advanced Beneficiary notices.

Without mandated interoperability, investments in HIT will remain risky. The first application of HIT in most organizations will be to increase charge capture, decrease accounts receivable, and incentivize providers to deliver the most expensive services. Lowering the costs of documentation and document retrieval are typically the next area of attention. Lowering other heath care costs and improving quality typically lag behind these efforts, in large part because lack of interoperable decision support. Other obstacles to decision support are liability and protection of intellectual property, both of which would benefit from proactive policies that balance the competing demands for making a profit and disseminating knowledge.

Health Care Information Transparency Initiative

Making patients (aka "consumers") aware of all health care costs could paradoxically increase costs, in part because patients cannot evaluate the risks of waiting for advanced disease before seeking services. In the area of infectious diseases, these risks are not just to the patient, but to the patient's community. It would be best to

separate the cost for consultative evaluation and preventive care from the costs for ancillary evaluation and the costs of management. Benefits from transparency are more likely to be in the area of the costs of management. Patients should not be incentivized to forgo consultative evaluation or preventive services, e.g. wait until a melanoma has metastases before seeking evaluation. The consequences of incentives to forgo other evaluation and management, services (e.g. excisional biopsy) are unclear, but are likely to have mixed effects.

Transparency should not be restricted to price, but should include transparency of payment. In the area of Medicare payment , these should include payments for work, practice costs and malpractice. Patients should be aware of these components of payment, as well as price. Patients will also need help understanding the complexities of where services are performed. For example, the same surgery will have a different price depending on whether it is performed in a hospital, an ambulatory surgery center, or an office. It is unclear if the average patient can grasp all of the implications, especially when they are faced with the burden of illness. Referring to patients as consumers obscures this difference between health care decisions and consumer decisions.

Submitter : **Ms. Laurel Sweeney** **Date: 10/09/2006**

Organization : **Philips Medical Systems**

Category : **Device Industry**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1321-P-680-Attach-1.DOC

#1680

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October 9, 2006

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Re: Proposed CY 2007 Physician Fee Schedule; CMS-1321-P

Dear Dr. McClellan:

On behalf of Philips Medical ("Philips" or "Philips Medical"), I am delighted to have this opportunity to provide these comments regarding the proposed revisions of the Physician Fee Schedule (PFS) for CY 2007 published on August 22, 2006 in the Federal Register (the "Proposed Rule"). Philips Medical is one of the largest manufacturers of medical systems in the world. Philips' product line includes technologies in general imaging and cardiac ultrasound, X-ray, Computed Tomography (CT), Magnetic Resonance Imaging (MRI), nuclear medicine (including Positron Emission Tomography (PET), radiation therapy planning, patient monitoring and resuscitation, as well as information technology solutions.

Preliminarily, Philips applauds CMS for its implementation of the abdominal aortic aneurism (AAA) screening benefit that is included in the Deficit Reduction Act. Philips is delighted that CMS has addressed this issue in the Proposed Rule, and urges the agency to make every effort to assure that this life-saving benefit becomes widely available to Medicare beneficiaries throughout the country.

However, Philips is extremely concerned about the potential cumulative impact of the various changes that are under consideration on Medicare allowances for diagnostic imaging services in non-hospital settings. There are a number of extremely significant changes that are likely to affect payment for these important services in CY 2007 and beyond: changes in the methodology used to determine practice expense relative value units (PE-RVUs), the increase in work relative value units for certain evaluation and management services, the Deficit Reduction

Act "cap" on medical imaging services provided in outpatient settings, and the potential 5.1% reduction in the conversion factor. Taken together, these changes have the potential to reduce Medicare payment for radiology by 16% in CY 2007, with many reductions continuing through 2010. Medicare payment for certain cardiac imaging services in non-hospital settings, such as echocardiography, are slated for reductions of almost 30% by 2010 due to the combined impact of these changes.

Many of these reductions are attributable to changes in the methodology for determining PE-RVUs, the results of the five year review, or both, which were the subject of a prior notice. Philips would like to incorporate by reference the comments submitted in response to that prior notice, a copy of which is submitted as an Attachment.

We understand that, in response to the prior notice, a number of professional associations, including the American Medical Association, objected to the budget neutrality adjustment methodology, under which the five year review changes are to be absorbed exclusively through a 10% reduction in W-RVUs. While we are sympathetic with the impact of this methodology on those performing services that are primarily comprised of W-RVUs, we urge CMS to ensure that technical component services, which are subject to extraordinary reductions under the Proposed Rule, are not disadvantaged by whatever budget neutrality adjustment methodology is chosen. In the event that CMS shifts the budget neutrality adjustment attributable to the five year review to the conversion factor, the budget neutrality adjustments necessitated by the new PE-RVU methodology (and most certainly the 32% reduction in direct cost allowances) clearly should be shifted to the conversion factor as well.[1]

Our comments on the Proposed Rule relate to four areas of particular interest to Philips: Implementation of the Deficit Reduction Act (DRA) provisions that "cap" medical imaging payment at the rates applicable under the Hospital Outpatient Prospective Payment System (HOPPS); the new standards proposed for Independent Diagnostic Testing Facilities (IDTFs); Medicare payment for cardiac monitoring services; and Medicare payment for proton beam therapy.

I. Medical Imaging Cap

Implementation of the DRA provisions limiting Medicare payment for medical imaging services to the amounts payable under comparable services under HOPPS will have a devastating impact on diagnostic imaging services, especially vascular ultrasound, MRI, CT, and PET. While we recognize that CMS is required by law to implement this provision, we urge CMS to refrain from

[1] The AMA and other organizations argue that the budget neutrality adjustment attributable to PE-RVU methodology changes should be absorbed exclusively by PE-RVUs until certain modifications are made in the equipment utilization and related assumptions and until a multi-specialty survey of indirect costs is completed by the AMA. However, neither changing the equipment -related assumptions nor substituting new indirect cost survey data would affect the 32% direct cost budget neutrality adjustment.

applying the cap to those procedures, like cardiac CT/CTA, PET, and PET/CT, for which payment allowances have not been established on a national basis. We also urge CMS to exclude from the "cap" certain vascular ultrasound and ultrasound guidance services that are not separately paid under HOPPS; to refrain from applying the multiple procedure discount to any service that is subject to the "cap"; and to adjust the HOPPS rates as necessary to include all payments made to hospitals for medical imaging services performed on an outpatient basis, before using the HOPPS rates as a "cap" on TC payments made to non-hospital providers.

A. Applicability of DRA "Cap" to Category III Codes

Section 5102(b)(1) of the DRA, the statutory provision directing CMS to establish the "cap", provides:

> A) IN GENERAL- In the case of imaging services described in subparagraph (B) furnished on or after January 1, 2007, if—
>
> > `(i) the technical component (including the technical component portion of a global fee) of the service **established for a year under the fee schedule** described in paragraph (1) without application of the geographic adjustment factor described in paragraph (1)(C), exceeds
> >
> > `(ii) the Medicare OPD fee schedule amount **established under the prospective payment system for hospital outpatient department services** under paragraph (3)(D) of section 1833(t) for such service for such year, determined without regard to geographic adjustment under paragraph (2)(D) of such section,
>
> the Secretary shall substitute the amount described in clause (ii), adjusted by the geographic adjustment factor described in paragraph (1)(C), for the fee schedule amount for such technical component for such year.

DRA, Section 5102(b)(1)(Emphasis added). Thus, for the cap to apply to an imaging service, the Secretary must have "established" the technical component of that service, and must also have "established" a payment amount for that service under the hospital outpatient prospective payment system.

CMS is proposing to apply this cap to Category III codes, including cardiac CT/CTA, PET, and PET/CT, even though the TCs of these procedures have not been "established for [CY 2007]" under the Physician Fee Schedule. Category III code allowances are determined by Medicare carriers on a locality by locality basis. For this reason, we do not believe that CMS should impose the DRA "cap" on Category III codes.

B. Applicability of DRA "Cap" to Ultrasound Guidance and Certain Vascular Codes

We also believe that any codes that are not separately reimbursed under HOPPS should be excluded from the DRA "cap." These include, for example, any ultrasound guidance code that is "packaged" under HOPPS. Because the payment allowances for these services are conceptually included in payment allowances for associated surgical or other interventional procedures, CMS has not "established" HOPPS payment allowances to which the Physician Fee Schedule allowances can be compared. For this reason, application of the DRA "cap" to these procedures would be inappropriate.

Similarly, application of the "cap" to duplex and transcranial Doppler procedures is inappropriate. These codes, like others excluded from the list of services subject to the "cap," include both imaging and a non-imaging component. In fact, most of the work involved in these services is related to the use of spectral Doppler, which is not an imaging service, but rather provides information regarding blood flow in a waveform.

C. Applicability of Multiple Procedure Reduction to Services Subject to the "Cap"

While we appreciate CMS's decision to refrain from implementing the 50% reduction in multiple procedures performed on contiguous body parts and to apply the reduction before capping payment at hospital outpatient department levels, we urge CMS to consider refraining from applying the multiple procedure reduction to any procedure subject to the DRA "cap." As CMS has noted in the Federal Register issuance setting forth the proposed HOPPS rates for CY 2007, the efficiencies of scale intended to be captured by the multiple procedure reduction already may be reflected in the HOPPS medical imaging rates. Therefore, in our view, it would be inappropriate to apply the multiple procedure reduction to any procedure that is subject to the DRA "cap."

D. Adjustment of HOPPS Rates for the Purpose of Implementing the DRA "Cap"

Finally, we urge CMS to adjust the HOPPS rates used for the purpose of the determining the cap to include all of the payments made to hospitals for medical imaging services, including outlier payments. Otherwise, the agency is "comparing apples to oranges" and establishing a capped rate that does not fully take into account all of the payments made to the hospital for the services involved.

II. IDTF Standards

In light of the findings of the Office of the Inspector General (OIG) audit of IDTF billing practices, we fully appreciate the need for clearer and more comprehensive standards for IDTFs. In general, we believe that the standards proposed are not unreasonable and may substantially improve compliance.

We note with particular interest CMS's proposal to include equipment standards among those standards to be met by IDTFs as a condition of participation in the Medicare program. We fully agree that compliance with equipment standards is crucial to ensure high quality medical imaging services, and specifically that compliance with manufacturers' instructions (as proposed in the Proposed Rule) is critical. We are concerned, however, that any standards that go beyond compliance with manufacturers' instructions be instituted only after full consideration and review. Equipment standards should not vary on a locality-by-locality basis based on local carrier determinations. We urge CMS to work with the National Electrical Manufacturers Association (NEMA), which has significant experience in the standard-setting arena, to develop any necessary equipment standards that go beyond manufacturers' instructions.

III. Cardiac Monitoring Services

We appreciate CMS's acknowledgement in the Proposed Rule that the current CMS data base does not include accurate direct cost data for cardiac monitoring services, such as cardiac event and holter monitoring. In our experience, such services are often provided by independent cardiac monitoring companies whose cost structures are very different from the cost structure of physician practices. This is especially true insofar as these companies generally incur substantial infrastructure, telecommunications, and software costs that are difficult to classify or categorize under the proposed PE methodology. We urge CMS to refrain from making any precipitous changes in Medicare payment for these services at this time, but rather to retain current allowances until more accurate data can be obtained and a more appropriate methodology can be designed.

IV. Proton Beam Therapy

Proton beam therapy, due to its recognized and desired biological effect on malignant tissue, has the clinical advantage of being significantly more precise in delivery. At this stage, allowances for Proton Beam Therapy performed in non-hospital settings are established on a local basis through individual carriers.

In the Proposed Rule, CMS solicits comments on the advisability of establishing national allowances for Proton Beam Therapy through the RUC process. Due to the relatively limited availability of these services in freestanding environments, we do not believe that it is appropriate to establish relative value units through the RUC for Proton Beam Therapy at this

time. However, we do note that the allowances established by those Medicare carriers that have addressed the valuation of these services (i.e. carriers in Indiana, Florida, and Texas) do not appear to take into account the considerable capital and operating costs involved. For example, the allowances established by one carrier for complex proton beam therapy services are less than 60% of the amounts proposed for comparable services in hospital outpatient departments. For this reason, we urge CMS to provide guidance to Medicare carriers addressing the appropriate methodology for establishing allowances for these important services.

We hope that these comments are helpful to CMS in finalizing the Physician Fee Schedule for CY 2007. If you have any questions regarding these comments, or if we can provide any further information, please do not hesitate to contact me at (978) 659-2972.

Sincerely yours,

PHILIPS MEDICAL SYSTEMS

Laurel Sweeney /BZ

Laurel Sweeney
Sr. Director, Reimbursement & Legislative Affairs

Submitter : **Ms. Pam Michael, MBA, RD** **Date: 10/09/2006**

Organization : **The American Dietetic Association**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

The American Dietetic Association provides comments on "Provisions," and "Other Issues." The attached letter describes specific comments and recommendations.

Impact

Impact

The American Dietetic Association supports CMS' decision to establish work RVUs for MNT codes. See the attached letter below for detailed comments.

CMS-1321-P-681-Attach-1.PDF

#681

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October 9, 2006

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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

The American Dietetic Association (ADA) is pleased to submit comments on docket 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" published August 28, 2006 in the Federal Register. The ADA represents nearly 65,000 food and nutrition professionals, including registered dietitians (RDs) who are eligible to provide medical nutrition therapy (MNT) under Medicare Part B.

These comments address specific items within the "Provisions" section, including the proposed bottom-up practice expense methodology work and PE RVUs for MNT codes, and other revisions that impact MNT services provided by RD Medicare providers.

Specific Comments to the Proposed Rule:

"Provisions"-- *Resource-Based Practice Expense (PE) RVU Proposals for CY 2007, Medical Nutrition Therapy MNT Services*

ADA acknowledges CMS' decision to establish work RVUs for MNT codes 97802, 97803, 97804 and HCPCS codes G0270 and G0271. Creating work RVUs is the fair and equitable action to take for MNT-covered services provided by RDs. Determining an appropriate work value for the MNT codes to better reflect the actual services is imperative to sustain an adequate number of RD providers in the Medicare program and to ensure beneficiary access to this vital benefit.

Analysis of Medicare payment data for the MNT benefit over the first 3 years of the program reveals much lower utilization than predicted. Physician and beneficiary lack of knowledge and awareness of Medicare Part B MNT services, along with the low payment rate that has discouraged RD provider participation, are factors driving the lower utilization. During the first year of Medicare Part B MNT coverage, CMS data shows less than $1 million was paid out for individual and group MNT services. ADA's utilization analyses over 2003-2004, reveal that Medicare paid approximately $3.3 million for

MNT services provided to 211,000 beneficiaries. The Congressional Budget Office had projected annual outlays of $60 million for Medicare Part B MNT, which is multifold higher than the actual $1-2 million annual average costs. Compared to estimates by the National Diabetes Information Clearinghouse and United States Renal Data System, approximately 8.6 million individuals 60 years and older are diagnosed with diabetes or acute renal failure, making most of them eligible for Medicare MNT services. Therefore, ADA believes that CMS' decision to establish work RVUs for the MNT codes at an equitable rate will positively impact future utilization of this important service.

Establishing work RVUs for MNT services
Since 2001, when CMS began drafting regulations for the Medicare MNT benefit, ADA has asked CMS to base the payment for MNT services on the Congressional statute which states that, "... the amount paid shall be 80 percent of the lesser of the actual charge for the services or 85 percent of the amount determined under the fee schedule established under section 1848(b) for the same services if furnished by a physician." In accordance with the MNT statute, ADA has suggested CMS use mid-level E&M codes 99203 and 99213 as the basis for establishing the MNT work values. ADA has also discussed other code work values for determining MNT work RVUs (e.g. use of ADA AMA survey data, see Appendix A, and the interim HCPAC data).

If CMS does not recognize the mid-level E&M code as the physician service basis for fulfilling the MNT payment level, as directed by the statute, then ADA strongly recommends that CMS should consider using the time-based individual psychotherapy code 90804 (see Appendix B) as the basis for establishing MNT work RVUs. While this code is for 20-30 minutes face-to-face time, the work RVU can be adjusted to15 minutes- the MNT code increment time. The psychotherapy code appropriately reflects equivalent comprehensive, complex, cognitive skills and behavioral modification interventions that are included in MNT services provided by RDs.

The CMS National Coverage Determination acknowledged the complexity of MNT services for diabetes and chronic kidney disease by making an allowance for additional hours of MNT coverage caused by changes in condition, treatment regimens or diagnosis. MNT includes ongoing behavioral therapy components for the intervention that is provided to complex beneficiaries with chronic diseases. The Medicare MNT benefit and regulations recognize the significant disease burden inherent in the service provided over time as defined in the statute: "nutritional diagnostic, therapy, and counseling services for the purpose of disease management which are furnished by a registered dietitian or nutrition professional ... pursuant to a referral by a physician..."

Flaws with HCPAC interim MNT code work values
The HCPAC interim RVUs for the MNT codes were determined using faulty premises and reasoning. The HCPAC did not fully understand the nature of MNT work provided by RDs (eg. the complex nature for beneficiaries who require care over time to modify unhealthy behaviors that negatively impact health outcome and disease management, as well as to maintain the new positive behaviors). The HCPAC's misunderstanding led them to inappropriately use a physical therapy (PT) code, 97110- "therapeutic procedure, one or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility," as the basis for the determining the interim MNT work values.

The HCPAC did not appreciate the need to find equivalent physician work to fulfill the statutory language that Congress defined in the MNT legislation. The MNT statute directs CMS to base the MNT payment on *physician* work for comparable service, not physical therapy work. The PT code linked to the HCPAC's interim MNT work RVUs does not describe the cognitive-based, complex work effort provided by physicians or RDs for MNT services.

Basis and analogy for all MNT work RVUs based on individual psychotherapy code 90804
The individual psychotherapy code 90804 (adjusted) appropriately describes the professional work effort of MNT better than the PT therapeutic exercise that HCPAC used for the interim MNT values. The adjusted work RVU for this psychotherapy code is also comparable to the RD AMA survey data reported by 72 RDs and 4 MDs in the original MNT code survey.

ADA recommends CMS also establish the group MNT work RVU based on the 90804 individual psychotherapy code. Recall in the 2002 Final Rule Physician Fee Schedule notice[1], CMS established that all time-based MNT codes should be calculated on the same hourly rate. The group MNT RVU would use the same hourly rate, divided by the average group size.

Need for physician input
ADA realizes that to base the MNT payment on the statute, CMS may require additional data to verify codes used by physicians from which to base the MNT work values. ADA is willing to go back to the RUC to work with physician societies to re-survey the MNT codes, and can lead this effort and dialog with various physician groups to coordinate a review of the MNT codes at a future RUC meeting.

CMS should establish MNT work RVUs. If the agency does not recognize the mid-level E&M codes as the physician service basis for determining the MNT work RVUs, then the individual psychotherapy code 90804 should be used as the reference code for the MNT work RVUs (for individual and group MNT work RVUs).

