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

Organization : **American Society for Microbiology**

Category : **Other Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-879-Attach-1.DOC

#879

AMERICAN SOCIETY FOR MICROBIOLOGY

Public and Scientific Affairs Board

October 10, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P
7500 Security Boulevard
Baltimore, MD 21244-1850

The American Society for Microbiology (ASM) appreciates the opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS) on its Proposed Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007, as announced in the *Federal Register* on August 22, 2006 [Vol. 71, No. 162, CMS-1321-P]. The ASM is the largest educational, professional, and scientific society dedicated to the advancement of the microbiological sciences and their application for the common good. The Society represents more than 42,000 microbiologists, professionally employed as scientists and science administrators working in a variety of areas, including biomedical, environmental, and molecular fields as well as in clinical microbiology and immunology.

Many of our members have primary involvement in clinical laboratory medicine including individuals directing clinical microbiology or immunology laboratories, individuals licensed or accredited to perform such testing, industry representatives marketing products for use, and researchers involved in developing and evaluating new technologies. Thus, our Society has a significant interest in the process of establishing reasonable reimbursement for medically necessary laboratory testing to ensure quality patient care for Medicare beneficiaries. The ASM will limit its comments to the sections of the proposed rule that pertain to clinical diagnostic laboratory tests.

Clinical Diagnostic Laboratory Tests

Section II. N. 1, 2 a. – c. Public Consultation for Medicare Payment for New Outpatient Clinical Diagnostic Laboratory Tests

Section 942(b) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA), requires the Secretary to establish fee schedules for clinical laboratory tests under Medicare Part B. It also specifies annual procedures for consulting the public on how to establish payment for the new or revised clinical laboratory test codes to be included in the annual update of the clinical laboratory fee schedule. CMS has conducted its "Laboratory Public Meeting" on an annual basis since 2002 as a result of Section

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531(b) of the Benefits Improvement and Protection Act of 2000, and, as recommended by the Institute of Medicine in its 2001 Report on Medicare Laboratory Payment Policy. ASM has appreciated the opportunity to participate in these public meetings to recommend payment methodology approaches for new microbiology and immunology laboratory tests. In particular, we support the CMS criteria for establishing payment decisions which is based on test purpose, test method, test cost, and the specific recommendation to crosswalk the new test to an existing code, or to gapfill the new test if there is no comparable test. We also appreciate the additional comment period provided after tentative payment determinations are made available by CMS. ASM believes that this kind of open and transparent process allows for a successful coordination of science, business, and program integrity interests which ensures quality laboratory medicine for Medicare beneficiaries. As such, we are pleased that CMS is proposing to codify this important public process.

ASM also supports that CMS provide the rationale, data or responses to comments from the public in its proposed and final payment determinations. Section 1833(h)(8)(B) of the MMA requires the Secretary to provide "an explanation of the reasons for each determination and the data on which the determinations are based" for both the proposed and final determinations. To date, ASM has not been privy to this information regarding proposed or final payment methodology for new laboratory tests. The only information that is provided is CMS's proposed or final payment methodology, and, the recommendations made by each of the organizations that participated and/or submitted comments to the Laboratory Public Meeting. ASM believes that providing this additional information would help to strengthen the payment methodology process by making it more transparent. In addition, ASM recommends that codes for which significant descriptor changes have been made, be open for public comment on appropriate payment methodology. Historically the process has publicized only new codes established by the American Medical Association.

II. N. 2. d. Proposed Payment for a New Clinical Diagnostic Laboratory Test – Crosswalking and Gapfilling (§414.408)

ASM supports CMS in its proposal to establish the payment amount for new laboratory tests via "crosswalking" and "gapfilling" methodology. We are pleased that CMS is clarifying the process by which the gapfilling methodology is applied, including the elimination of payment of new gapfilled tests at carrier specific amounts after the first year. ASM agrees with CMS that a gapfilled test can be payed at the carrier specific rate during the first year, but, that beginning in the second year, the test would be reimbursed at the national limitation amount, based on the median of the carrier gapfill amounts. In addition, ASM recommends that CMS provide guidance to carriers to help in setting carrier specific gapfilled rates so that there is consistency in determining reimbursement of new laboratory tests from carrier to carrier. Guidance could be based on the criteria used to determine payment for new test codes in CMS's annual Laboratory Public Meeting, i.e. test purpose, test methodology and test costs, and, recommendations could be solicited from the public sector during the annual meeting. Guidance might also encourage the use of scientific studies and professional guidelines to support the appropriate utilization and reimbursement for such new tests.

II. N. 3. a. Quality

ASM supports the use of a standardized terminology such as the Logical Observation Identifiers Names and Codes (LOINC) database to promote development of quality monitors for laboratory medicine. However, we appreciate that CMS acknowledges that there are significant functional, operational and other challenges that would need to be addressed before Medicare could begin to collect laboratory values in a comprehensive manner using common vocabulary standards. In particular, most traditional microbiology test results are reported in a narrative fashion, not using easily categorized qualitative or quantitative values. Further, narratives are often tailored to meet specific clinical needs of diverse patient population types. Therefore, the creation of common narratives to report microbiology test results would take a significant amount of time and scientific expertise. The ICD-10-PCS project more than a decade ago laid a foundation for such an endeavor, but is clearly outdated at this point. ASM stands ready to assist CMS should it decide to initiate the development of a process by which to define and categorize microbiology reporting for purposes of quality improvement.

II. N. 3. c. Other Lab Issues - Proposed Clinical Diagnostic Laboratory Date of Service (DOS) for Stored Specimens

ASM appreciates CMS's clarification of the date of service of a clinical diagnostic laboratory test that uses a stored or archived specimen on a hospital inpatient. We support CMS's proposal to use the date the specimen is obtained from storage for subsequent outpatient testing, even if the specimen is obtained less than 31 days from the date it was collected. ASM also supports that certain conditions to insure program integrity must be met which are outlined in the proposed regulation, as follows:

- The test is ordered by the patient's physician at least 14 days following the date of the patient's discharge from the hospital.
- The test could not reasonably have been ordered while the patient was hospitalized.
- The procedure performed while the beneficiary is a patient of the hospital is for purposes other than collection of the specimen needed for the test.
- The test is reasonable and medically necessary.

Again, thank you for the opportunity to provide comments on the Proposed Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007. Should you desire additional information about ASM's comments, please contact Suzy Leous in ASM's Office of Public Affairs, at 202-942-9262 or sleous@asmusa.org.

Regards,

Vickie S Baselski

Vickie S. Baselski, Ph.D., Chair
Committee on Professional Affairs
Public and Scientific Affairs Board

Submitter : **Mr. Glenn Hackbarth** **Date: 10/10/2006**

Organization : **Medicare Payment Advisory Commission**

Category : **Federal Government**

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-1321-P-880-Attach-1.DOC

#880

MEDPAC Medicare Payment Advisory Commission

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Glenn M. Hackbarth, J.D., Chairman
Robert D. Reischauer, Ph.D., Vice Chairman
Mark E. Miller, Ph.D., Executive Director

October 11, 2006

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

RE: file code CMS-1321-P

Dear Dr. McClellan:

The Medicare Payment Advisory Commission (MedPAC) is pleased to submit these comments on CMS's proposed rule entitled: *Medicare program; Revisions to payment policies under the physician fee schedule for calendar year 2007 and other changes to payment under Part B* [CMS-1321-P] Federal Register, August 22, 2006. We appreciate your staff's ongoing efforts to administer and improve the payment system for physicians' services, particularly considering the agency's competing demands.

Deficit Reduction Act of 2005 (DRA) proposals

Section 5102 – Proposed adjustments for payments to imaging services

In the physician fee schedule final rule for 2006, CMS adopted a policy to reduce the technical component payment for multiple diagnostic imaging services when they are performed on contiguous body parts during the same session. We recommended this policy in our March 2005 Report to the Congress because there are cost efficiencies when multiple studies of the same modality are performed on contiguous areas. CMS initially proposed a 50 percent reduction for subsequent imaging services when providers furnish more than one service from the same family of codes (e.g., computed tomography of the spine). CMS justified a 50 percent reduction based on an analysis of the clinical activities that are not duplicated for subsequent procedures, such as positioning and escorting the patient, providing education and obtaining consent, and preparing and cleaning the room. In addition, CMS assumed that supplies, with the exception of film, are not duplicated. Removing the costs of the activities and supplies that are not duplicated supported a payment reduction ranging from 40 to 59 percent for the additional services; the midpoint of this range was 50 percent. To allow for a transition, CMS decided in the final rule to phase in this reduction over two years by implementing a 25 percent reduction in 2006 and

planning to adopt a 50 percent reduction in 2007, subject to additional review. CMS also solicited data from providers on the efficiencies associated with different combinations of imaging studies.

In this proposed rule, CMS proposes to maintain the current 25 percent reduction for 2007 for two reasons:

- The interaction between this policy and a provision from the Deficit Reduction Act of 2005 (DRA) that caps the physician fee schedule technical component (TC) rate for an imaging service at the outpatient prospective payment system (OPPS) rate, and
- Data submitted by the American College of Radiology (ACR) for 25 common combinations of services that supports a reduction between 21 and 44 percent.

It is unclear why the DRA provision that caps the physician fee schedule TC rate at the OPPS rate justifies maintaining the 25 percent reduction for 2007 for all imaging services, rather than implementing a 50 percent reduction. The DRA policy does not apply to all imaging services, only to those for which the TC rate exceeds the OPPS rate.

In the final rule, we ask that CMS provide more information on the ACR cost data on multiple imaging services cited in the proposed rule. Are the data based on a physician survey or an analysis of practice expense inputs? If the data are from a survey, how representative was the survey and what questions were asked? Which combinations of codes did the ACR examine? What were the cost savings for each combination? How did the ACR's estimated cost savings compare to CMS's estimated savings (published in last year's final rule) for the same combinations of services? Given the lack of detailed information in the proposed rule, we are not convinced that the ACR data justify maintaining a 25 percent reduction for 2007.

Section 5107 – Revisions to payments for therapy services

The proposed rule notes that CMS is considering coding edits for therapy services in addition to the edits it implemented in 2006. The DRA required that clinically appropriate edits, including edits of clinically illogical combinations, for therapy services be implemented by July 2006. To comply with this requirement, CMS implemented the correct coding initiative (CCI) edits in all facility-based providers in January 2006. CMS also notified providers that it would implement additional edits in January 2007 to limit the number of untimed services that can be billed on the same day for one beneficiary.

The edits that CMS has implemented represent a good start in controlling inappropriate billings. We encourage further work and consultation with experts in areas such as utilization management and appropriateness of therapy services to develop clinically appropriate edits for timed services. Edits for timed services are especially important because they represent the majority of therapy services. Edits could limit the number of

timed units based on the amount of therapy that is typically tolerated by an elderly person. Other edits might target certain combinations of services that do not make clinical sense.

ASP Issues

In 2005, Medicare began paying for Part B drugs using the average sales price (ASP) methodology. In the first quarters of 2005, the new payment system produced dramatic price decreases for many products as Medicare payment rates began to approach the prices providers paid. By 2006, payment rates were more stable. In cases where generic products became available or branded drugs competed for market share, the payment rate has continued to decline. In other cases, payment rates are slowly increasing but, to date, less than other outpatient drug prices.

The Congress directed the Commission to conduct two studies on the effect of the changes in the payment rate. For these studies, we have conducted interviews with physicians, hospital administrators, wholesalers, manufacturers, and other stakeholders. Most physicians have told us that they can buy most drugs at the Medicare payment level but all report they cannot purchase some drugs at that payment rate. Interviewees talked about two issues: the gap between the average payments received by manufacturers and the average prices physicians pay when the calculation of ASP includes discounts that are not passed on to physicians, and how discounts are allocated in the calculation of ASP when drugs produced by one manufacturer are sold in a bundle.

The Commission encourages the Secretary to look into these issues and we intend to examine them further in the coming months as part of our mandated study. Although not perfect, the Commission views ASP as a vast improvement over the former payment method based on AWP. The objective of the ASP system should be to achieve accurate prices without creating inflationary incentives. Regarding the case of bundled discounts, the Commission is concerned about this issue and will be exploring whether to change the ASP calculation rules on how discounts are allocated between two drugs if a higher discount is provided when they are purchased together.

Finally, to ensure the accuracy of Medicare payments, the Secretary should monitor the acquisition costs of all providers who the Secretary pays under the ASP payment system, including physicians and dialysis providers. In this regulation, the Secretary is extending the 2006 payment policy of ASP plus 6 percent for separately billable drugs furnished by dialysis providers through 2007 and subsequent years. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) required that the payment rates for dialysis drugs approximate the costs that dialysis providers incur.

The Secretary initially set the payment rate for physicians and dialysis providers at ASP plus 6 percent to account for the variation in their acquisition costs. However, there is no recent evidence that this payment rate reflects the variation in the acquisition costs of physicians and dialysis providers so the Secretary should not set the payment rate indefinitely. In our June 2005 Report to the Congress, the Commission recommended that

the Secretary periodically collect acquisition cost data from dialysis providers and compare it to ASP data. Analysis could lead to a resetting of the rate at a different percentage.

ESRD provisions

CMS proposes a new method to annually calculate the growth update to the add-on payment to the composite rate (as mandated by the MMA). Using this new method, the agency proposes to update the add-on payment by 0.6 percent, thus increasing the total add-on payment from 14.5 percent in 2006 to 15.2 percent in 2007.

In our June 2005 report, the Commission recommended combining these two payments. The add-on payment is complex and administratively burdensome for the agency to maintain. Increasing the add-on payment to post-MMA spending for dialysis drugs risks overpayment for use of the drugs. For these reasons, the Secretary should seek Congressional authority to combine the composite rate and the add-on payment.

Reassignment and physician self-referral

CMS proposes changes to the reassignment and physician self-referral rules designed to eliminate "pod labs" for pathology services. In a pod lab arrangement, an entity leases an office building, subdivides it into separate cubicles, equips each space with laboratory equipment, and hires staff to perform the technical and professional components of pathology tests. The entity then subleases each cubicle to a physician group practice, which may be located far away. The group practice sends its specimens to this lab and pays the entity a fee to perform the pathology tests. The practice then bills Medicare for the services, typically at a markup from the fee it has paid the management entity. Some commenters alleged that these arrangements lead to the generation of unnecessary biopsies, kickbacks, and referrals that would otherwise be prohibited by the physician self-referral statute.

CMS proposes to prohibit pod lab arrangements by amending the reassignment provision, under which a physician may bill for a service performed by another provider. CMS also proposes to limit the in-office ancillary exception under the physician self-referral law. We support policies to restrict arrangements between physicians and other entities that create financial incentives for inappropriate use of services.

IDTF issues

In response to concerns about fraud and abuse involving independent diagnostic testing facilities (IDTFs), CMS proposes to establish 14 new standards for IDTFs to ensure that they follow good business practices and provide quality care. IDTFs are entities—independent of a hospital or physician office—in which nonphysician personnel furnish diagnostic procedures under physician supervision. Medicare requires that IDTFs meet minimum standards for staff qualifications, equipment, and the supervising physicians.

Carriers must verify through a site visit and document review that IDTFs meet these standards when they enroll in Medicare but are usually not required to perform follow-up monitoring. A recent report by the Office of Inspector General (OIG) found that many Medicare payments to IDTFs were improper due to poor documentation or lack of medical necessity (Office of Inspector General, Review of claims billed by independent diagnostic testing facilities for services provided to Medicare beneficiaries during calendar year 2001, June 2006). OIG also learned that IDTFs did not always comply with their initial enrollment applications and update requirements (IDTFs are required to inform carriers when they begin to furnish new types of services or change their supervising physicians). OIG recommended that CMS consider performing site visits to monitor compliance with IDTFs' enrollment applications and subsequent updates should funding become available. In response, CMS stated that it lacked the funds to require Medicare carriers to conduct site visits to monitor IDTF compliance and that it instead planned to propose business standards for these providers.

The IDTF business standards proposed by CMS are modeled on Medicare's standards for durable medical equipment suppliers. Examples of the requirements include:

- Maintaining a comprehensive liability insurance policy
- Agreeing to not directly solicit patients
- Maintaining a primary phone number and address
- Using testing equipment that is calibrated per equipment instructions and in compliance with national standards
- Ensuring that technical staff with appropriate credentials are on duty.

In our March 2005 Report to the Congress, we described rapid growth in imaging services paid under the physician fee schedule, quality problems with at least some imaging providers, and the lack of quality oversight for imaging tests provided in non-hospital settings. Consequently, the Commission recommended that the Congress direct the Secretary to set quality standards for providers who bill Medicare for performing and/or interpreting diagnostic imaging studies. We also recommended that, to reduce the burden on CMS, the Secretary should select private sector organizations to administer the standards. We encouraged CMS to set standards in at least the following areas: the imaging equipment, qualification of technicians, qualifications and responsibilities of the supervising and interpreting physicians, quality of the images produced, and patient safety procedures.

Our recommendations apply to imaging providers in all settings, but we encourage CMS to move forward with strengthening quality standards for IDTFs. About 85 percent of Medicare payments for IDTFs in 2002 were for imaging services (MedPAC, A data book: Healthcare spending and the Medicare program, June 2004). We support CMS's proposal to improve IDTF standards related to testing equipment and technical staff, and we urge the agency to go further by adopting standards for image quality, patient safety procedures, and the qualifications of physicians who interpret studies performed in IDTFs

(the professional component). CMS should also explore opportunities to set quality standards for imaging services performed in physician offices. To the extent necessary, CMS should pursue statutory authority to adopt such standards. We recognize that CMS has limited resources to enforce IDTF standards. Thus, the agency should consider authorizing private accreditation organizations to verify that IDTFs meet CMS's quality requirements for imaging. Private plans often rely on accreditation programs to certify that their imaging providers meet quality standards.

Clinical diagnostic lab tests

In the proposed rule, CMS seeks input on requiring laboratories to submit the clinical results of tests that they perform on the claims they make for payment. Steps toward this new requirement should begin now.

Currently, the administrative data derived from claims can only indicate whether a particular test has been performed. For example, current administrative data can indicate whether a diabetic patients' hemoglobin A1c (HbA1c) level has been tested. By performing the test, the physician is adhering to the evidence base that indicates this test is important for diabetic patients. Conducting the test, however, is only means to an end: in this case, the goal is to lower patients' HbA1c levels to a healthy level. Though the process of conducting the test is necessary to determine whether control has been achieved, strong evidence shows that actually achieving the intermediate outcome of controlling the HbA1c level leads to the best ultimate outcomes, namely, decreased mortality and morbidity among patients with diabetes.

Many private sector performance measurement systems have moved away from measuring whether the test has been done to measuring whether control has been achieved. For example, the Integrated Healthcare Association's physician pay for performance program included measures for testing diabetic patients' HbA1c and low-density lipoprotein (LDL) in their first year and introduced measures of control of HbA1c and LDL in their second and subsequent years. The Bridges to Excellence physician recognition program also has indicators of both testing and control in its physician quality measurement program. Measures of HbA1c and LDL control are also included in Medicare's physician voluntary reporting program (PVRP).

Requiring labs to report clinical values would allow Medicare's quality measurement to evolve in three ways. First, gathering clinical data from the labs that perform the tests—rather than requiring physicians to collect and report the lab value data—would allow quality measurement efforts to include the substantial number of physicians who would be excluded from measurement because they do not or cannot collect and report clinical lab values. So far, only about 6,000 physicians have participated in Medicare's PVRP which requires lab values. Second, the measures themselves could evolve from process to intermediate outcomes, thus improving the measures by moving them closer toward the goal of measuring whether patients' health is better. Finally, other important measures of control for other clinical conditions—such as the serum albumin level of elders at risk for

malnutrition or the hemoglobin levels for chemotherapy patients who use erythroid growth factors—could be added to the measure set without creating a new data burden on physicians. Reporting laboratory information as part of claims is not without burden. Industry representatives say that clinical and financial systems are often separated; it would take work to link them. It may be difficult to design fields to capture the variety of clinical lab results, including numeric results, codes, and narratives. However, because of the important role this information could play in the evolution of quality measurement, the changes needed to implement this new reporting function for clinical labs should be required as soon as possible.

Conclusion

MedPAC appreciates the opportunity to comment on the important policy proposals crafted by the Secretary and CMS. The Commission also values the ongoing cooperation and collaboration between CMS and MedPAC staff on technical policy issues. We look forward to continuing this productive relationship.

If you have any questions, or require clarification of our comments, please feel free to contact Mark Miller, MedPAC's Executive Director.

Sincerely,

Glenn M. Hackbarth, J.D.
Chairman

GMH/aw/w

Submitter : **Mrs. Michelle Major** **Date: 10/10/2006**

Organization : **Community Healthcare System**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-881-Attach-1.DOC

CMS-1321-P-881-Attach-2.DOC

#881-1

Community Healthcare System

Community Foundation Of Northwest Indiana, Inc.

Community Hospita
St. Catherine Hospita
St. Mary Medical Cente

October 6, 2006

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

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

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

New Technology APCs

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

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

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

CY 2002

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

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

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

In the November 30, 2001 Federal Register CMS also indicated that it was planning to adopt a new HCPCS code for fractionated (i.e. staged) radiosurgery procedures, which was introduced in a March 28, 2002 Program Memorandum[3]. While CMS eventually adopted the new HCPCS code - G0251 - this code did not specify that it be used only for image-guided treatment with robotics. (The descriptor for this code was "linear accelerator-based stereotactic radiosurgery,

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[1] Federal Register, November 30, 2001, page 59865.
[2] Federal Register, November 30, 2001, page 59866.
[3] CMS Program Memorandum A-02-026, 2002 Update of the Hospital Outpatient Prospective Payment System (OPPS), March 28, 2002.

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

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

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

CY 2003

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

CY 2004

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

CY 2005

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[4] Federal Register November 30, 2001, page 59868

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

CY 2006

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

Proposed CY 2007 APC Changes

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

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

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

1. The proposed APC classifications and rates are based on claims submitted in Calendar Years 2004 and 2005, before the CyberKnife® (the only true image-guided robotic stereotactic radiosurgery system on the market) was used in any substantial way for clinical purposes in the United States. In the beginning of CY 2004, there were only twelve (12) operational CyberKnife centers in the United States, with eight (8) of these

centers (67%) beginning operations during the calendar year and submitting claims to CMS for less than a full year.

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

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

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

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

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

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

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

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

Historical Precedent – Gamma Knife New Technology Codes

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

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

CY 2004 and CY 2005 Data Variability Summary

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

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

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

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

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

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

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

Conclusion

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

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

Recommendations

►No changes should be made in the APCs or payment rates for G0339 (APC 1528) and G0340 (APC 1525) for CY 2007.

►CMS continue to work with CyberKnife centers to establish accurate and adequate reimbursement for image-guided robotic stereotactic radiosurgery (r-SRS).

Sincerely,

Name / Title
Affiliation
Address, City, State Zip
Phone / email address

#881-2

Community Healthcare System

Community Foundation Of Northwest Indiana, Inc.

Community Hospital
St. Catherine Hospital
St. Mary Medical Center

October 6, 2006

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

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

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

New Technology APCs

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

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

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

CY 2002

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

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

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

In the November 30, 2001 Federal Register CMS also indicated that it was planning to adopt a new HCPCS code for fractionated (i.e. staged) radiosurgery procedures, which was introduced in a March 28, 2002 Program Memorandum[3]. While CMS eventually adopted the new HCPCS code - G0251 - this code did not specify that it be used only for image-guided treatment with robotics. (The descriptor for this code was "linear accelerator-based stereotactic radiosurgery,

[1] Federal Register, November 30, 2001, page 59865.
[2] Federal Register, November 30, 2001, page 59866.
[3] CMS Program Memorandum A-02-026, 2002 Update of the Hospital Outpatient Prospective Payment System (OPPS), March 28, 2002.

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

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

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

CY 2003

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

CY 2004

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

CY 2005

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[4] Federal Register November 30, 2001, page 59868

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

CY 2006

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

Proposed CY 2007 APC Changes

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

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

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

1. The proposed APC classifications and rates are based on claims submitted in Calendar Years 2004 and 2005, before the CyberKnife® (the only true image-guided robotic stereotactic radiosurgery system on the market) was used in any substantial way for clinical purposes in the United States. In the beginning of CY 2004, there were only twelve (12) operational CyberKnife centers in the United States, with eight (8) of these

centers (67%) beginning operations during the calendar year and submitting claims to CMS for less than a full year.

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

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

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

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

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

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

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

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

Historical Precedent - Gamma Knife New Technology Codes

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

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

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

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Conclusion

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

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

Recommendations

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►CMS continue to work with CyberKnife centers to establish accurate and adequate reimbursement for image-guided robotic stereotactic radiosurgery (r-SRS).

Sincerely,

Name / Title
Affiliation
Address, City, State Zip
Phone / email address

Submitter : Dr. Linda Trapkin **Date:** 10/10/2006

Organization : NYS Society of Pathologists

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1321-P-882-Attach-1.WPD

#882

Date: October 10, 2006

To: Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

From: New York State Society of Pathologists
PO Box 85
Solvay, NY 13209
www.nysspath.org
info@nysspath.org

Re: Comments on the Revision to Payment Policies Under the Physician Fee schedule for Calendar Year 2007

The New York State Society of Pathologists (NYSSPath) 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). NYSSPath is a professional society of pathologists who practice medicine in the State of New York. Our members perform a variety of services that are reimbursed under the physician fee schedule; thus, our members will be significantly affected by the changes in the Proposed Rule. NYSSPath'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

NYSSPath 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, NYSSPath 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, NYSSPath is supportive of the changes that CMS is making, but we are aware of additional helpful proposals to clarify or more closely define the requirements set out by CMS, as well as to address the issue of part-time employees.

Changes to the Reassignment Rule

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

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

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

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

NYSSPath's 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; however, NYSSPath does not oppose an anti-markup provision for the PC, similar to the requirements for the purchase of the Technical Component (TC), to protect against other abuses by ordering physicians billing for diagnostic testing.

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

  NYSSPath's 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. NYSSPath 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. NYSSPath 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

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

NYSSPath 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. **** 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. **** would strongly support this approach. These are more fully described in the comments of the American Clinical Laboratory Association, so they need not be repeated in detail here. Basically, if a pathologist arrangement did not meet this requirement, then the group practice would not be able to bill for pathology services that it refers to the pathologist. We believe that such a provision would limit restructuring that might be anticipated in response to the proposed changes in the contractor reassignment rules.

INDEPENDENT LAB BILLING

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

*NYSSPath 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,

Linda J. Trapkin, DO, FCAP
President, New York State Society of Pathologists
October 10, 2006

Submitter : Latinkic M. Mitchell **Date:** 10/10/2006

Organization : Proton Therapy Consortia

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-883-Attach-1.PDF

#883

PROTON THERAPY CONSORTIA

Loma Linda University Medical Center • Massachusetts General Hospital • The University of Texas M.D. Anderson Cancer Center • University of Florida Health Science Center • The Midwest Proton Radiotherapy Institute at Indiana University • University of Pennsylvania Medical Center/The Children's Hospital of Philadelphia • Arthur G. James Cancer Hospital/Ohio State University •Hampton University Proton Therapy Institute •Northern Illinois University

September 26, 2006

Hon. Mark B. McClellan, M.D., PhD.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8011 and 8014
Baltimore, MD 21244

RE: Hospital Outpatient Prospective Payment System Calendar Year 2007 Rulemaking, Code CMS-1506-P; and Physician Fee Schedule and Practice Expense Rulemaking, Code CMS-1512-PN: Proton Therapy

Dear Dr. McClellan:

We fully support the Proposed Calendar Year 2007 (CY'07) Hospital Outpatient Prospective Payment System (OPPS) Payment Rates for proton beam therapy, which are noted below.

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

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

As you know, the National Payment rates for proton therapy delivered in the Hospital Outpatient Hospital Department (HOPD) setting are determined based upon submitted claims and cost data received by CMS from centers delivering proton therapy in the United States.

Rate setting is a challenging and difficult task. We appreciate the diligence with which you have set the CY'07 proposed payment rates for proton therapy.

Freestanding Proton Therapy Centers

The Proton Therapy Consortia (Consortia) is concerned with the proposed treatment of the Freestanding Proton Therapy Centers by the Centers for Medicare and Medicaid Services (CMS) contracted Carriers in the State of Texas, Florida and Indiana. Contracted Carriers deviate significantly from the CMS National policy concerning proton beam therapy used to establish the existing payment rates as noted above for CY'06 and CY'07.

For Freestanding Proton Therapy Centers, CMS has given its contracted Carriers significant latitude with limited guidance from which to determine payment rates for proton therapy. As each State has its own Carrier, significant variations in payment rate determinations are occurring by State, as noted below.

Comparison of Freestanding Centers' Proton Therapy Rates by State			
	Indiana – Current	**Florida – Proposed 9/11/06**	**Texas – 9/1/06**
77520	-	$750.63	$652.75
77522	$516.36	$776.90	$653.90
77523	$782.43	$806.93	$783.79
77525	$782.43	$900.76	$954.41

Source: Indiana data provided by MPRI, as of September 29, 2006
University of Florida Health Sciences Center, as of September 11, 2006
TrailBlazer Health Enterprises, LLC provided to The University of Texas M.D. Anderson Cancer Center on September 1, 2006

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

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

Rationale for HOPD and Freestanding Payment Consistency: Capital Resources and Operating Costs

A typical proton beam therapy center will consist of 2-6 treatment rooms of which most include rotating gantry structures. Each gantry weighs in excess of 100 tons and is capable of rotating 360 degrees around the patient so as to deliver the proton beam therapy with sub-millimeter precision. Each facility requires up to $125 million and more than three years to develop.

A proton beam therapy center can be open up to 16 hours each day and employs radiation oncologists, physicists, nurses, medical dosimetrists, therapists and technical personnel.

For comparison, a typical conventional radiation therapy center, with 1-2 treatment vaults to accommodate a linear accelerator, gamma knife or cyber knife, will take 8-12 months to construct and prepare for clinical use. Capital requirements are between $4 and $6 million. Operating ramp-up for a conventional radiation therapy facility will usually require 2-3 months, or less in some instances.

It should be noted that due to the capital cost of proton therapy, both Freestanding and HOPD centers have similar costs for patient treatments.

Practice Expense Relative Unit Value

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

PROTON THERAPY CONSORTIA

Loma Linda University Medical Center • Massachusetts General Hospital • The University of Texas M.D. Anderson Cancer Center • University of Florida Health Science Center • The Midwest Proton Radiotherapy Institute at Indiana University • University of Pennsylvania Medical Center/The Children's Hospital of Philadelphia • Arthur G. James Cancer Hospital/Ohio State University •Hampton University Proton Therapy Institute •Northern Illinois University

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Proton Therapy Consortia

Proton beam therapy has been used in the clinical setting for more then 20 years, and employed in the hospital setting since 1990 to treat cancer patients (see Appendix 1 and 2). Positive clinical results from the use of proton beam therapy have stimulated worldwide interest in the clinical applications of proton beam therapy.

The Consortia consists of a group of premier cancer treatment centers in the United States that offer, or are in the process of building the capacity to offer, proton beam therapy. Members of the Consortia include nine institutions and contain both HOPDs and Freestanding centers, including:

Centers in Operations and Treating Patients:

- Loma Linda University Medical Center (October 1990): HOPD
- Massachusetts General Hospital (November 2001): HOPD
- Midwest Proton Radiotherapy Institute of Indiana University (February 2004): Freestanding
- The University of Texas M. D. Anderson Proton Therapy Center (May 2006): Freestanding
- The University of Florida Health Science Center (August 2006): Freestanding

Centers Currently Under Development:

- University of Pennsylvania Medical Center (planning stages): HOPD
- Arthur G. James Hospital / Ohio State University (planning stages): Freestanding
- Hampton University Proton Therapy Institute (planning stages): Freestanding
- Northern Illinois University (planning stages): Freestanding

Conclusion

Currently, over 40,000 patients have been treated with protons in many institutions around the world. In spite of the proven effectiveness of proton beam therapy, the development of a clinical proton beam therapy center is still challenged with the complexity, size and cost of the necessary equipment and physical facility.

Proton beam therapy is in an early stage of clinical adoption and the required equipment is significantly more expensive to purchase and maintain than standard radiation treatment equipment, which is a relatively more mature technology and has a large installed base and widespread clinical acceptance.

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

We strongly urge CMS to direct its Carriers on matters concerning proton therapy medical coverage and payment so that Carrier determinations regarding proton therapy payment rates for Freestanding centers are made in a consistent manner with those currently in effect for HOPDs.

As always, please feel free to call upon us at (713) 563-2314 if you have any questions or if we can provided further data that can assist CMS's rule making.

Sincerely,

M. Mitchell Latinkic
Division Administrator
Division of Radiation Oncology
The University of Texas
M. D. Anderson Cancer Center

Allan Thornton, M.D.
Medical Director
Midwest Proton Radiotherapy Institute
at Indiana University

Appendix 1

UNDERSTANDING PROTON BEAM THERAPY

Principles of Radiation Oncology

The beneficial aspects of all forms of radiation oncology result from ionization. Because of ionization, radiation damages DNA within the cells. Damaging the DNA destroys specific cell functions. While both normal and cancerous cells go through a repair process, the ability of cancer cells to repair after injury is frequently inferior. As a result, higher levels of ionization in cancer cells will ensure that they sustain more permanent damage and subsequent cell death, minimizing ionization to normal cells will allow them to repair and survive. This selective cell destruction is the objective of all sound cancer therapies.

Increased Effectiveness and Utilization

Physicians have looked for ways to use radiation to treat cancer since the discovery of x-rays by Wilhelm Roentgen and radioactivity by Marie and Pierre Curie 100 years ago. Advances in technology and a better understanding of its effects on the body have made radiation therapy an important part of cancer treatment.
The first proposal for the medical use of protons was made in 1946 in a paper by physicist, Robert Wilson, Ph.D. By 1954, proton beams from a high-energy physics research accelerator were first used to treat humans.

Over the last decade, radiation therapy has grown in its utilization as a result of early detection and cancer awareness programs. With greater emphasis placed on organ preservation, quality of life and productivity, the role of radiation oncology is expected to increase.

In fact, according to the American Cancer Society, about half of all people with cancer will receive radiation during their cancer treatment.

Objectives of Radiation Therapy

The classic intent of radiation oncology is to deliver ionizing radiation only to diseased tissue. In practice, this ideal is compromised; normal tissue is always included in the radiation fields. The tolerance of the normal tissue in those fields often determines the dose the radiation oncologist can deliver; the resulting dose is frequently insufficient to control the cancer.

Radiation oncologists seek the lowest rate of side effects and complications as possible, consistent with the attempt to achieve the best possible local and local/regional cancer control. Complications include disability, disfigurement, dysfunction, and even death.

Conventional Radiation Therapy Constraints

Radiation therapy requires delivery of photons and electrons into the body in total doses sufficient to ensure that enough ionization events occur to damage all of the cancer cells.

Unlike protons, photons lack charge and mass, thus most of their energy is deposited in normal tissue near the body's surface, as they travel through tissue, and beyond the targeted cancer. This undesirable pattern of energy placement results in unnecessary damage to healthy tissues.

Attempting to overcome the inherent characteristics of photons and electrons, radiation oncologists employ multi-field treatment delivery arrangements to build up the tumor dose and spare as much of the normal tissue as possible by restricting the dose in those tissues to a tolerable level.

Rationale for Proton Beam Therapy

Protons, unlike photons or electrons, are energized to specific velocities. These energies determine how deeply in the body protons will deposit their maximum energy. The precise stopping point of protons in the body is where the highest radiation dose is released; this is called the Bragg Peak. Protons' favorable absorption characteristics result from their charge and heavy mass, which is 1,835 times that of an electron. These factors allow the physician to predict and control their depth of travel within the patient. The heavy mass of protons results in minimal travel deviation, which reduces unwanted side effects and improves treatment benefit.

Appendix 2

MAJOR COMPONENTS OF A PROTON BEAM THERAPY SYSTEM

A proton beam therapy treatment center consists of a number of distinct technical components. All of the components are based on an established accelerator, medical physics, control systems and software technologies. The proton beam treatment center typically consists of a separate building or designated space to house all of the proton beam therapy equipment coupled with up to four distinct patient treatment rooms.

Accelerator: High energy proton beams are generated by a synchrotron or cyclotron accelerator, a compact particle accelerator that accelerates protons that can be reduced to variable energies in the range from 70 to 250 MeV. The accelerator consists of a ring of magnet(s) having a circumference length of approximately 23 meters that constrains the protons to travel in a circumscribed path inside a high vacuum chamber. Accelerated protons are extracted into the beam transport line, which directs the proton beam to the patient treatment room.

Beam transport line: The proton beam travels through the beam transport system inside a vacuum tube. The beam transport line consists of a series of bending and focusing magnets, which control the beam's focus and position as it travels to the patient treatment rooms.

Rotating gantry treatment rooms: Gantries are massive rotating steel structures that support the bending and focusing magnets, vacuum system, nozzle, and all equipment necessary for controlling and monitoring patient treatment. This complex structure, three floors in height, weigh in excess of 100 tons and rotate 360 degrees around the patient with sub-millimeter precision. The gantry is rotated to prescribe angles around the patient, thus directing the proton beam toward the tumor from different directions. In this manner, multiple portals (or beam entry points) can be used during a treatment session while keeping the patient in a fixed position.

Horizontal, fixed-beam treatment room(s): A fixed, horizontal, non-moveable beam transport and delivery system and an adjustable patient treatment couch or chair are used for large-field treatments, including treatments of prostate, and head and neck cancers. A small-field treatment system is specially designed to treat tumors of the eye.

Treatment delivery nozzle: In each of the patient treatment rooms, a nozzle is located at the terminus of each beam line. The nozzle contains devices that shape, focus and direct the proton beam to the precise configuration of the involved area specified by each patient's treatment plan, thereby allowing three-dimensional conformal treatment to the exact tumor volume. Advanced nozzle designs include magnets that sweep a pencil-beam of protons through the tumor volume, while varying the intensity of the beam or the speed of the sweeping pattern. This advanced form of treatment, called intensity modulation, will offer the optimum radiation treatment for cancer.

Patient positioning system: The patient positioning system includes digitally controlled platforms that hold the patient in a secure treatment position and moves the patient to the exact position required for treatment. Advanced imaging systems provide necessary data for movement corrections that position patient's cancer in the treatment beam to within sub-millimeter accuracy.

Treatment control and safety systems: The treatment control system is a fully integrated hardware and software system that monitors and controls all aspects of beam production, transport and delivery. The control system includes monitoring devices and diagnostics software that provide rapid problem identification and error reporting. Additional software displays the patient's treatment field, setup information, patient-specific treatment device information, and real time monitoring and reporting of the delivered dose. The safety system operates independently of the control system. It has both software and hardware systems that monitor all of the critical elements of beam delivery.

Treatment planning, record-and-verify, and interface software: In addition to the foregoing, treatment planning, information and image management software systems and workstations are needed to integrate with the facility control system.

Development Period: The full proton beam therapy treatment system requires an extensive period of time to install, test and commission prior to first patient treatment. The building, up to approximately 85,000 square feet in size, needed to house the proton beam therapy hardware and software takes approximately 12 months to complete before equipment can be installed. Approximately 24 months, if not more, are required to install and commission the proton accelerator, beam transport lines and gantries, to install and integrate the software systems, and to finish, test and commission the resulting integrated system to clinical specifications.

Submitter : **Mrs. Laura Cline** **Date: 10/10/2006**

Organization : **TAP Pharmaceutical Products Inc.**

Category : **Drug Industry**

Issue Areas/Comments

Background

Background

GENERAL

GENERAL

Please find attached a pdf file of TAP's 2007 Proposed Physician Fee Schedule Comments.
If you have questions please call Laura Cline 410-280-9726.

Impact

Impact

Provisions of the Proposed Rule

Provisions of the Proposed Rule

CMS-1321-P-884-Attach-1.PDF

Submitter : **Mrs. Laura Cline** **Date: 10/10/2006**

Organization : **TAP Pharmaceutical Products Inc.**

Category : **Drug Industry**

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CMS-1321-P-884-Attach-1.PDF

#884

October 10, 2006

Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert 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): ASP Issues

Dear Administrator McClellan:

TAP Pharmaceutical Products Inc. ("TAP" or the "company") appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' ("CMS" or the "agency") proposed rule regarding the physician fee schedule for fiscal year 2007 (the "Proposed Rule").[1] TAP is one of the nation's leading pharmaceutical companies and is committed to delivering high quality pharmaceutical products for patients. The company provides innovative and effective products in diversified treatment areas, including oncology, gastroenterology, and gynecology.

We fully endorse the comments submitted by the Pharmaceutical Research and Manufacturers of America (PhRMA) on behalf of the pharmaceutical industry. While TAP appreciates CMS' effort to provide additional guidance on the proper calculation of average sales price (ASP), which is utilized to set provider payment rates, there are certain issues in the Proposed Rule that we believe require further consideration to ensure that Medicare beneficiary access to important therapies is not jeopardized.

First, we ask that CMS reconsider its revision to the bona fide service fee guidance, and specify that fees paid to non-purchasers, and in particular group purchasing organizations (GPOs), not be considered in the ASP calculation. Next, we request that CMS specify in its final rule that the proposed estimation methodology for lagged ASP-ineligible sales need only be used to estimate and remove sales to ASP-ineligible possession-taking entities, and

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

that sales to ASP-ineligible entities that do not take possession need not be removed from the ASP calculation. Finally, with respect to the use of the 5% threshold for purposes of comparing ASP with average manufacturer price (AMP) and widely available market price (WAMP), we write to bring to CMS' attention certain flaws we see in the Office of Inspector General's (OIG) methodology for comparing ASP to AMP. We discuss each of these issues in more detail below.

I. Service Fees Paid to Non-Purchasers, Such As GPOs, Should Not Be Considered In The ASP Calculation.

In the preamble to the Proposed Rule, CMS purports to "clarify" that service fees paid to GPOs and pharmacy benefit managers (PBMs) are subject to the same bona fide service fee standard as that applicable to other distributors.[2] TAP strongly opposes this proposition because the ASP calculation is defined by statute as a measure of average "purchaser" price, and GPOs are not purchasers. As a practical matter, the application of the bona fide service fee definition to GPOs also would prove untenable, as that definition would require a manufacturer to prove that the GPO fees it pays are not passed on by the GPO to its members and manufacturers typically have no knowledge of whether such downstream fee sharing occurs.

The ASP statute defines the ASP calculation as including "the manufacturer's sales to all purchasers," with specified exceptions.[3] GPOs negotiate discount arrangements with vendors, such as pharmaceutical manufacturers, so that their members, typically hospitals and physician groups, can access those discounted prices. Significantly, GPOs in general do not themselves purchase products. These entities simply negotiate contracts with vendors, and it is the GPO's provider members that purchase the products. The inclusion in ASP of a fee paid to a non-purchaser will distort ASP by including a "discount" that was not provided to a purchaser of product. That is likely to result in lower provider reimbursement rates, which in turn could adversely affect patient access to needed treatments.

Even in situations in which a GPO passes on some portion of the fee to its members, as determined by the GPO's own contractual arrangement with its members, CMS should not consider the fee paid by the manufacturer as a discount to the GPO members. The GPO is free to allocate the fee it receives from a manufacturer in any way it sees fit; the manufacturer has no control over, and typically no knowledge of, how the GPO ultimately utilizes or distributes these fees. [4]

As mentioned above, CMS has also specified that administrative fees paid to PBMs are also subject to the bona fide service fee standard. To the extent PBMs do not take title

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2 Id. at 49,001.

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

4 This same analysis is applicable in the situation where a GPO is owned by its members and provides its members with some type of dividend. As in the above situation, the manufacturer has no control or knowledge of the GPO's arrangements with its members. Moreover, in this situation, any dividend paid likely would be based on factors other than the amount of fees received, such as the GPO's profitability and cost base.

to product, and, like GPOs, are not purchasers, TAP asks that CMS specify that service fees paid to PBMs not be considered in the ASP calculation. If CMS considers PBMs to be purchasers, TAP further requests guidance on whether administrative fees paid to PBMs that are not connected with the PBM's actual procurement of products are considered discounts unless the bona fide service fee standard is satisfied.

II. CMS Should Specify That Manufacturers Need Not Remove Units From The ASP Calculation Associated With ASP-Ineligible Entities That Do Not Take Possession.

TAP generally supports CMS' attempt in the proposed rule to promote a uniform methodology for the estimation of lagged ineligible sales. The proposed estimation methodology, however, does not distinguish between ASP-ineligible entities that do and do not take possession of product. The ASP statute can be read to provide that sales that are exempt from best price are also exempt from the ASP calculation.[5] Importantly, those ASP-ineligible entities identified by statute include both possession-taking purchasers, such as the Veterans Administration, and non-possession taking payers, such as Part D plans.[6] TAP urges CMS to clarify that the proposed estimation methodology for lagged ineligible sales does not need to be applied to ASP-ineligible entities that do not take possession of product, but rather act as reimbursers only.

As noted above, the statutory definition of ASP is stated in terms of measuring an average price to ASP-eligible purchasing entities. With this as the definition, it should follow that the only transactions that are to be removed from the ASP calculation are those involving ASP-ineligible entities that are purchasers. The inclusion in the lagged estimation methodology of ASP-ineligible entities that are not purchasers will have the result of removing units that initially were sold by the manufacturer (directly or indirectly) to an ASP-eligible entity that is a possession taker. In the case of Part D utilization, for example, the units subject to that utilization in general are units that the manufacturer originally sold to a wholesaler or retail pharmacy, both of which are ASP-eligible entities. The removal of the Part D utilization from the ASP calculation (through their inclusion in the lagged ineligible sales estimation methodology) will have the distorting result of removing units that were purchased by an ASP-eligible entity. Accordingly, TAP urges CMS to specify in the final rule that the estimation methodology for lagged ineligible sales is not to be applied to transactions involving ASP-ineligible entities that do not purchase and take possession of product.

III. The System Utilized By The OIG To Calculate Volume-Weighted AMPs To Compare To Volume-Weighted ASPs Requires Refinement.

Under the ASP statute, the OIG is required to compare the ASPs submitted for drugs and biologicals with their WAMP and AMP.[7] Where the ASP for a drug exceeds the WAMP or AMP of the drug by a specified percentage (proposed to be 5%), the Secretary may

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5 SSA § 1847A(c)(1).
6 Id. § 1927(c)(1)(C).
7 SSA § 1847A(d)(2).

disregard the ASP for the drug and substitute either the WAMP or 103% of AMP as the provider payment rate.[8] We appreciate CMS' recognition that there are "a number of operational issues" associated with the Secretary's authority to substitute a lower payment rate for drugs in these instances.[9] We commend CMS for recognizing the importance of "timing, stabilization of ASP reporting, ... and the accuracy of ASP and AMP data."[10] TAP echoes those concerns, and would like to bring to CMS' attention a problem with the method utilized by the OIG to compare ASPs with AMPs.

As you know, CMS develops a reimbursement rate for a given Healthcare Common Procedure Coding System (HCPCS) codes by generating a volume-weighted average of the ASPs for all NDCs in the code. When a manufacturer submits its ASP for a particular NDC to CMS, therefore, CMS also requires the manufacturer to submit the volume of ASP-eligible units sold in the quarter, to facilitate CMS' performance of the weighted averaging calculation. In contrast, no such weighted averaging is required in relation to AMP figures, and therefore manufacturers currently have no requirement to submit AMP-eligible unit data with their quarterly AMP submission. In order to properly compare a code's weighted average ASP and AMP figures, however, the AMP data also must also be weighted by some measure.

The method utilized by the OIG to compare weighted average ASP and AMP figures for a given HCPCS code uses ASP-eligible units to volume-weight the AMP figures, because the OIG does not have access to AMP-eligible unit data.[11] TAP recognizes that the OIG necessarily had to weight the AMP figures using ASP-eligible units for this reason, but is concerned that this approach could yield inaccurate results. ASP and AMP are generated using distinct subsets of sales data, with the sales data used to generate AMP in general being a smaller pool because of its limitation to retail entities. The use of ASP-eligible sales units to create a weighted average AMP is inappropriate because it does not weight the AMP figures in a code using the sales volumes that actually generated the AMP figures themselves.

To address this issue, TAP asks that CMS and the OIG give manufacturers the option of providing AMP-eligible units data when this analysis is performed so that the volume-weighted AMP can be calculated using both AMP-eligible sales data as well as ASP-eligible sales data. Moreover, where a manufacturer does agree to supply AMP-eligible units data, TAP urges CMS to specify that it will not substitute a product's payment rate based on the AMP comparison unless *both* the volume-weighted AMP calculated with ASP-eligible sales and the volume-weighted AMP calculated with AMP-eligible sales exceed the threshold percentage established by CMS. The OIG itself has recognized that the ASP to AMP comparison yields

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8 Id. § 1847A(d).

9 71 Fed. Reg. 49,004.

10 See Comparison of Fourth Quarter 2005 Average Sales Prices to Average Manufacturer Prices: Impact on Medicare Reimbursement for Second Quarter 2006, OEI-03-06-00370 (July 2006); Monitoring Medicare Part B Drug Prices: A Comparison of Average Sales Prices to Average Manufacturer Prices, OEI-03-04-00430. p. 18.

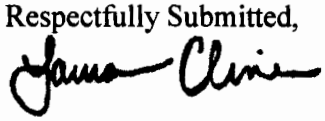
11 Id.

different results depending upon the method utilized to calculate the volume-weighted ASPs and AMPs.[12] We appreciate CMS recognizing the importance of accurate ASP and AMP data reporting, and encourage the agency to consider these issues before making a change to provider payment rates, which could affect beneficiary access to treatments. This can best be accomplished by requiring that the threshold percentage be met utilizing both of the methods discussed. TAP urges CMS to adopt this approach in its final rule.

* * * * *

TAP appreciates the opportunity to comment on these important issues, and we look forward to working with CMS to ensure that beneficiaries have continued access to critical treatments. We sincerely hope that the agency will give thoughtful consideration to our comments and will incorporate our suggestions in the final rule. Please contact Laura Cline at 410-280-9726 if you have any questions regarding our comments or need any additional information.

Respectfully Submitted,



Laura Cline
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[12] Monitoring Medicare Part B Drug Prices: A Comparison of Average Sales Prices to Average Manufacturer Prices, OEI-03-04-00430.

Submitter : Dr. Smith **Date:** 10/10/2006

Organization : Dr. Smith

Category : Physician

Issue Areas/Comments

Background

Background

Making the proposed revisions will negatively impact the ability for Medicare patients to have access to quality care and state of the art treatments.

GENERAL

GENERAL

The application of endovenous laser ablation of the greater saphenous vein has resulted in excellent clinical success in the treatment of symptomatic lower extremity varicose veins and associated sequalae. With these proposed cuts, the access to these procedures for Medicare patients would be severely limited and would adversely affect the access to a highly effective therapy. Any cuts on the reimbursement of these procedures would jeopardize the future treatment of these patients.

Submitter : **Mr. Dave Mason** **Date: 10/10/2006**

Organization : **American Physical Therapy Association**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-886-Attach-1.PDF

#886

APTA
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CSM 2007:
Combined Sections Meeting
February 14-18, 2007
Boston, Massachusetts

PT 2007:
The Annual Conference
& Exposition of the
American Physical Therapy
Association
June 27-30
Denver, Colorado

October 10, 2006

Mark McClellan, MD, PhD
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

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

Dear Doctor McClellan:

On behalf of our 67,000 member physical therapists, physical therapist assistants, and students of physical therapy, the American Physical Therapy Association is pleased to submit comments on the Center for Medicare and Medicaid Services (CMS) Proposed Notice regarding "Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B," published in the August 22, 2006 Federal Register. Outpatient physical therapy services are billed under the physician fee schedule in all settings, and thus this rule has a significant impact on physical therapists.

Revisions to Payments for Therapy Services (p.48997)

In the proposed rule, CMS states that effective January 1, 2007 the statutory financial limits on therapy benefits will remain in effect, but without the exceptions process currently in place as authorized by the Deficit Reduction Act of 2006. The dollar amount of the therapy caps in 2007 will be the 2006 rate ($1740) increased by the percentage increase in the Medicare Economic Index (MEI) (rounded to the nearest multiple of $10).

