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3

THE ALLIANCE FOR PATIENT ACCESS

October 3, 2006

Via Electronic Submission to: http://www.cms.hhs.gov/eRulemaking
Mark B. McClellan, M.D., Ph.D.
Administrator, Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attn: CMS-1321-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244

Re: Proposed Revisions to the Physician Fee Schedule for Calendar Year 2007
CMS-1321-P
Comments on Changes to Practice Expense Relative Values for codes 64612, 64613 and 64614

Dear Dr. McClellan:

As chairman of the Alliance for Patient Access (AfPA), an organization of physicians throughout the nation whose mission is to ensure and protect patient access to approved medical treatments in the U.S., and as a neurologist who has been practicing in an academic setting for 12 years, I am pleased to submit comments on the Proposed Rule for the 2007 Physician Fee Schedule. The Proposed Rule outlines changes to the work relative value units (RVUs), the practice expense RVUs and the conversion factor for services paid under the Physician Fee Schedule. If the changes are adopted as proposed, there will be substantial reductions in payments for many of the services provided by me and my fellow AfPA members, which may mean that we will no longer be able to offer these services to our Medicare patients.

In these comments, I focus specifically on changes in the practice expense RVUs for chemodenervation procedures (codes 64612, 64613 and 64614) because the proposed reductions in these procedures will have a particular impact on my practice and the practices of other AfPA members. These procedures are performed in the treatment of patients with serious movement disorders—many of which are rare diseases—for which chemodenervation offers a relatively noninvasive way to provide significant relief to these patients.

In the Proposed Rule, CMS is proposing to revise the practice expense RVUs for most procedures due to a change in the method CMS uses to determine these RVUs. As I understand it, these changes will result in drastic declines (35 to 54% drops) in the practice expense RVUs for codes 64612, 64613 and 64614 over the next 4 years.

228

ONE HUNDRED NINTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515–6115

JOE BARTON, TEXAS
CHAIRMAN

October 10, 2006

The Honorable Michael O. Leavitt
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Leavitt,

Proposed regulatory changes to the diabetes management protocol for skilled nursing facility (SNF) residents published by the Centers for Medicare and Medicaid Services (CMS) on August 22, 2006 (71 FR 49065, proposed 42 CFR 424.24(f)) are ambiguous and potentially harmful, and I ask you to review and amend them. Diabetes care in skilled nursing settings is too important to risk unintended consequences.

The current patient population within SNFs and other long-term care facilities is often very elderly and medically complex, complicating the management and treatment of diabetes. Many medical conditions may be a consequence of a sustained elevated or depressed glucose level, including comas, seizures or epilepsy, confusion, abnormal hunger, abnormal weight loss or gain, and loss of sensation – the risk for which is heightened in an elderly and frail population. Therefore, it is imperative that frequent blood glucose monitoring tests be performed on SNF residents who suffer from diabetes.

According to the American Diabetes Association (ADA), 20.8 million people in the United States, or 7 percent of the population, have diabetes. The same prevalence holds for my home State of Michigan. More than 10 million or 20.9 percent of all those over the age of 60 have diabetes, and this condition ranked as the sixth most common cause of death in the United States, in 2003 according to the National Center for Health Statistics.

CMS now requires physician certification for each and every blood glucose clinical lab test administered to a SNF resident to document medical necessity. That seems sensible. But CMS's proposed rule could now require physician certification for each blood glucose monitoring test administered to a SNF resident, as well. Currently, a standing physician order for

1321-P

229

CMS-1506-P-485

Submitter : Mrs. Kimberly Cantor **Date:** 10/10/2006

Organization : Association of Women's Health, Obstetric and Neona

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-485-Attach-1.PDF

THE UNIVERSITY OF CHICAGO
BIOLOGICAL SCIENCES

DEPARTMENT OF MEDICINE
Section of Gastroenterology, Hepatology & Nutrition

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October 2, 2006

Mark McClellan, M.D.
Centers for Medicare and Medicaid Services
Department of Health & Human Services
Attention: CMS-1512-PN & CMS-1321-PN
P.O. Box 8014
Baltimore, MD 21244-8014

Re: Medicare Program: Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology

To Whom It May Concern:

I have reviewed CMS' proposed rule relating to the five-year review of work relative value units, as published in the Federal Register dated June 29, 2006. I wish to take the opportunity to provide my comments to the agency on this proposal.

I am practicing gastrointestinal specialist, involved in the treatment of patients, including performing colonoscopies for colorectal cancer screening, as well as treatment of patients with indications for any of a myriad of different GI disorders.

1. Action Relating to Recommendation of the RUC Relating to Gastrointestinal Services Reviewed

In general, we applaud the agency for adopting the recommendations of the RUC with respect to retaining the identical work RVUs for the major GI codes. This has not always been the case, and we have objected in prior years when the agency decided not to follow the RUC recommendations.

That having been said, it is nonetheless clear that the RVUs assigned to GI colonoscopies and other procedures are not nearly high enough. Since the Medicare colorectal cancer screening benefit was enacted in 1997, CMS has cut the physician fee schedule payment for screening/diagnostic colonoscopies by almost 40%--from a little over $300, to the current level of just around $200, and trending downward (these are raw dollars—if inflation were factored in the reduction would almost certainly be in excess of 50%). No other Medicare service has been cut this much since Congress decided to make the eradication of colorectal cancer a national priority by encouraging every Medicare beneficiary over the age of 50 to receive screening.

Congress did the right thing in 1997 when it enacted the Medicare colorectal cancer screening benefit, and again in 2000 when it added the average risk colonoscopy benefit. Sadly, and whether intentionally or inadvertently, CMS has consistently emasculated the effectiveness and utilization of that benefit, by relentless and devastating cuts. When one looks at the bottom line on this proposal, it is clear that this disastrous trend would continue with major new cuts. We will address later the agency's proposal for a 10% across-the-board cut in work RVUs in the name of budget neutrality. At this point, we must simply say that—to the extent that increases in RVUs for cognitive and other services necessitate a decrease in the GI work RVUs, and therefore discount the RVUs which the RUC said should remain unchanged, we oppose those increases. And to the extent that CMS's concept of budget neutrality demands a 10% across-the-board cut in the payment for services, we believe the interpretation of budget neutrality adopted by the agency is incorrect and the result patently unfair.

Budget Neutrality

CMS argues in this proposal and elsewhere that: (1) the SGR will automatically cut the reimbursement for all Medicare services by somewhere around 5% next year; (2) the budget neutrality under the 5-year review necessitates an additional 10% across-the-board cut in the work RVUs for all Medicare services, including life-saving colorectal cancer screening colonoscopies; and (3) proposes to cut precipitously the facilty fees paid for cases performed in ambulatory surgery centers. This cumulatively would result in cuts of at least 15%, and when the new ASC payment reform policy is factored in, one-year cuts could be 30% or more. Basic economics demonstrates that no business/sector in the economy can endure the type of budget neutrality driven proposal being pursued by CMS, to cut all work RVUs by an additional 10% and still continue to function anywhere close to normally. The cumulative effect of these three CMS proposals, and specifically the 10% budget neutrality adjustment is to force physicians to limit access to Medicare beneficiaries or force them out of business altogether. This 10% across-the-board cut is wrong, and cannot stand. The alternative suggested by CMS of a roughly 5% cut to the conversion factor is equally unacceptable. At this point, CMS and the government have simply extracted too much money out of the system already; further cuts of the magnitude suggested will cause the system to collapse. My practice cannot continue to screen Medicare beneficiaries for colorectal cancer screening on the same basis and timetable as private pay patients if we are looking at cumulative cuts in excess of 50% since the colorectal cancer screening benefit was enacted in 1997. As we noted above, to the extent that CMS's concept of budget neutrality demands a 10% across-the-board cut in the payment for services, we must oppose all increases for cognitive services and other Medicare services for which increases would drive such precipitous cuts elsewhere in the system.

Changes to Practice Expense Methodology

We support in principle the proposal insofar as it relates to changes in the resource-based practice expense methodology. One of the few positive features of this rulemaking is the

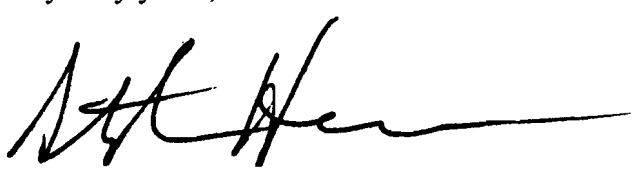
possibility that CMS will finally adopt the refinements to GI practice expense RVUs which were proposed, but then withdrawn by the agency last year. A single bright spot is the possibility that supplemental practice expense data may be accepted this year, which could moderate the net Medicare fee reduction for some GI services—unfortunately that modest moderation in the decline is not enough.

Conclusion

As we have noted above, despite our concurrence in retaining the work RVUs for the key GI services at their current level, as recommended by RUC and CMS, we are deeply concerned that the cumulative cuts from this rule, the SGR and the pending reform to the ambulatory surgery payment system will drive many practices (and ASCs) out of the Medicare system of out of business. These proposals may be the final straw in terms of breaking the American health care system, which has been the victim of a vicious and unprecedented cost-cutting siege, largely at the hands of the federal government, CMS, and the Medicare program over the past dozen years. This downward spiral must stop.

We appreciate the opportunity to submit our comments of this proposal, and we would be pleased to answer questions or otherwise engage in dialogue with the agency about how to improve/remedy the deficiencies in the current proposal.

Very truly yours,



Stephen B. Hanauer, MD
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231

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October 4, 2006

Mark McClellan, M.D.
Centers for Medicare and Medicaid Services
Department of Health & Human Services
Attention: CMS-1321-PN
P.O. Box 8014
Baltimore, Maryland 21244-8014

Re: Medicare Program: Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007, and Other Changes to Payment Under Part B

To Whom It May Concern:

The American College of Gastroenterology is pleased to provide these comments with respect to CMS' proposed rule, published in the ***Federal Register*** on August 22, 2006, on revisions to the payment policies under the Physician Fee Schedule and Other Changes to Payment under Part B for the (Calendar Year 2007).

INTRODUCTION

The American College of Gastroenterology (ACG) is a physician organization representing gastroenterologists and other gastrointestinal specialists. Founded in 1932, the College currently numbers more than 9,000 physicians among its membership. While the majority of these physicians are gastroenterologists, the College's membership also includes surgeons, pathologists, hepatologists and other specialists in various aspects of the overall treatment of digestive diseases and conditions. The College has chosen to focus its activities on clinical gastroenterology--the issues confronting the gastrointestinal specialist in treatment of patients. The primary activities of the College have been, and continue to be educational.

In addition to the College's comments, which follow, we also wish to endorse specifically the comments submitted jointly by the American College of Gastroenterology, the American Society for Gastrointestinal Endoscopy, and the American Gastroenterological Association.

Budget Neutrality and the Sustainable Growth Rate

The sustainable growth rate (SGR) formula continues to be a major impediment to fairness and quality in health care, despite Congressional intervention in the nature of a short-term fix to provide a two-year increase in overall physician reimbursements. Congress made it very clear in the Medicare Prescription Drug, Improvement and Modernization Act of 2004 (MMA) that the SGR policy is a failure, the result of its implementation is detrimental to the public health, and that it must be replaced. It confines physician payments within a budget baseline along with other non-physician health services, such as drugs and biologicals. Therefore, increases in non-physician payment Part B services prompt automatic reductions in the SGR. Tying the SGR baseline to the gross domestic product (GDP) produces similar problems.

We are very concerned about the proposed 5.1% payment cut for 2007. CMS knows that this is not an isolated cut—if the SGR formula is not fixed, these negative updates to the Medicare Physician Fee Schedule can be expected to continue a downward spiral in payment of 5% per year, more or less, each year through at least 2012. CMS argues in this proposal and elsewhere that: (1) the SGR will automatically cut the reimbursement for all Medicare services by somewhere around 5% next year; (2) the budget neutrality under the 5-year review necessitates an additional 10% across-the-board cut in the work RVUs for all Medicare services, including life-saving colorectal cancer screening colonoscopies; and (3) that precipitous cut to the facilty fees paid for cases performed in ambulatory surgery centers should be undertaken. This cumulatively would result in cuts of at least 15%. When the new ASC payment reform policy is factored in, the effective rate of the one-year cuts, including CMS's outrageous proposal to cut the average GI facility fee in the ASC setting by 27%, could be 30-40% or more. Basic economics demonstrates that no business/sector in the economy can endure the type of budget neutrality driven proposal being pursued by CMS, i.e., to cut all work RVUs by an additional 10% and still continue to function anywhere close to normally. The cumulative effect of these three CMS proposals, and specifically the 10% budget neutrality adjustment, would be to force physicians to limit access to Medicare beneficiaries or force them out of business altogether. This 10% across-the-board cut is wrong and must not stand. The alternative suggested by CMS of a roughly 5% cut to the conversion factor is equally unacceptable. At this point, CMS and the government have simply extracted too much money out of the system already; further cuts of the magnitude suggested will cause the system to collapse.

Separating Physician and Non-Physician Services

There is growing sentiment among physician organizations and in Congress that there are a few steps that can be taken by the agency right now to make the current formula more equitable with respect to physician payments. One would be to delink spending on physician payments from non-physician services. Annual spending growth on drugs and physical therapy far outstrip that of physician services. Despite CMS' prior statements

that it has no ability to avert the next fee schedule fiasco in 2007, the agency has direction from Congress to do so, and could exercise its role in administering the Medicare program to modify or amend the tenets of the SGR in this way. Creating completely separate funding pools under the global Medicare budget for physician services and non-physician services, each with its own respective target, would have an immediate and significant impact on alleviating the projected "negative adjustment" expected for physician services payments in the 2006 physician fee schedule. Such a modification would achieve a result that would be appropriate, reasonable and beneficial for physicians and beneficiaries.

So, we reiterate our plea that CMS announce its support for replacing the SGR policy, creating separate accounts for physician and non-physician services, and working with Congress on the development of an equitable and forward-looking successor to the SGR that can be implemented in time for the 2007 physician fee schedule

Payment for Physician Office Visit in Advance of a Medicare Screening Colonoscopy

There is an inconsistency and inequity in the Medicare Physician Fee Schedule as it applies to the provision of clinical gastroenterology services, particularly colorectal cancer screening for Medicare patients. Specifically, this concerns the need to secure payment for services provided when a beneficiary comes in for a pre-operative clearance visit prior to having a screening colonoscopy. The correct policy should be that the pre-operative clearance visit conducted in advance of (and not on the same day as) a screening colonoscopy should be reimbursed by all Medicare carriers.

Since the vast majority of patients undergoing colonoscopy receive sedating medications, which increase potential risks for a procedure, these risks should be discussed and certain medications discontinued before a patient takes off time from work and undergoes the colon preparation. For example, the physician needs to determine that the patient is an appropriate candidate for the test, as the Medicare population is, by definition, at greater risk for complications (e.g., if the patient is taking anticoagulants they might be excluded from the colonoscopy). Sound medical practice requires clarifying in advance certain key information that can only be determined through a thorough evaluation of the patient by a physician.

In fact, JCAHO, AAAHC and many state governments REQUIRE that the patient be seen by the physician before being sedated to determine medical history, their appropriateness for the procedure, and preparation instructions. The necessity for this pre-procedure office visit cannot be overstated. Patients are sent to the gastroenterologist or come on their own not only to discuss colonoscopy but also to review the options that the Medicare CRC screening benefit has provided. Colonoscopy may or may not be the most suitable screening option, depending on the patient's underlying medical condition. Whether the patient has a cardiac or pulmonary condition, hemophilia, diabetes or any other coexisting medical conditions or medication intake (and, commonly, more than one of these conditions), the gastroenterologist should

be able to consider the unique circumstances of the patient before ordering the preparation for the procedure and before performing the colonoscopy.

Some Medicare carriers, e.g., Trailblazer, have adopted the policy concerning this visit correctly. Unfortunately, there are carriers who deny payment for the pre-operative clearance visit held before the screening colonoscopy, even though the same carrier will pay for a similar pre-operative clearance office visit when it is provided before a diagnostic colonoscopy (i.e., the identical procedure, except that in a diagnostic colonoscopy there is an identified indication). This is one of the current incongruities which would be remedied if CMS adopts the consistent policy we are advocating for all colonoscopies, whether diagnostic or screening in origin. Before sedation is received, patients should have the option to visit the physician who will perform the procedure, and CMS should clarify that Medicare will pay for this visit (for most beneficiaries, colonoscopy is limited to once every ten years).

The history of the physician fee schedule demonstrates convincingly that HCFA: (1) did not bundle the pre-procedure service into the RVUs for the procedure itself; (2) anticipated that most Medicare patients would require a pre-operative clearance visit in advance of any colonoscopy; and (3) that all endoscopic procedures have always had a "0" global days, so all pre- and post- visits are separately billable. On page 25832 of the June 1991 proposed rule to establish the resource based relative value scale (RBRVS) fee schedule, HCFA stated:

> *"On the other hand, if documented evaluative services are performed in addition to the surgical procedure or 'scopy,' payment could be made for the visit. For example, a new patient is referred to a gastroenterologist for a possible scopy. The gastroenterologist conducts a thorough examination to first determine if the patient is a candidate for a scopy, and immediately proceeds to do the scopy. In this case, both the visit and a scopy could be billed if the visit is clearly documented."*

In summary, there are two major inconsistencies: (1) distinctly different policies for the pre-operative clearance visit for a screening colonoscopy depending on the Medicare carrier, and (2) different policies for screening colonoscopy versus diagnostic colonoscopy, though they are identical procedures. The inconsistencies would be remedied if CMS clarifies that the pre-screening/pre-operative clearance visits are reimbursable. To reiterate, currently, if a beneficiary is to have a *diagnostic* colonoscopy, all carriers recognize the need for the beneficiary to receive a pre-operative clearance visit in advance of the procedure. If, however, the beneficiary is having the identical procedure for *colorectal cancer screening*, the preoperative visit is equally important and should be covered. As CMS has not clarified these inconsistencies and recognized that this is an appropriate, medically necessary service, some carriers refuse to pay for the pre-screening/pre-operative clearance visit.

In conclusion, ACG requests CMS to rectify the inconsistencies in its current policy in order to reduce ambiguity and establish a universal policy that the pre-operative

clearance visit conducted in advance of (not the same day of procedure) a diagnostic or screening colonoscopy be fully covered.

Site of Service Policy for GI Endoscopies

The proposed fee schedule perpetuates a misguided CMS payment policy wherein essential GI procedures are reimbursed at higher rates when performed in an office setting than when performed in an ASC or HOPD. This site of service differential grossly distorts payment for physician services depending on where the procedure is performed without regard to which setting is more beneficial to patient outcomes. In its proposed rule for the 2005 Fee Schedule, CMS would reimburse a physician more than twice as much ($336.17 to $162.59) for an upper GI endoscopy with biopsy (43239) done in an office than for the same procedure performed in an HOPD or ASC. Yet both federal and state governments heavily regulate HOPDs and ASCs in order to receive Medicare and Medicaid certification; this is also the setting where 95% of most endoscopic procedures are still performed.

Ever since it was implemented, ACG has strongly opposed this policy because it is detrimental to patients and their ability to choose the appropriate location for the procedure with their physician. Much to the credit of gastroenterologists, they have refrained from "taking the bait" of the higher reimbursement level to shift to the office setting. Percentage volume for each respective site has not shifted, as the rate for performing a diagnostic colonoscopy in an office setting still hovers at less than five percent. CMS maintains this site of service bifurcated fee schedule even though these endoscopic procedures fail to meet the Agency's own criteria for such classification, namely, the presence of at least 10% office volume as stated in the June 1997 proposed rule.

The American Medical Association's *Archives of Surgery* released a study in September 2003 (Vol. 138, No. 9, September 2003), which identified data on whether patient safety is similar in ASCs and unregulated physician offices in Florida. Of thirteen deaths in a physician's office that occurred during the study period, two were related to endoscopy. In fact, this study concluded that there was a ten-fold increased risk of adverse incidents and death associated with surgical procedures provided in an unregulated physician's office (these are not "ASC look-alikes" which would meet Medicare ASC qualifications but for certificate of need problems; rather, these are essentially unregulated office settings with no controls on training, equipment or the like) versus the ASC. The study concluded that 43 injuries and 6 deaths per year in Florida could have been prevented if all procedures had been provided in facilities that met ASC criteria. This study completely debunks, with U.S. data, the false conclusion from the 2002 GAO report, which stated that there was little or no difference between the unregulated office setting and the ASC. The GAO report, from 2002, failed to find any United States surgical data and cited data from a study done in France, where circumstances, standards, training and care are decidedly different than in the U.S.

Some private payers are inclined to follow CMS' lead on this policy. As is noted on page 3, however, and in previous comments to the Agency, we have used the example of Blue Cross/Blue Shield of Massachusetts. Initially, the company instituted a CMS-like site-of-service policy for GI endoscopic procedures in 2002. Upon further review, however, BC/BS of Massachusetts set 37 endoscopic procedures with a single fee and total RVU so that prospectively all GI endoscopies are reimbursed at the higher office rate. This summer, Anthem BC/BS of Connecticut notified gastroenterologists in its network that it would follow CMS' lead and create a bifurcated fee schedule for endoscopic procedures. Once again, however, after reviewing the compelling patient safety evidence – as well as the precedent set by BC/BS of Massachusetts – the company decided not to pursue the site of service/bifurcated fee schedule.

ACG would appreciate the opportunity to work with the agency in framing and adopting an appropriate remedy for this problem. Ideally, the remedy would (1) shift these GI procedures out of the site-of-service policy (because they are below the 10% office volume threshold established by CMS); and (2) set these procedures with a single fee and total RVU at the **higher** office rate.

Conclusion

As we have noted above, despite our concurrence in retaining the work RVUs for the key GI services at their current level as recommended by RUC and CMS, we are deeply concerned that the cumulative cuts from this rule, the SGR, and the pending reform to the ambulatory surgery payment system will drive many practices (and ASCs) out of the Medicare system and/or out of business. These proposals may be the final straw in terms of breaking the American health care system, which has been the victim of an unprecedented cost-cutting siege, largely at the hands of the federal government, CMS, and the Medicare program over the past dozen years. This downward spiral must stop.

We appreciate the opportunity to submit our comments on this proposal and we would be pleased to answer questions or otherwise engage in dialogue with the agency about how to improve/remedy the deficiencies in the current proposal.

Very truly yours,

Jack DiPalma, M.D., FACG
President

Edward Cattau, M.D., FACG
Chair, ACG National Affairs Committee

Dr. Mark McClellan, MD PhD
Administrator
Centers for Medicare & Medicaid Services
P.O. Box 8012
Baltimore, MD 21244-8012

Dear Dr. McClellan:

We wish to express our serious concern that the Centers for Medicare & Medicaid Services (CMS) proposed rule making adjustments in Medicare Part B practice expenses and relative work values (71 FR 37170, 6/29/2006) severely cuts Medicare anesthesia payment without precedent or justification. We request the agency reverse these cuts.