*"**Provisions**"- Correct RVU values for97802, 97803 and G0270; 97804 and G0271*
ADA reminds CMS that in the "Medicare Program; Revisions to Payment Policies and Five-Year Review of and Adjustments to the Relative Value Units Under the Physician Fee Schedule for Calendar Year 2002; Final Rule," the agency determined that the total RVUs for 97802, 97803 and G0270 are the same. Since the codes are time-based, payment for MNT reassessment and intervention will be based on the shorter time involved in providing the MNT follow-up service.

In the 2002 Final Rule, CMS stated, "We have reviewed the payments for CPT codes 97802 and 97803 and agree with the commenter that these two codes should have the same values. The essential difference between an initial and follow up medical nutrition therapy service is the time spent performing the service. Initial visits will be longer than follow-up visits and will likely involve Medicare payment for more increments of service... The payment rate we are establishing in this final rule for CPT code 97803 will be the same as the proposed rate for CPT code 97802."

[1] 42 CFR Part 405 et al., Medicare Program; Revisions to Payment Policies and Five-Year Review of and Adjustments to the Relative Value Units Under the Physician Fee Schedule for Calendar Year 2002; Final Rule.

The total MNT RVUs should be the same for codes 97802, 97803 and G0270; and the total MNT RVUs should be the same for codes 97804 and G0271.

Bottom up PE methodology- Elimination of the NPWP

ADA applauds CMS in its decision to eliminate the non-physician work pool (NPWP). By making this change and establishing work RVUs for the MNT codes, this will correct the substantial code payment reductions that would have occurred using the new bottom-up methodology if work had not been recognized for the MNT codes. As discussed above, ADA believes the work values for MNT codes should be based individual psychotherapy code 90804, if the agency will not use mid-level E&M codes 99203 or 99213 as the basis for MNT work RVUs.

While ADA has recently discussed with CMS the omission of certain pre- and post-service tasks included in MNT services, ADA recognizes that the RD professional effort previously listed as PE will shift to the professional work RVU. Therefore some of the MNT PE inputs will be shifted to work RVUs over the proposed four-year transition. ADA agrees CMS should phase in the new bottom-up methodology over four-year transition as a means to implement the PE change.

As discussed in the September meeting with CMS, ADA has submitted additional data to CMS that should facilitate a correct PE calculation for all MNT codes (see appendix C for list of equipment and supplies).

"Provisions"- *Misc. Coding Issues*

Statutory changes to FQHC- Section 5114--Proposed Addition of Diabetes Outpatient Self-management Training Services (DSMT) and Medical Nutrition Therapy (MNT) for the FQHC Program

ADA agrees with the CMS decision to make statutory changes to the FQHC program to allow same day billing for MNT and DSMT services. This will benefit seniors who may not have regular access to transportation or be well enough to return to the FQHC clinic for medically-necessary MNT services to receive these services on the same day as other clinic services.

"Other Issues"

Budget Neutrality Adjustor

Based on the Omnibus Budget Reconciliation Act of 1989, ADA understands CMS' requirements to apply an adjustment factor to the Medicare physician fee schedule in order to maintain budget neutrality. Instead of the agency's use of a new "work adjuster" to ensure budget neutrality as outlined in proposed rule, ADA asks the agency to apply the adjustment to the Medicare conversion factor for the 2007 Medicare physician fee schedule. Using the Medicare conversion factor for next year's physician fee schedule is consistent with previous agency actions since CMS has used this adjuster in fee schedules since 1998. Application of the adjustment to the conversion factor is preferable because it has less impact on other payers who use the Medicare RVUs, it is more transparent than other adjusters, and it links the adjustment to budget neutrality and monetary reasons versus adjustments in the codes' work values.

ADA recommendation: Apply the 'work adjustor' to the Medicare conversion factor for the 2007 Medicare physician fee schedule.

Publishing Relative Value Units (RVUs) for Non-covered Services
ADA asks CMS to publish services and the RUC-approved relative values for numerous CPT codes that remain non-covered by Medicare. In particular, ADA believes CMS should publish the RVUs for education and training CPT codes (98960, 98961, and 98962). CMS has a responsibility to publish relative values for all services since cannot independently publish its relative value recommendations without prior publication by CMS. Many third party payers refer to the Medicare RBRVS, and omission of certain codes impacts coverage and payment decisions by other payers.

ADA recommendation: Publish RUC-approved relative values for CPT codes that remain non-covered by Medicare.

"Private Contracts and OPT-OUT"
ADA acknowledges CMS revisions to the ``opt-out" provisions by amending the current regulations at §405.400 to add RDs to the definition of practitioner. CMS previously recognized that this provision applies to registered dietitians, but this change now will acknowledge the correction in CMS regulations and Medicare manuals.

ADA Assistance with Physician and Beneficiary Education and Outreach
ADA offers to assist CMS in educating physicians, other providers and beneficiaries of the new MNT provisions.

Additionally, we would be happy to discuss in more detail the recommendations provided herein, should CMS require further information.

Respectively submitted,
Pam Michael, MBA, RD
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Appendix A

MNT Survey Data (AMA survey June 2000)

97802 Medical nutrition therapy; initial assessment and intervention, individual, face-to-face with the patient, each 15 minutes ADA survey data: ADA survey respondents felt a "reasonable" work RVU for MNT 97802 is: 0.67-0.52.
97803 re-assessment and intervention, individual, face-to-face with the patient, each 15 minutes ADA survey data: ADA survey respondents felt a "reasonable" work RVU for MNT 97803 is: 0.67-0.52.
97804 group (2 or more individual(s)), each 30 minutes ADA survey data: ADA survey respondents felt a "reasonable" work RVU for MNT 97804 is: 0.34-0.27

Appendix C
MNT Supplies and Equipment

patient education booklet	SK062	
paper, lazer printing	SK043	
label for files, folders	SK043	
computer media, floppy disk 1.44mb	SK014	
Chair, medical reclining	EF009	Not for 97804 (group MNT)
Body analysis machine, bio-impedance	EQ073	Not for 97804 (group MNT)
Food models, plus artery, muscle, fat, sodium and sugar displays	EQ123	
Nutrition therapy software	EQ187	
scale, high capacity (800 lb)	EF016	
PC projector ($1700)	new item- see cost data	
Table	EF025	
computer, desktop, with monitor	ED021	
printer, laser	ED032	

Submitter : **Date: 10/09/2006**

Organization :

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1321-P-683-Attach-1.PDF

#682

October 9, 2006

BY HAND DELIVERY AND EMAIL
www.cms.hhs.gov/regulations/eRulemaking

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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 Under Part B

Dear Administrator McClellan:

Hoffmann-La Roche Inc. ("Roche") appreciates this opportunity to submit comments regarding 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.*[1] As a company dedicated to bringing innovative, effective, high quality therapies to patients, Roche supports updating payment policies under the Medicare Physician Fee Schedule (the "PFS") to reimburse the provision of important services in a fair and equitable manner.

Roche understands the challenges the Centers for Medicare and Medicaid Services ("CMS") faces in advancing the healthcare system for Medicare beneficiaries so that they receive high-quality services at an appropriate cost. While we generally support most of the efforts proposed by CMS to promote fair drug[2] reimbursement practices, we ask for clarification and guidance regarding the following issue. In brief:

- Roche recommends that CMS provide clarity regarding the process surrounding widely available market price ("WAMP") determinations and exempt new products during a product's first year on the market subsequent to gaining FDA approval.

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

[2] The term "drugs" refers to both drugs and biologicals.

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Widely Available Market Prices and Average Manufacturer Price ("AMP") Threshold

According to the Social Security Act, the Secretary may disregard the average sales price (ASP) for a drug that exceeds the widely available market price or the average manufacturer price by the applicable threshold percentage.[3] In the 2006 Final Rule, CMS proposed a five percent threshold for both the WAMP and the AMP.[4] Significantly, however, no concrete policies have been made public as to the process by which the Office of the Inspector General ("OIG") and CMS plan to issue WAMP determinations, nor the specific criteria that will be used to determine WAMP reimbursement amounts. Although we agree with the proposed continuation of the 5-percent threshold, we ask CMS to publish rules or guidelines with a public comment period to clarify important aspects of how the federal government intends to implement the WAMP authority in the Medicare program.

As the OIG continues its comparisons of a number of drug products on both their WAMP and AMP levels, we believe that, before finalizing any pricing actions, CMS should provide the public the opportunity to evaluate in detail the validity of the processes used and the data collected by OIG. CMS also called for comments regarding issues such as timing and frequency of comparisons and effective date and duration of the rate substitution. We have outlined our questions and suggestions below:

Frequency of WAMP measures: How often will WAMP determinations be made?

Given that ASP reimbursement levels are modified quarterly, we believe that WAMP adjustments should also be reviewed on a quarterly basis.

Duration of WAMP measures: What is the length of time a manufacturer must be included under the WAMP threshold?

In any quarter in which a manufacturer can demonstrate that its ASP no longer exceeds the WAMP threshold, *proposed at five percent* – the WAMP reimbursement amount should be immediately replaced by the product's ASP reimbursement.

Clarification of survey sources and materials used for WAMP measures: What survey materials will be used to determine WAMP and how will the Secretary decide which sources are the most appropriate from which to obtain survey data?

According to the Act[5], the Inspector General will consider survey materials from physicians, suppliers and other potential sources. At this time, there has been no review of survey instruments nor a list of physicians and suppliers eligible to receive these surveys. We ask CMS to publish these

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[3] SSA § 1847A(d)

[4] 70 Fed. Reg. 70222 (November 21, 2005)

[5] SSA § 1847A(d)(5)(b)

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documents to ensure clarity and methodological soundness of these key instruments, as well as the sampling techniques and response rates.

Notice of WAMP measures: What type of notice will the manufacturer and provider receive that a WAMP determination will be issued? Will the company have the opportunity to remedy the problem in advance?

At a minimum, WAMP determinations should be publicized at the same time ASP data is released to the public.

Exclusion for New Drugs from WAMP measures: What is the proposed policy surrounding new drugs coming onto the market?

A new drug is not immediately eligible for ASP pricing. Accordingly, it should not be eligible for inclusion under the WAMP determinations for a minimum of one year post-FDA approval. Drugs need time to become established in the healthcare system and to produce reliable marketing data supporting an appropriate price. We urge CMS to exempt from WAMP consideration all drugs in the first year of market entry subsequent to gaining FDA approval.

Conclusion

We appreciate the opportunity to provide our comments and recommendations. We hope that our suggestions will assist CMS in its mission to provide Medicare beneficiaries with access to high quality therapies. Thank you for your attention to this matter. Please feel free to contact me if you have any questions or need additional information.

Respectfully submitted,

Evan T Morris

Evan Morris
Executive Director, Federal Government Affairs

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Submitter : **Mr. Evan Morris** **Date: 10/09/2006**

Organization : **Hoffmann-La Roche**

Category : **Drug Industry**

Issue Areas/Comments

Background

Background

see attachment

GENERAL

GENERAL

Hoffmann - La Roche is pleased to present submit the following comments to CMS. Please see attachment.

Impact

Impact

see attachment

Provisions of the Proposed Rule

Provisions of the Proposed Rule

see attachment

CMS-1321-P-682-Attach-1.PDF

#683

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October 6, 2006

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Re: Proposed Notice re: Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology (June 29, 2006); Comments re: Practice Expense

Dear Mr. McClellan:

On behalf of Gateway Cardiology and the four practicing cardiologists, we appreciate the opportunity to submit comments to the Centers for Medicare & Medicaid Service ("CMS") regarding the June 29, 2006 Proposed Notice ("Notice") regarding Proposed Changes to the Practice Expense ("PE") Methodology and its impact on our practice. Performing more than 1,500 patient procedures per year, Gateway Cardiology and its four physicians are dedicated to providing full non-invasive, invasive and interventional services in the States of Missouri and Illinois. Besides performing services in its offices and the major bi-state hospitals, Gateway Cardiology and its physicians also perform significant number of cardiac catheterization procedures in two outpatient labs.

The proposed approach is biased against procedures, such as outpatient cardiovascular catheterizations, for which the Technical Component ("TC") is a significant part of the overall procedure. Catheterization procedures are being used as an example of the impact of the proposed methodology on procedures with significant TC costs because they share the same problems that we will outline below. We also believe that the same solution should be applied to all of the procedures listed below.

With regard to catheterizations, the proposed change in PE RVUs would result in a 53.1 percent reduction of payments for CPT 93510 TC. Similarly, payment for two related codes—93555 TC and 93556 TC would be reduced substantially. In fact, under the

Medicare Physician Fee Schedule ("PFS"), payment for these three codes would fall from 94 percent of the proposed 2007 APC rate for these three codes to 34 percent of the APC payment amount. These codes are representative of a range of procedures performed in cardiovascular outpatient centers.

CPT Code	Description
93510 TC	Left Heart Catheterization
93555 TC	Imaging Cardiac Catheterization
93556 TC	Imaging Cardiac Catheterization
93526 TC	Rt & Lt Heart Catheters

The stated purpose of the proposed change to a bottom up micro-costing approach is laudable and consistent with the statutory requirement that the Medicare program base payment on the use of necessary resources. However, the proposed methodology and inputs to the calculation do not comport with the statutory requirement that would match resources to payments. After reviewing the proposed methodology, including the 19 step calculation, we have identified several flaws that result in the PE RVU underestimating the resources needed to provide the technical component of cardiac catheterizations. We will address our concerns with the calculation of direct costs and indirect costs separately, as set forth below.

Direct Costs

The estimate of direct costs is critical for the first step in calculating the PE RVU for each procedure code. The direct costs are based on inputs from the American Medical Association's RVS Update Committee ("RUC") and reflect the direct costs of clinical labor, medical supplies and medical equipment that are typically used to perform each procedure. The RUC-determined direct costs do not reflect estimates of additional labor, supply and equipment costs that were submitted by (The Society for Cardiovascular Angiography and Interventions ("SCAI") or an industry group). As a result, the RUC-determined cost estimate is about half of the estimate that would result if all of the data were included. The addition of these additional costs which are consistent with the RUC protocol would increase the proposed PE RVUs by 24 percent.

Even if the RUC estimates included the additional costs submitted by SCAI or an industry group, the estimate is not an accurate reflection of direct costs of the resources necessary to provide the procedure because the RUC takes a narrow view of direct costs. Specifically, the RUC includes costs only if they are relevant to 51 percent of the patients. This definition of direct costs does not count the costs of supplies and the clinical labor time that may be required for the other 49 percent of the patients that may not fit the average profile. This approach is particularly inconsistent with the realities of the clinical staff needed for a catheterization facility and does not reflect the differences in clinical practice patterns. For example, some catheterization labs may use wound closure devices that will increase supply costs while lowering clinical staff time. Other

labs may not use closure devices to the same extent and may allocate more staff time to apply compression to the wound. These costs would not be counted in the RUC-determined direct cost estimate unless they apply to 51 percent of the patients. Based on the PEAC Direct Input data from the CMS website, it appears that the RUC inputs assume the time that may be required if wound closures were used, but it fails to include a wound closure device in the supply list of direct costs.

Unless the RUC considers the actual costs of the clinical labor, supply and equipment used to perform a cardiac catheterization, the PE RVU that results at the end of the 19 step calculation will never reflect the actual resources needed to perform the procedure and will result in destabilizing practice expense payments to physicians. Therefore, CMS must evaluate the adequacy of the direct inputs and focus on developing a methodology that captures the average direct costs of performing a procedure, rather than the direct costs of performing a procedure that represents 51 percent of the patients.

A new methodology is needed based on the best data available so that the direct costs shown in the third column of the table below can be allocated in a manner similar to the allocation of indirect costs. This would result in a PE RVU that is a more accurate reflection of the direct and indirect costs for the resources that are critical to performing the procedure.

Categories of Cardiac Catheterization Direct Costs Included or Excluded From RUC-Determined Estimates

Direct Cost Category	*Included In RUC-Determined Estimate*	*Excluded From RUC-Determined Estimate*
Clinical Labor	• Direct Patient Care For Activities Defined by RUC • Allocation of Staff Defined by RUC Protocol (1:4 Ratio of RN to Patients in Recovery)	• Direct Patient Care For Activities Not Defined by RUC • Actual Staff Allocation Based on Patient Needs
Medical Supplies	• Supplies Used For More Than 51% of Patients	• Supplies Used For Less Than 51% of Patients
Medical Equipment	• Equipment Used For More Than 51% of Patients	• Equipment Used For Less Than 51% of Patients
All Direct Costs for Cardiac Catheterization	• Approximately 55% of the direct costs are included in the RUC estimate	• Approximately 45% of the direct costs are included in the RUC estimate

A complete accounting of all of the direct costs associated with performing a cardiac catheterization procedure would result in a PE RVU that is almost two times the proposed amount, and would begin to approximate the actual costs of providing the

service. There are additional improvements that can be made in the manner by which the indirect costs are estimated that are outlined below.

Indirect Costs

The "bottom-up" methodology estimates indirect costs at the procedure code level using data from surveys of practice costs of various specialties. The methodology uses the ratio of direct to indirect costs at the practice level in conjunction with the direct cost estimate from the RUC to estimate the indirect costs for each procedure code. As a result, the indirect costs of cardiac catheterization procedure codes are understated because the direct costs do not reflect all of the actual costs. In addition, most of the PE RVUs reflect a weighted average of the practice costs of two specialties – Independent Diagnostic Treatment Facilities ("IDTFs"), which account for about two-thirds of the utilization estimate for 93510 TC, and cardiology. The IDTF survey includes a wide range of facilities, but do not reflect the cost profile of cardiac catheterization facilities--that may have a cost profile similar to cardiology in terms of the higher indirect costs that are associated with performing these services.

If CMS were to base the PE RVU for cardiac catheterization on the practice costs from cardiology surveys rather than a weighted average of cardiology and IDTFs, the PE RVU would increase about 24 percent. However, the payment would still fall far below the costs associated with the resources needed to provide the service efficiently. This finding supports the conclusion that the inputs to the calculations are flawed and need to be changed to ensure that they reflect accurately both (1) the direct costs at the procedure level, and (2) the indirect costs at the practice level.

Solutions

We believe that the proposed "bottom up" methodology is flawed with respect to cardiac catheterization procedures and CMS needs to develop a new approach that identifies the actual direct costs at the procedure level. The set of costs that are considered by the RUC are incomplete and need to be expanded now that the non-physician work pool ("NPWP") has been eliminated. The RUC-determined costs need to reflect all of the costs of clinical labor, not only the labor associated with the sub-set of patient care time that is currently considered. The supply and equipment costs also need to reflect current standards of care.

