AMERICAN COLLEGE OF CHEST PHYSICIANS

The leading resource for the improvement in cardiopulmonary health and critical care worldwide.

September 28, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1512-PN, Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

Re: CMS Revision to Change in Consultation Policy Adversely Affecting Physicians

Dear Dr. McClellan:

I am submitting these comments on behalf of the American College of Chest Physicians (ACCP) regarding Transmittal 788 CMS Manual Change Request 4215 dated December 20, 2005, effective January 1, 2006 with an implementation date of January 17, 2006 on Reporting Consultation codes, CPT 99241-99255.

The ACCP comprises over 16,500 physicians and allied health professionals, whose daily practice involves diseases of the chest in the specialties of pulmonology, cardiology, thoracic and cardiovascular surgery, critical care medicine, sleep and anesthesiology. These health care professionals practice in virtually every hospital in this country, and many of the physicians head major departments in these hospitals. As a multidisciplinary society, the ACCP offers broad viewpoints on matters of public health and clinical policy in cardiopulmonary medicine and surgery. The ACCP appreciates the opportunity to submit comments for consideration on the CMS revision to its consultation policy following CPT's deletion of the follow-up inpatient consultation codes (99261-99263) and the confirmatory consultation codes (99271-99275) for 2006.

Our main area of concern is the Transfer of Care. As a specialty, we care for very complex patients that often have multiple physicians involved in their coordinated care. Although recent data (both from the Comprehensive Error Rate Testing Program and the recently released March 2006 Office of the Inspector General Report) reveal persistent errors in reporting and payments for consultations, the majority of the errors involve the level or type of

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consultative service, but not the existence or medical necessity for the consultation.

The appropriate reporting of consultation codes has become commonplace for most physicians. The recent elimination of both the inpatient follow-up and the confirmatory consultation codes will improve the accuracy by both physicians and contractors in reporting and paying for consultations, respectively.

Unfortunately, the recent change that Medicare implemented in the transfer of care has now caused great confusion in the physician community, specifically for chest physicians. Further, these changes extend beyond the ability of Current Procedural Terminology (CPT) codes to accurately describe the medically necessary physician work provided to Medicare beneficiaries by chest physicians.

The work chest physicians perform for a pre-operative evaluation prior to surgery on an asthmatic or COPD patient is indeed a consultation. However, if that same patient experiences a complication (a new problem), variable contractor interpretations mandate denials of consultation codes, because of the implicit erroneous assumption that the complete care of that patient has previously been transferred to the chest physician. Similarly, a surgeon's request for pre-operative evaluation of a patient known to the chest physician warrants new work, to appropriately evaluate and prepare that patient for the proposed surgical procedure.

TRANSFER OF CARE

The Medicare Transmittal 788 includes a definitional change from "complete" transfer of care to "partial" transfer of care. This new definition was certainly never discussed at the annual advisors meeting of the CPT Editorial Panel, never offered in draft form as part of any Notice of Proposed Rule Making, and never circulated widely through the physician community. Rather, the Transmittal was released as a "*fait accompli*," with severe unintended consequences. At a minimum, the consternation and confusion widespread throughout the physician community reflects the ambiguity in the language and the lack of collaborative, collegial preparation for any major policy change between Medicare and the physician community. The innumerable e-mails, telephone calls, letters, and committee meetings between Medicare officials and physicians with their society representatives certainly reflects the unilateral nature of the Transmittal.

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We believe the most appropriate venue for any such drastic changes in the definitions of a consultative service would be the CPT Editorial Panel. Drs. Kenneth Simon and Edith Hambrick are active participants in the CPT process for CMS. If the house of medicine were given an opportunity to discuss such issues in advance, we and many others would not be writing this letter asking for reconsideration of a change in consultation policy.

Defining a transfer of care as occurring when any aspect of a patient's care is transferred from one physician to another, unilaterally without the *a priori* agreement of the accepting physician, is **NOT** current practice. When a patient is sent to the consulting physician, the consultant generally knows nothing about that patient. An initial consultation, to adequately determine a course of action is medically necessary.

We do not agree in the office setting, nor do we believe you intended, the distinction between a consultation and an initial encounter to be whether care is rendered. The current policy implies that a physician in the office should report a consultation if in a letter back to the requesting physician, nothing needs to be done; but report a new office visit if any medical care should be rendered. In parallel, in the inpatient hospital setting, the new Transmittal suggests that the request for opinion or advice by a physician is only a consultation if the requesting physician expects the consultant to **not** participate in the management of that patient. Similarly, in the inpatient setting, for a patient with a new complication or problem, the Transmittal proposes that a physician who had previously seen a patient for a different reason could report only an inpatient subsequent hospital visit code.