APTA is deeply concerned about the negative impact that implementation of the financial limitations on therapy services without the extension of the exceptions process will have on Medicare beneficiaries needing therapy services. As CMS is aware, the AdvanceMed study published in November 2004 indicated that in 2002 14.5% of patients would exceed the physical therapy cap. Once exceeded, if there is no exceptions process in place beneficiaries will not receive services that are medically necessary unless they seek treatment from hospital outpatient departments or pay out-of-pocket for their care. As a result, the cap can be expected to have a significant

detrimental effect on beneficiaries needing rehabilitation services and could lead to complications, ultimately resulting in greater costs to the Medicare program. We recognize that it will take Congressional action to provide additional statutory authority and prevent the implementation of the therapy caps, and we continue to strongly urge Congress to take timely action to pass legislation that would repeal the therapy cap or extend the exceptions process if repeal is not feasible.

APTA commends you on the significant amount of work that CMS has conducted over the past few years in an effort to identify an alternative to the therapy cap. We strongly believe that therapy care should be based on the needs of the patient, not governed by an arbitrary financial limit. We urge CMS to place a high priority in resources and funding on continuing to conduct research that could be used to identify alternatives to the cap that would ensure that patients receive medically necessary therapy services. This research is a key factor in identifying more clinically appropriate ways to control the growth in Medicare spending.

In its June 2006 report to Congress, the Medicare Payment Advisory Commission (MedPAC) made specific recommendations regarding the direction CMS should take to reform the payment system. We encourage CMS to pursue MedPAC's recommendations with regard to research. Specifically, MedPAC states CMS should consider ways to reform the payment system and comments that before CMS considers changing Medicare's method of paying for therapy services, it needs more information about therapy users and their outcomes. MedPAC states that this would require CMS to design patient assessment tools that gather risk factor information and outcomes measures. CMS also would need to develop valid risk adjusters to account for differences in patients so that CMS can make valid comparisons of patient's outcomes.

One way for CMS to test its selection of patient assessment tools recommended by MedPAC would be to conduct pilot studies. These pilots would test the feasibility of assessment instruments for patients in various outpatient settings. At the completion of these studies CMS would be able to evaluate which tools work for which types of patients and settings. When more compete information about therapy users is available through these tools, CMS can consider how to appropriately reform the payment system.

In addition to MedPAC, the Government Accountability Office (GAO) published a report in November 2005 (GA0-06-59) in which they recommended that DHHS "expedite development of a process for ensuring that these services were considered in its efforts to standardize existing patient assessment instruments."

While we recognize that you face many important priorities in allocating limited funds for research and pilot projects, we believe that few would have as direct and immediate impact on beneficiaries as finding an appropriate alternative to the therapy cap. APTA strongly urges CMS to conduct these pilot studies so that the arbitrary cap can be removed and a new payment system can be developed that ensures the needs of the patients are met through the delivery of high quality care. We look forward to providing input and assistance as you proceed with these studies and the development of alternatives to the therapy cap.

Medicare Payment Rate for 2007: SGR methodology

APTA is also alarmed at the potential impact of the 5.1% reduction in payment that CMS is predicting for 2007. As CMS is aware, the "sustainable growth rate" (SGR) is a seriously flawed formula that will continue to result in significant, unsustainable payment cuts in the future. These cuts are forecasted to continue, totaling about 37 percent or more by 2015, while the practice costs faced by physical therapists and other providers continue to rise.

The potential impact of SGR cuts are magnified this year when combined with the proposed budget neutrality adjustment in the 5 year review rule. The combination of these adjustments would result in a cut in payments of around 10% for physical therapists and even more significant cuts for many other health care professionals in 2007. APTA is deeply troubled that these cuts will significantly hinder the ability of physicians to care for their patients and of physical therapists to care for Medicare beneficiaries needing rehabilitation services.

These proposed cuts undermine the goal of Congress and CMS to create a Medicare payment system that preserves patient access and achieves greater quality of care. If health care professionals experience significant and compounding cuts in payment at a time of rising practice costs, access to care for millions of elderly and disabled will be jeopardized.

Clearly, a new formula that bases updates on the increases in the cost of delivering health care services is needed. We recognize that it will be necessary for Congress to act to change the formula. However, until a new formula is adopted CMS should assist Congress in resolving the SGR problem by taking administrative actions that would reduce the size of the projected cuts.

To reduce the cost of an SGR solution, CMS should remove spending on physician-administered drugs from calculations of the SGR, retroactive to 1996. Drugs should not be considered physician services and therefore should not be included in the physician SGR pool. In addition, when establishing the SGR spending target, we urge CMS to take into account regulatory changes, such as national coverage decisions, that result in increases in spending. When the impact of the regulatory changes are not taken into account, the cost of the new benefits and program changes are financed by cuts in payments to physicians, physical therapists, and other health care professionals.

Payment for Splint and Cast Supplies

CMS proposes to allow separate payment using HCPCS Q-codes for certain medically necessary splint and cast supplies. This would allow payment for medically necessary splint and case supplies used for serial casing, wound care, or other interventions. CMS clarifies that practitioners would continue to bill the HCPCS Q-codes, in addition to the cast/strapping application procedure codes, to be paid for these materials. In the rule CMS specifies the supplies that would be paid separately and identifies the CPT codes that do not include splint and cast supplies in the practice expenses.

APTA commends CMS's decision to allow separate payment for the splint and cast supplies identified in the rule. It is important to allow payment for these and other medically necessary supplies.

Proposed Changes to Physician Self-Referral Rules Relating to Diagnostic tests

In the rule, CMS proposes changes related to the Stark II self-referral rules for diagnostic tests. CMS expresses concern about the existence of certain arrangements that are not within the intended purpose of the self-referral rules that allow physician group practices to bill for services furnished by a contractor physician in a "centralized building." They are also concerned that allowing physician group practices or other suppliers to purchase or otherwise contract for the provision of diagnostic tests and then realize a profit when billing Medicare may lead to patient and program abuse in the form of overutilization. We are pleased that CMS is revising its regulations to prevent arrangements that result in abusive practices.

Although CMS is addressing self-referral in the context of diagnostic tests in this rule, we would also like to highlight another physician ownership issue that CMS and the federal government should address. In the past few years, there has been significant increase in physician ownership in entities that provide physical therapy services. The physicians with a financial interest refer their patients to these entities for physical therapy services, creating an incentive for potentially abusive practices. APTA has seen a number of advertisements urging physicians to add a physical therapy clinic to their practice to make huge profits.

Situations in which physicians receive compensation as a result of referring for, prescribing, or recommending physical therapy services create serious potential for abuse. The purpose of the Stark II law was to discourage financial incentives from influencing the delivery of care. Therefore, APTA strongly urges CMS to create and implement regulatory measures to discourage physician self-referral of physical therapy services. We believe that this can be achieved by strengthening the physician self-referral (Stark) laws, specifically, by making revisions to the "in-office ancillary" exception. Physician self-referral creates a potential conflict of interest and must be avoided to protect patients and the overall healthcare system.

The APTA appreciates the opportunity to offer these comments to CMS. We look forward to working with you on these issues in the future.

Sincerely,

G. David Mason
Vice President, Government Affairs

Submitter : Dr. John Coster **Date:** 10/10/2006

Organization : National Association of Chain Drug Stores

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-887-Attach-1.DOC

#887

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

October 10, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P
Mail Stop C4-26-05
7500 Security Blvd
Baltimore, MD 21244-1859

Subject: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule for CY 2007 and Other Changes to Payment Under Part B; Proposed Rule

To Whom it May Concern:

The National Association of Chain Drug Stores (NACDS) is writing to provide comments on the proposed physician fee schedule regulation that includes proposed changes to the ASP-based reimbursement system for Medicare Part B drugs, including those provided by retail pharmacies. NACDS represents 188 chain pharmacy companies operating almost 35,000 community retail pharmacies. Our industry is the primary provider of outpatient pharmacy services in the United States, providing about 70 percent of all retail prescriptions. We are also providers of Medicare Part B drugs to Medicare beneficiaries.

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In summary, the lack of proposed increase in supplying fees or dispensing fees to be paid in 2007 may ultimately underpay pharmacies for their total cost of purchasing the drug and supplying or dispensing these Medicare Part B drugs. The lack of increase fails to take into account the increasing costs to pharmacies to supply Medicare Part B drugs, as well as the continued unique higher administrative burdens for pharmacies filling Part B prescriptions as compared to other third party prescriptions. If pharmacies' costs are not covered, Medicare beneficiaries may see a reduction in their ability to obtain Part B drugs from community retail pharmacy based suppliers without an increase in these fees.

Proposed Part B Rule Does Not Increase Supplying or Dispensing Fees for Part B Drugs

NACDS strongly urges that Part B drug supplying and dispensing fees be increased for 2007. The proposed rule does not do this. Administrative costs to pharmacies to participate in Part B remain costly and burdensome, while pharmacists and pharmacy-related salaries continue to increase.

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The use of ASP as a reimbursement method for retail pharmacies is problematic because ASP reflects manufacturer's revenues from sales to all pharmaceutical "classes of trade", including the rebates, discounts, and price concessions made available to those purchasers. However, retail pharmacies do not have access to the same discounts and other price concessions as other purchasers, such as hospitals, nursing homes and HMOs. This places retail pharmacies at a disadvantage compared to other purchasers, since the ASP for a product, inclusive of the 6 percent add on, may reimburse pharmacies at an amount lower than their costs of acquisition. ASP is retrospectively determined and therefore based on pricing information that is out of date by several months. As a result, pharmacies may have to absorb any manufacturer price increases for covered Part B drugs that occur before the ASP is updated.

For 2006, Part B supplying fees are set at $24 for the first Part B drug prescription in a month and $16 for each additional Part B drug prescription in a month. (The first prescription for an immunosuppressive is $50). In theory, the supplying fees set by CMS in 2006 were to pay pharmacies for the supplying costs and the additional administrative costs of participating in Medicare Part B. However in reality, these higher fees may have been necessary to compensate retail pharmacies in many cases for the underpayments for drugs under the ASP-based system.

CMS has taken steps over the past few years to reduce administrative burdens on pharmacies by eliminating the Assignment of Benefits (AOB) form and the DIF form for immunosuppressive drugs. However, there seems to be inconsistent interpretations among the DME MACs about how these new policies should be applied. Even with these changes, it still generally costs retail pharmacies significantly more to bill Medicare claims than other third party prescription claims because of cumbersome Medicare billing requirements. This leads to many Part B drug claims being rejected due to administrative errors. Also, several claims are never paid because the pharmacies cannot obtain the full or proper information. The bottom line is that pharmacies have significant unpaid claims in Medicare as compared to other third party plans whose claims are adjudicated online, in real-time. Thus, the amount of the supplying fee established by CMS is critical to ensuring that pharmacies are compensated for ASP-based product reimbursement that may be below their costs, and to compensate for Medicare Part B's unusually burdensome billing requirements.

Depending on the extent of their Part B business, many of our members have to hire additional personnel just to handle the extra burden of preparing Part B claims for submission to the DME MACs. A traditional third party prescription claim will have significantly less administrative tasks regarding its submission for payment. In addition, the pharmacy will know instantly whether or not the claim is adjudicated, and the amount that the pharmacy will be paid. That is not the case with Medicare Part B claims, which, even though electronically submitted in batch form through the NCPDP 1.1 standard, are not adjudicated real-time.

Each group of Part B drugs has different coverage and billing issues that must be resolved before the pharmacy can submit a "clean" claim to the DMERC. The extent of the additional time involved depends on the category of drug and the willingness of the physician to work with the pharmacy to obtain the information necessary for billing.

Transplant drugs tend to have the highest administrative costs, but the pharmacist must also check that the other oral drugs covered under Part B (i.e., anticancer drugs and antiemetic drugs) are being used for an indication that is covered under Part B. This requires that the pharmacist spend additional time working with the physician's office to obtain the appropriate information necessary to appropriately bill Medicare Part B.

Even after "clean claims" are submitted to the DMERC, Medicare Part B has a higher rejection rate than traditional third party prescription plans because of the lack on an online claims adjudication system. As a result, pharmacies incur a significant amount of "bad debt" in Medicare Part B as compared to other third parties, which must be reflected in the supplying fee amount paid. If just a single pharmacy or supplier claim for an expensive Part B drug is rejected by the DME MACs or eventually unpaid, it could eliminate or sharply reduce any margin that the pharmacy might earn on Part B prescriptions. This requires additional administrative tasks by the pharmacy to resubmit the claim to Medicare, even though they thought they were submitting a clean claim. Some of the rejections for these clean claims are due to the fact that the DME MACs still have issues with converting NDC codes for drugs to HCPCS codes.

Medicare Part B takes more time to pay pharmacies than traditional third party payers, tying up the pharmacies' cash flow for a longer period of time. This is especially true in regards to very expensive immunosuppressive drugs. Because of the higher number of rejects in Medicare Part B and the longer time it takes to pay Medicare claims on average, a pharmacy may have dispensed several expensive Part B drugs to a Medicare beneficiary before the pharmacy would even know if they were going to be paid for the initial Part B claim submitted.

At the pharmacy counter, the lack of a real-time claims adjudication system means that the pharmacy does not know whether the beneficiary is eligible for Part B or has met their annual Part B deductible. While this is primarily an issue at the beginning of each calendar year, the pharmacist should check the deductible status for each new beneficiary that seeks to have a prescription filled. The pharmacy must contact the DME MAC by phone and wait to get a response before the pharmacist can proceed with filling the prescription.

Pharmacies have the additional costs of needing to contract with a separate billing entity – other than the standard third party billing contractor – to convert Medicare Part B claims from an NCPDP format to an ANSI X837 format so they can batch bill the DME MACs. This factor, in and of itself, requires that Medicare Part B pay pharmacies a significantly higher supplying fee to maintain beneficiary access to these Part B products. The cost of installing and maintaining these systems are expensive. According to Mercer Consulting, the average hourly wage of a pharmacist increased by 8 percent to $46.01 from May 2005 to May 2006.

For these reasons, the agency should consider an increase in this fee to keep pace with inflation, additional administrative burdens, and escalating pharmacist salaries. We suggest at a minimum, that the supplying for all Part B drugs (other than the first immunosuppressive) be increased to $24 per prescription, inflated by the medical care component of the consumer price index for 2007, or be increased consistent with the increase in pharmacist salaries. CMS recognizes that costs have increased to suppliers over the past year because it is increasing the clotting factor furnishing fee by 4.2 percent for CY 2007.

Few businesses have seen a decrease in operating costs over the past year, so CMS needs to consider appropriate adjustments to its own fees to at least allow providers to keep pace with inflationary costs.

Moreover, CMS should periodically conduct its own comprehensive cost of dispensing study so that it can accurately reset the supplying and dispensing fees as the cost of providing Part B drugs and services changes in the market.

We also urge CMS to increase the fee paid for filling the initial-supplied prescription in the first month after a transplant, which is currently $50. In addition to all the paperwork involved in appropriately filling and billing this first prescription, there is also a higher level of intensity of monitoring services provided by pharmacies in the first several months after a transplant. This is critical to the successful transplantation of the organ, for which Medicare has invested tens of thousands of dollars. These added payments to pharmacies for the critical services provided can help ensure the success of a transplant.

Specifically, the additional administrative issues for retail pharmacy with the Medicare Part B program include: requiring pharmacies to obtain an actual hard copy of the prescription before billing the DME MAC; requiring that the "date of service" be the same as the "date of filling," requiring a Certificate of Medicare Necessity (CMN) for certain prescriptions; requiring testing logs for diabetic testing strips; rejection on early refills for diabetic testing strips; and inconsistent policies among the DME MACs.

Requirement that Actual Written Prescription be Obtained before Billing

Community pharmacies customarily dispense prescription medications and seek reimbursement from health plans after receiving either an oral prescription from a physician's office or a written prescription. In cases of both oral and written prescriptions, there are procedures in place to verify the validity of the prescription. The widespread acceptance of oral prescriptions is evidenced by the fact that private third party prescription drug plans as well as Medicare Part D plans allow pharmacies to dispense a prescription to a patient and subsequently seek reimbursement based on a legitimate oral prescription from a physician.

Nevertheless, pharmacies are not permitted to seek reimbursement from Medicare Part B based on oral prescriptions. A pharmacy may fill and dispense a Part B oral prescription, but a written prescription must be obtained from the prescribing physician before a request for payment can be submitted. This requirement places an unnecessary burden on both community pharmacies and physicians. It provides no additional protection against fraud and abuse, yet it requires pharmacists, physicians, and their staff to take time away from their patients merely to obtain a hard copy of a prescription for a medication that has probably already been dispensed.

Requirement that "Date of Service" be the same as the "Date of Fill"

Medicare Part B program's policy regarding "date of service" is similarly out of step with Part D plans and other third party prescription plans.

Often community pharmacies fill a prescription – "date of filling the prescription" – on a different date than the day a patient picks up the prescription – "date of service." This is particularly common with prescription refills, when patients use automated telephone numbers and other retail pharmacy customer service options to order a prescription in advance and pick it up at their convenience. All other third party plans recognize the frequency of this practice, and allow pharmacies to consider the "date of service" as the "date of filling the prescription."

In contrast, CMS requires under Part B that the "date of service" be the actual date that the product was dispensed to the beneficiary. This policy results in inconvenience for Medicare beneficiaries, and inefficiency and additional costs for pharmacies. Typically the pharmacist has no choice but to wait until the Medicare beneficiary arrives to fill the prescription, requiring the patient to wait to receive a prescription that otherwise could have been filled in advance.

In cases where a pharmacist may have filled a prescription in advance only to have the beneficiary arrive to pick up the prescription a day or two later, the pharmacist has to reverse the claim for the prescription filled previously, and refill it on the day the patient arrives. This is a costly and labor intensive process for the pharmacist. Moreover, Medicare allows other entities to consider the "date of fill" to be the "date of service." This includes mail order pharmacies, but not retail pharmacies.

Requirements to Maintain Testing Logs for Diabetic Test Strips

Many Medicare beneficiaries rely on community pharmacies for durable medical equipment (DME) in addition to prescription drugs and services. Diabetic testing supplies is an example of DME products that are usually obtained from retail pharmacies. Since frequency of testing varies by patient, quantity of testing strips needed over a thirty day period also varies. In order to justify the dispensing of certain quantities of testing strips, CMS requires Medicare beneficiaries to maintain a testing log. Furthermore, these testing logs in some cases must be submitted to CMS in order to receive a greater supply of testing strips. This is extremely burdensome for both beneficiaries and pharmacies. Medicare patients with diabetes work closely with their physicians, pharmacists, and others to manage their condition and determine the appropriate testing regimen. Complying with testing is critical to maintain good health in diabetic patients and avoid severe complications such as blindness and amputation. Placing additional requirements on patients may reduce access to diabetic testing supplies, resulting in diabetes complications and increased health care costs.

Eliminate Certificate of Medical Necessity for Certain Prescriptions

Physicians that administer immunosuppressive drugs for Medicare patients need to provide Part B with a Certificate of Medical Necessity (CMN). Pharmacies are also required to obtain a CMN from the prescribing physician, even though they already have a prescription, a policy that is clearly duplicative. Since the CMN includes a diagnosis code that is not on the prescription, in order to be reimbursed, a pharmacy must contact the prescribing physician's office to obtain additional information.

This is an example of another Medicare Part B policy that prevents pharmacies from fully utilizing their technical processing capabilities and instead requiring them to revert back to time consuming telephone calls to physicians' offices, a burden to both the pharmacy and physician's office. Allowing prescriptions to serve as sufficient documentation and forgoing the requirement of a CMN from pharmacies would significantly reduce the administrative workload for pharmacies serving Medicare patients.

Rejection of Immunosuppressant Claims

CMS eliminated the policy requiring submission of Durable Medical Equipment Regional Centers Information Forms (DIFs) in order to receive reimbursement for immunosuppressive prescriptions. (Medicare only covers these drugs for a Medicare-covered transplant.) NACDS supported the elimination of this DIF form. However, DME MACs now have no way to determine if an organ transplant was covered by Medicare. Claims that pharmacies submit for reimbursement for immunosuppressive drugs are being rejected. Pharmacies are therefore forced to wait for the hospital that performed the transplant to file the appropriate paperwork. Once the hospital has submitted its claim to Medicare, the pharmacy must submit its claim that was originally rejected and then file an appeal. This is a laborious process, which requires pharmacies to remain in constant contact with the DME MACs, in order to determine if the hospital has submitted its claim for the transplant.

This situation, which may take months to resolve, results in additional work and expense for the pharmacy, but also difficulties for Medicare beneficiaries who have recently undergone a transplant. During this process it is likely that the patient has needed several prescription refills for immunosuppressive medication. Either the pharmacy must bear the cost of dispensing several prescriptions for these costly medications without reimbursement, or the patient must pay for the medications out of pocket and later seek to be reimbursed by Medicare. This is an unnecessary and unfair burden on pharmacies and patients.

Rejection of Early Refills of Diabetic Testing Supplies

In working with their physician, pharmacist, or other diabetes educator, Medicare beneficiaries with diabetes may undergo changes to their therapy. For example, changes in condition may require a patient to begin testing their blood glucose more frequently. Consequently, a Medicare beneficiary would need to obtain a refill on diabetic supplies such as test strips earlier than initially planned. Despite the fact that a more rigorous testing regimen has likely been instituted to avoid a negative health outcome, Medicare Part B will not pay for an early refill of diabetic testing supplies. Medicare beneficiaries are forced to pay out of pocket for an early refill of diabetic testing supplies, even if they provide a prescription and testing logs and evidence of the need for additional supplies. All other third party payers recognize that changes in therapy occur, and make allowances for early refills of supplies in appropriate situations – a patient is not denied a medication or DME product. Nevertheless, this Medicare Part B policy requires beneficiaries to either pay for these supplies out of pocket or ignore the changes in their therapy recommended by their physician.

Inconsistent Policies Among Durable Medical Equipment Medicare Administrative Contractors

CMS contracts with private sector entities - Durable Medical Equipment Medicare Administrative Contractors (DME MACs) - to perform various administrative functions for the Part B drug and DME benefit. There are four DME MACs, and each is responsible for handling the claims for a specific region of the country. There is no uniformity of policies between DME MACs, which makes submitting claims for pharmacies very difficult. For example, one DME MAC may require certain documentation for submitting a claim for reimbursement, while another DME MAC may have an entirely different requirement.

This problem is compounded by the fact that unlike private third party payers and Medicare Part D plans, Medicare Part B claims are not processed online. A pharmacy bills a DME MAC based on the patient's primary billing address. For pharmacies that operate in more than one DME MAC region this is particularly complex. In these cases a pharmacy would have to follow different requirements for reimbursement depending on the address of the patient. A requirement by CMS for consistent policies across DME MACs would simplify and streamline processing Medicare claims for pharmacies and beneficiaries.

Fees Not Considered Price Concessions

NACDS supports the proposal to modify the current regulation found at 414.804 that would exclude "bona fide service fees" from the price concessions that a manufacturer has to deduct when calculating its ASP for a drug. While CMS has issued guidance on this matter, we see the value and wisdom in codifying the fact that bona fide service fees should be omitted from the calculation of ASP.

With respect to the definition of "bona fide service fees," the proposed rule would clarify that beginning with the ASP reporting for sales during the first calendar quarter of 2007, bona fide service fees that are paid to an entity, whether or not the entity takes title to the drug, are not considered price concessions in so far as, and to the extent that, they satisfy the definition of bona fide service fee being proposed under the regulation. These would include fees paid by a manufacturer to an entity that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in or whole or in part to clients or customers of an entity, whether or not the entity takes title to the drug.

CMS would further propose that fees, including service fees paid to GPOs or PBMs, are not considered price concessions insofar as, and to the extent that, they satisfy the definition of bona fide service fee. CMS is also seeking comments on the specific types of services that entities perform on behalf of manufacturers that would qualify as bona fide service fees, as well as comments on potential additional guidance on methods for determining the "fair market value" of these services.

NACDS strongly supports the proposal that bona fide service fees should be excluded from the calculation of ASP, especially where these fees are not ultimately passed through to the product's ultimate purchaser. Based on current law, ASP should represent the average price paid by pharmaceutical purchasers (with certain exceptions) for covered Part B drugs. A bona fide service fee pays for a bona fide service, so it does not reduce its cost of purchasing the drug. However, if these price concessions are deducted from the ASP, it could reduce the ASP further below the purchaser's costs for the drugs. Therefore, price concessions or discounts that do not decrease the actual purchaser's market price for the drug should not be deducted from the ASP.

NACDS does not support an attempt to list specific bona fide service fees. The market should be allowed to evolve regarding the services needed to assure that manufacturers can get their drugs to the market. This will allow for future flexibility and innovations to occur in a highly competitive marketplace. Manufacturers rely on wholesalers and others to perform various functions to allow their products to come to market in a safe and effective manner. A significant number of new biological products are likely to come to market over the next few years. For that reason, it is unclear as to what types of new services will be needed to be performed by wholesalers and chain pharmacy warehouses on behalf of manufacturers to ensure that their products get to the ultimate purchaser for dispensing or administration to the ultimate user.

In this regard, we recommend that the preamble to the final rule (but not the rule itself) provide an overview (but not an exclusive list) of the types of payments for bona fide service fees that would be acceptable for exclusion from the ASP calculation at this time, but allow for manufacturers and contracting entities to make future interpretations based on the needs of the marketplace. We do not believe that future guidance or rulemaking should be required for the purpose of adding to this list. Use of a "updated list" may actually reduce the level of innovation and could actually impede the delivery of new products to patients.

As an example of legitimate bona fide service fees, we would recommend that payments made by manufacturers to entities such as wholesalers and pharmacies for inventory management agreements or distribution service agreements, should not be deducted from a manufacturer's sales when calculating ASP. These payments do not lower the cost of purchasing prescription drugs. Moreover, not all purchasers are able to participate in these agreements, so deducting them when calculating ASP would be unfair to some smaller purchasers.

In addition, there are certain payments made by manufacturers to plans and purchasers that should not be deducted from the ASP because they reflect concessions relating to the "time value of money" or payments for services performed by the pharmacy on behalf of the manufacturer. These payments are not discounts or rebates off the actual drug product. These include PBM rebates, customary prompt pay discounts, payments for pharmaceutical returns, and payments for patient care programs.

Omit Customary Prompt Pay Cash Discounts Extended to Wholesalers

ASP should be calculated consistent with that of Average Manufacturers Price (AMP) as modified under the Deficit Reduction Act of 2005. To achieve this, we recommend that in the final rule, CMS instruct manufacturers to omit customary prompt pay discounts from the calculation of ASP, including those extended to wholesalers and chain warehouses. Like wholesalers, chain pharmacy warehouses take possession of drugs from manufacturers in larger quantities for distribution to potentially thousands of individual chain drug store outlets. There are costs associated with the distribution of these drugs from the warehouses to the individual pharmacies.

Thus, the ASP should be reflective of the cost to the chain pharmacy of getting the drug distributed to the individual end user pharmacy, which would argue that prompt pay discounts extended to chain drug warehouses should also be omitted from the calculation of ASP, not just those extended to wholesalers. In addition, because not all purchasers have the distribution infrastructure (i.e. warehousing and logistical capabilities) and cash flow to capitalize on these more favorable terms, the inclusion of prompt pay cash discounts in the calculation of ASP would be inappropriate.

Omit Rebates paid by Manufacturers to PBMs

Today most prescriptions are paid for through a third party entity – such as a PBM – that receives rebates and discounts from pharmaceutical companies. Manufacturers should not deduct these amounts when calculating the ASP because community pharmacies do not receive these rebates. These are generally received by the plan or program sponsor, not the dispensing pharmacy or physician. Including PBMs' sales and discounts unfairly lowers the ASP, making it unreflective of sales to purchasers.

Omit Manufacturer Payments for Pharmaceutical Returns and Related Service Fees

Payments for expired and recalled pharmaceuticals and the associated services should not be interpreted as discounts or rebates and should be omitted from the ASP. Each year, billions of dollars in expired and recalled pharmaceuticals must be returned by pharmacies and wholesalers to manufacturers. Manufacturers issue credit to wholesalers and pharmacies for these goods. Unfortunately, the level of credit provided is insufficient to cover the products' replacement value, the pharmacy's inventory cost of carrying the product to expiration, the reverse logistics cost of returning the expired and recalled product, as well as the administrative expense incurred by wholesalers and pharmacies to manage this process. A manufacturer's payment to a wholesaler or a pharmacy for expired and recalled merchandise as well as the fees for the associated services should be excluded from the manufacturer's ASP calculation. If these payments and service fees are included in the ASP calculation, community pharmacies will actually incur not only the deficiency in the level of manufacturer's credit for the product and service, but also a reduction in reimbursement going forward for the associated products.

Omit Manufacturer Payments for Patient Care Programs

Pharmacies sometimes receive payments from manufacturers for performing certain patient care programs, such as patient education and compliance and persistency programs. These payments should be omitted from the ASP calculation. These services provide valuable benefits to patients and the health care system because they improve patients' understanding of their medications and enhance patient compliance. They do not reduce the retail pharmacy's cost of purchasing the drugs.

If these payments are included in ASP, pharmacies would not have incentives to offer these programs because it would reduce the value of the ASP, thus potentially reducing reimbursement. This could make it appear that the pharmacy's acquisition cost for the drug is lower than it actually is. Moreover, since not all pharmacies participate in these programs, it would be unfair to include these payments in the ASP.

Estimation Methodology for Lagged Exempt Sales

NACDS supports the use of a methodology that would establish a uniform approach to estimating price concessions for generics that are available on a lagged basis. Use of a rolling average approach will help ensure that there is some consistency in ASP amounts, and thus reimbursements paid to purchasers, including pharmacies. Without such smoothing, it is very possible that upper limits for generics could be based on AMPs that are simply not reflective of the current market prices for drugs, further reducing generic dispensing incentives.

We appreciate the opportunity to submit comments on these issues. Please contact us if we can provide further information. Thank you.

Sincerely,

John M. Coster

John M. Coster, Ph.D., R.Ph.
Vice President, Policy and Programs

Submitter : **Dr. Richard Bennett** **Date: 10/10/2006**

Organization : **UCLA**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-888-Attach-1.DOC

#888

UCLA Medical Plaza

Dermatology Center
Mohs Micrographic Surgery
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To: Centers for Medicare & Medicaid Services (CMS) via electronic submission at http://www.cms.hhs.gov/eRulemaking

From: Richard Bennett, MD, St. Johns Medical Plaza, 1301 20th Street, Suite 570, Santa Monica, CA 90404-2053

Date: October 10, 2006

Re: Independent Diagnostic Testing Facilities (IDTF) issues
File code CMS-1321-P

I would like to comment on the IDTF issues published in the Federal Register pp. 49054-49062. As chairman of the Slide Review Committee of the American College of Mohs micrographic surgery, I am quite concerned regarding proliferation of insourcing and outsourcing laboratory arrangements in which Mohs Micrographic Surgery (CPT Code 17304-17310) is billed. These arrangements have many features that are reminiscent of the arrangements described relating to IDTF. Also of note is that the increased use of Mohs codes parallels the IDTF issues, especially in California. The Federal Register did not mention Florida related to the IDTF issues partially because the number of Medicare beneficiaries is increasing faster there than in California, but I believe Florida is another state where IDTF's are evolving.

Mohs micrographic surgery is a technique for removing skin cancers. It is billed by CPT codes 17304-17310. The technique is both a surgery and a pathologic method, although the CPT codes are listed under the surgical CPT codes rather than the pathology CPT codes. All training centers for Mohs micrographic surgery must have a dedicated **on-site** laboratory that is CLIA compliant and approved by the American College of Mohs Micrographic Surgery and Cutaneous Oncology. CMS also requires these laboratories to be CLIA compliant and requires the CLIA number for billing. **However, ironically, CLIA does not require a physician to have a physical laboratory or equipment to obtain a CLIA certificate of compliance for a high complexity laboratory**. This oversight has given rise to a proliferation in billing for Mohs micrographic surgery whereby the billing physician in actuality does not have a physical laboratory – that is dedicated space, equipment, or employed personnel. Instead, the technical and sometimes the professional pathology components are outsourced. This outsourcing raises issues of quality patient care.

There are three sets of independent laboratory arrangements that I am aware of that allow billing for Mohs Micrographic Surgery outside of standard Mohs labs.

1. An outside pathologist comes with lab equipment to the physicians office where the Mohs surgery if performed. The surgeon performs the surgery and the pathologist performs the frozen sections. The surgeon may also look at the frozen sections to keep within CPT guidelines. The pathologist is then paid by the surgeon a portion of the fee he or she receives from Medicare for the surgery.

   A worse case scenario for Medicare is where the pathologist bills for frozen sections and the surgeon bills for Mohs surgery. Since there are two different physicians billing for services on the same patient these services may not be computer linked. In this scenario both the physician performing the surgery and the pathologist will be able to receive even more money from Medicare.

2. A second scenario is where the surgeon removes tissue in his or her office, the tissue is sent to a pathologist outside the office, the pathologist performs the technical and professional component of CPT code 88331 (frozen section), then sends the slides back to the office of the surgeon who then performs a cursory reading. In this scenario, both physicians bill Medicare. There is a partial duplication of service (the pathology component). It is unlikely that Medicare would pick this duplicate billing up on their computer as there are two different physicians billing from two different addresses on the same date of service.

3. The third scenario, which is common in California, has a technician with lab equipment come into the physician's office. The technician functions as an outside contractor and is paid a fee. It should be pointed out that Mohs Surgery codes (17304-17310) do not have a technical and professional component associated with the slide preparation. In this scenario the surgeon functions as both pathologist and surgeon. However, note there is no laboratory in the sense that there is dedicated space and equipment in place that would be subject to CLIA inspection. A high complexity CLIA license is given to the physician in the absence of a high complexity laboratory. Here the overhead component of Mohs is less and complexity of cases is less. If a patient has an extensive tumor requiring more than one day for removal, the patient is frequently referred to a more well-equipped office with a Mohs surgery laboratory.

It would be helpful to ensure quality care for Medicare beneficiaries that several of the proposed CMS changes are made for the IDTFs. However, I would stress three points not made in the Federal Register.

1. Unless there is coordination between CLIA and the CMS rules, the rules themselves will be difficult to enforce.
2. Availability of services to beneficiaries may be decreased if the proposed rules are too restrictive, for instance, insisting on too much laboratory space.
3. No mention of standards at HMO's, PPO's, or other treatment centers for Medicare beneficiaries is mentioned. It makes logical sense that if you establish standards to "ensure quality care for Medicare beneficiaries" (p. 4060 Federal Register), then you

should apply the same standards to those entities to which Medicare beneficiaries "reassign" their benefits.

I agree with your 14 "Suppler" Standards discussed in section L2, p. 4061 and 4062. Of particular interest to me are the following:

A. Maintain a dedicated physical laboratory on the appropriate site. There should be enough designated space for equipment, etc. The proposal of 350 sq. feet (p.49057) is difficult to understand. The square footage would vary dependent upon the tests performed. For a frozen section laboratory, a minimum of 120 sq. feet is sufficient.

B. Have all appropriate testing equipment available on the physical site where the work is performed. I agree with this standard. I do not consider "portable" cryostats, as in "mobile Mohs labs," to render the highest quality frozen sections.

C. Have technical staff on duty with the appropriate training to perform tests. If these services are contracted out I do not believe that the quality will overall be as high as where the laboratory director specifically employs the technician. Furthermore, for more difficult and extensive cases, the laboratory must function for more than one day a month. If a patient's skin cancer cannot be totally removed in one day, then the patient should be able to return the next day for continued treatment. Thus your proposal on p. 49057 that the independent contractor will perform services exclusively for the group at least 35 hours per week is in the patient's best interest.

Sincerely,

Richard G. Bennett

Richard G. Bennett, MD
Clinical Professor of Medicine (Dermatology)

Submitter : Dr. Donald Quest **Date:** 10/10/2006

Organization : American Association of Neurological Surgeons

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Please see attached letter from the Presidents of the American Association of Neurological Surgeons and Congress of Neurologicial Surgeons

CMS-1321-P-889-Attach-1.PDF

#889

AMERICAN ASSOCIATION OF
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CONGRESS OF
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President
RICHARD G. ELLENBOGEN, MD
University of Washington
Seattle, Washington

October 10, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8017
Baltimore, Maryland 21244

Attention: CMS-1321-P: Medicare Program; Revisions to the Payment Policies Under the Physician Fee Schedule for Calendar Year 2007

Dear Dr. McClellan:

On behalf of the American Association of Neurological Surgeons (AANS) and Congress of Neurological Surgeons (CNS), we appreciate the opportunity to comment on the above referenced proposed rule published in the *Federal Register* on August 22, 2006. We will focus our comments on two issues: (1) the Sustainable Growth Rate (SRG) and the Budget Neutrality Adjustment and (2) Publication of all RUC-approved RVUs.

Sustainable Growth Rate (SGR) and the Budget Neutrality Adjustment

The proposed announces that physicians face a 5.1 percent payment cut as a result of the SGR formula. Obviously, this reduction in reimbursement is a huge concern to all physicians. However, the 5.1 percent cut is just the tip of the iceberg for neurosurgery. As CMS has noted, the budget neutrality adjustment for the changes in physician work resulting from the five year review work values is not reflected in the impact tables show in the proposed rule. Therefore, real the 2007 impact for neurosurgery and many other specialties is significantly understated and could reach double digits.

The AANS and CNS strongly believe that the only appropriate mechanism for adjusting the fee schedule to comply with the budget neutrality requirements is to adjust to the conversion factor, rather than applying an adjustment to the work relative values.. Implementing the reduction to the conversion factor would not affect the relativity of services, would maintain the integrity of the relative value units for use by other payers, and would make clear that the adjustment is being made for budget neutrality purposes. We, along with the AMA, RUC, American College of Surgeons and many other medical societies, have held this position since the inception of the Medicare Physician Fee Schedule. Furthermore, this approach is consistent with how CMS has made these adjustments in the past. From 1998 to the present time, CMS has made all work neutrality adjustments by adjusting the conversion factor and we believe there is no reasonable case to be made for changing this approach.

Publication of RUC-approved RVUs

The AANS and CNS urge CMS to publish RUC-approved values for all codes, whether or not Medicare covers the services. As the agency knows, many private payors, Medicaid, and workers

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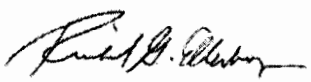
compensation plans determine physician payment based on the Medicare RBRVS. However, the values approved by the RUC are not publicly available until CMS publishes them as part of the Medicare Fee Schedule. CMS has been inconsistent in publishing non-covered values. For example, in Addendum B, CMS includes the values for CPT code 61630 *Balloon angioplasty, intracranial (e.g., atherosclerotic stenosis), percutaneous* and CPT Code 61635 *Transcatheter placement of intravascular stent(s), intracranial (e.g., atherosclerotic stenosis), including balloon angioplasty, if performed.* However, Addendum B does not include the values for CPT Code 61640, *Balloon dilatation of intracranial vasospasm, percutaneous; initial vessel,* CPT Code 61641, *Balloon dilatation of intracranial vasospasm, percutaneous; each additional vessel in the same vascular family,* or CPT Code 61642, *Balloon dilatation of intracranial vasospasm, percutaneous; each additional vessel indifferent* vascular *family.* These codes were passed by the RUC at the same time and we do not understand why the values for some codes are published and not others. We do not see any reason why CMS should not publish these values and request that the agency include RUC-passed values for all of the RUC-passed codes, including the three listed above, in the final fee schedule rule.

Conclusion

Thank you for considering our comments. As we have stated in previous comments, the AANS and CNS appreciate the dedication and hard work of individual CMS staff members. We understand that the work load is particularly onerous this year due to the major revision of the practice expense component of the fee schedule and the publication of the five year review proposed rule. However, we are extremely concerned about the potential payment reductions that will be implemented in 2007. We urge CMS to explore every avenue within its regulatory authority to mitigate these cuts. Most importantly, we feel it is essential that the budget neutrality adjustment to account for the change in work RVUs resulting from the five year review be applied to the conversion factor and not to the relative value units. The ability for neurosurgeons to continue to treat Medicare beneficiaries in the face of increased costs and plummeting reimbursement is rapidly becoming unsustainable.

Sincerely,



Donald O. Quest, MD, President
American Association of Neurological Surgeons

Richard G. Ellenbogen, MD, President
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Submitter : **Date: 10/10/2006**

Organization : **Atlantic Urological Associates**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-890-Attach-1.DOC

#890

Atlantic Urological Associates
545 Health Boulevard
Daytona Beach, Florida

October 10, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services

Re: Comments to Proposed Revision to Physician Fee Schedule for Calendar Year 2007: CMS-1321-P

Dear Dr. McClellan:

The physicians of Atlantic Urological Associates, P.A. appreciate the opportunity to comment on the proposed rule for changes to reassignment and physician self-referral rules relating to diagnostic tests as noted in the revisions to payment policies under the physicians fee schedule for calendar year 2007, as published in the August 22, 2006 *Federal Register*. Specifically, we will comment on the proposed changes to (i) proposed changes to existing physician self-referral rules (the "Self-Referral Rule" or "Stark"), and (ii) existing Medicare reassignment rules (the "Reassignment Rule") (collectively, the Self-Referral Rule and Reassignment Rule as, "Proposed Rules").

It is clear that the premise for these changes is the perception that "pod labs" are abusive arrangements that expose Medicare to risk of program abuse. Risks mentioned include: (i) the generation of medically unnecessary biopsies; (ii) kickbacks; (iii) fee-splitting; and (iv) prohibited self-referrals.

Our group is a urology group consisting of sixteen urologists in east central Florida. We perform our own pathology services using a centralized pathology laboratory, employed technicians and a contracted pathologist. Our laboratory is used exclusively by our group and is equipped with all the necessary technical equipment that is owned and used exclusively by our group.

Our group participated in the 2005 OIG audit outlined in the 2005 OIG Work Plan, looking specifically at in office pathology services, and we provided a plethora of data and specialty literature regarding urologic pathology. We have not received the results of this audit, but do not believe there was anything to suggest kickbacks, fee-splitting, prohibited self- referrals or unnecessary biopsies.

We will limit our comments to address the premise for the proposed changes. Please note that these comments are not made with the help of counsel, but are the views and comments of practicing urologists.

As a urology practice, prostate cancer is one of the most common diseases we diagnose and treat. Diagnosis of prostate cancer involves a biopsy of the prostate, done in the practice setting. The pathologic specimens are obtained and prepared in the office setting. It became a natural extension of the practice to bring the pathologic processing and interpretation of those specimens "in house". However, as the options of doing this were considered, it became abundantly clear that using a centralized office model would be most advantageous to quality of patient care.

The centralized office model allows our contracted pathologist to also be contracted and work for other urology groups and to exclusively do urologic pathology. This is a benefit that we would not be able to achieve if we had the interpretation done "in the same building". This expertise allows our patients the very best quality in urologic pathology, and we believe it surpasses the quality of any other available pathology service. There is copious information to suggest that extensive experience in performing a particular medical task generally improves the quality of the task. Our pathologist is a specialist in urologic pathology, and the centralized laboratory model helps promote that continued quality and specialization.

The provision of this service in our group allows direct and frequent communication between our urologist and pathologist. This type of communication has allowed unmatched patient care. It allows direct input from the specialists with regards to specimen collection and processing, another advantage not obtainable when pathology is not delivered as an extension of the practice. The pathologist has direct and immediate access to the patients' chart to guide his interpretation, yet an additional benefit of providing this service as a part of the practice.

The method of delivery of pathology services that we provide, clearly is done as an extension of our practice, and there are a myriad of patient benefits that derive from that. Delivering this service in a centralized building only further enhances the quality that is delivered.

The model of a centralized pathology laboratory (centralized building) does not lead to potential abuse or overutilization. The quality value of delivering this service as an extension of the practice is important to us. The advent of electronic communication and electronic medical records makes a remote centralized service location no different from one in the same building, except for the improved quality of care delivered using the centralized model. The perceived potential of abuse is not influenced by the size of the office, the time that employees spend in the office, the geographic location of the office, or whether the pathologist is contracted as a member in the group or employed by the group.

We are aware of no data that suggests overutilization. Our statistics show a greater percentage of positive prostate biopsies in our lab compared to the national average. This is concrete data that disproves claims of overutilization that are promulagated by competitors whose interest lies in maintaining their income stream. More positive biopsies mean that only those with a high suspicion of cancer are being biopsied. The corollary is that less biopsies are being done on people with a lower suspicion of cancer, and therefore is a benefit to both the patients and the economics of CMS. Nationally, over the last number of years, the number of biopsies done per patient has increased, based on scientific data showing this increases the accuracy of the biopsy. This increase is not a result of overutilization, but a result of scientific studies and is an increase seen in all practices, not specific to in house labs. Altering the regulations as to where these biopsies are interpreted, would not impact that number.

We would encourage CMS to reevaluate the real differences between the centralized pathology lab and pathology services delivered in the same building, and those delivered outside the practice and consider the benefits to the patients of the former. We would also encourage CMS to reconsider the presumption that the centralized model somehow promotes abuse. It is our belief that we can give our patients the best care for serious cancers utilizing the model described above, without any impact to the integrity or cost of CMS programs.

Thank you,

Michael S. Grable M.D. F.A.C.S.
President
Atlantic Urological Associates

Submitter : Dr. Laurie Young **Date:** 10/10/2006

Organization : Older Women's League

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-891-Attach-1.DOC

#891

OWL

THE VOICE OF MIDLIFE AND OLDER WOMEN

October 10, 2006

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

RE: **Physician Fee Schedule (CMS-1321-P)**

Hospital Outpatient Prospective Payment System (CMS-1506-P)

Dear Administrator McClellan:

In my capacity as the Executive Director of the Older Women's League (OWL), I am writing today to express OWL's concern over proposed Medicare reimbursement cuts to an important breast cancer treatment option – partial breast irradiation. OWL's mission and daily work is focused on improving the status and quality of life of the more than 60 million women age 40 and over in America.

As you know, breast cancer takes an incredible toll on midlife and older women and their families. According to the American Cancer Society, in 2006, over 200,000 new cases of breast cancer are expected to occur among women in the United States, and over 40,000 women are expected to die from the disease. Breast cancer is the most frequently diagnosed cancer in women. Great advances have been made in recent years, but clearly more needs to be done to combat this deadly killer.

Unfortunately, the risk of being diagnosed with breast cancer increases with age. Because of this increasing incidence, women's access to safe, effective, and patient-friendly treatments is extremely important to our constituents. Far too many women diagnosed with breast cancer do not receive the standard of care.

The current standard of care for women with early-stage breast cancer is lumpectomy followed by radiation therapy. Whole breast radiation treatment takes 5-6 weeks, placing great demands upon women's time. According to the National Cancer Institute's 2005 *Cancer Trends Progress Report*, of the 123,000 women who received lumpectomies in 2005, 42,000 did not receive radiation therapy. These statistics are very troubling.

Partial breast irradiation is an easier treatment option that makes it possible for more women to choose to receive radiation therapy. With PBI, the radiation source is placed inside the lumpectomy cavity where the cancer is most likely to recur. This method limits radiation to healthy tissue and other organs such as the lungs and heart, and can be completed in 5 days. This shortened treatment time is particularly helpful to older women who might find it difficult to travel to a radiation treatment facility for a lengthy period of time, or who don't have state of the art cancer facilities in their communities. Most importantly, partial breast irradiation, which

has been in use for over a decade, has demonstrated 5-year recurrence rates comparable to whole breast radiation.

Although we know that the purpose of the proposed rules is not to limit women's access to partial breast irradiation, it is a likely outcome. It is a mystery to us why the patient-friendly method of partial breast irradiation should receive a disproportionate payment cut, while the more invasive procedures of whole breast radiation and mastectomy are slated for very significant increases.

In order to ensure the availability of the widest range of breast cancer treatment options, OWL urges CMS to maintain adequate Medicare reimbursement of partial breast irradiation by not moving forward with the proposed payment cuts included in the recently released Physician Fee Schedule and Outpatient Prospective Payment System rules.

Sincerely,

Laurie Young, Ph.D.
Executive Director

Cc: Leslie Norwalk, Deputy Administrator, CMS
Kathleen Harrington, Director of External Affairs, CMS

Submitter : **Ms. Emily Graham** **Date: 10/10/2006**

Organization : **Alliance of Specialty Medicine**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-892-Attach-1.PDF

#892

Alliance of Specialty Medicine
Sound Policy. Quality Care.

200,000 Physicians Strong

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October 10, 2006

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

Attention: CMS-1321-P

RE: CMS-1321-P: MEDICARE PROGRAM; REVISIONS TO PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE FOR CALENDAR YEAR 2007

Dear Dr. McClellan:

On behalf of the undersigned members of the Alliance of Specialty Medicine, a coalition of 11 medical societies representing more than 200,000 specialty physicians in the United States, we would like to comment on the second part of the proposed rule for 2007 physician payment under the Medicare Program and published in the *Federal Register* on August 22, 2006.

The Alliance was founded in 2001 to serve as a strong voice for specialty medicine. Its mission is to improve access to quality medical care for all Americans through the unified voice of specialty physicians promoting sound federal policy. A fee schedule that adequately and fairly accounts for the costs of furnishing medical services to Medicare beneficiaries indisputably affects access to and the quality of care for our nation's elderly citizens, and thus, is of paramount concern to us.

The Alliance denounces the reduction of -5.1% scheduled for 2007. If not addressed by Congress before the end of this year, physicians of every specialty will have experienced five years of payments that have not begun to keep up with inflation as measured by the medical economic index (MEI). And, the proposed 5.1 percent reduction for 2007 is one of several years of additional cuts projected by the Medicare actuaries. Costs of staff, liability premiums, equipment, etc. continue to increase at rates above general inflation. While physicians may not completely drop out of the Medicare program, they will explore other means to limit their exposure to continuing losses, which in turn may have a negative effect on beneficiary access.

Changes in the Medicare Economic Index (MEI)

The Alliance is very concerned with the additional 0.5 percent reduction of the 2007 physician fee schedule update from -4.6 percent to -5.1 percent. The increase in the cut was caused by a downward revision of the Medicare Economic Index (MEI) which is a measure of annual increases in the cost of operating a private medical practice that is used in the annual update of the physician fee schedule. This reduction was not proposed or even discussed in the proposed rule. Based on the impact table in the proposed rule that shows $75 billion of allowed charges under the physician fee schedule, a -0.5 percent reduction in the update will result in a

$375 million cut in physician payments in 2007. Further, the reduced MEI was based on the use of a new measure of productivity by the Bureau of Labor Statistics (BLS) and lower projections of inflation. Few details were provided and comments on the changes were not requested. Had we been given the opportunity to comment, we would have questioned the use of data that shows increased productivity in a year when the productivity of most physician practices has been reduced significantly by the need to counsel Medicare beneficiaries about the new prescription drug benefit and the availability of preventive services and to comply with the agency's requests related to the Physician Voluntary Reporting Program (PVRP). We urge CMS to delay any changes in the MEI pending publication in the Federal Register of the proposed changes and the solicitation of public comments.

Publishing Relative Value Units (RVUs) for Non-covered Services

The Alliance urges CMS to recognize or publish services for CPT codes that remain non-covered by Medicare. The RUC identified and reviewed 24 CPT codes and CMS accepted the time data for each of these codes as submitted in June 2006. Since many other payers look to CPT codes, we strongly support CMS publishing relative values for all services, regardless of Medicare's coverage policies. It is our understanding that CMS can include a table in the final rule for New and Revised CPT codes.

Budget Neutrality Adjustment

We continue to strongly urge CMS to implement any statutory budget neutrality adjustments through an adjustment to the conversion factor rather than the work values. We are joined by the majority of physician specialties and there is long-established CMS precedent for this approach.

Practice Expense Issues

The Alliance strongly urges CMS to declare its intention to work with the physician community to provide support to the design and implementation of a new, multi-specialty practice expense survey. A well-designed survey conducted every few years will ensure that all specialties are reporting common data elements in a timely and equitable manner.

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The Alliance of Specialty Medicine appreciates the opportunity to comment on these important issues affecting Medicare beneficiaries and the physician community. The undersigned organizations thank CMS for considering our views on the proposed rule. Please do not hesitate to contact Emily Graham, ASCRS Manager of Regulatory Affairs, at egraham@ascrs.org or at 703-591-2220, or Robin Hudson, AUA Manager of Regulatory Affairs, at rhudson@auanet.org or at 410-689-3762 if you have any questions regarding our comments and recommendations.