The proposed rule mandates 7-8 percent cuts in anesthesiology and nurse anesthetist reimbursement by 2007, and a 10 percent cut by 2010. With these cuts, the Medicare payment for an average anesthesia service would lie far below its level in 1991, adjusting for inflation. The proposed rule does not change specific anesthesia codes or values in any way that justifies such cuts. In fact, during CMS' previous work value review process that concluded as recently as December 2002, the agency adopted a modest increase in anesthesia work values. Further, Medicare today reimburses for anesthesia services at approximately 37 percent of market rates, while most other physician services are reimbursed at about 80 percent of the market level. The Medicare anesthesia cuts would be in addition to CMS' anticipated "sustainable growth rate" formula-driven cuts on all Part B services effective January 1, 2007, unless Congress acts.

It is reasonable to expect that cuts such as these may impact the accessibility to care for our Medicare patients. Simply put, the Medicare reimbursement for anesthesia is already substandard and further cuts may push some providers to exclude this group from patient care services. I have had firsthand experience seeing this occur with other programs and specialties.

Last, hundreds of services whose relative values and practice expenses have been adjusted by the 5-year review proposed rule have been subject to extensive study and examination. However, the proposed rule indicates no such examination has been made on the effects that 10 percent anesthesia reimbursement cuts would have on peoples' access to healthcare services, and on other aspects of the healthcare system.

For these reasons, we request the agency suspend its proposal to impose such cuts in Medicare anesthesia payment, review the potential impacts of its proposal, and recommend a more feasible and less harmful alternative.

Sincerely,

Todd B. Oller, CRNA

Grand Strand UROLOGY, LLP

October 2, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P
Post Office Box 8015
Baltimore, MD 21244-8015

William Bogache, M.D., F.A.C.S.
Kenneth Krzyzaniak, M.D., F.A.C.S.
Neal Shore, M.D., F.A.C.S.
Richard Young, M.D., F.A.C.S.
Brian Roberts, M.D., F.A.C.S.
Attila T. Barabas, M.D.

RE: (REASSIGNMENT AND PHYSICIAN SELF-REFERRAL)

Dear Sir or Madam,

I am an actively practicing urologist in Myrtle Beach, South Carolina. I would like to take this opportunity to comment on your proposed rule changes on reassignment and self-referral for physician office laboratory and pathology services. On the surface, it would appear that these rules were written or promulgated by the large national pathology mills to prevent individual physician group competition with their labs. These pathology mills have no interest in providing quality care to our patients, and their only objective is to maintain a monopoly to generate profits for their shareholders by whatever means are available to them. Urologists, on the other hand, are intimately involved in providing high quality care directly to our patients, and operating our own office pathology lab allows us to provide more cost-effective, convenient care with better quality control.

I have been in practice 25 years and for many years relied on hospital-based pathologists to interpret prostate biopsies, but many of their reads were inadequate simply because a general hospital pathologist is not able to develop the same level of expertise as a dedicated GU pathologist. We were often sending slides out for second and third opinions before a final diagnosis was determined. Approximately eight years ago, I switched to using a national commercial lab such as Dianon, Bostwick Labs, and OURLab, that had dedicated GU pathologists. This initially seemed to be an improvement until they started switching pathologists to the lowest bidder. This again resulted in unreliable quality, requiring second opinions. Some of these labs were also in violation of state law by using pathologists who are not licensed in our state. Having our own dedicated GU pathologist as a member of our practice has greatly improved the quality and reliability of our pathology services while reducing the cost to our patients and CMS by eliminating the need for second and third opinions.

Our utilization of pathology services has not changed, but the cost to CMS has probably decreased due to fewer second and third opinions. The indications for prostate biopsies, techniques and number of cores required is well documented in urologic literature. A urologist who sees a patient with an elevated PSA, suspected prostate cancer, a prostate nodule or failure of radiation or cryotherapy is obligated to pursue further evaluation and diagnosis with biopsies in a standard of care fashion. Failure to diagnosis cancer is one of the more common causes of malpractice claims in our specialty and places a burden on the practicing urologist to provide the best quality care for his patients. Changing these regulations and decreasing accuracy of the diagnosis by mandating that prostate specimens must be sent to large national pathology mill laboratories who do not have the same level of expertise or interest in our patients that our pathologist has is not going to change the volume of specimens being processed.

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We have multiple satellite offices and there is no question that our lab is part of our practice. Just as every other office in our practice, we pay to outfit and lease the space, we pay and instruct our technicians, we own our own equipment and pay for our own disposable supplies. State licensing, lab inspections, quality control, proficiency testing and annual staff training is all the responsibility of our practice. We supervise our pathologists and all specimens are processed with our equipment and interpreted on our premises in full compliance with the Stark laws and CLIA. Therefore, there is no potential kickback arrangement among providers, staff or those who may have offices in the same complex.

The CLIA regulations allow pathologists to supervise five labs, and the Stark Laws and CLIA regulations do not specify how large a space is necessary for various lab equipment or tissue processing. In fact, our community hospital tissue processing room is only 200 square feet. Your proposal to require at least 350 square feet for physician office labs is a blatant attempt by national pathology mills to eliminate competitive free trade that could also have an impact on small hospital labs. We do not feel that it is in the best interest of our patients to rewrite Stark Laws or CLIA regulations to suit an industry that has an interest in establishing a monopoly.

The large national pathology mills would like to have CMS believe that a profit generated by services performed in a physician practice is somehow detrimental to delivering excellent healthcare and that it only leads to fraud, abuse and over utilization. Our own data and the recent OIG inspections show this to be a false assumption that has been promulgated by outside commentators who would profit if physician labs were shut down. Contrary to your own comments in the Federal Register August 22, 2006, ancillary profit in our practice allows us to continue to provide excellent care to our Medicare patients in the face of declining reimbursement for professional services and increasing overhead expenses. We have seen greater than a 50 percent decline in reimbursement for surgical services from Medicare over the past 15 years and most of us realize that Medicare is on the brink of collapse as more beneficiaries sign on to the program, and the first wave of physicians contemplate opting out of the program because it can no longer support their practice.

I urge you not to rewrite the Stark Laws, or CLIA regulations to benefit national lab chains who have no interest in providing quality care to our patients. The only way for Medicare to continue to provide quality care for all Americans is to continue to allow urologists to provide excellent care in their offices, laboratories, surgery centers and operating rooms. We must have a viable business model to continue to provide service to Medicare beneficiaries and I respectfully request that you delay any final decisions on this proposed rule change until all appropriate facts have been presented from all interested parties. Thank you for your consideration.

Sincerely,

Kenneth E. Krzyzaniak, MD
KEKslM

234

Baltimore Pain Management Center

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David Gichtin MD, Diplomate American Society of Pain Medicine
Diplomate American Society of Anesthesiology
Certified Independent Medical Examiner

4 October 2006

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
CMS-1321-P
P.O. Box 8015
Baltimore, MD 21244-8017

Re: CMS 1321-P

Dear Dr. McClellan:

I am truly saddened by your most recent proposed physician reimbursement cuts. I really just don't know what to do anymore. As my costs of running a business continue to rise, rent going up to 4% a year, salaries going up to 3% a year, I no longer know where the money is coming from. However, I do know who is responsible for changing the face of health care in this country.

I have never written a letter of this type before, but I recognize that my practice and its survival is now at stake. At a certain point, you just have to throw up your hands and say enough. If you go forth with your proposed cuts, that is exactly what is going to happen.

Rather than attack the physicians, who are the actual link between the patience and care, you should be looking for other sources as a means of balancing your budget. For example: the Medicare subcontracted carrier trailblazers seems to be running a fine business and making money. Why not cut, or limit their profit margins?

Along these lines, you yourself must admit that the new insurance company backed Medicare D. is a windfall for the insurance companies. Why else would they be going into it? Obviously, it is not a losing proposition for them. Again, limit their margins to one to 2% and see how many of them will remain in the business.

Yes, I am angry and upset as I see what is happening to healthcare today. So please, rather than institute these cuts impose a moratorium to ensure that Medicare patients will have continued access to interventional pain services.

Thank you for your consideration.

Sincerely,

David Gichtin

September 26th, 2006

Center for Medicare and Medicaid Services
Dept of Health and Human services
Attention : CMS-1321
PO Box 8015
Baltimore, MD 21244-8015

RE: **5.1% physician cut and upto 58% cut for Interventional Pain physicians when procedures performed in office.**

For years physicians have operated under a Medicare reimbursement system that does not keep track with inflation. Unless intervention takes place, this year payments to physicians will be cut by 5.1%. Some physicians like our specialty may face cuts as high as 58% as CMS is using bottom up methodology in calculating practice expenses and improving reimbursement for Evaluation and Management services. We think for evaluation and management the reimbursement is adequate.

Physicians cannot continue to operate in an environment of such uncertainty, and as a result more and more doctors are electing to stop taking on Medicare patients, and an even more threatening issue, all **other payers follow Medicare.**

I was doing my procedures at the Hospital for 5 years. It is a big loss for Medicare and other insurances when physicians do procedures at hospitals. Medicare and other insurances has to pay out more. Medicare has to **pay separately for Facility fees for hospitals and the professional component for the physicians**. It is like Medicare will be almost paying double reimbursement.

By doing the procedures in an office setting, Medicare receives only one bill, ie from the physicians, which is much lesser than if we were do in an hospital(facility). As it is lot of the medications we use for the procedures are bundled as overhead expenses and we do not get reimbursed.

We will definitely will not be able to survive doing procedures in an office setting if there is any further cut in the reimbursement for Interventional Pain Physicians(Anesthesiology and Radiology codes like **64475, 64476, 64470, 64472, 76005, 27096,72295, 64483, 64484, 64479, 64480, 64626, 64627, 64622, 64623 etc**).

We request your leadership on this issue and request your support in not passing this legislation.

Thanking you,

Sincerely,

Raymond Smith, MD
Pennsylvania Society of Pain Physicians

Interventional Medical Associates

of Bellingham, P.C.

Specializing in Evidence-based Spinal Diagnostic and Therapeutic Interventions

Way Yin, M.D.
Miguel A. Pupiales, M.D.

October 2, 2006

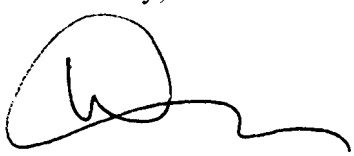
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1321-P
P.O. Box 801
Baltimore, MD 21244-8015

Dear Sir or Ma'am:

I am writing to you regarding the proposed 5.1% reduction in Medicare reimbursements proposed for 2007. In my specialty of Pain Medicine, reductions in reimbursement for Medicare beneficiaries has already had a significant effect on access to care for these patients in my community. As our overhead continues to grow, and as the Medicare population continues to grow, sequential cuts in Medicare reimbursements have forced many physicians in my specialty to close their doors to Medicare beneficiaries. In an older patient population where chronic pain issues affect a greater proportion of individuals, the economic realities of maintaining a practice where the highest quality of care is afforded to all patients are at fundamental odds with a process where reimbursements are continuously in decline.

On behalf of the Medicare beneficiaries in our community, I beg you to eliminate the proposed 5.1% across the board cut, and avoid further cuts in reimbursements affecting our field.

Sincerely,



Way Yin, M.D.
Medical Director
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Diplomate American Board of Surgery
Fellow American College of Surgeons

237

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1512-PN
P.O. Box 8010
Baltimore, MD 21244-8010

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 - "DRA Proposals."

Dear Dr. McClellan:

As a vascular surgeon and as a member of the Society for Vascular Surgery (SVS), I am writing in response to the publication of CMS-1321-P: Medicare Program; Revisions to Payment Policies Under the Physician Fee schedule for Calendar Year 2007.

I am particularly concerned that CMS has proposed to reduce payment for CPT code 93880, the non-invasive duplex scan of extracranial arteries.

The leading cause of strokes is disease of the carotid arteries, an extracranial artery, in the neck and this disease is silent in 80% of cases prior to the stroke. Duplex examination of the carotid artery is the best and lowest cost means of finding this silent carotid artery disease so that it can be managed prior to the stroke and devastating strokes prevented.

However, reduction of re-imbursement for duplex examinations of the carotid arteries can reduce the number of vascular laboratories that can remain financially viable to perform these examinations. The result can well be that stroke potential carotid disease will not be found before the stroke and that strokes that could have been prevented will not be prevented.

This is not only devastating for seniors since stroke is the worst medical condition that can occur to them but is not cost-effective for the medical care system. Strokes are the leading line item expenditure for Medicare at over $40 billion annually and instead of decreasing strokes and this expenditure, the reduction in reimbursement for duplex examinations of the carotid arteries will have the opposite effect.

We have published clinical research showing that use of duplex ultrasound to find the silent carotid disease that is the leading cause of strokes can both reduce strokes and that it is extremely cost-effective in so doing.

I greatly appreciate this opportunity to provide CMS with this information and will be most pleased to provide reprints of pertinent articles and discuss this matter further.

Sincerely,

George S. Lavenson, Jr., MD, RVT
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238

THE AMERICAN SOCIETY OF
Breast Surgeons

October 4, 2006

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

RE: CMS-1321-P: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for CY 2007 and Other Changes to Payment Under Part B, Specifically "Provisions Regarding Resource-Based Practice Expense (PE) RVU Proposals for CY 2007."

On behalf of the American Society of Breast Surgeons, a professional organization representing more than 2500 surgeons dedicated to improving the care of patients with breast disease, we are writing to address concerns regarding resource-based practice expense (PE) RVU proposals for CPT codes 76095 and 19103. The proposed PE RVUs for these two codes do not cover the costs of performing these procedures in a physician's office and thus will affect the treatment of patients with breast disease, severely limiting a Medicare beneficiary's access to optimal care.

Historically, the evaluation of patients with breast disease began with open surgical excision of palpable masses. Later, with the advent of widespread mammography, open surgical excision of mammographic densities following the placement of a localization wire became the standard for biopsy of non-palpable densities. In 1986, stereotactic needle biopsy and later ultrasound-guided needle biopsy became available, and has since become the standard of care for the initial diagnosis of most breast abnormalities. This has not only vastly improved patient care due to the ability to avoid an open surgical procedure, it has resulted in significant cost savings to the health care system by avoiding the attendant costs of an operating room and anesthesia. Fortunately, the initial PE RVUs associated with the relevant codes (19103 and 76095 stereotactic biopsy or 19103 and 76942 for ultrasound guided biopsy) appropriately covered the direct and indirect costs associated with the procedures.

The 2007 proposed rule will drastically reduce the non-facility PE RVUs assigned to stereotactic imaging (76095) to the point that it will no longer be possible for a surgeon or other physician to provide stereotactic guided needle breast biopsy in the non-facility setting. The practice expense associated with each of the relevant codes is outlined below:

5950 Symphony Woods Road, Suite 212, Columbia, MD 21044 USA • Phone: 410-992-5470, 877-992-5470 *(toll free)* • Fax: 410-992-5472
www.breastsurgeons.org • contact@breastsurgeons.org

76095 – Stereotactic breast imaging:

The current non-facility practice expense listed in the RUC database is 7.70 RVUs. This is scheduled to decrease to 6.25 beginning in 2007 (an 18% decrease), and to fall to 1.91 by 2010 (a more than 75% decrease), or the equivalent of $72 using the 2006 conversion factor. This does not come close to covering simply the direct costs of the procedure.

Stereotactic breast biopsy requires a dedicated unit consisting of a digital mammographic imaging camera and a fixed platform to compress the breast and to direct a biopsy needle. The units typically sell for $250,000 and require a special room and power supply, documentation equipment, as well as a certified radiology technologist to operate the equipment. Even in an ideal setting where the machine is used consistently 50% of the time, 88 procedures could be performed per month (4 biopsies a day x 22 days). The 2010 practice expense would amount to just over $6000 per month in practice expense reimbursement, using Medicare's proposed RVUs, which would just cover the lease on the stereotactic table itself, and none of the additional direct and indirect costs. At these proposed levels, the technology will just not be affordable outside the hospital.

19103 – Vacuum assisted/rotating cutter percutaneous breast biopsy:

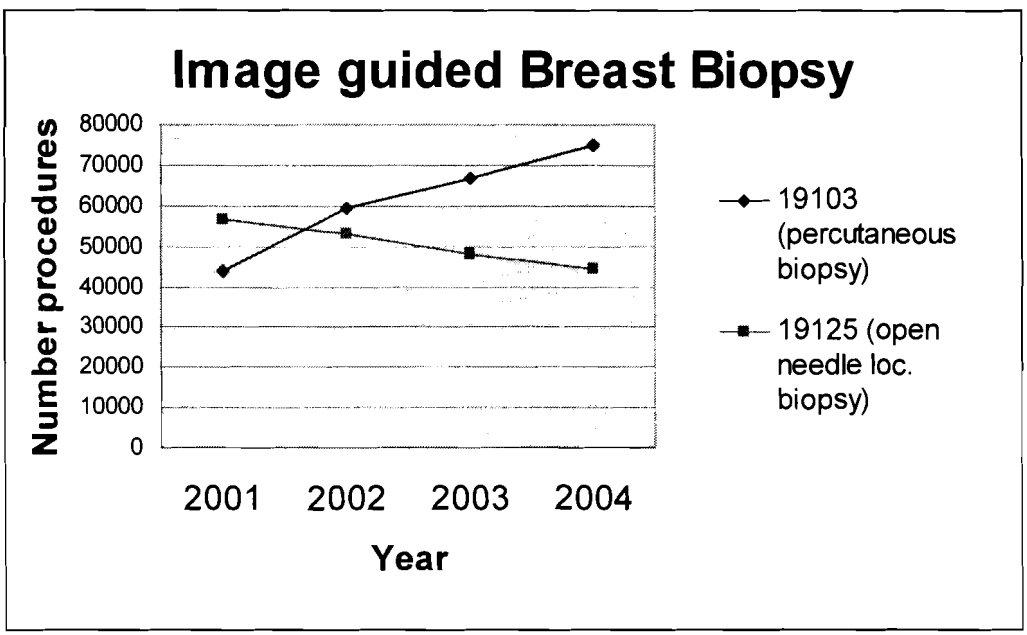
Over the past several years, a 10 to 11 gauge vacuum assisted or rotating cutter biopsy device has become the standard breast biopsy instrument used with stereotactic imaging. This is due to improved accuracy of sampling compared to a simple core biopsy needle, resulting in diagnosis that is more accurate and less likely to require a follow-up surgical biopsy. It requires a specialized biopsy device (approximate cost $250-$350), which is driven by a dedicated biopsy console (base price approximately $35,000), in addition to a biopsy tray and a full time assistant to help during the procedure. While the proposed reduction in non-facility practice expense is only 10%, this is sufficient to stress the ability of breast surgeons to provide this service.

In the past, surgeons could make up for inadequate practice expense reimbursement by "cost shifting" from the work RVUs. This was true whether the practice expense calculations were the result of an initial underestimation of cost, or were inadequate due to ever increasing direct and indirect costs. The 2007 proposed reductions are too substantial, however, to allow for this possibility. This is especially true given the anticipated 10% budget neutrality reduction to the physician work RVUs assigned to each code and the projected 5.1% reduction in the 2007 conversion factor scheduled to go into effect at the same time as these practice expense reductions.

The net effect of these combined reductions will severely limit patient access to this technology, which is currently considered a standard of care. The American Society of Breast Surgeons has recently published a position statement on image guided breast biopsy, advocating this as one of the preferred techniques for diagnosis of image detected breast abnormalities (http://www.breastsurgeons.org/mibb.shtml). In addition, we expect that image-guided percutaneous therapies will soon become available (studies on laser and radiofrequency ablation as well as cryotherapy are on going), so

that the continued availability of stereotactic breast imaging is crucial to the development of less-invasive, less-painful and less disfiguring cancer treatment modalities.

We understand that unrestrained growth in imaging services is a major source of concern in the 2007 proposed rule. We believe, however that stereotactic breast imaging is different from other purely diagnostic imaging studies. Instead, it is an integral part of a biopsy procedure, and as such has been restricted in its growth. The Medicare volume data from the AMA RUC database demonstrates that the increase in 19103 "percutaneous vacuum assisted needle biopsy of the breast," which is the biopsy technique used in stereotactic procedures, almost exactly parallels the decline in 19125 "open surgical biopsy with needle localization" which is the historical surgical alternative to needle biopsy:



Paradoxically, the proposed changes will not only diminish access to this technology, but also increase the costs of care. If percutaneous stereotactic biopsy is not available in the non-facility setting, one of two alternatives will remain: The patient will be able to undergo needle biopsy in a facility, with the additional costs and exposure, or will undergo needle localization open surgical biopsy, at several times the expense. There is a point beyond which cost shifting and good will gives way to simple financial survival, and stereotactic biopsy will simply not be possible in the non-facility setting if the proposed reductions go into effect.

The magnitude of the reduction for 76095 is so significant, that we wonder whether it is possible that a simple methodological error is the cause. This could be the result of a simple error in calculation, or from flawed assumptions concerning practice expense inputs. Breast surgery is included within the field of general surgery, but, we believe, is associated with a very different practice expense. This includes not just the specialty equipment noted above, but additional indirect costs due to the psychological and emotional aspects of breast cancer care. We are aware that the RUC has called for

specialty societies to re-survey for their specialty specific practice expense, and we are sensitive to how this may have affected some aspects of the proposed rule. A survey of dedicated breast practices will be conducted later this year. At this time, we recommend that implementation of the 2007 proposed rule be postponed for both 19103 and 76095 until more accurate practice expense data becomes available.

We would like to thank you for this opportunity to express these concerns, which we believe will have a significant adverse impact on patient access to state-of-the-art breast care. Because this issue is so crucial to delivery of care in breast surgery, we would like to request a meeting with your staff to discuss in greater detail the implications of the proposed reductions.

Yours truly,

Helen A. Pass, MD
President, American Society of Breast Surgeons

Eric B. Whitacre, MD

Eric B. Whitacre, MD
Secretary/Treasurer, American Society of Breast Surgeons

cc: Leslie Norwalk, Acting Administrator
Centers for Medicare & Medicaid Services

Cynthia Brown
American College of Surgeons
Director, Division of Advocacy and Health Policy

Charles Mabry, MD, FACS
American College of Surgeons
Board of Regents

NEPHROLOGY VASCULAR LAB
NEPHROLOGY ASSOCIATES, P.C.

Jerry W. Jackson, M.D.
James L. Lewis, M.D.
John R. Brouillette, M.D.
Jason J. Tsai, M.D.

October 5, 2006

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

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:

I am a Radiology Technologist specializing in interventional nephrology, and a leader in outpatient vascular access care. I am employed with RMS Lifeline also known as Nephrology Vascular Lab in Birmingham. We have a patient population of over 850 patients. In our facility there are 10 employees and 4 physicians. I have served here for the past 8 years. In these past 8 years, we have performed over 13,000 procedures.

Interventional nephrology is one of the newest and most rapidly growing specialties in medicine. We are on the leading edge of advances in imaging-guided minimally-invasive medicine. Procedures performed by interventional nephrologist -- through small catheters and other devices under radiological imaging -- are often less costly and significantly less invasive than alternative surgical therapies.

One of the chief missions of our vascular lab is to increase the placement and longevity of AV fistulas in our dialysis patient population. Over the last several years we have developed protocols for pre-operative mapping in patients approaching dialysis. Over 300 such procedures were performed in our lab in 2005. This serves to increase the number of fistulas initially placed by surgeons and is in keeping with DOQI Guidelines and the Fistula First Initiative. We also have developed the ability to do all manner of fistula maturation and maintenance procedures to keep these fistulas working in the dialysis clinic. As recently as 2003, only 13% of our cases involved patients with fistulas. Currently nearly a third of them do.