The new Transmittal is ambiguous and internally inconsistent in the language regarding transfer of care. As noted above, the Transmittal states that any partial transfer of care precludes reporting a consultation code. Yet, the Transmittal also states that the accepting physician must "...document this transfer of the patient's care, to his/her service, in the patient's medical record or plan of care." Absent this documentation of accepting responsibility for transfer of this care, the transmittal appears to allow continued appropriate reporting of a consultative service. Otherwise, implementation by the physician community of this apparent mandate to accept a transfer, without *a priori* approval and subsequent written acceptance, will result in havoc for Medicare beneficiaries and an explosion of malpractice allegations, as the Transmittal thereby puts the consulting physician under a mandate to provide all care for a problem merely at the request of another provider.

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EXAMPLES

Under the current definition including "partial" transfer of care, chest physicians will be under-compensated for new, medically necessary care of the unstable and acutely ill post-operative patient. If the ambulatory pre-operative consultation request states that the "...peri-op risk is high/medium/low for possible complications such as hypoxemia, pneumonia (aspiration or otherwise), respiratory/ventilator failure, pulmonary embolism, hypoxemia"; then according to the new Transmittal the patient with a massive pulmonary embolism does not warrant a new consultation to assess right heart strain, to recommend thrombolytic therapy and/or placement of an inferior vena cava filter would be appropriate, or to examine whether the family history merits a hypercoaguable evaluation. Each of these potential issues are so clinically remote and distinct from the initial pre-operative evaluation that a new consultation is warranted; however, the new Transmittal suggests that only a subsequent hospital visit code should be reported. As a very specific example, many pre-operative risk assessments might include a general query about bleeding or clotting disorders, but not necessarily ask if any of the patient's first-degree relatives ever had deep venous thromboses or pulmonary emboli, especially if the pre-operative risk was low.

As an additional example, even if the pre-operative risk was high for thromboembolic events and specific risk reduction mechanisms addressed in the pre-operative recommendations, the evaluation and management of the actual event merits a new evaluation of the patient for this new problem. In essence, risk reduction ***is*** different than disease management.

Other clinical examples abound, revealing flaws in the language of the new Transmittal. Most pre-operative pulmonary evaluations of a patient with asthma undergoing colon or biliary surgery do not include a chest CT scan. Imagine that stable asthmatic, whose asthma post-operatively was appropriately managed by the performing surgeon, in accord with the opinion and advice offered in the original consultation. When a post-abdominal surgery CT scan looking for an abscess reveals a new mass in the retrocardiac lung base, the pulmonary physician would be precluded from reporting a consultation for this completely new, totally unexpected new problem. Currently, most providers and patients would believe this completely new problem worthy of a new consultation.

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Similarly, if the pre-operative consultation noted high/medium/low risk without specifying any of the listed complications noted above, we believe even an aspiration pneumonia with recommendations for ventilator settings and antibiotic choices would not be part of a new consultation, since neither ventilator settings nor empiric antibiotics would normally be provided in a pre-operative consultation.

CONCLUSIONS

Chest physicians, medical and surgical specialists, hospitalists and primary care physicians, and other cognitive specialists, whose livelihood depends on consultations, are being downcoded inappropriately to office or subsequent hospital visits when indeed they are performing consultations. We remain pleased with the proposed increases to the evaluation and management codes that remain under the threat of dilution by budget neutrality requirements and ask a clarification be issued to Medicare Transmittal 788 to ensure recognizing true consultation services and not fostering inappropriate down-coding to office or subsequent hospital visits.

Should you or your staff have any questions, please do not hesitate to contact me, or Diane Krier-Morrow at dkriermorr@aol.com. Her telephone numbers if (847) 677-9464.

Sincerely,

W. Michael Alberts, MD, FCCP
President

Cc: Kenneth Simon, MD, CMS
Edith Hambrick, MD, CMS
ACCP Practice Management Committee
ACCP Government Relations Committee

We have shared the above recommendations with our identified Contractor Advisory Committee members and have asked them to support our recommendations.