American Academy of Dermatology Association
American Association of Orthopaedic Surgeons
American Association of Neurological Surgeons
American College of Emergency Physicians
American College of Obstetricians and Gynecologists
American Gastroenterological Association
American Society of Cataract & Refractive Surgery
American Urological Association
Congress of Neurological Surgeons
National Association of Spine Specialists

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

Organization : Astellas Pharma US

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-893-Attach-1.PDF

#893

astellas
Leading Light for Life

October 10, 2006

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

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

Dear Dr. McClellan:

Astellas Pharma US, Inc. ("Astellas") appreciates the opportunity to comment on the Medicare physician fee schedule proposed rule for calendar year 2007 published by the Centers for Medicare and Medicaid Services ("CMS").[1] Astellas is among the top 20 global pharmaceutical companies, with North American product lines that focus on the therapeutic areas of immunology, cardiology, dermatology, infectious disease, and urology. Our drugs and biologicals are used to treat Medicare beneficiaries in a variety of settings, including physician offices.

Astellas understands that CMS faces significant challenges in devising payment systems that encourage physician participation, facilitate beneficiary access to appropriate therapies, and ensure the continued fiscal integrity of the Medicare program. Our comments are designed to assist CMS in balancing these goals, as well as to preserve the incentives for therapeutic innovation that have enhanced Medicare beneficiaries' treatment options. The comments below focus on four key issues, and can be briefly summarized as follows:

(1) Supplying fees for certain Part B drugs, including immunosuppressives. CMS should carefully evaluate the need for increased supplying fees in 2007, and should adopt a mechanism for annually updating supplying fees to account for routine increases in pharmacies' costs.

(2) Physician administration fees and appropriate coding. To help ensure adequate reimbursement for physicians' drug administration services, CMS should instruct its contractors to pay for administration of biological response modifiers using the codes applicable to anti-cancer therapies.

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

(3) Average Sales Price (ASP) issues. CMS should issue guidance that improves the accuracy and efficiency of manufacturers' ASP calculations and ensures that the ASP-based payment system for Part B drugs supports continued beneficiary access to these essential therapies. Specifically, CMS should clarify that "bona fide service fees" include fees for data services; that manufacturers need not seek information on their customers' downstream transactions to determine that a fee qualifies as a bona fide service fee; and that fees to non-purchasers are not "discounts" for ASP purposes. Finally, CMS should adopt rules to ensure that comparisons between ASP, AMP and Widely Available Market Price (WAMP) produce reliable data and do not result in unwarranted payment reductions that jeopardize beneficiary access.

* * *

I. Supplying fees for certain Part B drugs, including immunosuppressive therapies

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") requires CMS to pay a separately billable "supplying fee" to pharmacies for dispensing Part B immunosuppressives and certain other drugs.[2] Currently, pharmacies receive a per-prescription supplying fee of: (1) $24, for the initial prescription filled for a beneficiary in a 30-day period (or $50, for the initial prescription of immunosuppressives supplied during the first month after a transplant); and (2) $16, for additional prescriptions filled for a beneficiary during a 30-day period.[3] CMS has not proposed any changes in these fees for 2007.

Astellas urges CMS to evaluate the adequacy of the existing fees, in light of the costs pharmacies currently incur to perform the range of services necessary to supply these critical medications to Medicare beneficiaries. The proposed rule does not explain the rationale for maintaining the 2006 fee structure, and we believe that a careful review of recent cost information provided by stakeholders is essential to ensure that the supplying fees for 2007 will be sufficient to cover pharmacies' costs and support beneficiary access.

Astellas also is concerned that the regulations set a specific payment amount for these pharmacy services, without a provision for annual fee increases due to ordinary increases in expenses (including labor costs), and will therefore result in deficient Medicare payment for these services over time. Consequently, we request that CMS incorporate a payment adjustment process to ensure that reimbursement to pharmacies for costs incurred in connection with supplying these important therapies remains adequate.

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[2] Social Security Act (SSA) § 1842(o)(6). Specifically, in addition to immunosuppressives, supplying fees also are required for oral anti-cancer chemotherapy drugs and oral anti-emetics. Id.

[3] 42 CFR § 414.1001(a), (b).

II. Physician administration fees and appropriate coding mechanisms

Consistent with its commitment to pay physicians adequately for drug administration services, CMS in 2005 adopted the AMA's revisions to the CPT codes for these services a year earlier than the 2006 effective date of the CPT revisions. Specifically, CMS created a set of G codes that, in part, incorporated the CPT panel recommendation to pay for administration of complex biologicals using the codes applicable to anti-cancer therapies.

Clearly, CMS and its contractors had the authority to interpret these G codes on a product-specific basis at the national or local contractor level. Many contractors did not apply these codes to biological response modifiers. Unfortunately, the various interpretations made by each contractor, for the most part, remain in effect even after the 2006 effective date of the CPT revision. These "policies" have not yet fully or uniformly operationalized the AMA's incorporation of biological response modifiers into the definition of products that fall within the chemotherapy administration codes.

CMS' longstanding policy has been to defer to the AMA on CPT code interpretation. Biological response modifiers clearly fall within the AMA's definition of products eligible for administration under the chemotherapy codes. CMS should therefore instruct its contractors to pay for administration of biological response modifiers under these codes. We suggest that CMS also invite biological manufacturers to provide product information and other guidance to the various contractors that identifies specific complex biologicals as biological response modifiers.

III. ASP Issues

Astellas shares CMS' interest in ensuring that the ASP-based payment system for Part B drugs and biologicals supports Medicare beneficiaries' continued access to appropriate new and established therapies, and we appreciate the Agency's ongoing efforts to improve the accuracy and reliability of ASP calculations. CMS recognized that manufacturers and other stakeholders may not have had sufficient experience with an ASP-based system to provide meaningful comment to the April 6, 2004 ASP interim final rule, and has requested additional comment. Astellas appreciates the additional opportunity for comment on the changes CMS proposes to ASP calculation and reporting.

1. Bona Fide Service Fees

For ASP calculation purposes, bona fide service fees that are paid by a manufacturer to an entity (e.g., distributors, GPOs or PBMs) are not considered price concessions. CMS proposes to define bona fide service fees as those fees "paid by a manufacturer to an entity that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on, in whole or in part, to a client or customer of an entity, whether or not the entity takes title to the drug."

CMS is seeking comment from stakeholders so that it can potentially provide further guidance on a variety of issues including: (1) the types of services that may qualify as bona fide services (which could vary by drug category); (2) the methodology manufacturers must use to determine the fair market value of a bona fide service; and (3) appropriate methods for determining whether a fee is passed on in whole or in part.

Astellas supports CMS' efforts to establish clear guidelines on these issues that will improve the accuracy and consistency of ASP calculations. Appropriate guidelines are also important to help ensure that manufacturers can contract with purchasers for needed services without risk that the fees for those services would constitute a "discount" for purposes of ASP calculation. We would also urge the agency to minimize the reporting burden and confusion that would accompany divergent guidelines between Medicare and Medicaid treatment of bona fide service fees.

Manufacturers frequently purchase data to guide business decisions and evaluate product lines. Some forms of valuable data contain a greater degree of validity if purchased directly from a distributor, wholesaler, PBM, or GPO. Accordingly, Astellas urges CMS to clarify that data services represent bona fide services.

Moreover, Astellas encourages CMS to specify that an administrative fee to a non-purchasing entity is not a price concession for ASP purposes, since it seems anomalous to identify a reportable "discount" without a purchase transaction. We would welcome clear CMS guidance on this issue.

Astellas would agree that a fee arrangement that provided for a downstream price reduction to purchasers should be treated as a discount for ASP calculation purposes. However, we are concerned that the language in the proposed rule stating that a bona fide service fee cannot be "passed on, in whole or in part, to a client or customer of an entity [receiving the fee]" could be misinterpreted as shifting responsibility to manufacturers for a purchaser's future transactions and business decisions. Manufacturers do not, and should not, have a right to demand confidential business information disclosures from their customers. If a manufacturer contracts for a service it needs, pays the contracted fee for the service, and receives the benefit of that service, the service fee should not be considered a discount for ASP purposes. Consequently, we encourage CMS to clarify that manufacturers can properly treat such fees as bona fide service fees for ASP purposes, without requesting information on the fee recipient's intended use of the fees.

2. <u>Widely Available Market Price and AMP Threshold</u>

Under the MMA, CMS may disregard a product's ASP in setting payment levels if the Office of the Inspector General (OIG) determines that the product's ASP exceeds its WAMP or AMP by a threshold determined by HHS. CMS proposes to continue to utilize 5% as the threshold, but expresses concerns regarding the operational issues associated with substituting a lower payment rate for a drug. Specifically, the Agency seeks comment on the timing and

frequency of ASP, AMP, and WAMP comparisons, as well as the effective date and duration of any rate substitution.

Astellas agrees that clear guidelines are needed on the timing of these price comparisons and the duration of any rate substitutions. Given the potential for fluctuations in WAMP, AMP, and ASP within and between quarters, it may be inappropriate to reduce Medicare payment for a product based upon a single quarter of data. We suggest that the data be compared quarterly, but that a determination to substitute a lower payment amount would not be made until the ASP exceeded the WAMP or AMP by the relevant threshold for a CMS-specified number of consecutive quarters. The substituted payment amount would apply until the quarter following the reporting period in which the product's ASP no longer exceeded the WAMP or AMP by the specified threshold.

* * *

We appreciate the opportunity to provide these comments. If you have any questions or require further information, please contact me at (847) 405-1640, or via email Michael.Ruggiero@us.astellas.com.

Sincerely,

Michael J. Ruggiero
Senior Director, Government Policy & External Affairs

Submitter : Dr. Samuel Masket **Date:** 10/10/2006

Organization : Amer. Society of Cataract and Refractive Surgery

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-894-Attach-1.PDF

#894

ASCRS OUTPATIENT OPHTHALMIC SURGERY SOCIETY, INC.

AMERICAN SOCIETY OF CATARACT AND REFRACTIVE SURGERY
OUTPATIENT OPHTHALMIC SURGERY SOCIETY

October 10, 2006

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

Re: Medicare Programs; Revision to Payment Policies to the Physician Fee Schedule for Calendar Year 2007; Proposed Rule

Dear Dr. McClellan:

The American Society of Cataract and Refractive Surgery (ASCRS) is a medical specialty society representing more than 9,500 ophthalmologists in the United States and abroad who share a particular interest in cataract and refractive surgical care. ASCRS members perform the vast majority of cataract procedures done annually in the United States.

The Outpatient Ophthalmic Surgery Society (OOSS) is a professional medical association of more than 1000 ophthalmologists, nurses, and administrators who specialize in providing high-quality ophthalmic surgical procedures performed in cost-effective outpatient environments, including ambulatory surgical centers (ASCs).

ASCRS and OOSS appreciate the opportunity to submit comments on the proposed rule for the 2007 Medicare physician fee schedule.

Sustainable Growth Rate (SGR)

As you know, physicians are faced with a 5.1% reduction in their Medicare payments beginning in 2007 as a result of the flawed SGR formula. The flawed formula is also slated to produce steep negative updates for the next several years. The Centers for Medicare and Medicaid Services (CMS) agrees with the medical community that the SGR formula is unsustainable, yet it takes no action to appropriately address problem areas over which it has control. We have

commented over the past several years about our concerns with the flawed SGR formula and offered realistic solutions for addressing some areas over which the agency has control. To recap, we describe these areas in following paragraphs.

Removal of Physician-Administered Medicare-Covered Drugs Retroactively

We, once again, urge CMS to use its administrative authority to remove drugs from the physician payment pool retroactive to 1996, filling the gap between actual spending and target spending, thereby making it more likely Congress will permanently repeal the SGR.

As we have stated previously, physicians do not have control over the cost of drugs and biologics. Furthermore, Part B drugs are not procedures, diagnostic tests, or services; Part B drugs are only used in conjunction with certain procedures, diagnostic tests, and/or services.

For the past several years, ASCRS and OOSS, as well as numerous other medical and specialty societies, members of the Medicare Payment Advisory Commission (MedPAC) and the Practicing Physicians Advisory Committee (PPAC), the Government Accountability Office (GAO), congressional committees with jurisdiction over the Medicare program, and the majority of Congress, have identified the cost of physician-administered drugs as a primary factor that drives physician spending above the expenditure target. Collectively and independently, these groups have consistently recommended CMS use its administrative authority to remove drugs from the definition of physician services back to the base year, 1996.

Why does the agency continue to believe it does not have the authority to make the necessary adjustments that would drastically reduce the cost of replacing the flawed SGR formula with a stable payment system? There is overwhelming support in favor of making this necessary change, and the agency has the authority to assist Congress in fulfilling its goal of replacing the flawed SGR formula.

Again, there is overwhelming support for CMS to take such action; it is time for the agency to finally act. Therefore, **we urge CMS to use its authority to remove drugs from the physician payment pool retroactive to 1996, filling the gap between actual spending and target spending, thereby making it more likely Congress will permanently repeal the SGR.**

Accurately Accounting for Changes in Law and Regulation

ASCRS and OOSS again urge CMS to accurately account for changes in law and regulation when calculating the physician payment update. Specifically, we urge the agency to ensure that national and local coverage decisions and screening benefits (including the services they generate) that have been added to the Medicare program be included in the expenditure target.

We continue to believe that new coverage decisions—national and local—have an impact on

utilization. Most notable are coverage decisions that require certain diagnostic tests be performed in conjunction with the procedure(s) being addressed by the coverage decision.

We understand that only coverage decisions added to the program by legislation—not by regulation—have been accounted for in the expenditure target. However, we continue to believe that CMS should include all coverage decisions—whether added to the program by statute or by the agency—when calculating the expenditure target.

In our previous comments, we used as an example the national coverage determination (NCD) on ocular photodynamic therapy (OPT) with verteporfin (Visudyne) for age-related macular degeneration (ARMD). This NCD, which was implemented in April 2004, expanded coverage for this type of therapy to beneficiaries with certain diagnoses; however, the coverage decision states that the newly expanded coverage is only allowed "provided certain criteria are met." As a result of the coverage policy created, physicians are required to perform certain diagnostic tests to perform OPT with verteporfin.

Therefore, **CMS is directly responsible for volume increases related to certain services and procedures and must adjust the SGR target accordingly.**

Pay for Performance and Health Information Technology

From the physician's perspective, it seems as though CMS has chosen to ignore the aforementioned concerns and instead highlight its commitment to moving the Medicare program toward becoming a value-based purchaser of health care services, alluding to the fact that linking quality to payment is a way to solve the SGR conundrum. Because CMS continues to view pay for performance as a panacea to the SGR problem, we would like to remind the agency that under the current flawed SGR payment system, pay for performance will not be successful and has the strong potential to increase the volume and intensity of physician services.

At the September 6-7, 2006, MedPAC meeting, Chairman Glenn Hackbarth made the following comments as they relate to the incompatibility of the current SGR formula and pay for performance:

> *The statutory and regulatory changes are, in theory, adjusted for in the target. But there are other changes in health care delivery that would not be captured by those that are desirable...For example, pay-for-performance. There are a lot of areas where there is known under service and quality care requires an increase in the provision of certain sort of services. The [SGR] formula doesn't adjust for those.*

If CMS wishes to see a true pay for performance system succeed, it must do everything within its statutory authority to enable Congress to repeal the SGR and replace it with a payment system that accurately reflects the cost of providing high-quality care to Medicare beneficiaries, such as the Medicare Economic Index (MEI). Furthermore, under the current flawed payment system, it would be difficult for physicians to adopt and maintain health information technology (HIT)

systems. In the proposed notice, CMS supports the adoption of HIT as the agency believes the use of HIT may contribute to improved processes and outcomes of care, including shortened illnesses and the avoidance of adverse drug reactions. Clearly, CMS views HIT as a key component in a successful pay for performance program. However, for the pay for performance program to be successful, CMS must provide incentives to physicians, and under the SGR this is not possible. It is unreasonable for the agency to expect physicians to invest in HIT and participate in pay for performance programs at a time when they are, yet again and in the future, facing steep reductions as a result of the current flawed SGR payment system.

Again, we urge the agency to take immediate action on the following recommendations:

- **Use its authority to remove drugs from the physician payment pool retroactive to 1996, filling the gap between actual spending and target spending, thereby making it more likely Congress will permanently repeal the SGR.**

- **Accurately account for changes in law and regulation when calculating the physician payment update. Specifically, we urge the agency to ensure that national and local coverage decisions and screening benefits (including the services they generate) that have been added to the Medicare program be included in the expenditure target.**

Budget Neutrality

ASCRS and OOSS urge CMS to reconsider its previous proposal to make budget neutrality adjustments to the work RVUs and encourage the agency to apply the budget-neutrality adjustments to the 2007 conversion factor.

Recently, we submitted comments on the five-year review of work relative value units (RVUs) proposed rule. In the rule, CMS proposed to meet its budget-neutrality requirement by reducing all work RVUs by an estimated 10 percent. In our comments on the proposed rule, we strongly urged CMS to apply the budget neutrality adjuster to the physician fee schedule conversion factor, rather than the work RVUs.

We, once again, ask CMS to apply the budget-neutrality adjustments to the 2007 conversion factor, rather than make budget-neutrality adjustments to the work RVUs.

Changes to the Medicare Economic Index (MEI)

We are very concerned with the additional 0.5 percent reduction of the 2007 physician fee schedule update from -4.6 percent to -5.1 percent. The increase in the cut was caused by a downward revision of the Medicare Economic Index (MEI) which is a measure of annual increases in the cost of operating a private medical practice that is used in the annual update of the physician fee schedule. This reduction was not proposed or even discussed in the proposed

rule. Based on the impact table in the proposed rule that shows $75 billion of allowed charges under the physician fee schedule, a -0.5 percent reduction in the update will result in a $375 million cut in physician payments in 2007.

Furthermore, the reduced MEI was based on the use of a new measure of productivity by the Bureau of Labor Statistics (BLS) and lower projections of inflation. Few details were provided and comments on the changes were not requested. Had we been given the opportunity to comment, we would have questioned the use of data that shows increased productivity in a year when the productivity of most physician practices has been reduced significantly by the need to counsel Medicare beneficiaries about the new prescription drug benefit and the availability of preventive services and to comply with the agency's requests related to the Physician Voluntary Reporting Program (PVRP). Therefore, **we urge CMS to delay any changes in the MEI pending publication of the proposed changes and solicitation of public comments in the Federal Register.**

* * * * *

ASCRS and OOSS look forward to working with CMS on the 2007 physician fee schedule and encourage CMS to include the recommendations outlined above in the final rule. Should you have any questions or comments, please contact Emily L. Graham, RHIT, CCS-P, CPC, ASCRS Manager of Regulatory Affairs, at 703-591-2220 or egraham@ascrs.org, or Michael A. Romansky, OOSS Legal Counsel, at MRomansky@OOSS.org.

Sincerely,

Samuel Masket, MD
President, ASCRS

William Fishkind, MD
President, OOSS

AMERICAN SOCIETY OF CATARACT AND REFRACTIVE SURGERY
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OUTPATIENT OPHTHALMIC SURGERY SOCIETY
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Submitter : Ms. Mary Jo Carden **Date:** 10/10/2006

Organization : Transplant Pharmacy Coalition

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See attachments

CMS-1321-P-896-Attach-1.PDF

CMS-1321-P-896-Attach-2.DOC

CMS-1321-P-896-Attach-3.DOC

CMS-1321-P-896-Attach-4.PDF

CMS-1321-P-896-Attach-5.DOC

CMS-1321-P-896-Attach-6.PDF

#896 -1

Transplant Pharmacy Coalition

October 3, 2006

Hubert H. Humphrey Building
Room 445-G
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

I Introduction

The Transplant Pharmacy Coalition (TPC) is pleased to provide comments on 42 CFR Part 405 et al. *Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B.* TPC's comments focus on the pharmacy supply fee for Medicare Part B immunosuppressant drugs. Since the implementation of changes in payment for Medicare Part B immunosuppressants approved under the "Medicare Modernization Act" (MMA), TPC has worked with the Centers for Medicare & Medicaid Services (CMS) on policy related to the supplying fee and average sales price (ASP).

TPC is a coalition of eight specialty transplant pharmacies that are both independently owned and public companies. The members of the coalition are Amber Pharmacy (Omaha, NE); BioScrip, Inc (Minneapolis, MN); Echo Drugs (Flushing, NY); F&M Specialty Pharmacy (New Orleans, LA); PharmaCare, Inc (Lincoln, RI); Skyemed Pharmacy (Pompano Beach, FL); Transcript Pharmacy (Jackson, MS); and Two Thousand Ten (2010) Pharmacy (Los Angeles, CA). Contact information for each of these pharmacies is found in *Appendix 1.* These companies supply immunosuppressant medications and associated, necessary pharmacy services to approximately 35% of all US organ transplant recipients and approximately 40% of Medicare Part B beneficiaries who have received an organ transplant.

TPC would like to thank representatives from the Centers for Medicare & Medicaid Services (CMS) and the Department of Health and Human Services (HHS) for their willingness to address our concerns regarding the pharmacy supply fee and ASP for immunosuppressant medications.

In 2004, TPC commissioned an independent study by the Lewin Group (*Appendix II)* that showed the average cost to supply each Medicare Part B immunosuppressant prescription is $35.48. Based on this study and data submitted by other chain and mail-order pharmacies, CMS currently pays $24 for the first immunosuppressant agent supplied and then $16 for each subsequent prescription supplied in a thirty-day period. In the past, CMS' preamble to the fee schedule rule suggested that much of the data presented in the Lewin Group study focused on the billing processes associated with Medicare Part B. Last year, CMS suggested that elimination of some of these billing procedures should have lead to a reduction in the cost to bill a Medicare Part B claim. However, as the comments below suggest, this has not been the case.

To provide CMS with further insight regarding the value of transplant pharmacy services, this year, a group of five of the eight members of TPC commissioned a study comparing immunosuppressant adherence rates for solid organ transplant recipients using one of the specialty pharmacies to recorded adherence rates for the general population. The adherence study shows that patients in the specialty pharmacies studied have a medication adherence rate of 84.2% versus 65% rates documented in medical literature. The researchers at Virginia Commonwealth University School of Pharmacy (VCU) showed that the potential annual savings to CMS could total $63 million or $4,150 if every transplant patient used a specialty transplant pharmacy. The study focused heavily on renal transplant patients, the most common transplant covered by Medicare. Therefore, it can be assumed that much of the cost savings is attributable to the Medicare program.[1]

These findings should encourage CMS, at a minimum, to restore the supplying fee to 2005 levels of $24 per prescription supplied plus a cost of living adjustment. This would increase the supply fee modestly to $25 per prescription based on the 4.2% consumer price index (CPI) for medical services As demonstrated by the adherence study, investing in the specialty pharmacy services could still result in cost savings to the Medicare program.

Recognition of the services of specialty pharmacies through a supplying fee increase is consistent with recent efforts by CMS to establish separate service payments for pharmacists under the Medicare Part D program and other initiatives, including pay-for-performance that encourages payment for providers that improve outcomes. In the future, the specialty pharmacies involved in the study intend to use this study to establish pay-for-performance initiatives for pharmacists. TPC understands that CMS presently has only the supplying fee to compensate pharmacies for the billing and professional services provided to patients with Medicare Part B. Therefore, until such time as other programs are developed, CMS should continue to recognize the services of specialty pharmacies and increase the supplying fee appropriately. TPC urges CMS to implement an inflationary adjustment to the supplying fee as indicated as a possibility in its 2006 fee schedule rule.[2]

The comments also provide information regarding continued pricing issues that result in transplant pharmacies' inability to access immunosuppressant medications at less than ASP+6%. TPC comments also note that 2006 ASP review studies conducted by the Department of Health and Human Services Office of the Inspector General (HHS-OIG) show that payments for immunosuppressants were not overly inflated during the first quarter of 2005 compared to a calculation established by HHS-OIG.[3] Medicare Part B did not over pay for immunosuppressants in 2005 and this continues to be the case. TPC urges CMS to take this information into account as it considers comments from the industry regarding potential modifications to the ASP data reporting process.

II. TRANSPLANT PHARMACY COALITION MEDICATION ADHERENCE STUDY METHODOLOGY & RESULTS

The complete adherence study is provided as *Appendix III.*

A. Participation by Pharmacies and Patients and Data Collection

Five of the eight TPC members participating in the study include Amber Pharmacy, Echo Drugs, F&M Specialty Pharmacy, Skyemed Pharmacy, and

Transcript Pharmacy. The remaining TPC members did not participate primarily because of time constraints for data collection. In the future, TPC may expand the adherence study to be more comprehensive. However, the other members concur that the findings are generally indicative of the adherence rates of all TPC member companies and demonstrate the value of the patient care services provided by specialty pharmacies.

Researchers at VCU examined medication possession rates (MPRs), a commonly accepted measure to determine adherence, in 1,590 renal transplant patients of the five specialty pharmacies. The study examined MPRs for the following immunosuppressants: Imuran® (azathioprine), CellCept® (mycophenolate mofetil), Myfortic® (mycophenolic acid), and Rapamune® (sirolimus). Two commonly used immunosuppressants; Neoral® (cyclosporine A) and Prograf® (tacrolimus) were excluded because of frequent dosage adjustments that made calculation of MPRs difficult.[4] Renal transplants were used as the basis because they are the most common transplant covered by Medicare.

Patient information for individuals identified as having Medicare primary coverage was submitted by each of the pharmacies to ensure that all identifiers and other patient identifiers were masked. Prescription fill data were obtained between January 1 and June 1, 2005. To be eligible, patients had to have one prescription filled in the first month, January 2005 and the last month, June 2005. The patients were identified as compliant if the MPR was greater than or equal to 80%. [5] The study calculated MPRs defined as:

> . . .the total number of days supply available during the investigation period (that is, the sum of all the days supply dispensed minus the days supply of the last fill) divided by the length of time between the first fill and the last fill.[6]

As the commentary in the study explains, MPR is a fairly accurate determination of medication compliance and is actually favorable to self reporting that tends to overestimate compliance.[7] The study acknowledges, however, that it cannot determine whether an individual takes the medications in the manner prescribed, which would involve a more invasive and extensive study requiring monitoring of laboratory levels and direct medication administration monitoring. However, based on the careful assessment by the participating pharmacies, this information is often available and specialty pharmacies often intervene immediately to manage the signs of rejection. Estimates for medical cost avoidance associated with improved adherence were based upon the 2005 Annual Data Report published by the United States Renal Data System USRDS (2005). This report contains information compiled through 2003.[8]

B. Study Methodology and Results in Brief

Overall adherence ranged from 81.5% on Rapamune (sirolimus) to a high of 89.1% on Imuran (azathioprine). The average across all age groups totaled 84.2% compared with 65% recorded in the literature.[9] Upon determining the adherence rates and drawing the comparisons, the researchers then assessed any potential cost avoidance and savings using expert clinical opinions and literature reviews. Cost estimates were based upon probability of death, probability of

survival with a functioning graft, and probability of survival with a failed graft. Using data from USRDS in 2002, the researchers estimated that the annual cost for patients in the five specialty pharmacies totaled approximately $27,853 compared to $32,003 for patients in other pharmacies. The total annual savings for each patient in the specialty pharmacies is estimated at $4,150 based on greater adherence rate alone.

Then, this information was extrapolated to determine the potential for annual savings and cost avoidance to the health care system. Researchers projected cost estimates based on costs associated with the number of renal transplants documented in 2003 by the Organ Procurement and Transplantation Network, a total of 15,136. Using this estimate, if each patient used a specialty transplant pharmacy from the study, the total cost to the health care would be $421.6 million versus $484.4 million for other pharmacies. This produces a net of $63 million in savings when using the specialty pharmacies.

III. Significance of the Study Findings & Implications to Medicare Part B

A. Specialty Pharmacy Patient Care and Billing Services Improve Adherence Rates

The positive adherence and cost avoidance findings in the study are attributed to the services often provided by specialty pharmacies. The 2004 Lewin Group study identified Medicare coordinated billing services by specialty pharmacies that help to lower patient costs by helping to eliminate patients' paperwork burden.[10] Coordination services include ensuring proper billing and payment of benefits among private insurers, Medicare Part D, Medicaid, and Medicare Part B. Specialty pharmacies often seek additional financial assistance to help beneficiaries pay for medications.[11] Billing services are shown to improve adherence by ensuring access to medications. These services are often not provided by community pharmacies and patients often struggle to understand the billing processes and pay for expensive medications. This can often lead to non-adherence. The positive outcomes associated with billing are only one piece of the services regularly provided by specialty pharmacies that improve outcomes.

Specialty pharmacies engage in other proactive patient follow-up and medication management that contribute significantly to improved adherence. All of the specialty pharmacies in the study engage in patient care activities including proactive refill reminders, education regarding the patient's disease state and medication interactions, and call centers dedicated to providing patients with information and education. The study concludes that a combination of the billing services and proactive patient interactions results in improved compliance for these specialty pharmacies versus the general population.

B. Implications of the Study Findings to Medicare Part B

Transplants are costly to the Medicare and to the overall health care system. However, the lifetime savings for individuals who receive transplants versus those who continue on dialysis only is approximately $200,000.[12] After a transplant, patients generally require a lifetime of immunosuppressant medications to protect

against organ rejection. Medicare costs for these immunosuppressant medications might be as high as $13,000 annually.[13] However, given the significant cost associated with the organ transplant and even greater costs associated with organ graft failure, return to dialysis, and re-transplantation[14], Medicare should invest in protecting transplanted organs. As the literature suggests, lack of interventions by pharmacies could significantly reduce adherence with immunosuppressant regimens.

A *Health Affairs* article recently considered the value of ensuring access to specialty medications.[15] This study examined the impact of cost sharing requirements by privately insured patients and the economic impact of limiting coverage to expensive specialty medications for patients who require them.[16] The study suggests that despite the cost of the specialty medications, patients properly identified as requiring them should be ensured access to these medications. The study further suggests that the insurers should find ways to manage utilization to ensure continued access.[17] The Medicare program faces the same economic challenges as the private sector and should also work to ensure appropriate access to specialty medications for those who require them.

Transplant patients are clearly proper candidates for life-long immunosuppressant therapy. Medicare Part B and the Medicare Part D programs have made a concerted effort to cover these medications. Like privately insured patients, Medicare patients also face significant co-payments for these medications and as the literature suggests, nearly 40% of transplant patients are non-adherent. However, the management techniques used by specialty pharmacies can and do improve adherence and thus promote access to these medications. Medicare Part B should continue to recognize the services that specialty pharmacies provide and ensure that an appropriate supplying fee is paid to pharmacies for these medications.

IV. TPC Recommendations for the 2007 Supplying Fee

A. Update the Supplying Fee Based on Inflation Adjustment

While the 2007 proposed rule makes no changes to the current supplying fee of $24 for the first prescription supplied in a thirty-day period and then $16 thereafter, TPC recommends that the supplying fee be updated to reflect increased costs in supplying these medications and consistency with the Lewin Group report finding a supplying fee of $35. Such an increase would also be consistent with initiatives including pay-for-performance and Medicare Part D payment to

pharmacists for medication therapy management services. In 2005, CMS implemented a supplying fee of $24 for each immunosuppressant prescription in a thirty-day period.[18] Then, in 2006, this fee was reduced to $24 for the first prescription in a thirty-day period and $16 for each prescription thereafter.

TPC recommends that CMS update the 2007 supplying fee to at least $24 plus an inflationary adjustment for each immunosuppressant prescription supplied during a thirty-day period. TPC recommends using an inflationary adjustment of 4.2%, the consumer price index (CPI) that CMS suggested as an increase for clotting factors.[19]

An increase in the supplying fee by 4.2% based on the CPI would result in a $25 fee for each immunosuppressant supplied. This modest increase is well below the Lewin Group estimate of $35 established in 2004 and would not result in unnecessary increased costs to the Medicare program as suggested by the analysis below. This increase is also consistent with initiatives recently considered or implemented by CMS to reward health care providers for positive outcomes.

B. Administrative Changes for Medicare Billing Do not Result in Proportionate Reductions in Billing Costs

Over the past two years, CMS eliminated several billing procedures, including the assignment of benefits form (AoB) and DMERC information form (DIF). CMS intended for these changes to reduce some of the $7.64 Medicare claims processing costs established by the 2004 Lewin Group study. CMS then decreased the supplying fee by $8 in 2006. However, TPC members have not experienced the proportional decrease in billing costs. Medicare Part B billing continues to be a labor-intensive process requiring a great amount of specialized staff within pharmacies. Many of the Medicare Part B billing costs are associated with verifying benefits, assisting individuals with Medicare understand benefits, and billing secondary insurers or foundations for co-insurance amounts.

Other billing problems occur because of inherent inefficiencies with the Medicare Part B eligibility and verification process. Medicare's common working file (CWF) is often outdated or incomplete resulting in rejection of claims or improper Medicare billing. This situation increases the already burdensome billing process.

Pharmacies continue to be penalized for the efficiencies described above. Most other pharmacy claims, including those processed for Medicare Part D, are electronic and pharmacies receive an instant response regarding patient payment responsibility and pharmacy reimbursement. TPC understands that CMS cannot currently change the Medicare Part B eligibility database or provide an electronic adjudication system. Until these changes and improvements are made, CMS should recognize the billing inefficiencies and pay pharmacies an appropriate supplying fee. As previously described, this fee should be at least $25 per prescription.

V. TPC Comments & Recommendations on ASP

A. TPC Member Companies Continue to Experience Problems Accessing Immunosuppressants at ASP+6% or Below

In February 2006, HHS-OIG analyzed Medicare ASP rates from the first quarter of 2005 and found that using a calculation different from Medicare's, 46% of nearly 500 Medicare Part B covered drugs were overpaid.[20] In contrast, HHS-OIG found that Medicare's ASP calculations for commonly used immunosuppressants are at or below the proper amount. HHS-OIG found that CMS' ASP for CellCept [J7517] was lower than its calculation.[21] OIG also found that CMS' ASP for Prograf [J7507] was $.02 greater than its calculation. Based

on these findings, the Medicare program reduced payment for this same product by this amount in the second quarter of 2006.

These findings support TPC's assertions that ASP payments for immunosuppressants are not associated with the alleged waste, fraud and abuse issues associated with other pharmaceuticals paid by Medicare Part B. TPC adds that these findings also do not consider that the ASP reimbursement for some immunosuppressants is at or below pharmacy acquisition prices. The consistent Part B underpayment to pharmacies makes it difficult to continue providing the critical services necessary to ensure proper management of immunosuppressant therapy.

The lag between ASP data collection and release of quarterly price information combined with the uncertainty of quarterly price adjustments by manufacturers impair pharmacies' ability to effectively negotiate for immunosuppressant products. This results in significant changes in purchasing ability from quarter to quarter. The net result is that most pharmacies do not purchase at or below ASP for all products over the course of the entire year. TPC believes that the recommendations below might improve the situation. TPC looks forward to working with CMS and the industry to overcome challenges associated with access to immunosuppressants at or below ASP.

B. TPC's Recommendations to Improve ASP Pricing for Specialty Pharmacies

1. **Exclude certain data collection efforts for immunosuppressant agents from the ASP when performed by pharmacies on behalf of manufacturers.** To the extent that pharmacies enter into data agreements that provide aggregate information regarding pharmaceutical utilization and inventory these agreements should be excluded from the ASP calculation. Of course, these agreements would be structured to meet federal privacy laws enacted by HIPAA and could not violate applicable fraud and abuse laws and regulations.

   While TPC supports exclusion of data collection agreements from ASP, the determination of fair market value (FMV) should be established by the parties using standard arms-length contract negotiation procedures. CMS has other means available for determining whether the FMV is proper.

Recognize class of trade distinctions. TPC believes that the data collection process could allow CMS to classify pharmacies in different trade classes when calculating ASP. This would eliminate disparities in contract pricing. For example, TPC members comprise approximately 40% of the Medicare market, but based on the adherence study, significantly improve patient outcomes. This should be recognized by CMS when determining whether manufacturers provide certain price differentials to "large" pharmacies that drive volume, but do not necessarily improve outcomes.

VI. SUMMARY

Once again, TPC thanks CMS for the opportunity to provide comments on this proposed rule. TPC encourages CMS to increase the 2007 supplying fee to properly compensate pharmacies for the billing and clinical services associated with improved outcomes for transplant patients and potentially lower Medicare costs. TPC looks forward to continuing work with CMS and the industry to establish mechanisms to improve ASP data collection within the provisions of the MMA. For questions regarding these comments, please contact Mary Jo Carden, TPC's Washington representative, at 202-744-2773 or MCarden@CardenAssociates.net.

Sincerely,

Mary Jo Carden, RPh, JD
On behalf of the Transplant Pharmacy Coalition

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[18] *See* note 2 above.
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[20] *See* note 3 above.
[21] *Ibid.*

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The Transplant Pharmacy Coalition
Comments Medicare Part B Supply Fee

Appendix I
Membership & Contact Information

#3

The Transplant Pharmacy Coalition
Comments Medicare Part B Supply Fee

Appendix II
2004 Lewin Group Report

#896-4

Assessing the Cost of Dispensing Immunosuppressive Drugs to Medicare Transplant Recipients

Developed for the Transplant Pharmacy Coalition

Prepared by:
Allen Dobson, PhD
Robert A. Book, PhD, MBA

September 24, 2004

The Lewin Group

Table of Contents

Executive Summary (1 of 2)

- The Medicare Prescription Drug, Improvement and Modernization Act (MMA) requires CMS to pay providers a "pharmacy supply fee" to cover the costs associated dispensing immunosuppressive drugs and providing associated professional services of pharmacists for Medicare transplant patients.
- CMS proposes a $10 per prescription payment for the supply of immunosuppressive drugs, determined solely from retail chain pharmacies' cost data, notwithstanding the retail pharmacies indicated a fee range of $12-$15 is appropriate.
- However, retail chain pharmacies typically do not supply immunosuppressive drugs, supply Medicare Part B drugs, or file Medicare Part B claims.
- To provide CMS with more data on which to base the mandated pharmacy supply fee, the Transplant Pharmacy Coalition – which provides services to about 40% of the Medicare transplant patient market –commissioned The Lewin Group to perform an analysis of the pharmacy costs associated with providing immunosuppressive drugs.
- The Lewin Group surveyed Coalition members for costs associated with providing immunosuppressive drugs and related pharmacy services to Medicare beneficiaries.

Executive Summary (2 of 2)

- The Lewin Group found that:
  - Transplant pharmacies have higher pharmacy supply costs than retail chain pharmacies because transplant patients require more extensive pharmacy services.
  - Unlike retail chain pharmacies, transplant pharmacies routinely provide drugs covered under Medicare Part B.
    - The cost of filing Medicare claims accounts for more than 22% of the pharmacies' supply cost (excluding the cost of goods sold).
    - Unlike other prescription drug payers, Medicare does not provide real-time online adjudication of claims, making coordination of benefits with secondary insurers costly and sometimes impossible.
  - The proposed supply fee of $10 is less than the transplant pharmacies' average cost of supplying those drugs, which is $35.48.

Summary of Results	
Ratio of Average Pharmacy Supply Costs to Average Total Costs	9.1%
Average Pharmacy Supply Cost per Prescription	$35.48
Apportion Attributed to Additional Cost for Medicare Claims	$11.58

Coalition & Study Introduction

The Transplant Pharmacy Coalition

- The Transplant Pharmacy Coalition is composed of eight specialty pharmacies. These coalition members collectively:
  - Fill more than 28,000 immunosuppressive prescriptions monthly.
  - Hold about 30% of the overall market share in immunosuppressive drug dispensing.
  - Hold about 40% of the Medicare Part B market share in immunosuppressive drug dispensing.
  - The remainder of the market is served by:
    - Retail pharmacy chains
    - Hospital outpatient pharmacies at transplant centers.
    - Pharmacy Benefit Managers (PBMs) which do not typically serve Medicare patients due to the high cost of filing Medicare claims.
- The Transplant Pharmacy Coalition commissioned the Lewin Group to do an analysis of the transplant pharmacy costs.

Study Purpose

- To identify the supply costs associated with providing pharmacy services to Medicare Part B transplant recipients;
- To approximate average total and component clinical administrative costs of providing these services; and
- To develop average per prescription pharmacy supply cost estimates to be included under the new payment methodology outlined by the *Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA).*

Transplant Pharmacy Overview

Transplants and Immunosuppressive Drugs

- Organ transplant is the most effective – and sometimes the only – treatment for patients with a non-functioning heart, lung, kidney, liver, pancreas, or intestine.
- The most common organ transplanted is the kidney (61%) for treatment of End Stage Renal Disease (ESRD).
- Transplanted organs are rarely an exact match for the patient, and therefore "rejected" by the patients immune system.
  - *Lifetime treatment with immunosuppressive drugs is required to suppress the patient's immune system to prevent organ rejection.*
  - *Without immunosuppressive drugs supplied at the proper dosage, the patient will reject the organ and either require re-transplantation or die.*

Pharmacies and Immunosuppressive Drugs

- Retail chain pharmacies typically do not supply immunosuppressive drugs due to:
  - The small number of transplant patients relative to population;
  - The high cost of inventory and high risk of waste due to drug expiration (due to the high cost of drugs and small number of patients); and
  - Lack of business desire to deal with complex Medicare claims' procedures.
- Transplant centers typically have outpatient pharmacies
  - But a large percentage of patients live too far from transplant centers to use them on a regular basis.
- Mail-order PBM pharmacies typically do not serve Medicare Part B transplant patients
- ***Specialty pharmacies are the only practical option for many patients, especially Medicare Part B patients.***

Special Features of Transplant Pharmacies

- Transplant pharmacies differ from retail pharmacies in several ways, all of which increase costs:
  - The initial prescriptions are often hand-delivered to the hospital on the day of discharge.
  - Until the correct dosage for the patient is determined (approximately four months), the pharmacist works closely with the prescribing doctor to determine the correct dosage, and with the patient to monitor for symptoms of incorrect dosage.
  - Transplant pharmacies file Medicare claims.
    - Filing Medicare claims is much more costly than filing other claims
    - Since most drugs are not covered by Medicare Part B, most retail and mail-order pharmacies do not have processes in place to file Medicare claims

Pharmacy Claims Procedures

- Non-Medicare payers – both private insurers and Medicaid – offer and require instant online adjudication of claims at the time a prescription is filled.
  - Pharmacies know before delivering the product how much they will be paid and how much of a co-payment to collect.
  - If the online adjudication system is not used on the date of service, pharmacies are typically ***not*** eligible for ***any*** reimbursement, even for covered services.
- Medicare Part B does not utilize the online adjudication system.
  - This increases billing errors and makes coordination of benefits with secondary insurers difficult and sometimes impossible.
  - Medicare often errs in identifying patients as having "primary" or "secondary" Medicare coverage.
  - Prior to filing a claim, pharmacies can call Medicare to determine this status, but the answers are often incorrect
    - At least one pharmacy calls Medicare 3 times for each claim
  - ***If Medicare incorrectly identifies a "secondary" patient as "primary," then denies the primary claim 3-4 weeks later, it is too late for the pharmacy to file a claim with the primary insurer. Since that insurer requires instant online adjudication on the date of service, the pharmacy has then dispensed a prescription for which is can never be reimbursed.***

Transplant Drug Reimbursement

Current Medicare Payments

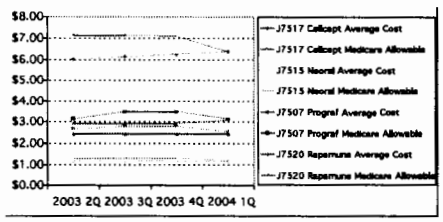
- Medicare spent about $174 M on immunosuppressive drugs in CY2002.
- Until recently, Medicare allowed 95% of average wholesale price (AWP).
- Currently, Medicare allows 85% of April 2003 AWP.
  - AWP is a list price, not a price based on actual wholesale transaction data
  - Medicare allows 85% of April 2003 AWP, but actual prices and published AWPs have increased since then.

Medicare rates for some drugs are now at or below the prices some pharmacies pay for those drugs

- Medicare does not reimburse providers separately for the costs of services associated with supplying drugs, including:
  - Pharmacist professional services (dispensing and counseling)
  - Delivery, storage, and inventory cost
  - Cost of filing Medicare claims
  - Pharmacy overhead

Medicare Allowables and Drug Prices

Medicare allowables for some immunosuppressive drugs are currently *at or below* pharmacies' actual acquisition costs



Proposed 2005 Medicare Payment Method

- *Medicare Prescription Drug, Improvement and Modernization Act* (MMA) passed December 2003 will change Medicare drug payments to average sales price (ASP) plus 6% as of CY2005.
- The law also requires an "add-on" payment to cover the supplying and dispensing immunosuppressive drugs to Medicare patients
  - CMS proposes to create a payment of $10 per prescription, based on the low end of the cost range submitted by retail chain pharmacies.*
  - However, retail chain pharmacies rarely provide immunosuppressive drugs or participate in Medicare Part B

Thus, retail chain pharmacy costs are not an appropriate benchmark for establishing the true cost of providing immunosuppressive drugs under Medicare Part B.

*CMS reports the cost range of retail pharmacies at $10-12 in CMS-1429-P, Federal Register 69:150 p. 47523 (Aug. 5, 2004)

Cost Differences

- Transplant pharmacies have higher costs than retail chain pharmacies because:
  - More intensive involvement of the pharmacist in providing patient care and coordinating with doctors and transplant centers increases clinical and administrative costs.
  - Higher drug prices increase average inventory costs.
  - Medicare claims add substantial costs due to:
    - Complicated filing process;
    - Coordination of benefits difficult due to absence of instant adjudication;
      - Medicare often provides inaccurate information about patient coverage status (primary vs. secondary); and
      - Secondary reimbursement is often lost due to Medicare errors discovered after date of service.

Proposed Changes in Billing Requirements

- CMS has proposed to streamline requirements to reduce the cost of filing Medicare claims. Specifically, they propose:
  - Relaxing the requirement for an "original signed order" to allow faxed, photocopied, or electronic orders
  - Eliminating the Assignment of Benefits form
  - Eliminating the DMERC Information Form (DIF)
  - CMS has already allowed billing for a refill processed 5 business days before the previous supply is exhausted, in order to reduce the need for overnight shipping of refills.
- While these changes are welcome and beneficial, they save approximately $0.72 per prescription* and do not address the true billing problems
  - Lack of real-time online adjudication of claims increases billing errors, increases processing time, and forces pharmacies to "bill blind."
    - It also increases Medicare bad debt, since co-payments cannot legally be collected at the time of service.
  - Errors in the telephone voice-response system to verify eligibility often cause pharmacies to irrevocably lose primary reimbursement when the system mistakenly identifies Medicare secondary beneficiaries as primary beneficiaries.
  - Medicare often erroneously verifies eligibility, makes a payment, and then requests a refund months later, when it is too late to collect payment from patients or secondary insurers.

*Coalition estimate

Study Design

Process Overview

- Developed study objectives
- Worked with the Transplant Pharmacy Coalition to identify pharmacy supply cost categories and to develop survey instrument
- Collected cost accounting data from participating transplant pharmacies
  - Cost data were allocated to the Medicare Part B transplant line of business using a top-down approach
- Reviewed data with participants for accuracy
- Analyzed survey data
- Presented draft study results for review
- Wrote report

Sample

- Data were obtained from eight specialty pharmacies of various sizes and geographic coverage.
- Together these providers:
  - Dispense immunosuppressive drugs in all 50 states
  - Serve approximately 30% of the overall immunosuppressive drug market
  - Serve approximately 40% of the Medicare Part B immunosuppressive drug market

Survey Instrument

- As part of survey development The Lewin Group and the Transplant Pharmacy Coalition identified and defined cost categories
- Executives at each transplant pharmacy completed a survey created by The Lewin Group
- To ensure consistency of reporting and accuracy of cost data, the Lewin Group worked individually with each company
- The survey collected recent data on:
  - Number of Medicare and non-Medicare prescriptions filled
  - Cost of goods sold
  - Clinical and administrative costs
  - Inventory and overhead costs
  - Cost of processing Medicare claims
  - Medicare bad debt and collection costs

Survey Analysis (1 of 3)

- Study calculations were made with the intent of accurately representing the transplant pharmacy industry as a whole.
  - Average cost per prescription was calculated for each company and then a weighted average was calculated according to the number of prescriptions, not by dollar volume.

Survey Analysis (2 of 3)

- Data were used to analyze the major cost components associated with providing immunosuppressive drugs to patients
- The percent of total cost for each component was also calculated
- Cost components include:
  - Cost of Goods Sold
  - Pharmacy Supply Costs
    - Pharmacy personnel
    - Medicare Part B claims processing
    - Inventory cost and inventory shrinkage*
    - Shipping
    - Rent
    - Sales and marketing
    - Administrative overhead
  - Medicare Bad Debt
    - Co-payments never made
    - Collection costs

*CMS reports the cost range of retail pharmacies in §10-12 in CMS-1429-P, *Federal Register* 69:150 p. 47523 (Aug. 5, 2004)

Survey Analysis (3)

- The table below lists the key calculations performed (Provider data reflect CY 2003)

Statistic	Numerator	Denominator
Ratio of Average Supply Costs to Average Total Costs	Aggregate pharmacy costs, except cost of goods sold (COGS)	Aggregate pharmacy total costs (includes COGS)
Average per-Prescription Supply Cost	Aggregate pharmacy costs, except cost of goods sold (COGS)	Number of prescriptions supplied to Medicare patients
Amount Attributable to Additional Cost for Filing Medicare Claims	Aggregate cost of submitting Medicare claims plus Medicare bad debt and collection costs	Number of prescriptions supplied to Medicare patients

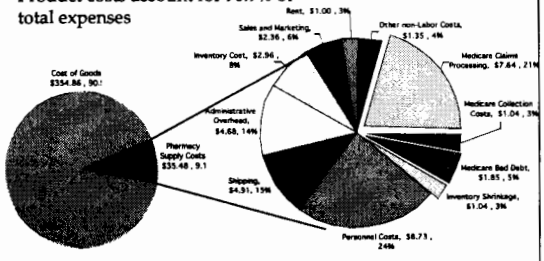
Study Results

Key Calculations

Statistic	Value
Ratio of Average Supply Costs to Average Total Costs	9.1%
Average per-Prescription Supply Cost	$35.48
Amount Attributable to Additional Cost for Filing Medicare Claims	$11.58

Allocation of Costs

Product costs account for 90.9% of total expenses



Conclusions

Conclusions

- Specialty pharmacies are a dominant supplier of immunosuppressive drugs to Medicare Part B transplant patients
  - Together they serve about 40% of Medicare transplant patients
- The Coalition's average cost of supplying a prescription to a Medicare Part B transplant patient is $35.48, exclusive of the cost of the drug itself
- CMS' proposed changes to the billing process provide only a nominal reduction in costs and do not solve the most critical problems associated with Medicare Part B billing.
- A payment of $10 per prescription will limit pharmacies' ability to provide immunosuppressive drugs to Medicare Part B transplant patients, and may drive them from the market entirely, because it does not cover their clinical, administrative and billing costs.
- Many patients do not have reasonable access to alternative sources for these essential drugs.
- Continued assurance that Medicare transplant patients have access to quality service and life-sustaining drugs is an important policy objective as Medicare Part B payment changes are considered.

#896-5

The Transplant Pharmacy Coalition
Comments Medicare Part B Supply Fee

Appendix III
2006 Transplant Pharmacy Adherence Report

#896-6

Assessment of Adherence with Immunosuppressant Medications in Transplant Patients and the Potential Cost Savings Associated with Increased Adherence

September 25, 2006

Prepared by:

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and

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F & M Specialty Pharmacy
Jackson, Mississippi

Skyemed Pharmacy
Pompano Beach, Florida

Transcript Pharmacy
Jackson, Mississippi

The sponsoring pharmacies are members of both the Transplant Pharmacy Coalition (TPC) and Specialty Pharmacies of America (SPofA). The TPC is a group of eight specialty pharmacies who collectively provide immunosuppressants for about 1 in every 3 Americans who have had an organ transplant. SPofA is a group of specialty pharmacies servicing patients with chronic medical conditions that include organ transplant, hepatitis, HIV, arthritis, and many other conditions.