In addition, our outpatient vascular access center has consistently outperformed traditional benchmarks along two key criteria: patient satisfaction and clinical success/safety. Historically, our patient satisfaction scores have averaged 87% while maintaining a 97.6% clinical success rate and a low 2.48% complication rate.

In light of our track record of clinical success, I am writing today to express my grave concern with CMS 2007 Update to the PE RVUs for Interventional Radiology CPT codes.

I urge CMS to reconsider the proposed 2007 cuts to the PE RVUs for interventional radiology stemming from the changes to the PE calculation methodology.

201 London Parkway, Suite 500
Birmingham, AL 35211

(205) 942-9896
Fax (205) 942-9948

I fully understand CMS needs to make difficult budgetary decisions to maintain the solvency of the Medicare trust fund. However, we have serious concerns with the proposed practice expense reductions for interventional radiology. Per Table 7 of the CMS-1321-P, the combined 2007 impact of Work and PE RVU Changes for Interventional Radiology is estimated to be -14%, the third hardest hit specialty.

A significant portion of our center's vascular access procedures involve imaging, and as such, these reductions will have a dramatic impact on our ability to treat patients. We would not want to see CMS inadvertently limit patients' access to convenient, efficient and clinically successful vascular access care. Their only alternative is to go back to the hospital for these services. This result is truly unfortunate since we can provide these services in their entirety for on average 30% - 40% of hospital rates.

In addition, we are concerned that the reductions did not adequately take into account the costs of providing imaging services. For example, a significant driver of costs is tied to the equipment. The [redacted] system does not have a specific mechanism for capturing those costs thus they may have been overlooked.

In closing, I thank you in advance for your thoughtful consideration of these comments.

Respectfully,

Terrie Blow, RT

240

THE FOOTHILL CENTER FOR WELLNESS & PAIN MANAGEMENT
CHRISTOPHER J. CHARBONNET, M.D.
HILARY J. FAUSETT, M.D.

1505 WILSON TERRACE, SUITE 240
GLENDALE, CALIFORNIA 91206
(818) 241 - 7246

October 6, 2006

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

Re: CMS 1321-P

Dear Dr. McClellan,

Please do not allow such drastic cuts to the reimbursement for Interventional Pain procedures.

The current proposal of cuts in reimbursement of up to 38% is unreasonable. It is especially poorly conceived because it discourages the physician from providing these procedures in the office. The current reimbursement levels allow us to offer to our patients a safe alternative to a facility based procedure. With the loss of this incentive, more procedures will be done in facilities, and this will only cause an increase in total costs.

Even in this day of managed care and cost containment, there are still some physicians with office based practices doing things the "old fashioned way:" with kindness, courtesy and an attention to the patient as an individual.

Please do not allow such draconian cuts. Please consider what a small part of the total C.M.S. budget actually goes to physicians in solo practice. We do not have the lobbying power of the pharmaceutical companies or managed care providers. But we are the ones caring for the older or ill Americans. We, the physicians, are providing the services that you may one day need. Please stop and consider all that is lost when we move from the familiarity of our local physician's office to the centralize facility. We all deserve to be cared for in a familiar environment. Please do not take that away.

I am one of many well trained and hard-working Interventional Pain Physicians. Please come and visit my office. Please watch how we care for our patients. It will make you a strong supporter of office based care.

Please impose a moratorium on these fee cuts to ensure that Medicare patients will have continued access to interventional pain services. And I look forward to your visit.

Hilary Fausett, M.D.

241

October 2, 2006

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1321-P
P.O. Box 8015
Baltimore, MD 21244-8015

To whom it may concern,

I am a pain management doctor in Dallas, Texas with approximately 50 to 60% Medicare patients in my clinical practice. Recently, I was made aware of the severe cuts in reimbursement for many of the office procedures I perform including epidural steroid injections, sacroiliac injections and facet injections. While these procedures are palliative, they nonetheless are essential to keeping my patients functional in their daily lives. This increased activity often helps with comorbid conditions such as diabetes, hypertension and obesity.

If these cuts pass I will be forced to drastically reduce the number of Medicare patients I see at my current clinic location. I likely will be forced to open a clinic in another area with a better payer mix. The result will be less access for seniors to the care they need.

Thank you,

William Moore, MD

William Moore, MD

P.O. Box 821507 * North Richland Hills, Texas 76182

242

Jerry D. Westerfield MD
Russell County Hospital
153 Dowell Road
Russell Springs, Ky 42642
October 06, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P
P.O.Box 8015
Baltimore, MD 21244-8015

RE: BONE MASS MEASUREMENTS
Fed. Reg., Vol.71, NO.162/August 22, 2006

In addition to wide general use in hospitals and imaging centers, QCT has been the mainstay technology used for bone density measurements in radiology departments located in smaller communities throughout the United States over many tears of use in both testing for osteoporosis and assessment of drug therapies. In many of these towns, central DXA is not an economic alternative. To allow QCT bone density tests but to insist that follow up studies be done on DXA is a disservice to the medical institutions and patients of these communities as well as to prove to be useless since QCT and DXA exams can not be readily compared.

- Patients will have to bear the cost and inconvenience of having to travel to another location for follow up studies.
- The Medicare cost is virtually the same if the follow up is done by QCT or DXA
- There is good evidence that QCT is more likely to accurately diagnose low bone density-particularly in the elderly population
- Many scientific, peer reviewed, studies confirm that assessment of drug therapies is more readily detected by comparisons of trabecular bone by QCT than by integral projection methods used by DXA
- Most importantly, using DXA as a follow up to QCT will not be valid because each modality measures different tissues and uses different techniques (Volumetric verse areal-projection). There is near unanimous agreement among experts in the field that follow up DXA exam would be meaningless-each modality must followed by the same test.

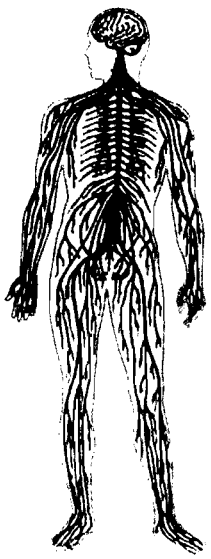
The proposal to regulate all follow up testing in bone density measurement DXA amounts to a virtual endorsement by CMA to create an exclusive franchise to DXA in assessment of bone density therapy response measurement when there is ample published scientific evidence that DXA may be a poor choice in this role and may also be misused in attempting to relate follow up data originated by QCT exams.

Input from Scientists who are not DXA users and who understand the physics of these devices is missing. It would be a disservice to current patients being followed by QCT and/or the many future patients who can better be studied with this highly reliable technique.

We use QCT, measurements here at Russell County Hospital and feel our values are highly accurate. If this proposed change you suggest is made then you will be doing many patients here in South Central Kentucky a disservice.

Sincerely Yours,
Jerry D. Westerfield MD

Jerry D Westerfield, MD



243

CCPM

Chattanooga Center for Pain Medicine

233 Ring Road • Hixson, TN 37343

October 2, 2006

Mark B. McClellan, M. D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
CMS-1321-P
P.O. Box 8015
Baltimore, MD 21244-8017

Re: **CMS 1321-P**

Dear Dr. McClellan:

I am an interventional pain physician, working too many hours every week and month attempting to take care of patients, and to earn enough money to cover my high overhead medical practice. Implementation of the proposed reduction in fees to physicians for interventional pain services will be the coup de grace of medical services for the medicare recipient in my practice. I ask that a hold be placed on the reduction, and reevaluation of the real cost of practice of pain medicine, and an appropriate physician reimbursement be reconsidered.

This recommendation is not simply so that I can make more money, it is to maintain the availability of medical care for American's medicare beneficiaries, many of whom have already experienced significant difficulty in finding a physician who will accept them.

Thank you.

Sincerely,

Roger Catlin, M.D.

Roger W. Catlin, M.D., DABPM
Medical Director

RWC:dc October 2, 2006

244

IMA

INTERNAL MEDICINE ASSOCIATES, P.C.
PROFESSIONAL CORPORATION

October 6, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1512-PN
P.O. Box 8014, Baltimore, MD 21244-8014

To whom it may concern,

I am writing this letter in support of the proposed increase in work RVUs for E/M services. I am a Board Certified Internist practicing in a community setting. I have seen a tremendous increase in complexity over the past several years in treating Medicare patients. Reasons for this include the following: increased number of treatment options, burden of supervising a widening array of services ie physical therapy, home health, hospice, etc), and increased complexity associated with the new myriad of pharmacy benefit companies related to Medicare part D. We are the point men in dealing with the whole patient and keeping them on track. We have become steadily discouraged as many of our peers are leaving the field and few are signing up to take their place. This is occurring because of several reasons, but is accelerated by the poor reimbursement for the difficult and exhausting work that we provide. If changes in compensation are not enacted soon, you will witness a serious crisis in primary care that will take a decade or more to fix. Physicians should be compensated for the complexity and time that it takes to take care of a Medicare patient in 2006. Please resist changes to decrease the change in work RVUs, as this is long overdue.

Sincerely,

Jon Commander, M.D.

MEDICAL ARTS CENTER
OF EAST ALABAMA

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245

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C. RITCHIE SPENCE, M.D.
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October 4, 2006

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

Re: **"REASSIGNMENT AND PHYSICIAN SELF-REFERRAL"**

To Whom It May Concern:

Urology San Antonio is a 21-person urology group in San Antonio, Texas. We specialize in the provision of urological surgical and medical services, such as the diagnosis and treatment of prostate cancer. Our practice provides a full array of urological care to men, women and children of all ages, including a significant number of Medicare beneficiaries.

We are writing to express our deep concern over sections of the CMS proposed physician fee schedule rule that address reassignment and Stark rules relating to laboratory services.

In order to assure that we could provide the best and most cost efficient laboratory services, our practice began working with a company called Uropath in 2003 to develop, implement and manage a specialized urological laboratory facility. Unfortunately, adequate specialized uro-pathology services were not available locally. We own the lab located in San Antonio and Uropath provides the management services essential to providing world class specialty pathology.

Uropath has many benefits that the US government is looking for. It improves quality of care while decreasing overall costs. Our Uropath lab is staffed by a world class GU pathologist who spent twelve years at the Health Science Center as head GU Pathologist before taking on his role as lead GU Pathologist for our lab. His only responsibility is the reading of prostate biopsies. He does not read any other tissue specimens. His backup in case of discrepancies is Dr. William Murphy, a world renowned GU Pathologist with specific expertise in prostate pathology. As can be gleaned from the table below, the number of prostate biopsies performed by our group has decreased over the past three years.

Year Visits	Office Visits	No. of Biopsies	Rate/1000
2001	60,619	1663	27.4
2002	63,101	1735	27.5
2003	68,500	1508	22.0
2004	69,336	1430	20.6
2005	76,500	1595	20.8
Jan-June 2006	40, 727	719	17.7

This world class prostate specific pathology expertise has actually decreased the number of prostate biopsies done with our group even though the number of physicians in our group increased by three, therefore saving the US government and Medicare money. This is not just budget neutral, but actually budget beneficial.

It is obvious that the issue of Uropath vs. large corporate labs is a competitive issue and not a quality issue, and if examined closely by the CMS, costs are improved and quality is better.

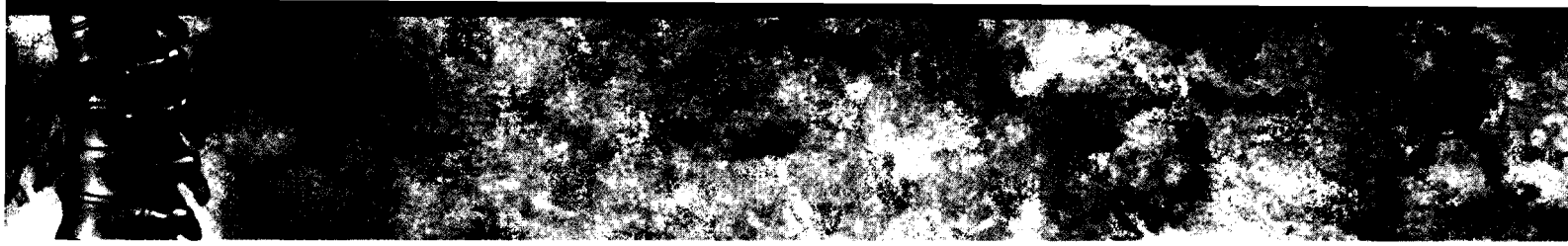
As part of the physician fee schedule rule issued on August 22, CMS has proposed two rules related to diagnostic services that, if adopted, would force us to drop our relationship with Uropath and close the specialized lab the company manages for us.

According to CMS, the whole purpose of the changes is to outlaw the business structure of Uropath and similar companies. However, CMS has not offered any evidence of fraudulent or abusive laboratory practices, inappropriate billing or poor quality to justify their actions.

This proposed rule is not needed. We request that you contact the CMS Administrator and ask him to withdraw the proposal unless, and until, the agency publicly provides evidence demonstrating a need for this proposed action.

We appreciate your careful and prompt consideration of our request.

Sincerely,



Spinal Diagnostics, PLLC
Interventional Pain Management & Diagnosis

Arthur S. Watanabe, M.D.
Medical Director

September 29, 2006

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-1321-P

P.O. Box 801

Baltimore, MD 21244-8015

Dear Sirs:

I am a solo private practice physician who has just opened a new office. I believe in personalized one-to-one healthcare for my patients and do not believe in the bureaucratic corporate care provided by large medical groups, clinics and hospitals.

I do not have the luxury of spreading my costs among a number of physicians as corporate clinics do nor do I have the luxury of cost shifting as hospital bureaucracies do. I struggle to make ends meet and pay my employees a salary. I do not yet draw a salary from my practice.

Since 70-75% of my patients are Medicare, your proposed cuts for physician services will threaten to place my practice in jeopardy of bankruptcy. The larger corporate practices of medicine and the bureaucratic hospitals will be able to absorb these cuts without much difficulty. Some corporate practices of medicine will likely move towards excluding Medicare patients as many have with Medicaid patients.

As a solo physician trying to provide personalized care to Medicare beneficiaries, I hope you will reconsider in your decision making processes that your cuts will hurt the little physician while hardly touching the profit driven corporate practices of medicine and hospital bureaucracies and potentially reduce access to care for all Medicare beneficiaries.

Respectfully yours,

Arthur S. Watanabe, M.D.

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Orlando Cardiovascular Center
Affiliated with Orlando Regional Healthcare System

October 5, 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: C4-26-05
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 the Orlando Cardiovascular Center, LLLP, 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

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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 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 that 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.

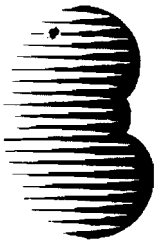
We thank you for the opportunity to describe our concerns about the proposed rule, specifically as it relates to payment for cardiac catheterization-related procedures and the development of standards for centers that perform these procedures on an outpatient basis.

Sincerely,

Irwin Weinstein M.D., F.A.C.C.

Irwin Weinstein
Medical Director

248



American Society of Pediatric Nephrology

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aspn@northwestern.edu
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October 9, 2006

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

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

Dear Administrator McClellan,

The American Society of Pediatric Nephrology (ASPN) is a professional society composed of pediatric kidney specialists whose goal is to promote optimal care for children with renal disease and to disseminate advances in the clinical practice and basic science of pediatric nephrology. The ASPN currently has over 600 members, making it the primary representative of the pediatric nephrology community in North America. Unlike previous fee schedules, the Proposed Rule for Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year (CY) 2007 (Proposed Rule) does not include pediatric specific ESRD proposals. Therefore, ASPN would like to take this opportunity to highlight comments made by others in the kidney community, which the Society feels are important to promoting quality care for patients with kidney disease. These include:

1. ASP issues: Given the importance of separately billable drugs to the kidney care community, it is important to ensure that reimbursement rates are stable and predictable. We encourage the Agency to be more direct in the Final Rule and state expressly that for CY 2007 the Secretary will reimburse separately billed drugs at ASP+6 percent. This statement would be consistent with the statutory mandate and provide needed clarity to the community.

2. Clarify the budget neutrality calculation for the geographic wage index: As CMS continues to implement the geographic wage index, CMS is encouraged to examine the effect of these changes on dialysis facilities. The calculation of the budget neutrality factor for the geographic wage index is not transparent in the Proposed Rule. Dialysis facilities need to

understand that the budget neutrality factor is being calculated correctly. Small differences have a large impact on the payments to these facilities. Thus, ASPN urges CMS to provide the data and methodology it used to calculate the budget neutrality factor in the Final Rule to allow the community to assess the impact of the proposed changes.

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

ASPN supports the Agency's decision to reimburse for medical nutritional therapy, diabetes self-management training, and blood flow monitoring. These are important preventive treatment options that can have a positive impact on the ability of physicians, facilities, and patients to slow the progression of and better manage kidney disease. We encourage CMS to continue its efforts to provide coverage for these and other services that can help slow the progression of kidney disease and help patients who have kidney failure have a higher quality of life.

Patients with chronic kidney disease who require hemodialysis must obtain vascular access for dialysis. For long-term hemodialysis patients, an AV fistula is the best type of access. However, the ultimate treatment for most pediatric patients with end-stage renal disease is not dialysis, it is kidney transplantation. Thus, dialysis is often intended as a temporary treatment, justifying the use of a catheter that is easily removed when the patient is transplanted in less than a year and no longer needs dialysis. For those children who require hemodialysis for extended periods of time, such as those who have already experienced failure of a kidney transplant or who are highly sensitized to the donor pool, improving rates of permanent vascular access may be beneficial.

Ultimately, monitoring a patient's access, whether it is a fistula, graft, or catheter, is extremely important to assuring that the patient can receive life sustaining dialysis treatments. ASPN supports the Agency's efforts in promoting blood flow monitoring services, and encourages appropriate coverage of these services.

Thank you in advance for your consideration of our comments. ASPN stands ready to work with CMS in its efforts to improve the quality of care provided to the nation's pediatric ESRD patients. Please contact Jennifer Shevchek at 202-546-4732, or by email, jshevchek@dc-crd.com, if you should need additional information or clarification regarding ASPN's comments.

Sincerely,

Sharon P. Andreoli, M.D.
President

CC: Dr. Barry Straube
Brady Augustine

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

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

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

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

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

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

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

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

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

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[3] SSA § 1847A(d)

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

[5] SSA § 1847A(d)(5)(b)

Hoffmann-La Roche Inc. 1425 K Street, N.W. Suite 650 Washington, D.C. 20005 Federal Government Affairs Tel 202-408-0090 Fax 202-408-1750

MAYO CLINIC

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Rochester, Minnesota 55905
507-284-2511

October 3, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P
P.O. Box 8015
Baltimore, Maryland 21244-8015

We appreciate the opportunity to comment on the Proposed Rule of August 22, 2006 regarding changes to the Physician Fee Schedule for calendar year 2007. We offer the following comments for your consideration.

DRA PROPOSALS

We appreciate the opportunity to comment on Section 5102 of the DRA of 2005 regarding payments for imagining services. Although we do not agree with the concept of comparing two payment mechanisms that are unlike in their composition, we recognize that CMS is bound by legislation that enacted the provision.

Nevertheless, we do not believe it is appropriate to use carrier-priced services as a proxy for the RBRVS relative value. These services have not yet been incorporated into the national PPS for physicians because of the variability in costs physician practices are experiencing to provide them. We do not agree that carrier-priced services fall within the scope of Section 5102. CMS has no way of removing the geographic adjustment amount from a carrier --priced service as required in subsection (4)(A)(i) which states "(i) the technical component (including the technical component portion of a global fee) of the service established for a year under the fee schedule described in paragraph (1) without application of the geographic adjustment factor described in paragraph (1) (C)...." Since there is no national RVU for carrier-priced services, there is no way to remove the "geographic adjustment factor" related to each locality's carrier-price service.

We also recommend that CMS remove services that are packaged under the hospital outpatient PPS and have no additional APC payment but do have a TC amount under the Medicare PFS. The list of packaged services under the APC payments will vary from year to year and we believe it is inappropriate to not make a payment for the service under the Medicare PFS as there is no packaging of the service into another procedure.

Based on the above, we recommend CMS exclude carrier-priced services from this proposed rule as they do not meet the definition of how to identify the geographically adjusted amount to compare with the hospital PPS amount.

We support the views of the American College of Cardiology, the American College of Radiology and other professional societies regarding the definition of medical imaging and recommend the following:

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

SERVICES INCLUDED IN ADDENDUM F

The preamble to the proposed rule states "We excluded all HCPCS codes for imaging services that are not separately paid under the OPPS since there would be no corresponding OPPS payment to serve as a TC cap." However, Addendum F includes 93555 and 93556 (Imaging, cardiac catheterization). Under OPPS imaging guidance is bundled into the payment of cardiac catheterization, so there is no separate OPPS payment corresponding to either 93555 or 93556. We believe CMS included these two codes in error and we urge that they be removed from Addendum F.

CLARIFICATION OF THE TERM "PHYSICIAN" OR DOCTOR OF MEDICINE OR OSTEOPATHY

We would also like to take this opportunity to provide information on the following unsolicited comment.

We respectfully request CMS clarify when the term "physician" or "doctor of medicine or osteopathy" (MD/DO) is used to refer to the provider type existing Medicare regulations and manual instructions. Specifically, when is it appropriate for a non-physician practitioner (NPP) to order and/or provide services when the terminology states physician or MD/DO.

In recent years, CMS regulations and instructions have expanded on the term physician to also include NPPs in conversation information. However, previous as well as some new regulations and instructions continue to use the term physician or MD/DO without including NPP. CMS and Medicare contractors have varied in interpretation and guidance when reference to provider type does not include NPP.

Examples

1. CMS provides foot care coverage in the presence of a systemic condition. CMS manual instruction further outlines foot care coverage when the patient is under the care of a doctor of medicine or osteopathy who documents the condition [Medicare Benefit Manual, Chapter 15, §290]. The guideline outlining care under an MD/DO is only in CMS manual instruction and not in regulation [42 CFR, §422.15]. It is prudent to expect patients with systemic conditions be under the

care of NPP when the NPP is legally authorized to perform the service by the State in which the services are performed.

2. CMS guidelines for Medical Nutrition Therapy (MNT) state that a treating physician is to order MNT, where another guideline for Diabetes Self Management Training (DSMT) states that a physician or NPP may order this service [42 CFR §410.132, 42 CFR §410.141]. These inconsistent guidelines have created much confusion and inconsistent application by Medicare contractors. It is prudent to expect patients with diabetes or renal disease to be under the care of NPP when the NPP is legally authorized to perform the service by the State in which the services are performed.

Finally, we respectfully request that CMS allow reimbursement for services performed or ordered by NPPs which the NPP is legally authorized to perform by the State in which the services are rendered. We also ask CMS clarify in regulation and instructions when the term physician or MD/DO includes NPPs for the examples referenced as well as other Medicare instruction.

Thank you for the opportunity to comment on the proposed rule. Please feel free to contact either Desiree Ramirez (904) 953-0579 or me at (507) 284-4627, if you have any questions.

Very truly yours,

Ronald W. Grousky
Director Medicare Strategy Unit

RWG

cc: Donald Hertel
Brenda Mickow
Desiree Ramirez

251

iCAD

October 3, 2006

Mark McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8015
Baltimore, MD 21244-8015

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

Dear Dr. McClellan:

On behalf of iCAD, which is headquartered in Nashua, NH and develops, manufactures and markets Computer Aided Detection (CAD) solutions for mammography that enable healthcare professionals to identify breast cancer, we appreciate the opportunity to comment on the Proposed Notice published by CMS in the *Federal Register* of August 22, 2006 which describes proposed changes to the relative value units used to establish payment for services to Medicare patients under the Physician Fee Schedule.