The problem created under the PE-RVU methodology set out in the Notice would result in a draconian cut in reimbursement for cardiac catheterization performed in practice or IDTF locations. The magnitude of the inequitable treatment caused by the resulting cuts is immediately apparent from a comparison with the APC payment rate for similar procedures. As a result, we request that CMS freeze payment for these cardiac catheterization-related procedure codes for one year to allow time for a complete assessment of the cost profile of the services listed in the chart provided above.

We will be collaborating with our membership organization, the Cardiovascular Outpatient Center Alliance ("COCA") to develop improved estimates of direct and indirect costs that may be submitted to CMS to supplement these comments either separately or as part of our comments in our response to the Proposed Rule addressing Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year

2007. It is our understanding that CMS will accept additional data that helps CMS in evaluating the impact of the PE RVU methodology on our practices.

Sincerely,

Gus Assi
Practice Administrator

Submitter : **Mrs. Tamar Thompson** **Date: 10/09/2006**

Organization : **Bracco Diagnostics Inc.**

Category : **Drug Industry**

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment

CMS-1321-P-684-Attach-1.DOC

#684

LIFE FROM INSIDE

October 10, 2006

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

Re: Comments on Proposed 2007 Medicare Part B Physician Fee Schedule Rule–CMS-1321-P

Dear Administrator McClellan:

Thank you for providing Bracco Diagnostics Inc. the opportunity to submit comments on the 2007 proposed Medicare Part B Physician Fee Schedule (MPFS) rule published in the August 23, 2006 Federal Register. Bracco Diagnostics Inc. is global manufacturer of contrast imaging agents and radiopharmaceuticals used in medical imaging procedures. The products that we offer are used in outpatient hospital procedures performed in radiology departments, cardiac catheterization laboratories, and nuclear medicine departments across the United States.

In this letter we are specifically commenting on the proposed payment policy for high osmolar contrast media (HOCM). We are also taking this opportunity to ask the Centers for Medicare and Medicaid Services (CMS) to reconsider and update its payment policy for contrast agents used in magnetic resonance (MR) imaging procedures.

In the 2006 MPFS proposed rule, CMS recommended separate payment for HOCM. Unfortunately, delays in the implementation of the revised practice expense (PE) methodology also resulted in the delay of implementing separate payment for HOCM in the physician office setting.

In the 2007 proposed MPFS, CMS again recommended separate payment for HOCM and continued separate payment for low osmolar contrast media (LOCM) under the Average Sales Price (ASP) methodology. Bracco applauds CMS'

107 College Road East Princeton NJ 08540 Telephone (609) 514-2200 Fax (609) 514-2429

decision to establish separate payment for HOCM in the physician office setting. However, because HOCM was not paid separately under ASP in 2006, we are asking that CMS develop a claims processing transmittal to instruct the Medicare carriers to allow payment for HOCM under ASP effective January 1, 2007.

In 2005, when CMS removed the payment restrictive criteria for LOCM in the physician office setting, CMS did not immediately instruct carriers to change their systems to allow payment for unrestricted payment for LOCM. Consequently, carriers did not update their payment systems until CMS released transmittal 627 on July 29, 2005 with a retrospective effective date of January 1, 2005. We believe that such instruction is of particular importance in 2007, when CMS estimates that Medicare reimbursement for ***all*** medical imaging procedures will be reduced by 16 percent as a result of the Deficit Reduction Act and changes to the practice expense methodology. **For these reasons, Bracco recommends that CMS establish separate payment for HOCM under ASP. We also recommend that CMS develop and release a claims processing transmittal to communicate this payment change to local Medicare carriers in early January 2007.**

On March 11, 2005, CMS released claims processing transmittal 502. This transmittal communicated new Healthcare Common Procedural Coding System (HCPCS) code assignments and a new payment methodology for contrast agents. In the transmittal, CMS stated that effective April 1, 2005 payment for contrast agents would be on the basis of ASP plus six percent in accordance with the standard methodology for drug pricing established by the Medicare Modernization Act (MMA) for other than hospital outpatient claims.

Since the implementation of this new policy, CMS has not revisited the existing payment policy for MR contrast written in chapter 13, section 40 of the Medicare claims processing manual. The language in the claims processing manual limits the payment for MR contrast to high dose (third dose). And, this section of the manual still refers providers to the deleted MR contrast HCPCS code A4643.

In order for physicians to receive the appropriate payment for all contrast agents, **Bracco is asking that CMS clarify its intention for reimbursing MR contrast under ASP with the recently developed "Q" codes for MR contrast agents and update chapter 13, section 40 of the claims processing manual to reflect the April 1, 2005 payment policy for contrast agents.** Allowing separate payment for all administered doses of MR contrast agents is consistent with CMS policy for contrast agents and ensures beneficiary access to procedures involving the use of this contrast material. **Similar to our recommendation on HOCM, we also ask that CMS develop a transmittal to instruct carriers to allow separate payment for all administered doses of MR contrast agents.**

Bracco recognizes the challenges that CMS faces in revising payment methodologies and would welcome the opportunity to meet with CMS to expand on upon our recommendations in greater detail.

Thank you for the opportunity to comment on this important rule. Should you have any questions, please do not hesitate to contact me via telephone at 609-514-2274 or email tamar.thompson@diag.bracco.com.

Respectfully,

Tamar Thompson, RMA, CCS, CCS-P
Manager, Reimbursement Services
Nuclear Medicine

Attachments:

CMS Claims Processing Manual Chapter 13 Radiology Services and Other Diagnostic Procedures, section 40:
http://www.cms.hhs.gov/manuals/downloads/clm104c13.pdf

Claims Transmittal 502, New HCPCS codes for Contrast Agents, March 11, 2005: http://www.cms.hhs.gov/transmittals/downloads/R502CP.pdf

Claims Transmittal 502, New HCPCS codes for LOCM/Payment Criteria, July 29, 2005: http://www.cms.hhs.gov/transmittals/downloads/R627CP.pdf

the case of Crohn's disease, fistulae.[3] Without proper treatment, the pain associated with rheumatoid arthritis and Crohn's disease can severely impact the quality of life of afflicted individuals.

Although rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, plaque psoriasis, Crohn's disease, and ulcerative colitis are chronic and debilitating conditions, Remicade® is a highly effective treatment that can slow the progression of these diseases and significantly enhance the quality of patients' lives by reducing their pain and other incapacitating conditions. Because Remicade® cannot be self-administered by patients, the Medicare Program provides Part B coverage for this infused therapy both in the hospital outpatient department and physician office settings. Thousands of Medicare beneficiaries afflicted with these conditions rely on Remicade® and other medications to manage their conditions and improve the quality of their lives.

I. Prolonged Physician Services Should be Compensated

We request that CMS recognize through separate payment the prolonged physician time and effort associated with Current Procedural Terminology (CPT) codes 99358 and 99359, Prolonged Physician Service Without Direct (Face-to-Face) Patient Contact. Currently, Medicare does not pay separately for these codes and, as a result, physicians caring for medically complex patients are not sufficiently compensated for the extended time they spend managing the disease apart from direct patient encounters. Developing treatment plans for chronically ill patients requires additional attention and consumes additional resources that are not captured in the current chemotherapy infusion codes or the evaluation and management (E&M) codes recognized by Medicare. Other activities include consulting with other professionals involved in treating these patients, and answering questions from the patients and their families.

Recognizing and compensating physicians for these activities would be consistent with the following testimony you gave before the Energy and Commerce Subcommittee on Health on July 27, 2006:

> There is good evidence that by anticipating patient needs, especially in those patients with chronic diseases, health care teams that partner with patients and coordinate across physician practices can help implement physicians' plans of care more effectively, reducing the need for expensive procedures, hospitalizations for preventable complications and perhaps even some office visits. Medicare's current payment system reimburses physicians based on the number and complexity of specified services and procedures that they provide, not how physicians work together to avoid problems in the first place.[4]

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[3] Fistulae are painful, draining abnormal passages between the bowel and surrounding skin.

[4] CMS Administrator Mark McClellan, Medicare Physician Payment: Building a Quality-Based System (July 27, 2006).

The work and practice expense inputs associated with CPT codes 99358 and 99359 were approved by the American Medical Association's Relative Value Update Committee and represent costs that are not associated with other E&M codes. In fact, many other payers currently use these codes to compensate physicians for prolonged services in addition to direct, face-to-face, patient services.

We believe all physicians should be fully compensated by Medicare for providing these services, particularly in the management of chronic diseases. This would be entirely consistent with the movement to align Medicare's payments with improved quality of care. As a first step, CMS could activate these codes for patients receiving complex drug or biologic therapies, the administration of which is described by CPT codes 96401 through 96417.

II. Drug Administration Codes Should Not be Revised Under the New Methodology

The Proposed Rule indicates that CMS will respond to comments it received on its revised practice expense methodology proposal[5] as part of the final 2007 changes to be published this fall. The practice expense relative value units (RVUs) published in the Proposed Rule reflected the proposed 3-year phase-in of the new "bottom-up" methodology.[6] Centocor submitted comments (letter dated August 21, 2006) on the proposed new methodology, and we continue to believe that CMS should make the following changes to its practice expense proposal:

- exclude the drug administration codes from the "bottom-up" calculation of practice expense RVUs until it establishes new codes to recognize pharmacy management costs;

- delay the implementation of the "bottom-up" methodology until it has received updated and consistent indirect practice expense data for all specialties. If implementation cannot be delayed entirely, we recommend that, until the indirect practice expense data are updated, the implementation of the proposed methodology should go no further than a blend of 50 percent of practice expense RVUs calculated using the current methodology and 50 percent of practice expense RVUs calculated using the "bottom-up" methodology; and

- it is critically important to recognize prolonged patient services without face-to-face patient contact should CMS elect to include the drug administration practice expense RVUs under the "bottom-up" methodology. Otherwise the agency will be taking the risk of impeding patient access to these services.

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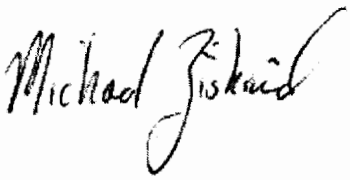
[5] 71 Fed. Reg. 37,170 (June 29, 2006).

[6] 71 Fed. Reg. at 49,070.

III. Conclusion

We appreciate the opportunity to comment upon the important issues raised by this Proposed Rule, and look forward to working with the agency to ensure that the Final Rule will reflect these changes to ensure that beneficiaries continue to have full access to quality health care under the Medicare Program. Please contact us if you have any questions about this matter.

Sincerely,



Michael Ziskind
Senior Director
Public Payer Policy, Strategy and Marketing
Centocor, Inc.

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Horsham, PA 19044
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fax: 610.651.6100

Submitter : Mr. Michael Ziskind **Date:** 10/09/2006

Organization : Centocor, Inc.

Category : Drug Industry

Issue Areas/Comments

Background

Background

Please see attached comment letter.

GENERAL

GENERAL

Please see attached comment letter.

Impact

Impact

Please see attached comment letter.

Provisions of the Proposed Rule

Provisions of the Proposed Rule

Please see attached comment letter.

CMS-1321-P-686-Attach-1.PDF

#686

centocor inc

October 10, 2006

By Electronic Delivery

Honorable Mark B. McClellan, M.D., Ph.D
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Ave., 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 Under Part B

Dear Dr. McClellan:

On behalf of Centocor, Inc., I am writing to comment on the Centers for Medicare & Medicaid Services' (CMS's) Proposed Rule entitled "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007" published in the August 22, 2006 Federal Register.[1] Centocor appreciates this opportunity to comment on this Proposed Rule, and looks forward to working with CMS to make appropriate adjustments in the CY 2007 physician fee schedule Final Rule to reflect its concerns.

As a leading biopharmaceutical company that discovers, acquires and markets innovative medicines and treatments that improve the quality of life of people around the world, Centocor believes in ensuring equitable and fair access to all necessary medicines for all patients. Among other life-improving medicines,[2] Centocor manufactures Remicade®, a product used by patients who suffer from the debilitating effects of rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, plaque psoriasis, Crohn's disease and ulcerative colitis, enabling these individuals to enjoy longer, more productive lives. Rheumatoid arthritis is a chronic disease that attacks the body's joints, causing inflammation, tissue destruction, and joint erosion. It affects over two million Americans, many of whom are Medicare beneficiaries. Each year, an additional 50,000 Americans are diagnosed with rheumatoid arthritis. Ankylosing spondylitis is a painful and progressive form of spinal arthritis that can also affect internal organs, peripheral joints, and vision. Psoriatic arthritis is characterized by the complex symptoms of joint inflammation and skin lesions. Plaque psoriasis is an inflammatory disorder characterized by raised and inflamed lesions or plaques, which can cause physical pain and emotional distress. Crohn's disease and ulcerative colitis are relatively rare conditions, causing inflammatory disease of the intestine with symptoms that include diarrhea, severe abdominal pain, fever, chills, nausea and, specifically in

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

[2] Centocor also manufactures ReoPro® for acute coronary care.

the case of Crohn's disease, fistulae.[3] Without proper treatment, the pain associated with rheumatoid arthritis and Crohn's disease can severely impact the quality of life of afflicted individuals.

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- delay the implementation of the "bottom-up" methodology until it has received updated and consistent indirect practice expense data for all specialties. If implementation cannot be delayed entirely, we recommend that, until the indirect practice expense data are updated, the implementation of the proposed methodology should go no further than a blend of 50 percent of practice expense RVUs calculated using the current methodology and 50 percent of practice expense RVUs calculated using the "bottom-up" methodology; and

- it is critically important to recognize prolonged patient services without face-to-face patient contact should CMS elect to include the drug administration practice expense RVUs under the "bottom-up" methodology. Otherwise the agency will be taking the risk of impeding patient access to these services.

---

[5] 71 Fed. Reg. 37,170 (June 29, 2006).

[6] 71 Fed. Reg. at 49,070.

III. Conclusion

We appreciate the opportunity to comment upon the important issues raised by this Proposed Rule, and look forward to working with the agency to ensure that the Final Rule will reflect these changes to ensure that beneficiaries continue to have full access to quality health care under the Medicare Program. Please contact us if you have any questions about this matter.

Sincerely,

Michael Ziskind
Senior Director
Public Payer Policy, Strategy and Marketing
Centocor, Inc.

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800 Ridgeview Drive
Horsham, PA 19044
phone: 610.651.6000
fax: 610.651.6100

Submitter : **Date: 10/09/2006**

Organization : **AHCA/The Alliance for Quality Nursing Home Care**

Category : **Long-term Care**

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-687-Attach-1.DOC

#687

ahca®
American Health Care Association

The Alliance
For Quality Nursing Home Care

October 10, 2006

BY ELECTRONIC MAIL AND OVERNIGHT DELIVERY

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:

The American Health Care Association ("AHCA") and the Alliance for Quality Nursing Home Care (the "Alliance") appreciate 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.

AHCA is a non-profit federation of affiliated state health organizations, together representing more than 10,000 non-profit and for-profit assisted living, nursing facility, developmentally-disabled, and subacute care providers that care for more than 1.5 million elderly and disabled individuals nationally. AHCA's ultimate focus is on providing quality care to the nation's frail, elderly and disabled, who are served by the long-term care professionals who comprise AHCA's membership. Similarly, the Alliance is a coalition of 16 national long-term care provider organizations that care for approximately 300,000 elderly and disabled patients each year in nearly 1,800 facilities across America. The Alliance is also dedicated to improving the quality of nursing home care in the United States through measured results and outcomes and to assuring the government resources necessary to provide high quality care and services. Since Medicare Part B beneficiaries comprise a significant portion of the patients residing in our member SNFs, members of AHCA and the Alliance are directly impacted by 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 members' 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 have enclosed a proposed protocol for blood glucose monitoring that we believe best serves the critical needs of institutionalized Part B beneficiaries with diabetes. AHCA and the Alliance look forward to working with CMS in continuing to fight this debilitating disease and adopting as many of these recommendations as possible.

I. 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

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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.

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.

II. 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.[2] Moreover, the preamble discussion references no 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

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

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 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.

III. 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.[3] 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);

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3 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 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

- 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 are 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 Glucose Testing

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 have enclosed with our comments two proposed protocols for "finger stick" blood glucose determinations that were designed, respectively, by the AHCA and Highmark Medicare Services ("Highmark").[4] See Exhibits A, B. 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

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

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.

V. 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.

VI. 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.

VII. 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.

ahca
American Health Care Association

The Alliance
For Quality Nursing Home Care

We find it alarming that 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. Consequently, 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.

* * * *

AHCA and the Alliance appreciate the opportunity to present these comments to CMS. We hope our the information presented, including the proposed blood glucose monitoring protocol, will be useful to CMS in revisiting the policies set forth in the Proposed Rule and affirmatively developing appropriate diabetes treatment and management policies in the future.

Respectfully submitted,

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American Health Care Association

Alan G. Rosenbloom
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EXHIBIT A – AHCA PROTOCOL

MANAGEMENT OF DIABETES MELLITUS IN LONG TERM CARE FACILITIES: PROPOSED PROTOCOL FOR PHYSICIAN NOTIFICATION FOR FINGER STICK BLOOD GLUCOSE DETERMINATIONS

Purpose: To further address the Centers for Medicare and Medicaid Services (CMS) Program Memorandum (PM) AB-00-108, December 1, 2000 concerning sliding scale insulin dosage determination by glucose monitoring and the requirement to notify the physician after each finger-stick test result to obtain a prescription for continuation or modification of insulin dosage.

Goal: To establish a guideline for glucose monitoring using a sliding scale for insulin dosage with the frequency of physician notification in managing patients with Diabetes Mellitus (DM) in long term care facilities. The guideline is offered as an interim measure until a relevant professional association with expertise in this area (e.g. the American Medical Directors Association) develops a more definitive clinical practice guideline that is specific to patients with long-term, chronic care needs.

Date: March 20, 2002

INTRODUCTION:

Diabetes Mellitus (DM)/Type II is a disorder of carbohydrate metabolism that leads to abnormalities of fat and protein metabolism. It is the most common endocrinologic disorder and is the most prevalent endocrinologic disorder in individuals over the age of 55 years. According to statistics recently reported by David Eddy, M.D., Ph.D. at the 2001 Health Legacy Partnership Conference, Type II diabetes affects about 16 million people in the United States and it is estimated that approximately 6 million of these individuals have not yet been diagnosed. In addition, 20 million people have impaired glucose tolerance resulting in elevated fasting plasma glucose levels. The incidence of DM will increase over the next three decades as the graying of America continues. The impact of this disorder on quality of life and on economic costs is substantial.