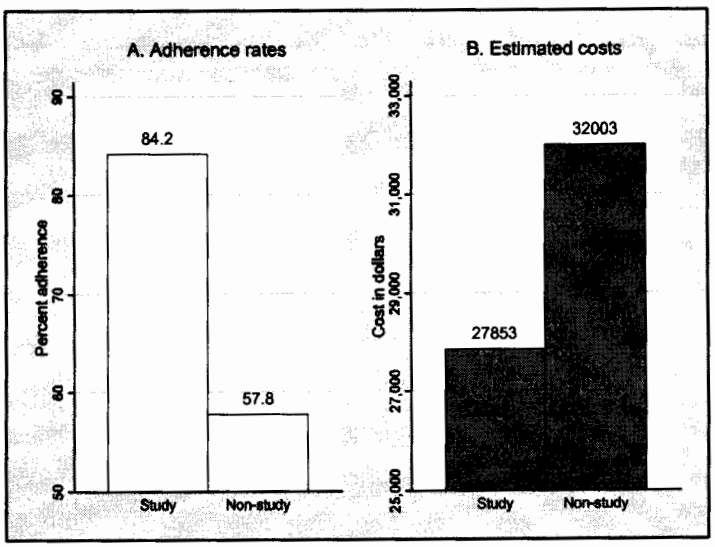
ASSESSMENT OF ADHERENCE WITH IMMUNOSUPPRESSANT MEDICATIONS IN TRANSPLANT PATIENTS AND THE POTENTIAL COST SAVINGS ASSOCIATED WITH INCREASED ADHERENCE

PROJECT SUMMARY

Objective:
The primary goal of the study was to examine the rate of adherence with immunosuppressant medications in transplant patients served by a group of five specialty pharmacies. The adherence estimates were then compared to literature-based adherence estimates for the purposes of determining whether potential cost savings were associated with increases in adherence.

Findings:
Adherence was estimated for 1,590 patients receiving four immunosuppressant agents: azathioprine, mycophenolate mofetil, mycophenolic acid, and sirolimus. Medication possession ratios (MPRs) were calculated for each drug taken by each patient. Patients were identified as "adherent" if the MPR was ≥ 0.8 for all prescribed immunosuppressant agents. The estimated adherence rate among the five study pharmacies was 84.2%, which was significantly higher than the literature-based estimate of 65% (Panel A below). The adherence estimates were applied to current Medicare cost estimates for functioning renal grafts and failed renal grafts to determine whether the differences in adherence were associated with potential cost savings. With the increased adherence rate from the group of study pharmacies, the estimated yearly cost was $27,853. The cost associated with the literature-based estimate was $32,003 resulting in a potential cost savings of $4,150 per patient per year linked to an increase in adherence with immunosuppressant regimens (Panel B below). With a total of 15,136 renal transplants in 2003, this cost difference translates to a potential savings of almost $63 million per year.

Conclusions:
These findings suggest that the reduced risk of rejection associated with increased adherence with immunosuppressant agents translates into avoidance of significant costs associated with a failed renal graft. The service model used by the group of study pharmacies involves a high level of patient contact to promote adherence, which is enhanced from the services provided by traditional mail-order and retail pharmacies. The higher level of service attributed to the specialty pharmacy service model is likely responsible for the increased adherence rates. Instituting policies to ensure appropriate reimbursement, such as CMS's proposed pay-for-performance framework, would be an important step to support and promote patient care.



Introduction

Lack of adherence with medication regimens is a well-established problem in many patients with chronic disease states. Despite marked advances in the safety and efficacy of medications, no agent will work if the patient fails to take their prescribed regimen. Non-adherence may include failure to take medication doses as directed (with respect to dose and frequency), failure to finish a prescribed course of therapy, taking medications that were not prescribed for the condition, and even failing to pick up the prescription once filled (Wainwright & Gould, 1997).

Adherence in transplant patients represents a unique situation given the potentially serious consequences of non-adherence (Chisholm, 2002). More importantly, the consequences of on-adherence may be realized sooner than in other conditions, such as hypertension or hyperlipidemia. Immunosuppressant agents are quite effective at preventing rejection of a transplanted organ; however, lack of adherence to the course of therapy can significantly reduce positive transplant outcomes. In fact, lack of adherence can significantly increase the risk of rejection of the transplanted organ (Butler et al., 2004; Denhaerynck et al., 2005). Non-adherence and its consequences in the transplant population have been the focus of some investigators since the mid-1970s (Owens, Maxwell, Goodnight, and Wolcott, 1975). In addition to rejection, other adverse consequences of non-adherence may include increased hospitalizations and health care costs and decreased quality of life. Despite the potential for rejection and other untoward consequences, non-adherence to immunosuppressant regimens is surprisingly high with some estimates as high as 68% (Chisholm, 2005; De Geest et al., 2005; Dew et al., 1996). A 2004 meta-analysis of adherence in the renal transplant population reported an estimated median non-adherence rate of 22% with an interquartile range of 18% to 26% (Butler et al., 2004). Interestingly, non-adherence is an increasingly important problem in the pediatric population. Literature reports of non-adherence among pediatric renal transplant recipients range from 8% to 70% with a mean value of around 40% (Wolff et al., 1998). Research suggests that determinants of adherence in the pediatric population are somewhat different that their adult counterparts and tend to focus on the psychosocial development of the adolescent patient, level of family-functioning, and parent/caregiver stress levels (Wolff et al., 1998; Griffin & Elkin, 2001; Gerson, Furth, Neu, and Fivush, 2004).

Non-adherence may be the result of numerous factors, including the provision of poor instructions to the patient, apathy on the patient's part, lack of established patient-pharmacist relationship, patient confusion, and adverse effects associated with the agents. One major factor that is repeatedly mentioned in the literature is the potential financial barrier associated with immunosuppressant agents (Paris et al., 1999; Chisholm, 2004). Unfortunately, the number of non-elderly adults in the US without any health insurance is estimated to be between 16% and 18% (Hoffman & Schwartz, 2006). Medicare does provide coverage for kidney transplants in ESRD patients and some costs for other transplants depending on whether eligibility requirements are met. State Medicaid plans and third party insurers also provide some coverage for transplants (Chisholm, 2004; Yen, 2004; Woodward, 2001). The cost of immunosuppressant therapy is significant with annual estimated costs as high as $13,000 (Yen et al., 2004). Research findings suggest that access to prescription drugs continues to be a problem in the US. A 2003 survey by the Center for Studying Health System Change (CSHSC) reported that the percentage of adults who reported trouble filling a prescription for financial reasons was 12.8%. This figure was even higher at 18.3% among adults with at least one chronic

condition. Moreover, some 15% of adults with chronic health conditions reported not filling all of their prescriptions due to financial reasons. All of these figures represent significant increases over findings from a similar study in 2000 (CSHSC, 2005).

In a perfect world, the measurement of adherence would involve objective, practical, and unobtrusive processes (Rudd, 1979). Current measurement methods can generally be broken down into two categories: direct and indirect methods. Direct methods involve the assessment of whether the medication was actually taken and may include detection of the parent drug compound or metabolite in blood or urine. Personal observation of medication ingestion is another method of direct assessment. Indirect methods tend to be less intrusive but may also be less accurate. Methods such as patient self-reporting, pill counts, and electronic monitoring devices are all indirect methods with varying degrees of accuracy (Chisholm, 2002). One frequently used indirect method of assessing adherence involves using administrative claim data from prescription refills. Administrative claims can provide information on the number of doses dispensed (i.e., the days supply) and the days on which refills were processed. The medication possession ratio (MPR) is a frequently used measure of prescription adherence when using administrative claim data. It is defined as the sum of the days supply during the investigation period divided by the number of days during the same period (Sclar et al., 1991). The resulting value represents the percentage of time during the investigation period that the patient would have been in possession of a dose of the medication, hence the name of the measure. A patient is defined as "adherent" by selecting some cut-off value for the MPR. Although there are other methods for calculating adherence, the MPR has a long track record in the literature (Sikka, Xia, and Aubert, 2005; Steinger & Prochazka, 1997). As with most administrative claim-based measures, the MPR assumes that the patient actually took the medication as directed after the prescription was filled and in the patients' possession (Fairman & Motheral, 2000).

The current study sought to determine the adherence of transplant patients from the participating study pharmacies and then compared these estimates of adherence with literature-based adherence estimates. Using these estimates, the potential cost differences associated with varying adherence rates were examined, specifically the potential costs which would be incurred if patient's kidney graft failed.

Methods

Prescription fill data on transplant patients were obtained from each of the five participating study pharmacies. All patient identifiers, including names and dates, were masked so that patient confidentiality was maintained. Prescription fill data were obtained from January 1, 2005, to June 30, 2005, for patients with Medicare listed as the primary payer. In order to be eligible for analysis, patients had to have at least one prescription filled in the first month (January) and the last month (June) of the evaluation period. This criterion provided an equal follow-up period for each patient. The MPR was calculated for each immunosuppressant agent for each patient. As mentioned previously, MPR is defined as the total number of days supply available during the investigation period (that is, the sum of all the days supply dispensed minus the days supply of the last fill) divided by the length of time between the first fill and the last fill. Adherence was then defined as an MPR $\geq$ 0.8 (or 80%). The estimate of adherence in patients from the study pharmacies was used in a decision analysis to determine the potential

cost savings associated with increased compliance. For the purposes of this investigation, four immunosuppressant agents were included in the sample: azathioprine (Imuran®, Prometheus Laboratories), mycophenolate mofetil (CellCept®, Roche), mycophenolic acid (Myfortic®, Novartis), and sirolimus (Rapamune®, Wyeth). Cyclosporine A and tacrolimus, two commonly used immunosuppressant agents, were excluded since patients receiving these agents often undergo frequent dosage adjustments. With these frequent changes in dosages, great difficulty can arise in estimating the appropriate days supply value. Without an accurate estimation of days supply, significant discrepancies could arise between the estimated refill date and the actual refill date resulting in biased estimates of adherence for these agents. Estimates for overall compliance were obtained from the literature, and clinical and economic outcome estimates were obtained from the 2005 Annual Data Report published by the United States Renal Data System, or USRDS (2005). This report contains information compiled through 2003. Economic data were provided from Medicare's perspective since it is the primary payer for most renal transplant patients. Sensitivity analyses were conducted to examine the effects of changing the adherence and outcome estimates along clinically plausible ranges. Given that information on the type of organ transplanted was not available, all patients were assumed to have received kidney transplants to simplify the analysis. Statistical analyses were conducted in Stata/SE version 9 (StataCorp LP; College Station, TX). The decision analysis was performed using TreeAge Pro 2006 (TreeAge Software; Williamstown, MA).

Results

Assessment of adherence

A total of 16,537 individual prescriptions representing 3,362 patients were identified from the pharmacies. After applying the eligibility criteria, 1,599 patients were identified. In nine patients, age could not be determined so these patients were excused from the analysis resulting in a final sample size of 1,590. The mean ($\pm$ standard deviation) age of patients was 52.3 ($\pm$ 15.0) years. Age was divided into four categories for the analysis (Table 1). The two most frequently used products were mycophenolate mofetil (73.0% of patients) and sirolimus (19.3% of patients). The other two agents were used in less than 10% of the study sample. Most patients received only one immunosuppressant agent; however, two received both sirolimus and mycophenolate mofetil. The distribution of immunosuppressant usage by agent and age category is provided in Table 2.

To assess adherence with medication therapy, the MPR for each immunosuppressant agent for each patient was calculated. The mean MPR values for each agent across age categories are presented in Table 3. Overall, adherence was relatively high with most MPRs being greater than 0.8. Using the aforementioned adherence cutoff of an MPR $\geq$ 0.8, overall adherence ranged from 81.5% for sirolimus to 89.0% for azathioprine (Table 4). For patients receiving more than one agent, overall adherence was established if the MPR was greater than 0.8 for each prescribed immunosuppressant agent. Adherence was not significantly different across age categories. The adherence rate over all immunosuppressant agents and age was 84.2% for the study pharmacies.

Decision analysis

The second portion of the study involved assessing whether there were any potential cost savings associated with increased adherence. The adherence estimates generated above were

compared to adherence estimates from the literature. An expected adherence of 65% was used for the general transplant population (i.e., those other than the participating study pharmacies) (Chisholm, Mulloy, and DiPiro, 2005). Given the wide range of reported non-adherence rates, this "non-study" group adherence rate was varied from 40% to 95% in the sensitivity analysis. Clinical outcome probabilities and cost estimates were obtained from the literature and expert opinion. These estimates represented the probability of death, probability of survival with a functioning graft, and probability of survival with a failed graft. Using the most recent estimates from the USRDS, estimated annual costs for functioning grafts were $15,537 and $70,930 for failed grafts. The estimates are notably higher for failed grafts since they represent a return to chronic dialysis and associated dialysis maintenance services. The base probabilities and sensitivity analysis ranges are provided in Table 6. The decision tree was constructed using the outcome estimates. After rolling back the decision tree, the expected annual cost within the group of study pharmacies was $27,853 and $32,003 for other pharmacies (Figure 1). This represents a potential savings of $4,150 per patient over the course of a year associated with increases in adherence (Figure 2). In 2003, there were 15,136 kidney transplants according to the Organ Procurement and Transplantation Network (2006). Applying the cost estimates generated in this study to those kidney transplants, the study pharmacy adherence rate would result in projected costs of just over $421.6 million compared to $484.4 million for the non-study pharmacies resulting in a potential cost savings of almost $63 million due to increased adherence.

Discussion

Overall, the group of five study pharmacies exhibited a significantly higher adherence rates than literature-based estimates. These differences in adherence were associated with a significant cost avoidance per person. Still, it is important to note the assumptions made during the analysis. The decision analysis did not take into account any demographic information such as race or gender as it was unavailable for analysis. To simplify the analysis, overall probabilities and costs irrespective of age were used. Also, all transplanted organs were assumed to be kidneys. While it is unlikely that there are significant differences in adherence associated with other organ types (Schweizer et al., 1990; Dew et al., 1996; Wainwright & Gould, 1997; De Geest, 2005), it is possible that differences in adherence among those patients receiving other transplanted organs (ex., heart, liver, lung, etc.) could change the results. Renal transplantation was chosen for the current study because of the well-documented costs associated with functioning and failing grafts.

Another important potential limitation is the selection of literature-based estimates for cost and probabilities. Estimates for costs and graft survival probabilities were obtained from various literature reports as described above and in Table 6. Furthermore, all costs were provided with the assumption that the full costs would be incurred over the course of the following year, that is the individual would survive for an entire year and not die during that time period. When conducting a decision analysis, it is common to perform sensitivity analysis to determine whether changing any particular estimates might change the conclusions. Aside from changing the rates of adherence in the two study groups, the study pharmacies resulted in the lowest cost in almost all situations unless the probability of graft survival was extremely low (< 40%) in which case increased adherence would not be sufficient to overcome the low graft survival rate.

In the absence of drawing blood levels, there are various methods for estimating adherence using non-invasive means such as pill counts, patient surveys, and pharmacy refill data (Steiner & Prochazka, 1997; Chisholm, 2002; Chisholm, Lance, Williamson, and Mulloy, 2005). In this study, adherence was estimated using pharmacy claims by the medication possession ratio. Unfortunately, every method has certain limitations. The MPR method has been used extensively in the literature. Although the MPR does provide fairly accurate information about the percentage of time that medication is available for consumption, it does not provide information about the appropriate usage of medications with respect to time that the dose is taken (Sikka, Xia, and Aubert, 2005). It is possible that non-adherent patients were misclassified as adherent based solely on their refill history; however, these effects should be minimal. Actually, using administrative data theoretically avoids biases such as the "Hawthorne effect" associated with allowing patients to self-report adherence or directly inquiring about adherence through questionnaires (Fairman & Motheral, 2000).

One likely explanation for the difference in adherence rates is the service model that the study pharmacies employ in providing care to their patients. The five participating organizations all represent specialty pharmacies. These specialty pharmacies provide focused therapeutic management, medication distribution, and patient counseling to patients affected by high-cost, chronic disease states, such as multiple sclerosis, rheumatoid arthritis, hemophilia, and solid organ transplantation. The specialty pharmacy practice model provides unique benefits to the patient. Among these benefits are consolidated and controlled distribution of medications and financial support (ex., paperwork necessary for insurance reimbursement, patient assistance program applications, etc.). Specialty pharmacies may use such methods as proactive refill reminders, disease-focused education, and pharmacist-staffed patient call-centers to improve adherence and maximize patient outcomes (Pharmaceutical Care Management Association, 2005).

In addition to the financial barriers associated with adherence, there are strong behavioral and educational components to adherence that must be addressed (Newton, 1999). Through their proactive efforts, specialty pharmacies can address the important educational and behavioral barriers to adherence through direct and frequent patient-contact. Indeed, the dedicated support staff available at most specialty pharmacies provide an outlet for patients to seek information concerning their condition and potential effects of their medications, as well as a mechanism for reinforcement of concepts important for adherence. The increased level of contact could be of added benefit in the pediatric population where families and caregivers may encounter a variety of behavioral and psychological issues that adversely affect adherence (Griffin & Elkin, 2001; Gerson, Furth, Neu, and Fivush, 2004). Frequent contact with a pharmacist might provide increased awareness of the potential psychosocial barriers to adherence and promote dialogue between the pediatric patient, parent/caregiver, and pharmacist in order to promote adherence with the therapeutic regimen.

Medicare does provide payment to specialty pharmacies serving transplant patients. However, increases in drug acquisition costs and decreases in reimbursement may result in discontinuation of extra services for financial reasons. The results of this analysis support CMS's goal of using a "pay-for-performance" reimbursement framework to improve outcomes and reduce medical costs. In the new age of medication therapy management and the potential for increased reimbursement, it is important for actions to be taken by policymakers to ensure

that appropriate levels of reimbursement are available for pharmacists who provide high levels of service that add value through improving outcomes for their patients, thereby reducing the financial burden on the health care system.

Conclusions

Increased adherence was associated with a potential cost-avoidance due to patients surviving with functioning kidney transplants rather than returning to dialysis, which is very costly at over $70,000 per year per patient. Given the increasing cost of drugs, it is necessary to ensure that patients have access to appropriate care and are adherent with their treatment regimens. Pharmacies that provide patient-focused services to improve adherence can be successful at increasing adherence rates; however, policies such as appropriate reimbursement for services provided must be implemented to support these operations in order to support and promote the provision of optimal patient care.

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Table 1. Distribution of age categories

	Number	Percent
≤18	32	2.01%
19 – 40	344	21.64%
41 – 65	848	53.33%
> 65	366	23.02%
Total	1,599	100.00%

Table 2. Drug utilization across age categories*

	Azathioprine	Mycophenolate mofetil	Mycophenolic Acid	Sirolimus
≤18	3.13% (1)	78.13% (25)	0% (0)	21.88% (7)
19 – 40	4.65% (16)	73.55% (253)	2.62% (9)	19.19% (66)
41 – 65	6.25% (53)	73.47% (623)	1.53% (13)	18.87% (160)
> 65	7.92% (29)	71.04% (260)	2.19% (8)	18.85% (69)
Total	6.23% (99)	73.02% (1,161)	1.89% (30)	19.31% (302)

Values in parentheses indicate cell frequency.
*Percentages are within each age category. Each row may not sum to 100% as patients may have received multiple agents.

Table 3. Mean medication possession ratio (MPR) by drug and age category

	Azathioprine (n = 99)	Mycophenolate mofetil (n = 1,165)	Mycophenolic Acid (n = 30)	Sirolimus (n = 307)
≤18	0.97 (n/a[b])	0.96 (0.22)	—[c]	0.98 (0.19)
19 – 40	0.90 (0.23)	0.94 (0.18)	0.96 (0.13)	0.96 (0.22)
40 – 65	0.98 (0.15)	0.95 (0.18)	0.95 (0.13)	0.93 (0.18)
> 65	0.96 (0.14)	0.94 (0.20)	0.99 (0.12)	0.96 (0.27)
Overall[a]	0.96 (0.16)	0.95 (0.18)	0.96 (0.12)	0.94 (0.21)

Values in parentheses represent standard deviations.
[a]Overall values calculated on total sample within each drug (represented as "n" in the column headings).
[b]Standard deviations not calculated because there was only 1 person in that category.
[c]No patients were in this category.

Table 4. Adherence by drug and age category (defined as MPR ≥ 0.8)[a]

	Azathioprine (n = 99)	Mycophenolate mofetil (n = 1,165)	Mycophenolic Acid (n = 30)	Sirolimus (n = 307)
≤18	100.0% (1)	84.0% (21)	—[b]	85.7% (6)
19 – 40	81.3% (13)	82.6% (209)	77.8% (7)	83.4% (57)
40 – 65	90.6% (48)	85.7% (534)	84.6% (11)	81.3% (130)
> 65	89.7% (26)	83.5% (217)	87.5% (7)	76.8% (53)
Overall	89.0% (88)	84.5% (981)	83.3% (25)	81.5% (246)

Values in parentheses indicate cell frequency.
[a]Percentages represent the percent of patient within that age group who had an MPR ≥ 0.8.
[b] No patients were in this category.

Table 5. Total adherence by age category

	Percent adherent (Number)
≤18	84.4% (27)
19 – 40	83.1% (286)
40 – 65	85.1% (722)
> 65	82.8% (303)
Overall	84.2% (1,338)

Table 6. Decision analysis probability and cost estimates

	Initial estimate	Sensitivity analysis range
Adherence in group of study pharmacies	0.842	0.60 – 0.95
Adherence in other pharmacies	0.65[a]	0.40 – 0.95
Probability of death (regardless of graft survival status)	0.03[b]	0.02 – 0.10
Probability of functioning graft in adherent patients	0.894[c]	0.80 – 0.99
Probability of graft failure in non-adherent patients	0.578[d]	0.15 – 0.99
Cost of functioning graft per patient per year	$15,357[c]	$8,000 – $30,000
Cost of failed graft per patient per year	$70,930[c]	$30,000 – $140,000

[a]Chisholm, Mulloy, and DiPiro, 2005
[b]Yen et al., 2004
[c]USRDS, 2005
[d]Gaston et al., 1999

Figure 1. Decision tree with expected values

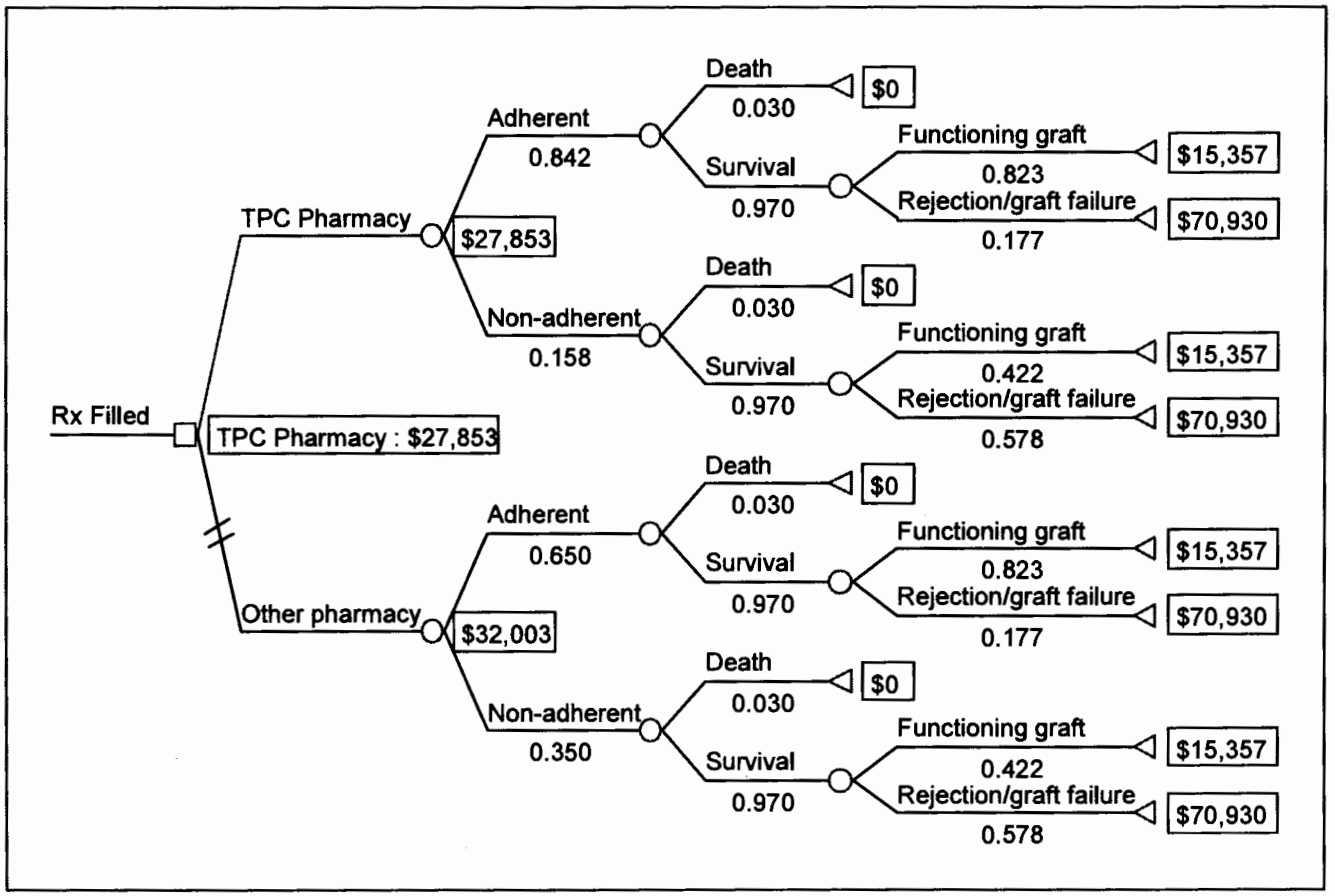
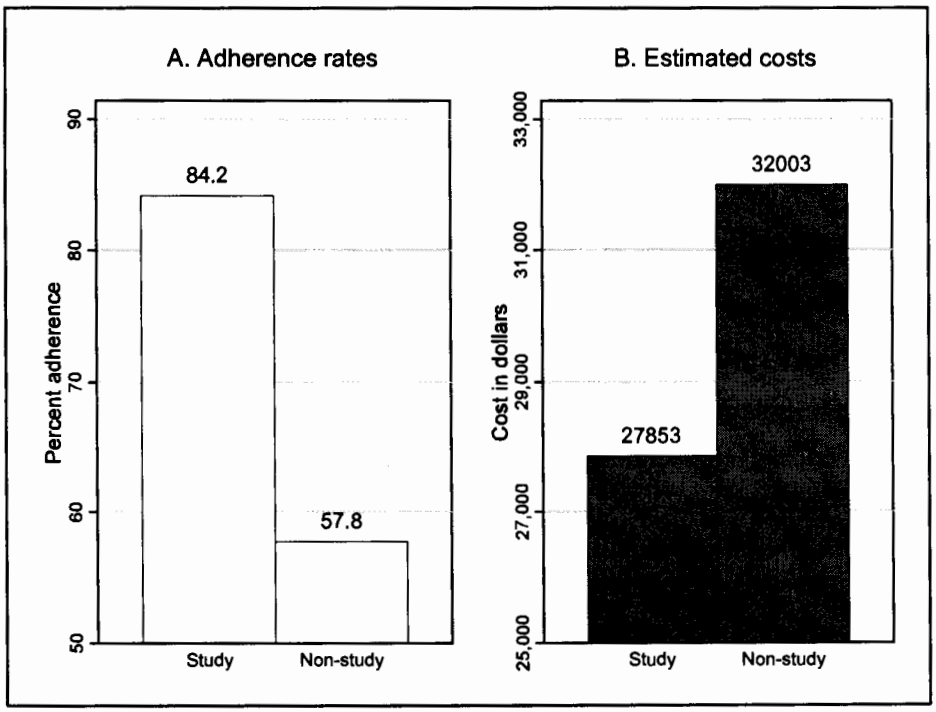


Figure 2. Comparison of adherence rates and estimated annual costs per person associated with type of pharmacy



Submitter : Mr. Jayson Slotnik **Date:** 10/10/2006

Organization : Biotechnology Industry Organization

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-897-Attach-1.PDF

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

Organization : **Medical Group Management Association**

Category : **Health Care Professional or Association**

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-898-Attach-1.PDF

MGMA

MGMA Center for Research
American College of Medical Practice Executives
Medical Group Management Association

October 10, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007

Dear Dr. McClellan:

The Medical Group Management Association (MGMA) is pleased to submit the following comments in response to the proposed rule entitled "Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007," as published in the Aug. 22, 2006 *Federal Register*. We appreciate the Centers for Medicare & Medicaid Services' (CMS) outreach to the provider community and their willingness to participate in constructive dialogue to improve the Medicare program. We look forward to continuing to collaborate on this and other administrative simplification issues. For these reasons, MGMA offers the following critiques and recommendations related to this rule, as outlined below.

MGMA, founded in 1926, is the oldest and largest organization representing physician group practices. MGMA's 20,000 members manage and lead more than 12,000 organizations nationwide in which over 242,000 physicians practice medicine. Individual members, including practice managers, clinic administrators and physician executives, work on a daily basis to ensure that the financial and administrative mechanisms within group practices operate efficiently so physician time and resources can be focused on patient care.

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Sustainable Growth Rate

The downward spiral of payment updates for providers paid under the Medicare physician fee schedule is prolonged for the fifth consecutive year with the 2007 projected cut of 5.1 percent. Without Congressional action, physician payments would have been reduced over 19 percent since 2001. If the current trend remains, providers will face difficult decisions as they evaluate the economic practicability of caring for Medicare beneficiaries. According to the responses of more than 1,600 group practices to a June 2006 MGMA questionnaire, 39 percent of practices anticipate limiting the number of Medicare patients seen in their offices if reimbursement is reduced by the projected 5.1 percent. Another 19 percent may refuse to accept new Medicare patients. The economic viability of practices is further undermined by the widespread use of the Medicare physician fee schedule as a benchmark for private insurance reimbursement rates.

MGMA has conducted extensive surveys of medical practice costs for more than 50 years. MGMA-collected data indicate that the cost of operating a group practice rose by an average 4.48 percent per year over the last 10 years. In fact, between 2000 and 2005, MGMA data show that operating costs have risen more than 26.1 percent. Medicare reimbursement rates for physician services have fallen far short of the increased cost of delivering quality services to Medicare patients. Agency-initiated administrative modifications can help mitigate the anticipated cuts for calendar year 2007 and beyond.

Definition of "physician services"

The statutory language of the Social Security Act that defines the payment update formula requires CMS to assess the allowed and actual expenditures of the Medicare program. MGMA maintains that the definition used by CMS for "physician services" in the sustainable growth rate (SGR) formula is inappropriate because of the inclusion of the cost of physician-administered outpatient prescription drugs.

A significant factor in the growth in Medicare expenditures has been the introduction of the program's coverage of costly new prescription drugs administered in the physician's office. Since 1996 (the SGR base year), SGR spending for physician-administered drugs has more than doubled. These expenses reflect the acquisition of products rather than services rendered by a medical professional, and therefore, are different from "physician services." The inclusion of drugs in the definition of physician services is inaccurate and runs counter to CMS' stated goal of paying appropriately for drugs and physician services. MGMA asserts that the definition of "physician services," as required by the statute, does not include the cost of prescription drugs.

A separate definition of physician services used by the Medicare program clearly distinguishes physician-administered outpatient prescription drugs from services rendered by physicians. CMS adopted this definition in the Dec. 12, 2002 "Inherent Reasonableness" rule (67 FR 76684). Plainly, the definition of physician services must be applied consistently for fair and equitable administration of the Medicare program. Furthermore, the recent reforms to the payment system for physician-administered prescription drugs establish a separate venue to address the utilization and cost of drugs. MGMA strongly urges CMS to remove prescription drug expenditures from the definition of "physician services" used to calculate the physician payment update factor.

Full impact of law and regulation

The current SGR calculation fails to adequately capture the impact of changes to laws and regulations as required by law. For example, the formula fails to account for the downstream services that will result when the new screening benefits reveal health problems. The same is true of the Medicare prescription drug benefit, which will unquestionably lead to more medical visits, and in turn, will generate additional tests and care. The SGR does not account for this inevitable spending.

Additionally, the impact of CMS coverage decisions is excluded from the SGR entirely, even though those decisions may have as great an impact on patient demand for services as a statutory change. Such changes are likely to be highly beneficial for patients, but they may also contribute to negative reimbursement updates through the SGR calculation. MGMA believes CMS has the administrative authority to better account for the full impact of such changes to law and regulation, and vigorously urges CMS to assert this authority.

MEI calculation

Another component of the Medicare physician reimbursement formula that requires improvement is the Medicare Economic Index (MEI). The MEI was established in 1973 to reflect the rising cost of practicing medicine. However, the current MEI calculation is showing its age, and fails to incorporate all of the costs a medical group practice bears to care for patients. MGMA agrees with a 2004 recommendation by the Practicing Physicians Advisory Council to CMS that the MEI be expanded to reflect costs, such as compliance with extensive new billing regulations, hiring new staff and increased training for current staff to comply with expanding regulations. The MEI also should reflect steps taken to improve patient safety and include those additional costs not included in the MEI in 1973, but which clearly must be a part of the calculation today.

Additionally, the MEI must reflect the modern level of support staff. MGMA is particularly concerned that employee wages used in the MEI formula do not capture those of highly skilled professionals now considered essential for the delivery of medical services. These professionals include nurse practitioners, physician assistants, certified nurse specialists, nurse midwives, certified registered nurse anesthetists, occupational therapists, physical therapists, certified practice managers, computer professionals, transcriptionists and certified coders. MGMA recommends that CMS work with other government agencies such as the Bureau of Labor Statistics and private organizations to identify other nationally collected data sources or to collaborate in the development of survey methodology and data collection if no such source currently exists.

Practice Expense

MGMA brings a particularly valuable perspective to this issue. As a research-oriented organization, MGMA has collected practice expense data since 1955. Our data collection involves group practices which range in size from two to several hundred physicians. As such, we understand the magnitude and complexity of CMS' task. In addition, MGMA represents an equal proportion of primary and specialty care practices that are in the primary care and specialty care sectors. Consequently, we are able to detach ourselves from the "outcome" and focus primarily on the "methodology" applied.

Methodology

MGMA supports CMS' decision to implement a bottom-up methodology as opposed to the previous top-down approach. While the results of both approaches depend on the quality of the medical practice expense data collected, MGMA believes the bottom-up approach has a greater likelihood of resulting in accurate values. History has shown that calculating practice expenses using a data- based methodology is more accurate when compared to a method that uses estimates of actual inputs.

In previous years, CMS has provided a significant amount of specificity regarding the process for developing the practice expense methodology. This year CMS did not include in the NPRM a thorough explanation of the calculations to allow specialties to determine their individual impact level of the practice expense changes to their specialty. CMS did not present sufficient examples to the provider community to make the change in methodology understandable. MGMA recommends that CMS provide explicit examples for selected specialties to demonstrate to the provider community how the methodology is calculated. In addition, CMS provides data on the first and fourth year of the transition period; however, there is no data provided on the impact of the changes to the methodology for years two and three. MGMA recommends that CMS provide that information to the provider community in an interim final rule with comment period.

Data Source

As in previous comments, MGMA maintains its concern that the practice expenses methodology is based on the American Medical Association's (AMA) Socioeconomic Monitoring System (SMS) data, which is dated, and the Clinical Practice Expert Panel's (CPEP) data, which is extremely subjective. The SMS data used to calculate practice expenses for FY2007 is from 1995-1999. MGMA recommends CMS conduct a new SMS survey in order to develop more accurate data that would result in equality for all specialties. The entity or organization contracted to conduct this new survey needs to be one that has proven its reliability in this area previously.

MGMA agrees with CMS that while the AMA SMS survey data is dated, a survey of this nature is the most appropriate and only primary data set in existence to determine specialty-specific cost pools. We believe that not only does a new survey need to be conducted, but the methodology for conducting the survey needs to be enhanced as described below.

It is critical that the unit of observation used in a new survey reflect the organization rather than individual physicians who are owners or part-owners of their practices. The primary responsibility of the particular respondents is often the practice of medicine rather than the business operations of the practice. There are several reasons why the organization is preferable. First, the respondent must have both adequate knowledge about the business of medical practices and a comprehensive understanding about the information being sought. Second, the respondent must have the ability to access such information for the entire practice.

While AMA's survey response rate has been strong historically at about 60 percent, not all respondents answered the practice expense portion of the survey. Specifically, the 1996 SMS report based on 1995 data indicates that of the 4004 overall respondents to the survey, 2352 were self-employed physicians and therefore eligible to report data on practice expenses. Of the 2352, 1552 provided total professional expenses, 1595 payroll, 1504 medical equipment, 1538 medical supply optimal resources, and 1573 office expenses. The overall response rate to the practice expense portion was 39.9 percent. While we understand that it is difficult for physicians who are owners or part-time owners of practices to respond to the practice expense portion, MGMA is hopeful that the response rate and thus the quality of responses will improve when the practice becomes the unit of observation.

AMA collected data on clinical labor, supplies, equipment and other practice costs. MGMA recommends that the entity chosen to conduct a new survey refine the expense categories to identify ancillary service expenses and activity data. Our experience has shown that medical groups with radiology or laboratory ancillary services have different expense experience than medical groups that do not have these services. Future refinements of the practice expense Relative Value Unit (RVU) component should isolate the effect of ancillary services from the total expense profile of the practice. This can only be accomplished if ancillary service expense data is separately collected. When conducting a new survey, there must be a mechanism to validate data. The benefit of collecting data from profit and loss statements is that the practice expense responses cannot be exaggerated.

MGMA remains concerned about the quality of the data gathered by the CPEPs but is pleased that it plays less of a role in the bottom-up methodology. Historically, our concern can be summarized as follows: (1) the composition of the CPEPs was inadequate as it consisted primarily of practicing physicians without adequate representation from practice managers; (2) there was no uniform policy on how CPEPs should deal with issues such as duplication of time or efficiencies that might result from performing more than one task at a time; and (3) there was inadequate time allotted for the CPEPs to meet. For example, because of the vast number of codes the CPEP had to value during their meetings, there simply was not enough time to devote to differences among codes.

As CMS, or an entity in its place, considers the practice expense issue, it must seek input from practice managers, especially since the information sought focuses largely on clinical and administrative staff time and not on physician time. Assuming the make-up of the panels is appropriate, they have the potential to refine the CPEP's data. However, to the extent that the panels will not have access to any actual practice expense data gathered from physician practices, they will have limited effectiveness. Nevertheless, convening panels could help identify egregious errors and/or highly anomalous results. MGMA recommends that panels be convened subsequent to the accumulation of actual practice expense data to allow them to complete their work based on more accurate information.

MGMA is concerned about the process that CMS used to determine practice expenses. The bottom-up methodology loses an element of the data that accounts for the significant differences between practices of the same specialty. To create a resource-based approach that conforms to real-world practice costs, CMS must collect actual service-level practice expense data directly from physician practices and base both direct and indirect PE RVUs on that data. Such data would give CMS a far more accurate database for direct costs than the current estimates developed by the CPEPs' process. Recognizing time constraints established by Congress and limited resources, at the very least, CMS should undertake a limited study on a cross-section of practice settings nationwide to obtain actual practice expense data from physicians' offices. The agency could use this data, however limited, to validate or refine the existing data obtained through the panels' process.

Four-year transition

MGMA supports a transition period and applauds CMS for the development of a transition period. We appreciate CMS' consideration of the upcoming negative update factor for CY 2007; however, we believe that the implementation timeline is not ideal because of the level of uncertainty surrounding the cumulative impact of the reductions in reimbursements on medical practices. MGMA recommends that CMS delay the implementation of practice expenses until all of the provisions within the Medicare Modernization Act have been implemented. This would allow all specialties sufficient time to implement provisions regulated prior to the practice expense changes.

Budget neutrality adjustor

MGMA believes that CMS should reconsider applying the budget neutrality adjustment factor to work RVUs. CMS does not provide an adequate rationale for shifting the budget neutrality adjustor to the work RVUs. In the past, CMS has suggested the same proposal and the provider community responded negatively. By placing the budget neutrality factor on the work RVUs, the affect to specialties is varied because of the different levels of work involved. Constant variation in the work RVUs due to budget neutrality adjustments hinders the process of establishing work RVUs for new and revised services. MGMA recommends that CMS apply the budget neutrality adjustor to the conversion factor in order to make the calculations more equitable and understandable to the provider community. MGMA believes that applying the budget neutrality adjustor to the conversion factor will have less impact on other payers who use the Medicare resource-based relative value scale and will be consistent with the notion of budget neutrality.

CMS is moving towards making pricing information for physicians, hospitals and other providers more transparent. MGMA recommends that CMS apply the principles of transparency to the Medicare policy that govern these prices. By applying the budget neutrality adjustment to the conversion factor, pricing information to the provider community will be more transparent. Transparency of the financial effect of these changes will enable physicians and policymakers to more easily understand the impact of the cuts.

In order to achieve CMS' goal of transparency of pricing information, the budget neutrality adjustments should be made to the conversion factor.

GPCIs

As noted in our previous comments, MGMA remains opposed to CMS using inappropriate data sources to calculate the geographic practice cost indices (GPCIs). This includes the use of census data to calculate GPCI values. The very nature of the data render the values outdated by the time CMS is able to use the information. Additionally, although the statute mandates updating the GPCI values every three years, they are in essence updated every 10 years since the census is collected once every decade. MGMA maintains that this is unacceptable. A separate source with more timely data must be identified to adhere to the three year update schedule that Congress intended. MGMA recommends that CMS work with other government agencies, including the Bureau of Labor Statistics and private organizations, to identify alternative data sources. Alternatively, CMS should work with these groups to identify an appropriately indexed data source to meet the statutory requirements.

Of particular concern to MGMA is that employee wages used in the GPCI formula do not capture highly skilled professionals now considered essential for the delivery of medical services. These professionals include nurse practitioners, physician assistants, certified nurse specialists, nurse midwives, certified registered nurse anesthetists, occupational therapists, physical therapists, certified practice managers, computer professionals, transcriptionists and certified coders. While it remains true that the 2000 census definitions of certain medical professionals are more expansive than the 1990 definitions, limited improvements result for the updated GPCI values. The wages of several prominent professions continue to be excluded, including physician assistants, occupational and physical therapists, certified practice managers, IT professionals, transcriptionists and certified coders. MGMA recommends that CMS revise the GPCIs to include these employees to ensure that the occupations used in the formula reflect the numerous categories of medical workers found in modern practices.

As in years past, the office rental indices used to calculate the practice expense GPCIs are based on the Department of Housing and Urban Development's (HUD) residential apartment rent data. While MGMA is sympathetic to the difficulty CMS has in identifying alternative sources for pricing medical office space, MGMA remains opposed to the use of residential and not commercial data for this purpose. Such use is inconsistent with the core objective of the Balanced Budget Act of 1997 to make Medicare payments resource based.

As noted in our previous comments, MGMA also highlights the findings of the Government Accountability Office (GAO) in their March 2005 report on HUD estimates of fair market rents (GAO-05-342). The report identified major concerns raised by the HUD estimates, substantiating the level of inaccuracy reported by many MGMA members. The report also explains that HUD will soon use a new data source, the American Community Survey (ACS). It is important to note that ACS processes rates differently than HUD has in the past. With this impending data shift, MGMA urges CMS to work with HUD and the Bureau of Labor Statistics to determine whether the values populating the GPCI calculations for medical practice rent are accurate and will meet the agency's needs once ACS data is adopted by HUD.

Miscellaneous Coding Issues

MGMA appreciates CMS seeking input on radiation oncology because there is tremendous uncertainty on how services should be submitted both during the treatment period as well as in the post treatment period, which is defined as three months in the CPT definition. Brachytherapy and Proton Beam therapy fall under the narrative instructions in the CPT manual for Radiation Oncology. In the narrative instructions,

it specifically states that the services included in this section (77261-77999) includes "normal follow-up care during treatment and for 3 months following its completion." The provisions do not explicitly state that CMS will pay for the post-op visit separately; therefore, MGMA recommends that CMS specifically state that there will be separate payments for any and all medically necessary post therapy visits based on the documented level of Evaluation and Management (E/M) service for the post procedure encounter(s).

CMS' proposed change would likely cause some problems for practices with private payer contracts that follow Medicare's RVUs and CPTs definitions. The RVUs will change, but by current CPT definition, no other follow-up evaluation and management services are billable for 90 days after treatment. MGMA is aware that CMS does not have jurisdiction over other payers' actions, but we do recommend that if this change occurs that it take place concurrently with a revision to the CPT manual to remove the 90 day global period from the definition of these services.

Deficit Reduction Act (DRA) Proposals

Imaging

CMS will reduce payment for the technical component for multiple imaging services performed on contiguous body parts by 25 percent. While MGMA appreciates CMS' decision to limit cuts in payment to 25 percent rather than the proposed 50 percent for calendar year 2007, we are concerned that the 25 percent reduction is arbitrary. CMS claims to have based this figure on data relating to costs, but CMS has not released its actual calculations used to justify the 25 percent reduction. MGMA maintains that the proposed cuts do not cover costs and would limit patient access to imaging services. We urge CMS to share its data before making a policy change that would severely impact certain specialties. While MGMA appreciates CMS' decision to calculate the multiple services reduction before applying the statutorily-mandated cap (the OPPS amount), we urge further consideration and evaluation of the multiple services reduction before it is implemented.

Furthermore, MGMA urges CMS to educate providers of diagnostic imaging services and Medicare contractors regarding the continued ability to bill globally for diagnostic imaging services subject to the reduction. As previously experienced with physician scarcity and health professional shortage area payments, global payments for services with technical components that are treated differently caused major system errors and necessitated that these codes be unbundled for several months. MGMA seeks clarification and assurances that these services may continue to be billed globally.

Therapy Cap

CMS implemented two annual therapy caps, one for speech-language pathology and outpatient physical therapy and another for outpatient occupational therapy, on Jan. 1, 2006. In Section 5107(a) of the Deficit Reduction Act of 2005, which was enacted on Feb. 8, 2006, Congress mandated that the Secretary of the Department of Health and Human Services create an exceptions process for the therapy caps. This exceptions process is scheduled to expire on Dec. 31, 2006. MGMA feels that since the exceptions process is scheduled to expire at the end of the calendar year, CMS should develop a process to deal with exceptions and appeals issues. MGMA believes that the continuity of a process would lessen possible administrative burdens and is willing to assist the administration in developing a procedure.

End-Stage Renal Disease (ESRD) Provisions

Hospital data used

MGMA remains concerned about the appropriateness of using acute care hospital wage index data in the calculation of the ESRD-Composite Payment Wage Rate Index. This index is used to determine payment to both hospital-based and independent ESRD facilities. The use of only hospital data in this calculation would indicate that wages in hospital-based and ambulatory facilities are the same or similar in nature; however, no such determination has been made. In fact, the costs for hospital-based facilities and ambulatory centers vary greatly. The ESRD-Composite Payment Wage Rate Index needs to take into consideration wages paid in independent facilities, in addition to those paid in acute care hospital inpatient settings. MGMA urges CMS to locate an alternative data source that reflects information directly tied to ESRD facilities.

Use of Floor/Ceiling Values

CMS has again proposed reducing the wage index floor for the ESRD-Composite Payment Wage Rate Index. This decrease will penalize ESRD facilities that have already faced cuts from the transition to the average sales price drug reimbursement methodology. These cuts to facilities' reimbursement will make it even more difficult to recruit and retain qualified personnel in areas affected by the removal of this floor.

Private Contracts and Opt-Out

MGMA is appreciative of CMS' efforts to include registered dieticians and nutrition professionals in the definition of a practitioner. This inclusion will provide registered dieticians and nutrition professionals with the same opportunity as other health care providers to opt-out of the Medicare program if they so choose, especially in light of the anticipated declines in provider reimbursement.

Reassignment and Physician Self-Referral

The proposed fee schedule contains a number of provisions aimed at curbing what CMS has deemed abusive "pathology pod laboratories." While some such arrangements may be problematic, the proposed new restrictions would apply much more broadly to all types of provider groups. Given that CMS has not fully explained exactly why "pod labs" are abusive, major changes of general applicability to the reassignment and Stark rules seem both overbroad and premature. If adopted, these changes will certainly inhibit flexibility in group practices, and likely preclude many legitimate arrangements that enhance patient convenience and quality of care. MGMA urges CMS to target any changes much more narrowly so as to preserve and encourage legitimate arrangements.

MGMA is particularly concerned with CMS' apparent intention to limit the ability of group practices to provide medically necessary services to patients through collaborative arrangements between groups and independent contractors. Providing specialized and ancillary services though group practices serves patient convenience, enhances coordination of care, facilitates access and patient compliance, and often produces much faster diagnostic or therapeutic benefits, thus improving quality. These benefits apply equally to the technical component (TC) and the professional component (PC) of diagnostic tests.

Limitations on the ability of an independent contractor to reassign benefits

Group practices utilizing independent contractors on the premises of the practice have long been permitted to accept reassignment of the independent contractors' benefits. Sec. 952 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) explicitly permits similar reassignment in the case of services provided off-site. At a time when teleradiology and other technological advances make the provision of services off-site feasible and clinically appropriate, this MMA change provided badly needed flexibility. We see no reason to reverse that change now, especially when it has been in effect so briefly.

In comments on the proposed 2005 Medicare physician fee schedule, MGMA expressed concerns regarding CMS' characterization of these arrangements. "Parties should be mindful that contractual arrangements involving reassignment may not be used to camouflage inappropriate fee-splitting arrangements or payments for referrals." At that time, CMS further solicited comments on program "vulnerabilities" and proposed to "monitor reassignment arrangements for potential program abuse." MGMA reiterates its concern here. Nearly all physicians and non-physician practitioners participate in the Medicare program in good faith and abide by the program's rules and regulations. CMS' restrictive new proposals signal an inherent, and we think unwarranted, distrust of providers without documented proof of program abuse. Rather than finalizing the reassignment provisions proposed, MGMA recommends that the agency continue using current monitoring techniques employed by Medicare carriers where medical groups document all provider agreements and financial arrangements and provide copies of this documentation to the government upon request. Most, if not all, enrollment contractors request copies of provider contracts, including joint and severable liability stipulations between the provider and group practice, at the time of enrollment. As part of the Medicare enrollment process, Medicare carriers must ensure that arrangements between Medicare providers and their independent contractors are legitimate. If CMS has evidence of abuse uncovered through these efforts, MGMA requests that it be made public, so the medical specialty societies and state medical boards can act to limit the activities of abusive providers.

Anti-markup provisions for an independent contractor's technical component services

The proposed rule contains anti-markup provisions that are virtually identical to those contained in the Medicare statute at 42 U.S.C. § 1842(n)(1), as well as in the regulations at 42 CFR § 414.50. There are also virtually identical provisions in the Medicare Claims Processing Manual (Pub. 100-04), Chap. 1, Sec. 30.2.9. This guidance is sufficient to prevent fraud and abuse, making the provisions included in the current proposal unnecessary and redundant. MGMA is unclear as to the reasoning behind the inclusion of these provisions.

However, MGMA is more concerned by the language CMS has proposed that would require the physician or group to "directly" perform the PC where the group bills for a TC performed by an outside supplier or independent contractor. The use of the term "directly" raises some questions and interferes with a group practice's ability to contract freely, and MGMA opposes the inclusion of this requirement in the proposal.

According to the *American Heritage Dictionary of the English Language 4th Edition* (2000), the word "directly" is defined as "[w]ithout anyone or anything intervening." Based on this definition, a contract between the practice and the independent provider would create an intervening relationship, indicating that the practice could not use an independent contractor to perform the PC if it had already used an independent contractor, be it the same contractor or a different one, to perform the technical component. However, there are tests where it is clinically appropriate for the physician to perform both the TC and the PC of a diagnostic test, and MGMA sees no policy justification for prohibiting a group from contracting for both.

The use of the term "directly" effectively excludes independent contractors from the group practice for some purposes. However, under the definition of a "physician in a group practice" included in the Stark regulations contained in 42 CFR 411.351, an independent contractor is considered a physician in a group practice during the time he is performing patient care services for that practice. Additionally, independent contractors are considered part of a group practice under "incident to" billing rules. Where one or more laws or regulations consider independent contractors to be part of a group practice, it is ill-considered to exclude them from a group practice under other provisions. Group practices spend a great deal of time and money in an effort to comply with federal and state laws and regulations. To create situations where the same individual may legally be permitted to do one thing but not another based purely on the specific

facts of the situation is to create a scenario ripe for inadvertent legal violations and a field day for attorneys. This will, in turn, increase the costs of such services and overall practice costs. MGMA is opposed to the proposed changes to an already burdensome and overly complex statute and regulations.