We are extremely concerned about the proposed impact of these changes on Medicare payment for Computer Aided Detection (CAD) systems used with mammography (Codes 76082 and 76083)[1].

We understand that CMS is proposing a major change to calculating practice expense relative value units (RVUs). The impact to global payments for codes 76082 and 76083 is projected to be a decrease of about 39% by 2010. Another significant concern is the projection that the conversion factor will decrease by 5.1%, resulting in an across-the-board reduction in all Medicare payment rates in 2007.

CAD systems for mammography are important diagnostic tools which enhance the ability of mammography to detect breast cancer in its early stages. The use of CAD requires the purchase and maintenance of medical equipment which is operated by certified mammography technologists. The process of digitizing images for CAD is time and labor-intensive. In clinical studies, iCAD has been shown to find up to 72% of the cancers that had been missed on the previous mammogram exam.

We are concerned that payment reductions of the magnitude outlined in the Proposed Notice may have an adverse impact on the overall quality of mammography services

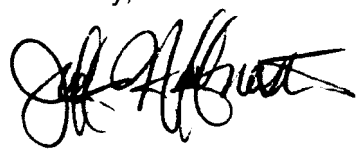
[1] 76082 Computer aided detection (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation, with or without digitization of film radiographic images; diagnostic mammography

76083 Computer aided detection (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation, with or without digitization of film radiographic images; screening mammography

provided to patients at the very time that the federal government is seeking to improve quality through various quality-related initiatives.

We ask that CMS impose a delay for at least one year so that the impact of the various changes in the physician fee schedule can be assessed.

Sincerely,



Jeff Hoffmeister, M.D. MSEE
Vice President, Medical Director

2572

CHRONIC PAIN MANAGEMENT

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Stephen D. Watson, M.D., Ph.D.
Board Certified Anesthesiologist
Board Certified Pain Management

Andreas H. Syllaba, D.O., NM/OMM
Board Certified Neuromusculoskeletal Medicine

29 September 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P
P.O. Box 801
Baltimore, Maryland 21244-8015

Dear Sirs,

I am writing in reference to the proposed CMS changes in reimbursement for physicians in the office setting. I am originally an anesthesiologist but practicing full-time as an interventional pain physician for some 7 to 8 years. I just moved my office on Memorial Day of this year from my original office to a relatively new building, some 7,000 sq. feet, which has been refurbished for me and my staff.

My office-based practice is the only comprehensive pain medicine practice in this city and several counties. I do all of the minor and major procedures involved in managing pain including epidurals, selective nerve injections, facets, stimulator placement, vertebroplasty, discectomy, etc. I am the only pain medicine physician in my city that practices full-time, exclusive pain medicine. Clark County has, as you know, as very high percentage of Medicaid and, indeed, Medicare patients. We are the only practice in the city that takes care of Medicaid patients. The hospital-based anesthesiologists are happy to perform their short list of blocks on these patients but they do not and will not manage long-term patients with Medicaid that have chronic pain and need chronic medications and other care. I am the only physician in pain medicine here caring for those individuals.

When I read the ASIPP article about the proposed CMS cuts, I was absolutely devastated. You need to understand that because of several convergent factors including a dramatically increased building lease cost this summer, I took no salary whatsoever for 3 months this summer. My senior staff took that same hit. I believe that we are seeing a gradual upturn in the practice income as we make slow inroads into the practice patterns of physicians in this community, Dayton, Tipp City, Troy and others. I believe that my commitment as a Christian and a physician to giving the most up-to-date and effective care to all comers is slowly resulting in a greater number of referrals and hence more income. Needless to say, however, my personal income at this juncture is markedly decreased from the norm associated with my specialty. My personal income, in comparison to others who have made not only the professional commitment but also the business commitment in investing so heavily in an attractive office, is even more miserable by comparison. As I understand the proposed cuts, the typical "bread and butter" pain medicine procedures performed in the office setting would be hit with a 30-40% cut in reimbursement rates. Even the vertebroplasty procedure, 22520-22522, that is a very highly technical and potentially life-threatening procedure, would sustain a 20% cut in reimbursement while still requiring me to pay approximately $700 for the equipment and cement necessary to accomplish the procedure! That one procedure would become very difficult to rationalize because of the time input necessary with the diminished reimbursement. In addition, you should know that I currently lease a $225,000 OEC 9800 fluoroscope with digital subtraction angiography to do my procedures. This is the latest generation machine, the best that I could find and represents my personal commitment to have the very best equipment to perform the very safest procedures on my patients. No one in Springfield or even Dayton uses the equivalent equipment to perform procedures at the very latest and safest technical level. Needless to say, this $3500 lease enters into my office expenses in a major way!

In summary, you need to understand on an individual level that I will be out of the private practice of interventional pain medicine should the CMS proposals be implemented. You must realize that financially, it would be utterly futile for me to try to keep the practice open with a 30-40% decrease in reimbursement. You need to know that Aetna actually reimburses pain medicine <u>less</u> than Medicare rates! That means that we probably run about 60-65% of our 15-20 new patients every week having one of the three worst paying insurances. You might think that my personally closing the doors would not be a problem for anyone else. Remember that I have been and

remain the lone full-time pain medicine physician in the Clark, Champaign, Madison and Green Counties practicing in a private office. All of the rest of those doing "pain medicine" either do so part-time or practice in a hospital. They have no personal investment in the community or the practice as pain practitioners. You should also remember that I am the only one seeing and treating chronically the Medicaid patient population in these same counties. If I go, they have no one. If these cuts are not abandoned, pain medicine will of necessity return to a hospital-based specialty with physicians working only as they have spare time in between anesthesia cases to do so. This will diminish both the quality and the comprehensiveness of the care rendered. None of that will be good for the patient population. Please understand my personal concern about my personal practice. I certainly understand your position means looking at the entire picture of health care costs. Whatever you can do to stop these deleterious cuts in reimbursement for the office-based pain physician would be "life-saving" for me and many others, directly and indirectly. Please feel free to contact me if you would like any more specific information.

Sincerely,

Stephen David Watson, M.D., Ph.D.

253

Robert H. Aki, M.D., F.A.C.S.

Diplomate American Board
of Surgery

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September 20, 2006

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Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

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

Dear Administrator:

Thank you for the opportunity to provide comment on the proposed revisions to the Physician Fee Schedule for 2007 and especially to voice concern regarding the impact these proposed rates will have on breast conservation therapy in those patients diagnosed with breast cancer.

The changes as proposed would have a significant impact on my practice, and particularly on the treatment options I would be able to present to my breast cancer patients. Access to partial breast irradiation which is delivered in the course of 5 days as opposed to whole breast irradiation over 6-7 weeks is an important treatment option for these patients. CMS has proposed drastic cuts in the RVUs assigned to the global fee schedule for breast brachytherapy, making this option almost impossible to preserve. As currently planned, CMS is scheduled to reduce each year in the transition period and the total reduction for this treatment is -31% as illustrated in the table below.

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

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

There are several RVUs that are decreasing by more than 5%. I recommend that CMS implement a floor of 5% reduction and this floor should remain in effect during the required time for CMS and the RUC to re-evaluate the data applicable to these RVUs, specifically, breast brachytherapy. I may be willing to

provide data to my specialty society so that they may in turn provide the necessary data to CMS and the RUC in order to make a more informed proposal in the readjustment of these RVUs applicable to breast brachytherapy.

Sincerely,

Robert Aki, MD
605 W. Central Road, #201
Arlington Heights, IL 60005

cc. Carolyn Mullen, Deputy Director, Division of Practitioner Services
Helen Pass, MD, FACS, American Society of Breast Surgeons
Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

254

The Alliance for Better Bone Health

October 6, 2006

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

RE: BONE MASS MEASUREMENT TESTS

CMS Should Adopt the Proposal to Revise the Definition of Bone Mass Measurement (§410.31(a)) and Make Conforming Changes to Conditions (§410.31(b)) and Standards on Frequency (§410.31(c)) for Coverage, with Cautionary Considerations.

The Alliance for Better Bone Health appreciates CMS' efforts to incorporate scientific advances into its coverage policies and supports the proposed changes to Medicare's coverage of bone mass measurement tests, with cautionary considerations.

Medicare beneficiaries are at risk of bone disease and fracture, and bone mass measurement is a valuable tool to diagnose patients that may be at risk and allow for appropriate interventions. The technology for conducting a bone mass measurement has changed, however, and single-photon absorptiometry (SPA) is not considered an accurate predictor of fracture risk. Rather, the medical community generally agrees that dual energy x-ray absorptiometry (DXA) is more precise, safe, and is lower in radiation exposure than SPA. We believe CMS' proposal to revise the definition of "bone mass measurement" to remove coverage of SPA is consistent with current medical literature, and we support the proposed revision.

Further, the Alliance for Better Bone Health supports CMS' proposal to change the conditions of coverage and standards on frequency of bone mass measurement to encourage the use of DXA of the axial skeleton for confirmatory baseline tests (§410.31(b)(3) and §410.31(c)(2)(ii)) and for monitoring a patient's response to therapy (§410.31(b)(2)). DXA tests provide useful data on whether a patient is adhering to medication and responding to therapy. We caution, however, that the medical literature does not support the use of DXA or other bone mass measurements to assess efficacy of osteoporosis therapies. (Cummings et al. Am. J. Med. 2002;112:281-289; Sarkar, et al. *JBMR* 2002; 17(1): 1-10; Watts et al, JBMR, 18 (Suppl 2): SU334 (2003); Watts et al. J Clin Densitom 2004;7:255-261.) We recommend that CMS clarify that bone mass measurement is not appropriate for monitoring the efficacy of osteoporosis therapies in preventing bone fractures.

CMS Should Adopt the Proposal to Revise the Definition of Beneficiaries Who May Be Covered (§410.31(d)).

We support CMS' proposal to lower the threshold for BMM coverage for individuals receiving or expecting to receive glucocorticoid therapy. A threshold equivalent to 5 mg/d prednisone per day for 3 months or longer will help initiate prevention in patients at high risk for fracture. We urge CMS to implement this proposal in its final rule and to consider further lowering the threshold to 2.5 mg/d (Van Staa TP et al, J Bone Miner Res 2000;15(6) 993-1000).

CMS Should Clarify that the National Coverage Determination (NCD) Process Proposed in (§410.31(f)) Is An Additional Avenue for Coverage of New Technologies.

Although we support CMS' proposal to cover DXA, we request that CMS give Medicare carriers discretion to cover new and advanced technologies that become available to screen for risk of fracture rather than

requiring that such technologies go through the national coverage determination (NCD) process. The NCD process can often be long and cumbersome, and requiring that new technologies be added through this process could prevent beneficiaries from having access to these new and better technologies for some length of time.

We note for CMS that the World Health Organization (WHO) is currently in the process of developing a standardized methodology for determining fracture risk. Although DXA is one tool for measuring fracture risk, there are other clinical risk factors that also are important to the evaluation, specifically to determine which patients are likely to best respond to treatment. Employing the risk assessment methodology developed by the WHO will lead to better patient outcomes by helping providers better identify those patients who should be on therapy. The Alliance for Better Bone Health asks that upon WHO releasing this assessment, CMS recognize this fracture risk assessment, as well as DXA, for coverage under Medicare Part B.

We also are deeply concerned that CMS' proposal to encourage the use of DXA will be of little benefit to Medicare beneficiaries if CMS' proposal to change the methodology for calculating practice expense (PE) Relative Value Units (RVUs), published on June 29, 2006, goes into effect. The proposal may have a devastating impact on providers of bone densitometry, resulting in a 71 percent drop in reimbursement for central DXA (Current Procedural Terminology (CPT) code 76075) when fully implemented over the next four years. These cuts in reimbursement may significantly reduce Medicare beneficiaries' access to care in the physician office where DXA services currently are being delivered. We urge CMS to revise its proposed changes to ensure adequate reimbursement for this important tool for measuring the risk of bone disease and fracture.

Thank you for considering these comments. Please do not hesitate to contact us with any questions.

Sincerely,

Hugh O'Neill
Vice President
Sanofi-aventis U.S.
Bridgewater, NJ 08807

Alison B. King, Ph.D.
Public Policy & Government Relations
Procter & Gamble Pharmaceuticals
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255

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

Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B

Introduction:
On behalf of CLMA, the Clinical Laboratory Management Association, an organization of more than 4,600 clinical laboratory professionals and consultants representing hospitals, independent clinical laboratories, physician office laboratories, skilled nursing facilities, and medical device companies, I am writing in response to the August 22, 2006 *Federal Register* notice, 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).
The proposed rule published on August 22, 2006 addresses certain provisions of the Deficit Reduction Act of 2005, as well as makes other proposed changes to Medicare Part B payment policy.
CLMA's comments address issues in the following sections:

1. **Public Consultation for Medicare Payment for New Outpatient Clinical Diagnostic Laboratory Tests**
2. **Proposed Payment for New Clinical Laboratory Diagnostic Test-Crosswalking and Gapfilling**
3. **Other Laboratory Issues - Quality**
4. **Other Laboratory Issues - Blood Glucose Monitoring in SNFs**
5. **Other Lab Issues- Proposed Clinical Diagnostic Laboratory Date of Service (DOS) for Stored Specimens**

Public Consultation for Medicare Payment for New Outpatient Clinical Diagnostic Laboratory Tests:
Section 942 of the "Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)" requires CMS to codify the process for payment for new clinical laboratory tests through public input. In practice the agency has been using procedures that permit public consultation for payment determinations for new tests since 2001. Currently the agency meets the requirements of Section 942 by posting a list of new laboratory tests for the next year on the CMS website, publishing a Federal Register notice and convening a public meeting to receive comments and recommendations for payment, and using the input to prepare a list of proposed and final payment recommendations that are both made available to the public.
CLMA has participated in the process for public consultation each year since its inception. We support this process and applaud the agency for its commitment to working with the laboratory

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community by providing numerous opportunities for input and comment. We believe an open and transparent process benefits the Medicare program, its beneficiaries and laboratories.

Proposed Payment for New Clinical Laboratory Diagnostic Test-Crosswalking and Gapfilling

CLMA would like to take this opportunity to make some specific recommendations regarding crosswalking and gapfilling. In order to further improve the public consultation process regarding payment determinations for new laboratory tests, we believe that it would be beneficial for the public to have a clear understanding of the details of the process of crosswalking and gapfilling. This would allow for more succinct input of specific criteria that can be applied to new tests to allow an initial determination of whether a test should be crosswalked as opposed to gap filled. We believe this would encourage the consistent application of the process. In addition, definitions of what makes a test "substantially new" as opposed to a test that is a "refinement or modification" of an existing test would also be useful.

Specific criteria defining how to determine an appropriate code to crosswalk a test would ensure that appropriate crosswalks are made in the future. Formal criteria might include such things as, similar methods are employed, the test is clinically similar in its application, costs, availability, and frequency of use and the amount of variance in the regional fee schedules is insignificant.

For gap filling, CLMA recommends that CMS establish requirements for documentation and standardize the sources and quantity of data that contractors use in gathering the charge and cost information. We also recommend that information be made available to the public for comment prior to making payment determinations. We believe that if the gapfilling process was clearly defined and rational, it could truly be considered as an option by the laboratory community in making recommendations for payment determinations for new CPT codes.

Once CMS determines that a new test should be gapfilled, the agency instructs Carriers to determine a payment amount to use for the first year within the Carrier's geographic area. Those payment amounts are then used to establish a National Limitation Amount (NLA) for subsequent years. Beginning in the second year, the new test is paid at the lower of the gap fill amount or the NLA. The proposed rule would eliminate payment of new tests at the gapfill amount determined by the Carriers after the first year. CMS is proposing to pay all new tests that are gapfilled at the NLA starting in the second year, and CLMA supports this decision.

Finally, regarding the process for public consultation CLMA recommends that CMS make available to the public prior to the final opportunity for comment the rationale for the agency's tentative payment determinations, including the data used to make the determination and the agency's responses to comments from the public. We believe this would result in more efficient and appropriate payment determinations.

Other Laboratory Issues – Quality

CMS is exploring the development of measures related to quality and efficiency of care, including services provided by clinical laboratories. As part of quality measures for physicians, the proposed rule would require clinical laboratories to submit laboratory test results using common vocabulary standards such as those included in the Logical Observation Identifiers Names and Codes (LOINC®).

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The proposed rule indicates that CMS is aware of "significant operational and other challenges" associated with reporting laboratory test result data, and that agency is seeking to work collaborative with the laboratory community on these issues. CLMA stands ready to work with CMS and would like to take this opportunity to briefly outline our concerns. We do so in order to stress the significant burden submitting test results as part of quality measures for physicians will impose on clinical laboratories.

The cost of adapting systems to comply with submitting laboratory test results is exceptionally high. There are no existing commercially available software programs and development costs may drive up the price of such programs, or laboratories will be required to use resources to develop their own internal programs. Fulfilling the requirements will entail hiring additional staff and further add costs to the laboratories.

Many laboratories use outside contractors for the submission of claims and the cost of including laboratory test results on claims may increase the price of these contracted services.

Since the data submitted with the claims will be used to evaluate "pay-for-performance" for physicians and not laboratories, there is no return on investment. Laboratories will be bearing the cost of including laboratory test results on claims while physicians will reap the potential benefits.

Currently there are no commonly accepted standards for the communication of laboratory data, which is highly-complex due to the number of tests (well over 1,000) and the lack of standardization of test name, reference ranges, and test performance characteristics. Time will be required to develop standards and implementation guidelines, and for widespread acceptance of mapping systems such as LOINC.

A large number of laboratory results do not report reference values, but instead are in free-form narrative format. For example, services such as cytopathology, flow cytometry, and microbiology provide narrative results. Again, mapping systems such as LOINC will be required to accommodate such narrative data.

The current HIPAA standard transaction for electronic health care claims (ASC X12N 837) is not designed to accommodate laboratory values for all 1,100 tests on the Medicare clinical laboratory fee schedule. Although in September 2005 CMS issued a notice of proposed rulemaking regarding the adoption of a joint X12 / HL7 standard as a HIPAA standard transaction for electronic claims attachments, the X12 / HL7 standard has not been widely adopted voluntarily, and significant implementation challenges lie ahead.

The "Clinical Laboratory Improvement Amendments (CLIA) of 1988" require clinical laboratories to release the results of laboratory tests only to authorized persons or the individual responsible for utilizing the test results. An "authorized person" is defined as an individual authorized under State law to order tests or receive test results, or both. No state law includes CMS as an authorized person.

In the absence of more stringent State law governing the disclosure of such protected health information (PHI), the HIPAA Privacy Rule would permit clinical laboratories to disclose lab results to CMS for its payment purposes (e.g., pay for performance). In making such disclosures clinical laboratories would be obligated to make reasonable efforts to disclose only the "minimum necessary" PHI to achieve the purpose of the disclosure. Therefore, laboratories may be restricted in the release of results to CMS based on CLIA and privacy regulations under HIPAA.

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Physician Office Laboratories (POLS) account for the largest number of clinical laboratories. The majority of these laboratories do not yet have results stored in an information system and deliver results on paper. As a result, a requirement to report laboratory test data poses a significant financial and technological burden for these laboratories with major obstacles to overcome.

CMS also needs to carefully consider how laboratory values will be used to evaluate physician performance. It is also impractical and ineffective to review laboratory results outside of the patient's full medical record.

Other Laboratory Issues - Blood Glucose Monitoring in SNFs

The proposed rule would amend CMS regulations at §424.24 to include that "for each blood glucose test furnished to a resident of a SNF, the physician must certify that the test is medically necessary." CMS would also amend §424.24 to clarify that a standing order is not acceptable for routine blood glucose monitoring.

CLMA does not support CMS' intent to no longer consider a standing order for routine glucose monitoring as acceptable. This would impose an unfair burden on clinical laboratories that provide services to SNFs.

Physicians that treat patients in SNFs rely on standing orders for patient care and laboratories that service SNFs in turn rely on standing orders to determine the specimens to draw and tests to perform. If standing orders are no longer acceptable, a significant burden would be placed on clinical laboratories to confirm individual orders for blood glucose monitoring. Time spent confirming such orders could delay appropriate treatment based on test results, which in turn threatens patient safety.

Laboratories would also be in the unfair position of ensuring that SNFs comply, and implementing this proposal could create false claims potential for laboratories that perform the tests.

Other Lab Issues- Proposed Clinical Diagnostic Laboratory Date of Service (DOS) for Stored Specimens

The proposed rule includes changing the date of service (DOS) for laboratory tests performed on archived specimens. Currently an archived specimen is defined as one that is stored for more than 30 calendar days before testing. The DOS for specimens stored 30 days or less is the specimen collection date. The DOS for archived specimens is the date the specimen is retrieved from storage. However, situations may arise where specimens may be archived for an inpatient, but then tested after the patient is discharged from the hospital. The DOS may effect whether or not payment for the test would be bundled as part of the hospital service. As a result, CMS is proposing to the change the DOS for an archived specimen to the date the specimen is obtained from storage, even if the specimen is removed less than 31 days from the date it was collected, if the following conditions are met:

- The test is ordered 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 in the hospital

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- The procedure performed while the patient is hospitalized is for a purpose other than just collecting the specimen for the test
- The test is reasonable and necessary

It is CLMA's understanding that this proposal is in response to specialty testing on specimens collected during surgery, e.g., response to chemo or molecular diagnostics. Since the test is often not related to the surgery, CLMA believes that it should not be bundled into the DRG payment for the patient.
Therefore, CLMA supports the proposed change to the DOS for an archived specimens under the specific conditions listed above.

In closing, CLMA appreciates the opportunity to comment on these important issues.
Our members and staff stand ready to answer any questions or concerns that you may have regarding these comments.

Please contact Katharine I. Ayres, CLMA Director of Legislative and Regulatory Affairs, at kayres@clma.org or 610.995.9580 for further assistance.

Sincerely,

Judy A. Lien
President

256

REMOTE CARDIAC SERVICES PROVIDER GROUP

October 9, 2006

Via Overnight Federal Express

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, Maryland 21244-1850

Re: 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

Ladies and Gentlemen:

The Remote Cardiac Services Provider Group (the Provider Group) is pleased to have the opportunity to comment on the Proposed Rule related to changes in the policies related to independent diagnostic testing facilities (IDTFs), as published in the August 22, 2006 Federal Register at 71 Fed. Reg. 48,982 (the Proposed Rule). The Provider Group, which represents nine companies, provides the majority of remote cardiac monitoring services for Medicare patients. Our comments focus on the proposed creation of business standards for IDTFs and the impact these proposed standards will have on remote cardiac monitoring services. Our comments also address CMS's request for comments relating to the potential application of an anti-markup provision to the reassignment of the professional component of IDTF services performed under a contractual arrangement.

Millions of Americans, including Medicare beneficiaries, suffer from cardiac conditions related to arrhythmias each year and the cardiac monitoring services provided by members of the Provider Group are essential to the timely diagnosis and treatment of these illnesses. The Provider Group exclusively provides such remote cardiac monitoring, primarily billing for services provided under CPT codes 93012, 93226, 93232, 93271, 93733, 93736, G0248, and G0249.