A series of clinical studies have demonstrated that "tight" control of glucose levels leads to significant decreases in the incidence of complications seen over time in many diabetic patients. **It is important to note that the patient population in today's long term care (LTC) facility is substantially older and more medically complex than in the past ("older and sicker").** Today's LTC patient with DM is older and has more co-morbid conditions than the average LTC facility patient with DM a decade ago. According to a study published in the *Journal of Cardiovascular Nursing*, April 1, 2000, titled "Patient Problems and Nurse Interventions During Acute Care and Discharge Planning," the frequency of problems experienced by individuals over the age of 65 averaged 8.6 problems during the acute care stay that required nurse attention and care planning. In this study, 68% of the nursing interventions associated with these problems related to surveillance activities. The most frequently cited surveillance activity was drawing lab specimens. The number of patient problem discovered in this study is also consistent with the number of patient problems identified via the Resident Assessment Instrument (RAI) process.

In comments provided to the Centers for Medicare and Medicaid Services (CMS) on the Resident Assessment Protocol (RAP), the American Health Care Association (AHCA) reported that with each

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Minimum Data Set (MDS) assessment, approximately 6 to 10 RAPs are generated. This constitutes about 50% of the RAI RAPs that can be triggered for care planning. In 6 of the 17 provided RAPs, DM is listed as an "internal risk factor." Among these six are the more commonly triggered RAPs. There is thus a current need for monitoring that is mandated by the RAI process and a growing need for more intense management of blood glucose levels for an increasing number of residents in LTC facilities who have DM.

BLOOD GLUCOSE MONITORING IN MANAGEMENT OF DM:

The technology now exists and can be effectively operated at LTC facilities to permit the staff at LTC facilities to determine blood glucose levels rapidly and accurately using blood obtained from a finger stick and processed by a simple to calibrate glucometer. This technology and approach facilitates feedback of the results of the blood glucose value to facility professional staff, the identification of trends, and more timely decisions regarding the delivery of treatments that require the glucose value to help determine the next steps (e.g. the precise amount of additional insulin, if any, that should be administered to the individual patient).

There are four levels of clinical situations where glucometer/finger stick glucose monitoring in LTC patients is indicated. These situations are based on patient acuity, clinical judgment, patient diet, patient activity levels and standards of practice for clinical management of patients with DM. Any attempt to codify this dimension of DM management must reflect both current medical knowledge and the need to ensure a reasoned level of accountability in the overall process. To accomplish these goals, we recommend that the physician's orders for the monitoring of patients with DM include the following five (5) components if the ordered finger stick glucose determinations are to be considered "covered tests" and reimbursable by CMS.

The order for finger stick monitoring should contain the following elements:

1. The specific hypoglycemic medication to be administered, the route of administration (oral or sub-cutaneous) and the specific dose of the medication related to the blood glucose value obtained;
2. The order should also specify the conditions under which the physician must be notified immediately for an abnormal value ((e.g. "Notify the physician immediately for any glucose value that falls outside a prescribed range (e.g. <60 mg% or >300 mg%) or if patient exhibits any of the signs or symptoms of hypo or hyper-glycemia")) and the route of administration for the medication;
3. The level of instability of the DM patient (see below) and the frequency for staff to communicate to the physician all of the blood glucose determinations (to support use of these values in the real time management decisions of the treating physician);
4. The frequency for obtaining the blood glucose determinations; and
5. The duration of the order (a set time for the order to expire unless specifically extended as a new order for specified clinical reasons). This period should not exceed 10 days.

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The Protocol proposes using four (4) levels of DM patients. The Levels include:

A) Level I – Patients with unstable DM (blood glucose values of <60 mg% or >350 mg% or with signs and/or symptoms of hypo- or hyper-glycemia). These patients often require finger stick glucose monitoring to be performed at least 3 or more times per day. The physician orders for this level include specific circumstances that will mandate immediate physician notification (e.g. notify physician immediately for glucose levels less than 60 mg% or more than 350 mg%). The specific levels noted for immediate notification under such a "sliding scale" order are clearly dependent on individual patient characteristics and physician judgment.

The physician's order may also call for the administration of differing amounts of additional medications (e.g. insulin for blood glucose levels that are in certain ranges. That is to say, as an example, give no additional insulin for a determination of between 60 and 150mg%, give 4 units of regular insulin subcutaneous if blood glucose is between 151 and 250 mg% and give 8 units of regular insulin subcutaneous for a determination between 251 and 350mg%). If the glucose level is greater than 350 mg%, the physician would be called immediately and specific orders obtained for how best to respond.

In all these patients, the pattern of all the glucose determinations over time - and not the individual points along the time line - is of critical importance in the management of the patient's DM. The physician must review the pattern of these values over time to determine if the diet, activity level and/or hypoglycemic drug regime is appropriate or ought to be changed (or if the situation is stabilizing and monitoring frequency can be safely decreased). Hence, the physician's order for this category of individual with DM also should reflect that the facility staff shall notify the physician of all the individual determinations at a time interval specified in the physician's order for the individual patient/resident, whether or not any of the levels had previously triggered an immediate notification. For this level of monitoring intensity, the frequency of physician notification and review, in our view, should be every 24 to 48 hours. The more acutely ill (unstable) the patient, the shorter the frequency of notification. The more stable the patient, the less frequent the notification ordered within the above range.

B) Level II – Patients with a significant clinical risk for blood glucose instability, as determined by the attending physician, but who are more stable than the patients noted under Level I noted above. These individuals may or may not have any current fluctuation in glucose levels. For this level to be supported, the patient's glucose values would **either** be in the range of (≥300 mg% but <359 mg%) or (<80 mg% but >60 mg%) **or** the patient would have a specific medical reason for being at risk for blood glucose instability (e.g. acute urinary tract infection, steroid medications, etc.). The patients in this level may have blood glucose monitoring performed between one (1) and three (3) times per day. Again, as described above, the same type of sliding scale order may be written that allows immediate notification for levels that are very low or very elevated. At Level II, the physician would order notification of the pattern of blood glucose values for his/her evaluation in a range of (e.g.) every 2 to every 3 days.

C) Level III - Patients who are relatively stable, but still exhibit some risk for fluctuations in glucose control (although with less probability and/or lower magnitude of fluctuations). In these individuals, the monitoring frequency would be between one per day to twice per week. In this circumstance, the physician notification of all determinations would be at a frequency between every three 3 to 7 days, depending on the patient's stability and clinical context.

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D) Level IV: Routine Glucose monitoring for relatively stable patients with DM: These patients would demonstrate no blood glucose values outside the ranges noted above and would not exhibit any of the specific clinical factors that would generate a risk for such instability. These patients would have monitoring less than 2/week. **In these patients, the facility would not bill for the finger stick determinations and they would be considered part of a routine monitoring function.**

EXAMPLE: An individual who historically has relatively stable insulin dependent diabetes mellitus (blood glucose values normally in 150 to 180 mg% range). The physician's initial orders were to check blood glucose levels by finger stick once per week. This individual would be at Level IV under the proposed approach.

This individual then develops an acute urinary tract infection (UTI), with fever and an increased risk for glucose fluctuations. The individual would then transition to Level II, after the appropriate new orders are received from the physician. The physician orders that glucose values be measured three (3) times per day for clinical management during this period of increased risk. The order calls for notification of the physician immediately for specific glucose values that are in specified emergency ranges. The order also requires that the physician be notified of all the glucose values recorded at least every 48 hours. The blood glucose values for this resident over the next two days are in the 200 to 275 mg% range. None are in the "emergency" range, requiring "stat" notification.

This individual then progresses to develop signs and symptoms of hyperglycemia, with a blood glucose value of 375 mg% (in the "emergency range of ≥350 mg%). The physician is notified immediately by the staff, in accordance with the orders. A new order is received that calls for additional insulin to be administered immediately. In addition, the glucose values are to be obtained four (4) times per day. Notification of all the values is ordered to be communicated to the physician at least every 24 hours. The individual has filled the criteria for a Level I patient during this time period.

Over the next several days, the blood glucose values begin to improve, although they are still elevated (235 to 275 mg%). The fever has subsided and the individual is on appropriate antibiotics for the infection. The frequency of glucose determinations is reduced by a new order from the physician to three (3) times per day and notification of all results is ordered to be communicated to the physician at least every 2 days (Level III). This status is continued over a four-day period. During the last 72 hours of this period, the blood glucose values are generally in the 180 to 220 mg% range, with none ≥235 or <150 mg%. The patient appears to be making an uncomplicated recovery from the UTI. The physician then orders the frequency of blood glucose determinations to be reduced to two (2) times per week. (back to Level IV).

This clinical example is presented to demonstrate how this process can accomplish the following:

A) Ensure that good medical practice is supported by the overall framework and approach to patient management.
B) Ensure that the physician has access to all the information needed to make optimal clinical management decisions in a timely fashion, and
C) Ensure that there are easily understood criteria that will clearly distinguish between "routine monitoring" (analogous to the home setting for stable diabetic patients) and measurement of glucose values that are needed and used for real time management of the patient's disease when glucose instability is present or there is a documented increased risk of such instability occurring.

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Essentially, we concur that physicians should be expected to review all blood glucose determinations at intervals that reflect the relevant time frame within which clinical management decisions need to be made. The protocols discussed here -- immediate notification already required for any substantial deviation of blood glucose levels and the new proposed requirement that the pattern of values over the appropriate time frame should be communicated to the physician -- should ensure that tests submitted for payment under Medicare Part B regulations are medically necessary. The proposed approach also attempts to address the concerns expressed by CMS about avoiding "unending orders" and creates a clear structure to distinguish between blood glucose determinations to assist in the management of unstable or at risk patients and those who receive these determinations as part of routine monitoring of stable diabetic patients;

The framework outlined here for management of diabetic patients in the LTC population of increasingly frail individuals is consistent with accepted clinical practice. It creates a framework and expectation for effective communication between the physician and the facility staff concerning the relevant laboratory data. This approach also creates a series of opportunities for the physician to review the appropriateness of the treatment regime, dietary intake, activity level, clinical management and the frequency of monitoring required for each individual patient.

The use of the clinical situation level approach to glucose monitoring provides increased opportunity for the physician to review sequentially the on-going appropriateness of the management plan and the level of intensity of monitoring. This approach is in concert with quality clinical management and testing.

* * * *

The following physicians have participated in the development of this proposed protocol:

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EXHIBIT B – DRAFT HIGHMARK PROTOCOL

LOCAL COVERAGE DETERMINATION: 06-03
BLOOD GLUCOSE MONITORING IN A SKILLED NURSING FACILITY (SNF)

Contactor Name

Highmark Medicare Services

Contactor Number

00366

Contactor Type

Fiscal Intermediary

LCD Database ID Number

DL22369

LCD Title

Blood Glucose Monitoring in a Skilled Nursing Facility (SNF)

Contactor's Determination Number

06-03

AMA/CPT and ADA/CPT Copyright Statement

CMS National Coverage Policy

Title XVIII of the Social Security Act, Section 1862(a)(7). This section excludes routine physical examinations.

Title XVIII of the Social Security Act, Section 1862(a)(1)(A) states that no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury.

Title XVIII of the Social Security Act, Section 1833(e) states that no payment shall be made to any provider for any claim that lacks the necessary information to process the claim.

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Code of Federal Regulations, Title 42, Chapter 4, Parts 410.32 and 411.15

CMS On-line Manual Pub. 100-2, Chapter 15, Section 80.1 addresses coverage of clinical laboratory services.

CMS On-line Manual Pub. 100-4, Chapter 16 addresses billing of laboratory services.

CMS On-line Manual Pub. 100-8, Chapter 6, Section 6.1, "Medical Review of Skilled Nursing Facility Prospective Payment System (SNF PPS) Bills"

CMS On-line Manual Pub 100-3, Chapter 1, Section 190.20, "Blood Glucose Testing"

CMS Program Memorandum AB-00-108, Change Request 1362

CMS Transmittal 446, Change Request 3637

Primary Geographic Jurisdiction

Maryland
District of Columbia

Secondary Geographic Jurisdiction

Alabama, Arkansas, California – Entire State, Colorado, Connecticut, Delaware, Florida, Georgia, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maine, Massachusetts, Michigan, Missouri – Entire State, Nebraska, Nevada, New Jersey, New Mexico, New York- Entire State, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, Wisconsin, Washington state, and Wyoming

Oversight Region

III

CMS Consortium

Northeast

Original Determination Effective Date

06/15/2006

Original Determination Ending Date

Revision Effective Date

N/A

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Revision Ending Date

Indications and Limitations of Coverage and/or Medical Necessity

Compliance with the provisions in this policy may be monitored and addressed through data analysis and medical review audits.

Blood glucose determination may be done using whole blood, serum or plasma. It may be sampled by capillary puncture, as in the fingerstick method, or by vein puncture or arterial sampling. Meter assay of whole blood acquired through a finger stick using a device approved for home monitoring allows a patient to have access to blood glucose values on a digital display in a minute or less and has become a standard of care for control of blood glucose, even in the inpatient setting.

Blood glucose values are often necessary for the management of patients with diabetes mellitus, where hyperglycemia and hypoglycemia are often present. They are also critical in the determination of control of blood glucose levels in the patient with impaired fasting glucose (FPG 110-125 mg/dL), the patient with insulin resistance syndrome and/or carbohydrate intolerance (excessive rise in glucose following ingestion of glucose or glucose sources of food), in the patient with a hypoglycemia disorder such as nesidioblastosis or insulinoma, and in patients with a catabolic or malnourished state. In addition to those conditions already listed, glucose testing may be medically necessary in patients with tuberculosis, unexplained chronic or recurrent infections, alcoholism, coronary artery disease (especially in women), or unexplained skin conditions (including pruritis, local skin infections, ulceration and gangrene without an established cause).

Many medical conditions may be a consequence of a sustained elevated or depressed glucose level. These include comas, seizures or epilepsy, confusion, abnormal hunger, abnormal weight loss or gain, and loss of sensation. Evaluation of glucose may also be indicated in patients on medications known to affect carbohydrate metabolism.

The home glucose monitoring device is on the list of instruments that can be administered by providers registered under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), including providers registered with only a certificate of waiver.

The frequency of monitoring of blood glucose values should be determined by the physician on an individual basis while considering the following factors that affect glycemic control:

- Variations and degree of glycemic control as documented by hemoglobin A1C levels
- Treatment with insulin versus oral agents
- Frequency of symptoms of hypoglycemia
- Frequency of prior adjustments in therapy
- Motivation/ability for self-care and the presence of limitations such as language barriers and mental illness

- Presence of diabetic complications

Patients who have exhibited long-term control of blood glucose levels as evidenced by normal or steady A1C levels, minimal or no symptoms, minimal or no changes in therapy and no complications do not require frequent blood glucose monitoring.

Abnormal fasting glucose values may be defined as those below 70 mg/dL or above 125 mg/dL for a patient with diagnosed diabetes mellitus and below 70 mg/dL or above 100 mg/dL for a patient who has not been diagnosed with diabetes mellitus.

Abnormal random glucose values may be defined as those below 70 mg/dL or above 200 mg/dL for a patient with diagnosed diabetes mellitus and below 70 mg/dL or above 140 mg/dL for a patient who has not been diagnosed with diabetes mellitus.

Sections 42 CFR 410.32 and 411.15 specify that for a laboratory service to be reasonable and necessary, it must not only be ordered by the physician but the ordering physician must also use the result in the management of the beneficiary's specific medical problem. Implicitly, the laboratory result must be reported to the physician promptly in order for the physician to use the result and instruct continuation or modification of patient care; this includes the physician's order for another laboratory service. Compliance program guidance for laboratory services sets forth conditions under which a physician's order for a repeat laboratory service can qualify as an order for another covered laboratory service. A standing order is not usually acceptable documentation for a covered laboratory service.

Orders for continuing laboratory studies must be frequently updated. The medical record must reflect that the attending physician has evaluated the results of any laboratory study previously ordered. Orders for continuing lab work must have a reasonable cutoff time frame and be re-ordered as necessary. Any laboratory study ordered on a continuing basis without a cutoff time frame and without documentation in the medical record supporting that any previously ordered study was evaluated, will be considered a standing order and therefore, not reimbursable. Examples of acceptable time frames are as follows: daily times 4 days, weekly times 4 weeks, monthly times 3 months.

It should be noted that this policy does not prohibit a nursing home's Medical Director from authorizing services or procedures in emergency situations in a manner consistent with the Medical Director's obligations under state or federal law. In such instances, however, there must be documentation as to why the circumstances warrant intervention into the attending physician's role of caring for the patient.

As stated above, for a laboratory test to be covered, the result must be reported to the physician promptly in order for the physician to use the result and instruct continuation or modification of patient care. The following are time frames for use in reporting the results of blood glucose testing to the physician.

<u>Reporting Abnormal Blood Glucose Results</u>

When reporting the abnormal values listed below, the time frame in which the blood glucose result must be reported to the physician is dictated by that result.

EXHIBIT B – DRAFT HIGHMARK PROTOCOL

The further outside the normal range the value is, the shorter the time frame for reporting it becomes.

Blood Glucose Value		**Time frame for reporting to physician**
Low	High	
60-70 mg/dl	200-299 mg/dl	Within 24 hours
50-59 mg/dl	300-400 mg/dl	Within 6 hours
Below 50 mg/dl	Over 400 mg/dl	Immediately

The above timeframes are appropriate for most patients. Depending on patient history and circumstances, shorter time frames may be clinically warranted.

When reporting an abnormal blood glucose value to the physician, the previous two or more results, as appropriate, should also be provided for trending purposes.

Reporting Blood Glucose Results within Normal Limits

In the absence of abnormal blood glucose results, the condition of the patient dictates the time frame for physician notification. The physician should be provided with a trending report consisting of the appropriate number of blood glucose values based on the frequency of monitoring.

Patient Category	**Time frame for reporting to physician**
A – most unstable – see below for details	Within 12 hours
B – unstable – see below for details	Within 24 hours
C – fairly stable – see below for details	Within 36 hours

Category A

Patients who:

- have unstable diabetes mellitus with unstable glucose levels or significant risk for alterations in glucose levels,
- have fingerstick glucose monitoring performed at least three (3) times per day, and
- may have orders for (additional) insulin administration on a sliding scale.

Category B

Patients who:

- have unstable diabetes mellitus with or without unstable glucose levels but are at risk for alterations in glucose levels,
- have fingerstick glucose monitoring performed one (1) to three (3) times per day,
- may have orders for (additional) insulin administration on a sliding scale.

Category C

Patients who:

- have diabetes mellitus which is not completely stable and are at some risk for alterations in glucose levels (although with less probability and/or lower magnitude of fluctuations), and
- have fingerstick glucose monitoring once (1) time per day or less.

Limitations

Blood glucose measurements without prompt physician notification as outlined above are not covered as diagnostic laboratory tests.