Instead of using independent contractor arrangements, group practices may be forced to use part-time employment arrangements. These arrangements may be more costly because of payroll tax and benefit considerations, and they can greatly complicate benefit programs for both the employer and the part-time employee.

It is not clear from the proposal precisely what policy objective CMS seeks to advance by prohibiting the reassignment of TC services in instances where the group practice also contracts for PC services rather than providing those through its own owners and employees. It is clear, however, that the effect of such a prohibition will be to reduce flexibility for groups, and tilt the competitive playing field for certain diagnostic services towards certain specialties. This is a questionable result generally and appears to have nothing to do with the underlying purposes of either the reassignment rules as they apply to independent contractors, or the anti-markup provisions as they apply to purchased TC services. If there are abuses related to contracting for PC services, they would seem more properly the province of the anti-kickback law and its enforcement.

The use of independent contractors to provide PC services

Anti-markup provisions

MGMA opposes application of the current anti-markup statute, which on its face applies only to TC services, to the PC of a diagnostic test. Independent contractors are reimbursed for their PC services under terms negotiated by the contractor and group practice. Stark and anti-kickback law considerations generally require that compensation meet a fair market value test. Frequently, payment is made based on time spent providing those services, as opposed to a per interpretation price. Alternatively, payment may be made at a fixed rate per month or year. Yet another model is a per service price reflecting a blended rate of different payor pricing, not just the Medicare allowable amount. In some of these situations, it is impossible for a group practice to determine the unit price of an independent contractor's individual PC service in order to apply an anti-markup requirement. In others, the anti-markup rule would prevent the group from recouping legitimate administrative costs such as billing, scheduling, transcription, patient records, and similar costs.

Reassignment provisions

While no specific language has been proposed, CMS contemplates new restrictions on the reassignment of PC services. Once again, the rule does not articulate what policy objective is being pursued. Existing manual provisions permit groups to bill for independent contractors providing professional interpretations of diagnostic tests under two different scenarios. One is a reassignment of an independent contractor's billing rights under the provision adjusted by the MMA discussed above; the other is billing for a purchased interpretation under very restrictive rules and is not technically a reassignment. While admittedly there has been some confusion in the field as to the interplay between these two different manual provisions, MGMA believes they are legally clear. A group may rely on either depending on how it chooses to structure its relationship with the physician providing the interpretation. We urge CMS to leave these provisions as is, thus preserving that flexibility to groups and their contracting partners.

MGMA does not understand what would be accomplished by permitting reassignment only where the reassigning physician does not see the patient. For example, if the treating physician is a "physician in the group" for Stark purposes, and is qualified to perform the PC of a diagnostic test, why require someone

else to perform the PC, possibly increasing the cost to the practice and leading to more fragmented rather than better coordinated care?

Independent contractors who reassign their billing privileges to a group do so for many reasons that have little if any potential for abuse. These include administrative simplicity and efficiencies for both practices, global billing, reduced confusion in the minds of patients (one bill and one co-pay as opposed to two of each), one-stop claims processing and adjudication with carriers, and similar administrative reasons. For example, some private insurance companies do not recognize claims modifiers. Where diagnostic testing services are not billed globally and the modifier is removed, the private insurance company questions what appears to be double billing for the same service from different practices, generating additional work and expenses for both practices.

Receipt of two separate bills for what patients perceive as one service will lead to additional confusion for patients. In all likelihood, the patient will not be aware that he has seen an independent contractor and will be confused when he receives multiple bills after having the test at one location. This will typically result in two different reactions from patients. One group of patients will make repeated telephone calls to the group practice, requiring the practice to retain additional staff to handle such inquiries, thus increasing overall costs of providing these services to the practice. The second group will simply not pay their bills. The practices will either write off the bills as bad debt, or more likely, will be forced to send the accounts to collection agencies. Either of these responses will cost the practice time and money and may cause credit problems for those senior citizens who have difficulty paying their bills or fail to respond in a timely manner.

It appears that CMS is attempting to limit, through the reassignment provisions, which specialties can perform the professional component of a diagnostic test. This determination is more appropriately made by the medical specialty societies, state medical boards and medical schools and should take into consideration many factors, including professional liability considerations. Alternatively, CMS may be looking once again to constrain the volume of diagnostic testing performed. If so, coverage criteria, practice guidelines and performance measures would appear a much more appropriate way to do so than through a blunt instrument like the reassignment rules.

Use of locum tenens physicians

Practices are explicitly permitted to use and bill for the services of locum tenens physicians in certain circumstances. Locum tenens physicians are by definition independent contractors. These proposals, if extended to locum tenens physicians, would limit the ability of group practices to bill for services performed by locum tenens physicians in the normal course of business. It is MGMA's understanding that locum tenens arrangements would be unaffected by these proposed changes; however, the proposed language and preamble leave this point unclear. In the event that CMS does not withdraw the proposals limiting the use of independent contractors, MGMA requests clarification of this point regarding the use of locum tenens physicians.

Proposed changes to the Stark regulations

Definition of a "centralized building"

Under current law and regulations, the term "centralized building," as defined at 42 CFR 411.351, includes no limitations on size, nor does it define the location of the building and the equipment that must be contained within it. CMS now proposes to complicate an already mind-numbingly complex set of laws and regulations that impose severe restrictions on the ability of group practices to manage themselves by altering this definition to require groups to purchase or rent more space and equipment than they actually

need for longer periods of time than necessary to deliver services under the in-office ancillary services exception to the Stark law. Groups are already struggling to comply with this proposed provision before it has even been finalized and are finding that they will be faced with increased costs because of the requirement that the space be used on a full-time basis, as opposed to the current exclusive use requirement.

While the current definition of a centralized building requires that space be occupied exclusively by the group on a 24-hour, seven-days-a-week basis, there is no requirement the space be used on a full-time basis. Forcing groups to use the space on a full-time basis will lead to increased costs for the group practice, including but not limited to new electricity, billing and support staff expenses. Forcing the group to use a full-time independent contractor negates one of the primary purposes of using an independent contractor: to perform services that are not required on a full-time basis. This requirement is unlikely to reduce the number of pod labs in existence; instead, it is almost certain to make it more difficult, if not impossible, for small group practices to offer necessary services to their patients in a cost-effective manner. MGMA opposes any such limitations on the flexibility of groups to offer services in a cost-effect manner that is also convenient for patients and conducive to patient care.

The proposed "90 percent test" on equipment used in centralized buildings is particularly arbitrary. The use of the word "permanently," defined by the *American College Dictionary* as "remaining unchanged," would seem to restrict practices – whether or not they share the same physician in a practice with more than two other practices – from storing equipment in an office or storage closet within the confines of their space and moving it into an examination room as necessary. In order to do so, such equipment would have to be on wheels, which would generally allow the equipment to be removed from the space. Even if it is the group's intention not to remove the equipment from the space, it would appear that this would be impermissible under the proposed changes because it would not be in a location that will not change.

Many patients, especially those in rural areas, depend on mobile equipment to obtain diagnostic imaging services. Group practices providing such services generally depend on their ability to have multiple centralized buildings. They generally accomplish this by purchasing or leasing mobile equipment and sharing it amongst their offices. Under this proposal, groups will be forced to either purchase or lease additional equipment for longer periods of time than they can afford, rather than share one set of equipment amongst their various office locations. Instead, they will no longer be able to offer these services to their patients. These patients will either be forced to visit the nearest hospital or travel long distances to obtain such services. MGMA has received reports from members that their practices anticipate possible reductions in mobile diagnostic imaging services. According to a practice administrator of a 10-physician cardiology practice in Arkansas that is considering no longer holding outreach clinics that provide diagnostic imaging services, patients will be forced to travel as much as three hours to obtain care.

The "90 percent test" will also discriminate between and among different groups. Those with large ancillary programs with plenty of fixed equipment in place will still be able to use some mobile equipment because it will generate less than 10 percent of their Medicare DHS total. Smaller groups with fewer ancillaries, but the need for some mobile equipment on a part-time basis will be precluded from using it because they will be in excess of 10 percent. Groups whose DHS utilization patterns vary from month to month and year to year will live under a cloud of uncertainty with respect to when or whether they will cross the 10 percent barrier.

MGMA strongly opposes any change to the definition of a centralized building that further reduces a practice's discretion to manage their facilities in a cost-effective manner.

MGMA also opposes CMS' proposal to further regulate office locations when state lines are involved. There are many practices that may have offices in multiple states or may see patients from multiple states, especially those located in border areas. The Washington, D.C. metro area is a prime example of such a location where patients may live in one jurisdiction but visit a provider in another. Depending on the facility hours and those of the provider, it may be more convenient for the patient to see the provider in one jurisdiction and to obtain the diagnostic test in another. CMS' proposal would prevent these practices from having an office meeting the definition of a centralized building in a different state than an office meeting the definition of a same building. Group practices will be forced to either have all of their offices comply with the definition of a same building or a centralized building. They will be precluded from utilizing the tools available to them under the Stark law that allow them to design contracts and facilities in a cost-effective manner that is also convenient for patients.

MGMA urges CMS to refrain from making any changes to an already overly burdensome regulatory scheme at this time. This proposal is yet another attempt by CMS to micro-manage the internal workings of group practices through the ever-changing intricacies of the Stark law. In the alternative, MGMA recommends that CMS limit these changes to entities that have been identified by the Office of the Inspector General – the agency charged with rooting out fraud and abuse in the Medicare program – as having the highest potential for fraud and abuse. The proposed changes are overly broad and burdensome on group practices already struggling to comply with the regulatory scheme currently in place. At a time when Medicare payment rates are set to decrease by more than 5 percent in the upcoming year and 40 percent over the next five years, regulations that reduce flexibility and increase practice costs and burdens will only cause practices to cease offering medically necessary services to Medicare patients.

Definition of a "physician in a group practice"

CMS has proposed altering the definition of a "physician in a group practice," as defined by 42 CFR 411.351, to require that independent contractors comply with the proposed reassignment rules for TC services, as well as PC services. While MGMA does not intend to diminish the importance of compliance with the Medicare program billing rules, the consequences of a violation of the Stark law are far more serious and far-reaching.

The proposal is an attempt by CMS to bootstrap the reassignment rules into the Stark regulations, a set of regulations that is already overly complex and difficult for an attorney to navigate, let alone a lay person. The reassignment rules are generally contained within the Medicare Manuals, a set of guidelines published by CMS without notice to providers and with little, if any, opportunity for public comment. Given the ease with which these guidelines are amended, group practices may find themselves with violations of these guidelines because of a lack of notice. A group practice committing what is now a 4technical error, would face the potential for enormous penalties if the reassignment references are incorporated into the Stark regulations. MGMA vigorously opposes this proposal and urges CMS not to incorporate the reassignment provisions of the Medicare Manuals into the Stark regulations.

The definition of a physician in a group practice does require that an independent contractor furnish his services in the group's facilities in order to be part of the group practice for the purposes of Stark, but does not define "facilities" for this purpose as the "same building" or a "centralized building." The "centralized" and "same" building tests have no applicability beyond the in-office ancillary services exception. They were developed in conjunction with that exception to restrict the locations in which ancillary services can be provided and still receive Stark law protection. They were never designed to restrict where physicians – whether owners, employees or independent contractors – can provide professional services for a group practice. Altering the regulations in the manner proposed by CMS would prohibit physician owners and employees from providing interpretive services while in a location, such as a hospital, nursing home or surgery center, and prohibit contract physicians from providing a professional

service in the group's professional space simply because it does not meet the requirements for ancillary space. These changes would make little practical sense; rather, they simply reduce group flexibility in the design of clinical space and force physicians to serve Medicare patients where it is convenient for consistency in the Stark law, not necessarily convenient for the physician or the patient.

MGMA opposes the addition of an on-site requirement for physician owners and employees, as well as the re-introduction of the requirement for independent contractors. Under the MMA, Congress clearly indicated that independent contractors should not be required to perform their services on-site when it is unnecessary for them to do so.

Employee Access to Claims Billed on Reassignment

While MGMA shares CMS' interest in program integrity, MGMA opposes the proposed new requirements on employee access to billing records. Congress authorized CMS to develop additional protections related to reassignment by contractors. It evidenced no intent to change the reassignment rules, which have applied to owners and employees of physician practices for decades. Nor is there any evidence of which MGMA is aware to suggest that this is a current program integrity issue.

While employed providers generally have some access to records in the practice, they do not necessarily have unfettered access to all billing records. This is a matter generally left to the terms of a provider's employment contract with the practice, record retention and storage policies and common sense as billing or audit issues arise. Overlaying new regulatory requirements on this aspect of the employer-employee relationship is fraught with potential issues not addressed by this proposal. For example:

1. Does the requirement extend to employees? For how long?
2. Can it be used to harass a former employer in a manner unrelated to any legitimate concern about prior Medicare billings?
3. What about standard contract provisions that prevent a former employee from taking group records as part of a non-compete or non-solicitation provision in the employment contract?
4. What does "unrestricted" mean? Who decides?
5. Does it mean access to original records or only copies? Who pays for copying costs, retrieval from storage, separation of one provider's records from those of the others, of Medicare records from those related to other payers?
6. How much time does the group have to produce the records?
7. What if the records are no longer available?
8. How does the group prevent unauthorized disclosure of HIPAA-protected patient information now in the hands of a former employee?

Not only does the proposed rule not answer these questions, but many are simply not answerable in a "one size fits all" manner. Were CMS to try to answer them all, this perhaps well-intended change would become a major new regulatory burden at a time when both government and physician practices are seeking ways to simplify the administration of healthcare.

One of the benefits of group practice is the use of centralized administrative staff to perform billing and records functions, leaving providers the time and opportunity to focus on clinical care. While both the group and the employed providers generally share liability to Medicare if billing problems exist, it is generally the group's obligation to have systems in place to prevent them to the extent possible and to resolve them if and when they arise. Most groups have billing compliance programs. It is those programs that set the framework for involvement of individual providers in order to ensure integrity. MGMA believes that is the better approach to protecting program integrity, not the addition of yet another regulatory requirement.

Independent Diagnostic Testing Facility (IDTF) Issues

CMS' proposal to adopt performance standards for independent diagnostic testing facilities (IDTFs) raises several concerns. MGMA believes that requiring federal certification at the time of enrollment or upon periodic inspections by CMS' agents will not control the growth in utilization of these services and will not ensure that medical imaging studies are being performed in a clinically appropriate manner. It also will not ensure routine high-quality and will not control the costs of an IDTF. Rather, compliance with and implementation of these standards will further increase costs to individual medical practices and will yield little information for policy makers or health care consumers.

IDTF certification imposes a new layer of federal regulation on physicians providing diagnostic imaging services. CMS has not given any explanation of how the new standards will result in substantial savings, especially given the fact that IDTFs are already subject to federal accreditation standards. Before imposing additional administrative hurdles for IDTFs, CMS should evaluate the effectiveness of current requirements in order to ensure that additional regulations will not merely impose more costly burdens without achieving CMS' stated goals.

In addition, professional specialty societies are working to ensure the quality and safety of medical imaging performed by developing residency training standards and CMS programs for ultrasound, MR, CT, and PET. They are also developing appropriateness criteria and practice guidelines for reasonable incorporation of these technologies into patient care. Performance measures and other quality-improvement tools are also being considered. CMS should recognize and not duplicate or override specialty society efforts to ensure quality and safety by imposing non-specialty specific requirements. IDTFs are already subject to independent, specialty-specific requirements, as well as state laws and regulations currently in place that stipulate equipment quality controls and technologist training requirements. Specialty society efforts should be encouraged and quality-related initiatives for diagnostic imaging should be considered by CMS only in the context of broader pay-for-performance concepts.

In addition to MGMA's general concerns about the overall certification scheme, MGMA specifically questions CMS' proposed standard requiring IDTFs to have a comprehensive liability insurance policy of at least $300,000 or 20 percent of the IDTF's average annual Medicare billings, whichever amount is greater. This requirement is overly burdensome. In its proposed rule, CMS does not provide justification for how it established these numbers, nor does it explain why linking comprehensive liability insurance to a percentage of Medicare billings will improve the quality of care to Medicare beneficiaries. MGMA knows of no other health care entity that has insurance requirements linked to Medicare billings.

MGMA is also concerned about the proposed prohibition on solicitation of patients. This proposed standard, as written, would prohibit IDTFs from advertising and would require a patient to receive a referral from an attending physician in order to be seen at an IDTF. By limiting the ability of IDTFs to solicit patients, CMS is also limiting the ability of Medicare beneficiaries to be informed about and to select their health care providers. Instead, a beneficiary must rely on the referral arrangements developed by his or her attending physician. MGMA supports a beneficiary's ability to be fully informed about health care providers and to be allowed to direct his or her care.

While the IDTF regulations on their face do not appear to mandate the involvement of any particular specialty, they do include physician supervision requirements that, under CMS instructions to Medicare carriers, designate radiologists as the sole specialists qualified to serve as supervising physicians for a number of important diagnostic imaging procedures. MGMA believes that CMS should modify its instructions to Medicare carriers to ensure that specialty certification is not used to determine which physicians are qualified to supervise diagnostic imaging studies.

Health Care Information Transparency Initiative

Introduction

This section of the proposed CY 2007 fee schedule describes the amount of money spent annually within the U.S. on medical and healthcare related services, $1.9 trillion or 16 percent of the national economy. The proposed fee schedule cites projections that by 2015, health care will consume 20 percent of the national economy. In addition, according to the 2006 OASDI Board of Trustees Report, the Medicare program consumes 3.2 percent of the gross domestic product (GDP) and by 2040 estimates predict that it will consume 8.0 percent of the GDP.

Citing these figures, the fee schedule concludes that the lack of information patients typically have regarding the cost of their medical services is responsible for the steady increase in both the utilization and cost in this sector of the economy. The statistics cited in the proposed 2007 physician fee schedule purport to make the case that the price paid for medical services are too high, due to the lack of pricing pressure seen in a free market. MGMA would like to note the implausibility of this argument. Reimbursement to physician group medical practices for health care services is highly regulated and completely price controlled through complex statutory formulas. Medicare fee schedule rates for physician services then become the base fee schedule for group practices negotiating with third party payers nationwide. In fact, physicians providing services to Medicare beneficiaries today are effectively reimbursed at levels equivalent to those paid in 2001. As a result, it is hard to understand the statement in the proposed fee schedule, "[t]thus, providers of care are not subject to the competitive pressures that exist in other markets for offering quality services at the best possible price."

The Health Care Information Transparency Initiative comments point to the rising cost of healthcare services. The fee schedule commentary argues that this trend, combined with the supposed lack of pricing constraint seen in an economic free market, points to the need for greater transparency of pricing. However, others have argued that rising costs in the healthcare sector are largely a result of decreased productivity in this sector of the economy. This lack of productivity is related to the highly labor intensive nature of health care services, much of which could be offset by appropriate investments in healthcare information technology. These arguments are described in detail in the September 25, 2006 issue of *BusinessWeek* cover story entitled, "What's really propping up the economy."

According to the article, the healthcare sector of the economy has added 1.7 million jobs since 2001, while the rest of the economy has not added any. One reason that so many jobs have been created is that healthcare services in the U.S. remain labor intensive, which could be stemmed by appropriate investment in healthcare information technology. The article cites one Harvard University economist, Dale Jorgenson, as saying, "Low productivity in health is mostly a product of low investment [in health information technology]." Another healthcare economist, Gerard Anderson of John Hopkins University, agrees, "Every other country has the payers paying for IT, in the U.S. we're asking the providers to pay for IT." The article continues on to underscore the widely acknowledged point that clinical providers are not the primary beneficiaries of health information technology.

Another relevant point made by the article is that higher real incomes and improved GDP are matched by growth in healthcare expenditures, since improvements in relative health status are costly. Princeton economist Uwe Reinhart is quoted in the article as saying, "if you did geriatric health properly, you'd need a lot more geriatricians." Instead, the administration's transparency initiative purposefully limits the conversation to the supposed lack of an economic market for healthcare services.

It is relatively easy for medical groups to know and therefore, to make publicly available, their Medicare rates, since these rates are totally controlled by federal regulation and policy. However, there are a variety of factors that limit the amount of private payer information available to group medical practices.

MGMA has created a broad policy regarding the transparency of both pricing and quality information. The first section outlines barriers that practices experience in obtaining clear, accurate and timely information about what they will be paid by third party payers. This section, entitled "Transparency: Pricing and Benefit Policies" goes on to outline recommendations for promoting greater price and benefit policy transparency. The second and inter-related section of the MGMA policy is entitled, "Transparency: Physician Quality Performance Data." MGMA policy is firmly committed to the inclusion of relevant quality data wherever pricing or cost data is made public. Consumers need access to both types of data to make appropriately informed decisions. This portion of the MGMA's policy outlines the appropriate sources of clinical performance measures and makes recommendations for the fair use of efficiency measurement. MGMA's entire transparency policy follows.

Transparency: Pricing and Benefit Policies

MGMA supports the intent of the president's call for price transparency. However, simply requiring physicians and other providers to disclose their walk-in charges for common procedures is not the solution. Patients are increasingly responsible for co-insurance payments based on a percentage of the charges allowed under their insurance plans, so it is essential that they know the amount that their insurance will pay for services received. Because most physicians participate in 20 or more insurance plans, and because many insurers have different reimbursement rates for different products, it is not unusual for a service to have as many as 100 prices in a particular physician's practice. Accordingly, the physician is unlikely to have the price that will be paid by a particular insurer, for a particular patient's plan, for a particular procedure readily at hand.

Furthermore, contractual restrictions in health plan contracts often prohibit medical practices from releasing pricing information. These restrictions often fall under confidentiality provisions that classify health plans' pricing structures as proprietary information. As a result, medical practices cannot disclose this information, even to patients. Price transparency will be impossible unless these provisions are removed from health plan contracts with physicians and hospitals.

Recommendations for Achieving Price Transparency:

Require health plans to release fee schedules showing total allowed charges and methods used to calculate fees to physicians and hospitals as part of their provider contracting process. An MGMA statewide survey of Colorado practices found that 31 percent of primary care groups could not obtain fee schedule information from insurers at the time of contracting. Physicians and hospitals are unable to provide accurate price information to patients if insurers are not required to provide fee schedule information to them.

Require that health plan contracts with physicians and hospitals clearly specify that disclosure of insurer fee-schedule information to patients, for services that are to be provided to the patient by the physician or hospital and charged to that insurer, is permissible. MGMA supports research to investigate what fee information is most valuable to patients and consumers, especially those in preferred provider organizations (PPOs); health savings accounts (HSAs) and high-deductible health plans; and for self-pay patients. Studies should also investigate whether health plan use of efficiency ratings of medical practices or individual physicians is useful to consumers in estimating their out-of-pocket costs for certain conditions. If not, additional research should be undertaken to investigate what is most beneficial for consumers.

The president's goal of empowering consumers and patients with pricing information to permit comparative shopping for health care services is hampered by the complexity of the health insurance market. It adds significant costs that are borne by medical practices and the health care system at large and are not apparent to consumers. Much of the estimated $300 billion spent annually on administrative activities results from needless complexity or duplication.

Recommendations for Increasing Administrative Benefit Transparency and Reducing Administrative Complexity:

- Simplify insurance product design by limiting the number of policy forms (including self-insured plans) and adopting a common electronic inquiry system for verifying insurance coverage;
- Simplify payer and provider contracting by creating standard contracts at the state level, including standard effective date and contract terms;
- Simplify billing and payment processes by developing a standard content layout for patient bills, creating standard policies for documentation required for any specific CPT* codes and agreeing on common coding policies across health plans;
    - Simplify credentials verification by using the Council for Affordable Quality Healthcare Universal Credentialing Datasource; and
    - Simplify health care fees by revealing fee structures to medical practices and hospitals at the time of contracting.

Transparency: Physician Quality Performance Data

The following sections outline the measure sets that currently exist to assess physician quality and efficiency.

Clinical Performance Measures

Measures designed to assess the clinical performance of individual physicians and physician groups are developed and validated through existing organizations. The American Medical Association-convened Physician Consortium for Performance Improvement has developed (to date) more than 98 evidence-based performance measures and expects to have developed over 170 measures by the end of 2006. The consortium brings together technical experts from multiple medical specialty societies to develop evidence-based clinical performance measures and ensure that their implementation can be consistent and accurate.

The consortium's work is guided by the following principles:

- Measures must be based on medical evidence and represent substantial potential for improvement between current clinical practice and evidence-based optimal practice.
- Measures must be relevant to physicians and their patients, and accurate and consistently reproducible across health care organizations and clinical settings.
- Measures must be tested for validity. Each measure should include specifications that describe its intent and targeted population, definitions of sampling procedures, definitions of data elements and instructions for collecting data.
- The results of the measures should be risk-adjusted and easily interpreted by clinicians.
- Measures must be feasible to collect, adaptable to various settings and not impose unreasonable cost burdens on practices.

Performance measures from the consortium and other sources are considered for validation by the National Quality Forum (NQF), a private, nonprofit organization that Congress has charged with endorsing consensus-based national standards for measurement and public reporting of health care performance data. NQF-endorsed measures must provide meaningful information about whether care is safe, timely, beneficial, patient-centered, equitable and efficient.

Patient Satisfaction Measurement

The Agency for Health Care Research and Quality has developed a series of patient satisfaction survey instruments, collectively called Consumer Assessment of Healthcare Providers and Systems. These surveys, designed to assess satisfaction with health plans, hospitals and medical groups, allow patients and consumers to evaluate their experiences with health care.

Efficiency Measures

The AQA (formerly the Ambulatory Care Quality Alliance) is working to develop a standard, statistically valid method to measure how a physician's use of health care resources to treat a patient within an episode of care compares with expected average costs.

Recommendations for Achieving Transparency of Quality and Efficiency Data:

MGMA supports quality improvement activities that focus on improving patient care, outcomes, satisfaction and the cost-effective use of resources. MGMA also believes it is inappropriate to post efficiency ratings (i.e. cost and utilization data) without commensurate quality data.

Quality improvement programs that are initiated outside the medical practice (such as those conducted by health plans, accrediting bodies or public agencies) should comply with the following the guidelines:

- Before physician profiles of performance on different domains of care are made public, medical practices and their administrators must be able to review all relevant data and make appropriate corrections.

- Measures used in such programs must be consistent across all organizations involved. To ensure consistency, only measures that have been created through the Physician Consortium for Performance Improvement and approved by the NQF should be deployed. Nothing will hamper quality improvement efforts more quickly than having multiple programs collecting and reporting different measures. The resultant chaos would force medical to practices to focus on meeting competing administrative requirements rather than improving medical care.

- Medical practices must not be solely responsible for funding the costs associated with patient satisfaction surveys. Instead, all parties interested in using the resulting data should help defray the cost of statistically valid survey methods, which would otherwise be cost-prohibitive for most medical practices.

- Efficiency measurement must be restricted to areas where there is both information on the cost of care delivered (including pharmaceuticals, especially if prescription drugs represent the standard of care for the diagnosis) and information on performance of clinical care measures. Efficiency measurement should be limited to specific episodes of care and be risk-adjusted for each patient. Payers using efficiency measurement should make their methodology and data sources easily accessible to physicians being measured, and to their administrators.

MGMA appreciates your consideration of these comments and looks forward to collaborating to educate medical group practices on the numerous Medicare program changes. If you have any questions, please contact Lisa P. Goldstein in the Government Affairs Department at (202) 293-3450.

Sincerely,

William F. Jessee, MD, FACMPE
President and Chief Executive Officer

Submitter : **Ms. Ann Richardson Berkey** **Date: 10/10/2006**

Organization : **McKesson Corporation**

Category : **Private Industry**

Issue Areas/Comments

GENERAL

GENERAL

Please see McKesson Corporation's comments on the ASP reporting aspects of the 2007 Medicare Physician Fee Schedule and Other Changes to Payment under Part B proposed rule.

CMS-1321-P-899-Attach-1.DOC

Submitter : **Dr. richard adelman** **Date: 10/10/2006**

Organization : **Dr. richard adelman**

Category : **Physician**

Issue Areas/Comments

Background

Background

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

GENERAL

GENERAL

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

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

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

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

While practice expenses consistently rise, (salaries, utilities, etc.) it has become increasingly difficult to provide these necessary services. High tech equiptment such as ultrasound units, lasers, support equiptment and disposables must be upgraded and replaced periodically and continue to rise in price. and
As you know, the 2007 Medicare Physician Fee Schedule is already scheduled for a 5.1% across the board cut in reimbursement. Additionally, there are proposed cuts for non-invasive vascular imaging (vascular ultrasound). All these cuts will cripple the ability of physicians to perform this extremely important procedure and ultimately result in a loss of access to care for Medicare beneficiaries.

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

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

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

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

As a minimum, reimbursement should not be reduced in the face rising provider coasts to provide the same service.

Respectfully submitted,

Richard Adelman MD
Panama City, FL
adelmanr@msn.com

Impact

Impact

See General Comment below.

Provisions of the Proposed Rule

Provisions of the Proposed Rule

See General Comment below.

Submitter : Mrs. Caroline York **Date:** 10/10/2006

Organization : MedImmune

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1321-P-901-Attach-1.PDF

#901

MedImmune

October 10, 2006

BY ELECTRONIC DELIVERY

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

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

Dear Administrator McClellan:

MedImmune is pleased to have this opportunity to comment on the Centers for Medicare and Medicaid Services' ("CMS") Proposed Rule regarding revisions to payment policies under the physician fee schedule for calendar year 2007 (the "Proposed Rule").[1] MedImmune is a biopharmaceutical company that is committed to advancing science to develop better medicines that help people live healthier, longer, and more satisfying lives.

MedImmune commends CMS for providing additional guidance and clarity with regard to average sales price ("ASP") reporting. Given the importance of ASP to provider reimbursement, and therefore to patients' access to important and life-saving drugs and biologicals, MedImmune believes that clarity regarding the proper calculation and reporting of ASP is essential. We generally support CMS' proposals regarding the ASP calculation, including the proposals regarding nominal sales, the estimation of lagged price concessions for products with less than 12 months of sales data, and redesignated NDCs.

MedImmune would like to comment specifically on the bona fide service fee standard and the proposed estimation methodology for identifying lagged exempt sales. First,

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

MedImmune urges CMS to clarify in the final rule that fair market value for a service can be established by any industry-accepted methodology. Second, MedImmune expresses its support for CMS' proposed estimation methodology for identifying lagged exempt sales. We discuss each of these issues in more detail below.

A. MedImmune Requests That CMS Clarify That Fair Market Value Can Be Demonstrated Utilizing Any Industry-Accepted Methodology.

In the Proposed Rule, CMS requests comments on "appropriate additional guidance or alternative methods for determining fair market value" for purposes of the bona fide service fee standard. MedImmune applauds CMS for recognizing that additional guidance on this issue is needed. Indeed, the only guidance provided has been in the definition of a bona fide service fee itself, in which a bona fide service fee is defined as an expense "that would have generally been paid for by the manufacturer at the same rate had these services been performed by other entities."[2]

This definition seems to assume that there are, in fact, other entities in a position to perform the services required by the manufacturer. MedImmune first asks that CMS clarify that a service is not precluded from being considered a bona fide service simply because it is one that must be performed by a purchaser of the manufacturer's products. It is often the case, such as with certain data services, that the purchaser of the product from the manufacturer is in the best, if not the only, position to perform the identified service. Secondly, MedImmune asks that CMS provide guidance explaining that any industry-accepted methodology can be used to demonstrate that a service fee represents fair market value. There are numerous methods that can be used to determine fair market value. Specifying that a particular method be used is problematic, however, because not all services can be analyzed in the same way. Some methods also may be more appropriate for certain services than others. Therefore, we urge CMS to specify that a manufacturer may utilize any industry-accepted methodology to establish fair market value for a bona fide service.

B. MedImmune Supports CMS' Proposal On the Proper Estimation Methodology to Be Used to Identify Lagged Exempt Sales.

We are pleased that CMS has recognized the need to develop an estimation methodology for purposes of identifying lagged exempt sales so that manufacturers utilize a uniform methodology for estimating and excluding the sales from the ASP calculation.[3] As CMS has recognized, manufacturers identify certain exempt sales through rebates and chargebacks, which are often not available in time for purposes of the ASP calculation. It is for that reason that CMS developed an estimation methodology for lagged price concessions. Requiring manufacturers to utilize an estimation methodology to identify lagged exempt sales

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2 Id.
3 Id.

will ensure that these sales also are appropriately removed from the ASP calculation as required by the statute,[4] and it will reduce quarter to quarter variations in the ASP.

MedImmune supports CMS' proposal to require manufacturers to utilize a units-based rolling average ratio methodology to estimate lagged exempt sales. This methodology is similar to the methodology manufacturers are required to use for purposes of estimating lagged price concessions. MedImmune agrees with CMS that requiring similar estimation methods will reduce potential errors in the ASP calculation.[5] Moreover, utilizing a units-based ratio limits any possibility that price changes during the 12-month period will skew the ratio result. Accordingly, MedImmune requests that CMS include this estimation methodology in its final rule.

* * *

MedImmune is thankful for this opportunity to offer comments on these important issues. We hope to work with CMS in the future to ensure that provider reimbursement for, and patient access to, important and life-saving therapies is maintained. Please call me at 301-398-4447 if you have any questions, or if MedImmune can be of any further assistance.

Sincerely,

Caroline York
Vice President, Reimbursement

4 Social Security Act (SSA) § 1847A(c)(1).
5 71 Fed. Reg. at 49,002.

October 10, 2006

BY ELECTRONIC DELIVERY

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

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

Dear Administrator McClellan:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) Proposed Rule regarding revisions to payment policies under the physician fee schedule for calendar year 2007 and other changes to payment under Part B (the "Proposed Rule").[1] BIO is the largest trade organization to serve and represent the biotechnology industry in the United States and around the globe. BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in the United States. BIO members are involved in the research and development of healthcare, agricultural, industrial and environmental biotechnology products.

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

BIO represents an industry that is devoted to discovering new treatments and ensuring patient access to them. Accordingly, we are greatly concerned about the impact of Medicare's reimbursement on access to drugs and biologicals. If Medicare does not compensate providers appropriately for their acquisition and administration costs, Medicare beneficiaries may be denied access to essential drugs and biologicals. If physicians and hospitals stop providing innovative therapies to their patients as a result, manufacturers could be discouraged from developing new therapies. BIO urges CMS to protect beneficiary access to important drug and biological therapies by ensuring that physicians are appropriately reimbursed for all of the services associated with providing these therapies.

It is in this spirit that we offer comments to CMS' proposals regarding the elimination of the deductible for colorectal cancer screening, myriad average sales price (ASP) issues, increasing the clotting factor furnishing fee, placing limits on CMS' substitution of widely available market price (WAMP) or average manufacturer price (AMP) for ASP, clarifying the treatment of drugs and biologicals furnished through durable medical equipment (DME), including resources involved in compounding when pricing compounded drugs, continuing the preadministration-related services for standard and specialty intravenous immune globulin (IVIG), reimbursement for all end-stage renal disease (ESRD) drugs and biologicals at ASP plus six percent, improving the current system of setting payment rates for new outpatient clinical diagnostic laboratory tests, and ensuring adequate reimbursement for drug administration services. These issues are discussed in depth below.

I. BIO strongly supports CMS' proposal to amend its regulations to exempt colorectal cancer screening from the Part B deductible requirement ["DRA Proposals"].

Colorectal cancer is a particularly grave disease that often exhibits no symptoms until it reaches an advanced stage. It is for this reason that timely screening for colorectal cancer is imperative in order to fight it. Under the provisions of the Deficit Reduction Act of 2005 (DRA), colorectal cancer screening services are no longer subject to the Part B deductible beginning January

1, 2007.[2] In the Proposed Rule, CMS states its intention to conform its regulations to this statutory change, and, accordingly, its regulations now also will except from the Part B deductible colorectal cancer screening services.[3] BIO strongly supports this proposal as it will increase patient access to this important screening service and will help in the fight against this deadly disease.

II. CMS should continue to provide guidance to providers and patients that the implementation of Part D does not alter coverage for drugs and biologicals under Part B ["ASP Issues"].

In the Proposed Rule, CMS states, "The Medicare Part D program does not change Medicare Part B coverage."[4] BIO agrees with this statement. The Part B benefit design is substantially different from Part D, and patients and providers need to understand the continued availability of coverage for certain provider-administered drugs and biologicals under Part B. We appreciate this and previous CMS statements regarding continuing Part B coverage that help ensure that patients and providers clearly understand that benefits for provider-administered drugs and biologicals remain available. We are concerned, however, by reports of providers asking Medicare beneficiaries to obtain drugs traditionally covered under Part B through Part D pharmacies instead. This "brown bagging" raises several safety concerns, particularly for drugs with special storage and handing requirements. It is opposed by several medical societies and should be opposed by CMS as well. We are further concerned by reports of Medicare Advantage plans denying Part B coverage of drugs traditionally covered under Part B and instead requiring members to obtain these drugs using their Part D coverage, sometimes coupled with a requirement that the drugs be administered at home by a home health agency nurse instead of in a physician office or hospital setting. This raises safety concerns and also increases beneficiaries' out-of-pocket costs since most beneficiaries do not have wraparound coverage for Part D as many do for Part B.

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2 DRA, § 5113, Pub. L. No. 109-171 (2005).

3 71 Fed. Reg. at 48,999.

4 Id. at 49,000.

III. BIO urges CMS to use formal rulemaking procedures to provide clear guidance to manufacturers so they are able to submit accurate and consistent ASP data.

Since ASP is intended to serve as and is clearly defined in Federal Statute[5] as a reimbursement mechanism, it is important that CMS carefully consider any changes in the way ASP is calculated. BIO supports predictability and transparency in the ASP calculation, and we therefore have consistently urged CMS to provide clear guidance to manufacturers so that they are able to submit accurate and consistent data.

Although we have been pleased by CMS' efforts to date to work with manufacturers to resolve questions about ASP reporting obligations in the past, we believe that it is critically important that CMS use its annual formal rulemaking procedures to make any changes to the ASP calculation. BIO appreciates the informal guidance CMS has provided on the ASP calculation and the flexibility that it provides, yet we believe it is important that manufacturers and others be given the opportunity to comment on specific proposals prior to further ASP calculation changes. Indeed, to date, CMS has made significant changes and clarifications through Questions and Answers (Q&As) on its website, rather than through formal rulemaking. For example, until this Proposed Rule, the only significant guidance provided by CMS on the proper treatment of service fees in ASP has been through a Q&A.[6] The calculation of ASP is complex, and even a minor change to the way ASP is calculated could have detrimental effects on provider reimbursement and, in turn, patient access. Moreover, stiff penalties are associated with misrepresentations of ASP, making clear guidance even more vital to manufacturers. Unambiguous guidance can be accomplished best through an annual formal rulemaking in which all interested stakeholders are given an opportunity to review and comment on the proposed rule, and CMS is able to consider and respond specifically to the comments made.

A. CMS should define the term purchaser.

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5 Social Security Act SSA § 1847(A).

6 See Q&A #3318, located at http://questions.cms.hhs.gov.

In the Proposed Rule, CMS attempts to revise its guidance on the proper treatment of administrative and service fees in the ASP calculation. This amended guidance provides that fees paid by manufacturers to an entity, whether or not that entity takes title to the product, must be considered price concessions for purposes of the ASP calculation unless the fees meet the Proposed Rule's definition of a bona fide service fee.[7] The preamble to the Proposed Rule clarifies that this standard is applicable to service fees paid to group purchasing organizations (GPOs) and pharmacy benefit managers (PBMs).[8] BIO strongly opposes the application of the bona fide service fee standard to entities, such as GPOs, that do not take title to product. Even if CMS were to conclude that such entities are included in the ASP calculation, BIO urges CMS to exclude from the ASP calculation fees paid to non-purchasers where such fees are otherwise protected by safe harbors under the Anti-Kickback Act. .

ASP is defined by statute as the measure of "the manufacturer's sales to all purchasers . . ."[9] The Medicare Modernization Act does not define the term purchaser, and BIO urges CMS to define this crucial term so as to provide clarity regarding the types of entities that are statutorily eligible for the ASP calculation. ASP is intended measure the acquisition costs of those entities whose reimbursement will be based on ASP. Accordingly, BIO believes it is appropriate to define a purchaser as an entity that takes title to and possession of a product. It is only entities that take title to and possession of product, such as hospitals, clinics, physicians, and pharmacies, which are reimbursed based on ASP, and therefore only transactions involving such entities should be included when measuring this important reimbursement metric. The inclusion of non-purchaser transactions in the ASP calculation that do not impact provider acquisition cost necessarily will have the effect of decreasing the accuracy of ASP as a measurement of provider acquisition costs, potentially having a drastic impact on provider reimbursement and, therefore, patient access.

B. CMS should clarify that fees paid to non-purchasers are not price concessions.

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7 71 Fed. Reg. at 49,001.

8 Id.

9 Social Security Act (SSA) § 1847A(c)(1) (emphasis added).

With the term "purchaser" defined in this way, BIO urges CMS to revise the Proposed Rule to clarify that GPOs are not purchasers and, for that reason, fees paid to GPOs need not be evaluated for inclusion in the ASP calculation. GPOs are entities that negotiate contracts with vendor manufacturers on behalf of their members that are health care providers, such as hospitals, clinics, nursing homes, and physician practices. GPOs do not themselves purchase drugs and biologicals, but instead negotiate contracts that providers use in making their own purchases. GPOs allow health care providers to band together for the purpose of negotiating with manufacturers, but GPOs in general never themselves purchase product. Given that GPOs are not purchasers, any fees paid by a manufacturer to a GPO should not be considered a price concession that is eligible for the ASP calculation.

The Office of Inspector General has studied GPOs and their relationships with their members and found that there are situations in which a GPO may share some portion of the fee paid by a manufacturer with its members, who are purchasers.[10] Manufacturers have no control over these arrangements and typically are unaware of the contractual terms between the GPO and its members.[11] Accordingly, even when the GPO shares some portion of a manufacturer fee with its members, the exact amount is not known by the manufacturer and therefore, those fees should not be considered discounts provided by the manufacturer to a purchaser.

A requirement to treat GPO administrative fees as a discount in the above situations also would face a significant practical hurdle. Specifically, manufacturers would have no basis for determining the amount of the fee that is

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[10] The Office of Inspector General (OIG) found in an audit conducted of three large GPOs that the GPOs retained a significant amount of the administrative fees and that their practices regarding passing on administrative fees to members differed. See Review of Revenue from Vendors at Three Additional Group Purchasing Organizations and Their Members, OIG Report A-05-04-00073 (May 2005).

[11] BIO recognizes, however, that where the contract between the manufacturer and the GPO directs the GPO to pass on service fees to the GPO's members, the manufacturer indirectly would be paying fees to a purchaser, and, therefore, the bona fide service fee standard should be applied to the portion of the fee passed on to the members.

shared with the member purchasers or to which product the fee should be attributed as a price concession. Without this information, manufacturers have no basis for including these fees in the ASP calculation.

The Proposed Rule also purports to clarify that the bona fide service fee standard applies not only to GPOs, but also to PBMs.[12] BIO asks that CMS explain the basis for the proposed application of the bona fide service fee definition to fees paid to PBMs. Specifically, we ask CMS to explain whether it considers PBMs to be a purchaser, as defined above, such that fees paid to PBMs are subject to evaluation under the bona fide service fee definition. If that is the basis for CMS' position, BIO asks that CMS clarify whether this position is applicable to fees paid to PBMs that are not associated with product purchased by the PBM, e.g. product that is purchased by a pharmacy other than by a mail order pharmacy that is owned by the PBM. As discussed above, if the basis for the Proposed Rule's application to PBMs is that the bona fide service fee standard is applicable to entities that do not take title to the product, then BIO again strongly urges CMS to reconsider its position.[13]

In the event CMS moves forward on its proposal to include fees paid to GPOs and PBMs as price concessions, except where the fees meet the bona fide service fee standard, BIO requests that CMS not include as discounts those fees that meet a safe harbor to the anti-kickback law.[14] The anti-kickback law is quite broad,[15] and, as a result, the OIG developed certain safe harbors to permit health care providers to engage freely in business practices that encourage competition

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12 71 Fed. Reg. at 49,001.

13 This same analysis is also relevant to manufacturer transactions with healthcare plans that are not purchasers. Under these arrangements, the plan does not take title to or possession of the manufacturer's product, but rather reimburses the dispensing pharmacy for the manufacturer's product at an agreed upon price, and then the manufacturer pays the plan a specified rebate amount on each unit of its product reimbursed by the plan.

14 See 42 C.F.R. § 1001.952. In the case of fees paid to PBMs, The Office of Inspector General has explained that manufacturers can protect payment arrangements made with PBMs by structuring them so that they are consistent with the GPO safe harbor. See OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731, 23,736 (May 5, 2003).

15 See SSA § 1128B(b).

and economy[16] while also reducing the potential for abuse.[17] Administrative and service fee arrangements that satisfy the safe harbor requirements, or in the case of administrative fees paid to PBMs, are consistent with those requirements, represent arrangements that the OIG already has recognized as acceptable and non-abusive. This approach would ensure a consistent characterization of such fees for purposes of reporting net price to purchasers as required under the discount safe harbor of the Anti-Kickback Act and for ASP calculation purposes BIO urges CMS to exclude from the ASP calculation fees that meet these requirements.

C. CMS should provide more detailed guidance to manufacturers on the standard for determining when fees qualify as bona fide service fees.

In the Proposed Rule, CMS explains that fees that meet the criteria of a bona fide service fee are not considered price concessions for the purpose of calculating ASP.[18] Although BIO generally supports CMS' proposal regarding bona fide service fees, we ask that CMS provide more detailed guidance to manufacturers on the standard for determining when a fee qualifies as a "bona fide service fee." Moreover, BIO strongly urges that CMS provide this guidance in a formal rulemaking, rather than through program instruction. As discussed, even minor changes in the way ASP is reported can have dramatic impacts on provider reimbursement and, therefore, patient access. BIO asks that guidance provided in this area be through a formal rulemaking so that CMS has access to public comments on this issue and is able to fully understand the ramifications of any rule change.

1. CMS should provide guidance on the fair market value standard.

Bona fide service fees are defined in the Proposed Rule as "fees paid by a manufacturer to an entity that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the

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16 54 Fed. Reg. 3088 (Jan. 23, 1989).

17 Id.

18 71 Fed. Reg. at 49,001.

manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on, in whole or in part, to a client or customer of an entity, whether or not the entity takes title to the drugs."[19] CMS stated that it was "considering providing further guidance on or revising the approach or methodology manufacturers must use to determine the fair market value of bona fide services performed on their behalf,"[20] and BIO encourages CMS to do so.

CMS' current guidance on the proper fair market value standard is ambiguous at best. This guidance, found through a Q&A on CMS' website, fails to specify any appropriate methodology for determining fair market value and instead directs only that fees be paid "at the same rate had the[] services been performed by other [non-buyer] entities."[21] This definition assumes that manufacturers are able to choose between purchaser and non-purchaser entities for the performance of services. Many services performed by wholesalers and distributors for a manufacturer only can be performed by a purchaser. For example, manufacturers often enter into data agreements with distributors whereby the distributor provides the manufacturer with data regarding the entities that purchase the manufacturer's products. This data only is available from that entity.

Given that many services performed on behalf of manufacturers must be performed by a purchaser, BIO first requests that CMS confirm that fair market value need not be shown by demonstrating the cost of obtaining the service from a non-purchaser. BIO next requests that CMS clarify that manufacturers may establish fair market value for bona fide services through any accepted industry methodology. Specifically, CMS should provide guidance that any reasonable and supportable method for determining fair market value is appropriate. Acceptable methodologies would include, but not be limited to the income method,[22] the

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19 Id.

20 Id.

21 See Q&A #4136, located at http://questions.cms.hhs.gov.

22 The income approach to fair market valuation involves the determination of the present value of the future earnings associated with an asset or service. In other words, one would determine the present value of the future earnings a manufacturer could expect as a result of the services rendered.

market method,[23] or the cost method.[24] CMS also should make clear that while documentation to support FMV must be retained by the manufacturer, FMV, which by definition is a range, is not required to be stated in the actual service fee agreement.

BIO also asks that CMS explain further what is meant by requiring that the bona fide service be "itemized." We recognize the value in requiring service fee contracts to specify the services to be performed, but we advocate that no separate itemized payment for each service be required. Manufacturers should be permitted to pay a service fee that covers an array of services provided and still be compliant with the bona fide service fee definition. Moreover, manufacturers should be permitted to obtain a fair market value analysis of the array of services offered rather than for each service individually.

2. CMS should provide additional guidance on the documentation required to demonstrate that fees paid to an entity have not been passed on to a customer.

In the Proposed Rule, CMS also states that it is considering giving additional guidance on the methodology to be used to demonstrate that a fee paid to an entity has not been passed on to a customer.[25] BIO asks that CMS clarify that manufacturers need not have an affirmative contract provision in their contracts with distributors that prohibits the passing on of service fees. Instead, the absence of an affirmative requirement in the contract that requires the passing on of fees should be sufficient. A requirement that service fee contracts contain a specific provision prohibiting the passing on of service fees will pose a significant barrier when existing contracts do not contain such a provision. If CMS determines that a specific contract provision is required, BIO asks that manufacturers be given a minimum two quarter implementation period during

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[23] The market method involves a determination of what others in the market are paying for similar services.

[24] The cost method to fair market valuation requires the manufacturer to determine the cost of replacing the service. Specifically, the manufacturer would need to determine how much it would cost to have a third party provide the service.

[25] 71 Fed. Reg. at 49,001.

which they can amend their service fee contracts before such a requirement becomes effective.

3. CMS should specify the types of services that qualify as bona fide services.

CMS has explained that it is considering providing guidance on the types of services that may qualify as bona fide services for purposes of the ASP calculation.[26] BIO urges CMS to provide a list of services that are illustrative and non-exhaustive to allow for multitude of particular situations that might arise in the future. For example, many services performed by distributors, such as inventory management (i.e. stable purchasing patterns that do not have excessive highs or lows), ensuring timely delivery of product to the end-user, patient education, and data services, are important functions performed on behalf of the manufacturer that a wholesaler or distributor need not perform as part of its business model. Manufacturers cannot perform these services themselves, and they provide a great value to the manufacturer. Certain types of products require different types of services. For example, certain drugs may have specific patient education requirements, whereas other products may require little in the way of patient education. Accordingly, rather than specify the types of services that can qualify as bona fide services, BIO requests that CMS provide a standard for manufacturers to use when determining the types of services that can qualify as bona fide services. BIO recommends that CMS specify that a bona fide service include any service performed by an entity on behalf of the manufacturer that provides a value to the manufacturer.

4. CMS should recognize explicitly that ASP reporting standards differ from financial accounting standards.

BIO appreciates that CMS has requested guidance on how Medicare's treatment of service fees for ASP may differ from the treatment of such fees for financial accounting purposes and the implications this may have for manufacturers. The rules and requirements for price reporting differ significantly from the rules and requirements applicable to financial accounting. Most

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[26] Id.

significantly, in the financial accounting realm many fees that would qualify as bona fide service fees for ASP calculation purposes may be required to be counted as a reduction in revenue for financial accounting.

Pursuant to the Financial Accounting Standards Board (FASB) guidance, fees paid to a distributor, even when the fees are for an itemized service performed on behalf of the manufacturer, must be included as a price concession if the identified benefit to the manufacturer is not sufficiently separable from the recipient's purchase of the vendor's products such that the vendor could have entered into an exchange transaction with a party other than a purchaser of its products in order to receive the benefit.[27] As discussed above, many of the services performed by distributors on behalf of a manufacturer are not "sufficiently separable" from the sale of product under this standard. For instance, data provided by distributors to a manufacturer typically involves information on the resale of a manufacturer's products, and thus the data service provided could not be performed by a non-purchaser of the manufacturer's products. In another example, manufacturers have paid service fees to ensure that their products are delivered by distributors to healthcare providers within a specified time frame often related to patient need or stability requirements. This timely delivery is a benefit to the manufacturer because it encourages providers to use its products. This service, however, is tied to the purchase of its product and could not be performed by a non-purchaser entity, and thus may be required to be treated as a discount for financial reporting purposes.

CMS should not amend its guidance on the proper treatment of service fees to be consistent with financial reporting standards. Instead, CMS explicitly should recognize the different purposes served by these standards. Whereas ASP is meant to determine average acquisition cost for a manufacturer's products and is used by CMS to set reimbursement rates, financial accounting standards are meant to show the financial position of a business. Accordingly, CMS should clarify that a manufacturer need not treat service fees as discounts for ASP when it must do so for purposes of its financial accounting.