While we support CMS's goal of ensuring that IDTFs meet minimum standards to protect beneficiaries and the Medicare Program, we feel that these standards may need

certain modifications so as not to negatively impact the appropriate provision of services to Medicare beneficiaries. **Certain provisions of the Proposed Rule will substantially burden IDTFs' ability to provide the cardiac monitoring services. In some cases, the proposed regulations may make the continued operation of IDTFs impossible.** Consequently, the Provider Group is offering the following comments and recommendations regarding the Proposed Rule in an attempt to mitigate the harmful effects of some of these provisions and work with CMS to achieve the goals of each.

IDTF Issues

1. Supervising Physician

The proposed regulation constitutes a broad expansion of the role and responsibilities of supervising physicians in IDTFs from the existing regulation. The responsibilities included under the proposed regulation are far more similar to those performed by someone with training in business administration and operations rather than the practice of medicine. Since physicians are generally not trained or experienced in business administration, it is our position that such responsibilities should remain in the hands of business experts and that the supervising physician should be responsible only for the clinical services provided by the IDTF.

To make supervising physicians responsible for not only the clinical services of the IDTF but the administrative and operational duties as well is overly onerous on such physicians, particularly where they are providing general supervision of the services ordered in the IDTF, which is the case for the services provided by members of the Provider Group. These rules would essentially make the physician the CEO of the IDTF which is not typically the responsibility of the physician assisting with an IDTF.

In addition, the definitions of the various levels of supervision (e.g., general, direct, or personal) set out at 42 C.F.R. § 410.32(b)(3) do not include responsibility for the operation and administration of the IDTF. the Provider Group is unique in that it solely offers remote cardiac monitoring services. These services are provided to patients remotely and trans-telephonically. Therefore, for the services provided, the appropriate level of physician supervision is general supervision. As explained above, general physician supervision does not encompass the responsibilities proposed to be included.

Furthermore, by holding the supervising physician accountable for the clinical, operational, and administrative duties of the IDTF, the proposed regulation creates the potential for the supervising physician to be deemed an employee of the IDTF. Since state licensing laws prohibit the practice of corporate medicine (e.g., physicians employed by corporate entities), this could lead to licensing actions against physicians

acting as supervising physicians for IDTFs. It may also make it impossible for IDTFs to locate physicians to act in such capacities.

2. Multi-State Entities

The addition of paragraph (2) to this regulation, in conjunction with the addition of subsection (i), will substantially and adversely affect the providers of remote diagnostic testing services. We would like to clarify the application of this concept in relationship to provision of such remote services, where the beneficiary is at their residence and the diagnostic test is taking place over the phone or the Internet (e.g., remote cardiac monitoring). In such instances the actual point of delivery of services should be where the information is received and analyzed, regardless of the location of the beneficiary. The service is actually being performed at the IDTF in that the receipt and analysis of the clinical data occurs at the location of the certified technician, the IDTF. We request that CMS clarify that the place of service for remotely provided diagnostic tests is the place where the test is received and analyzed, not where the beneficiary is located.

To make the point of the actual delivery of services the beneficiary's location in such instances would result in substantial hardship on IDTF providers of remote services, making it nearly impossible for such provider to continue to exist and operate. The addition of this proposed regulation would require the IDTF to be enrolled with each carrier in every state in which a beneficiary is located rather than just the states in which the IDTF has physical facilities where the remote service provided is actually taking place. In real terms, this means that each IDTF providing remote services would potentially have to enroll with 40 or more additional carriers. Aside from the severe administrative burden this creates on the IDTFs, we believe that it would be impossible for a carrier to approve an IDTF that is physically located in another state. In the past, carriers have proved unwilling to cross state lines to conduct inspections, a necessity under current Medicare regulations for a provider to maintain enrollment with a carrier which is further emphasized by the proposed business standards in this Proposed Rule.

3. Business Standards

a. Enrollment Application

The current requirement as listed on the Medicare Enrollment Application for Clinics/Group Practices and Certain Other Suppliers, Form CMS-855B, which applies to IDTFs, is that changes in the information be reported to the designated contractor within 90 days. We believe this is a more reasonable time frame for reporting changes in the enrollment information of IDTFs. In the alternative, we support quarterly reporting of any changes that have occurred in the preceding quarter.

Further, depending upon the type of change that occurs, the requirements of Form CMS-855B only require an IDTF to fill out certain sections of the application. We wish to clarify that this will remain the case under the proposed regulation and that IDTFs will not be required to complete an entire application in order to report changes in their enrollment information (unless currently required to do so by the application).

b. Physical Facility

We wish to have the meaning of "current" medical records clarified in order to ensure our ability to fully comply. It is unclear from the proposed regulation whether "current" includes only those medical records for patients receiving services from the IDTF at that time or whether medical records of past patients remain "current" for some period of time. We request that CMS clarify that "current" means within the last six months.

We recommend that off-site storage of both business records and current medical records be permitted to satisfy the "storage" requirement, as is implied for medical records under paragraph (13) of the proposed standards. Further, we recommend that electronic storage of medical records be permitted as well.

c. Testing Equipment

Given the nature of remote services provided by IDTFs, such as the remote cardiac monitoring provided by the Provider Group, equipment is often sent out to the beneficiary or their physician for use in the recording and transmission of health data. Given the beneficiary's location away from the IDTF (often in other states) and the beneficiary's need for the continued possession and use of the equipment, the proposed requirement under paragraph (4) that all equipment be available for inspection within two business days is unworkable for IDTF providers of remote services. Given the impracticality of this requirement as applied to remote services, we believe that this paragraph should be altered to allow samples of the equipment sent to beneficiaries to be provided for inspection rather than each individual piece of equipment. Remote service IDTFs would still maintain an up-to-date list of the equipment's serial numbers and a current inventory of all equipment owned and used by the IDTF as required by the proposed regulation, but would not be required to produce an actual piece of equipment that is being used by a physician or in the possession of a patient at the time of inspection.

Further, we request clarification of the requirement that the designated fee-for-service contractor be notified of changes in equipment within 90 days. We request that this provision be interpreted to mean notice of changes in the *types* of equipment used by the IDTF rather than changes in each individual piece of equipment used. To require providers of remote IDTF services to notify the contractor of every change in individual

pieces of equipment would be extremely onerous considering the nature of the services being provided and the use of equipment by beneficiaries on an ongoing basis. Given that equipment is sent to beneficiaries directly and used by them, there is a higher than normal rate of loss and damage to this equipment. In addition, by virtue of the continuous usage of some of this equipment, the average lifespan of such equipment can be significantly shorter than that of other medical equipment commonly used. While the IDTF would certainly keep an accurate and up-to-date list of the relevant serial numbers and a current inventory as required in paragraph (4), to require the IDTF to continuously notify the contractor of the continuous turnover in equipment used by beneficiaries is extremely burdensome and unrealistic. We feel that it is sufficient to require the IDTF to notify the contractor when it makes a change in the *type* of equipment it uses.

d. Liability Insurance

We request that the proposed regulation be clarified as to whether the liability insurance policy amount is meant to apply on a per-occurrence or an aggregate basis. We recommend that CMS require aggregate coverage. We also suggest that the appropriate level of liability insurance should not be tied to an IDTF's billings as that amount would change constantly. Further, it is not clear in the proposed regulation when alteration in the amount of coverage following a change in the amount of billings would need to be made. Rather we support the current industry standard of carrying $3 million aggregate liability insurance policy coverage at a minimum.

We are also concerned about the requirement that the policy list the serial numbers of "any and all equipment" used by the IDTF. Currently, no such practice exists for remote cardiac service providers. Furthermore, in relation to remote service providers and their use of small, portable equipment that is sent to patients, this requirement is onerous. We do not believe that insurance companies require such a listing in order to cover damage to or loss of smaller equipment, such as that used in remote cardiac monitoring services. Finally, if the purpose of this requirement is to ensure an accurate inventory is kept, this requirement is redundant. IDTFs will already be required to keep complete and up-to-date inventories of their equipment under paragraph (4).

e. Solicitation of Patients

We feel this portion of the proposed is confusing and may potentially conflict with already existing state and federal law and regulations. While the first part of the proposed regulation seems to be dealing with "solicitation" of patients, the second part of the proposed regulation seems to be dealing more with the criteria for patients to whom the IDTF may provide services.

As to the first part of the proposed regulation regarding solicitation of patients, the Provider Group feels that the proposed regulation is not the right framework for dealing

with the very broad topic of such activities. It is not clear from the proposed regulation the extent of the activities included in the term "solicitation." We believe the term should be defined in a very clear and narrow way to avoid crippling IDTFs from managing their businesses and providing the services for which they exist. Specifically, the Provider Group wishes CMS to clarify that the following activities do not constitute solicitation under the proposed regulation: (a) contacting the patient with the consent of his/her physician or (b) providing a patient with information regarding his medical condition, available procedures to treat that medical condition, and available training with regard to that medical condition. The latter activities are especially important when dealing with patients that receive services for a long period of time, such as those with implanted devices or those suffering from chronic conditions and should not be prohibited.

In addition, we wish to point out that activities potentially deemed by CMS to be "solicitation" are already heavily regulated through a network of state and federal laws and regulations, from federal law prohibitions on beneficiary inducement, various consumer protection laws, and applicable healthcare-related confidentiality and privacy laws and regulations (including HIPAA). There does not appear to be a reasonable basis to prohibit this contact. Adding another layer of regulations by way of the proposed regulation will only create additional confusion and inefficiency. In keeping with these existing laws, we also suggest that similar caveats to those that currently apply to permitted uses of protected health information by a healthcare provider under HIPAA should apply in this matter as well.

Due to the nature of IDTF services and existing laws and regulations, we are not clear what purpose CMS is hoping to achieve through implementing the proposed regulation. Currently, an IDTF may only provide a service to a Medicare beneficiary based on and according to a physician order. For all practical matters, whether the patient is aware of a particular IDTF and its services, it is the discretion and decision of the ordering physician whether or not to refer a patient for diagnostic testing. However, we would like to note that remote cardiac IDTF providers are discriminated against under the proposed regulation and placed at a disadvantage in relation to other IDTF providers that perform in-person services to the patient and interact directly with the patients through those other services.

With regard to the second part of the proposed regulation, it seems to unreasonably and materially expand the duties and liabilities of the IDTF provider. By requiring the IDTF to "accept only" only those patients described in the proposed regulation, the regulation seems to require the IDTF to verify that the prescribing physician is performing various evaluation and management procedures with regard to the patient and the ordered diagnostic tests. We are unsure how IDTFs are to accomplish this verification. So long as a physician is ordering the test, we feel it is not possible and is further inappropriate to have the IDTF determine how the physician is using the information. Further, the distinction between the "ordering" or "prescribing" physician

(as referenced in other CMS regulations) and "attending" physician as referred to in the proposed regulation is unclear. We request that CMS clarify the distinction if it intends there to be one. If there is no distinction intended, we recommend that CMS use an alternative term consistent with its existing regulations and manuals.

Furthermore, the services provided by IDTFs to patients, based on physician orders (i.e., prescriptions) are already regulated under existing Medicare regulations and manual provisions that apply the requirements for treatment based on medical necessity and reasonableness. If it is CMS's intent through this proposed regulation to place the additional responsibility of verifying the conditions set out regarding use of the ordered tests. An IDTF, especially a remote cardiac IDTF that provides mainly technical services without "face to face" encounters with the patient or ordering physician, should not be subjected to these additional requirements. In addition to the inappropriateness of placing such responsibility with the IDTF, IDTFs simply have no means or tools to comply with such requirements or to ensure the "attending" physicians' compliance with such requirements.

f. Questions and Complaints

We suggest, in lieu of maintaining these documents at the physical facility, that IDTFs be given two business days to retrieve such records upon request by CMS or its designated fee-for-service contractor as allowed for retrieving medical records under paragraph (13). The volume of such documentation could easily exceed the capacity of a typical physical facility to easily store and manage within a short period of time. Requiring that the documentation be maintained on-site would result in substantial inconvenience and may ultimately interfere with efficient provision of IDTF services to beneficiaries as the amount of documentation in storage continued to grow.

g. Posting of Standards

We seek to clarify what, specifically, is included in the meaning of "these standards" for the purposes of posting. Additionally, we seek clarification on whether posting the required standards on an IDTF's website would be sufficient, particularly in the case of remote service IDTFs which may not have a lobby or similar facilities open to patients and the public where such standards could physically be posted. In the alternative, given that the Provider Group ships equipment to patients to be used in remotely monitoring their cardiac functions, we suggest that this proposed requirement could be satisfied by including a copy of the requisite standards in the packaging with the shipped equipment.

h. Calibration of Equipment

At this time, there are no national standards for calibrating the equipment used in remote cardiac monitoring services. Therefore, we seek to clarify that calibration of equipment in compliance with the instructions of the manufacturer would be sufficient in the absence of national standards.

i. Record Storage

We seek to clarify that the medical records in question under this proposed regulation refer only to the medical records of the IDTF, created and maintained in the treatment of individual patients, and not to the medical records in the possession of referring physicians or practitioners.

j. Site Inspections

IDTFs that provide remote diagnostic services (i.e., remote cardiac monitoring) are typically not open to either beneficiaries or the public. The nature of the services provided do not require that patients come to the physical facility, instead working with monitoring equipment at their homes and transmitting data from that equipment to the IDTF via phone or Internet. If a patient were to experience difficulty with the monitoring equipment, they can call a toll-free number to talk to an IDTF representative or they may visit their attending physician rather than the IDTF. For these reasons, as well as for reasons of protecting patient records and privacy, remote service IDTFs do not hold themselves out as open to the public. Therefore, the requirement under this proposed regulation that the IDTF be accessible to beneficiaries is contrary to common practice and inappropriate in the context of remote service IDTFs where the beneficiary has no cause to enter the facility.

Additionally, the nature of certain remote services results in the IDTF operating continuously, on a 24-hour a day basis, seven days a week. For this reason, we seek clarification of the intended meaning of the term "regular business hours." Specifically, we request that the term be construed only to apply to the customary hours of operation in the business community (i.e., 9:00 am to 5:00 pm) rather than the actual operating hours of the IDTF in question.

4. Safe and Appropriate Use in Residential Setting

In the preamble of the proposed regulations for IDTFs, CMS specifically requested comments regarding the types of services that can be safely and appropriately used in a residential setting. We maintain that remote cardiac monitoring services are safe and appropriate for such use. With the provision of the appropriate monitoring equipment, training regarding the use of the equipment and transmission of the recorded

data, and technical support from both the attending physician and the IDTF, beneficiaries are easily and safely able to use remote cardiac monitoring services.

Reassignment and Physician Self-Referral

In the preamble of the proposed regulations for IDTFs, CMS specifically solicited comments on whether an anti-markup provision should apply to the reassignment of the professional component (e.g., test interpretation) of diagnostic tests performed under contractual arrangements with the billing entity. CMS also requested comments on how to determine the appropriate amount to be billed to Medicare if such a provision were implemented. We believe that an anti-markup provision would be inappropriate as applied to the reassignment of billing for the professional component (PC) of IDTF services performed under a contractual arrangement. With the remote cardiac monitoring services provided by the Provider Group, the IDTFs enter into contractual arrangements with physicians to interpret the data received from the diagnostic tests ordered when the ordering physician needs a cardiologist, for example, to read the ECG. The physicians providing interpretation services have reassigned their rights to bill Medicare for those services to the IDTFs. Despite the fact that the IDTFs do not incur costs associated with an in-office physician, the IDTFs nevertheless incur substantial costs associated with the interpretation services provided. There are costs associated with arranging for the interpretation services, contracting with the third-party physicians and billing for these services. The Provider Group's IDTFs also incur costs for receipt of the interpretation and then transmittal of the results to the ordering physician. If an anti-markup provision was applied to the contractual reassignment arrangements for the PC services, the IDTFs would not be reimbursed for these incurred costs. This is inequitable to the IDTFs and we, therefore, strongly oppose the application of such a provision.

Given the Provider Group's strong opposition to the implementation of an anti-markup provision, we are not in a position to comment on the appropriate amount to be billed under such a restriction. It is our opinion that the proper billing for services provided by IDTFs is that currently allowed under the relevant CPT code without further restriction.

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We thank you for the opportunity to comment on these important issues. If you have any questions about our comments, please contact our Washington DC representatives, James Jorling, Esq. at 202-466-6550.

Sincerely,

David Bondietti (CAH)

David Bondietti, Senior Vice President
Biomedical Systems
St. Louis, MO

Phillip Leone (CAH)

Phillip Leone
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257

ASTRO
AMERICAN SOCIETY FOR THERAPEUTIC RADIOLOGY AND ONCOLOGY

October 9, 2006

Mark McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services,
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Attention: CMS–1321–P
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Baltimore, MD 21244–1850

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 Therapeutic Radiology and Oncology, Inc. (ASTRO) [1] appreciates the opportunity to provide written comments on the "Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B" published in the *Federal Register* as a proposed notice on August 22, 2006. Our comments focus on: (1) our previous recommendations for the 2007 physician fee schedule following publication of the June 29, 2006 proposed rule; (2) the global period for remote afterloading high intensity brachytherapy procedures; (3) the assignment of RVUs to CPT® codes for proton beam treatment delivery services; (4) the reduction in technical component (TC) payments for imaging services under the physician fee schedule to the outpatient department payment amount; (5) the Sustainable Growth Rate (SGR); and (6) revisions of the Medicare Economic Index (MEI).

I. ASTRO Comments on the June 29, 2006 Proposed Rule

In our comments on the first proposed rule for the 2007 physician fee schedule that was published on June 29, 2006, we made several recommendations which we restate here.

ASTRO position:

- We support the CMS proposal to accept the Relative Value Update Committee (RUC)-recommended work Relative Value Units (RVUs) for the nine (9) radiation oncology services that were submitted by CMS to the RUC for review.

[1] *ASTRO is the largest radiation oncology society in the world, with more than 8,500 members who specialize in treating patients with radiation therapies. As a leading organization in radiation oncology, biology and physics, the Society is dedicated to the advancement of the practice of radiation oncology by promoting excellence in patient care, providing opportunities for educational and professional development, promoting research and disseminating research results and representing radiation oncology in a rapidly changing socioeconomic healthcare environment.*

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- We support the CMS proposal to apply a separate adjustment of approximately -10 percent to the work RVUs for the purpose of maintaining budget neutrality following completion of the 5-year review of physician work.
- We recommend a transition of the revised work RVUs similar to the transition CMS proposed for the practice expense RVUs.
- We support the CMS proposal to change the methodology used to calculate practice expense (PE) RVUs from a "top-down" approach to a "bottom-up" approach.
- We recommend a correction of the PE/hr data for radiation oncology, based on the proportion of physician time spend in hospitals or free-standing centers.
- We recommend elimination of the use of indirect practice cost indices (IPCIs) in the last step in the calculation of revised PE RVUs.

II. Miscellaneous Coding Issues (71 Fed. Reg., 48995)

1. Global Period for Remote Afterloading High Intensity Brachytherapy Procedures

All four (4) CPT® codes in the family of remote afterloading high intensity brachytherapy services (CPT codes 77781–77784) are currently designated as 90-day global services. Remote afterloading high intensity brachytherapy is used to treat many clinical conditions. Patients undergoing this type of brachytherapy usually receive several treatments (2– 10) over a two to ten day period. Due to the increasing variability in treatment regimens, it is difficult to assign RVUs for a ''typical'' patient based on a global period of 90 days. Therefore, CMS proposes to remove the 90-day global period and assign the CPT codes a global period of ''XXX'' which will permit separate payment each time the services are provided and allow payment to be based on the actual service(s) provided.

The work RVUs of each of the four (4) CPT codes is proposed to be reduced by 0.45 work RVUs corresponding to the elimination of a level II E/M service (CPT code 99212) from the post-operative period. In addition, the proposed rule includes dramatic changes in practice expense RVUs as shown in the table below:

CPT® Code	MOD	2006 Non-Facility PE RVUs	Proposed 2007 Non-Facility PE RVUs	Proposed 2010 Non-Facility PE RVUs	% Change in Non-facility PE RVUs 2006-2007	% Change in Non-facility PE RVUs 2006-2010
77781	TC	20.36	16.20	3.90	-20.4%	-80.8%
77782	TC	20.36	18.10	11.48	-11.1%	-43.6%
77783	TC	20.36	20.89	22.67	2.6%	11.3%
77784	TC	20.36	26.01	43.12	27.8%	111.8%

ASTRO position: ASTRO supports the CMS proposal to change the global period from 90 days to "XXX." However, we strongly object to the arbitrary reduction in work RVUs that is not supported by any data. In fact, a careful review of the history of the work RVUs for these CPT codes indicates that if any reductions in work RVUs could be justified they would need to be

much smaller than 0.45. The following table lists the work RVUs and global periods from previous Federal Register notices. During the first two years of the fee schedule, these CPT® codes had global periods of "XXX." In 1994, the global period was changed to 90 days, but there was no corresponding increase in work RVUs. In fact, ironically, the work RVUs decreased slightly because in that year CMS (formerly HCFA) made a budget neutrality adjustment across all the RVUs. In 1998, the work RVUs were increased slightly (as were all services with global periods of 90 days) to be consistent with the increases in work RVUs for E/M services that had been granted in 1997 after completion of the first 5-year review.

CPT® Code	1992 Work RVU (global period = xxx)[2]	1994 Work RVU (global period changed to 90)[3]	1998 Work RVUs (all global services increased to be consistent with 1997 E/M work RVU changes)[4]	2006 Work RVUs
77781	1.64	1.59	1.66	1.66
77782	2.46	2.39	2.49	2.49
77783	3.68	3.58	3.73	3.72
77784	5.52	5.37	5.61	5.60

If any adjustment must be made, it should be to return the work RVUs to their level in 1992 when the global period was "XXX." However, such changes would require only about a 1 percent reduction of the current work RVUs, and we question whether this degree of precision is necessary. We recommend no change in the work RVUs of CPT codes 77781-77784 or, if CMS believes a change must be made, then we recommend a reduction to the 1992 levels.

We also are concerned by the dramatic swings in PE RVUs for the TC services with CPT code 77781 decreasing by more than 80 percent and CPT code 77784 increasing by more than 110 percent by the end of the transition period in 2010. Given the history of the work RVUs described above, it appears that the PE inputs should not have been reduced to reflect the removal of a post-operative visit since no such visit exists. We ask that CMS address this issue in the final rule and make the necessary adjustments to the PE RVUs.

Finally, we are prepared to work with the RUC to revalue these services as quickly as possible so that appropriate RVUs can be in place by 2008.

2. Assignment of RVUs to CPT® Codes for Proton Beam Treatment Delivery Services

CMS received a request to assign PE inputs for the non-facility setting to proton beam treatment delivery services represented by CPT codes 77520 through 77525. These services are currently carrier-priced. Therefore, payment in the facility or non-facility setting is established by each carrier. CMS notes there is an established process utilizing the AMA–RUC to recommend work RVUs, as well as the direct PE inputs used to compute the PE RVUs. No RVUs are proposed but CMS requests comments on this issue.

[2] Federal Register. Monday, November 25, 1991. page 59502.
[3] Federal Register. Thursday, December 2, 1993. page 63626.
[4] Federal Register. Friday, October 31, 1997. page 59048.