Coverage Topic

Lab Services

Bill Type Codes

22X SNF inpatient or HH visits (Part B only)
23X SNF outpatient, HHA-A

Revenue Codes

030X Laboratory – general classification

CPT/HCPCS Codes

82962 Glucose, blood by glucose monitoring device(s) cleared by the FDA specifically for home use

ICD-9 Codes that Support Medical Necessity

011.00-011.96	Tuberculosis
038.0-038.9	Septicemia
112.1	Candidiasis of vulva and vagina
112.3	Candidiasis of skin and nails
118	Opportunistic mycoses

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157.4	Malignant neoplasm of Islets of Langerhans
158.0	Malignant neoplasm of retroperitoneum
211.7	Benign neoplasm of Islets of Langerhans
242.00-242.91	Thyrotoxicosis
250.00-250.93	Diabetes mellitus
251.0-251.9	Disorders of pancreatic internal secretion
253.0-253.9	Disorders of the pituitary gland
255.0	Cushing syndrome
263.0-263.9	Malnutrition
271.0-271.9	Disorders of carbohydrate transport and metabolism
272.0-272.4	Disorders of lipoid metabolism
275.0	Disorders of iron metabolism
276.0-276.9	Disorders of fluid, electrolyte and acid-base balance
278.3	Hypercarotinemia
293.0	Delirium due to conditions classified elsewhere
294.9	Unspecified persistent mental disorders due to conditions classified elsewhere
298.9	Unspecified psychosis
300.9	Unspecified nonpsychotic mental disorder
310.1	Personality change due to conditions classified elsewhere
337.9	Unspecified disorder of autonomic nervous system
345.10-345.11	Generalized convulsive epilepsy
348.31	Metabolic encephalopathy
355.9	Mononeuritis of unspecified site
356.9	Unspecified hereditary and idiopathic peripheral neuropathy
357.9	Unspecified inflammatory and toxic neuropathy
362.10	Background retinopathy, unspecified
362.18	Retinal vasculitis
362.29	Other nondiabetic proliferative retinopathy
362.50-362.57	Degeneration of macula and posterior pole
362.60-362.66	Peripheral retinal degeneration
362.81-362.89	Other retinal disorder
362.9	Unspecified retinal disorder

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365.04	Ocular hypertension
365.32	Corticosteroid-induced glaucoma residual
366.00-366.09	Presenile cataract
366.10-366.19	Senile cataract
367.1	Myopia
368.8	Other specified visual disturbance
373.00	Blepharitis, unspecified
377.24	Pseudopapilledema
377.9	Unspecified disorder of optic nerve and visual pathways
378.50-378.55	Paralytic strabismus
379.45	Argyll-Robertson pupil, atypical
410.00-410.92	Acute myocardial infarction
414.00-414.07	Coronary atherosclerosis and aneurysm of heart
414.10-414.19	Aneurysm and dissection of heart
425.9	Secondary cardiomyopathy, unspecified
440.23	Arteriosclerosis of extremities with ulceration
440.24	Arteriosclerosis of extremities with gangrene
440.9	Generalized and unspecified arteriosclerosis
458.0	Orthostatic hypotension
462	Acute pharyngitis
466.0	Acute bronchitis
480.0-486	Pneumonia
490	Bronchitis, not specified as acute or chronic
491.0-491.9	Chronic bronchitis
527.7	Disturbance of salivary secretion
528.0	Stomatitis
535.50-535.51	Unspecified gastritis and gastroduodenitis
536.8	Dyspepsia and other specified disorders of function of stomach
571.8	Other chronic nonalcoholic liver disease
572.0-572.8	Liver abscess and sequelae of chronic liver disease
574.50-	Calculus of bile duct without mention of cholecystitis, without obstruction
574.51	Calculus of bile duct without mention of cholecystitis, with obstruction
575.0-575.12	Cholecystitis

576.1	Cholangitis
577.0	Acute pancreatitis
577.1	Chronic pancreatitis
577.8	Other specified diseases of pancreas
590.00-590.9	Infections of the kidney
595.9	Cystitis, unspecified
596.4	Atony of bladder
596.53	Paralysis of bladder
599.0	Urinary tract infection, recurrent
607.84	Impotence of organic origin
608.89	Other disorders male genital organs
616.10	Vaginitis and vulvovaginitis, unspecified
626.0	Absence of menstruation
626.4	Irregular menstrual cycle
628.9	Infertility, female of unspecified origin
648.00	Diabetes mellitus complicating pregnancy, Childbirth or the puerperium, unspecified as to episode of care or not applicable
648.03	Diabetes mellitus complicating pregnancy, Childbirth or the puerperium, antepartum condition or complication
648.04	Diabetes mellitus complicating pregnancy, Childbirth or the puerperium, postpartum condition or complication
648.80	Abnormal glucose tolerance complicating pregnancy, childbirth or the puerperium, unspecified as to episode of care or not applicable
648.83	Abnormal glucose tolerance complicating pregnancy, childbirth or the puerperium, antepartum condition or complication
648.84	Abnormal glucose tolerance complicating pregnancy, childbirth or the puerperium, postpartum condition or complication
656.60-656.63	Fetal problems affecting management of mother - large for-date of fetus
657.00-657.03	Polyhydramnios
680.0-680.9	Carbuncle and furuncle
686.00-686.9	Other local infections of skin and subcutaneous tissue
698.0	Pruritis ani
698.1	Pruritis of genital organs
704.1	Hirsutism
705.0	Anhidrosis
707.00-707.9	Chronic ulcer of skin
709.3	Degenerative skin disorders
729.1	Myalgia and myositis, unspecified

730.07	Acute osteomyelitis of ankle and foot
730.17	Chronic osteomyelitis of ankle and foot
730.27	Unspecified osteomyelitis of ankle and foot
780.01	Coma
780.02	Transient alteration of awareness
780.09	Alteration of consciousness, other
780.2	Syncope and collapse
780.31	Febrile convulsions
780.39	Other convulsions
780.4	Dizziness and giddiness
780.71-780.79	Malaise and fatigue
780.8	Generalized hyperhidrosis
781.0	Abnormal involuntary movements
782.0	Disturbance of skin sensation
783.1	Abnormal weight gain
783.21	Loss of weight
783.5	Polydipsia
783.6	Polyphagia
785.0	Tachycardia, unspecified
785.4	Gangrene
786.01	Hyperventilation
786.09	Dyspnea and respiratory abnormality, other
786.50	Chest pain, unspecified
787.6	Incontinence of feces
787.91	Diarrhea
788.41-788.43	Frequency of urination and polyuria
789.1	Hepatomegaly
790.21-790.29	Abnormal glucose tolerance test
790.6	Other abnormal blood chemistry
791.0	Proteinuria
791.5	Glycosuria
796.1	Abnormal reflex
799.4	Cachexia
V23.0-V23.9	Supervision of high risk pregnancy
V58.63	Long-term (current) use of antiplatelets/antithrombotics
V58.64	Long-term (current) use of non-steroidal anti-inflammatories (NSAID)
V58.65	Long-term (current) use of steroids
V58.67	Long-term (current) use of insulin

V58.69	Long term current use of other medication
V67.2	Follow-up examination, following chemotherapy
V67.51	Follow up examination with high-risk medication not elsewhere classified
V77.1	Special screening for endocrine, nutrition, metabolic, and immunity disorders (use for 82947 only)

Diagnosis Codes that Support Medical Necessity

ICD-9 Codes that DO NOT Support Medical Necessity

Any ICD-9 code not listed under the "ICD-9 Codes That Support Medical Necessity" section of this policy.

Diagnosis Codes that DO NOT Support Medical Necessity

Documentation Requirements

Documentation must be evident in the patient's medical record to substantiate the medical necessity of the testing performed. The ordering physician should retain in the patient's medical record, history and physical examination notes documenting evaluation and management of one of the Medicare covered conditions/diagnoses, with relevant clinical signs/symptoms or abnormal laboratory test results, appropriate to one of the covered indications.

Documentation must support that blood glucose monitoring was ordered by the physician and the laboratory result was reported to the physician promptly. The medical record must reflect the time the blood glucose result was obtained and the time the physician was notified. The documentation must also support that the results were used in the continuation or modification of care for the beneficiary's specific medical problem including changes/alterations in medications prescribed for the treatment of the patient's condition. Documentation must be submitted to Medicare upon request.

Utilization Guidelines

In accordance with CMS Ruling 95-1 (V), utilization of these services should be consistent with locally acceptable standards of practice.

Sources of Information and Basis for Decision

HGSAdministrators LCD V-42

Associate Contractor Medical Director

HGSAdministrators Medical Director

EXHIBIT B – DRAFT HIGHMARK PROTOCOL

Advisory Committee Meeting Notes

This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with advisory groups, which includes representatives from the appropriate specialty (ies).

Start Date of Comment Period

01/20/2006

End Date of Comment Period

03/08/2006

Start Date of Notice Period

04/27/2006

Revision History Number

06-03

Submitter : Mr. Kent Thiry **Date:** 10/09/2006

Organization : Kidney Care Partners

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachments

CMS-1321-P-688-Attach-1.PDF

CMS-1321-P-688-Attach-2.PDF

#688-1

KIDNEY CARE
PARTNERS

October 10, 2006

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

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

Dear Administrator McClellan,

Kidney Care Partners (KCP) is pleased to have the opportunity to provide the Centers for Medicare and Medicaid Services (CMS) with comments about the Proposed Rule for Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year (CY) 2007 (Proposed Rule).[1] KCP is an alliance of members of the kidney care community that works with renal patient advocates, dialysis care professionals, providers, and suppliers to improve the quality of care of individuals with irreversible kidney failure, known as End Stage Renal Disease (ESRD).[2] Specifically, KCP urges CMS to:

- Establish price and utilization estimates for purposes of calculating the update to the drug add-on adjustment that are tied to an existing index or based on accurate data;
- State clearly that for CY 2007, CMS will reimburse separately billable drugs at Average Sales Price (ASP)+6 percent; and
- Clarify the budget neutrality calculation for the geographic wage index by explaining the methodology CMS uses.

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

[2] A list of Kidney Care Partner coalition members is included in Attachment A.

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

I. ESRD PROVISIONS: CMS should consider adopting a proxy to estimate the update to the drug add-on adjustment for CY 2007 and allow for forecast error adjustments to ensure that the estimates are correct.

KCP supports the use of an index to establish the update to the drug add-on adjustment. However, we are concerned that the Proposed Rule's methodology does not provide an accurate estimate of 2007 prices and utilization of ESRD separately billable drugs. We agree with the recommendations outlined in The Moran Company's report "The Proposed ESRD Prospective Payment System Update for CY 2007: Evaluating Technical Options for Improved Payment Accuracy" that CMS should (1) use a proxy for CY 2007 to calculate the update and (2) establish a mechanism that would allow for forecast error adjustments if the estimates are incorrect.

A. KCP encourages CMS to clarify how it developed its estimates for price and utilization.

KCP encourages CMS to re-examine its estimates of price and utilization for purposes of calculating the update to the drug add-on adjustment. Given the data and methodological concerns about the price and utilization estimates used to calculate the update to the drug add-on adjustment in the Propose Rule, KCP encourages CMS to clarify how it developed its estimates. As described below, KCP urges CMS to recognize that because of the data and methodological problems associated with the proposal, the Agency should use a more stable and predictable proxy to estimate price and utilization for purposes of calculating the update to the drug add-on adjustment for CY 2007. Given that the payment to cost ratio for dialysis payment, including separately billable drugs, remain negative,[3] as reported by MedPAC, it is important that the method used to calculate the update results is an accurate assessment of the price and utilization changes to ensure economic stability for kidney care providers.

In terms of the price estimate, KCP understands the value of using the Producer Price Index (PPI). However, we are concerned that the forecast outlined in the Proposed Rule is significantly lower that what other sources suggest it should be. The Proposed Rule states that CMS estimates the PPI to be 4.9 percent. The current reported PPI 2006 is 6.3 percent. Looking at the 2004/2005 PPI would result in 5.1 percent. If CMS determines it is appropriate to continue to use the PPI to estimate price changes, we suggest that the Agency review the 2006 PPI and other data to ensure that in the Final Rule the PPI estimate reflects the most current data available.

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[3]MedPAC "Report to the Congress" (2006).

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

Although we acknowledge that it is unlikely there has been double-digit growth in utilization for separately billable drugs, our data as well as an analysis conducted by The Moran Company on behalf of the Kidney Care Council suggest that utilization is not flat, but slightly higher. Additionally, we are also concerned that CMS has assumed, without having data to confirm its conclusion, that the new EPO Monitoring Policy will result in a significant decrease in the utilization of EPO. While we may disagree about the accuracy of this statement, CMS should not incorporate potentially premature assumptions into a calculation as complex as estimating utilization. Moreover, the data upon which the estimate is based is not the most recent data available about separately billable drugs. Because of these problems and based upon its review of the Proposed Rule and CMS data, The Moran Company concludes that the use of the proposed methodology is flawed. These flaws make it difficult to ensure that any utilization estimate accurately reflects reality.

Given the questions about the price and utilization estimates, KCP believes that CMS should adopt a proxy index for both price and utilization that will avoid the pitfalls outlined above.

B. Given the difficulties associated with the proposed methodology to calculate the update to the drug add-on adjustment, KCP encourages CMS to adopt a stable proxy index for both price and utilization and to establish a mechanism to permit forecast error adjustments.

As noted, KCP is concerned that the proposed methodology does not accurately reflect the changes in price and utilization for separately billed drugs. Given the lack of data (especially for purposes of estimating utilization changes), we encourage CMS to (1) adopt an appropriate proxy index that accounts for both price and utilization changes and (2) establish a mechanism for making adjustments to account for forecasting errors in prior estimates before calculating subsequent years' updates.

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

Regardless of how CMS addresses the proxy issue in the short-term, CMS should also establish a mechanism that will allow it to "check its work" on a prospective basis until it has stable

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

II. ASP ISSUES: The Final Rule should expressly state that CMS will reimburse separately billed drugs at ASP+6 percent for CY 2007.

Given the importance of separately billable drugs to the kidney care community, it is important to ensure that reimbursement rates are stable and predictable. We understand that the Agency intends to reimburse separately billable drugs at ASP+6 percent for the foreseeable future. However, we wanted to raise a discrepancy between the preamble and the text of the regulation. The preamble states that separately billable drugs will be reimbursed "based on section 1847A of the Act." 71 *Fed. Reg.* at 49004. However, the regulation text more clearly states that these drugs will be reimbursed at "106 percent of the average sales price." To avoid potential confusion, we suggest that CMS state clearly in the preamble to the Final Rule that it will reimburse separately billed drugs at ASP+6 percent. This statement would be consistent with the regulatory text and provide needed clarity for the community.

III. ESRD PROVISIONS: KCP urges CMS to clarify the budget neutrality calculation for the geographic wage index by explaining the methodology it used.

As CMS continues to implement the geographic wage index, KCP encourages CMS to examine the effect of the changes on facilities. Similar to last year, we are concerned that the calculation of the budget neutrality factor for the geographic wage index is not transparent in the Proposed Rule. The modifications to the geographic wage index have an enormous impact on small providers. They need to understand that the budget neutrality factor is being calculated correctly. Small differences have a large impact on the payments to these facilities. Thus, KCP urges CMS to provide the data and methodology it used to calculate the budget neutrality factor in the Final Rule to enable the community to assess the impact of the proposed changes.

IV. CMS should encourage patient services, such as self-management for diabetics, as well as blood flow monitoring and medical nutritional therapy through appropriate reimbursement.

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

One precursor to chronic kidney disease (CKD) is diabetes. Patients who manage their diabetes effectively can slow the progression or even prevent the onset of kidney disease. The more opportunities patients have to learn how to manage their disease, the less likely they will need dialysis services. For these reasons, KCP supports the proposal regarding diabetes self-management services. Patient education and training is a critical tool in the prevention of conditions related to diabetes, including kidney failure; KCP encourages CMS to continue to explore additional services that help slow the progression of CKD.

Once patients are diagnosed with progressive kidney failure, they must have surgery to create an access for dialysis. For hemodialysis patients, an AV fistula is the best type of access. Monitoring a patient's access, whether it is a fistula, graft, or catheter, is extremely important to assuring that the patient can receive the appropriate dialysis treatments. As indicated in the Kidney Care Quality and Improvement Act, KCP strongly supports further support for blood flow monitoring services. These services allow dialysis professionals to assess a patient's access and determine whether additional maintenance services are required before a problem occurs. These services allow a provider to accurately assess a patient's blood flow rate and the status of the vascular access. By enhancing the quality of the dialysis treatment being provided, blood flow monitors not only enhance the quality of care the patient receives but also lower overall costs by reducing patient morbidity and the need for numerous other tests and procedures, all of which add costs to the Medicare program and inconvenience for a dialysis patient. This preventive care is critically important in maintaining the patient's well-being. CMS should recognize the importance of providing dialysis patients with blood monitoring services and ensure appropriate coverage and reimbursement of these services for physicians and facilities.

Finally, KCP also supports increased coverage for medical nutritional therapy. The limited access to nutritional therapists is problematic for many patients with Stages 3 and 4 kidney disease. Patients will be best served by a system that encourages the multidisciplinary approach to CKD care, including dietitians. Medical nutritional therapy and counseling are important tools to assist patients to optimize nutritional status by controlling the levels of several critical elements in their bodies. Dietary counseling is important for certain electrolytes in Stages 3 and 4 patients such as sodium (which is important in blood pressure regulation), potassium (which can lead to fatal arrhythmias) and phosphorous (which has a long term effect on bones and cardiovascular disease). Nutritional therapy is also important to ensure protein intake is optimal to avoid malnutrition at inadequate levels of intake and rapid loss of kidney function at excessive levels of intake. Since diabetes is the

most common cause of CKD in the United States, patients with CKD and diabetes have the additional consideration of carbohydrate intake regulation, emphasizing the complexity of nutritional management in CKD. The availability of nutritional therapy will help patients understand how to better manage their disease.

KCP is pleased that CMS continues to recognize the importance of providing preventive care, such as blood flow monitoring, medical nutritional therapy, and self-management for diabetics. These programs not only help to slow the progression of CKD, but also help dialysis professionals manage their patients better. We encourage CMS to continue to provide incentives for educational and preventive services.

V. Conclusion

On behalf of KCP, I would like to thank you for your willingness to consider our comments about the Proposed Rule. As in the past, we hope to work with you to resolve these issues and ensure appropriate implementation of the Final Rule. Please do not hesitate to contact Kathy Lester at (202) 457-6562 if you have comments or questions.

Sincerely,

Kent Thiry
Chairman
Kidney Care Partners

KIDNEY CARE
PARTNERS

Abbott Laboratories
American Kidney Fund
American Nephrology Nurses' Association
American Regent, Inc.
American Renal Associates, Inc.
American Society of Nephrology
American Society of Pediatric Nephrology
Amgen
Baxter Healthcare Corporation
California Dialysis Council
Centers for Dialysis Care
DaVita, Inc.
DaVita Patient Citizens
Fresenius Medical Care North America
Genzyme
Medical Education Institute
Nabi Biopharmaceuticals
National Kidney Foundation
National Renal Administrators Association
Northwest Kidney Centers
Renal Advantage Inc.
Renal Physician's Association
Renal Support Network
Roche
Satellite Healthcare
Sigma Tau
U.S. Renal Care
Watson Pharma, Inc.