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

D. BIO requests that CMS clarify that the proposed estimation methodology does not apply to non-purchasers and applies prospectively only.

The Social Security Act requires manufacturers to exclude from the ASP calculation those sales that are exempt from the Medicaid best price calculation.[28] As recognized by CMS, manufacturers identify many ASP-ineligible sales through chargeback and rebate data that may not be available at the time the ASP is calculated.[29] BIO generally supports CMS' proposal to establish a uniform approach to estimating lagged exempt sales that is similar to the estimation methodology employed to estimate lagged price concessions. As noted by CMS, the use of similar methodologies for estimating lagged exempt sales and lagged price concessions should reduce errors in the ASP calculation and reduce the likelihood of quarter to quarter variations in ASP.[30] However, BIO urges CMS to clarify that the proposed estimation methodology does not apply to ASP-ineligible entities **that are payors rather than purchasers, e.g., SPAPs and Part D plans.**

1. CMS should provide clarifications regarding the removal of certain ASP-ineligible sales from the ASP calculation.

Although not addressed in the Proposed Rule, BIO asks that CMS provide additional guidance on the removal of certain ASP-ineligible sales from the ASP calculation. First, BIO asks that CMS clarify that only those units sold to possession-taking ASP-ineligible entities, as opposed to units reimbursed by ASP-ineligible entities, be removed from the ASP calculation. As discussed above, ASP is intended to be an average price to purchasers and is used by Medicare to set provider reimbursement rates that are tied to acquisition cost.[31] Indeed, one impetus behind the use of ASP as a reimbursement rate was the recommendation

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28 SSA § 1847A(c)(2).

29 71 Fed. Reg. at 49,001.

30 Id. at 49,002.

31 See SSA § 1847A(c)(1).

by the Government Accounting Office that providers be reimbursed "at levels reflecting providers' acquisition costs."[32]

Certain ASP-ineligible entities, such as Part D plans and state pharmaceutical assistance plans, do not purchase product themselves, but instead reimburse providers for their purchase of product. Therefore, removing sales in which these ASP-ineligible entities reimbursed an ASP-eligible purchaser will unfairly distort the ASP calculation by removing sales made to ASP-eligible purchasers. For example, a sale of an oral oncology product to a retail pharmacy should be included in ASP. Under the current ASP methodology, when the retail pharmacy is reimbursed for the product by a State Pharmacy Assistance Program, the sale is removed from the ASP calculation despite the fact that the initial sale to the retail pharmacy is an ASP-eligible sale. Accordingly, CMS should clarify that manufacturers should not remove sales reimbursed by ASP-ineligible entities from the ASP calculation.

In the event CMS does not adopt this proposal, BIO asks that it recognize that manufacturers need not (and cannot) remove ASP-ineligible utilization when they are unable to identify it. In calculating ASP, manufacturers are directed to exclude all best price exempt sales and units.[33] The Medicaid drug rebate statute excludes from best price "any prices charged which are negotiated . . . by a qualified retiree prescription drug plan (as defined in section 1860D-22(a)(2)) with respect to such drugs on behalf of individuals entitled to benefits under part A or enrolled under part B of such title."[34] Manufacturers typically identify such transactions through rebate data. For example, when a Medicare Part D plan reimburses a provider for a drug, it subsequently sends the manufacturer a rebate claim that allows the manufacturer to identify that transaction in order to exclude it from the ASP calculation. Identifying sales to qualified retiree prescription drugs plans, however, is more problematic.

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[32] Medicare Prescription Drug, Improvement, and Modernization Act of 2003 Conference Report, H.R. Rep. No. 108-391.

[33] SSA § 1847A(c)(2).

[34] SSA § 1927(c)(1)(C).

Typically, rebates made available to qualified retiree prescription drug plans are included in a contract with a PBM that includes commercial plans as well. The rebate claims submitted to the manufacturers under these contracts typically do not separately quantify the utilization for the qualified retiree plans. To address this situation, BIO asks CMS to confirm that a manufacturer's inability to remove such utilization based on lack of data does not render the calculated ASP inaccurate for purposes of the statute, certification, and civil monetary penalties provision. BIO also notes that the best-price exemption for these plans can be interpreted to apply only to the rebates paid on the qualified retiree utilization and not that of the dependents who also are covered by the qualified retiree plan.[35] Even where utilization can be separately quantified for the qualified retiree plan, such utilization data often does not distinguish between the retiree and his or her dependents. To address this situation, BIO asks CMS to clarify that where qualified retiree plan utilization is available, manufacturers may exclude the entirety of that utilization from the ASP calculation without regard to whether or not that utilization includes retiree dependents.

2. CMS should clarify the ineligible sales estimation methodology, specify that it is to be applied prospectively only, and provide sufficient lead time for implementation.

In describing the estimation methodology, CMS explains that the rolling average percentage estimate is to be applied to the ASP denominator and that "manufacturers must make a corresponding adjustment to the numerator of the ASP calculation to ensure that the total in dollars for the reporting quarter does not include revenue related to lagged exempted sales excluded from the denominator using the proposed estimation methodology."[36] BIO requests that CMS specify that manufacturers make the adjustment to the numerator by applying the calculated ratio to the sales dollars counterpart to the units figure to which the Proposed Rule directs the application of the ratio. In addition, BIO requests that

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[35] The Medicaid drug rebate statute excludes from best price "any prices charged which are negotiated . . . by a qualified retiree prescription drug plan (as defined in section 1860D-22(a)(2)) with respect to such drugs on behalf of individuals entitled to benefits under part A or enrolled under part B of such title." Id. Typically, it is only the retiree who is entitled to benefits under Part A or Part B, and, therefore, only prices charged to the retiree are to be excluded from ASP.

[36] Id.

CMS specify that manufacturers may develop the estimate ratio either on a class of trade specific basis or across all ASP-ineligible classes of trade.

BIO asks that CMS clarify in its final rule that use of the estimation methodology for lagged exempt sales is required on a prospective basis only and postpone the implementation date until the quarter that is two full quarters after a final rule is issued. Although many manufacturers already may have adopted an ineligible sales estimation methodology, some manufacturers may not have done so, and those with existing methodologies may need to revise those methodologies to comply with the rule. In either case, the methodology should be applied prospectively only, and manufacturers should be provided with the significant lead time necessary to ensure that compliant and accurate ASP figures result.

E. CMS should adopt the definition of nominal sales found in the DRA in order to ensure consistency across the Medicaid and Medicare programs.

In the Proposed Rule, CMS recognizes that changes to the definition of a nominal sale for purposes of Medicaid mandated by the DRA will have implications for ASP reporting as well.[37] Under the ASP reporting statute, manufacturers are required to exclude from the ASP calculation sales that are merely nominal in amount, as that term is defined under the Medicaid statute, "except as the Secretary may otherwise provide."[38] Currently, for both Medicaid and ASP reporting purposes, a nominal sale is a sale at a price less than 10 percent of the AMP in the same quarter for which the AMP is computed. The DRA made several significant changes to the Medicaid statute, including, effective January 1, 2007, to the definition of a nominal sale.[39] Under the current ASP reporting rule, this change also will apply to the definition of nominal sale for purposes of the ASP calculation.[40]

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37 Id.

38 SSA § 1847A(c)(2)(B).

39 DRA, § 6001(d)(2), Pub. L. No. 109-171. The DRA amended the definition of nominal sales so that only sales to specified entities, such as 340B Public Health Service covered entities and state-owned or operated nursing homes, can be considered nominal in amount.

40 71 Fed. Reg. at 49,002.

CMS is seeking comments on whether the Secretary of Health and Human Services (the "Secretary") should establish an alternative definition of nominal sales for ASP purposes as permitted by the Social Security Act.[41] BIO strongly supports CMS' current proposal that manufacturers continue to use the Medicaid definition of nominal sales for purposes of the ASP calculation.[42] As noted by CMS, this approach helps "maintain continuity in the ASP calculation and minimizes manufacturers' reporting burden."[43] The reporting burden for manufacturers is lessened to the extent continuity is maintained between Medicaid and Medicare price reporting.

Although BIO generally supports CMS' proposal, we ask that CMS consider providing manufacturers the option of using the prior quarter's AMP for calculating its nominal prices in order to assist manufacturers with the timely reporting of ASP. Use of the current quarter's ASP forces manufacturers to wait until their quarterly AMP is finalized before calculating ASP. This can impose significant time pressure on some manufacturers. Therefore, manufacturers should have the option of using the prior quarter's AMP so long as a manufacturer uses the same methodology across all products. In addition, BIO asks that CMS further explain how the DRA's requirement for the monthly reporting of AMP translates into a quarterly AMP for purposes of establishing a nominal price.

We also recommend that CMS clarify the definition of safety net provider for purposes of nominal sales determinations. Under the Social Security Act, the Secretary may designate any facility or entity "that the Secretary determines is a safety net provider to which sales of such drugs at a nominal price would be appropriate," based on factors enumerated in the statute. Currently, manufacturers cannot always readily determine whether an entity would qualify as a safety net provider. It would promote accuracy and consistency in ASP reporting if CMS maintained and posted a list of entities that the Secretary determines to be qualifying safety net entities for ASP reporting purposes.

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41 Id.

42 Id. at 49,003.

43 Id.

F. BIO supports CMS' proposals regarding the estimation of lagged price concessions for (1) National Drug Codes (NDCs) with less than 12 months of sales, and (2) redesignated NDCs.

BIO appreciates CMS' willingness to provide additional guidance on the proper estimation methodology to be used to determine lagged price concessions when a product has less than 12 months of sales data. BIO supports CMS' proposal to clarify in the rule that the period used to estimate lagged price concessions for products with less than 12 months of sales is the total number of months the NDC has been sold.[44] This revision is reasonable, and it provides manufacturers with needed guidance on this issue.

BIO also generally supports CMS' proposal related to redesignated NDCs. CMS has proposed that when an NDC is changed as the result of a modification of its package design or other non-drug feature of the NDC and the price concessions offered for the prior NDC remain in effect for the redesignated NDC, manufacturers must use 12 months of sales and price concession data from both the prior and redesignated NDCs to estimate the lagged price concessions applicable to the redesignated NDC.[45] BIO supports this proposal and understands the importance of preventing manufacturers from restarting the 12 month period when no product change has occurred.

BIO requests, however, that CMS provide further guidance on the types of situations to which this rule will apply. In the preamble discussion, CMS refers to situations when the labeler code is changed or when the manufacturer modifies its package design or other "non-drug feature" of the NDC.[46] BIO asks that CMS provide further details on the types of situations to which this rule will apply, as well as those situations for which it will be inapplicable (such as where a product receives a new NDC-9). Moreover, BIO asks that CMS provide further details regarding the appropriate application of this rule when both the prior NDC and the redesignated NDC remain on the market. For example, CMS should

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44 Id.

45 Id.

46 Id.

explain whether, in such a situation, the manufacturer is required to combine the price concession data for both products to create a single ratio that is used to estimate lagged price concessions for both products. Additionally, CMS should clarify for how long the data on the two products must be combined. For example, CMS should explain whether the combination of data should extend through the period in which the last lot of the prior NDC expires.

Finally, BIO urges CMS to revisit this issue following the issuance of the Food and Drug Administration's (FDA) final rule on establishment registration and listing. An NDC consists of a labeler code, product code, and package code. Under the current regulations, FDA issues a manufacturer a labeler code, and the manufacturer assigns to its own drugs the product and package codes pursuant to certain parameters set forth by the FDA.[47] Under the proposed rule on establishment registration and listing, the FDA would begin assigning all parts of the NDC to a drug, i.e., the labeler code, product code, and package code.[48] FDA's assumption of the NDC assignment process could alter the need for and application of the Proposed Rule. Accordingly, once the FDA takes over responsibility for assigning NDCs, this issue should be revisited to determine the necessity of the provision.

G. Bundled Price Concessions

BIO appreciates that CMS has requested industry comments to better understand the impact of "bundled price concessions" on the calculation of ASP as the agency considers providing further guidance in this regard. Because of the sensitive competitive and individual company business issues inherent in these arrangements, BIO is unable to provide detailed comments on bundling arrangements and urges the agency to proceed methodically. As stated later in our comments, we welcome the opportunity to work with CMS to find solutions to ASP issues that are market-based and preserve beneficiary access to innovative therapies.

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47 21 C.F.R. § 207.35.

48 71 Fed. Reg. 51,276, 51,280 (Aug. 29, 2006).

BIO supports clear guidelines to ensure that manufacturers can carry out their reporting obligations in compliance with all applicable laws and regulations. Predictability is essential for compliance reasons. Yet at the same time, we are concerned that any methodology adopted may be inelastic and fail to foster beneficial arrangements. To help ensure that any additional guidance that CMS ultimately may issue on the treatment of "bundled price concessions" in ASP calculations provides the clarity, elasticity, and predictability, CMS should publish a specific proposal in draft form and give manufacturers, physicians, beneficiaries, and other stakeholders a meaningful opportunity to comment before it is finalized.

H. CMS should seek the authority to exclude prompt payment discounts from the ASP calculation.

CMS should seek authority from Congress to exclude prompt payment discounts from the ASP calculation so that ASP better approximates provider acquisition costs and to bring about consistency between the Medicaid and Medicare programs. Although BIO recognizes that, as of now, the ASP statute requires manufacturers to include prompt payment discounts as price concessions in the ASP calculation,[49] we ask CMS to urge Congress to amend the statute to exclude such discounts.

ASP is used by CMS to set provider reimbursement rates and is meant to be a measure of provider acquisition costs. Prompt payment discounts are typically unavailable to providers because providers do not purchase directly from the manufacturer. Instead, they purchase through a distributor. As such, the inclusion of this discount in the ASP calculation serves to lower the ASP, and subsequently provider reimbursement, despite the fact that the vast majority of providers have no access to this discount.

The exclusion of prompt payment discounts from the ASP calculation also is consistent with Congress' recent amendments to the Medicaid statute. In amending the Medicaid statute so as to use AMP to set payment rates,[50] the DRA also amended the statute to not include prompt payment discounts in the

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49 Id. § 1847A(c)(3).

50 See DRA § 6001(a)(2), Pub. L. No. 109-171 (2005).

calculation of AMP.[51] CMS should urge Congress to similarly amend the ASP statute. By excluding prompt payment discounts from the ASP calculation, the ASP will better reflect provider acquisition costs and will be more consistent with the AMP calculation.

I. CMS should clarify that civil monetary penalties stop accumulating as of the date a manufacturer notifies CMS of a correction.

Under the ASP regulations, a civil monetary penalty in an amount of up to $10,000 may be applied "for each price misrepresentation and for each day in which the price misrepresentation was applied."[52] As CMS may not always revise its published reimbursement rates in response to a manufacturer's submission of corrected ASP figures, BIO requests that CMS clarify that the civil monetary penalties cease to apply as of the date the manufacturer submits the corrected figures. Such a rule will encourage manufacturers to submit corrected figures as soon as possible because such a submission will stop the accumulation of any potential penalties, whether or not CMS chooses to revise reimbursement rates in response to the corrected submission.

IV. BIO welcomes the opportunity to work with CMS to find solutions for certain inadequacies in the use of ASP to determine provider reimbursement.

As CMS has recognized, ASP is an imperfect metric for determining real-time provider acquisition costs for the purpose of setting reimbursement rates. The two-quarter lag between the quarter for which an ASP is calculated and the quarter for which that ASP sets a reimbursement rate can lead to significant payment inaccuracies. Most significantly, this lag means that the reimbursement rate is too low for at least a two-quarter period following any price increase. In addition, this lag means that when a generic enters the market and it uses the same Healthcare Common Procedure Coding System (HCPCS) code as a more expensive branded product, the government overpays for the generic for at least

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51 Id. §§ 6001(c)(1)(A), 6003(b)(2).

52 42 C.F.R. § 414.806.

two quarters because during that lag the ASP is based on a weighted average of the ASPs of branded product within the same HCPCS code. The OIG, in its 2007 work plan, has expressed interest in this issue and proposed studying the top ten multi-source drugs purchased by a sample of oncology practices to determine whether the Government would benefit if Medicare reimbursed multi-source Part B drugs based on the ASP of their individual NDCs.[53] BIO would welcome the opportunity to work with CMS to find solutions that ensure the government purchases products at an appropriate price and providers are reimbursed adequately. If ultimately recommended by the OIG, BIO would support a proposal to reimburse multi-source Part B drugs based on the ASP of their individual NDCs, at least for the first two quarters after a generic enters the market.

There are also situations in which Medicare underpays providers for certain drugs and biologicals. In a 2005 report, the OIG found four payment codes used by physicians practicing hematology and oncology in which physicians were unable to purchase the therapies at ASP plus six percent.[54] BIO believes that CMS should develop a system for tracking the sufficiency of ASP-established payment rates. Additionally, CMS should have the discretion to adjust physician payment rates upward when the OIG or the agency determines that physicians are being under-reimbursed for specific drugs or biologicals. Again, BIO would welcome the opportunity to collaborate with CMS to find a mutually agreeable mechanism to monitor rates and adjust them systematically in order to ensure that physicians are reimbursed adequately for critical therapies.

V. BIO supports increasing the clotting factor furnishing fee.

CMS has proposed, consistent with the Social Security Act,[55] to increase the clotting factor furnishing fee by the percentage increase in the consumer price index (CPI) for medical care for the 12-month period ending in

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53 See HHS OIG 2007 Work Plan, located at http://oig.hhs.gov/publications/docs/workplan/2007/Work%20Plan%202007.pdf.

54 See Adequacy of Medicare Part B Reimbursement to Physician Practices for the Treatment of Cancer Patients, OIG Report A-06-05-00024 (September 2005).

55 SSA § 1842(o)(5)(C).

June 2006.[56] BIO supports this proposal and requests that CMS publish the updated furnishing fee in the final rule once the CPI data becomes available.

VI. CMS should place limits on its substitution of WAMP or AMP for ASP to set reimbursement.

The Medicare statute allows the Secretary to substitute the WAMP or AMP for ASP if ASP exceeds WAMP or AMP by a certain percentage.[57] The legislative history of this statutory provision clarifies that Congress intended for the Secretary to provide "a number of procedural and substantive safeguards to ensure the reliability and validity of the data" when deciding to substitute WAMP or AMP for ASP.[58] The proposed regulation states, "If the Inspector General finds that the average sales price exceeds the widely available market price or the average manufacturer price by 5 percent or more in calendar year 2007, the payment limit in the quarter following the transmittal of this information to the Secretary is the lesser of the widely available market price or 103 percent of the average manufacturer price."[59] Not only does this regulation fail to provide for any procedural or substantive safeguards to ensure the reliability of the data, but it does not express the Secretary's discretion in determining whether to substitute WAMP or AMP for ASP.

The regulation's language is inconsistent with section 1847A(d)(3)(A) of the Social Security Act that specifies that the Secretary "may" disregard ASP where the ASP exceeds WAMP or AMP by a certain threshold. Accordingly, we ask that this regulation be clarified to specify that the Secretary has discretion as to whether to substitute WAMP or AMP for ASP. Moreover, BIO urges CMS to obtain public input prior to determining whether to make such a substitution given that many drugs and biologicals have unique market dynamics that could skew

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56 71 Fed. Reg. at 49,004.

57 See SSA § 1847A(d)(3)(A).

58 Medicare Prescription Drug, Improvement, and Modernization Act of 2003 Conference Report, H.R. Rep. No. 108-391, at 592 (noting that the safeguards include "notice and comment rulemaking, identification of the specific sources of information used to make [a determination to use WAMP instead of ASP], and explanations of the methodology and criteria for selecting such sources").

59 Proposed 42 CFR § 414.904(d)(3); 71 Fed. Reg. at 49,083.

these studies. Without obtaining all relevant information, CMS may reduce payment rates where it should not, ultimately harming patient access to important therapies.

BIO specifically requests that CMS revise its regulatory test to modify 42 C.F.R. § 414.904(d)(3) to read: "If the Inspector General finds that the average sales price exceeds the widely available market price or the average manufacturer price by 5 percent or more in calendar year 2007, the Secretary may, after notice and an opportunity to comment, revise the payment limit in the quarter following the transmittal of this information to the Secretary to the lesser of the widely available market price of 103 percent of the average manufacturer price." It is imperative that CMS provide the public an opportunity to comment on any substitution of ASP before the agency proceeds. Moreover, in order for the public to comment meaningfully, BIO urges CMS to provide a thorough description of the sources of information used in the OIG's study, the methodology and criteria for selecting these sources, a description of any surveys and how they were conducted, and CMS's plans to use the data.

CMS specifically requested comments on the timing and frequency of the price comparisons, as well as the effective date and duration of the rate substitution. Although BIO does not have generally applicable comments on these issues, given the significance of this provision, we request that CMS issue a proposed rule so that all stakeholders have the opportunity to comment on a specific proposal.

VII. BIO urges CMS to clarify the payment of infusion drugs and biologicals furnished through DME.

The Medicare statute establishes payment for infusion drugs furnished through an item of DME on or after January 1, 2004 at 95 percent of the average wholesale price for the drug in effect on October 1, 2003, with one exception. That exception provides that, for DME infusion drugs furnished in a DME competitive acquisition area on or after January 1, 2007, the payment will be at the amount provided in the DME competitive bidding statute (SSA § 1847).[60] In the

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[60] SSA § 1842(o)(1)(D).

DME competitive bidding proposed rule issued earlier this year, CMS indicates that the initial phase of the competitive bidding program is not likely to be implemented until October of 2007.[61] CMS has not explained the impact of the competitive bidding program on payment for DME infusion drugs, and BIO asks that CMS address two issues in the final rule in this regard:

1. What will the payment rate be for DME infusion drugs in 2007, and what will happen if such products are included in a competitive bidding program in late 2007?

2. Because class III devices under the Federal Food, Drug, and Cosmetic Act are excluded from the DME competitive bidding program,[62] CMS needs to identify how drugs that are necessary for the effective use of a class III device will be reimbursed, as it would be unusual to include the drug in competitive bidding when the device would not be.

Finally, BIO asks that CMS maintain and update the DME infusion drug portions of its quarterly released ASP file. When CMS first established the ASP file, it included some columns on the spreadsheet for DME infusion drugs. For the most part, however, these columns have not been updated since then. This is especially problematic for new DME infusion drugs, as CMS' unwillingness to include such therapies in the file creates difficulties with Medicare contractors.

VIII. BIO recommends that CMS instruct its contractors to include resources involved in compounding when pricing compounded drugs and biologicals.

In recent ASP transmittals that CMS has released,[63] the agency indicates that pricing for compounded drugs and biologicals is performed by local

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61 71 Fed. Reg. 25654, 25690 (May, 1, 2006).

62 SSA § 1847(a)(2)(A).

63 E.g., "October 2006 Quarterly ASP Medicare Part B Drug Pricing File, Effective October 1, 2006, and Revisions to January 2006, April 2006 and July 2006 Quarterly ASP Medicare Part B Drug Pricing Files" Transmittal 1059 (Sept. 15, 2006), available at http://www.cms.hhs.gov/transmittals/downloads/R1059CP.pdf).

contractors, with no further direction offered to the contractors. With the lack of guidance from CMS, Medicare contractors have approached pricing in a multitude of varied ways. This situation is reminiscent of the manner in which payments for drugs were calculated prior to the establishment of the Single Drug Pricer, with rates varying significantly. Ultimately, CMS stepped in to create standardization across the country through the Single Drug Pricer.

There is a similar need to promote standardization with regard to compounded drugs and biologicals, particularly with regard to ensuring that pricing for these therapies recognizes the costs incurred to produce the compounded drug or biological that a physician has ordered. For example, some physicians that specialize in pain management maintain the equipment, conditions, and personnel in their office or clinic to prepare and administer currently available intrathecally administered drugs. Most intrathecally administered products are purchased from the manufacturer, however, and are prepared for administration by compounding pharmacists that specifically are trained in the technique for preparing these compounds and have the necessary laminar flow hood to assure that the specific conditions for product preparation are met. The physician then purchases the prepared product from the pharmacy and bills through current Part B billing channels to the Medicare carrier. The list of sterile compounding requirements is extensive and the process is expensive, but both requirements *and* process ultimately serve to deliver *quality patient care*. Due to the strict regulations levied by the state boards and FDA, however, pharmacies incur additional expenses that greatly *exceed* the cost of the required pharmaceutical powders. Indeed, one contractor recently announced that it was discontinuing payment of a compounding fee for no apparent reason. [64]

BIO believes that it is inappropriate for a contractor not to account for the costs that are incurred in producing a compounded therapy. By its nature, work must be undertaken to mix products according to the physician's prescription and the labor and costs of doing so properly and safely are not negligible. Indeed, CMS has acknowledged this in the Medicare Part D context – "the labor costs

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[64] See, "Medicare B News," Issue 227 (Apr. 4, 2006), at 45, located at https://www.noridianmedicare.com/p-medb/news/bulletins/docs/Medicare_B_News_Issue_227_April_4,_20061.pdf (Noridian discontinues payment of compounding fee effective May 1, 2006).

associated with mixing a compounded drug product that contains at least one FDA approved prescription drug component can be included in dispensing fees." 70 Fed. Reg. 4194, 4232 (Jan. 28, 2005). Accordingly, BIO asks that CMS' instructions to its contractors on pricing for compounded drugs and biologicals include a direction to recognize the costs of compounding in its pricing of these therapies.

IX. BIO urges CMS to continue the payment for preadministration-related services for standard and specialty IVIG.

As you know, BIO has been very concerned about Medicare beneficiary access to standard and specialty IVIG over the past few years as a result of the changes in the Medicare payment methodologies for drugs and biologicals. BIO was pleased that CMS recognized the unique aspects of this therapy, as well as its importance to Medicare beneficiaries, through the establishment of a payment for preadministration-related services for IVIG in last year's physician fee schedule final rule, with physicians billing G0332 to receive this payment. Although there is no discussion of the preadministration-related services payment in the preamble to the Proposed Rule, the inclusion of "D" as a status indicator in Addendum B suggests that the agency intends to eliminate this payment.[65]

If the agency's intent is to discontinue this payment, BIO is very disturbed by both the policy determination and the lack of explanation. As noted above, we believe that CMS made positive strides in ensuring access to IVIG through the preadministration-related services payment, and the elimination of the payment would be a significant step backward. All of the costs that CMS identified last year that physicians incur related to standard and specialty IVIG will continue to be incurred next year, and CMS offers no evidence that these costs would not continue to be incurred. As such, the cost must continue to be reimbursed.

BIO also notes that it is very problematic to make significant policy changes such as this without explaining the basis for the change in a proposed rule. Accordingly, BIO believes that CMS must articulate its reasons for discontinuing

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[65] 71 Fed. Reg. at 49,235.

the payment and solicit and respond to comment on the proposal before finalizing a determination to discontinue the preadministration-related services payment. Unless this happens before January 1, 2007, CMS should continue to pay physicians for preadministration-related services related to standard and specialty IVIG.

X. BIO supports CMS' decision to reimburse all ESRD drugs and biologicals at ASP plus six percent ["ESRD Provisions"].

BIO continues to support CMS' decision to reimburse all ESRD drugs and biologicals at ASP plus six percent when separately billed by freestanding or hospital-based ESRD facilities.[66] ASP-based reimbursement is the best option available under the statute, and it is more accurate and easier to administer than updating a prior year's acquisition cost data.

XI. BIO is troubled by the current system of setting payment rates for new outpatient clinical diagnostic laboratory tests ["Clinical Diagnostic Lab Tests"].

Section 942(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) requires the Secretary to develop, through regulations, procedures for determining the basis for, and the amount of, payment for new clinical diagnostic lab tests. The provision also requires CMS to provide opportunities for public input on the proposed new tests and pricing methodologies and amounts, and to take into consideration such input when developing the payment amounts. In implementing this section of the MMA, CMS essentially takes the position that its current process for providing for public consultation on the establishment of payment amounts for new lab tests already is consistent with Section 942(b), and the only thing left to be done is to codify the existing procedures.

Although BIO certainly appreciates the opportunity to have more transparency in CMS' pricing of new lab tests and to provide CMS with recommendations and data, the current methodologies of crosswalking and gap-

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66 Id. at 49,005.

filling, and CMS' application of them, are not adequate for many of the new diagnostics being developed. If the era of personalized medicine is to become a reality, personalized medicine diagnostics must be seen as the entryway, and must be evaluated in a new manner. Many of the newer lab tests, and even more of those in development, represent a whole new generation of diagnostics that can predict who is likely to develop certain cancers and other diseases, whether and how they will respond to particular therapeutics, what dosage of a particular drug is optimum for the individual, how combinations of drugs will be metabolized by people with particular genetic traits, and the likelihood of recurrence of certain cancers. Furthermore, many other novel molecular diagnostics are being developed for disease sub-typing, disease prognosis and treatment side-effects. These diagnostics will facilitate treatment that is far more tailored to individual characteristics than ever has been possible before, and will save money and lives by avoiding futile or even dangerous therapies while helping to ensure the use of the most appropriate treatment. Indeed, diagnostic tests increasingly will be inextricably linked with certain therapeutics, with the diagnostic test result being a prerequisite to determine whether to prescribe the therapeutic at all, or to establish the treatment regimen. We are concerned, however, that maintaining the current system for setting payment for such tests will not provide sufficient incentive to encourage these innovations.

Developing and bringing to market this new generation diagnostic tests typically is far more costly and complex than the traditional lab test. And even under CMS' gap-filling methodology, aimed at new tests for which there is no comparable, existing test, we are concerned that pricing variations among carriers may be so great, and so unpredictable, that innovation will be stifled and beneficiary access to these tests impeded. We also are concerned that setting a national payment amount when the market for the tests is not yet well-established, and little claims experience is available, will lead to inappropriate reimbursement, and little opportunity for adjustment even if the pricing is later acknowledged to have been set too low.

In addition, because many of these new tests are proprietary and may be offered and performed by only one lab in the country, the gap-filled price established by the carrier serving that lab becomes a de facto national price, and if

it is insufficient, it may not be economically feasible for the lab to offer the test at all.

BIO urges CMS to engage in discussions, both internally and with external stakeholders, to explore the research, therapeutic and economic environments in which these new generation diagnostic tests are developed and to ensure that Medicare's payment policies take into consideration the investment of human and capital resources that go into these diagnostics, as well as the tremendous potential benefits, in terms of cost savings, clinical outcomes, and quality of life for Medicare beneficiaries. In the short term, we also ask that CMS seek input from interested parties in this arena regarding the appropriate guidance and criteria to provide to carriers who are pricing these novel lab tests. By ensuring appropriate value recognition of molecular diagnostic tests, the agency will create financial stability and attractiveness for the industry further facilitating continued investment and development of these diagnostics. This will go a long way towards the realization of personalized medicine.

XII. CMS should ensure adequate reimbursement for drug administration services.

As discussed in depth in our comments on CMS' proposed notice regarding the five-year review of work relative value units (RVUs) and proposed changes to the practice expense methodology under the physician fee schedule,[67] BIO is very concerned that the agency's proposed changes to the work and practice expense RVUs for drug administration services, combined with the projected substantial cut to the conversion factor, will harm beneficiary care. As noted in the Proposed Rule, the conversion factor is projected to decrease by 5.1 percent in 2007 under the current statutory formula.[68] Accordingly, BIO urges CMS not to implement any cuts to reimbursement for drug administration services until it has confirmed that beneficiary access to quality care will not be harmed by the changes.

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[67] Letter from Jayson Slotnik, Director, Medicare Reimbursement and Economic Policy, BIO, to Mark McClellan, Administrator, CMS (Aug. 21, 2006), available at: http://www.bio.org/healthcare/medicare/20060821.pdf.

[68] 71 Fed. Reg. at 49,077.

BIO remains particularly concerned about the proposed changes to the payment rates for administration of therapeutic doses of radioimmunotherapies. If the proposed 5.1 percent reduction in the conversion factor is implemented, payment for Current Procedural Terminology (CPT) code 79403 (radiopharmaceutical therapy, radiolabeled monoclonal antibody, by intravenous infusion) would decrease by 12 percent under the 2007 transitional RVUs and 34 percent under the fully implemented RVUs. This could seriously harm patient access to critical radioimmunotherapies such as Zevalin® and Bexxar® in freestanding centers, and BIO therefore again urges CMS not to implement these changes.

BIO also is concerned that Medicare does not provide a separate payment for the intravenous administration of echocardiographic imaging drugs. These drugs are critical for optimizing echocardiographic images, and the costs for their administration are not insubstantial. We urge CMS to remove any edits from the Correct Coding Initiative (CCI) that combine intravenous injection code(s) into codes for the associated echocardiography procedures. Providing for the separate payment for the administration of these drugs should encourage appropriate use of contrast enhancement to help salvage images when the echocardiographic image is suboptimal.

We appreciate CMS' efforts to promote quality care for Medicare beneficiaries and believe that adequate reimbursement is an imperative part of this process. Along this line, we ask that CMS continue the oncology demonstration project, improved as necessary, because it serves not only to gather data regarding quality, but also as an opportunity to promote evidence-based best practices that may lead to improved patient outcomes.

Moreover, BIO remains concerned about CMS' recent guidance to Part D plans suggesting that payment of administration fees available under Part B applies only to vaccines covered by Part B. In guidance issued to Part D plans on May 8, 2006, and again on July 11, 2006, CMS stated that Part B administration fees cover only those vaccines specifically covered under Part B. This new interpretation is drastically different from the policy specified in the final Part D rule and in subsequent guidance, in which CMS stated that costs related to the administration of Part D vaccines could be paid as a component of physician fees

under Part B.[69] In the instructions specified in the final rule, CMS explained the importance of covering vaccine administration in a manner that ensures that Part B and Part D provide a seamless benefit and that CMS' regulations reflect Congressional intent that Part D provide beneficiaries with access to vaccines not covered under Part B. In its Coordination of Benefits guidance for 2006, CMS reiterated this policy, expressly stating that "costs directly related to vaccine administration may be included in physician fees under Part B, since Part B pays for the medically necessary administration of non-Part B covered drugs and biologicals."[70]

As discussed, Congress intended that Part B and Part D together provide a seamless benefit to Medicare beneficiaries. The recent CMS guidance on this issue will lead to beneficiaries losing access to important vaccines if the cost of administering the vaccines is not also covered. Congress clearly intended that vaccines not covered under Part B be covered under Part D, expressly defining these vaccines as "Part D drugs." That Congress expressly included vaccines in the statutory definition of Part D drugs, strongly suggests that Congress' intended for Part D to provide access to those vaccines not covered under Part B. Beneficiaries are not afforded meaningful access to vaccines where the costs of administering those vaccines are not also covered by Medicare.

CMS' new approach to the administration of Part D vaccines will greatly limit access to these highly effective, safe, and cost-saving therapies. In addition to being inconsistent with stated CMS policy and guidance, this approach is contrary to the recent pro-active, public health-oriented approaches being taken by CMS to encourage vaccinations and other preventive health interventions in the Medicare population. Indeed, CMS has recently increased provider payment rates for the administration of Part B vaccines, such as influenza and pneumococcal vaccines. From both a public health and economic policy perspective, it is clearly in the interest of the federal government and CMS to eliminate economic barriers for Medicare beneficiaries in accessing these critical vaccines.

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69 70 Fed. Reg. 4,194, 4,328, 4,231 (Jan. 28, 2005).

70 Part D Coordination of Benefits Guidance for 2006 (July 1, 2005).

BIO strongly urges CMS to issue a Healthcare Common Procedure Coding System (HCPCS) code for Part D vaccine administration, consistent with the codes already available for administering Part B vaccines. Another option for providing meaningful coverage of vaccines would be to expand the definition of dispensing fees, as CMS suggested in the proposed Part D rule,[71] to include the professional services necessary to administer a Part D drug or biological such as a vaccine.

Finally, although BIO has appreciated the clarification that CMS has offered regarding the appropriate billing for chemotherapy administration, the agency has not completed its task. In addition to including the administration of monoclonal antibodies under chemotherapy administration, CMS should clarify that standard and specialty IVIG and DNA or RNA based therapies are biologic response modifiers that also should be billed under chemotherapy administration codes. BIO asks CMS to make this clarification in the final rule.

* * *

BIO greatly appreciates the opportunity to comment on the important issues raised by the Proposed Rule, and we look forward to working with CMS to ensure that Medicare beneficiaries continue to have access to critical drug and biological therapies. As discussed, it is imperative that Medicare compensate providers adequately for the costs associated with acquiring and administering these therapies in order to ensure that Medicare beneficiaries are not denied access to vital drugs and biologicals administered in physician offices. We sincerely hope that CMS will give thoughtful consideration to our comments and will incorporate our suggestions into its final rule. Please feel free to contact me at (202) 312-9273 if you have any questions regarding these comments. Thank you for your attention to this very important matter.

Respectfully submitted,

/s/

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[71] 69 Fed.Reg. at 46,632, 46,648 (Aug. 3, 2004).

Jayson Slotnik
Director, Medicare Reimbursement &
Economic Policy
Biotechnology Industry Organization (BIO)

Submitter : **Ms. Kimiko Miller** **Date: 10/10/2006**

Organization : **Ms. Kimiko Miller**

Category : **Physician Assistant**

Issue Areas/Comments

Background

Background

A much needed advanced procedure to eliminate varicose vein in a less invasive and patient friendly procedure, Endovenous laser treatments, have not even become the standard in treating varicose veins, and you want to reduce the reimbursement. This will discourage future physicians from investing in the equipment and training needed to perform this procedure. And vein stripping will continue to plod along as the standard of care.

Submitter : **Dr. Umesh Sharma** **Date: 10/10/2006**

Organization : **Southwest Vein Clinic**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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

Provisions of the Proposed Rule
See General Comment below.

Background
See General Comment Below

General Comment

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

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

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

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

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

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

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

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

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

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

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

Respectfully submitted,

Umesh Sharma, M.D.
Joliet, IL 60432
Umeshswvc@aol.com1800 - HEALTH CARE ADVISORY BOARD - PUBLIC LANDING

Submitter : **Dr. David Brodland** **Date: 10/10/2006**

Organization : **American College of Mohs Micrographic Surgery and**

Category : **Other Association**

Issue Areas/Comments

Background

Background

IDTF ISSUES

GENERAL

GENERAL

See attachment.

CMS-I321-P-904-Attach-1.DOC

#704

American College of Mohs Micrographic Surgery and Cutaneous Oncology

555 East Wells Street • Suite 1100 • Milwaukee, WI 53202-3823 • Phone: 414-347-1103 • Fax: 414-272-6070
Email: info@mohscollege.org • www.mohscollege.org

To: Centers for Medicare & Medicaid Services (CMS) via electronic submission at http://www.cms.hhs.gov/eRulemaking

From: American College of Mohs Micrographic Surgery and Cutaneous Oncology (ACMMSCO)

Date: October 10, 2006

Re: Independent Diagnostic Testing Facilities (IDTF) issues
File code CMS-1321-P

The American College of Mohs Micrographic Surgery and Cutaneous Oncology (ACMMSCO) would like to comment on the IDTF issues published in the Federal Register pp. 49054-49062. The ACMMSCO strongly supports dedicated laboratory space for ACMMSCO-approved training programs, as we feel it is an important element of optimal patient care and training for physicians who wish to practice Mohs surgery.

Mohs micrographic surgery is a technique for removing skin cancers. It is billed by CPT codes 17304-17310. The technique is both a surgery and a pathologic method, although the CPT codes are listed under the surgical CPT codes rather than the pathology CPT codes. All training centers for Mohs micrographic surgery should have a dedicated **on-site** laboratory that is CLIA compliant and approved by the ACMMSCO. CMS also requires these laboratories to be CLIA compliant and requires the CLIA number for billing. However, ironically, CLIA does not require a physician to have a physical laboratory or equipment to obtain a CLIA certificate of compliance. This oversight, we presume, has given rise to a proliferation in billing for Mohs micrographic surgery whereby the billing physician in actuality does not have a physical laboratory – that is dedicated space, equipment, or employed personnel. Instead, the technical and sometimes the professional pathology components are outsourced.

We agree with your 14 "Suppler" Standards discussed in section L2, p. 4061 and 4062. Of particular interest to the ACMMSCO are the following:

A. Maintain a dedicated physical laboratory on the appropriate site. There should be enough designated space for equipment, etc. The proposal of 350 sq. feet (p.49057) is difficult to understand. The square footage would vary dependent upon the tests performed. For a frozen section laboratory, a minimum of 120 sq. feet is sufficient.

B. Have all appropriate testing equipment available on the physical site where the work is performed. We agree with this standard. We do not consider "portable" cryostats, as in "mobile Mohs labs," to render the highest quality frozen sections.

C. Have technical staff on duty with the appropriate training to perform tests. If these services are contracted out we do not believe that the quality will overall be as high as where the laboratory director specifically employs the technician. Furthermore, for more difficult and extensive cases, the laboratory must function for more than

one day a month. If a patient's skin cancer cannot be totally removed in one day, then the patient should be able to return the next day for continued treatment. Thus your proposal on p. 49057 that the independent contractor will perform services exclusively for the group at least 35 hours per week is in the patient's best interest.

Sincerely,

David Brodland, MD
President
American College of Mohs Micrographic Surgery and Cutaneous Oncology (ACMMSCO)

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

Organization : Infectious Diseases Society of America

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-905-Attach-1.DOC

IDSA

Infectious Diseases Society of America

#905

October 10, 2006

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

Re: Comments on Proposed Rule [Docket No. CMS-1321-P]: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B

Dear Dr. McClellan:

The Infectious Diseases Society of America (IDSA) and the HIV Medical Association (HIVMA) appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) Physician Fee Schedule Proposed Rule for Calendar Year 2007.

IDSA represents over 8,000 physicians and scientists devoted to patient care, education, research, and community health planning in infectious diseases. The Society's members focus on the epidemiology, diagnosis, investigation, prevention and treatment of infectious diseases in the U.S. and abroad. Our members care for patients of all ages with serious infections, including meningitis, pneumonia, tuberculosis, surgical infections, those with cancer or transplants who have life-threatening infections caused by unusual microorganisms and new and emerging infections, such as severe acute respiratory syndrome (SARS) and influenza. Housed within IDSA is HIVMA, which represents more than 2,600 physicians working on the frontline of the HIV/AIDS pandemic. HIVMA members conduct research, administer prevention programs and provide clinical services to individuals with HIV disease. Together, IDSA and HIVMA are the principal organizations representing ID and HIV physicians in the United States.

Before addressing specific concerns, we would like to express appreciation for the time CMS staff has spent in developing this proposed rule, including discussions on the Agency's efforts in support of health information technology (IT) and transparency. As the age of our population grows and as more Medicare beneficiaries live with chronic conditions, such as HIV, hepatitis C, diabetes, and heart disease, IDSA and HIVMA share CMS's goals of improving quality and efficiency through the adoption of health IT and by allowing consumers to make

more informed decisions about their care. We specifically look forward to providing feedback and comments on the healthcare information transparency initiative as CMS works with medical specialty societies, providers, and insurers to collect cost and quality data.

Additionally, the proposed rule discusses methodological changes to the Average Sales Price (ASP) drug payment system. IDSA's clinician members' continue to experience serious problems in acquiring most antibiotics and other products at or below the ASP since the program was implemented on January 1, 2005. These problems have been underscored in numerous letters and a May 2005 meeting with CMS officials. Far broader changes will be necessary to ensure Medicare beneficiaries continued access to life saving antibiotics commonly administered by infectious diseases (ID) physicians in the outpatient setting.

IDSA and HIVMA will comment on the following issues raised by the proposed rule:

- The Sustainable Growth Rate (SGR) formula for calculating physician payments is flawed and should be replaced by a formula that more accurately reflects the cost of providing high quality healthcare to Medicare's elderly and disabled beneficiaries.

- CMS should reduce the cost of a future legislative fix to the SGR by removing Part B drugs from the calculation retroactive to the SGR base year (April 1, 1996 through March 31, 1997).

- CMS should work with Congress to extend the 1.0 Geographic Practice Cost Index (GPCI) floor until the SGR is replaced with a more equitable formula for calculating annual physician payment updates.

- The proposed changes to the ASP payment methodology fall far short of the changes necessary to ensure Medicare beneficiaries' continued access to the life saving antibiotics commonly administered by ID physicians.

- All seven adult vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) should be covered under the Physician Fee Schedule. The 2007 Proposed Rule only covers vaccinations for influenza, pneumococcus, and hepatitis B.

- IDSA and HIVMA support CMS' goal of improving quality and efficiency by empowering consumers to make more informed decisions about their health care.

SUSTAINABLE GROWTH RATE

Physicians continue to face multiple years of payment cuts due to the inherently flawed physician payment update formula, the sustainable growth rate (SGR). As you are acutely aware, the SGR is linked to the gross domestic product and penalizes physicians and other practitioners for volume increases that they cannot control and that the government actively promotes through new coverage decisions and other initiatives. According to the most recent projections, these flaws will result in physician payment cuts totaling 37% over nine years, beginning January 1, 2007, unless a permanent legislative or administrative solution is found.

The 2007 proposed rule includes an overall physician payment cut of 5.1%. This payment cut, if enacted, could cause serious access problems for Medicare beneficiaries and will unfairly strain the resources of those infectious diseases physicians who continue to serve this nation's elderly and disabled. After a 5.4% physician payment cut in 2002, Congress acted to avert payment cuts over the past four years, replacing steep cuts with increases of 1.6% in 2003, 1.5% in 2004 and 2005, and a freeze in 2006.

But these positive payment updates have only exacerbated the long term problem. Each time Congress passes a one-year physician payment fix that does nothing to fix (or repeal) the flawed physician payment formula, the gap between target spending and actual spending further widens. Moreover, even with the small positive updates Congress has provided, medical practice costs as measured by the Medicare Economic Index (MEI) continue to increase more than physician payments. Medical practice costs have increased by 43% from 1991-2006, whereas during the same time period, Medicare payments to physicians have increased by only 18%. Costs are projected to increase an additional 20% by 2015 even as physicians face sustained and severe cuts.

A long-term solution to the physician payment mess will require the Administration and Congress to work together to replace the SGR with a methodology that provides positive, stable and predictable updates to physician payments and shifting monies from Part A to Part B (as the site of service continues to shift from the hospital to the physician office). In the meantime, the Administration has the authority to take additional action to help ease problems created by the SGR and lead the way for a permanent legislative solution down the road.

REMOVING PHYSICIAN-ADMINISTERED DRUGS FROM THE SGR

CMS includes the costs of Medicare-covered physician-administered drugs when determining whether spending on physicians' services has exceeded the SGR spending target. Drug products are not a physician service and should never have been included in the SGR calculation. IDSA favors replacing the SGR, but the estimated cost of a fix will make it extremely difficult for Congress to act unless the Administration first removes Part B drugs from the physician payment formula. According to recent estimates, administratively removing Part B drugs from the SGR calculation could reduce the cost of a future legislative fix by more than $100 billion.

IDSA and HIVMA support the development of new and novel life-saving drugs and the federal policies that spur their development. However, it is neither right nor realistic to finance the cost of these drugs through cuts in payments to physicians. In several other sections of Medicare law, CMS has officially held that drugs are not a physician service. To include them in the SGR is inconsistent with those policies and incompatible with the government's goal of enhancing Medicare patients' access to new medical treatments.

GEOGRAPHIC PRACTICE COST INDICES (GPCI)

Rural areas have historically suffered from a shortage of qualified physicians across most specialties, including infectious diseases. The 1.0 GPCI floor mandated by section 412 of the

2003 Medicare Modernization Act (MMA) helped to ensure rural beneficiaries continued access to high quality medical care by making these areas more financially viable to physicians. Removal of the 1.0 floor at a time when Medicare projects continued increases in medical practice costs and decreases in reimbursement rates through 2015 could devastate rural beneficiaries' access to high quality medical care. The 1.0 GPCI floor should be extended until the SGR is replaced with a more equitable formula for calculating annual physician payment updates.

AVERAGE SALES PRICE

ID physicians continue to experience difficulty in acquiring many of the Part B drugs and biologicals that are commonly used to treat Medicare beneficiaries with serious infections at or below the Average Sales Price (ASP) +6%. While IDSA and HIVMA will comment on proposed methodological changes to the ASP reporting provision below, these proposed changes are relatively minor and do little to address the cost and reimbursement gap many ID physicians continue to experience.

Section 1847A(c)(5)(A) of the MMA directs manufacturers to include certain price concessions in their quarterly ASP calculations. CMS proposes to exclude bona fide fees, including service fees, administrative fees and other fees that manufacturers pay to group purchasing organizations or pharmacy benefit managers, from the ASP calculation as price concessions. According to the definition employed by CMS in the proposed rule, bona fide service fees are:

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

IDSA supports this proposed methodological change in so far as it would provide further clarification to manufactures that bona fide service fees should be excluded from the ASP calculation, thus potentially increasing their reported average sales prices and physicians' reimbursement rates.

CMS requires manufacturers to exclude exempted sales, many of which are known on a lagged basis, from the quarterly ASP calculation. In order to prevent errors and improve accuracy in the ASP calculations, CMS proposes to require that all manufacturers calculate lagged exempted sales by using a 12-month rolling average ratio methodology that produces a percentage estimate. When this percentage estimate is multiplied by the number of regular (non-exempt) sales in a given quarter, a more accurate and consistent estimate of lagged exempted sales should result. While this methodological change will likely not lead to significant increases in reimbursements for antibiotics, IDSA and HIVMA support any change that will lead to more stable and accurate quarterly ASP reporting by manufacturers.

IDSA and HIVMA are disappointed that CMS has not proposed more far reaching changes that would more closely align reimbursement rates for drugs and biologicals with physician-owned

practices' and clinics' acquisition costs. At a minimum, IDSA and HIVMA join Representative Nancy Johnson in urging CMS to conduct a study that collects and compares both large-volume providers' and small-volume providers acquisition costs for Part B drugs and biological products to determine the appropriateness of ASP +6% reimbursement rates.

MEDICARE COVERAGE OF ACIP RECOMMENDED VACCINES

The development of vaccines and the implementation of appropriate immunization policies and programs have been among the leading preventatives against death and debilitating diseases over the last 50 years. Immunizations are usually associated with preventing childhood diseases, but they also can play a significant role in sustaining a healthy adult population. According to the Advisory Committee on Immunization Practices (ACIP), adults should have up-to-date vaccinations for the following conditions: pneumonia, influenza, hepatitis A, hepatitis B, tetanus, varicella (chickenpox), and meningitis. However, CMS only covers vaccines and administration for pneumonia, influenza, and hepatitis B.

According to previous CMS guidance, including the Part D Final Rule (issued in January 2005), costs related to the administration of Part D covered vaccines could be included in the physician fees under Part B "since Part B pays for the medically necessary administration of non-Part B covered drugs and biologicals." CMS restated this policy in the Part D Coordination of Benefits Guidance issued in July 2005.

IDSA supports Medicare coverage and reimbursement for all ACIP-recommended vaccines as well as for their administration. This would include coverage for both the vaccine as well as their intranasal counterparts (in the case of the flu vaccines). We believe such actions to be sound from both a fiscal and public health perspective as Prevention is more cost effective than treatment. IDSA also urges CMS to follow its original guidance regarding the administration of Part D covered vaccines by including reimbursement for immunization services in the physician fee schedule under Part B.

HEALTH CARE INFORMATION TRANSPARENCY INITIATIVE

IDSA and HIVMA share CMS' concerns about the skyrocketing cost of health care, especially as the number of uninsured steadily increases. We further agree that consumers empowered with information on the quality and pricing of their health care could potentially make decisions that improve system-wide quality and efficiency. However, it is crucial that the information collected by CMS is comprehensive in nature and provided to health care consumers in a meaningful way.

The President's August 22, 2006 Executive Order, entitled, Promoting Quality and Efficient Health Care in Federal Government Administered or Sponsored Health Care Programs, further clarifies the health care pricing information that CMS will make available to beneficiaries in the coming months. In the Executive Order, the President says:

> *"Each agency shall make available to the beneficiaries or enrollees of a Federal health care program (and, at the option of the agency, to the public) the prices that it, its health insurance issuers, or its health insurance plans pay for procedures to providers in the health care program with which the agency, issuer, or plan contracts."*

As CMS works to make health care prices more transparent, IDSA and HIVMA urge the Agency to include all the determinants of the *actual* price paid for a given service or procedure, including providers' *listed* fees/charges as well as the *allowed* amounts paid by health plans/insurers and patients. Such an approach to health care pricing transparency would give both large and small consumers the information necessary to make more informed decisions about electing specific services and about choosing the most cost effective health plan. Likewise, providers would have the knowledge necessary to align their internal fee schedules more closely with what health plans and insurers are willing to pay and vice-versa, thereby promoting more consistent pricing across the health care system.