ASTRO position: ASTRO would be pleased to participate in the development of practice expense RVUs for these services should CMS decide that carrier-pricing for these services is no longer appropriate.

III. DRA Proposals (71 Fed. Reg., 48996)

Reduction in TC for Imaging Services Under the PFS to OPD Payment Amount

As required by Section 5102(b)(1) of the Deficit Reduction Act (DRA), beginning January 1, 2007, CMS will cap the physician fee schedule (PFS) payment amount for the technical component of imaging services (including the technical component portion of a global fee) at the CY 2007 outpatient prospective payment system (OPPS) payment amount. They will then apply the PFS geographic adjustment to the capped payment amount.

The DRA defines imaging services as "imaging and computer-assisted imaging services, including X-ray, ultrasound (including echocardiography), nuclear medicine (including positron emission tomography), magnetic resonance imaging, computed tomography, and fluoroscopy, but excluding diagnostic and screening mammography."

In order to implement section 5102(b) of the DRA, CMS needed to determine which CPT® and alpha-numeric HCPCS codes fall within the scope of "imaging services" defined by the DRA provision. The proposed rule describes the inclusion and exclusion criteria they applied:

- The service provides visual information regarding areas of the body that are not normally visible, thereby assisting in the diagnosis or treatment of illness or injury.
- Excluded nuclear medicine services that were either non-imaging diagnostic or treatment services.
- Excluded all codes for unlisted procedures.
- Excluded all mammography services, consistent with the statute.
- Excluded radiation oncology services that were not imaging or computer-assisted imaging services.
- Excluded all HCPCS codes for imaging services that are not separately paid under the OPPS.
- Excluded any service where the code describes a procedure for which fluoroscopy, ultrasound, or another imaging modality is either included in the code whether or not it is used or is employed peripherally in the performance of the main procedure.
- Included carrier priced services that are within the statutory definition of imaging services.

The proposed list of codes identified by CMS as imaging services subject to the DRA OPPS cap provision is in Addendum F of the proposed rule.

ASTRO position: ASTRO concurs with the CMS decision to exclude radiation oncology services that are "not imaging or computer-assisted imaging services" since radiation therapy services clearly cannot be considered "imaging." However, we believe CMS has misinterpreted Congressional intent by including on the list of "imaging services" codes that assist in the treatment of illness such as services performed in conjunction with radiation therapy that are

never performed for diagnostic purposes. ASTRO recommends that CMS remove the following radiation oncology services from the list of services subject to the DRA cap because they are associated with the treatment and not the diagnosis of cancer:

- 76370; *Computed tomography guidance for placement of radiation therapy fields;*
- 76950; *Ultrasonic guidance for placement of radiation therapy fields;*
- 76965; *Ultrasonic guidance for interstitial radioelement application;*
- 77417; *Therapeutic radiology port film(s); and*
- 77421; *Stereoscopic X-ray guidance for localization of target volume for the delivery of radiation therapy.*

IV. ASTRO Comments on the Sustainable Growth Rate (SGR) and Revisions of the Medicare Economic Index (MEI)

Updates to Medicare physician payments are made each year based on a statutory formula established in section 1848(d) of the Social Security Act. The calculation of the Medicare physician fee schedule update utilizes a comparison between target spending for Medicare physicians' services and actual spending. The update is based on both cumulative comparisons of target and actual spending from 1996 to the current year, known as the Sustainable Growth Rate (SGR), as well as year-to-year changes in target and actual spending. The use of SGR targets is intended to control the growth in aggregate Medicare expenditures for physicians' services.

In many previous comment letters, we have described the flaws in the SGR formula that led to a 5.4% payment cut in 2002. Additional cuts in 2003 through 2006 were averted only after Congress intervened. Consistent with the position of the American Medical Association (AMA), we identified several steps that should be taken that would significantly reduce the costs associated with a permanent legislative fix to the SGR formula. Most importantly, we recommended that CMS remove Medicare-covered, physician-administered drugs and biologics from the physician payment formula, retroactive to 1996.

ASTRO position: We are extremely disappointed that CMS continues to believe it does not have the authority to make necessary these changes. In the proposed rule, CMS announced its most recent estimate of a 5.1 percent reduction in the 2006 conversion factor from $37.8975 to $35.9647 in 2007. If these cuts begin on January 1, 2007, average physician payment rates will be less in 2007 than they were in 2000, despite substantial practice cost inflation. These reductions are not cuts in the rate of increase, but are actual cuts in the actual amount paid for each service. Physicians simply cannot absorb these severe payment cuts and, unless CMS or Congress acts, physicians will be forced to reevaluate their relationship with Medicare and will be forced to avoid, discontinue or limit the provision of services to Medicare patients.

We recommend that that CMS remove Medicare-covered, physician-administered drugs and biologics from the physician payment formula, retroactive to 1996.

There is only a passing reference in the 2007 proposed rule to the Medicare update for the coming year. The Regulatory Impact Analysis section includes the following statement: "Table

7 below shows the specialty level impact of section 5102 of the DRA and our most recent estimate (-5.1 percent) of the CY 2007 Medicare PFS update." This number was unexpected because it is lower than the estimate recently contained in the President's Budget.

To understand why the update would be 0.5 percentage points lower than the estimate contained in the President's Budget, it was necessary to read the Fact Sheet on the Medicare Economic Index (MEI) that was released on August 8, 2006, the same day that the proposed rule was released. The lower MEI was attributed to 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.

ASTRO position: We object to the 0.5 percent reduction of the 2007 physician fee schedule update. The 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. We believe that CMS may be in violation of the Administrative Procedures Act (APA) which requires publication in the Federal Register of most rules and a period for public comment. 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.

Conclusion

Thank you for the opportunity to comment on this proposed rule. We look forward to continued dialogues with CMS officials. Should you have any questions on the items addressed in this comment letter, please contact Trisha Crishock, MSW, Director of ASTRO's Health Policy Department at (703) 502-1550.

Respectfully,

Laura Thevenot
ASTRO, Chief Executive Officer

Cc: Trisha Crishock
Herb Kuhn
Ken Simon, MD
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American Academy of Family Physicians

October 06, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator, Centers for Medicare and Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS-1321-P
P. O. Box 8015
Baltimore, MD 21244-1850

Dear Dr. McClellan:

I am writing on behalf of the American Academy of Family Physicians (AAFP), which represents more than 94,000 family physicians and medical students nationwide. Specifically, I am writing to offer our comments on the proposed notice regarding "Medicare Program: Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B," as published in the *Federal Register* on August 22, 2006.

Discussion of Comments – Background

Regarding budget neutrality; CMS notes that in the proposed notice for the Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to Practice Expense Methodology, CMS has proposed to establish a separate budget neutrality adjustor that would be applied to the calculation of work RVU's. I would like to take this opportunity to again comment that we disagree with CMS's proposed approach to budget neutrality. We believe that CMS should implement any statutory budget neutrality adjustments through an adjustment to the conversion factor. An adjustment to the conversion factor reflects the nature of the budget neutrality adjustment which is made for fiscal reasons and not based upon a change in work values. As we previously noted, there are at least five reasons that we disagree:

1. Adjusting the conversion factor does not affect the relativity of services reflected in the total RVU's. Adjusting the work RVU's has the potential to inappropriately affect that relativity.
2. If the RVU's are adjusted as proposed, it will obfuscate the recommended changes and obscure the hard work done by the RUC.
3. An adjustment in the Medicare conversion factor is preferable because it has less impact on other payers who use the Medicare RVU's. We believe that CMS must consider such "ripple effects" as it decides how to adjust for budget neutrality.
4. CMS has attempted this approach in the past and found it to be problematic. Following the first five-year review, CMS implemented a similar work adjustor in 1997. Two years later, CMS eliminated it, noting that:

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[W]e did not find the work adjustor to be desirable. It added an extra element to the physician fee schedule payment calculation and created confusion and questions among the public who had difficulty using the RVU's to determine a payment amount that matched the amount actually paid by Medicare" (*Federal Register*, Vol. 68, No. 216, Pg. 63246).

5. We believe an adjustment to the conversion factor is preferable because it recognizes that budget neutrality is a fiscal issue, not an issue of relativity. Budget neutrality is mandated for monetary reasons. Thus, the conversion factor, as the monetary multiplier in the Medicare payment formula, is the most appropriate place to adjust for budget neutrality.

CMS also notes the expiration of the 1.0% floor of the work GPCI enacted January 01, 2004. Included in the NPRM is a table showing those localities which will have a negative percent change in the Geographic Adjustment Factor. We note that many of the areas indicated in this table are rural locations in which physician recruitment and retention are already difficult. Those localities where the negative change in geographic adjustment factor is greatest, South Dakota, North Dakota, Missouri and Montana, have many regions designated as Health Professional Shortage Areas. This negative adjustment may further exacerbate the difficulty of recruiting physicians to these areas and limit access to care for Medicare beneficiaries in these areas. The AAFP has previously commented regarding the flawed methodology of the GPCI and continues to support the elimination of all geographic adjustment factors from the Medicare Fee Schedule except for those designed to achieve a specific public policy goal (e.g., to encourage physicians to practice in underserved areas). We believe that reimbursement of physician services should not be based on the geographic location where the service is provided and that equivalent service should result in equivalent compensation. As noted, a policy of uniform payment should only be modified to achieve explicit policy goals (e.g., targeted adjustments for demonstrated shortfalls in access to care). I would urge CMS to support a legislative extension of the work GPCI floor.

As noted in the Combined CY 2007 Total Allowed Charge Impact table, family medicine as a whole faces another year of flat updates if this proposed fee schedule is enacted without Congressional intervention or action by CMS to administratively adjust the SGR formula. Family medicine physicians effectively lose the gains that resulted from the five-year review of the evaluation and management codes. This combined with the expiration of the 1% floor for the GPCI will result in a negative update for many family medicine physicians in underserved areas. We urge CMS to take action towards preventing this. As we commented one year ago, "Until a complete revision of the reimbursement formula is accomplished, there is an administrative adjustment that CMS can make immediately. Specifically, CMS should immediately remove, retroactive to the inception of the SGR, the physician-administered drugs from the SGR. These in-office medications are not reimbursed under the Medicare physician fee schedule and should never have been part of the formula used to calculate the conversion factor for physician services. Moreover, the Medicare Modernization Act restructured how these medications are paid for. CMS's continued inaction, in the face of a growing Medicare ambulatory care reimbursement crisis, is of great concern."

Discussion of Comments – Provisions – RUC Recommendations

The AMA's Relative Value Update Committee (RUC) established a new committee, the Practice Expense Review Committee (PERC), to assist the RUC in recommending direct practice expense inputs (clinical staff, supplies, and equipment) for new and existing CPT codes. The PERC reviewed the PE inputs for over 2000 existing codes, some of which were unresolved practice expense issues from the CY 2006 PFS final rule with comment period, at their meetings held in September 2005, February 2006 and April 2006.

CMS has reviewed the PERC-submitted recommendations and proposes to adopt all of them. CMS has worked with the AMA staff to make corrections for any typographical errors and to ensure that previously Practice Expense Advisory Committee (now PERC)-accepted standards are incorporated in the recommendations.

The AAFP participated in the PEAC process and supports this proposal.

Standard Supplies and Equipment for 90-Day Global Codes

CMS is proposing to revise the CPEP supply and equipment inputs for those 90-day global procedures for which the RUC has only refined the clinical labor inputs. As recommended by the RUC, for supplies, CMS proposes to include one minimum supply visit package for each postoperative visit assigned to each code and a post-surgical incision care kit (suture, staples, or both) where appropriate, along with additional items recommended by the RUC for certain procedures. CMS indicates that in some cases, the recommendations from the RUC contain additional items in quantities that appear excessive.

We agree that it is likely that CMS is reimbursing physicians for post-operative supplies that are not actually provided in all cases. As indicated in our comments related to the five-year review, we have suggested that CMS redefine the global surgical policy to eliminate the post-operative visits from the global package. This will eliminate the need to define how many post-operative visits are related to a procedure and how many supplies should be input to the practice expense for these visits. Although this would result in an increased number of evaluation and management service claims, it would also eliminate any excessive spending related to over-estimated post-operative visits and the related supplies. This would also hold all physicians to the same standards for the medical necessity and documentation of evaluation and management services.

Discussion of Comments – Provisions - Splint & Cast Supplies

In commenting on CMS's proposal in the NPRM for the 2006 Medicare Physicians Fee Schedule to include casting supplies in the practice expense for fracture care, we noted that inclusion of these supplies in the practice expense would simplify billing of fracture care. However, we agree that CMS should continue to reimburse the HCPCS Q-codes for splint and cast supplies to allow for billing of these items when not related to the care of a fracture. This will negate the need to review the effect of including the expense of these materials into the practice expense of the codes for fracture care.

Discussion of Comments – DRA Proposals – Ultrasound Screening for AAA

Section 5112 of the Deficit Reduction Act of 2005 amended section 1861 of the Act to provide for coverage under Part B of ultrasound screening for AAA's. CMS proposes to amend Section 1861(ww)(2) of the Act (the IPPE benefit) by adding the new ultrasound screening benefit to the list of preventive services for which physicians and other qualified non-physician practitioners must provide "education, counseling and referral" to new beneficiaries who take advantage of the initial preventive physical examination benefit within the first six months after the effective date of their first Part B coverage period.

The AAFP supports the use of evidence-based medicine. The United States Preventive Services Task Force (USPSTF) found good evidence that screening for AAA and surgical repair in men aged 65 to 75 who ever smoked leads to decreased AAA mortality. We support that the benefit is extended to those

beneficiaries who have received a referral for an ultrasound screening as part of initial preventive physical examination, have not been previously furnished an ultrasound screening examination under the Medicare program and is included in one of the following risk categories:

- Has a family history of AAA
- a male patient aged 65 to 75 who have smoked at least 100 cigarettes in his lifetime
- is an individual who manifests other risk factors that are described in a benefit category recommended by the USPSTF regarding an AAA that has been determined by the Secretary through the NCD process

However, as addressed in the AAFP comments on the NPRM for the Changes to the 2005 Medicare Physician Fee Schedule, I would again express our disappointment at the devaluing of the work and expense of providing the Initial Preventive Physical Examination service which is assigned 2.57 RVU's (roughly equal to a 99203 visit which is assigned 2.56 RVU's). As is evidenced by the language of section 1861(ww) (2), physicians must provide "education, counseling and referral" in addition to a comprehensive age/gender appropriate history and examination. This work is equal to that of CPT code 99387 which describes this preventive service. I respectfully request that as CMS adds this additional "education, counseling and referral" to this benefit, CMS also reconsiders the value assigned to the service and aligns it's value more appropriately to code 99387 which has been valued at 4.00 RVU's.

Discussion of Comments – DRA Proposals – Colorectal Cancer Screening Tests

Current Medicare policy requires that, with limited exceptions, incurred expenses for covered part B services are subject to, and count toward meeting the Part B annual deductible. Section 5113 of the DRA amended section 1833(b) of the Act to provide for an exception to the application of the Part B deductible with respect to colorectal cancer screening tests. Beginning January 1, 2007, colorectal cancer screening services, as described in section 1861(pp) (1) of the Act, are no longer subject to the Part B deductible. CMS proposes to add an exception to the Part B deductible of colorectal cancer screening tests to section 410.160 to conform to regulations of the Deficit Reduction Act.

We strongly support this proposal which may encourage beneficiaries to undergo these important preventive services.

Discussion of Comments – Reassignment and Physician Self-Referral

CMS proposes to amend §424.80 of the regulations to clarify that any reassignment pursuant to the contractual arrangement exception is subject to program integrity safeguards that relate to the right to payment for diagnostic tests. First, CMS would amend §424.80 to provide that if the technical component of a diagnostic test (other than clinical diagnostic laboratory tests paid under § 1833(a)(2)(D) of the Act, which are subject to the special rules set forth in § 1833(h)(5)(a) of the Act) which is billed by a physician or medical group under a reassignment involving a contractual arrangement with a physician or other supplier who perform the service, the amount billed to Medicare by the billing entity, less the applicable deductibles and coinsurance, may not exceed the lowest of the following amounts:

- The physician or other supplier's net charge to the billing physician or medical group
- The billing physician or medical group's actual charge
- The fee schedule amount for the service that would be allowed if the physician or other supplier billed directly

for at least 35 hours per week may negatively affect those small group practices whose utilization of ancillary services does not require a full-time staff person (over 35 hours) or who offer job-share opportunities to staff who do not wish to work full-time. Where a group practice may have locations in more than one state, a reasonable mileage limitation may be difficult to prescribe and may negatively impact those physicians who travel to remote locations across a state line on a regular basis.

I would encourage CMS to not take a broad stroke approach to addressing this perceived area of risk related to contracted physician services. Where legitimate small group practices find means to provide convenient and cost-effective care to patients, it is in no ones best interest to restrict these practices. It would be more appropriate to limit the response to the specific labs identified as potential abusers, issue a fraud alert and investigate whether the labs are in conflict with anti-kickback or other current regulations. This perceived area of risk certainly should not be used to validate sweeping changes which make an already overly complex rule more difficult for physicians to understand and abide by.

Finally, CMS is proposing to change regulations to state that the supplier who reassigns his or her right to bill and receive Medicare payment to an entity has unrestricted access to claims information submitted by that entity for services supposedly furnished by the individual supplier, irrespective of whether the supplier is an employee or independent contractor of the entity. If adopted, the proposal would also mean that if an entity receiving the reassigned benefits were to refuse to provide the billing information to the employee supplier requesting the information, the entity's right to receive reassigned benefits may be revoked.

We agree that a party who can be held responsible for inaccurate claims information must have access to that information. The OIG has indicated that physicians will be held responsible for the accuracy of claims submitted in their names regardless of their knowledge of the claims. Therefore, it is imperative that said physicians have access to claims records. Limitations to access should include only that for which the party bears no liability.

Discussion of Comments – Health Care Information Transparency Initiative

CMS comments that part of the reason health care costs are rising so quickly is that most consumers of health care--the patients--are frequently not aware of the actual cost of their care. Health insurance shields them from the full cost of services, and they have only limited information about the quality and costs of their care. 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. CMS will post geographically-based Medicare payment information for common elective procedures for ambulatory surgery centers this summer and for common hospital outpatient and physician services this fall.

CMS is developing a project with the goals of providing more comprehensive information on quality and costs, including more complete measures of health outcomes, satisfaction, and volume of services that matter to consumers, and more comprehensive measures of costs for entire episodes of care, not just payments for particular services and admissions. CMS intends for the project to combine public and private health care data to measure cost and quality of care information at the physician and hospital levels. Quality, cost, pricing, and patient information will be reported to consumers and purchasers of health care in a meaningful and transparent way.

The AAFP supports transparency but has concerns that medical care is not equivalent to many other services for which the pricing and quality may be more easily defined. For instance, providing a patient

We appreciate this opportunity to comment on matters related to the Medicare Fee Schedule. As always, the American Academy of Family Physicians looks forward to working with CMS in its continued efforts to ensure access to appropriate physician services.

Sincerely,

Larry S. Fields MD

Larry S. Fields, M.D., FAAFP
Board Chair

259

ETHICON ENDO-SURGERY, INC.
a Johnson & Johnson company

Matt Moore
Director
Healthcare Policy and Economics
4545 Creek Road, ML 96
Cincinnati, Ohio 45242
(513) 337-7353

October 6, 2006

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

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

Dear Dr. McClellan:

Ethicon Endo-Surgery, Inc. (EES), a Johnson & Johnson company, welcomes the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) Proposed Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 (CMS-1321-P, *Federal Register*, Vol. 71, No. 162, Tuesday, August 22, 2006, p. 48981). EES is a medical device and diagnostics company with a mission to "transform patient care through innovation".

Understanding the economic pressures that exist in equitably delivering coverage and payment to Medicare participants, EES would like to commend you and your staff on the work done with regard to the proposed Medicare Physician Fee Schedule rule (PFS). The proposed rule provides a number of very important and positive modifications. However, there is one change that we feel will be detrimental to the access of certain advanced medical technologies. This particular modification is in relation to the Deficit Reduction Act (DRA) provisions related to imaging services.

Effective January 1, 2007, the DRA requires payments for the technical component of certain imaging procedures performed in a physician office be capped at the lesser of the Medicare physician fee schedule or the outpatient department (OPD) reimbursement rate. The capping of the technical component will significantly reduce reimbursements for specific procedures done in an office setting. The procedures we are concerned about would be diagnostic procedures that require image guidance to perform breast biopsies, most notably the vacuum-assisted breast biopsy (VAB).

EES recognizes that CMS does not have the authority to change or adjust the statutory provisions of the DRA. However, EES is concerned that limiting payment for all imaging procedures to no more than the OPD amount may reduce reimbursement to levels that restrict patient access to necessary care, and we request below that CMS use its administrative discretion to mitigate the negative impacts of this policy.

The image guidance for the VAB can be performed via 3 modalities: Stereotactic localization, Magnetic Resonance localization, and Ultrasound localization. The localization is a critical component of this procedure. The VAB has allowed over 2 million women to receive diagnoses for breast abnormalities without having open surgery. The American Society of Breast Surgeons recently issued a statement that "Image guided percutaneous needle biopsy is the diagnostic procedure of choice for image-detected breast abnormalities" (source: http://www.breastsurgeons.org/mibb.shtml, accessed August 17, 2006).

One thing that has made this diagnostic option more widely available is the fact that physicians can perform this procedure in their office rather than sending patients to a hospital outpatient department.

However, in order to perform a VAB in an office setting, capital equipment must be purchased. Along with the biopsy capital, which can cost up to 40,000 dollars, there is also the cost of the imaging equipment. Depending on the practice, the physician will incur capital and operational costs associated with the stereotactic table, ultrasound equipment and MRI magnet. Due to the high cost of the capital, the technical component is a critical piece of the physician's overall reimbursement for the VAB and allows the physician to afford such a large capital purchase. Physicians' offices generally have a lower procedure volume than hospital outpatient departments, therefore it is not unreasonable that the per procedure payment is higher for an office setting. Nonetheless, the proposed rule would apply the DRA imaging limit to image-guided treatment procedures and result in 30-50% decreases in reimbursement for these imaging codes in a physician office setting.

As a consequence of the DRA with regard to the VAB, there will be a lack of access due to decreased reimbursement in the physician's office. Ultimately, this will drive higher costs as physicians are forced to use a less advanced but higher reimbursed option of an open surgical breast biopsy. The result will be higher-costs and more invasive procedures, contrary to the standard of care endorsed by the American Society of Breast Surgeons.

In order to continue to make available necessary access to these technologies for Medicare Beneficiaries, EES requests that caps to the technical component of imaging services not be applied to CPT codes **76942** – Ultrasound Guided Biopsy, **76393** - MR. Guided Biopsy and **76095** - Stereotactic Guided Biopsy. CMS has interpreted the DRA provisions regarding imaging issues as relating to both "*diagnostic*" and "*image guided*" procedures. However, this interpretation is not borne out by the Medicare Payment Advisory Commission's (MedPAC) recommendations, which focus specifically on the over utilization of diagnostic imaging services leading to increased costs within the Medicare system. In its March 2005 report to Congress MedPAC cites the efficacy of two image-guided procedures, biopsies for bone-cancer and coronary angioplasty, as examples of image guided procedures, which benefit patients.