#688-2

The Proposed End Stage Renal Disease Prospective Payment System Update for 2007:

Evaluating Technical Options for Improved Payment Accuracy

October 5, 2006

THE MORAN COMPANY

The Proposed End Stage Renal Disease Prospective Payment System Update for 2007:

Evaluating Technical Options for Improved Payment Accuracy

As part of the Medicare Professional Fee Schedule rulemaking on August 22, 2006, the Centers for Medicare & Medicaid Services (CMS) proposed updates to the End Stage Renal Disease Prospective Payment System, which it has administered, since 2005, under the requirements of the Medicare Modernization Act of 2003[1] (MMA). Under that system, dialysis providers are paid for their services in two ways: they receive a prospective payment for each treatment, and they are separately reimbursed for drugs that are not explicitly "packaged" in the per treatment payment rate.

The prospective payment rate is itself composed of two components. The largest component, called the "composite rate," is fixed by statute, and provides for a $4 positive differential in payment for treatment in a hospital. A second component, which was implemented in 2005, is called the "drug spend add-on." This component, which is valued at $18.88 per treatment in 2006, is designed to hold dialysis providers harmless for reductions in pharmaceutical reimbursements mandated by the MMA.

In 2005 and 2006, CMS established the amount for these payments by projecting the expected volume of separately-reimbursable drugs likely to be used in the program year, and the reimbursement rates for each drug under both prior and current law. The aggregate drug spending "spread" between prior and current reimbursement policies was then divided by the projected number of dialysis treatments to establish a per treatment payment amount.

Citing the growing complexity of maintaining this estimation method in an environment of changing payment methodologies, CMS has proposed, for 2007, to simplify this calculation by indexing the 2006 drug spread add-on value to a two-part index.

The first part of the index would be a proxy for rising drug reimbursement rates under the current payment methodology. CMS is proposing to use a projection of the increase in the Producer Price Index (PPI) for pharmaceutical manufacturing as a proxy for this value. The projected PPI value they published for calendar year 2007 is 4.90%

The second part of the index would be a projection of the likely increase in drug volume consumed per dialysis beneficiary. In its proposed rule, CMS used data on reimbursement changes from 2004 to 2005 to estimate the year-over-year change in volume, which they then imputed to the 2006-2007 period. In the NPRM, the projected value of this component is proposed to be zero, i.e., the update would be limited to 4.9% of the 2006 drug spend add-on amount.

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[1] *Federal Register*, Vol. 71, No. 162, p. 49004ff.

The Moran Company was engaged by the Renal Leadership Council, a trade group of companies providing dialysis services, to evaluate the data CMS used and the methodology it employed to make this estimate, and to evaluate technical alternatives that could improve the accuracy of the projected payment update for 2007[2]. The highlights of our findings are as follows:

- Several aspects of the methodology CMS has proposed are not fully transparent based on the description of the methodology in the preamble.

- The volume growth projection is based on estimated values for "enrollment growth," the volume-weighted change in drug pricing, and the year-over-year change in drug reimbursements from 2004 to 2005.

- They estimate 3% "enrollment growth," but do not indicate what "enrollment" concept this value relates to. The actual growth in Part B enrollment, for example, was 1.7% from 2004 to 2005.

- They estimate a 12% decline in volume-weighted drug reimbursement rates from 2004 to 2005, based in part on a prior estimate of a 13% reduction from AWP-based reimbursement to reimbursement based on Average Acquisition Price.

- They estimate a 9% decline in total reimbursements for separately billable drugs between 2004 and 2005. We checked this estimate using data from the 2004 Outpatient Standard Analytical File, and from a new 2005 ESRD Limited Data Set (LDS) file. After working with CMS staff to resolve discrepancies between the documentation of the LDS and the data actually placed in the file, we obtain a slightly higher value for this ratio, which would increase CMS's volume projection by about 1%.

- Under the CMS methodology, however, the real issue is what the projected update would be once their formula is run through the values observed in the later claims data they will use for the final rule.

- The closer that value gets to the present projection of zero volume growth, the less likely it would be to serve as a valid proxy for volume growth *in 2007.*

- We believe that using the National Health Expenditures projection published by CMS each February, adjusted to restrict the projection to Part B drugs, would prove a better interim measure for 2007 than the index proposed.

- However this index is generated, it should be retrospectively rebased each year to prevent a permanent accumulation of conservative underestimates of ESRD drug spending growth.

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[2] During the course of this engagement, the RLC formally changed its name to the Kidney Care Council.

The CMS Volume Estimating Methodology

The methodology CMS chose to employ was, we believe, motivated by concerns about coding accuracy in ESRD claims data, particularly for erythropoietin (EPO), which comprises 70% of the drug volume billed by dialysis providers. The table below summarizes reported drug claims volumes, as measured by discrete claims lines, billed by dialysis providers over the 2001-2005 period[3].

Claims Lines Billed for Separately-Reimbursed Drugs

	2001	2002	2003	2004	2005
Epogen & Aranesp	2,496,480	2,697,620	2,820,000	5,183,120	6,319,323
Other Drugs	4,193,240	4,543,760	4,927,000	6,368,880	6,176,360
Total	6,689,720	7,241,380	7,747,000	11,552,000	12,495,683

As these data indicate, there was a sharp jump in reported claims lines in 2004, particularly for Epogen® . It is our understanding that this increase is due to a change in coding guidance. Prior to 2004, Medicare intermediaries apparently paid separately reimbursed drug claims for dialysis treatments without requiring accurate HCPCS coding, particularly for Epogen, as long as the claims had proper revenue codes. The claims counts in the table above for Epogen and Aranesp® were, in fact, generated by identifying claims by revenue code[4]. Since the claims line count more than doubled after the requirement for HCPCS coding was implemented, it is likely that many prior claims bundled billings for multiple days of EPO that are now being billed separately.

Given this trend, CMS reasonably concluded that it could not infer a volume trend directly from historical volume data. Instead, it elected to estimate volume by looking at the percentage change in reimbursement between 2004 and 2005, and then adjust for known changes in reimbursement rates between periods to back into the implied volume change. Their decision to impute the 2004-2005 experience to 2006-2007 implicitly suggests that they believe that the experience of the period prior to 2004 was likely to be atypical of trends going forward.

They based their calculation on three key data points:

- The increase in "enrollment" between 2004 and 2005.
- The change in drug reimbursements from 2004 (when they were based on prior payment policy) to 2005 (when they were based on Average Acquisition Price (AAP); and

[3] Throughout our analysis, the data for 2001-2004 are Moran Company estimates developed using the Outpatient 5% Standard Analytical Files for each of these years. The data for 2005 were extracted from the 2005 ESRD PPS Ratesetting Limited Data Set, which CMS released in the last week of September.

[4] Under the Uniform Bill revenue coding structure, EPO claims are billed with revenue codes 634(EPO < 10,000 units) or 635 (EPO >10,000 units). Fewer than 10% of these claims had accurate HCPCS codes for EPO in 2001-2003.

- The volume-weighted change in reimbursement rates from prior policy to AAP.

In the calculations presented on p. 49007 of the August 22, 2006 *Federal Register,* they show the following values:

"(.91 / (1.03 * .88) =1.00)"

Presumptively:

- The .91 factor is the assumed change in drug reimbursements between 2004 and 2005.
- The 1.03 factor is "enrollment growth"; and
- The .88 factor is the volume-weighted change in reimbursement rates.

This calculation is presented as the support for their conclusion that the adjustment for drug volume growth should be zero in 2007.

Discussing these values in reverse order:

Volume-Weighted Drug Reimbursement Rate Changes

The volume-weighted change in payment rates, applied to both EPO and non-EPO drugs, reflects the result of the calculation of this ratio in prior rules. CMS updated the 2004 reimbursement rates for non-EPO drugs to 2005 by applying the PPI (which they did not disclose, but which was 5.17% in 2005). They then applied the ratio of AAP to prior policy payment rates calculated in the Final Rule for 2005. This resulted in a determination that the ratio of AAP to prior payment rates was .88, which is then used in the denominator of the CMS formula to deflate the magnitude of the year-over-year declines in payment rates.

Refining this estimate would require more complete payment data for 2005, since the CMS factor of .88 is sensitive to assumptions about market share by product. As we indicate below, the best way to resolve uncertainties about this estimate would be to retrospectively rebase their calculated 2007 price and volume forecast using later data prior to developing their forecast of the 2008 index.

"Enrollment Growth"

The derivation of the enrollment growth factor used in the CMS methodology is unclear, since the term "enrollment" is undefined. If this is an attempt to estimate an increase in the prevalence of dialysis use, the source of the 3% factor is unclear. If it is intended as a measure of Part B enrollment growth, it is substantially too high, since the 2006 Trustees Report shows Part B enrollment growth of 1.7% in 2005 over 2004.

Because this factor appears in the denominator of the CMS volume estimating equation, lowering the enrollment factor would increase the estimated volume growth. Applying

actual Part B enrollment growth of 1.7% in lieu of the assumed 3% factor would increase the estimate from 1.0040 to 1.0168

Change in Drug Reimbursement

In the preamble, CMS did not directly present their estimate of year-over-year change in reimbursements for separately reimbursed dialysis drugs. They indicated that they started with twelve months of paid claims for services incurred in 2005, and adjusted upward by 13% to reflect the lack of claims run out[5]. In their formula, the value they enter is .91, implying that their adjusted reimbursement totals in 2005 were 9% below 2004.

We attempted to replicate this estimate. We used the data furnished in the new ESRD PPS Ratesetting Limited Data Set released at the end of September to tabulate 2005 values for drug reimbursements, compared to estimates of 2004 drug reimbursements generated using the 2004 Outpatient 5% Standard Analytical File.

Our initial attempt at replication was unsuccessful. In comparison to the CMS estimate of a -9.0% change from 2004 to 2005, we were computing a modest 1-2% increase in total drug payments between years. Since this is a substantial disparity, we shared our data with CMS staff. Upon analysis, it was determined that the disparity was the result of a mismatch between the data concepts used to create the file, and the description of the data concepts presented in the data dictionary accompanying the file. While the payment field was described in the documentation as comprising payments from intermediaries to providers excluding beneficiary cost sharing[6], the payment values actually contained in the file did contain the cost sharing amounts. When we corrected the data concept employed to tabulate the 2004 values using the same data concept, most of the disparity went away.

Here is the payment comparison prior to adjustment for differences in the duration of paid claims experience:

Reimbursements for Separately Billable Drugs

	2004	2005	2005/2004
EPO	$ 2,126,524,032	$ 1,915,636,264	0.9008
Other	$ 1,061,015,152	$ 679,171,618	0.6401
Total	$ 3,187,539,184	$ 2,594,807,883	0.8140

2004 Data from Outpatient 5% Standard Analytical File, as Paid through 6/30/05
2005 Data from ESRD PPS Ratesetting Limited Data Set as Paid Through 12/31/05

[5] For 2004, CMS had claims data for reflecting all payment adjustments made to these claims throughout 2005. For 2005 claims, by contrast, their data don't reflect payments or adjustments after December 31, 2005.

[6] It is our understanding that the CMS program staff had intended that the data concept described in the documentation would be used in creating the file.

The data in the table show total tabulated payments in both files, without trimming of outliers. As the data in the table indicate, claims incurred in 2005, as paid through December 31, 2005, were 18.6% below claims incurred in 2004, as paid through June 30, 2005. As CMS noted in the preamble, a significant part of this difference is attributable to the difference in the duration of paid claims history, since the claims set they used to compute the proposed rule values contained only twelve months of payment history for claims incurred in 2005. They used the relationship between 2004 incurred claims paid by June 30, 2005 to 2004 incurred claims paid through December 31, 2004 to calculate an adjustment factor for claims incurred but not paid of 13%. Lacking access to the detailed National Claims History, we cannot look behind this estimate.

Applying it, in unrounded form, we obtain a slightly different factor than does CMS for the adjusted year-over-year change:

$$.8140 * 1.13 = .9198$$

We note that the difference between our calculated factor and theirs is greater than could be explained solely by rounding of their 1.13 adjustment factor to two decimal places. It may be attributable to trimming of certain claims observations in their analysis – in combination with rounding. Given the large volume of ESRD drug claims in the 2004 5% sample, we would not expect estimating error to be material.

Alternative Adjustment Factor

Based on this analysis, we conclude that their estimate that the total volume change in 2005 over 2004 was zero is probably too conservative. In addition to the factors identified above, we believe that there are additional grounds to conclude that drug reimbursement volumes rose at least slightly in 2005 over 2004. In addition to anecdotal evidence from the provider companies that volume growth is decelerating but is not zero, we have the evidence of an observed year-over-year increase in claims lines for drugs, which may not be due solely to differences in coding practices. In all, we believe that when CMS recomputes this estimate using later data on 2005 volumes, their estimate of year-over-year volume growth is likely to rise – but is unlikely to reflect the double-digit volume growth observed in the 2001-2004 period.

Regardless of how these issues are resolved in the Final Rule, the foregoing discussion makes clear that the use of different data at different times can produce materially different estimates of ESRD drug volume growth. This reality creates substantial uncertainty about the likely accuracy of any forecast. When CMS recomputes their estimate using a longer claims run out, both CMS and the industry will have confidence that the new estimate of 2005 volume growth was better than the previous estimate, which was based earlier, less complete data. We would, however, still be without information on which to render a judgment regarding whether either of these estimates represented the best possible estimate of *likely volume growth between 2006 and 2007,*

which is the data concept actually required to implement the proposed CMS methodology.

The closer the value CMS estimates comes to the zero growth forecast presented in the proposed rule, the more difficult it will be to conclude that the 2005 experience represents a valid proxy for drug volume growth in 2007. Growth in the volume of drugs used to treat ESRD patients has been consistent for many years, as new drugs are added to the arsenal of treatments available to nephrologists to better manage care. While there are valid reasons for CMS to conclude that volume trends may be turbulent between 2004, when the previously-described coding changes were implemented, and 2006, when efforts to modify EPO dosing are being implemented, there is no reason to assume continued turbulence going forward from 2006 into 2007 and later years.

Until volume trends stabilize, therefore, CMS may find it useful to consider alternative proxies for price and volume change in ESRD drugs. Historically, the growth in drug pricing and volume in the ESRD program has been comparable to that observed for drug reimbursements under Part B generally. Since the CMS Office of the Actuary has traditionally forecast the Medicare share of growth in prescription drug expenditures as part of the annual National Health Expenditures (NHE) projection, CMS could easily link the update of the drug spend add-on to that forecast.

In the preamble to the proposed rule, CMS indicated that it considered this option, but rejected it due to the fact that, for 2006 and 2007, the NHE forecast of Medicare drug spending is heavily dominated by assumptions about the early trend under the new Medicare Part D drug program. While we are sympathetic to that concern about using the aggregate NHE trend projection, it would be possible for the Actuary to decompose that forecast into Part B and Part D forecasts, respectively, and use the former to index growth of the drug spend add-on until such time that it has credible trend data for price and volume growth under the ESRD program itself.

Retrospective Rebasing

Given the state of the data, we see no clearly superior methodology for improving this estimate. Accepting that reality, it strikes us as prudent to suggest that it would be in the interest of both the agency and the industry to adopt an update mechanism that makes provision for retrospective rebasing of prior estimates before calculating the subsequent year's update. Such rebasing should be for both pricing and volume effects. Whatever 2007 value CMS calculates under it final rule methodology for both price and volume, their methodology should provide for adjusting that value (up or down) to reflect known variations from the forecast trend (PPI +Volume or NHE) before projecting forward from that base to calculate the 2008 update.

In saying this, we are not endorsing a permanent policy of basing the drug spend add-on for a year on the assumption that volume growth in a year will be equal to the volume growth rate observed two years prior. Clearly, what CMS is doing now is a stopgap measure designed to bridge to a period when time series data on actual drug volumes can

be used to make this projection. Until that time, however, we believe it's important to have some ability to retrospectively adjust toward reality. Given CMS's fiduciary responsibility to be inherently conservative in indexing future program growth, failure to do so could accumulate a substantial payment deficit relative to the stated policy intent of making providers whole for the impact of changes in drug reimbursement policy.

Submitter : **Mrs. Anne Paone Gallagher, MS, CPC** **Date: 10/09/2006**

Organization : **Great Valley Cardiology**

Category : **Other Health Care Professional**

Issue Areas/Comments

Background

Background

In performing a quick analysis of the proposed cuts in reimbursement for 2007, we stand to lose more that half a million dollars. We are a nine physician cardiology group in Scranton, Pennsylvania. As such, we are already getting paid 25% less than in Philadelphia. These can potentially force us to cut back on staff members and benefits and will greatly impact the quality of care we have always prided our patients with.

GENERAL

GENERAL

We ask that you reconsider the proposed 2007 budget and help continue to support our staff and offer quality medical services to our patients. Thank you for your time.

Impact

Impact

The major provision of the new rules that affect our group are the lowering of the technical fee for in-office testing and the 5.1% paycut. While the proposed increase in office visits helps to a degree, it is not enough to sustain our practice of nine physicians and 46 employees.

#690

Nuria M. Lawson, M.D.
General & Laparoscopic Surgery

October 4, 2006

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

Attention: CMS-1321-P; Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and other Changes to Payment under Part B

Dear Administrator:

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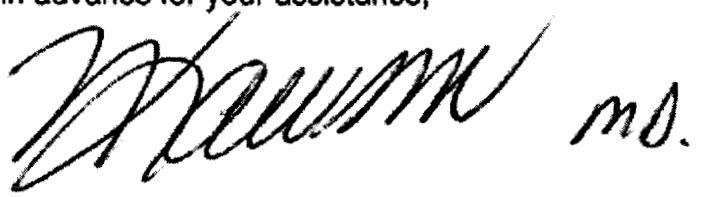
Thank you in advance for your assistance,



cc: Senator Mike Enzi, Chair, Senate Health, Education, Labor and Pensions Committee
Senator Dianne Feinstein, Co-Chair, Senate Cancer Committee
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Senator Thad Cochran, Chairman, Senate Appropriations Committee
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Helen Pass, MD, FACS, President, American Society of Breast Surgeons
Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

Submitter : **Date: 10/09/2006**

Organization :

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

"SEE ATTACHMENT" ROBERT COMPRTORE MD

CMS-1321-P-691-Attach-1.DOC

#691

Robert Comperatore
M.D., F.A.C.S.
Diplomate American Board of Surgery
General and Advanced Laparoscopic Surgery
Clinical Associate Professor
Nova Southeastern University

7180 WEST 20TH AVENUE
SUITE 215
HIALEAH, FL. 33016
PALMED BUILDING
(305) 558-4428

601 N. FLAMINGO RD.
SUITE 408
PEMBROKE PINES, FL. 33028
MEMORIAL HOSPITAL
WEST OFFICE BUILDING
(954) 437-9560

October 2, 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

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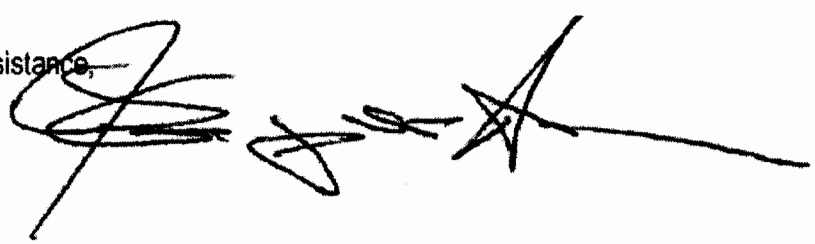

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Helen Pass, MD, FACS, President, American Society of Breast Surgeons
Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

Submitter : **Date: 10/09/2006**

Organization :

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

"SEE ATTACHMENT" LAWRENCE BLACK DO FACOS

CMS-1321-P-692-Attach-1.DOC

#692

LAWRENCE R. BLACK, D.O., F.A.C.O.S.