CONCLUSION

IDSA and HIVMA appreciate the opportunity to comment on the 2007 Physician Fee Schedule Proposed Rule. We believe that CMS should use its administrative authority to remove the cost of Part B drugs from the SGR calculation. This much needed change will contribute dramatically to more appropriate physician payment updates and will pave the way for a permanent legislative solution to the SGR physician payment formula. We also have commented on several other issues, including the elimination of the GPCI floor, proposed methodological changes to the ASP reporting provision, and the lack of clear and consistent policies surrounding Medicare's coverage of vaccines and their administration.

If you have any questions or comments, please feel free to contact Robert J. Guidos, JD, IDSA's Director of Public Policy and Government Relations, at 703/299-0200. We look forward to working with CMS as it finalizes these regulations.

Sincerely,

Lawrence P. Martinelli, MD, FIDSA
Chair, IDSA's Clinical Affairs Committee

Daniel R. Kuritzkes, MD, FIDSA
Chair, HIV Medicine Association

Submitter : **Mr. Robert Howard** **Date: 10/10/2006**

Organization : **Midtown Nutrition Care**

Category : **Dietitian/Nutritionist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Impact

Impact

Medical Nutrition Therapy Services, CPT 97802-4: G0270-1

Provisions of the Proposed Rule

Provisions of the Proposed Rule

Comment on October 9, 2006 submission by the American Dietetic Association

CMS-1321-P-906-Attach-1.TXT

#906

MIDTOWN NUTRITION CARE
119 WEST 57TH STREET
NEW YORK, NY 10019
(212) 333-4243

October 10, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P
7500 Security Boulevard
Baltimore, MD 21244-1850

Issue Identifier: PROVISIONS—MEDICAL NUTRTION THERAPY SERVICES, CPT 97802-4; G0270-1

Dear Sir or Madam:

Yesterday our professional society, the American Dietetic Association (ADA), submitted electronically an 8-page comment addressing specific items within the "Provisions" section, and other revisions that impact medical nutrition therapy (MNT) services provided by registered dietitians. We support that comment but would like to expand upon a statement on page 3 thereof:

"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 to lead this effort and dialog with various physician groups to coordinate a review of the MNT codes at a future RUC meeting."

We submit that if CMS bases work values on established codes such as CPT 90804 or 99213, it would be unnecessary to gather additional data. However, if CMS does require additional data, we submit that CMS should, starting in Calendar Year 2007, use on an interim basis work values based on CPT 90804 or 99213 instead of the physical therapy code-based HCPAC recommendations, until the data has been gathered. (However, if CMS instead uses the HCPAC recommendations, then CMS should nevertheless value the MNT codes so that all will have the same hourly rate; that is, CPT 97803 and G0270 would have the same value as CPT 97802; and CPT 97804 and G0271 would be equal to CPT 97802 times 2 divided by 5.)

Sincerely yours,

Robert Howard, RD, JD
Managing Partner

Submitter : Dr. Mark S. Birenbaum **Date:** 10/10/2006

Organization : American Association of Bioanalysts

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-907-Attach-1.DOC

#907

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

Dear Sir or Madam:

The American Association of Bioanalysts (AAB) is a national professional association whose members are clinical laboratory directors, owners, managers, supervisors, medical technologists, laboratory technicians, and phlebotomists.

AAB wishes to comment on the Proposed Rule, 42 CFR Parts 405, 410, et.al., published in the August 22, 2006, Federal Register concerning the Medicare Program's revisions to payment policies under the Physician Fee Schedule for Calendar Year 2007 and other changes to payment under Part B.

AAB has concerns about the proposed changes to Section 424.24, "Requirements for medical and other health services furnished by providers under Part B" relating to paragraph (f) "Blood glucose monitoring in skilled nursing facilities."

The Department is proposing to amend Section 424.24 to clarify that a physician's standing order is not sufficient to order routine blood glucose monitoring for patients in skilled nursing facilities (SNFs).

AAB's concerns are several-fold:

1. The definition of "routine blood glucose monitoring." Section 90.1, "Glucose Monitoring", of the Medicare Claims Processing Manual proclaims "Routine glucose monitoring of diabetics is never covered in a SNF, whether the beneficiary is in a covered Part A stay or not. Glucose monitoring may only be covered when it meets all the conditions of a covered laboratory service, including use by the physician in modifying the patient's treatment."

   The distinction between "routine glucose monitoring of diabetics" and covered glucose monitoring needs to be made clearer.

   Section 90.1 may be misinterpreted to mean that blood glucose monitoring of diabetics in a SNF is covered only if the physician modifies the patient's treatment. However, Transmittal AB-00-108 states that for a laboratory service to be covered it must be "reasonable and necessary," i.e., it must be ordered by the physician (treating the patient) and the ordering physician must also use the result in the management of the

beneficiary's specific medical problem. According to Transmittal AB-00-108, this implies that 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.

Therefore, reasonable and necessary blood glucose monitoring of a diabetic may result in **continuing**, not just modifying, patient treatment.

2. The conditions under which a physician's standing order for blood glucose monitoring of a diabetic patient is permissible needs to be clarified.

   Obviously, if **routine** blood glucose monitoring is not covered, then a physician's standing order for **routine** blood glucose monitoring would also not be covered.

   But for many diabetics in SNFs, blood glucose monitoring is **not** routine; rather it is reasonable and necessary and is used by the physician to determine whether to continue or modify patient care.

   In that situation, a physician's order for repeat testing is standard medical practice and is **not** prohibited by CMS. (see Federal Register, Vol. 63, No. 163, p. 45081, paragraph 4, "reliance on Standing orders")

   CMS's position is that a standing order, by itself, is not usually acceptable documentation that tests are reasonable and necessary, and that **additional documentation** may be required to support the medical necessity of the test.

   AAB urges CMS to make clear what additional documentation is necessary.

   The OIG's Compliance Program Guidance for Clinical Laboratories states that "...while laboratory compliance programs may permit the use of standing orders executed in connection with an extended course of treatment the compliance program should require the laboratory to periodically monitor standing orders. Standing orders should have a fixed term of validity and must be renewed at their expiration."

To reiterate: a physician's order for repeat blood glucose testing of a diabetic patient during an extended course of treatment in a skilled nursing facility is standard medical practice. If that testing is ordered by the treating physician, the results are transmitted to the ordering physician promptly, and the ordering physician uses the results to continue or modify the patient's treatment, then the testing is reasonable and necessary and is a covered service. In addition, a physician's order for repeat testing is permissible if the order is monitored periodically, has a fixed term of validity, and is renewed upon expiration.

AAB urges the Department to clarify, in these proposed regulations, the points enumerated above so that physicians, laboratories, contractors, and beneficiaries can clearly understand when these tests are covered.

AAB also urges CMS to clarify the difference between repeat testing using fingerstick blood glucose monitoring and quantitative venous blood glucose testing. AAB believes that **routine** blood glucose monitoring refers, in most cases, to the former (fingerstick testing) and not to quantitative venous blood glucose testing.

Comments submitted by:

Mark S. Birenbaum, Ph.D.
AAB Administrator
October 10, 2006

American Association of Bioanalysts
906 Olive Street
Suite 1200
St. Louis, MO 63101-1434
Phone: (314) 241-1445
Fax: (314) 241-1449

Submitter :

Date: 10/10/2006

Organization : **American Society for Microbiology**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-908-Attach-1.DOC

#908

AMERICAN
SOCIETY FOR
MICROBIOLOGY

Public and Scientific Affairs Board

October 10, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P
7500 Security Boulevard
Baltimore, MD 21244-1850

The American Society for Microbiology (ASM) appreciates the opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS) on its Proposed Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007, as announced in the *Federal Register* on August 22, 2006 [Vol. 71, No. 162, CMS-1321-P]. The ASM is the largest educational, professional, and scientific society dedicated to the advancement of the microbiological sciences and their application for the common good. The Society represents more than 42,000 microbiologists, professionally employed as scientists and science administrators working in a variety of areas, including biomedical, environmental, and molecular fields as well as in clinical microbiology and immunology.

Many of our members have primary involvement in clinical laboratory medicine including individuals directing clinical microbiology or immunology laboratories, individuals licensed or accredited to perform such testing, industry representatives marketing products for use, and researchers involved in developing and evaluating new technologies. Thus, our Society has a significant interest in the process of establishing reasonable reimbursement for medically necessary laboratory testing to ensure quality patient care for Medicare beneficiaries. The ASM will limit its comments to the sections of the proposed rule that pertain to clinical diagnostic laboratory tests.

Clinical Diagnostic Laboratory Tests

Section II. N. 1, 2 a. – c. Public Consultation for Medicare Payment for New Outpatient Clinical Diagnostic Laboratory Tests

Section 942(b) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA), requires the Secretary to establish fee schedules for clinical laboratory tests under Medicare Part B. It also specifies annual procedures for consulting the public on how to establish payment for the new or revised clinical laboratory test codes to be included in the annual update of the clinical laboratory fee schedule. CMS has conducted its "Laboratory Public Meeting" on an annual basis since 2002 as a result of Section

1752 N Street, NW – Washington, DC 20036
tel: 202-942-9209 – fax: 202-942-9335 – email: publicaffairs@asmusa.org

531(b) of the Benefits Improvement and Protection Act of 2000, and, as recommended by the Institute of Medicine in its 2001 Report on Medicare Laboratory Payment Policy. ASM has appreciated the opportunity to participate in these public meetings to recommend payment methodology approaches for new microbiology and immunology laboratory tests. In particular, we support the CMS criteria for establishing payment decisions which is based on test purpose, test method, test cost, and the specific recommendation to crosswalk the new test to an existing code, or to gapfill the new test if there is no comparable test. We also appreciate the additional comment period provided after tentative payment determinations are made available by CMS. ASM believes that this kind of open and transparent process allows for a successful coordination of science, business, and program integrity interests which ensures quality laboratory medicine for Medicare beneficiaries. As such, we are pleased that CMS is proposing to codify this important public process.

ASM also supports that CMS provide the rationale, data or responses to comments from the public in its proposed and final payment determinations. Section 1833(h)(8)(B) of the MMA requires the Secretary to provide "an explanation of the reasons for each determination and the data on which the determinations are based" for both the proposed and final determinations. To date, ASM has not been privy to this information regarding proposed or final payment methodology for new laboratory tests. The only information that is provided is CMS's proposed or final payment methodology, and, the recommendations made by each of the organizations that participated and/or submitted comments to the Laboratory Public Meeting. ASM believes that providing this additional information would help to strengthen the payment methodology process by making it more transparent. In addition, ASM recommends that codes for which significant descriptor changes have been made, be open for public comment on appropriate payment methodology. Historically the process has publicized only new codes established by the American Medical Association.

II. N. 2. d. Proposed Payment for a New Clinical Diagnostic Laboratory Test – Crosswalking and Gapfilling (§414.408)

ASM supports CMS in its proposal to establish the payment amount for new laboratory tests via "crosswalking" and "gapfilling" methodology. We are pleased that CMS is clarifying the process by which the gapfilling methodology is applied, including the elimination of payment of new gapfilled tests at carrier specific amounts after the first year. ASM agrees with CMS that a gapfilled test can be payed at the carrier specific rate during the first year, but, that beginning in the second year, the test would be reimbursed at the national limitation amount, based on the median of the carrier gapfill amounts. In addition, ASM recommends that CMS provide guidance to carriers to help in setting carrier specific gapfilled rates so that there is consistency in determining reimbursement of new laboratory tests from carrier to carrier. Guidance could be based on the criteria used to determine payment for new test codes in CMS's annual Laboratory Public Meeting, i.e. test purpose, test methodology and test costs, and, recommendations could be solicited from the public sector during the annual meeting. Guidance might also encourage the use of scientific studies and professional guidelines to support the appropriate utilization and reimbursement for such new tests.

II. N. 3. a. Quality

ASM supports the use of a standardized terminology such as the Logical Observation Identifiers Names and Codes (LOINC) database to promote development of quality monitors for laboratory medicine. However, we appreciate that CMS acknowledges that there are significant functional, operational and other challenges that would need to be addressed before Medicare could begin to collect laboratory values in a comprehensive manner using common vocabulary standards. In particular, most traditional microbiology test results are reported in a narrative fashion, not using easily categorized qualitative or quantitative values. Further, narratives are often tailored to meet specific clinical needs of diverse patient population types. Therefore, the creation of common narratives to report microbiology test results would take a significant amount of time and scientific expertise. The ICD-10-PCS project more than a decade ago laid a foundation for such an endeavor, but is clearly outdated at this point. ASM stands ready to assist CMS should it decide to initiate the development of a process by which to define and categorize microbiology reporting for purposes of quality improvement.

II. N. 3. c. Other Lab Issues - Proposed Clinical Diagnostic Laboratory Date of Service (DOS) for Stored Specimens

ASM appreciates CMS's clarification of the date of service of a clinical diagnostic laboratory test that uses a stored or archived specimen on a hospital inpatient. We support CMS's proposal to use the date the specimen is obtained from storage for subsequent outpatient testing, even if the specimen is obtained less than 31 days from the date it was collected. ASM also supports that certain conditions to insure program integrity must be met which are outlined in the proposed regulation, as follows:

- The test is ordered by the patient's physician at least 14 days following the date of the patient's discharge from the hospital.
- The test could not reasonably have been ordered while the patient was hospitalized.
- The procedure performed while the beneficiary is a patient of the hospital is for purposes other than collection of the specimen needed for the test.
- The test is reasonable and medically necessary.

Again, thank you for the opportunity to provide comments on the Proposed Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007. Should you desire additional information about ASM's comments, please contact Suzy Leous in ASM's Office of Public Affairs, at 202-942-9262 or sleous@asmusa.org.

Regards,

Vickie S Baselski

Vickie S. Baselski, Ph.D., Chair
Committee on Professional Affairs
Public and Scientific Affairs Board

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

Organization : American Society for Clinical Pathology

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Please find attached ASCP's comments on the phsycian fee schedule.

EPARTMENT OF HEALTH AND HUMAN SERVICES
ENTERS FOR MEDICARE AND MEDICAID SERIVICES
FFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

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

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

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

Organization : Dr.

Category : Physician

Issue Areas/Comments

Background

Background

The proposed revisions will negatively impact the Medicare population, and will limit access to physicians who perform these treatments.

GENERAL

GENERAL

RVU's have consistenly been reduced from 2005 levels, while practice expenses continue to rise. In order to comply with CMS guidelines, our practice employes Registered Vascular Technologists to provide imaging. These highly skilled professionals are in demand, and command high salaries. The 2007 Medicare Physician Fee Schedule is already declining across the board 5%. All these cuts limit the ability of physicians to perform this important procedure and result in loss of access to care for Medicare beneficiaries.
I would requiest that the fully implemented, non-facility practice expense RVU remain at the 2006 rate for 36475 of 51.5, and that the RVU for 36478 be increased to this same level.

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

Organization : GE Healthcare

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-911-Attach-1.PDF

#901

GE Healthcare

Michael S. Becker
General Manager, Reimbursement

3000 N. Grandview Blvd., W-400
Waukesha, WI 53188

T 262-548-2088
F 262-544-3573
michael.becker@med.ge.com

October 10, 2006

The Honorable Mark McClellan, M.D., Ph.D.
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
ROOM 445-G
200 Independence Avenue, S.W.
Washington, DC 20201

ATTN: FILE CODE CMS-1506-P

Re: Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; Proposed Rule

Dear Dr. McClellan:

GE Healthcare (GEHC) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule regarding changes to the Medicare hospital outpatient prospective payment system for calendar year (CY) 2007(*Federal Register*, Vol. 71, No. 163, August 23, 2006).

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

GE Healthcare is a $15 billion unit of General Electric Company that is headquartered in the United Kingdom with expertise in medical imaging and information technologies, medical diagnostics, patient monitoring, life support systems, disease research, drug discovery and biopharmaceuticals manufacturing technologies. Worldwide, GE Healthcare employs more than 43,000 people committed to serving healthcare professionals and their patients in more than 100 countries.

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

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

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

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

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

Thank you for providing the opportunity to comment on this important issue. Should you have any questions or wish to discuss our comments further, please contact me at (262) 548-2088.

Sincerely,

Michael S. Becker
General Manager, Reimbursement

Submitter : Dr. Gary Falk

Date: 10/10/2006

Organization : American Society for Gastrointestinal Endoscopy

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-1321-P-912-Attach-1.DOC

#912

20 Kensington Rd, Suite 202
Oak Brook, IL 60523
573-0600 / FAX 630/573-0691
mail: info@asgeoffice.org
Internet: www.asge.org

October 10, 2006

Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
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:

The American Society for Gastrointestinal Endoscopy (ASGE) is pleased to submit the following comments on the above captioned rule. The more than 9,000 members of ASGE specialize in the use of endoscopy to diagnose and treat gastrointestinal diseases and conditions, such as colorectal cancer.

Reassignment and Physician Self Referral

The proposed rule would change the current policy regarding reassignment and self referral relating to diagnostic tests, such as pathology and imaging services. The preamble chiefly addresses pathology issues, particularly the so-called "Pod Lab" and the agency concludes that this business model should be outlawed. ASGE shares CMS' concern to eliminate fraudulent and abusive practices in Medicare; however, the breadth of the proposal and the lack of specific information indicting these and other arrangements suggest that further work is required before this rulemaking is finalized.

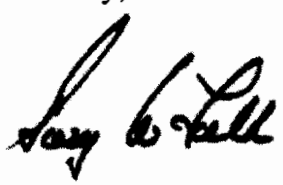
Gastroenterologists obtain many pathology specimens as biopsies or removal of potentially cancerous or pre-cancerous tissue when performing screening for colorectal cancer or when examining patients for other abnormalities such as ulcers or Barrett's esophagus. Physicians naturally want the most accurate pathology review of these samples in order to be certain of the diagnosis and recommendations for follow up. In recent years, ASGE has received many expressions of concern by members about the availability of well qualified pathologists with expertise in gastrointestinal cancers. Our members have also been frustrated by the actions of private health plans to restrict their access to the most qualified pathologists in their area of specialty. All too often, these restrictions undermine the ability of gastroenterologists to consult directly with expert pathologists examining the specimens and result in a loss of confidence in the pathology report. This can lead to repeat or additional procedures and biopsies, with attendant costs to the medical system and risk to the patient.

As a result, gastroenterologists have been exploring a variety of arrangements to assure that they have access to well qualified pathologists, with specific expertise in GI diseases. This effort is based on the physicians' wish to provide the best possible service to their patients.

As we read the proposal, some types of arrangements for expert pathology services could be curtailed or eliminated altogether. ASGE could understand this action if CMS laid out a factual case of abuse or fraud; however, such evidence is lacking. We believe that no action should be taken unless, and until, the agency can document the need for these kinds of restrictions and prohibitions. Further, the absence of this information, if the agency does have it, makes commenting on the proposed rules virtually impossible because we are unable to make any attempt to explain or refute the case that is being made against certain kinds of referral arrangements.

ASGE does not condone actions that defraud the Medicare program, and we are prepared to work with CMS to assure that our members' referral arrangements for pathology and other diagnostic services remain well within the boundaries of the law. However, the agency has not provided us with sufficient information to judge whether or not the proposed regulations are needed or are the appropriate response. Therefore, we recommend that CMS withdraw this portion of the proposed rule and collect the evidence that will support appropriate regulatory action. If such evidence is found then ASGE will work with the agency to craft rules that will prevent fraud while still allowing our members the flexibility to access the most qualified pathologists on behalf of their patients.

Sincerely,



Gary W. Falk, MD, FASGE
President

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

Organization : **Tri-State Hematology/Oncology, PSC**

Category : **Physician**

Issue Areas/Comments

Impact

Impact

Comments deal with ASP Issues:
As a physician, therapy choices & products always reflect clinical preferences, not contract terms. The CMS proposed changes to ASP calculations are concerning because any ASP based on "theoretical allocations of discounts" and not actual available market prices can only lead to the unintended but inevitable consequence of depriving physicians of the choice to use the best products for patients.

Submitter : **Ms. Sherry Salway Black** **Date: 10/10/2006**

Organization : **Ovarian Cancer National Alliance**

Category : **Consumer Group**

Issue Areas/Comments

Background

Background

See Comments in attached file. Below is proposed change information.

COMMENT TOPIC: CLINICAL DIAGNOSTIC LAB TESTS

Section II.N.3.c. Other Lab Issues--Proposed Clinical Diagnostic Laboratory Date of Service (DOS) for Stored Specimens. In this section of the Proposed Rule, CMS reviews the history of the date of service policies for clinical diagnostic laboratory services, and states: In the final rule of coverage and administrative policies for clinical diagnostic laboratory services that we published on November 23, 2001 (66 FR 58792), we adopted a policy under which the date of service for clinical diagnostic laboratory services generally is the date that the specimen is collected.

GENERAL

GENERAL

See Attachment

Impact

Impact

CMS-1321-P-914-Attach-1.DOC

#914

Comment on MMS-1321-P – Comments on the Medicare Physician Fee Schedule Proposed Rule for Calendar Year 2007

Dear Administrator McClellan:

I write on behalf of the Ovarian Cancer National Alliance (the "Alliance") to raise concerns about a recent Medicare proposal. As you may know, the Alliance leads the national movement to conquer ovarian cancer through awareness, education and advocacy. As an umbrella for over 50 local, state and national organizations, we reach more than a million people, including many of the 172,000 ovarian cancer survivors in the United States.

We just became aware of a proposal by Medicare that would affect existing policy with respect to chemoresponse tests. These tests are used principally by gynecological oncologists in the treatment of ovarian, cervical, epithelial and fallopian tube cancers. They enable oncologists to determine whether a patient's tumor is "sensitive" to, or "resistant" to, a particular chemotherapy agent before administering it to the patient.

We are focused exclusively on ovarian cancer patients. It is our understanding that these chemoresponse tests are currently used predominantly with women who experience a recurrence or multiple recurrences. While it may not as yet be standard practice to determine treatments through this method, chemoresponse tests are an option in a treatment toolkit that must be expanded. We strongly support the continued access to the widest number of effective diagnostics and treatments for ovarian cancer patients.

Because we recently became aware of the proposal by Medicare, we have been unable to fully explore the possible consequences to ovarian cancer patients who currently benefit from these tests and those who may benefit in the future. We understand that changes to Medicare payment of these tests from Part B to Part A may negatively impact the availability of these tests for Medicare beneficiaries who are ovarian cancer patients. If that is the case, this is an unacceptable consequence of this change.

Please review this proposed change with the utmost caution if it would be a detriment to ovarian cancer patients' options for treatment. If this change creates barriers to access, we ask that you reconsider your decision.

We request that you provide information to the Alliance regarding the potential impact of this change on ovarian cancer patients prior to finalizing this proposal.

Sincerely,

Submitter : Beth Wild Shiring **Date:** 10/10/2006

Organization : UPMC Cancer Centers

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-915-Attach-1.DOC

#915

UPMC Cancer Centers

October 9, 2006

The Honorable Mark A. McClellan, M.D., Ph.D.
Office of the Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn.: CMS-1321-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Dear Dr. McClellan:

UPMC Cancer Centers welcomes the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) Proposed Rule 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."

UPMC Cancer Centers encompasses 180 cancer specialists at approximately 40 hospital-based and office-based locations throughout western Pennsylvania and serves a population of more than 6 million. Treating approximately 30,000 new patients per year, UPMC Cancer Centers is one of the largest cancer care networks in the nation. Our vast network represents the full spectrum of cancer care delivery including: physicians operating sole practices in rural areas; free-standing medical and radiation oncology facilities in rural and suburban areas; and a large group of academic physicians providing hospital-based outpatient care at the flagship Hillman Cancer Center and Magee Women's Hospital in Pittsburgh.

Since our region has one of the highest concentrations of individuals age 65 and over, the age group most at risk of being diagnosed with cancer, we rely heavily on CMS to provide fair and adequate reimbursement for us to care for these patients. We commend CMS for its increased research and analysis into the costs of providing cancer care; however, we do have some concerns regarding the proposed rule that we outline below.

GPCI

We urge CMS not to implement the act that was amended with the MMA which would eliminate the floor of 1.0 for the work GPCI. Removing the floor will negatively impact our locality reducing the work RVU GPCI to 0.992, thereby dropping our GAF by 0.44%. We are a large urban medical practice whose locality is lumped in with many rural areas. This negatively impacts our local GPCI causing it to fall below comparable urban localities. We commend CMS in their willingness to work with MEDPAC and the GAO to look at alternative options for reconfiguring physician localities. While the groups are studying the options, we request that the floor continue to be maintained at 1.0.

DRA Proposals

Section 5102-Proposed Adjustments for Payments to Imagining Services

We commend CMS for reviewing the ACR data and in combination with the imagining cuts described in the DRA, proposing to maintain the multiple imaging payment reduction at its current 25 percent level. However, we urge CMS to postpone the second provision that will limit payment for the technical portion of certain imagining services to the hospital outpatient department. While we are grateful that radiation oncology services have been excluded, PET and PET/CT will incur significant reimbursement cuts. PET/CT is a relatively new diagnostic tool that continues to be adopted and approved by medical societies and physicians. It is less invasive, ensures that radiation is delivered accurately and has become a key component of comprehensive oncology care. Because these services are less invasive, they translate into better and more comfortable care that means reduced hospital stays, surgeries and complications. If the second provision is adopted, oncology patients' access to these minimally invasive diagnostic tools will be severely limited. If implemented the impact of these changes, compounded with reductions to these services in the OPD, is estimated at a reduction of $900 / scan.

ASP Issues
In CY 2005, CMS adopted the physician fee schedule the methodology of ASP+6% for drug reimbursement. There are several problems with the ASP calculation. Some issues include:

- ASP is based on the price that manufacturers charge to distributors, including any prompt pay discounts. These prices and discounts often are not passed along to providers but are included in the calculation of ASP.
- ASP is based on sales to all entities, including group purchasing organizations and large hospital systems on one end of the spectrum and one-physician oncology practices on the other. It means that many physician practices, particularly the smaller ones without purchasing power, will purchase drugs above ASP.
- There currently is a two-quarter lag in the calculation of ASP, meaning that reimbursement is based on prices that are six-months old. Since manufacturers typically raise prices two to three times per year, there is potential for physicians to suffer losses each time they administer drugs. Even as a large volume buyer, UPMC currently pays greater than ASP for many of our most highly utilized drugs and, in some cases, pay greater than ASP +6%.
- ASP also does not make allowances for the inevitable bad debt that is associated with many Medicare claims. Despite aggressive collection efforts, UPMC Cancer Centers' bad debt percent associated with Medicare claims is approximately 4.5%. This coupled with the aforementioned issues with ASP creates an unsustainable reimbursement methodology for oncology drugs.

Quality Cancer Initiative and Demonstration Project
We commend CMS for continuing the quality initiative for the management of cancer and chemotherapy-related symptoms. This is the first major pay-for-performance program implemented by CMS for cancer care and should be extended as an ongoing program. The project was reformatted in CY06 and reduced payments to our physicians by $2M over the previous year. Eliminating this program in CY 2007 will further reduce cancer care payments by $1.3M. UPMC Cancer Center is very supportive of the pay for performance initiative and we urge CMS to continue with this program or a similar one in CY 2007.

Practice Expenses
We urge CMS to work with Congress to replace the SGR formula with annual fee updates. The 5.1% decrease that is proposed for 2007 along with the elimination of the chemotherapy demonstration project will result in the severe under-reimbursement of expenses necessary to provide quality care to cancer patients. In the interim, providing relief to the SGR in 2007, will provide some relief until a more permanent solution can be devised.

UPMC Cancer Centers would like to thank you for the opportunity to offer our formal comments for your consideration. As always, we are committed to serving the senior citizen population through the Medicare program. We stand ready to work with you to improve that program so that seniors can continue to access the highest quality care.

Sincerely,

Beth Wild Shiring
Chief Operating Officer
UPMC Cancer Centers

Submitter : Dr. Gregory Reaman **Date:** 10/10/2006

Organization : Children's Oncology Group

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-916-Attach-1.PDF

#916

Children's Oncology Group

October 10, 2006

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

RE: Proton Therapy Payment Rates

Dear Dr. McClellan:

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

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

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

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

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

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

STATEMENTS OF CONCERN REGARDING FREESTANDING FACILITIES

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

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

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Fax: (301) 718-0047
greaman@childrensoncologygroup.org

Group Operations Center
440 E. Huntington Drive
Arcadia, CA 91006
Phone: (626) 447-0064
Fax: (626) 445-4334

Statistics & Data Center
Headquarters
440 E. Huntington Drive
Arcadia, CA 91006
Phone: (626) 447-0064
Fax: (626) 445-4334

Gainesville Office
104 N. Main Street
Suite 600
Gainesville, FL 32601
Phone: (352) 273-0550
Fax: (352) 392-8162

Omaha Office
984350 University of Nebraska Medical Center
Omaha, Nebraska 68198-4350
Phone: (402) 559-4112
Fax: (402) 559-7259

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

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

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

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

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

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

CONCLUSIONS

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

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

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

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

Sincerely,

Gregory H. Reaman, M.D.
Professor of Pediatrics
The George Washington University
School of Medicine and Health Sciences
Division of Hematology/Oncology
Children's National Medical Center
Chairman, Children's Oncology Group

Submitter : **Ms. Deborah Outlaw** **Date: 10/10/2006**

Organization : **Pediatrix Medical Group**

Category : **Private Industry**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1321-P-917-Attach-1.DOC

#917
The Honorable Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Blvd., CA-26-05
Baltimore, MD 21244

October 10, 2006

RE: CMS 1321-P; Medicare Program, Revisions to Payment Policies Under the Physician Fee Schedule for 2007

Dear Dr. McClellan:

Pediatrix Medical Group, Inc. appreciates the opportunity to comment on the August 22, 2006 Proposed Rule: "Revisions to Payment Policies Under the Physician Fee Schedule (PFS) for Calendar Year 2007 and Other Changes to Payment Under Part B."

Pediatrix is a national medical group of more than 870 physicians and 350 advanced nurse practitioners who provide newborn intensive, maternal-fetal, pediatric cardiology and pediatric intensive care patient services in 32 states and Puerto Rico. We are large providers of Medicaid pediatric subspecialty physician services, caring for premature and critically ill newborns, sick and injured children and women with high-risk pregnancies.

CMS indicates in this proposal that it intends to respond to comments received on its earlier June 29, 2006 notice "Five Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology" as part of the final Medicare PFS rule. Because of the significant impact that certain provisions contained in the June 29 notice may have on neonatology and other pediatric subspecialty services, we would like to take this opportunity to reiterate our primary concerns:

- Impact of the proposal on non-Medicare services: The policies adopted by CMS relative to the overall physician fee schedule and the specifics of the 5-year review clearly will have a significant impact on both Medicaid and private payers, since Medicare payment policies are frequently adopted by other third party payers. Ultimately, this draft proposal may harm the most vulnerable Medicaid beneficiaries' access to needed care.
- Budget Neutrality Adjustments for Physician Work: We urge CMS to reconsider its current proposal to make the necessary budget neutrality adjustment through using a 10% adjustment for Work RVUs, in lieu of reducing the conversion factor. We believe that the 10 percent reduction in physician work value for many pediatric services, which are generally not reimbursed by Medicare, will result in costs being shifted to more

expensive emergent care and, over time, will undermine the agency's objective of obtaining budget neutrality.

- Practice Expense Methodology: We urge CMS to delay implementation of Practice Expense changes, pending completion of a planned multispecialty physician practice survey, in order to ensure the accuracy of the data used to calculate both direct and indirect expenses.

Budget Neutrality Adjustment for Physician Work:

We urge CMS to reconsider its proposal to make necessary budget neutrality adjustments through a 10% reduction to Work RVUs. The proposed reductions in physician work reaches beyond the Medicare payment system and affects reimbursement by Medicaid and commercial payors, while having no impact on CMS' budget neutrality mandate.

The vast majority of states periodically update their rates using Medicare RVUs. Reducing physician work RVUs would create inaccurate, undervalued physician work and total RVUs that will deflate Medicaid payments further. In many communities where Medicaid rates are significantly lower than Medicare rates, an access to care problem has already emerged and some physicians no longer accept Medicaid payments or have ratcheted back their total number of Medicaid patients. There is common agreement throughout the healthcare system that limited early preventive and prenatal care may lead to far greater clinical complications, at greater overall expense to all payors, including state and federal governments.

Finally, pediatric subspecialty patients, including newborns, are almost universally not Medicare eligible. Adoption of the current Work RVU provision will result in large reimbursement reductions for pediatric subspecialty services, yet CMS will not achieve any reduction in actual expenditures related to services provided for codes 99293 through 99300.

Practice Expense Methodology Changes

CMS proposes a transition to a new practice expense methodology. For many specialties, CMS will still be using outdated methodology to calculate indirect practice expenses while moving to the new system. Mixing more recent data on total indirect practice expense for some groups is not sound Medicare policy. With practice expense accounting for 45% of total physician payments, it is essential that PE distribution be done fairly and accurately.

Physician groups initially raised these concerns with CMS last year, when the distortion of the data utilized by CMS became apparent. Over the years, supplemental surveys have been treated differently; with some supplemental data being blended with the SMS data and some replacing it. Combining different sets of data into the same

calculation methodology is inappropriate and results in different data being used for different medical specialties.

A four-year transition window, ostensibly during which errors will be uncovered and corrected, is not the right solution, and would be highly disruptive for Pediatrix day-to-day business operations and accounting. A more productive, and infinitely fairer, system for medicine would be to survey all of medicine at once, using a consistent approach. We understand that a new survey is now being developed by the AMA.

Until that occurs, however, small sub-specialty physician services such as neonatology, pediatric cardiology and pediatric hospitalist services should not be unfairly penalized through implementation of a new practice expense methodology that is at best, grossly outdated, and does not consider the myriad changes that have come about over the last decade in caring for the nation's sickest and most vulnerable infants and small children. All relevant issues related to practice expenses should be considered and vetted in a forum such as the AMA multi-specialty survey that will result in a more accurate assessment of practice expense costs associated with neonatology and other pediatric critical care services.

Criteria for National Certifying Bodies-Advanced Practice Nurses

CMS indicates that it is soliciting public comments on criteria or standards that could be used to determine whether an organization is an appropriate national certifying body for advanced practice nurses. Pediatrix' advanced practice nurses serve as integral team members working with our physicians in providing critical health care services to sick and injured infants and children.

As such, we recognize the role served by the existing credentialing bodies that are referenced in the proposed rule and listed in manual instructions, and we urge that any certification standards developed by CMS must ensure that the current listed organizations continue to serve this valuable function. In addition, we urge CMS to ensure that any new certification standards developed in the future would be closely aligned with current practices within state boards of nursing and that such new standards do not conflict or restrict current practice.

In closing, we urge CMS to work with Congress during the time remaining in this session to develop a more workable approach to reform physician payments to avert fee schedule reductions in 2007, and to issue a final PFS rule that modifies the proposed policies regarding Work and Practice Expense adjustments. Thank you for the opportunity to provide these comments, and we look forward to continuing to work with CMS on these issues.

Pediatrix Medical Group, Inc.

Submitter : **Mr. Edward Eichhorn** **Date: 10/10/2006**

Organization : **Medilink Consulting Group**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

See Attachement

CMS-1321-P-918-Attach-1.PDF

#918

October 10, 2006

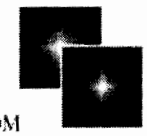
Dear Sir:

Thank you for the opportunity to provide my comments about the proposed rule changes that were announced in the Federal Register on August 22, 2006. I am most interested in commenting on the plans to invoke the anti-markup provisions and the reimbursement conditions that CMS is considering for application to radiology and medical imaging.

I own the Medilink Consulting Group; we are focused on providing strategic planning, marketing and operational consulting services to outpatient imaging centers.

For a long time, medical imaging has led the rest of healthcare in its application of Information Technology (IT) to improve access to quality care. Over the last ten years, through the use of teleradiology and Picture Archiving and Communication Systems (PACS) the diagnosis of disease has been greatly improved. These technologies allow any medical practice to supervise an imaging center or imaging service in a physician's office and have the resulting imaging studies evaluated and read by a highly qualified specialized medical reader across town or thousands of miles away. The contemplated rule change requiring that the physician or medical group billing for the interpretation or PC must have also performed the TC of the test would all but eliminate this extremely important use of technology to improve patient outcomes.

A second concern that I would like to bring to your attention relates to the anti-kickback rule expansion and the proposed changes for global billing. The proposed rule requires that an imaging center can only bill globally, if that practice provides both the technical and professional components of the imaging studies that they provide. If the professional component is provided by another group that group must bill the entire professional component. If the rule was applied as written, the physician owned or managed center that provides both the professional and technical components would have a great advantage over other providers because they would have the option to divert any part of the global fee to their operational expenses. For them it would be business as usual while



11 EAST LINDEN AVENUE • DUMONT, NJ 07628 • 201-384-6179 • ED@MEDILINKGROUP.COM

the rest of the market would have no flexibility in using their Medicare revenue to meet their obligations. The DRA of 2005 imposes great change on the most capital intensive segment of healthcare and this rule change eliminates what has become the normal market flexibility for negotiating interpretation service expenses.

It is not uncommon for a multimodality imaging center to spend as much as $14 million for a complete upgrade of all of its imaging modally systems. If an imaging center has made this large commitment in the last two to three years they would be in the middle of a very large fixed monthly payment schedule for the new equipment that they have acquired. It is likely that the financial analysis that was the basis for this investment included radiology reading contracts that were based on negotiated rates that were below the full professional component. 2007 will be a year of great adjustment for all outpatient imaging centers as they learn to do more with less while striving to maintain the quality levels that are important in this capital intensive medical service market. This reimbursement change for the PC or global component may be the difference between survival and failure of many imaging centers that have made the investment in the highest quality level of equipment available in the market over the last few years. By the same token, imaging centers that have made little or no investment in equipment replacement or upgrades over the last several years will be paid at the same rate as the high tech centers in the market. These centers will all have a much easier time coping with this large reimbursement change.

If this aspect of the proposed rule change is an important part of the CMS strategy to control medical imaging costs, I would suggest that you allow the reductions in the technical component to go into effect in January of 2007 without changing the anti-markup provision for at least the balance of 2007. This would allow for a more orderly review of the potential impact of this change on outpatient imaging centers and would minimize the potential impact on the access to imaging services for Medicare beneficiaries during this period of great change in the outpatient imaging market.

Thank you for the opportunity to comment on these important rule changes.

Ed Eichhorn
President
Medilink Consulting Group
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(201) 384-6179

Submitter : Dr. Thomas Olsen **Date:** 10/10/2006

Organization : Dermatopathology Lab of Central States

Category : Laboratory Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Submitter : Mr. Mattthew Schulze **Date:** 10/10/2006

Organization : American Society for Clinical Pathology

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Please see attached letter.

Impact

Impact

On behalf of the American Society for Clinical Pathology, I write to submit the following comments on the proposed 2007 physician fee schedule rule, published in the August 22, 2006 Federal Register notice. ASCP s comments concern the annual PFS update, flow cytometry, reassignment, date of service, independent laboratory billing, and clinical laboratory diagnostic tests.

PARTMENT OF HEALTH AND HUMAN SERVICES
NTERS FOR MEDICARE AND MEDICAID SERIVICES
FICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

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

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

Submitter : Mr. Thomas C. Fox **Date:** 10/10/2006

Organization : Reed Smith LLP

Category : Attorney/Law Firm

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-921-Attach-1.DOC

#921

ReedSmith

October 10, 2006

BY ELECTRONIC MAIL

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

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

Dear Ms. Greenberg:

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

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

to submit these written comments to the proposed changes to physician certification requirements for blood glucose testing services (the "Proposed Rule").[1]

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

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

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

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

A. Procedural History

On March 28, 2006, we filed a Complaint with supporting exhibits on behalf of a Medicare Part B beneficiary residing in a SNF (the Aggrieved Party or Beneficiary), challenging the validity of Mutual of Omaha's ("Mutual's") LCD on blood glucose testing as legal authority for denying Medicare

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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.

coverage of her blood glucose tests. The Aggrieved Party is a 72 year old individual with advanced diabetes and blindness as a result of that illness. Her condition requires blood glucose testing four times a day to maintain control over her blood glucose levels. This frequency of blood glucose testing is supported by the orders of her physician.

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

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

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

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

to continue to deny needed blood glucose testing services to Medicare Part B residents of SNFs now that the LCD has been exposed to be without any medical support, and the policies described therein invalid as a matter of law. Among the unsupported coverage policies now retired is a requirement that a physician order be obtained prior to each blood glucose test, as CMS has now proposed in the Proposed Rule. From our review of similar LCDs published by other CMS contractors, we know that this is a common basis for contractors to deny reimbursement for blood glucose testing.

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

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

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

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

Mutual's withdrawal of its blood glucose testing LCD has the same legal effect as an ALJ decision to invalidate that LCD under the reasonableness standard, pursuant to 42 C.F.R. § 426.460(b). As such, Mutual is required to reopen denied claims of the Beneficiary and adjudicate those claims, and any new claims submitted by the Beneficiary, for blood glucose testing services without using the

invalid policies reflected in the LCD, now that it is withdrawn. Any and all claims submitted to Mutual for blood glucose testing services with dates of service on or after August 11, 2006 must be adjudicated without using the invalid policies in the LCD.

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

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

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

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

Id. (emphasis added).

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

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

The Medicare statute defines an LCD as "a determination by a fiscal intermediary or carrier under part A or part B, as applicable, respecting whether or not a particular item or service is covered on an intermediary—or carrier—wide basis under such parts, in accordance with section 1862(a)(1)(A)." 42 U.S.C. § 1395ff(f)(2)(B). Simply stated, the LCD is an official statement of the contractor's policies on the coverage of specific items or services for Medicare reimbursement. It applies to claims for the

listed items or services whether the contractor proclaims it on every claim determination, or chooses not to mention it on any. It is binding on claimants until retired or otherwise invalidated. And once it is no longer valid – as was the case here – the coverage policies enunciated in that LCD can no longer be enforced by the contractor.

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

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

The restrictive coverage policies in Mutual's now-retired and invalid LCD on blood glucose testing can no longer be applied to providers and beneficiaries that Mutual services. The LCD was Mutual's attempt to reflect, in one document, its coverage limitations on blood glucose testing services. Mutual started with the broadly permissive coverage policy of the NCD on blood glucose testing. Mutual then added the restrictive coverage policy language from Transmittal AB-00-108 (*e.g.*, "prompt" notification of test results to the ordering physician). Mutual finished with its own unsupported policy interpretations of Transmittal AB-00-108 (that "prompt" means before the next test); the Medicare

Claims Processing Manual § 90.1 (which Mutual interprets to prohibit coverage of blood glucose testing for SNF residents, as opposed to coverage for beneficiaries in their own homes); and 42 C.F.R. § 410.32 (which Mutual interprets to prohibit standing physician orders for blood glucose testing). Now that the LCD is retired and invalid, all of the coverage limitations on blood glucose testing services reflected in the LCD are unenforceable by law. Any other conclusion or result would be a total perversion of justice and fraud upon the Aggrieved Party and the thousands of other Medicare beneficiaries whose claims have been or will be denied.

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

II. The Proposed Rule Is Inconsistent with Applicable Legal Authorities

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

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

In recognition of the fact that Congress provided for Medicare Part B coverage of blood glucose testing services, the Medicare regulations further describe the circumstances under which blood glucose testing is reasonable and necessary. The regulations define blood glucose testing with a device approved for home use as a "diagnostic laboratory test." 42 C.F.R. § 493.15. For Medicare beneficiaries residing in a SNF, coverage exists for diagnostic laboratory tests if they are "ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem." Id. § 410.32(a). Thus, the only requirement in the Medicare regulations for blood glucose monitoring to be reasonable and necessary is an order by the treating physician for such testing. Nothing in the Medicare regulations imposes any additional requirements, and it would be inappropriate

and inconsistent for CMS to implement a new rule – as proposed to be codified at 42 C.F.R. § 424.24(f) – that would require physician orders for each individual blood glucose test that is part of a reasonable and necessary protocol of blood glucose monitoring.

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

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

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

Specifically, the NCD states that "[f]requent home blood glucose testing by diabetic patients should be encouraged," and that "[t]he convenience of the meter or stick color method . . . has become a standard of care for control of blood glucose, even in the inpatient setting." 66 Fed. Reg. 58,846 (Nov. 23, 2001). The NCD also states that "[d]epending upon the age of the patient, type of diabetes, degree

of control, complications of diabetes, and other co-morbid conditions, more frequent testing than four times annually may be reasonable and necessary. . . . [R]epeat testing may be indicated where results are normal in patients with conditions where there is a confirmed continuing risk of glucose metabolism abnormality." Id. Taking into account the health factors of institutionalized diabetics, nowhere in the NCD are there specific limitations on the frequency of testing, and nowhere is there mention of requiring an order for each blood glucose test administered to patient with a "confirmed continuing risk of glucose metabolism abnormality." The NCD simply lists the number of maladies that may require blood glucose testing and reiterates that reasonable and necessary tests will be reimbursed. See id. at 58,846, 58,848.

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

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

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

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3 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

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

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

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

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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

disclose in detail the thinking that has animated the form of a Proposed Rule" and provide a reasoned analysis of the data. Id.

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

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

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

A. Blood Glucose Testing is a Cornerstone of Diabetes Care

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

Clinical authorities support the use of sliding scale insulin administration supported by glucose testing for nursing home residents, although prolonged use of sliding scale insulin is not recommended. See Managing Diabetes in the Long-Term Care Setting: Clinical Practice Guideline, American Medical Directors Association (AMDA) (2002), pg. 26. This approach uses a base dose of intermediate or long acting insulin, and regular insulin, supplemented by regular insulin administered by the nurse based on the patient's blood sugar and the treating physician's orders. The established best practice is for the

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

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

The medical literature clearly indicates that day-to-day control of insulin levels reduces the severity of existing consequences of diabetes, and can prevent the onset of new symptoms and complications. Diabetes is common in the nursing home setting, with over 18 percent of nursing home residents having this disease. See Managing Diabetes in the Long-Term Care Setting: Clinical Practice Guideline, American Medical Directors Association (AMDA) (2002), pg. 2. The literature demonstrates that nursing home patients have a high prevalence of cognitive and physical impairment and need help in daily activities and maintaining recommended dietary and exercise regimens. The prevalence of these impairments is higher among diabetic nursing home patients than in the nursing home population as a whole, which increases the complexity of diabetes management, and makes it unlikely that these patients can manage their diabetes on their own. See id., pg. 3. Diabetic nursing home residents are susceptible to hyperglycemia (a condition that impairs cognition, decreases pain thresholds, impairs vision,

increases the risk of infections and may increase the risk for falls) and hypoglycemia (which, untreated, can cause falls or permanent neurological impairment). See id. Nursing home residents are frequently unable to perceive or communicate hypoglycemic symptoms. See id. "Frequent monitoring of blood glucose levels is critical to avoid hypoglycemia and its consequences." Subacute Care for Seniors: Management of Elderly Diabetic Patients In the Subacute Care Setting, A. Lee, MD, Clinics In Geriatric Medicine, 16:4 (Nov. 2000), reprinted at http://home.mdconsult.com, pg. 8.

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

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

During the past decade, clinical trials have demonstrated the importance of glycemic control, as measured through regular blood glucose testing, to prevent and reduce the complications of diabetes. See The Importance of Tight Glycemic Control, J.E. Gerich, MD, The American Journal of Medicine, 118:9A (September 2005), reprinted at http://home.mdconsult.com, pg. 4. Several new therapeutic agents have become available to improve and monitor glycemic control in patients with type 2 diabetes, including less painful and continuous monitoring devices. See id. Although continuous monitoring is not at issue with respect to the Proposed Rule, the optimization of glycemic control by any means has been shown to be cost-effective. See id. Regular blood glucose testing with home use devices is less expensive in the long run than the costs of surgery and other treatments for patients who develop complications due to poor glycemic control. However, despite the advances in monitoring devices and

therapeutic agents, at least one study suggests that there has not been a corresponding improvement in glycemic control for diabetic patients. See id. The likely explanations for this include "lack of time and resources due to reimbursement considerations, for physicians to treat patients with diabetes," provide needed education, and other factors. Id.

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

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

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

Adherence to the current best practices for glucose testing is particularly important in elderly patients whose age has compromised the body's ability to maintain stability and uniformity on its own. To help elderly diabetics maintain a homeostatic state, the clinical practice model of the AMDA recommends a blood glucose test on admission, bedside glucose testing several times a day (more

frequently if the patient's glucose level is poorly controlled), daily blood glucose review, and physician alert when values fall below or above the recommended range or a range indicated in the physician's order. See Managing Diabetes in the Long-Term Care Setting: Clinical Practice Guideline, American Medical Directors Association (AMDA) (2002), pgs. 11, 27-28, 39-42. These carefully designed clinical practices are clearly "reasonable and necessary" for the ongoing diagnosis and treatment of diabetes in institutionalized beneficiaries.

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

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

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

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

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

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

that reside in SNFs. We believe that CMS has a key opportunity to improve diabetes care in this vulnerable population and firmly establish practice guidelines that can be adopted by physicians and institutional providers participating in the Medicare program. As discussed above, a series of clinical studies have demonstrated that tight control of glucose levels leads to significant decreases in the incidence of complications seen in many diabetic patients. Furthermore, the patient population in today's long-term care setting is substantially older and more medically complex than ever before, and current practices for treating diabetes in these patients must be adopted. We, therefore, urge CMS to take the logical next step by affirmatively establishing clinically-proven policies and protocols for combating diabetes in non-ambulatory residents of nursing facilities and other institutions.

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

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

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

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

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

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

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

beneficiaries, not frustrate such efforts by imposing unnecessary administrative burdens on these providers.

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

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

In general, nursing home patients have a high incidence of cognitive and physical impairment and need help in daily activities. The prevalence of these impairments is higher among diabetic nursing home patients than in the nursing home population as a whole, which increases the complexity of diabetes management, and makes it unlikely that these patients can independently manage their diabetes. Diabetic nursing home residents are susceptible to hyperglycemia and hypoglycemia, and are frequently unable to perceive or communicate hypoglycemic symptoms to their caregivers. Nevertheless, CMS would impose additional administrative requirements – unwarranted by current clinical evidence and industry practices – on nursing homes and physicians that provide such critical services to Medicare beneficiaries. Given the increased vulnerability of diabetic nursing home residents, there is simply no rational basis for making it more difficult for such individuals to receive adequate blood glucose monitoring services than for those that can perform such services at home, without assistance. In the event that a physician fails to certify an individual blood glucose test for a nursing home resident, the Proposed Rule would effectively penalize the beneficiary for obtaining the necessary supervision and care that a Medicare-certified SNF can provide. Because the Proposed Rule presents an issue of national significance that cannot, and should not, be relegated to a general "one-size-fits-all" regulatory requirement, we urge CMS to withdraw the Proposed Rule.

VII. CMS Failed to Adequately Perform the Regulatory Impact Analysis

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

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

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

By requiring physicians to certify the medical necessity of each individual blood glucose test, the Proposed Rule would effectively impose a significant information collection requirement on physicians, SNFs, and the fiscal intermediaries that process Part B claims for blood glucose testing services. First, treating physicians would be required to render prescription orders for each glucose test administered to their patients (which could be three or four additional orders per day, per patient). Second, SNF personnel would be obligated to document each additional physician order in each patient's medical record, resulting in additional paperwork and written communications between the SNF and each prescribing physician. Lastly, the fiscal intermediaries processing the resulting Part B claims would be faced with vast amounts of additional paperwork, particularly when conducting desk audits or reviews to

determine the medical necessity of each individual blood glucose test administered to a Medicare beneficiary residing in a SNF.

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

Respectfully submitted,

Thomas C. Fox
Jason M. Healy
REED SMITH LLP

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

Organization :

Category : **Nurse**

Issue Areas/Comments

Background

Background

The reduction in reimbursement will make it more difficult for certain Medicare providers to offer this service to their Medicare patients. Some physicians may have to stop performing this service and find a referral source elsewhere for their patients.