Moreover, these changes do not even include the 5.1 percent decrease due to the sustainable growth rate (SGR). Further concern regarding negative impacts on patient access comes from the AMA website stating, the "results of a recent AMA member connect survey indicate that Medicare payment cuts to physicians will hurt access to care for America's seniors. The results show that 45 percent of physicians will either stop accepting or decrease the number of new Medicare patients they accept if Medicare payments are cut in 2007." Ultimately the patient will have less access to this procedure and the initial dollars saved by cutting the practice expense will be lost as a more costly and invasive procedure is financially rewarded.

Lastly, we recommend that caps to the technical component of imaging services not be applied to any image guided treatment procedures such as the vacuum assisted biopsy.[1] In order to reduce adverse patient impact, we further recommend that any caps to the technical component of imaging services be applied in the most prudent manner possible.

[1] Approximately 18 image guided treatment procedures would be affected by the DRA caps. These codes are all done in conjunction with a surgical or other procedure. Eliminating these codes from the DRA cap would have nominal impact, estimated at 2%, on total projected savings.

ETHICON ENDO-SURGERY, INC.
a Johnson & Johnson company

Matt Moore
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Thank you, for your time and consideration of our comments and recommendations. We urge you to fully consider the comments submitted as we feel there will be negative repercussions of this decision that have not been thought through. We look forward to continuing to work with you and your staff in resolving these complex issues.

Sincerely,

Matt Moore
Director – Health Care Policy and Economics

Cc. Kathy Buto

The Coalition for Living Cell Cancer Treatment Testing
555 12th Street, NW
Washington, DC 20004

260

October 10, 2006

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

VIA FED EX

Re: CMS-1321-P -- Comments on the Medicare Physician Fee Schedule Proposed Rule for Calendar Year 2007
COMMENT TOPIC: CLINICAL DIAGNOSTIC LAB TESTS

To Whom this May Concern:

These comments are submitted on behalf of the Coalition for Living Cell Cancer Treatment Testing (the Coalition). We appreciate this opportunity to comment on the Medicare Physician Fee Schedule proposed rule for calendar year 2007 (the Proposed Rule).[1] The Coalition includes Precision Therapeutics, Inc. (Precision), a leader in the development of clinically proven decision support tools and services that assist physicians treating cancer patients. Precision's mission is to improve the treatment outcomes for patients living with cancer through technology that enables the individualization of therapy. The Coalition also includes Oncotech Inc., an innovator of molecular diagnostic testing for cancer patients whose mission is to extend the survival and improve the quality of life of cancer patients. Both Precision and Oncotech perform tests generally known as chemoresponse testing.

I. Background

Cancer patients with the same tumor histology (cancer type based on microscopic tissue characteristics) do not always respond to the same chemotherapy drugs, dosing schedule, or dose of chemotherapy. The growing number of therapeutic drug options for cancer create a challenge for cancer specialists in determining the best course of therapy for each patient. Chemoresponse tests are cell-based tests that quantify an individual patient's likely tumor response to single or multiple chemotherapeutic agents for various

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

types of cancer. One of many applications is the treatment of women with solid epithelial ovarian tumors.

The use of these tests are supported by clinical trials demonstrating the potential of a two to three fold improvement in progression-free survival. Chemoresponse testing is designed to provide predictive information to help physicians choose between chemotherapy drugs, eliminate potentially ineffective drugs from treatment regimens and assist in the formulation of an optimal therapy choice for each patient. This approach spares the patient from unnecessary toxicity associated with ineffective treatment and offers a better chance of tumor response resulting in progression-free survival.

We are commenting on 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."

In the Proposed Rule, CMS proposes to add a new regulatory section, § 414.410, to address concerns that have been raised regarding the DOS for some clinical diagnostic laboratory tests.[2] The Coalition believes that the proposed rule was likely meant to clarify jurisdictional issues related to fixed tissue archived as part of an inpatient hospital stay. However, there has been some confusion as to whether or not the ruling would apply to tests that rely on access to fresh tissue during the inpatient stay. We request clarification of this proposal in the final rule.

Chemoresponse testing requires fresh tumor tissue that is typically the result of a surgical procedure when the patient's tumor is biopsied or excised. These surgical procedures to remove presumably cancerous tissue are commonly done during an inpatient stay, and are therefore subject to payment under Medicare Part A. For chemoresponse testing, a fresh tissue sample is obtained from excess tissue from the surgery, and some of the cells from the fresh tissue are later used in testing. While cells are isolated from fresh tissue that is taken at the time of surgery, these cells do not represent a pathology or laboratory specimen. These cells are sent to special facilities outside of the hospital and kept alive for possible chemoresponse testing if and only if certain conditions are met. Chief among these conditions is the final tissue diagnosis of a certain cancer that confirms the clinical impression that led to the conditional request for further analyses. This chemoresponse testing that may occur is not related to the cancer diagnosis but instead provides information about candidate drugs to target the tumor.

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[2] Id. at 49065.

Therefore, the only service related to the assay that was provided to the inpatient was harvesting the specimen which was done in conjunction with and not in addition to or independent of a surgical procedure.

Once all of the prerequisites are satisfied, it is then, and only then, that cells are isolated and tested from the fresh tissue that was previously sent to a specialty facility. The chemoresponse test results in no way influence the inpatient care or treatment. It is post-discharge Part B chemotherapy that is guided by the chemoresponse testing.

II. Discussion and Recommendations

A. Chemoresponse Testing is Currently Covered and Paid for by Medicare as a Part B Service

Medicare Part B covers many categories of benefits, including according to SSA § 1861(s) "medical and other health services." Among these medical and other health services are laboratory tests performed in an outpatient setting. Medicare contractors have paid for chemoresponse testing through Part B for approximately ten years. The chemoresponse test results are generally available after the patient has left the hospital in order to assist in chemotherapy regimen decisions. It is not related to the patient's inpatient hospital stay except that the fresh tissue must be obtained from part of the surgical biopsy excised at the time of inpatient surgery. Therefore, these tests have been and most appropriately should remain a Medicare Part B service.

B. Chemoresponse Testing is not a Medicare Part A Service

Chemoresponse testing has never been provided as a hospital inpatient service. Hospitals do not provide the service and it has never been reflected in hospital costs. The prospective payment system for hospital inpatient services does not and has never accounted for this technology.

Covered inpatient hospital services are described in the Social Security Act § 1861(b) and 42 C.F.R. Part 409. The specific regulation that governs services such as chemoresponse testing is 42 C.F.R. § 409.16, Other diagnostic or therapeutic services, which reads:

> Diagnostic or therapeutic services other than those provided for in §§ 409.12, 409.13, and 409.14 are considered as inpatient hospital or inpatient CAH services if--
> (a) They are furnished by the hospital or CAH, or by others under arrangements made by the hospital or CAH;
> (b) Billing for those services is through the hospital or CAH; and
> (c) The services are of a kind ordinarily furnished to inpatients either by the hospital or CAH or under arrangements made by the hospital or CAH.

Chemoresponse testing meets none of these criteria and therefore is not an inpatient hospital (or Part A) service.

The key provision quoted above is (c), i.e., whether the service is "of a kind ordinarily furnished to inpatients." Chemoresponse test results are generally available after patients are discharged from the hospital for use in decision making during outpatient cancer chemotherapy. The only aspect of the chemoresponse testing that occurs in the hospital is the initial collection of the tissue by the surgeon during the inpatient surgical procedure. The scientific requirements of chemoresponse testing are such that fresh tumor tissue is an absolute necessity. There is no other type of sample that can be substituted for fresh tumor tissue, and there is no other opportunity to collect the fresh tissue sample other than during the inpatient surgery. In fact, not collecting the fresh tissue at the time of surgery and attempting to collect it at another time would be unethical. Furthermore, these services are generally not furnished by hospitals but instead by highly specialized laboratories employing advanced techniques that are not readily available outside of these specialized facilities.

A new policy that redefines chemoresponse testing as a hospital Part A service for the first time and does not create a new payment methodology will simply take access to this important technology away from Medicare beneficiaries. Hospitals will quite properly decline to add a new service that has no payment and is furthermore unrelated to the hospital course of treatment. The new and unnecessary bundling with a Part A DRG will even prevent Medicare beneficiaries from requesting and obtaining service when it is declined by the hospital. With this new policy interpretation Medicare will lose an important advance in chemotherapy and Medicare beneficiaries will lose all choice in the matter.

Current payment policy that considers chemoresponse testing a Part B service when testing is done outside of the hospital and for purposes unrelated to hospital treatment is sound. This policy interpretation has made chemoresponse testing available to Medicare beneficiaries for over a decade.

C. Recommendation

CMS should continue current practice which makes chemoresponse testing available to Medicare beneficiaries as a Part B service.

We appreciate the opportunity to provide these comments and are eager to work with CMS to ensure that physicians and patients continue to realize the clinical benefits offered by chemoresponse testing. Please let us know if we can answer any further questions.

Sincerely,

Sean McDonald
Sean McDonald
President and CEO
Precision Therapeutics, Inc.

Frank J. Kiesner
Frank J. Kiesner
President and CEO
Oncotech, Inc.

IDTFs; (2) Preventing IDTFs from utilizing any form of self-insurance; and (3) Imposing posting requirements. (See 71 Fed. Reg. 49080 (Aug. 22, 2006), proposed changes to 42 C.F.R. sec. 410.33.)

262

OREGON UROLOGY INSTITUTE
2400 Hartman Lane
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(541) 746-1618

October 9, 2006

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

Sirs,

We, the undersigned, are partners in the Oregon Urology Institute, a 15 physician Urology group practice in the Eugene area of Oregon. We recently purchased a pod lab in Leesburg, Florida that is operated by Uropath, LLC. In making our decision to purchase we were aware that the Office of the Inspector General had been reviewing these types of arrangements, but were so impressed with the quality and efficiency of the operation that we made the decision to purchase. The key factors in our decision were:

1. We believe that Uropath provided superior quality to that of local general pathologists. The quality of the pathologists, the specific focus on urologic pathology and the volume of cases reviewed led us to conclude that they do a better job than the general pathology laboratories.

2. We believe that the Uropath operation was more efficient and effective than most pathology laboratories. The unique focus of these labs allows for operational focus not available in general labs.

Given our research and conclusion, we find it hard to believe that CMS would come up with a different conclusion. The reported reason for CMS concern is potential program abuse. This concern is no different than volume abuse risk inherent in the ordering of surgeries and procedures and should be treated as such. Abuse can be easily monitored by reviewing existing data on the percent of positive cancer interpretations as a percent of total interpretations and outliers can be dealt with.

So, we respectfully request that CMS withdraw its proposed rules on pod labs and allow these types of arrangements to receive CMS approval. CMS rulings to solely affect the viability of pod labs should be instituted only if there is sufficient data to determine abuse does exist.

Thank you for allowing us the opportunity to provide comments.

Sincerely,

Mark R, Carson, MD

David DiMarco, MD

David Esrig, MD

Thomas Kollmorgen, MD

Bryan Mehlhaff, MD

Brady Walker, MD

ACR™
AMERICAN COLLEGE OF RADIOLOGY

October 6, 2006

Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; Proposed Rule

Dear Dr. McClellan,

The American College of Radiology (ACR), representing 32,000 diagnostic radiologists, radiation oncologists, interventional radiologists, nuclear medicine physicians and medical physicists, appreciates this opportunity to comment on the proposed notice "Hospital Outpatient Prospective Payment System (HOPPS)" published in the *Federal Register* on August 23, 2006. We will address format of the proposed rule, Category III codes, brachytherapy procedural and seed payments, placement of positron emission tomography/computer tomography (PET/CT) codes, cost data for magnetoencephaolgraphy (MEG), hospital cost data and the threshold for bundling drugs and radiopharmaceuticals.

Format of the Proposed Rule

This proposed rule was released with proposed changes on two other payment systems (i.e., Ambulatory Surgical Center and Inpatient Prospective Payment Systems). Although the ACR understands that the changes to these payment systems are somewhat related, we are concerned that an important issue will be overlooked while sorting through the proposal. **The ACR recommends that Centers for Medicare and Medicaid Services (CMS) continues to publish the three payment systems in separate *Federal Register* notices.** However, if CMS decides to continue to combine these proposals, then **the ACR recommends that each proposal is tabbed separately for each payment system under the main proposal and not be intertwined.**

Category III CPT® Code Placements

The ACR has noticed that the eight category III CPT® codes (i.e., 0144T to 0151T) that were developed for coronary computed tomography angiography (CTA) and implemented on January 1, 2006 have been placed in regular Ambulatory Payment Classification (APCs) for cardiac imaging. The ACR believes that coronary CTA is a

new technology and the purpose of the development of the Category III codes was to determine how this study is typically performed and then to determine value. **The ACR recommends that CMS place the eight category III codes for coronary CTA into new technology APCs so that data can be collected and pricing can be determined prior to their assignment into permanent APCs.**

Code	Description	Current APC	Rate	New APC	Rate
0144T	CT heart wo dye; qual calcium	0398	$261.66	1505	$300.00
0145T	CT heart w/wo dye funct	0376	$306.34	1505	$350.00
0146T	CCTA w/wo dye	0376	$306.34	1505	$350.00
0147T	CCTA w/wo, quan calcium	0376	$306.34	1505	$350.00
0148T	CCTA w/wo, strxr	0377	$415.12	1506	$450.00
0149T	CCTA w/wo, strxr quan calc	0377	$415.12	1506	$450.00
0150T	CCTA w/wo, disease strxr	0398	$261.66	1504	$250.00
0151T	CT heart funct add-on	0282	$95.72	1503	$100.00

CMS proposes to accept the APC Panel's recommendation to maintain the packaged status of code 0152T [computer aided detection with further physician review for interpretation, with or without digitization of films radiographic images; chest radiograph(s)]. **The ACR supports the APC Panel's recommendation to pay this code separately when performed at a different site from the chest x-ray.**

Placement of Tumor PET/CT Codes

For 2007, CMS proposes to reassign tumor PET/CT codes 78814, 78815 and 78816 from New Technology APC 1514 to clinical APC 0308. The ACR has significant concerns regarding this proposal. First, the new PET/CT codes were effective January 1, 2005. This means that the CMS proposal to move these codes out of the new technology APC is based on relatively limited claims data. Second, the ACR does not support the proposal to place tumor PET and PET/CT codes into the same APC as the resources needed to provide PET and PET/CT procedures are different.

Accordingly, **the ACR supports the APC Advisory Panel's recommendation to keep PET/CT in the new technology APC for one additional year to allow CMS to collect further data and recommends that CMS keep codes 78814, 78815 and 78816 in the New Technology APC 1514 at the payment rate of $1,250.**

Code	Description	2006/ 2007 SI	2006 APC	2006 Payment Rate	2007 APC	2007 Payment Rate
78811	Tumor imaging (pet), limited	S	1513	1,150.00	0308	862.29
78812	Tumor image (pet)/skull-thigh	S	1513	1,150.00	0308	862.29
78813	Tumor image (pet) full body	S	1513	1,150.00	0308	862.29
78814	Tumor image pet/ct, limited	S	1514	1,250.00	0308	862.29
78815	Tumorimage pet/ct skull-thigh	S	1514	1,250.00	0308	862.29
78816	Tumor image pet/ct full body	S	1514	1,250.00	0308	862.29

Various New Codes on Stereotactic Radiosurgery

The ACR is aware that there are new CPT® codes for the services described by the G codes for stereotactic radiosurgery (SRS) and stereotactic body radiation therapy (SBRT) which will become effective January 1, 2007. The ACR would like to request that CMS work with the specialty societies to develop appropriate crosswalks from the G codes to CPT® codes and the assignment of the new codes to APCs. This is vitally important to make sure that hospital coding, cost reporting and payment rates are consistent in the future.

Magnetoencephaolgraphy (MEG)

CMS proposes to accept the APC Panel's recommendation to move the MEG codes 95965, 95966 and 95967 from new technology into clinical APCs. The ACR is concerned that this reassignment is based on few claims with highly variable costs and charges. MEG is beneficial in localizing abnormalities in patients with epilepsy and gives the surgeon a guide in order to perform seizure surgery with minimal loss of brain tissue. There are only limited number of sites in the country that offer this important procedure. The ACR is concerned that inappropriate payments will make this limited access even worse. **The ACR recommends that CMS work with the sites that provide MEG and consult with them on how to most accurately report their services. A few inaccurate claims could have a big impact on the hospital cost data from which the APC median is created.**

Code	Description	2006 APC	2006 Payment rate	2007 APC	2007 Payment rate
95965	Meg, spontaneous	1523	$2,750.00	0038	$3,155.27
95966	Meg, evoked, single	1514	$1,250.00	0209	$706.89
95967	Meg, evoked, each add'l	1510	$850	0209	$706.89

Recommendations on How Hospitals Can Better Report Their Costs

The HOPPS process does not strictly define a "cost center" and this creates the potential for wide variance in calculation of costs.

There is relatively little guidance or procedural rules for how hospitals should allocate fixed costs, particularly those of expensive imaging equipment, between inpatient and outpatient procedures.

There are also no consistent reporting requirements to identify an identical set of individual costs to be reported by each cost center.

In addition, there is little if any guidance for hospitals on how to update their chargemasters determining the relativity of charges among procedures. Accordingly, a hospital could be charging four to five times its cost for a long-established procedure while charging only 1.5 times its cost for a newer, more complex procedure. The resulting aggregate cost/charge ratio may well result in a severe undervaluation for the newer procedure, as is the case with chest CT angiography.

The ACR continues to remain concerned that hospitals do not report their costs in a consistent and accurate way nor do they update their charge masters regularly with charges that reflect appropriate relativity. **The ACR recommends that CMS develop a standard methodology that addresses all four of the above described deficiencies, and we offer to work closely with CMS in that process.**

Radiology Procedures

At the March 2006 meeting, the APC Advisory Panel made a recommendation that CMS review payments for computed tomographic angiography procedures to ensure that their payment rates are consistent and accurately reflect resources used. The ACR is concerned that the current OPPS methodology that applies historical cost to charge ratios to charges submitted by hospitals for a specific new technology creates an artificial reduction in the cost attributed to that technology and an inaccurate APC designation. The ACR recommends that CMS develop a more accurate methodology for calculation of true costs for new technology, independent of historical cost to charge ratios prior to 2001.

The ACR would like to discuss this further with CMS and determine how this can be accomplished.

Drugs and Radiopharmaceuticals

CMS set the threshold for establishing separate APCs for separate biologicals and drugs to $50 per administration, which will expire by end of calendar year 2006. To determine the appropriate packaging threshold proposal for biologicals, drugs and radiopharmaceuticals for the CY 2007, CMS evaluated four options. CMS proposes to adopt the fourth option (update the packaging threshold for inflation). Accordingly, this proposal would increase the packaging threshold for radiopharmaceuticals from $50 to $55 for 2007, the same threshold that would apply to drugs and biologicals.

In sharp contrast, the APC Panel, at its August 2006 meeting, recommended that CMS eliminate the drug packaging threshold for all drugs and radiopharmaceuticals with HCPCS codes. **The ACR strongly supports this August panel recommendation.** The ACR is concerned that if radiopharmaceuticals and drugs are bundled in with the procedure, hospitals will not receive adequate reimbursement for them. Furthermore, we believe that drugs and radiopharmaceuticals reimbursed separately in a non facility setting should be treated the same in a facility setting.

Conclusion

Thank you for the opportunity to comment on this proposed rule. The ACR looks forward to continued dialogues with CMS officials. Should you have any questions on the items addressed in this comment letter, or with respect to radiology and radiation oncology, please contact Pam Kassing at 1-800-227-5463, ext. 4544 or via email at pkassing@acr.org.

Respectfully Submitted,

Harvey L. Neiman, MD

Harvey L. Neiman, MD, FACR
Executive Director

Cc: Herb Kuhn, CMS
Kenneth Simon, MD, CMS
Edith Hambrick, MD, CMS
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October 6, 2006

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

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

Dear Dr. McClellan:

The American College of Radiology (ACR), representing over 32,000 diagnostic radiologists, interventional radiologists, radiation oncologists, nuclear medicine physicians and medical physicists, is pleased to submit comments on the proposed notice "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007" published in the Federal Register on August 22, 2006. We will address the Deficit Reduction Act proposals; miscellaneous radiology supply and equipment issues; the global period for brachytherapy; independent diagnostic testing facility requirements; the reassignment rule; and the impact of the geographic practice cost index on physician practices in Puerto Rico.

Deficit Reduction Act Proposals

A. Multiple Procedure Reduction

The ACR appreciates the Centers for Medicaid and Medicare Services' (CMS) decision to not implement a 50 percent payment reduction for the technical component of multiple procedures performed on contiguous body areas in the same session for 2007. The ACR agrees that there are some efficiencies in clinical labor activity when certain combinations of multiple imaging procedures are performed in the same session. However, we do not agree that these efficiencies are uniform across all families and we do not believe the data support a 50 percent reduction. CMS proposes to exercise its discretion in the case of imaging services potentially affected by both the multiple imaging procedure reduction and the Outpatient Prospective Payment System (OPPS) cap by applying the multiple imaging procedure reduction **first** and then the OPPS cap. We compliment CMS for taking this step to minimize the negative consequences of these interrelated policies, and we support this approach, since it will somewhat abate what could have been an unintended compounding of payment reduction. However, in light of the DRA, the ACR believes that **any** technical component reduction for contiguous imaging is inappropriate and should be eliminated, since the Ambulatory Payment Classification (APC) payment rate already accounts for any cost-efficiencies incurred when contiguous body parts are examined.

B. Reduction in TC for Imaging Services Under the Physician Fee Schedule (PFS) to Outpatient Department (OPD) Payment Amount

As required by the DRA, CMS proposes to cap Medicare payment amounts for certain imaging services at the amount paid to hospitals under the OPPS. ACR views this policy as ill-advised and inappropriate, and believes it will lead to inequitable payment amounts and compromise Medicare beneficiaries access

and believes it will lead to inequitable payment amounts and compromise Medicare beneficiaries access to high quality imaging services. However, we recognize that CMS is simply attempting to implement a statutory requirement. Nevertheless, we believe that CMS should use its discretionary authority to the greatest extent possible to limit the potential disruption to patient access. This could be done by tightly circumscribing the list of affected services as noted below.

Definition of Diagnostic Imaging

In the Deficit Reduction Act of 2005, section 5102 (B) describes imaging as follows:

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

In the proposed rule, CMS defines imaging as services that provide visual information regarding areas of the body that are not normally visible, thereby assisting in the diagnosis or treatment of illness or injury. CMS considered the CPT® 7XXXX series codes for radiology services and added other CPT codes and alpha-numeric HCPCS codes that describe imaging services. The ACR believes that the list of procedures affected by the DRA should not include imaging guidance for interventional procedures. While supervision and interpretation codes for diagnostic angiography may meet the definition of an imaging procedure, the ACR believes that supervision and interpretation for endovascular procedures such as angioplasty, stent placement, and imaging guidance for biopsy, injections or drainage do not.

Recently, imaging guidance has been incorporated into new CPT codes for surgical procedures to include cryoablation of the prostate, endovascular stent placement in the carotid artery and bone ablation. These codes are not affected by the DRA and for consistency, when imaging guidance is used to facilitate a surgical procedure, those codes should not be defined as diagnostic imaging nor included on the list of codes subject to the DRA provisions.

Based on the definition above, the ACR believes that the DRA list needs to be further refined to exclude interventional radiology codes as we believe that the DRA was not intended to include imaging guidance that is integral to the performance of interventional treatment or diagnostic procedures.