GENERAL SURGERY

Diplomate of American Osteopathic Board of Surgery

October 2, 2006

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

Attention: CMS-1321-P; Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and other Changes to Payment under Part B

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Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

Submitter : **Date: 10/09/2006**

Organization :

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

"SEE ATTACHMENT" JOSE MANIBO MD

CMS-1321-P-693-Attach-1.DOC

#693

SURGICAL SPECIALISTS
OF SOUTHWEST FLORIDA, P.A.
DIPLOMATES / AMERICAN BOARD OF SURGERY
AND VASCULAR LABORATORY

GORDON D. BURTCH, MD, FACS
General, Vascular & Transplant Surgery

AJAY KALRA, MD
General, Vascular & Endovascular Surgery

JOSE MANIBO, MD
General Surgery

ANTHONY J. D'ANGELO, MD, FACS
General and Vascular Surgery

October 2, 2006

October 4, 2006

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

Attention: CMS-1321-P; Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and other Changes to Payment under Part B

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Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

Submitter : **Date: 10/09/2006**

Organization :

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

"SEE ATTACHMENT" DENISE ORTEGA SANDERSON MD

CMS-1321-P-694-Attach-1.DOC

#694

The Breast Care Center
of the Treasure Coast

James J. Vopal, M.D., F.A.C.S.
Denise Ortega Sanderson, M.D.
Gina Bradley, A.R.N.P.

801 SE Osceola Street - Stuart, Florida 34994
(772) 220-4050 - Fax (772) 220-0502

October 4, 2006

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

Attention: CMS-1321-P; Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and other Changes to Payment under Part B

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M.D.

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Submitter : **Date: 10/09/2006**

Organization :

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

"SEE ATTACHMENT" JAMES VOPAL MD

CMS-1321-P-695-Attach-1.DOC

#695

The Breast Care Center
of the Treasure Coast

James J. Vopal, M.D., F.A.C.S.
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October 4, 2006

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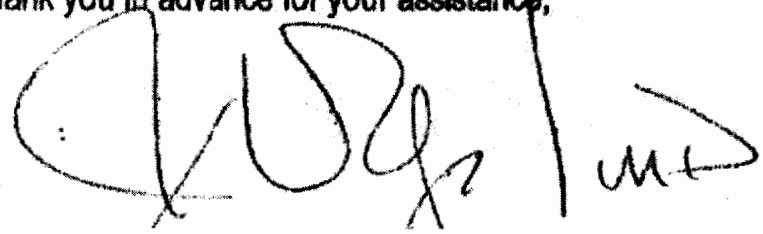

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Submitter : **Date: 10/09/2006**

Organization :

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

"SEE ATTACHMENT" GINA BRADLEY ARNP

CMS-1321-P-696-Attach-1.DOC

#696

The Breast Care Center
of the Treasure Coast

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October 4, 2006

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Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

Submitter : **Date: 10/09/2006**

Organization :

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

"SEE ATTACHMENT" YVETTE LACLAUSTRA MD

CMS-1321-P-697-Attach-1.DOC

#697

Women's Breast Care Center, Inc.

October 4, 2006

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

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Thank you in advance for your assistance,

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

Submitter : Dr. Mark Victor **Date:** 10/09/2006

Organization : Cardiology Consultants of Philadelphia

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-698-Attach-1.DOC

#698

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

Dear Dr. McClellan:

On behalf of the 83 Physicians comprising Cardiology Consultants of Philadelphia, we appreciate the opportunity to submit these comments to the Centers for Medicare & Medicaid Services ("CMS") regarding the above proposed Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B; Proposed Rule ("Proposed Rule"). We are concerned about several provisions that will impact Medicare beneficiaries' access to services in outpatient cardiac centers, particularly those related to cardiac catheterizations. Specifically, we are concerned about the payment method proposed for cardiac catheterization related procedures. The Cardiovascular Outpatient Center Alliance ("COCA"), of which we are a member, will address the CMS proposal to require standards for Independent Diagnostic Testing Facilities ("IDTFs"). Our concerns related to the payment method are outlined below.

Payment Method

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

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

#699

David H. Owen, M.D.

Breast Cancer Surgeon

2240 Woolbright Road #405 Boynton Beach, FL 33426 (561) 733-6565

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October 2, 2006

October 4, 2006

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

Attention: CMS-1321-P; Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and other Changes to Payment under Part B

Dear Administrator:

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

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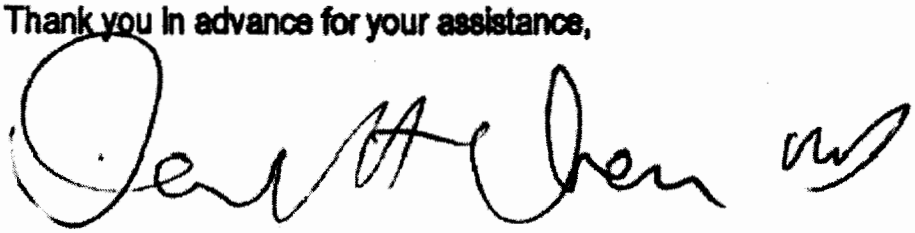
Thank you in advance for your assistance,



cc: Senator Mike Enzi, Chair, Senate Health, Education, Labor and Pensions Committee
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Carolyn Mullen, Deputy Director, Division of Practitioner Service
Helen Pass, MD, FACS, President, American Society of Breast Surgeons
Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

Submitter : **Ms. Kathy Lester** **Date: 10/09/2006**

Organization : **Patton Boggs on behalf of BioSphere Medical, Inc.**

Category : **Attorney/Law Firm**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-700-Attach-1.PDF

II. The Process to Establish the Values for the New UFE CPT Code Is So Flawed that It Is Highly Unlikely the Values Will Reflect the Cost of Providing the Services

Access to UFE is threatened because CMS is poised to adopt a new CPT code for the procedure that is based on flawed survey data and that will undervalue this procedure. If the code is adopted, physicians may not be able to cover the cost of providing UFE. Women suffering from uterine fibroid tumors may be forced to rely solely on surgical options.

Biosphere Medical understands the importance of establishing codes that properly capture the cost of providing medical services and CMS's role as a responsible fiduciary for the federal government. As part of this responsibility, it is especially important that CMS exercise all of its possible resources to ensure that the value inputs assigned to individual service codes reflects the true costs of furnishing the service. We also appreciate the difficulty in developing the appropriate values and CMS's reliance upon the RUC.

However, BioSphere Medical is extremely concerned by the process that has unfolded this year with regard to a single CPT code to bill UFE services. Currently, interventional radiologists bill for the service using a combination of existing office visit, radiology, and transcatheter placement CPT codes to capture all of the components of the UFE procedure. Given the difficulties multiple codes create in the billing and auditing process, we appreciate the need to establish a single code. Yet, when undertaking this process the RUC and the Society for Interventional Radiology (SIR) have failed to base their evaluation of the practice expense and work values on solid data. As you are aware, the RUC met over the weekend to finalize the values for this and other codes. In doing so, we understand that they failed to consider the full scope of the procedure. As described below, we have serious concerns about the process used to develop these values and worry that if they are adopted they will result in fewer UFEs being performed. This will not only cost the health care system more in terms of treatment dollars, but also result in fewer women being able to access a less-invasive treatment option.

First and foremost, we are concerned that the RUC lacks comprehensive and correct data on the costs and physician time associated with of performing UFE. Although an early attempt to collect survey information from practitioners performing the service was conducted by the SIR, the RUC dismissed the results because of flaws in the data collection process. It is our understanding that SIR conducted another survey and that the results of this survey are currently being tabulated for submission to the RUC. We are concerned that this survey may repeat one of the most glaring errors of the initial survey, which is the estimated number of global days that CMS should assign to the procedure.

As Dr. James Spies (Professor of Radiology, Chairman and Chief of Service, Department of Radiology at Georgetown University Hospital) has discussed with CMS staff, the clinical literature focuses on only a small piece of the actual UFE procedure. These studies describe the process from the time the catheter is inserted in the patient to the time it is removed. As an author of many of these studies, Dr. Spies stresses that they do not account for the preparation time or the follow-up

care. Clinicians who actually perform these services (and many of who were not survey during the SIR process) suggests that while the procedure is performed on an outpatient basis, most UFE patients spend the night following the procedure at an inpatient facility for pain management and observation purposes. In fact, in one of the leading peer-reviewed clinical studies on the UFE procedure involving more than 3000 patients. Ninety-four percent of the patients were kept in the hospital overnight and discharged the next day.[2] They also typically receive several follow-up calls with their physician during the week following the procedure and a follow-up office visit. Thus, while some patients may go home the day of the procedure, the vast majority of patients have one night of inpatient care as standard practice. When these factors are taken into account, it is most appropriate to assign 10-day global to the new code. SIR, however, has not recognized this fact because it has not consulted with the key experts in the community.

We understand that SIR has attempted to resolve this problem, but it appears to be too little too late. Dr. Spies attended the RUC meeting, but only after the survey was conducted. Because the RUC bases its values on the surveys, we are concerned that the SIR's decision to involve experts at the eleventh hour is not sufficient to ensure that the RUC assigns the appropriate values for the new code. The RUC may still be tempted to move forward with a decision based upon this unreliable data because of a single member of the panel. It would be unfortunate indeed if a biased physician who does not perform UFE procedures could establish a value for UFE that does not reflect the true cost of providing the service. If the code is undervalued, those interventional radiologists will not be able to cover their costs when providing the service and are likely to stop performing it. This will result in fewer women being able to access the procedure.

III. To Ensure Access to UFE for All Women, CMS Should Delay Adoption of the UFE CPT Code.

To ensure that all women have access to UFE, any new code must appropriately account for the time, skill, and intensity it takes to provide UFE. The proposed code likely to be adopted is based upon an incorrect number of global days and, thus, will undervalue the work involved. Therefore, BioSphere Medical urges CMS to refrain from adopting a new CPT code for UFE until appropriate survey data that is based on an accurate understanding of the procedure can be gathered. Until that time, CMS should allow physicians to use the set of codes that are currently used to process claims.

CMS has the authority not to adopt all of the CPT codes proposed by the AMA. BioSphere Medical understands that the code will remain in the AMA CPT code book even if CMS does not adopt the code. However, under the HIPAA transactions and code set regulations, all health insurers must use codes that have been adopted by the agency for electronic claims transactions.[3] If CMS does not adopt this particular code, it will not become part of the HIPAA code set and,

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[2]Robert Worthington Kirsch, *et al.*, "The Fibroid Registry for Outcomes Data for Uterine Embolization," 106 Obstetrics & Gynecology (July 2005).

[3]45 C.F.R. 162.925.

therefore, cannot be used to process claims transactions. We understand that applying this rule in this manner should be a rare occurrence. However, given the potential harm that the new CPT code would likely create, we believe this extreme measure should be exercised.

If CMS does not adopt the code, the SIR, RUC, and the specialists who perform this procedure will have the additional time they need to resolve the outstanding questions and concerns questions. To assist with the appropriate valuation of the codes, we encourage CMS to acknowledge that it agrees that a 10-day global period would be appropriate to assign to the code. In addition, CMS should encourage the interested parties to resolve the issue in a thoughtful and deliberative manner that demonstrates a comprehensive understanding of the procedure and the needs of patients. Although Medicare beneficiaries do not frequently suffer from fibroid tumors, it is nonetheless important that the procedure is properly valued given the impact of Medicare values on reimbursement in other sectors, including Medicaid and the private insurance market.

IV. Conclusion

BioSphere Medical appreciates the opportunity to comment on this important issue for women. It is imperative that CMS provide appropriate guidance to the RUC and SIR to ensure that its coding decisions do not threaten access to UFE and thwart the desire of many Members of Congress who are working to educate more women, especially those in the African-American community, about this important and effective alternative to surgery. We understand the role of the RUC in assisting CMS with the valuation of codes; however, there are times when it is appropriate for the Agency to address problems that the RUC process creates. Thus, to remain consistent with Agency's overall objective to assign appropriate values to codes and to ensure patient access to promising, new technologies, CMS should not adopt the UFE CPT code in the Final Rule. We would welcome the opportunity work with CMS to ensure the code is appropriately value and available for adoption next year. Please do not hesitate to contact me at 202-457-6562.

Sincerely,

Kathleen J. Lester
Partner

4833866
4834046v1

Submitter : **Date: 10/09/2006**

Organization :

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

"SEE ATTACHMENT" DONNA KELBAN, MD

CMS-1321-P-701-Attach-1.DOC

#701

Donna H. Kleban, M.D., F.A.C.S., P.A.

1395 State Road 7
Suite 410
Wellington, FL 33414
Telephone (561)791-3301 ♦ Facsimile (561)791-7745

October 2, 2006

October 4, 2006

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

Attention: CMS-1321-P; Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and other Changes to Payment under Part B

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Thank you in advance for your assistance,

Donna H. Kleban, MD, FACS

cc: Senator Mike Enzi, Chair, Senate Health, Education, Labor and Pensions Committee
Senator Dianne Feinstein, Co-Chair, Senate Cancer Committee
Senator Sam Brownback, Co-Chair, Senate Cancer Committee
Senator Thad Cochran, Chairman, Senate Appropriations Committee
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Carolyn Mullen, Deputy Director, Division of Practitioner Service
Helen Pass, MD, FACS, President, American Society of Breast Surgeons
Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

Submitter : **Date: 10/09/2006**

Organization :

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

"SEE ATTACHMENT" KISHORE DASS MD

CMS-1321-P-702-Attach-1.DOC

#702

KISHORE K. DASS, M.D.

P.O. Box 212080
Royal Palm Beach, FL 33421
Phone: (561) 753-2688
Fax: (561) 472-2512

October 3, 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: Physician Fee Schedule Rule# CMS-1321-P

Dear CMS Administrator:

Thank you for the opportunity to provide comments about the CMS proposed rule #CMS-1321-P published in the Federal Register on August 23, 2006. This letter is written to share my concerns regarding the proposed reduction in professional fees for Radiation / Oncology Brachytherapy services.

With the prevalence of breast cancer, I urge CMS to reconsider the proposed Work RVU reduction for Brachytherapy. What CMS is proposing - a 2007 work RVU slated to be 0.33 - is a drastic cut in the professional component for breast brachytherapy services. Of note, the work RVU for 2006 was 0.53.

The reduction CMS is proposing will have a detrimental impact on my ability to offer the Brachytherapy / Partial Breast Irradiation Therapy treatment to my Medicare patients. Access to Brachytherapy is critical. Brachytherapy allows the radiation process to move quickly so that other treatments such as chemotherapy can be started in a timely fashion. The preparation and effort for planning & treatment is quite time consuming and proper catheter placement must be confirmed before each fraction is given. The CMS proposed reduction to all Brachytherapy codes, especially CPT 77781, will not adequately cover the time and involvement required to prepare a patient for Brachytherapy. I must stress that if the reduction does take place, CMS will be limiting access to Brachytherapy for Medicare patients.

CMS should implement a goal is to preserve the Work RVU on the professional side. Please leave the Brachytherapy codes as they currently stand in 2006, and, if needed, make only a slight reduction in the conversion factor. I appreciate your careful review and analysis of this important matter. I strongly urge CMS to reconsider the significant, negative impact that would result from the proposed reductions.

Regards,

_____ M.D.

cc: Senator Mike Enzi, Chair, Senate Health, Education, Labor and Pensions Committee
Senator Dianne Feinstein, Co-Chair, Senate Cancer Committee
Senator Sam Brownback, Co-Chair, Senate Cancer Committee
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Carolyn Mullen, Deputy Director, Division of Practitioner Services
James Rubenstein, MD, Chairman, American College of Radiation Oncology
Prabhakar Tripuraneni, MD, Chair, American Society of Therapeutic Radiation Oncology
W. Robert Lee, MD, President, American Brachytherapy Society

Submitter : **Date: 10/09/2006**

Organization :

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

"SEE ATTACHMENT" E WENGLER MD

CMS-1321-P-703-Attach-1.DOC

703

FRANK R. BRIGGS, M.D.
JAMES KEVIN CHANDLER, M.D.
H. RICHARD JOHNSON, M.D., *Emeritus*
STEVEN J. PATTERSON, M.D.
PAT H. SCANLON, JR., M.D.
RICHARD L. YELVERTON, M.D.
RICHARD L. YELVERTON, JR., M.D.

Diplomats of the American Board of Surgery
Fellows of the American College of Surgeons

LAKELAND SURGICAL CLINIC, PLLC

General Surgery *Thoracic Surgery* *Breast Surgery*

October 4, 2006

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

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Thank you in advance for your assistance,

E Wengler MD

(E Wengler MD)
509 RIVERSIDE DRIVE
STUART, FL 34996

cc: Senator Mike Enzi, Chair, Senate Health, Education, Labor and Pensions Committee

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Senator Dianne Feinstein, Co-Chair, Senate Cancer Committee
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Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

Submitter : **Date: 10/09/2006**

Organization :

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

"SEE ATTACHMENT" STEVE PATTERSON MD

CMS-1321-P-704-Attach-1.DOC

#704

FRANK R. BRIGGS, M.D.
JAMES KEVIN CHANDLER, M.D.
H. RICHARD JOHNSON, M.D., *Emeritus*
STEVEN J. PATTERSON, M.D.
PAT H. SCANLON, JR., M.D.
RICHARD L. YELVERTON, M.D.
RICHARD L. YELVERTON, JR., M.D.