GENERAL

GENERAL

In January 2002, the FDA approved the original 810nm for endovenous laser ablation for the GSV. It was approved to be an alternative to ligation and stripping. Radiofrequency received its approval prior to that. Since then, many other wavelengths have been approved. In some instances, the SSV and superficial incompetent tributary veins associated with varicose veins and varicosities have been approved by the FDA for certain endovenous laser wavelengths.

Overall, these procedures are much easier for this age group to experience. It's a doctors office/out patient procedure. Patients are given local anesthesia only. In addition, they walk into the treatment room and walk out under their own power. Activity is encouraged and those who still work part-time or volunteer have 0-1 days off at maximum.

The cost of practice continues to increase including but not limited to supplies, salaries, rent, and premiums for malpractice insurance. In addition, most offices don't employ a full-time RVT (Registered Vascular Technologist). A physician must contract with an RVT to assist in these endovenous procedures and that adds to the overhead. RVT's are in short supply at this time so the premium that is asked for is higher than when RVT's were more plentiful. Since ultrasound in included in the CPT coding for the endovenous procedures instead of added to, it drives the bottom line of reimbursement down that much further.

The office based procedure cuts out the hospital/facility fees and anesthesia costs often associated with stripping and ligation. It also keeps the patient active immediately as opposed to several weeks of "down-time" which cuts down on many other health risks and complications. The advantages of local anesthesia as opposed to general anesthesia are obvious. The Medicare patients already pay for their compression stockings as per Medicare policy. The office based procedure is of benefit for Medicare as to what they reimburse the providers as opposed to the hospital. There is great benefit to the patient also. I find it difficult with the saving already gained that there would be consideration to decrease reimbursement further.

I ask, based on these simple observations of our practice that you make both radiofrequency and laser equal in reimbursement to the highest level that it's been paid since it's FDA approval status. I appreciate your time in reviewing my comments.

Thank you

Impact

Impact

See General Comments.

Provisions of the Proposed Rule

Provisions of the Proposed Rule

See General Comments.

Submitter :

Date: 10/10/2006

Organization :

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-923-Attach-1.DOC

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

Re: CMS-1321-P

I am 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). I am a pathologist practicing in San Antonio, Texas, and perform a variety of services that are reimbursed under the physician fee schedule. Thus, I will be significantly affected by the changes in the Proposed Rule. My 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. The opinions expressed are my individual opinions.

I. REASSIGNMENT AND PHYSICIAN SELF-REFERRAL

It is prudent and important that CMS is taking action designed to curb the growth of so-called "pod" or condo laboratories. These arrangements give referring physicians the opportunity to earn revenues based on their own referrals for services performed by other physicians, and essentially engage in fee splitting and self-referral. CMS is appropriate in taking the measures to curb the abuse these arrangements allow in its revision to the reassignment rules and the Stark self-referral laws. In order to have maximum effect in addressing the pod issue, CMS must implement the independent contractor reassignment revisions that pertain to the technical and professional components of anatomic pathology, and measures that would limit the use of part-time employee pathologists in such arrangements.

CMS is wise to recognize the two different 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. For the most part, I am supportive of the changes that CMS is making, but wish to offer additional helpful proposals to clarify or more closely define the requirements set out by CMS, as well as to address the issue of part-time employees.

Changes to the Reassignment Rule

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

- Clarify that physicians acting pursuant to the contractual arrangement exception must still meet the requirements applicable to the purchase of

diagnostic testing, with regard to the professional component, and I **support** applying the current purchased-services limitations in situations of reassignment.

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

I believe **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.

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. TSP 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. TSP 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

I am gravely 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. The end result is what is occurring today. So I have the firm opinion that it is essential CMS address both structures in its rulemaking.

I understand some groups may decide to hire their own pathologist, which is their prerogative. However, they should be required to make the same investment in compensation and capital that any other business would have to make in that endeavor and undertake the same type of business risk. Medical practices should not be able to simply change a pathologist from an "independent contractor" pathologist to a "part-time employee" pathologist, without incurring the additional costs and risk attendant to hiring that person. If there is no limitation on this practice, groups will simply take advantage of new ambiguities and restructure without any risk and continue to profit from their own self-referrals. 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.

The "substantially all" requirements for group practices under Stark is an available remedy to the situation and I support the proposed regulatory changes. 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 unless additional ancillary services such as radiology services begin to be abused as well. Another alternative at the disposal of CMS in the same provision of Stark is to establish a maximum number of group practices to which any one pathologist could belong. I have no issue with this concept. 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. I believe that such a provision would limit restructuring that might be anticipated in response to the proposed changes in the contractor reassignment rules.

DEFINITION OF SAME BUILDING AND CENTRALIZED BUILDING

The issue of the DHS service being furnished in the "same building" or "centralized building" needs to be more strictly defined to help prevent abuse. I do support the proposal of a minimum space requirement for a number of reasons including safety, and actually suggest a larger area such as 350 square feet be considered. However, I do believe a defined geographical boundary is needed to curb the abuse of the pod labs. I am not sure a state border is the best definition to use since there is the potential for practices in communities close to state lines to serve patients in more than one state. As such these situations should not be penalized because of their proximity to a state border if the practices are compliant with all other regulations and laws. A mileage radius, population statistical defined area, Metropolitan Statistical Area, or some other identifiable definition should be considered. What is abusive of the in office exception is when a medical practice establishes their "in office" facility hundreds of miles from the true clinical practice. In San Antonio, Texas there are "in office" laboratories for practices based in Lubbock, Texas (over 400 miles from San Antonio), the Rio Grande Valley (over 250 miles away), Waco, Texas (175 miles away), and others all several hundred miles from the "in office" facility. By using a more restrictive definition of the location of the centralized building the spirit of the Medicare regulations is less likely to be abused. Restricting the location of a pod lab to the locality to where the group has a patient clinic is appropriate.

INDEPENDENT LAB BILLING

In the Proposed Rule, CMS states, "We continue to believe, however, that hospital prospective payment amounts already compensate hospitals for the TC of physician pathology tests and that additional payment under the PFS is inappropriate." *Id.* Therefore, CMS is proposing to amend § 415.130 to provide

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

*I believe 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." I believe the intent was to state, "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." I implore CMS to correct this language if this concept is to appear in the final rule.

Given this major change to these historical billing rules, I 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:

I wish to thank you for the opportunity to comment on the proposed regulations. The comments made submitted reflect my personal opinion.

Sincerely,

William W. Hinchey, MD
601 Canterbury Hill
San Antonio, Texas

Submitter : Mr. Bruce McMaken **Date:** 10/10/2006

Organization : University of Texas, MD Anderson Cancer Center

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-924-Attach-1.PDF

#924

THE UNIVERSITY OF TEXAS
MD ANDERSON
CANCER CENTER
PROTON THERAPY CENTER

October 10, 2006

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

RE: Proton Therapy Payment Rates

Dear Dr. McClellan:

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

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

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

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

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

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

2. STATEMENTS OF CONCERN REGARDING RATES FOR FREESTANDING FACILITIES

For freestanding (non hospital-based) proton therapy centers, the CMS has given its contracted carriers significant latitude but limited guidance from which to determine payment rates for proton therapy.

We remain concerned with the manner in which contracted carriers have dealt with rates for freestanding proton therapy centers in the states of Texas, Florida and Indiana. The existing or proposed proton therapy payment rates by state are as follows:

Comparison of Freestanding Centers' Proton Therapy Rates by State			
CPT	**Indiana – Current**	**Florida – Proposed 9/11/06**	**Texas – 9/1/06**
77520	-	$750.63	$652.75
77522	$516.36	$776.90	$653.90
77523	$782.43	$806.93	$783.79
77525	$782.43	$900.76	$954.41

As each state has its own CMS-contracted carrier, variations in existing CY'06 and proposed CY'07 proton therapy coverage and payment rates are occurring. Further, these carrier-determined rates are significantly less than under CMS's own National Payment Policy for protons as expressed in the OPPS rules.

Curtailing the development of freestanding proton beam therapy centers through inadequate payment rates may have the negative long-term effect of precluding future cost reductions provided by proton beam therapy and denying this important therapy to patients.

We are requesting that CMS direct its carriers regarding proton therapy rates for freestanding centers so that the rates are consistent with that of the CMS for hospital-based providers under the OPPS rules.

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

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

3. CONCLUSIONS

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

We strongly agree with CMS's proposed CY'07 payment rule for proton beam therapy for hospital outpatient departments.

We strongly urge CMS to direct its carriers regarding proton therapy payment rates for freestanding facilities so that these rates are consistent with national payment policy decisions currently in effect for hospital-based facilities.

Very truly yours,

Bruce R. McMaken
Managing Director

Submitter : Mr. Charles Lock **Date:** 10/10/2006

Organization : Sutherland Cardiology Clinic

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-925-Attach-1.DOC

CMS-1321-P-925-Attach-2.DOC

#925-1
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
Mail Stop: C4-26-06
7500 Security Boulevard
Baltimore, MD 21244-1850

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

Dear Dr. McClellan:

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

Payment Method

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

adequate solution will take time and, therefore, request that CMS set the 2007 relative value units for the three codes listed based on the 2006 values.

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

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

In our response to CMS' Proposed Changes to the Practice Expense Methodology (Federal Register, June 29, 2006) we outlined our concerns with the proposed changes to the PE Methodology, i.e., use of a bottom-up methodology and the elimination of the non-physician work pool. The proposed payment rates resulting from the use of the practice expense RVUs for the left heart catheterization procedure alone (CPT code 93510 TC) reduce payment levels in 2007 by 16 percent, and by 2010 make overall reductions of 53 percent. The flaws in the methodology, particularly as they relate to the cardiac catheterization procedure codes were described in general in our comment letter of August 21, 2006, and more specifically in the August 22, 2006 comment letter submitted by COCA.

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

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

The need to develop unique standards for each type of diagnostic testing facility provider is consistent with the observation that CMS made in the Proposed Rule regarding the practice expense for different types of remote cardiac monitoring and anticoagulation monitoring. Similar to CMS's observation that these types of IDTFs are different, we believe that cardiac catheterization centers are unique and that their cost structure and

quality standards are similar regardless of whether they are performed in a cardiology practice or an independent outpatient center. The COCA cost study shows that the cost profile of outpatient cardiac centers is quite different from the average profile of all IDTFs. We believe the COCA cost analysis will be helpful to CMS as it begins to develop standards, specifically for cardiac outpatient centers because the data can be used to estimate the impact that each standard has on practice expenses. The cost study will also be helpful as CMS works to develop a practice expense RVU for cardiac catheterization procedures that reflect the resources needed to perform the service.

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

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

Sincerely,

J. Charles Lock, MSA
Executive Director
Sutherland Cardiology Clinic

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#925-2
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
Mail Stop: C4-26-06
7500 Security Boulevard
Baltimore, MD 21244-1850

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

Dear Dr. McClellan:

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

Payment Method

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

adequate solution will take time and, therefore, request that CMS set the 2007 relative value units for the three codes listed based on the 2006 values.

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

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

In our response to CMS' Proposed Changes to the Practice Expense Methodology (Federal Register, June 29, 2006) we outlined our concerns with the proposed changes to the PE Methodology, i.e., use of a bottom-up methodology and the elimination of the non-physician work pool. The proposed payment rates resulting from the use of the practice expense RVUs for the left heart catheterization procedure alone (CPT code 93510 TC) reduce payment levels in 2007 by 16 percent, and by 2010 make overall reductions of 53 percent. The flaws in the methodology, particularly as they relate to the cardiac catheterization procedure codes were described in general in our comment letter of August 21, 2006, and more specifically in the August 22, 2006 comment letter submitted by COCA.

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

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

The need to develop unique standards for each type of diagnostic testing facility provider is consistent with the observation that CMS made in the Proposed Rule regarding the practice expense for different types of remote cardiac monitoring and anticoagulation monitoring. Similar to CMS's observation that these types of IDTFs are different, we believe that cardiac catheterization centers are unique and that their cost structure and

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

Organization : American Society for Clinical Pathology

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

This web site doesn't work properly. I'm trying to attach several files to submit my comments and this does not seem to be working. If three files are not attached than my efforts to use this website failed. I can be reached at (202) 347-4450 for any missing information.

Matt Schulze
ASCP

CMS-1321-P-926-Attach-1.PDF

CMS-1321-P-926-Attach-2.PDF

CMS-1321-P-926-Attach-3.PDF

#926-1

THE AMERICAN SOCIETY FOR CLINICAL PATHOLOGY
POLICY STATEMENT

FEE SPLITTING, MARKUPS AND RELATED PRACTICES
(04-03)

YEAR INITIALLY APPROVED: 2004 DATE LAST REAFFIRMED: N/A DATE OF NEXT REVIEW: 02/07

POLICY STATEMENT:

ASCP is opposed to fee splitting, mark-ups, and related billing practices, as these practices adversely affect patient health and safety. The Society supports initiatives, such as direct billing, anti-markup, and patient notification provisions, to eliminate or reduce the likelihood of these inappropriate billing practices.

BACKGROUND AND RATIONALE:

I. Introduction

Fee splitting and markups for clinical laboratory services are a growing problem for patients, clinical laboratories and pathologists. These billing arrangements involve a practice whereby the clinician requires the clinical laboratory and/or the pathologist to share a portion of the reimbursement received for the performance of analytical or professional services. These practices distort rational medical decisions and lead to the overutilization of certain health care services. These practices are illegal under Medicare and Medicaid and have been declared unethical by the American Medical Association.

Because the practice of laboratory medicine is highly dependent on patient referrals, clinicians are in a unique position to control the flow of business to clinical laboratories. As such, clinical laboratories and pathologists have little power to prevent fee splitting, markups and similar practices by the clinician.

Fee splitting, markups and related practices cause a host of problems, such as inflating the cost of laboratory services for patients, federal and state governments, and other payers as well as undermining patient trust in the medical profession. These practices can also adversely affect clinical laboratories and patient welfare. Patients most likely to be affected by this inappropriate practice are uninsured individuals and those covered by a private third party payer.

These practices can have a number of different permutations. In a nutshell, these involve clinicians or other health care providers referring patient specimens to clinical laboratories or pathologists for analysis on the basis of an understanding that the referring practitioner or healthcare practice receives a financial or other benefit for referring patient specimens. This can involve a practice where the clinician bills for the services provided by the clinical laboratory or pathologist and forwards a portion of the overall reimbursement to the laboratory or pathologist.

Among the policy options to address these practices are direct billing, anti-markup and patient notification requirements. Direct billing requires the laboratory to bill for the patient's testing services. Anti-markup provisions would allow the clinician to bill the patient for testing services but would prohibit the physician from charging the patient more for the laboratory services than the laboratory billed the physician. Patient notification requirements would mandate than when physicians bill patients for testing services that they also inform the patient how much the physician was billed by the laboratory for the testing services.

II. Fee Splitting Results in Overutilization of Laboratory Services

Fee splitting, markups and related billing practices distort rational medical decisions as a result of an economic incentive to overutilize testing services. An incentive to overutilize laboratory services exists when the referring physician is in a position to be compensated for work performed by the clinical laboratory or pathologist.

This incentive is similar to the incentives prohibited by the first Stark anti-referral law, which bars clinicians from referring patient specimens to laboratories in which they had a financial interest. Studies by the U.S. Department of Health and Human Services (HHS) and other government agencies have shown that referrals to entities in which physicians have a financial relationship encourage excessive use of services.[1] An HHS Inspector General study found that physicians with a financial interest in the clinical laboratories to which they "referred Medicare patients [ordered] 45 percent more laboratory services than did physicians who did not have such financial interests."[2] In addition, the Center for Health Policy Studies found that laboratory charges per enrollee under private health insurance programs were 41 percent higher in non-direct billing states.[3] This study also found that laboratory test utilization is higher in non-direct billing states.

Fee splitting and markups also increase the potential for harm to patients that result from unnecessary testing and treatments.[4] Moreover, the practice harms patients by unnecessarily raising the costs of health care (particularly for the uninsured) and undermines patient trust in the medical profession.[5]

III. These Billing Practices Violate Federal and Some State Laws

With few exceptions, fee splitting and markups violate Medicare and Medicaid anti-kickback and federal self-referral laws. Federal anti-kickback laws prohibit payment, receipt, offering, or solicitation of remuneration in exchange for the referral of services of items covered by Medicare or Medicaid.[6] Besides prohibiting clinicians from engaging in these practices, federal anti-

kickback laws would also appear to apply to pathologists who participate in such practices. Enforcement of the anti-kickback law requires proof of "knowing" and "willful" illegal remuneration, such as bribes or rebates, for patient referrals, and it can result in criminal sanctions.

Federal self-referral laws prohibit physicians from referring Medicare patients for certain health care services, such as laboratory tests, to entities with which the physician or their immediate family members has a financial relationship. Moreover, numerous states, such as Louisiana, California, New York, New Jersey, and Nevada have banned the practice of fee splitting by requiring that clinical laboratories directly bill the patient for services performed.[7,8]

IV. Ethical Implications of Fee Splitting and other Similar Practices

The American Medical Association (AMA) Council on Ethical and Judicial Affairs (CEJA) outlines the AMA's strong opposition to fee splitting, markups and similar practices regarding clinician compensation for services performed by clinical laboratories and/or pathologists. The following opinions are published in the AMA Code of Medical Ethics.

In Opinion E-6.02, CEJA states "[p]ayment by or to a physician solely for the referral of a patient is fee splitting and is unethical." CEJA has also explained that if anatomic pathology services are provided at a discount, the purchasing physician should not charge a markup.

AMA Opinion E-8.09(2) states, "[a] physician should not charge a markup, commission, or profit on the services rendered by others." This opinion describes a markup as "an excessive charge that exploits patients if it is nothing more than a tacked on amount for a service already provided and accounted for by the laboratory." The opinion does allow the clinician to bill "an acquisition charge or processing charge" but that the "patient should be notified of any such charge in advance." Moreover, this opinions states that a "physician who disregards quality as the primary criterion or who chooses a laboratory solely because it provides low-cost laboratory services on which the patient is charged a profit, is not acting in the best interests of the patient."

Additionally, CEJA favors direct billing of laboratory services in opinion E-6.09. This opinion states that "[w]hen it is not possible for the laboratory bill to be sent directly to the patient, the referring physician's bill to the patient should indicate the actual charges for laboratory services, including the name of the laboratory, as well as any separate charges for the physician's own professional services."

Opinion E-8.03 elaborates that "[i]n general, physicians should not refer patients to a health care facility outside their office at which they do not directly provide services and in which they have a financial interest."

It should be noted that CEJA has also addressed the practice of clinical laboratories engaging in fee splitting by compensating physicians for their referrals. In opinion E-6.03, CEJA states "clinics, laboratories, hospitals, or other health care facilities that compensate physicians for referral of patients are engaged in fee splitting which is unethical."

V. Economic Harm to Clinical Laboratories

Over the past two decades federal and state reimbursements (Medicare and Medicaid) for laboratory services have declined significantly. Repeated erosions to the caps for laboratory fee schedule (known as the national limitation amounts) have declined 36 percent. Moreover, for almost 15 years now the annual adjustments for laboratory reimbursements haven't kept pace with inflation. In fact, the lack of a reliable annual update has further eroded laboratory reimbursements by over 20 percent. At the same time, the cost of providing laboratory services has increased steadily, making it very difficult for clinical laboratories to provide state-of-the-art diagnostic facilities. This inability to keep pace with the high costs of laboratory services is affectively undermining the ability of clinical laboratories to provide "accessible, efficient, and high quality testing."[9] Fee splitting, markups and other similar practices are compounding the financial difficulties facing clinical laboratories today. The practice may force laboratories to reduce testing services and could force some laboratories to close, thereby reducing patient access to care.[10] This could be particularly problematic for patients in rural and underserved areas.

REFERENCES:

[1] Hearing on Physician Self-Referral Regulations. Hearing before the Committee on Ways and Means Subcommittee on Health, U.S. House of Representatives. Testimony of Kathy Buto, Deputy Director, HCFA Center for Health Plans and Providers, U.S. Department of Health and Human Services. May 13, 1999.

[2] Financial Arrangements Between Physicians and Health Care Businesses: Report to Congress. U.S. Health and Human Services Department Office of the Inspector General Office of Analysis and Inspections. May 1989.

[3] Dyckman, Z. Impact of Direct Billing Requirements For Laboratory Tests on Laboratory Charges, Utilization and Costs. Center for Health Policy Studies. March 1993. p. 15.

[4] Hearing on Physician Self-Referral Regulations. Hearing before the Committee on Ways and Means Subcommittee on Health, U.S. House of Representatives. Testimony of Kathy Buto, Deputy Director, HCFA Center for Health Plans and Providers, U.S. Department of Health and Human Services. May 13, 1999.

[5] Financial Arrangements Between Physicians and Health Care Businesses: Report to Congress. U.S. Health and Human Services Department Office of the Inspector General Office of Analysis and Inspections. May 1989. p. 3

[6] Financial Arrangements Between Physicians and Health Care Businesses: Report to Congress. U.S. Health and Human Services Department Office of the Inspector General Office of Analysis and Inspections. May 1989. P. 4.

[7] Wood, JP. Discounted Account Billing and Markups. American Pathology Review. Winter 2003. p. 2.

[8] Financial Arrangements Between Physicians and Health Care Businesses: Report to Congress. U.S. Health and Human Services Department Office of the Inspector General Office of Analysis and Inspections. May 1989. P. 4.

[9] Statement of the American Clinical Laboratory Association. U.S. House Ways and Means Subcommittee on Health. April 20, 1993. p. 3.

[10] Statement of the American Clinical Laboratory Association. U.S. House Ways and Means Subcommittee on Health. April 20, 1993. p. 2.

THE WALL STREET JOURNAL. ONLINE

September 30, 2005

PAGE ONE

Lucrative Operation

How Some Doctors Turn a $79 Profit From a $30 Test

Physician Groups Add Markup To Work Done by Others, Despite Ethics Concerns

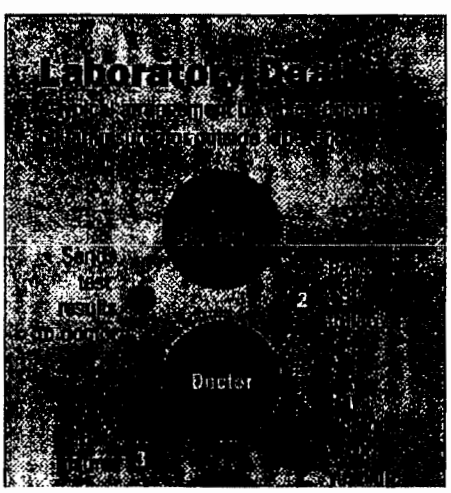
Administrative Costs Cited

By DAVID ARMSTRONG
Staff Reporter of THE WALL STREET JOURNAL
September 30, 2005; Page A1

After her mother was diagnosed with skin cancer, Lori Hansen went to a local dermatologist in North Carolina to have her skin tested. When she got the results -- with a worrisome mention of "atypical" levels -- she was surprised to learn her doctor had sent the samples across the country to California.

Even more surprising: Her doctor stood to make nearly $200 on the test, she says. Ms. Hansen later learned her skin biopsies weren't abnormal. Also, the California testing center's owner had once directed a lab that the state called a threat to public health.

Arrangements such as the one between Ms. Hansen's North Carolina doctor and the California operation -- sometimes called referral deals -- are common in the more than $40 billion medical laboratory business.



It works like this: A doctor sends a patient sample to an outside lab for testing. The lab charges the doctor a discounted price -- say, $30 for a skin biopsy. The doctor then gets reimbursed by the patient's insurer for a much higher amount, say $100. The difference, $70, is profit for the doctor.

Typically the doctor doesn't tell the insurer that an outside lab did the work for a steep discount. Insurers could put a stop to the practice by refusing to pay the inflated reimbursement, but they are often unaware of the arrangements.

Critics say referral deals are harmful because doctors have an incentive to send work to the cheapest lab, not necessarily the best one, to maximize their profit margins. Also, by enticing doctors to order many tests, the arrangements drive up the nation's health-care bill.

"Patients should wonder if this dermatologist is doing this biopsy because I need it or he is going to make money from it," says Lisa Lerner, a Boston-area dermatopathologist.

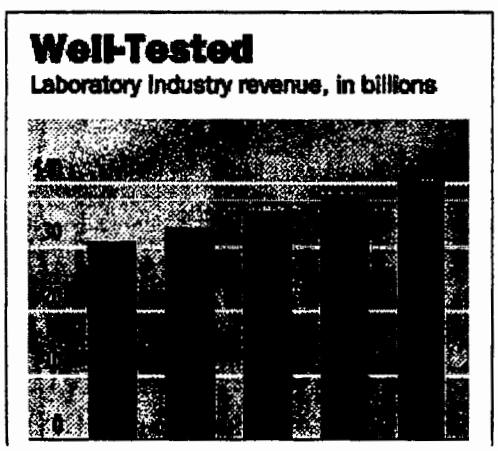
While referral deals aren't new, people in the industry say they have grown rapidly in recent years as doctors seek new sources of income and demand grows for expensive lab work to detect diseases such as prostate cancer. "Five years ago, no one was interested in this," says Bernie Ness, the owner of a laboratory industry consulting firm in Toledo, Ohio. "That has changed dramatically. I get calls every week from people who want to get in on the billing."

One of the few private insurers to block doctors from profiting on outside lab work is Blue Cross Blue Shield of Georgia. Starting Aug. 1, it required those performing lab tests to do the billing themselves, a practice known as direct billing. That eliminated deals where doctors bill for work they didn't perform. It isn't clear why other insurers don't do the same. Several of the biggest ones declined to comment.

Medicare requires direct billing, as do a few states. In some other states, doctors and local medical societies upset at the prospect of losing revenue have thwarted such legislation. Some doctors still bill Medicare for lab work performed off-site by owning "condo" labs within a larger facility.

The American Medical Association's code of ethics says under the heading of laboratory services that a "physician should not charge a markup, commission, or profit on the services rendered by others." It adds, however, that doctors can levy a processing charge on such services. The AMA code says that a doctor "who chooses a laboratory solely because it provides low-cost laboratory services on which the patient is charged a profit is not acting in the best interest of the patient."

Federal laws broadly prohibit doctors from receiving inducements for referrals or engaging in "self-dealing" -- referring patients for services in which they have a financial interest. Doctors and companies involved in lab referrals say what they do is legal. Companies say they're just offering a service for a price, and that doesn't add up to illegal inducement. In general doctors don't own a stake in the outside labs, which they say clears them of any charge of self-dealing. They say they're entitled to mark up work farmed out to a contractor to cover costs such as billing for the work and delivering results to patients.



Last year, the U.S. attorney in Oklahoma City indicted three former executives of a lab, UroCor Inc. The indictment says UroCor charged discount prices to doctors who turned around and billed private insurance companies at a much higher rate for the lab work. Doctors were charged as little as $2.75 for a common analysis to detect prostate cancer, called the PSA test, and got reimbursement of $25 and up, the indictment says. It says the discount was a kickback to induce the doctors to also refer work covered by Medicare, which was billed directly by the lab.

The study's author, economist Zachary Dyckman, says he would expect the same results today. The extra testing, he says, "appears to be done exclusively to earn more revenue and increase profits."

Ms. Hansen, the North Carolinian who was worried about skin cancer, had her skin biopsies analyzed by National Dermatopathology Laboratory of Lake Balboa, Calif. Ms. Hansen, of Cary, N.C., says she asked a local pathologist, Keith Nance, to review her biopsies after hearing that they were "atypical." Dr. Nance found no abnormalities.

Dr. Nance, who considers client billing unethical and pushed an unsuccessful effort to ban the practice in North Carolina, urged her to report the situation to the state medical board and helped write a complaint. He helped her find out how much the California lab was charging doctors by contacting the lab and pretending to be a potential customer.

In her October 2003 complaint to the medical board, Ms. Hansen cites an email in which National Dermatopathology quoted Dr. Nance a rate of $35 to analyze a biopsy. Ms. Hansen, who had four biopsies analyzed, says in the complaint that the lab must have charged her dermatologist, William Ketcham, no more than $140 for her lab work. Insurance records show Dr. Ketcham was paid $328 for the work by her insurance company.

Dr. Ketcham declined to discuss dollar figures but says his deals with labs are appropriate and don't cost patients anything. He says paperwork is easier when he doesn't have to exchange patient information with the lab. The North Carolina Medical Society has said that "markups are a legitimate business practice" for lab services.

Dr. Ketcham says he has stopped using National Dermatopathology because the state medical board told him he must send his biopsies to pathologists licensed by North Carolina. The board took no disciplinary action against Dr. Ketcham. He now sends his lab work to Dermatopathology Laboratory of Central States in Dayton, Ohio.

Central States won't say what it charges doctors for lab work. But a 2003 fee schedule from the lab states that doctors were charged $25 for the first biopsy and $15 for each additional specimen. The same fee schedule indicates that when Central States billed insurers directly for biopsy interpretations it charged a rate of $95.

The owner of National Dermatopathology Laboratory, Cyrus Milani, was banned from performing certain laboratory work by the state of California in 1989 after state officials accused a lab he directed of operating "in a manner which poses a threat of injury to public health." The state said the lab had an error rate of 21.2%.

Dr. Milani says the charges were "totally false." He acknowledged a settlement barred him from serving as medical director of any lab conducting pap smear tests "for a year or two." California authorities couldn't find a copy of the settlement.

For several years after the ban, Dr. Milani says he had "a very meager income." Even now, he says, his life is one of "simple living." Los Angeles County real-estate records show him as the owner of a home assessed at $4.1 million on the same street in Bel Air where the actress Elizabeth Taylor lives.

According to a court filing, the pathologist who analyzed Ms. Hansen's biopsies was Hong Li,

who worked at National Dermatopathology between July and December 2003. Dr. Milani is suing Dr. Li, accusing her of breaking a one-year employment contract. In the court filing, Dr. Li says her daily volume "far exceeded the generally accepted workload" in her specialty and "directly affected the quality of patient care." She says she quit from fatigue. Dr. Milani says Dr. Li's allegations are false.

Getting Around Medicare Ban

Although Medicare refuses to pay doctors for work performed by others, some companies have figured out a way to let doctors bill Medicare for off-site lab work. It involves doctor groups creating a "condo" or "pod" lab within a building that also houses labs for many other practices. Since the doctors own their "condo" lab, they believe they can bill Medicare for work performed there.

One such facility is operated by Uropath LLC at a medical office building in San Antonio. The door of the building lists the names of 15 urology practices from as far away as Missouri. Inside, there is a long hallway with a series of doors that open into small rooms with labels such as "Lab F -- Urologic Associates of South Texas." Technicians and pathologists in white lab coats move in and out of the small rooms conducting tests.

Each doctor group buys the microscope and other supplies used in its lab. Uropath is paid a management fee by the doctor groups and is reimbursed for rent, personnel costs and other expenses. The doctor groups pay pathologists for their work on a per-case basis. The doctor group does all of the insurance billing, including for patients on Medicare.

The inspector general for the U.S. Department of Health and Human Services evaluated a somewhat different condo arrangement last December. In that case, the lab company provided the pathologists and equipment while receiving a monthly management fee from the referring doctors, who did the billing and kept any profit. The inspector general said the deal could constitute a violation of antikickback laws since the lab company was giving the doctors an opportunity for near-certain profits in exchange for the business.

A lawyer for Uropath, Greg Cardenas, says the company has carefully constructed its dealings with doctor groups to comply with federal laws including the antikickback law.

Another company offering doctors a chance to profit from lab work for both Medicare and privately insured patients is PathOptions of Hollywood, Fla. It solicited business from Edward Coles, a gastroenterologist in New Braunfels, Texas, saying he could bill insurance companies for four times what tests cost him. A financial "snapshot" attached to the letter claimed Dr. Coles could boost revenue for his small practice by a quarter million dollars. Dr. Coles says the proposal "didn't sound kosher" and he declined to participate.

But dozens of other doctors have signed up with PathOptions, says company co-founder Daniel Karten. Mr. Karten says lawyers have reviewed the company's model to make sure it is legal.

Getting a cut of lab revenue is attractive to gastroenterologists, who specialize in stomach and intestinal diseases. One of their cash cows used to be endoscopy, in which the doctor puts a tube down the patient's throat to examine the digestive tract, but Medicare reimbursement for that procedure fell more than 50% in the five-year period ended in 2002, according to a government study.

At an April 2004 seminar in Knoxville, Tenn., sponsored by the American Society for Gastrointestinal Endoscopy, gastroenterologist Bergein Overholt began with a review of reimbursement cuts before dangling some big numbers in front of the audience.

Dr. Overholt showed how his practice of 12 doctors, Gastrointestinal Associates in Knoxville, netted $643,000 by sending its lab work to GI Pathology Partners in Memphis, Tenn. According to information presented at the seminar, Dr. Overholt's group paid $52.55 to GI Pathology Partners for each biopsy the lab examined and then billed insurance companies an average of $94.55 for the work.

Dr. Overholt has presented the material at similar seminars, including some underwritten by GI Pathology Partners. He says he typically receives a $1,000 honorarium for such talks. Dr. Overholt was among those who fought a bill in Tennessee last year to ban client billing. The legislature eventually approved a watered-down measure.

In an interview, Dr. Overholt says the $643,000 figure he cited at the 2004 meeting doesn't include "significant administrative" costs in billing patients and losses from patients who don't pay. He says the profit to his practice from billing on lab work is about 10% to 20%.

GI Pathology Partners says it does work for doctors in 14 states. Pat Dean, a pathologist and lab co-founder, says his company has a "business model of focused, factory efficiency," which along with client billing has "been a real boon for us."

Some doctors who send lab work to Dr. Dean, however, eschew client billing.

"We are a little old-fashioned," says one of them, Michael Freeman of Cape Girardeau, Mo. "It's one of those ethical things. Pat is doing the work. We just assume that Pat does the billing."

Write to David Armstrong at david.armstrong@wsj.com[1]

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October 10, 2006

Mark B. McClellan, MD, PhD
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1321-P
P.O. Box 8015
7500 Security Boulevard
Baltimore, MD 21244-8015

Dear Dr. McClellan:

On behalf of the American Society for Clinical Pathology, I write to submit the following comments on the proposed 2007 physician fee schedule rule, published in the August 22, 2006 *Federal Register* notice. ASCP's comments concern the annual PFS update, flow cytometry, reassignment, date of service, independent laboratory billing, and clinical laboratory diagnostic tests.

The ASCP is a nonprofit medical specialty society representing 140,000 members, including board certified pathologists, other physicians, clinical scientists, medical technologists and technicians. It is the world's largest organization representing pathology and laboratory medicine. As the leading provider of continuing education for pathologists and medical laboratory personnel, the ASCP enhances the quality of the profession through comprehensive educational programs and publications and self-assessment materials.

Physician Fee Schedule Annual Update (Sustainable Growth Rate)
ASCP is very concerned about the Centers for Medicare and Medicaid Services (CMS) projected 5.1 percent negative update to the physician fee schedule. ASCP believes that it is imperative that Congress and the Administration work together to address the flawed sustainable growth rate formula under Medicare. If the projected negative update is imposed on the physician fee schedule, reimbursement under the physician fee schedule will be about the same as it was in 2001. The negative update, combined with the 5 percent reduction in pathologist practice expenses means pathologists could see a 10 percent reduction in Medicare reimbursement rates in 2007, assuming Congress does not act to stop the negative 5.1 update from being applied next year, will reduce reimbursement for pathologists by 10 percent next year. These annual negative updates, brought about by the flawed sustainable growth rate, are having a negative impact on the practice of pathology and laboratory medicine and requires urgent attention.

Current estimates indicate that if the anticipated negative updates were applied to the physician fee schedule, reimbursement would be reduced by approximately 37 percent by 2015, yet physician practice costs are expected to increase by approximately 20 percent. Negative updates are already having a detrimental effect on the practice of pathology and laboratory medicine. These projected negative updates signal an impending crisis. Further cuts in physician reimbursement jeopardize patient access to care, create physician shortages and limit patient access to advancements in medical technology.

Resource-Based Practice Expense RVU Proposal for Flow Cytometry
ASCP supports CMS's proposal to revise the direct practice expense inputs for flow cytometry CPT codes 88184 and 88185, per supplemental data submitted by the American Clinical Laboratory Association. ASCP believes these changes more accurately reimburse these services.

Reassignment and Physician Self-Referral
ASCP greatly appreciates, and strongly supports, the Centers for Medicare & Medicaid Services actions to prevent "pod" or "condo" laboratories from engaging in abusive billing practices. These laboratories participate in contractual joint ventures enabling non-pathologists physicians and other entities to secure the revenues resulting from the referral of pathology services.

These arrangements enable clinicians to be compensated on the volume of services referred. They exploit a financial incentive that distorts rational medical decisions and leads to over-utilization of health care services. This financial incentive, akin to fee-splitting and markups, causes a host of problems, such as inflating the cost of laboratory services and undermining patient trust in the medical profession. These abusive arrangements increase the potential for harm to patients resulting from unnecessary testing and treatments.

The practices in which "pod" laboratories engage have been declared unethical by the American Medical Association. AMA's Council on Ethics and Judicial Affairs (CEJA) has outlined AMA's strong opposition to fee splitting and markups. Opinion E-6.02 states that "[payment] by or to a physician for the referral of a patient in fee splitting and is unethical." CEJA has also opined that if anatomic pathology services are provided at a discount, the purchasing physician should not charge a mark-up.

Of particular concern is the fact that the financial incentive preyed upon by these pod laboratories can result in physicians selecting laboratories not on the basis of quality, but on cost. Test quality may suffer, increasing the risk of injury to the patient. AMA Opinion E-8.02 addresses this dilemma by stating that a "physician who disregards quality as the primary criterion or who chooses a laboratory solely because it provides

low-cost laboratory services on which the patient is charged a profit, is not acting in the best interests of the patient."

ASCP strongly supports the clarification that reassignment of benefits rules pertaining to contractual arrangements are subject to program integrity safeguards relating to the right of payment for diagnostic testing. ASCP also supports the proposal to amend the regulations for payment of the technical component so that when a reassignment involves a contractual arrangement with a physician or other supplier who performs the test, payment may not exceed the lowest of the physician or other supplier's net charge to the billing physician or medical group, the billing physician's or medical group's actual charge, or the fee schedule amount for the service that would be allowed if the physician or other supplier billed directly.

ASCP supports the proposal that when billing for the technical component, the billing entity would be required to perform the interpretation as well as the proposed changes to the definition of a "centralized building" to restrict the types of space ownership or leasing arrangements that would qualify for purposes of the physician self-referral in-office ancillary services exception and physician services exception.

Requiring these spaces to contain, on a permanent basis, the necessary equipment to perform substantially all the designated health services that are performed in the space will, hopefully, help prevent abusive contractual arrangements by making it more expensive for "pod" laboratories to operate.

That said, ASCP does not perceive the proposed square footage requirement as sufficiently stringent. We are concerned that allowing exceptions to these requirements may allow smaller pod labs to operate, possibly without notice. Such arrangements would still be in a position to engage in abusive billing practices. This proposal permits clinicians to be reimbursed based on the volume of services referred. Such an allowance may result in further abusive billing practices, thus distorting medical decisions and endangering patient health. It should not be tolerated.

To increase the likelihood that the laboratory is operating as a bona fide entity, ASCP supports CMS' proposal that these laboratory arrangements be staffed by a full-time employee or independent contractor. Therefore, ASCP supports the proposal that: (1) a group be required to have a non-physician employee or independent contractor on site in a "centralized facility" and (2) that the person be required to perform services for the group at least 35 hours per week.

In addition, ASCP is opposed to allowing a group practice to maintain a "centralized building" in a state other than the one in which it has an office meeting the requirements of §411.355(b)(2)(i). ASCP encourages CMS to bar entities from billing for services

provided by a facility located out of state or geographically removed from any of the clinical sites of the practice, a common trait of pod labs.

ASCP's comments regarding abusive contractual arrangements relate only to the laboratory industry. ASCP has no position on whether these sort of restrictions should apply to other physicians and specialties. Our comments are intended solely to reflect on the abuses that have occurred in laboratory medicine and pathology.

I am attaching a copy of ASCP's policy statement on fee-splitting and markups, which provides additional information on the problems that can be traced to the contractual arrangements in which pod laboratories engage. I am also attaching a copy of a recent Wall Street Journal article highlighting some of the billing abuses engaged in by these laboratories. Though the article isn't directly focused on Medicare, it focuses on the abusive practices engaged in by pod labs.

Date of Service
ASCP appreciates CMS proposal to change the date of service for analysis of archived specimens. While ASCP supports the change, we believe that the conditions for payment should be modified. ASCP believes that the policy should also cover all tests performed on archived specimens post-discharge, not just those performed 14 days after discharge. If post-discharge testing is medically necessary, then Medicare should provide reimbursement.

Independent Laboratory Billing
ASCP is concerned about CMS' plans to no longer allow independent laboratories to bill for the technical component of pathology services furnished to inpatients. While CMS maintains that laboratories are compensated as part of the prospective payment for applicable laboratory tests, ASCP disagrees with the agency that the prospective payment system already compensates hospitals for the TC of these services. We are aware of no such documentation that suggests that the prospective payments covers these services for in patients or outpatients.

Clinical Diagnostic Lab Tests
CMS is proposing to codify its current process for public consultation for new clinical diagnostic laboratory tests reimbursed under Medicare Part B. ASCP supports the agency's proposal. ASCP appreciates CMS' proposal to publish its rationale for its initial and final payment decisions. To maintain the integrity of the reimbursement system, ASCP believes CMS should outline to stakeholders why a particular payment was chosen. We believe this information would aid stakeholders should they wish to appeal a payment decision.

Regarding Quality issues, CMS proposed to "require those who perform laboratory tests to submit laboratory values using common vocabulary standards, such as those found in the Logical Observation Identifiers Names and Codes (LOINC) database." ASCP

strongly supports reasonable efforts to promote quality, and supports the agency's proposal to use the Logical Observation Identifiers Names and Codes (LOINC) database for this purpose. ASCP appreciates CMS' desire to work with the physicians, providers, and clinical laboratory community on this proposal. ASCP believes strong working relations on such proposals is necessary to promote patient quality while at the same time minimizing administrative and regulatory burdens.

ASCP appreciates this opportunity to provide the agency with comments on the physician fee schedule. Please feel free to contact me or Matthew Schulze, ASCP's Senior Manager for Federal and State Affairs, at (202) 347-4450 if you need additional information.

Sincerely,

Fred H. Rodriguez, Jr., MD, FASCP
President, ASCP

Submitter : **Dr. Thomas Olsen** **Date:** **10/10/2006**

Organization : **Dermatopathology Lab of Central States**

Category : **Laboratory Industry**

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-1321-P-927-Attach-1.DOC

CMS-1321-P

Dermatopathology Laboratory of Central States (DLCS), founded in 1984, is a private, national, full-service dermatopathology laboratory, located in Dayton, Ohio. DLCS has a staff of three board certified dermatopathologists, two of whom are pathologists/dermatopathologists and the third a dermatologist/ dermatopathologist. The mission of the laboratory is to provide quality and efficient processing and interpretation of cutaneous specimens, i.e. perform the global service, to over 350 referring physicians. Additionally, DLCS provides the technical service/processed slide (TC) to many individual dermatologists who elect to interpret (PC) their own patient's skin specimens.

In the last 25 years, there has been tremendous confusion regarding pathology billing and the concept of a mark up of a purchased diagnostic test. While Medicare led the way in 1992 by prohibiting mark up of a purchased diagnostic test, i.e., the concept of being reimbursed for the medical service you provide, nothing more and nothing less, surprisingly a large number of private insurers did not follow suit, leaving opportunities for physicians to profit on work they did not perform. The waters are so muddied that the lab is often asked whether global billing is allowed, even on Medicare patients, when the pathology reading was not performed by that individual. Moreover, during this same time period, individuals have broadly interpreted certain Stark and anti-kickback loopholes with the resulting fall out of overutilization, condo/pod labs, etc. DLCS strongly believes that CMS's current proposals detailed in Proposed Changes to Reassignment and Physician Self-Referral have positive, far reaching consequences in terms of clarification of reassignment issues on a number of fronts while allowing physicians to be appropriately reimbursed for the medical services they provide, nothing more and nothing less.

DLCS has more specific comments to follow.

Since 1992, Medicare has enforced the regulation that one cannot mark up a "purchased diagnostic test", i.e., technical portion (TC) of the pathology service. Thus, DLCS agrees with the proposed amendment to 424.80 to require the TC of a diagnostic test be subject to these same purchased diagnostic test provisions when reassigned in a contractual arrangement, regardless of where the service is performed. DLCS also agrees with the requirement that, in order to bill for the TC, the billing entity under reassignment involving a contractual arrangement must perform the professional interpretation, in accord with Section 1842(b)(6) of the Act, which prohibits Medicare payment to anyone other than the Medicare beneficiary or the physician who performed the service for the beneficiary, with limited exceptions. As a corollary, that same physician performing the professional interpretation and billing for this service must be CLIA certified at a high complexity level and subject to all regulations. Physicians performing the interpretation should be pathologists, dermatopathologists and appropriately trained dermatologists. The Feb.28, 1992 Federal Register (Vol. 57, No. 40, page 7179(1)(2)(B)(3)), attests to the training and qualifications of dermatologists for interpretation of dermatopathology specimens.

DLCS also agrees with the additional proposed amendments to 424.80(d) imposing certain conditions on when a physician or medical group can bill for a reassigned PC of a diagnostic test.

DLCS agrees that the current rules on purchased diagnostic tests should apply in all cases of reassignment and that an anti-markup provision should apply to the

reassignment of the PC of diagnostic tests, regardless of whether or not the service is performed on the premises of the billing entity. Pathologists are often paid a "per slide" fee and there should be a simple mechanism to determine this amount in a contractual arrangement.

CMS's implementation of the proposed regulations and restrictions as outlined and delineated on pages 49054-49056 effectively remove the financial incentive for profit on contracted or reassigned pathology services. Thus, the proposed requirements for a "centralized building" and technician time requirements are unnecessary and administratively burdensome to federal and state regulators.

Thank you for the opportunity to comment on these complex and very important issues.

Submitter : Lynda Barton **Date:** 10/10/2006

Organization : South Texas Oncology and Hematology, PA

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

SEE ATTACHED PDF FILE ... We appreciate the opportunity to submit comments on 42 CFR Parts 405, 410, 411, 414, 415, and 424 [CMS-1321-P] RIN 0938-AO24 Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B.

CMS-1321-P-928-Attach-1.PDF

#928

South Texas Oncology and Hematology, PA
7979 Wurzbach Road Suite U415
San Antonio, TX 78229

October 9, 2006

Reference file code: CMS-1321-P

We appreciate the opportunity to submit comments on 42 CFR Parts 405, 410, 411, 414, 415, and 424 [CMS-1321-P] RIN 0938-AO24 Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B.

Image-guided robotic stereotactic radiosurgery (r-SRS) is both an alternative to surgery and an adjunct to radiotherapy involving a defined set of clinical resources to deliver effective treatment. Image-guided robotic stereotactic radiosurgery is not radiotherapy, as it is intended to ablate identifiable lesions, while preserving normal tissue adjacent to the target volume, rather than treat microscopic disease. The CyberKnife® is a complex image-guided robotic stereotactic radiosurgery system (r-SRS), delivering radiosurgical precision throughout the body, for as many treatments (fractions) as the clinician deems necessary for a given situation. CMS currently allows for up to five fractionated image-guided robotic stereotactic radiosurgery treatments and our data indicate that treatments average 3 fractions per course of treatment. Clinicians and patients have recognized the benefits of radiosurgery, which include no incisions, no anesthesia, lower risk of complications, and, therefore, improved patient quality of life.

Image-guided robotic stereotactic radiosurgery is substantially more resource-intensive than other forms of linac-based systems. It was for this reason that CMS created separate HCPCS codes to distinguish these technologies. Further, it is clear that the resources required for image-guided robotic stereotactic radiosurgery treatment are the same regardless of whether the treatment is performed in the first or a subsequent session.

Image-guided robotic stereotactic radiosurgery is a capital intensive technology, and, due to the relatively small number of patients for whom it is clinically appropriate (as compared with, for example, conventional external beam technology), it is not necessarily cost-efficient for a single hospital to provide these services by itself. Robotic stereotactic radiosurgery facilities that are associated with a particular hospital are typically available for use only by physicians on staff at that hospital, thus restricting their ability to serve the larger community and limiting access. Allowing carriers to pay for the technology when provided in freestanding centers would facilitate cost sharing among a number of hospitals (and others) to provide these services, improving device access to a more diverse population of patients in a given geographic region.

Comment:

A number of temporary codes have been established to enable hospitals to report the technical component costs of image-guided robotic stereotactic radiosurgery (r-SRS) treatment (HCPCS Codes G0339 and G0340). The proposed Rule regarding the Physician Fee Schedule for 2007 designates codes G0339 and G0340 as "C – Carriers price the code."

This is consistent with the technical component radiation oncology services of all kinds that are reimbursed under the Physician Fee Schedule, and have been since the inception of the Physician Fee Schedule methodology.

Recommendation:

The CyberKnife Coalition respectfully recommends and encourages CMS to:

- *Adopt the proposed change to include HCPCS Level II codes G0339 and G0340 on the CY 2007 PFS, classifying the codes with the modifier "C" to indicate that they may be carrier priced.*

We support this modification that would clearly establish carrier authority to cover image-guided robotic stereotactic radiosurgery in freestanding settings, subject to their establishment of appropriate quality assurance measures to ensure patient safety and regulatory compliance, to the satisfaction of the carrier.

We appreciate your consideration of our comment.

Sincerely,

Lynn Kuhn, CPA
Chief Operating Officer
South Texas Oncology and Hematology, PA
South Texas Stereotactic Radiosurgery
Member CyberKnife Coalition

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

Organization : **Feldesman Tucker Leifer Fidell LLP**

Category : **Attorney/Law Firm**

Issue Areas/Comments

Impact

Impact

GPCI/GAF

This comment is submitted on behalf of Colegio de Medicos-Cirujanos de Puerto Rico ("CMC-PR"), a professional association representing physicians and surgeons in the Commonwealth of Puerto Rico. The purpose of this comment is to express concern and to raise questions over the method by which CMS derived the work Geographic Practice Cost Index ("GPCI") and Geographic Adjust Factor ("GAF") for Puerto Rico in CY 2007.

The first concern relates to the bases on which CMS determined the work GPCI figure of 0.906 identified in Addendum D of the proposed rule. Although CMS suggests that the work GPCI derives from decennial census data -- a suggestion confirmed by previous PFS revision notices -- there is nothing in the proposed rule or in any other CMS resource we have been able to locate that would indicate what those data show for the Commonwealth of Puerto Rico. Such decennial census figures are, in any event, of questionable relevance to the setting of rates for periods after January 1, 2007 -- some six to seven years after the collection of census data. Certainly, more current survey data gathered by HHS agencies (e.g., the Health Resources and Services Administration, the Agency for Health Research and Quality, and the Office of the Assistant Secretary for Planning and Evaluation) would be more reliable for the purposes of determining provider compensation and other costs figuring into any geographic adjustments to the PFS.

On a related point, CMC-PR understands based on conversations with CMS that the calculation of the work GPCI for Puerto Rico was performed by an outside contractor. CMC-PR requested copies of the contractor's working papers and other materials that reflect that calculation and relevant methodology and source documentation. CMS, however, indicated that such records are not available for public view. In light of CMS's denial of access to the contractor's papers, CMC-PR is separately filing a request for those records under the Freedom of Information Act in an effort to obtain an understanding of the bases for the work GPCI determination. CMC-PR asks for an opportunity to submit a supplemental comment on the proposed rule once it receives a response to its FOIA request.

As to the GAF(s) for Puerto Rico listed in the August 22, 2006 proposed rule, we note that there are two vastly different figures provided. Whereas Table 3 identifies the 2007 GAF for Puerto Rico as 0.883, Addendum E proposes a 2007 GAF of 0.790. Of these two numbers, the former appears to be the more accurate, as application of the GAF formula ((.52466 x work GPCI)+(.03865 x MP GPCI)+(.52466 x PE GPCI)) to the GPCIs for Puerto Rico yields a multiplier of 0.852 -- a percentage far closer to that listed in Table 3 than the one in Addendum E. This calls for some correction of the arithmetic in the proposed rule or some detailed explanation of the variance.

CMC-PR greatly appreciates the opportunity to submit comments on the proposed rule and would welcome the chance to provide additional input after it obtains the source documentation for the work GPCI.

Sincerely,

Robert A. Graham
Attorney for CMC-PR