Exclusion of Carrier-Priced Services

The ACR believes that a case can be made for excluding carrier-priced services, such as PET, from the list of services subject to the payment limitations required under section 5102 of the DRA. While the proposed rule argues that such carrier-priced services are "within the statutory definition of imaging services and are also within the statutory definition of PFS services," we believe there are other factors

that need to be taken into account in determining whether carrier-priced services should be subjected to the DRA-mandated payment limitations. To begin with, section 5102 of the DRA speaks of the technical component established under the physician fee schedule, and by definition, carrier-priced services do not have a technical component calculated in the usual manner or published in the *Federal Register*. Further, the DRA provision in question speaks specifically about the technical component prior to the application of the relevant geographic adjustment factor. Once again, it may not be possible to tease apart the various components of a carrier-priced payment amount for a service or to assure oneself that the portion of the fee in question has not been adjusted for geographic considerations by the carrier. By making these points, we do not wish in any way to imply that we believe that some imaging services somehow "deserve" to experience a payment limitation while others do not. We are simply urging CMS to exercise

its discretion to limit the application of what the ACR considers to be an inappropriate payment policy, particularly when it involves procedures that do not have a specific technical component value published in the Federal Register.

Effects of Professional Liability Insurance (PLI) Payments as a Result of DRA

Since 1999, the ACR has been expressing concern to CMS that the malpractice relative values (MPRVUS) are inappropriately assigned between the professional component (PC) and technical component (TC). The ACR advocates that physicians incur the highest costs for malpractice insurance and are ultimately responsible when a study is in question in a malpractice case. Therefore, the ACR has taken the longstanding position that the MPRVUS assigned to the TC should more appropriately be placed in the PC and vice versa. Although CMS' methodology did not allow for this change in the past, it was felt that medical practices who bill globally would still benefit from the global malpractice values. Now that the Deficit Reduction Act will cause severe cuts in the technical component of many imaging codes, this will also significantly cut the total malpractice value paid and malpractice funding available in the Medicare Trust Fund.

The ACR requests that CMS consider implementing ACR's previous requests to simply reverse the malpractice rate paid in the TC and PC to more accurately reflect where the liability risks and costs exist.

Provisions

A. Practice Expense Review Committee

CMS proposes to accept Practice Expense Review Committee (PERC) recommendations for all new codes that went through the Relative Value Update Committee from September 2005 through April 2006. ACR welcomes this decision.

However, the ACR believes that the new CMS practice expense methodology has caused inappropriate reductions in payment for certain procedures. The ACR believes that as we review the causes for these reductions that further refinement of direct inputs may be appropriate and requests that CMS support a society's ability to take these codes back to the PERC for review if necessary to insure accurate inputs and equipment costs.

B. Low and High Osmolar Contrast Media

The ACR agrees with CMS's proposal to delete low osmolar and high osmolar contrast media from the practice expense database because they are separately reimbursed under the fee schedule.

C. Medical Supplies, Equipment, Imaging Rooms

The ACR appreciates CMS's proposal to accept and implement updates to the various imaging rooms, the pricing for certain radiology equipment as submitted, and the updated cost information for the vertebroplasty kit.

D. Supply for code 50384

The ACR agrees with CMS's proposal to delete a ureteral stent from the practice expenses for code 50384 (Removal (via snare/capture) of internally dwelling ureteral stent via percutaneous approach, including radiological supervision and interpretation). The ACR agrees that this supply item was submitted in error.

E. Table 2: Equipment Items Needing Specialty Input for Pricing and Proposed Deletions

The ACR supports CMS's efforts to keep pricing information updated in the practice expense database. The ACR appreciates CMS's decision to accept the cost information submitted on the film alternator.

Miscellaneous Coding Issues

A. Global Period for Remote Afterloading High Intensity Brachytherapy Global Procedures

High intensity brachytherapy codes 77781, 77782, 77783 and 77784 are currently assigned a 90 day global period. In the proposed rule, CMS proposes to assign a global period of XXX for these codes to permit separate payment each time the services are provided and allow payment to be based on the actual service provided. CMS states that it is difficult to assign a relative value for a "typical" patient based on a global period of 90 days due to increasing variability in treatment regimens. The ACR supports this proposal and recommends that CMS change the global period for codes 77781, 77782, 77783 and 77784 from a 90 day to XXX global period.

Independent Diagnostic Testing Facility (IDTF) Issues

The Office of Inspector General (OIG) found a potential $71 million in improper payments made to IDTFs and as a result, CMS proposes that each IDTF be required to meet 14 standards, which resemble those that currently apply to suppliers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS), in order to obtain or retain enrollment in the Medicare program. In addition to the following comments on the specific elements of this proposal, the ACR recommends that CMS consider a requirement for all non-facility diagnostic testing to comply with IDTF rules.

1. Operate in compliance with all applicable licensure and regulatory requirements;

   The ACR believes that this proposed standard is too broad. Specifically, which licensure and regulatory requirements would CMS require? Would they be state requirements or new federal requirements? Since there is no uniformity among current state requirements, the ACR recommends that CMS draft minimum federal requirements that all IDTFs must adhere to.

2. Provide complete and accurate information on its enrollment application;

   The ACR believes that this standard is very basic and should already be in place under the current IDTF and enrollment rules.

3. Maintain a physical facility (not a post office box or commercial mailbox);

   The ACR supports this standard as it will be useful, especially with regard to conducting inspections as suggested in proposed standard 14.

4. Have all applicable testing equipment available at the physical site, excluding portable equipment;

   The ACR has no comments as this standard seems to be a logical follow-up to the proposed standard 3.

5. Maintain a primary business phone under the name of the business;

   The ACR believes that this standard should already be in place under the current IDTF rule.

6. Have a comprehensive liability insurance policy of at least $300,000 or 20 percent of its average annual Medicare billings, whichever is greater, that covers both the place of business and all customers and employees;

   The ACR recommends that CMS explain how insurance for IDTFs advances the stated purpose of protecting beneficiaries and the Trust Fund. The ACR also recommends that CMS more precisely define the type of insurance an IDTF should carry, and boost the minimum threshold of comprehensive liability coverage to $1 million individual or $3 million in aggregate liability limit.

7. Agree not to directly solicit patients;

   The ACR agrees strongly with this proposed standard, although CMS must be very specific on what is the definition of "solicit". For instance, if an orthopedic surgeon has a long-time patient that may need an MRI on a particular visit and the surgeon offers an MRI at his facility, is that soliciting? Also, would this standard mean that an imaging-only facility could not advertise to the general public or work with physicians who do not have a financial interest in the facility to arrange a referral relationship?

8. Answer beneficiaries' questions and respond to their complaints;

   This standard, as written, is fairly basic and subject to wide variation in compliance. The ACR would prefer a standard that requires an IDTF to have a written standard operating procedure for response to patient questions and complaints and a requirement to keep such questions and complaints on file.

9. Openly post these standards for review by patients and the public;

   The ACR supports this standard.

10. Disclose to the government any person having ownership, financial or control interest, or any other legal interest in the supplier;

    The ACR supports this standard.

11. Have its testing equipment calibrated per equipment instructions and in compliance with applicable national standards;

    The ACR supports this standard, but recommends that it be modified to state that equipment must be evaluated by a qualified medical physicist or other appropriate expert (depending upon the type of equipment being used by a given IDTF).

12. Have a technical staff on duty with the appropriate credentials to perform tests;

    The ACR supports this standard.

13. Have proper medical record storage and retrieval capabilities;

    The ACR supports this standard, but, considering the rapid evolution but sporadic prevalence of digital image storage capacity, would like to have significant input into what would constitute "proper medical record storage and retrieval capabilities."

14. Permit CMS or its agent/contractor to conduct unannounced on-site inspections.

The ACR supports this standard.

Supervision

The ACR supports the proposal to limit the number of IDTF's a physician can supervise to no more than three sites.

Place of Service

CMS proposes to define the "point of the actual delivery of service" as the correct "Place of Service" for the claim form in the case of diagnostic testing performed outside the IDTF's physical location.

For reasons of patient safety, quality of examination, and potential environmental hazard, the ACR believes that there should be limited medically necessary reasons to perform radiological or other medical imaging procedures at a beneficiary's residence.

Reassignment Rule and Physician Self-Referral

The ACR shares the CMS concern "that allowing physician group practices or other suppliers to purchase or otherwise contract for the provision of diagnostic tests and then to realize a profit when billing Medicare may lead to patient and program abuse." We strongly support the intent of CMS to address this issue in the proposals it has made in this rule. Specifically, the ACR agrees completely with the language proposed by CMS to amend § 424.80 of its regulations. **The ACR also believes that "diagnostic tests in the Designated Health Services (DHS) category of radiology and certain other imaging services" should not be excepted from CMS's proposed reassignment changes.** Published evidence has shown that diagnostic test volume has increased dramatically in recent years, causing higher costs for federal and private payers.

The Medicare Payment Advisory Commission and the Blue Cross and Blue Shield Association reported in 2003 that diagnostic imaging was the fastest growing type of medical expenditure in the United States, with an annual growth rate of nine percent that more than doubles general medical procedures.[1] Blue Cross data in 2005 confirms that diagnostic imaging continues to accelerate in the United States.[2] More importantly, this development has resulted in medically unnecessary diagnostic tests being performed on patients.[3]

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[1] Hackbarth GM, Reischauer RD, Miller ME. Assessing payment adequacy and updating payments for physician services. *Medicare Payment Advisory Commission Report to Congress*, March 2003. BlueCross BlueShield Association, *Medical Technology as a Driver of Healthcare Costs: Diagnostic Imaging* (2003).

[2] Blue Cross and Blue Shield Association, *Medical Cost Reference Guide, Section 4, Projected Growth in Imaging Procedures, U.S. Market 1998-2008* (2006).

[3] Moskowitz H, Sunshine J, Grossman D, Adams L, Gelinas L. The effect of imaging guidelines on the number and quality of outpatient radiographic examinations. *AJR* 2000; 175:9-15. See also Litt AW, Ryan DR, Batista BA, et al., Relative Procedure Intensity with Self-Referral and Radiologist Referral: Extremity Radiography. *Radiology* 2005;235:142-147.

- The ACR has advocated that Congress and CMS adopt quality standards to reverse this disturbing trend, ensure program integrity and safeguard against patient abuse. Consequently, we believe that the proposed reassignment changes could advance those critical objectives by influencing many physicians, medical groups and other entities to separately bill the technical and professional components of diagnostic studies. Although CMS focuses on suspect "pod lab" pathology arrangements that apparently involved potential fee-splitting and anti-kickback violations, the ACR maintains that those fraud and abuse concerns also apply in certain diagnostic test arrangements within the Designated Health Services (DHS)category of "radiology and certain other imaging services." For example, the ACR has learned of arrangements where the technical component (TC) for MRI procedures performed under a lease arrangement is billed to Medicare at a significant markup to the supplier's actual charge to the billing entity.

The ACR also strongly supports adoption of further amendments to § 424.80(d) that CMS is considering in regard to when a physician or medical group can bill for a reassigned professional component (PC) of a diagnostic test, and recommends that diagnostic tests in the DHS category of radiology and certain other imaging procedures not be excepted from those amendments. The amendments under consideration, if included in the final rule, would serve as a logical and supportive corollary to the proposed amendments regarding the TC.

The ACR is aware of arrangements in which the billing entity reportedly does not pay an independent contractor physician the full professional component fee, yet bills Medicare for the entire PC while retaining an amount that cannot be attributable to legitimate billing or other administrative expenses. **Therefore, the ACR firmly believes that an anti-markup provision should apply to the reassignment of the PC of diagnostic tests performed under a contractual arrangement.** In response to the request for comments on "how to determine the correct amount that should be billed to the Medicare program", the ACR suggests that CMS use the same language it has proposed for the TC anti-markup provision, i.e. "the amount billed to Medicare by the billing entity, less the applicable deductibles and coinsurance may not exceed the lowest of the following amounts:

- 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
- The fee schedule amount for the service that would be allowed if the physician or other supplier billed directly."

The ACR also supports CMS's efforts to change the definition of "centralized building" in the regulations to address certain space ownership or leasing arrangements that seek to meet the "physician services" or "in-office ancillary services" exceptions. However, we are concerned that inclusion of a minimum 350 square feet in the definition of "centralized building" would not effectively curtail potential program or patient abuse that could occur through provision of diagnostic tests in the DHS category of radiology and certain other imaging services. **The ACR therefore suggests that CMS consider a larger and more appropriate minimum square footage in the definition of "centralized building" for those specific DHS.**

Alternatively, the ACR would more strongly recommend that CMS require that all "non-facility" provision of diagnostic tests in the DHS category of radiology and certain other imaging services be subject to the rules for Independent Diagnostic Testing Facilities (IDTF). The ACR agrees with the proposal that the "centralized building" permanently contain the necessary equipment. We also believe that the potential for "pod" type abuse for radiology and imaging services would be minimized by requiring the group practice using the "centralized building" under the physician services exception or the in-office ancillary services exception to employ, in that space, a nonphysician employee or independent contractor who will perform services exclusively for the group for at least 35 hours per week. CMS is considering such a policy (at least in the case of pod labs) and we believe that it is reasonable and should be applied more broadly.

Finally, the ACR also supports amending the regulation to allow the reassigning supplier to have unrestricted access to claims information submitted to Medicare by the billing entity, irrespective of whether the supplier is an employee or an independent contractor of the billing entity.

Geographic Practice Cost Indices (GPCI)

Effective January 1, 2007, CMS is mandated to drop the current floor of 1.00 for the work GPCI. CMS seeks suggestions on alternative ways that CMS could administratively reconfigure payment localities that could be developed and proposed in future rulemaking. In this regard, the ACR remains concerned that the current GPCI for Puerto Rico is making it difficult for physician practices to retain professional and technical staff, who are being recruited away by physician offices from locales with much higher GPCIs, particularly in the State of Florida. We, therefore, urge CMS to examine more carefully the reasonableness of the data for Puerto Rico that are used in constructing the applicable GPCI and to consider alternative data sources or ways to configure payment localities that would address these concerns.

Conclusion

Thank you for the opportunity to comment on this proposed notice. The ACR encourages CMS to continue to work with physicians and their professional societies. The ACR looks forward to a continuing dialogue with CMS officials about these and other issues affecting radiology. If you have any questions or comments on this letter or any other issues with respect to radiology, please contact Angela Choe at 800-227-5463 ext. 4556 or via email at achoe@acr.org.

Respectfully Submitted,

Harvey L. Neiman, MD

Harvey L. Neiman, MD, FACR
Executive Director

cc: Herb Kuhn, CMS
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265

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September 29, 2006

Hon. Mark B. McClellan, M.D., PhD.
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COMMENT TO: CMS-1321-P "IDTF Issues"

File Code CMS-1321-P: Comments Related to Proposed Rulemaking re: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B

Dear Dr. McClellan,

I am writing to address the 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) as it relates to the provision of Home INR Monitoring services (G-0248 and G-0249) provided by Independent Diagnostic Testing Facilities (IDTFs). I have written to CMS on two occasions[1] over the past year about my concern that potential rule changes governing the "place of service" for this "lifesaving"[2] benefit could seriously compromise the clinical objectives of the benefit – to "reduce the risk of strokes and bleeding"[3]. The implication of these potential rule changes was that legitimate providers of this service would be required to establish separate facilities in all 50 states, rather than service beneficiaries from an efficient, central office.

In response to my previous two inquiries, my constituent Mr. Robert Knorr, CEO of Tapestry Medical Inc., a leading national provider of these services, received a letter from Thomas Gustafson, Ph.D. on February 21, 2006, indicating that the potential rules changes would not be implemented. Specifically, Dr. Gustafson confirmed that *"the location of the IDTF is considered the place of service and the training (G-0248) and associated supplies (G-0249) must be billed to the carrier with the jurisdiction for the location of the IDTF."*

[1] September 26, 2005 letter to Herb Kuhn and December 8, 2005 letter to Mark B. McClellan, M.D., Ph.D.
[2,3] CMS Press Release – September 26, 2001.

Medicare News

For Immediate Release:

Wednesday, September 26, 2001

Contact:

CMS Office of Public Affairs
202-690-6145

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MEDICARE WILL COVER HOME TESTING FOR BLOOD THINNESS

The Centers for Medicare & Medicaid Services (CMS) will begin national Medicare coverage of home testing that enables patients with mechanical heart valves to measure how well their blood is thinned.

Previously there had been no national coverage policy for self testing in the home prothrombin level (also called INR testing) for patients with mechanical heart valves, and the insurance companies that process and pay Medicare claims had been denying claims for home prothrombin self testing.

"This simple home test can help Medicare beneficiaries reduce their risks of strokes and bleeding," Health and Human Services Secretary Tommy G. Thompson said. "The decision reflects our commitment to expanding Medicare coverage to include effective preventive care and services."

"Once more, Medicare is moving aggressively to assure that beneficiaries get the high quality, and sometimes lifesaving, care they need and deserve," said CMS Administrator Thomas A. Scully. "This decision will give a new option to Medicare beneficiaries who need to get frequent prothrombin tests. The scientific data we reviewed showed that when patients with mechanical heart valves used these devices at home, they may suffer fewer strokes and bleedings."

Under local carrier coverage policies, patients receiving home health care could have their prothrombin level measured by home health personnel, and phlebotomists could come to patients' homes to draw samples that were processed in laboratories. The new national coverage policy allows beneficiaries to perform the test themselves and could permit more frequent monitoring of a patient's response to blood thinning medication.

After a review of the scientific and clinical evidence, CMS determined that the evidence regarding more frequent home testing was sufficient to provide national Medicare coverage for patients with mechanical heart valves.

The decision was posted on the CMS web site on Sept. 19, 2001. Implementation is expected later this year. More information on this coverage decision is available at http://www.hcfa.gov/coverage/8B3-PP.htm.

266

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October 10, 2006

Leslie Norwalk, Esq., Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
File Code CMS-1321-P
Hubert H. Humphrey Building, Room 445-G
200 Independence Ave., S.W.
Washington, D.C. 20201

RE: Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B," [CMS-1321-P] RIN 0938-AO24

Dear Acting Administrator Norwalk:

The American Psychiatric Association (APA), the national medical specialty society representing more than 35,000 psychiatric physicians, appreciates the opportunity to submit these comments in response to the proposed rule by the Centers for Medicare & Medicaid Services (CMS), entitled "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B," concerning 42 C.F.R. Parts 405, 410, 411, 414, 415 and 424, published in the Federal Register on August 22, 2006.[1]

Psychiatric Screening Should not be Excluded from Medicare Coverage

CMS should include psychiatric screening examinations in the list of preventive health screenings and examinations exceptions from services that are excluded from Medicare coverage, under proposed Sec. 411.15. Especially with the high prevalence of psychiatric disorders within the Medicare population, it is essential that these beneficiaries receive psychiatric screening examinations. Psychiatrists will be motivated to encourage such examinations if they can obtain Medicare reimbursement for them. Early identification of psychiatric disorders can often lead to better patient outcomes and

[1] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B;" [CMS-1321-P] RIN 0938-AO24 [Federal Register: August 22, 2006 (Vol. 71, No. 162)].

RVUs or office expenses because they could not have been anticipated. Elements of compensation must cover physician time with patients; physician time spent handling administrative issues with external parties, such as pharmacies in Part D; staff time spent with patients and third parties; and office equipment, such as computer systems.
(from comments to the five-year review notice.)

APA is currently engaged in a national study to obtain data on administrative requirements of the Medicare Part D program in 2006, as they affect dually eligible beneficiaries.[7] By extension, this data will illuminate the demands placed upon these patients' psychiatrists, as a direct result of Part D. The initial data show Part D problems for about half of these psychiatric patients. This means that psychiatrists treating those patients had to expend some degree of increased administrative time dealing with these programmatic complications, as well as additional patient time.[8] Specific problems with administration of the drug plans added to the administrative burden upon physicians.[9] One particularly labor-intensive area is that of psychiatrists assisting patients with

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[7] American Psychiatric Institute for Research And Education (APIRE): "THE IMPACT OF MEDICARE PART D ON MEDICATION ACCESS AND CONTINUITY: Preliminary Findings from a Large, National Study of Dual Eligible Psychiatric Patients;" September 14, 2006:

"The American Psychiatric Institute for Research and Education (APIRE) is systematically monitoring and characterizing medication access and continuity among the "dual eligible" patients with mental and addictive illnesses through a large, national study. The primary aims of this study are to:

1) Assess access to medications and the extent of any potential disruptions in medication continuity;
2) Characterize any potential adverse clinical or other consequences which may result from unintended medication disruptions or access problems; and
3) Evaluate the administrative functioning and requirements of the new PDPs.

"This study will track medication access and continuity from January 1, 2006 through December 31, 2006 among a nationally representative sample of dual eligible patients treated by psychiatrists." page 1.

[8] American Psychiatric Institute for Research And Education (APIRE): "THE IMPACT OF MEDICARE PART D ON MEDICATION ACCESS AND CONTINUITY: Preliminary Findings from a Large, National Study of Dual Eligible Psychiatric Patients;" September 14, 2006:

"Overall, the preliminary findings from the first four months of data collection (Jan-April 2006) showed approximately half of all the dual eligible psychiatric patients studied had at least one problem with medication access or continuity reported since January 1, 2006." pages 1-2.

[9] American Psychiatric Institute for Research And Education (APIRE): "THE IMPACT OF MEDICARE PART D ON MEDICATION ACCESS AND CONTINUITY: Preliminary Findings from a Large, National Study of Dual Eligible Psychiatric Patients;" September 14, 2006:

"Problems with Prescription Drug Plan (PDP) Administration

- Nearly one-third of all patients had problems reported with plan enrollment or changing to a desired plan.
- Approximately one-quarter of patients had to have exceptions requests or appeals initiated on their behalf.
- Medication access problems were significantly higher for patients with prior authorization, requirements to use generics, or limits on number/dosing of medications reported by the physician." page 2.

making requests to drug plans for formulary exceptions when their needed medications, dosages and/or delivery systems are not on the formulary. Physicians also must assist patients when they appeal denials of such requests.

According to the APIRE preliminary findings, *"(a)pproximately one-quarter of patients had to have exceptions requests or appeals initiated."* Psychiatric patients are among the most cognitively and emotionally challenged, therefore are most likely to require assistance from their psychiatrists in navigating Part D and other federal program requirements. In addition, psychotherapeutic medications are highly idiosyncratic and must be carefully titrated to suit the individual patient. This can require dosages outside the typical parameters of usage that are appropriate for the patient, yet may provoke "safety edits" of prescriptions, to which psychiatrists must respond. That incurs yet another dimension of administrative burden upon psychiatrists. Results from this study and other sources should be analyzed and applied by CMS in the course of determining appropriate reimbursements for psychiatrists, as well as for other physicians.

CONCLUSION

APA urges CMS to continue to update its databanks relevant to physician compensation, through specialty society surveys and other reliable data-collection instruments. CMS should use this data as a basis to fairly compensate psychiatrists and other physicians for administrative and patient time expenditures related to the new, ongoing demands imposed upon them by federal programs, in particular, Medicare Part D.

APA further advocates that CMS continue to work diligently with Congress to resolve the undue limitations placed upon the development of fair and equitable physician reimbursements by the outdated SGR system.

Thank you for allowing APA the opportunity to communicate its concerns.

Sincerely,

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