Diplomats of the American Board of Surgery
Fellows of the American College of Surgeons

LAKELAND SURGICAL CLINIC, PLLC

General Surgery *Thoracic Surgery* *Breast Surgery*

October 4, 2006

Office of the Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
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Submitter : **Date: 10/09/2006**

Organization :

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

"SEE ATTACHMENT" KEVIN CHANDLER MD

CMS-1321-P-705-Attach-1.DOC

#705

FRANK R. BRIGGS, M.D.
JAMES KEVIN CHANDLER, M.D.
H. RICHARD JOHNSON, M.D., *Emeritus*
STEVEN J. PATTERSON, M.D.
PAT H. SCANLON, JR., M.D.
RICHARD L. YELVERTON, M.D.
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Diplomats of the American Board of Surgery
Fellows of the American College of Surgeons

LAKELAND SURGICAL CLINIC, PLLC

General Surgery *Thoracic Surgery* *Breast Surgery*

October 4, 2006

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

Attention: CMS-1321-P; Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and other Changes to Payment under Part B

Dear Administrator:

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

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

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

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

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

Thank you in advance for your assistance,

J Kevin Chandler MD

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

Submitter : **Dr. Franklin Fleischhauer** **Date: 10/09/2006**

Organization : **Cardiology Consultants**

Category : **Physician**

Issue Areas/Comments

Background

Background

CMS' proposed changes for the technical component of outpatient cardiac imaging (catheterization, nuclear, and echo) use a flawed methodology that does not reflect the actual costs of the procedure. Furthermore, the belief that this draconian cut in fees will slow the number of procedures is very shortsighted. A similar effort was made a decade ago when fees where drastically cut for the physician component of angioplasty and surgery and no such drop occurred. This effort will actually cost Medicare more money by forcing patients to go to high cost hospital centers for their outpatient needs. I would urge CMS to work with the necessary specialty societies to develop a methodology that is fair and accurately reflects the costs of these procedures rather than arbitrarily making up a new system. It will restrict access to care and I am certain will result in many cardiologists no longer participating in Medicare.

GENERAL

GENERAL

See impact statement.

Submitter : Ms. Kathy Lester **Date:** 10/09/2006

Organization : Patton Boggs on Behalf of BioSphere Medical, Inc.

Category : Attorney/Law Firm

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-707-Attach-1.PDF

#707

PATTON BOGGS LLP
ATTORNEYS AT LAW

2550 M Street NW
Washington DC 20037
202-457-6000

Facsimile 202-457-6315

October 10, 2006

Dr. Mark McClellan
Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1506-P
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: **CMS-1506-P:** Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates Proposed Rule – Assignment of newly developed CPT code 37XXX to an APC with an appropriate level of payment.

Dear Dr. McClellan,

I am writing on behalf of Biosphere Medical, Inc. (Biosphere Medical) to provide you with comments regarding the Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates Proposed Rule (Proposed Rule), published in the *Federal Register* on August 23, 2006.[1] Biosphere Medical is a medical device manufacturer specializing in the development of embolotherapy technology, including the use of microsphere embolization for the treatment of benign uterine fibroid tumors. We work with physicians, patients, and patient advocates to raise awareness about uterine fibroid embolization (UFE) as a safe and effective alternative to surgical options, such as myomectomies and hysterectomies. We appreciate the opportunity to comment on the Proposed Rule and look forward to working with the Centers for Medicare and Medicaid Services (CMS) staff to ensure access to effective, quality services for women with fibroid tumors.

As we discussed with CMS staff earlier this year (August 9, 2006), there is a newly developed CPT code 37XXX for UFE that will be effective January 1, 2007. Due to some unforeseen circumstances, this new code was pending valuation by the RVS Update Committee (RUC) of the American Medical Association (AMA) at its October 2006 meeting. We have some concerns that the procedure may be undervalued during the RUC process due to a lack of accurate cost data. In such a circumstance, we would hope that CMS would decline to accept the RUC recommendation in favor of a future valuation based on more developed cost data. Nonetheless, if CMS decides to move forward with the adoption of the new code, it is essential that the code be assigned to the proper APC group under the hospital outpatient prospective payment system in order to protect access to the procedure for women with fibroid tumors. We

[1] 71 Fed. Reg. 49506.

hope that the following comments provide CMS with the information necessary to make the most appropriate APC assignment for this new CPT code.

I. Background on Uterine Fibroid Embolization

Uterine Fibroid Embolization (UFE) is a promising new treatment for uterine fibroid tumors for which a new CPT code that bundles all elements of the treatment into the descriptor (eliminating the need for component coding) will be effective January 1, 2007. Uterine fibroids, one of the most prevalent women's health conditions in the United States today, are benign tumors that grow on the muscle tissue of a woman's uterus and can cause serious symptoms including heavy menstrual bleeding, back and pelvic pain and pressure, abdominal bloating urinary pressure or incontinence and possible infertility. Twenty to forty percent of women of childbearing age experience fibroids, and more than five million women are symptomatic. African-American women are three times as likely to be affected by the condition. Although Medicare beneficiaries do not frequently suffer from fibroid tumors, it is nonetheless important that the procedure is properly valued given the impact of Medicare values on reimbursement in other sectors, including Medicaid and commercial insurers.

Research has demonstrated that UFE is safe, clinically effective and preferred by patients suffering from fibroid tumors. When compared to traditional surgical treatments like hysterectomy and myomectomy, UFE has a significantly shorter length of recovery period and a lower risk of adverse events associated with the procedure. Additionally, the procedure allows a woman to maintain the ability to have future pregnancies by preserving the uterus. A recent study shows that 96 percent of women who undergo UFE are satisfied with the treatment 12 months following the procedure, and clinical data demonstrate that one year after UFE 90 percent of women are symptom free while 73 percent remain symptom free five years after the procedure.[2] In a recent case series including 2,126 women who underwent UFE, it was reported that the patients experienced a mean improvement in menorrhagia (heavy menstrual bleeding) of 88 percent and a mean improvement in pain and pressure of 71 percent. The mean reduction in the volume of the targeted fibroids was 20 percent at 2 months after the procedure and 60 percent at 12 months after the procedure. Only 8 women, 0.3 percent of the study population, required a follow-up hysterectomy due to complications.

In addition to its clinical benefits and patient-friendly attributes, UFE has also been shown to be more cost-effective than traditional surgical treatments for fibroid tumors. The fact that the procedure generally allows a patient to go home on either the day of the procedure or following an overnight hospital visit, rather than requiring a two to four day hospital stay like hysterectomy, significantly reduces the overall costs of treating fibroid tumors. Furthermore, because a patient is typically able to return to work and normal activity within ten days instead of

[2] James B. Spies, *et al*, "Uterine Artery Embolization for Leiomyomata," *Obstetrics & Gynecology* (March 2001), 98, 29-34; James B. Spies, *et al*, "Long-Term Outcome of Uterine Artery Embolization of Leiomyomata," *Obstetrics & Gynecology* (November 2005), 106, 933-939.

Submitter : **Mr. Michael Borton** **Date: 10/09/2006**

Organization : **Hematology Oncology Patient Ent.**

Category : **Health Care Industry**

Issue Areas/Comments

GENERAL

GENERAL

In my opinion, CMS should not allow contracts that bind products to other product offerings that do not have equivalent product in the market. This is a restraint of trade, as the only way to provide "standard of care" for the treatment and prevention of neuropathy in the outpatient setting is through the use of Neulasta. Unless a practice is able to hit and maintain a minimum threshold, set by AMGEN, purchasing Neulasta comes at a loss on purchase, let alone the cost of preparing, maintaining, bad debt and so on. I can t say that I would change the way ASP is calculated on AMGEN s products, only that contract s that bundle monopolistic products is an unsound practice. If AMGEN wanted to make practice whole in purchasing Neulasta separately and wanted to provide the incentive to make money through the use of sweetened rebate, I could find more support for this tactic.

Provisions of the Proposed Rule

Provisions of the Proposed Rule

I manage a six-physician medical oncology practice in Central Virginia. My comments incorporate the spirit and thoughts of my physicians. There are sevcral issues that I could share on the 2007 Fee schedule, I am going to focus my energy on the "Bundled Price Concessions" issue. I feel this issue is significant and could cost CMS, our patients, and my practice(H.O.P.E.) significant expense.

As a medical oncology practice we are a significant purchaser of EPO. We use both Aranesp and Procrit. As you are aware, AMGEN's contract ties the rebates available on Neulasta with Aranesp, hence those who choose to use primarily Procrit for there Red CSF product are unfairly penalized in their Neulasta usage; and Neulasta is industry standard, NCCN endorsed way of providing White CSF care in the outpatient-setting. The way AMGEN contracts, a practice actually looses money by purchasing their drugs and is only made whole through rebates; Rebates they may not receive if they do not use both Aranesp and Neulasta. While I understand why this would be done from a business decision, this practice within a monopolistic environment (Neulasta) is unfair due to the limitations it places on physician choice and the financial impact it may have on our patients.

Submitter : Ms. **Date:** 10/09/2006

Organization : Cardiology Advocacy Alliance

Category : Health Care Professional or Association

Issue Areas/Comments

Impact

Impact

see attachment

CMS-1321-P-709-Attach-1.PDF

#709

CARDIOLOGY ADVOCACY ALLIANCE

National leadership on issues that affect cardiovascular patients and their physicians 734.878.5449 • mburrage@cardiologycaa.com

October 10, 2006

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

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

Dear Dr. McClellan:

On behalf of our 4,200 members, the Cardiology Advocacy Alliance (CAA) appreciates the opportunity to submit comments to the Centers for Medicare and Medicaid Services (CMS) regarding the above proposed Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B; Proposed Rule (Proposed Rule). Our organization, which represents the physicians of more than 220 cardiology practices, is concerned about several provisions:

1. Payment Method proposed for cardiac catheterization related procedures. We believe the proposed changes will adversely affect Medicare beneficiaries' access to services in outpatient cardiac centers, particularly those related to cardiac catheterizations. Specifically, we are concerned about the payment method. The Cardiovascular Outpatient Center Alliance (COCA), to which many of our members belong, will address the CMS proposal to require standards for Independent Diagnostic Testing Facilities (IDTFs). Our concerns related to the payment method are outlined below.

2. Deficit Reduction Act (DRA) Proposed Adjustments for Payments for Imaging Services. We wish to reiterate our concerns regarding the use of hospital

Outpatient Payment Perspective System (OPPS) rates to determine physician and practice expense payments for imaging services. Our concerns related to these proposed adjustments are related below as well.

1. Payment method proposed for cardiac catheterization related procedures

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

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

The current relative value units result in a payment rate that is in relative parity with the payment amount hospitals receive under the hospital outpatient prospective payment system. In fact, the 2006 physician fee schedule (PFS) payments for the three CPT codes included in the Ambulatory Procedure Classification (APC) for cardiac catheterizations are 93 percent of the relevant APC rate. In our response to CMS' Proposed Changes to the Practice Expense Methodology (Federal Register, June 29, 2006) we outlined our concerns with the proposed changes to the PE Methodology, i.e., use of a bottom-up methodology and the elimination of the non-physician work pool. The proposed payment rates resulting from the use of the practice expense RVUs for the left heart catheterization procedure alone (CPT code 93510 TC) reduce payment levels in 2007 by 16 percent, and by 2010 make overall reductions of 53 percent. The flaws in the methodology, particularly as they relate to the cardiac catheterization procedure codes were described in general in CAA's comment letter

of August 21, 2006 and more specifically in the August 22, 2006 comment letter submitted by COCA.

Cardiac catheterizations that are billed through the Medicare PFS are performed primarily in cardiology groups and freestanding centers which are grouped into a diverse group of diagnostic testing facilities known as IDTFs. We believe that the development of unique standards for each type of diagnostic testing facilities will facilitate the development of a consistent Medicare policy for outpatient cardiac catheterization services. The standards will provide a solution to the issue that cardiac catheterization labs faced when the national coverage determination for outpatient catheterizations was rescinded because of the change of scope in the CMS contracts with the Peer Review Organizations in January 2006.
The need to develop unique standards for each type of diagnostic testing facility provider is consistent with the observation that CMS made in the Proposed Rule regarding the practice expense for different types of remote cardiac monitoring and anticoagulation monitoring. Similar to CMS's observation that these types of IDTFs are different, we believe that cardiac catheterization centers are unique and that their cost structure and quality standards are similar regardless of whether they are performed in a cardiology practice or an independent outpatient center. The COCA cost study shows that the cost profile of outpatient cardiac centers is quite different from the average profile of all IDTFs. We believe the COCA cost analysis will be helpful to CMS as it begins to develop standards, specifically for cardiac outpatient centers because the data can be used to estimate the impact that each standard has on practice expenses. The cost study will also be helpful as CMS works to develop a practice expense RVU for cardiac catheterization procedures that reflect the resources needed to perform the service.

2. <u>DRA Proposed Adjustments for Payments for Imaging Services</u>

CAA reiterates it concerns with the DRA provision that would lower the imaging technical component to the lesser of the Physician Fee Schedule (PFS) or OPPS rates:

a. Of primary concern is that the physician payment system consistently used by the Centers for Medicare and Medicaid Services (CMS) since 1992 would be arbitrarily replaced with a payment calculation formula geared toward hospitals. As CMS has acknowledged through its use of separate reimbursement formularies, hospitals have a fundamentally different reimbursement methodology based on charges, and are reimbursed for capital purchases and medical education in addition to payments for services. The way in which hospitals report their costs also affects their reimbursement. Conversely, CMS' PFS methodology bases physician payments on actual costs, including compensation for capital equipment outlay and other expenses. The provision in the DRA would cast aside the CPT code payment structure for physicians and leave them without adequate reimbursement for the substantial equipment

costs that imaging services by their nature incur. Physicians also must fight annual payment reductions resulting from Medicare's flawed Sustainable Growth Rate formula, while hospitals receive payment increases annually.

b. A study conducted in June 2006 by The Moran Company (attached) determined that Hospital and physician payments already are on par with one another. But should the DRA cuts go into effect, the study states that "imaging reimbursement in the office would be materially lower, perhaps by 16 to 18 percent, than in the outpatient setting." **The Moran study also found that 87 percent of imaging procedures whose payment would be affected by the cap (126 of 145 affected procedures) would be paid at rates below the cost of performing the procedures in the doctor's office.** In addition, private payers also base their payments on CPT code calculations, which will exacerbate the already disastrous effect of the DRA imaging cuts. Not only will physicians see their Medicare reimbursement shrink significantly; third-party insurers will follow Medicare's lead, creating a second tidal wave of reductions.

c. The cuts will increase Medicare patients' out-of-pocket costs because hospital outpatient co-pays are higher than those required for physician office services. This is one of many reasons why patients prefer to receive services at their doctor's office.

d. The DRA provision may reduce patient access to office-based imaging, as hospital outpatient departments often have significantly longer wait times than physician offices. Rural access may be more difficult for the elderly if they must drive farther for imaging services.

In light of the concerns listed above, CAA requests that CMS delay implementation of the DRA imaging provisions for two years to study the effects the reimbursement changes would have on Medicare beneficiaries.

Summary: Payment method proposed for cardiac catheterization procedures

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

Summary: DRA Proposed Adjustments for Payments for Imaging Services

The proposed adjustments to payments for imaging services under the Deficit Reduction Act would arbitrarily replace CMS's established physician fee payment formula with one geared to hospitals' vastly different methodology and would set a poor precedent. Reimbursing physicians at rates lower than the costs of providing services is unreasonable and may force physicians to reduce or eliminate services to Medicare beneficiaries, **who will higher co-pays, reduced access**, and longer wait times for critical diagnostic tests. We ask that CMS delay implementation of the DRA provisions for two years and conduct a review of the effects that the reimbursement changes will have on Medicare patients.

Sincerely,

Margo L. Burrage, Administrator
on behalf of the members of the
Cardiology Advocacy Alliance
11065 Home Shore Drive
Pinckney Michigan 48169
734.878.5449
mburrage@cardiologycaa.com

Submitter : Dr. Randy Stevens **Date:** 10/09/2006

Organization : White Plains Hospital-Dickstein Cancer Center

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1321-P-710-Attach-1.DOC

Comment #710

September 18, 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 allowing me the opportunity to provide comment 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.

CMS has proposed drastic cuts in th RVUs assigned to the global fee schedule for HDR breast brachytherapy. They are scheduled to reduce by 20% each year in the transition period and the total reduction for this treatment is -55% as illustrated in the table below.

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%

their clients who bring their business "in-house" or to a more efficient, patient-friendly organization.

8) Radiological services should likewise not be jeopardized. As Urologists we are trained during residency to perform and interpret the full spectrum of Urological imaging. To take away our ability to perform and interpret these vital studies would severely and adversely effect our ability to efficiently provide the highest quality of care to our patients. Many of the arguments mandating our ability to continue Pathology services apply to Radiological services also. The potential for abuse is always present, however, the good of our patients must come first. Please do not punish our patients or the many Urologists who provide excellent care because of the very few who abuse what is considered by most to be a fair system.

9) We rarely have any patient complaints about the quality, convenience, efficiency, or cost of our pathology. Before we provided this service to our patients, our staff was constantly fielding complaints regarding all of these issues.

In summary, we are trying to provide the highest quality services possible, which includes comprehensive care, including Pathology services. We have an arrangement, which is within the law to provide these services, which, as enumerated above, are in the best interest of our patients. Changing the CMS rules specifically targets this one service, which is quite arbitrary and unfair. We believe the rules changes should be held off to further define what the abuse is and how battle it. We believe that is the job of the OIG, as this is the investigative branch of the government responsible for such actions. A bureaucratic decision to change the rules circumvents this process, already in place and functioning.

Thank you in advance for your careful consideration of our comments on this issue.

Harvey Taub, M.D. Mark Dersch, M.D. Jack Paulk, M.D. Dinesh Rao, M.D.

Submitter : **Date: 10/09/2006**

Organization :

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

What is the difference between a Urologist owning a Pathology Laboratory and a Urologist owning Radiotherapy/Radiology equipment to where he sends his own patients. Or what about a Plastic Surgeon that owns an Outpatient surgical center where he refers his patients ??

Submitter : **Dr. Oliver Khakmahd** **Date: 10/09/2006**

Organization : **Dialysis Access Center, Inc.**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

I support the position as outlined by the American Society of Diagnostic and Interventional Nephrology (ASDIN).

Submitter : Mr. Scott Bailey **Date:** 10/10/2006

Organization : Cardiology Clinic of San Antonio

Category : Other Health Care Professional

Issue Areas/Comments

Background

Background

DRA PROPOSALS:

GENERAL

GENERAL

DRA PROPOSALS: We are opposed to the PFS being capped by the OPPS. Hospitals can afford to accept the lower OPPS rates because they get highly reimbursed for inpatient services reimbursed under the DRG method. Physician offices meanwhile do not enjoy this privilege.

The impact of the imaging cuts will be great. All of our expenses are increasing. This increase in expenses coupled with a decrease in reimbursement will require to look hard at our operations. This reduction will affect staff raises and benefits. This reduction will affect future job opportunities, hiring practices, and may lead to lay-offs as we may be forced to reduce overhead.