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Reviewed and approved by the pulmonary Medicare Contractor Advisory Committee members as noted below:

Alaska: Norman Wilder, MD, FCCP
Connecticut, Dave Hill, MD, FCCP
Florida, Jeffrey Berman, MD, FCCP
Illinois: Anthony Marinelli, MD, FCCP
Indiana: Praveen Mathur, MBBS, FCCP
Iowa: Michael Witte, DO, FCCP
Kentucky: Kenneth Anderson, MD, FCCP
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Ohio: Gail E. Mutchler, MD, FCCP
Oregon: Alan F. Barker, MD, FCCP
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09/21/2006

Department of Health and Human Services
RE: CMS1321-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 Sir/ Madame,

I am one of four board certified pulmonologists in a group serving patients in Boca Raton, Delray Beach and Boynton Beach, Florida. I have served as President of Delray Community Hospital's medical Staff. I have been on the Medical Executive Committee at Boca Raton Community Hospital for four years and I am on the volunteer medical faculty at the new FAU/Miller School of Medicine. In this capacity, I wish to raise serious concern about the above referenced proposed rules.

You have made this proposal to address concerns of "certain commentors" about "pod labs" which are owned by surgeons to process and bill for outpatient pathology services. These "commentors" allege that urologists or other specialists perform unnecessary biopsies in order to profit from pathology services.

These rulings will severely impact other physicians who are in the process of developing other types of centralized building arrangements allowed by recent legislation enacted in 2004.

The above rules, I suspect, were written by or on the behalf of the American College of Pathology. The reasoning is self serving and does not have an effect on Medicare costs and further may shift patient care back to the more costly hospital inpatient and outpatient facilities.

The"commentors" further suggest that in the current environment, more and unnecessary biopsies are being done to increase profit. Firstly, the costs to Medicare are pathologist driven. Multiple expensive stains are done at the pathologist's discretion. What is the motivation to do unnecessary procedures? None, really. The medico-legal risk of endangering a patient by doing unwarranted biopsies is on the surgeons mind at all times. Furthermore, the pathology literature is replete with recommendations for more biopsy samples for urology and gastroenterology procedures in order to make earlier diagnoses and to start appropriate therapy in a more timely fashion.

The effect of this ruling is to shift the compensation from the physicians who care for and are responsible the Medicare Beneficiaries to those who never see the patient. Medicare reimburses precisely the same amount for professional and technical components regardless of the specialty of the physician to whom payment is made. Thus the concept of a "markup" of professional services is inappropriate. Global billing seems a better way to protect the program from fraud and abuse. Again, the proposed rules smack of special

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September 26, 2006

Via FedEx and Electronic Submission to: http://www.cms.hhs.gov/eRulemaking

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U.S. Department of Health and Human Services
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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 - Comments on Drug Administration and CCI edits

Dear Dr. McClellan:

Bristol-Myers Squibb Medical Imaging (BMSMI) appreciates this opportunity to submit comments to the Centers for Medicare and Medicaid Services (CMS) on the Proposed Rule updating the Medicare Physician Fee Schedule ("MPFS").[1] A subsidiary of Bristol-Myers Squibb Company (BMS), the global pharmaceutical and related health care products company, BMSMI is one of the leading manufacturers of radiopharmaceuticals and other medical imaging drugs, including DEFINITY®,Vial for Perflutren Lipid Microsphere Injectable Suspension, a medical imaging drug used to enhance and delineate cardiac structures during echocardiography procedures.[2]

In these comments, BMSMI would like to call to your attention a specific issue with respect to payment for the intravenous (IV) administration of echocardiography contrast imaging drugs, like DEFINITY®. As described more fully below, under current coding policies, Medicare is aggregating the payment for the IV injection of the echocardiography contrast imaging drug into the payment for the associated echocardiography procedure. This policy is impractical for two reasons:

1. It ignores the fact that the echocardiography procedure codes do not describe the use of imaging drugs, and
2. There is no evidence that the costs for administration of the imaging drugs are included in the associated echocardiography procedures.

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

[2] Activated DEFINITY® (Perflutren Lipid Microsphere) Injectable Suspension is indicated for use in patients with suboptimal echocardiograms to opacify the left ventricular chamber and to improve the delineation of the left ventricular endocardial border.

We request, therefore, that CMS remove any coding edits from the Correct Coding Initiative (CCI) that aggregate the IV administration code 90774 "Therapeutic, prophylactic or diagnostic injection (specify substance or drug); Intravenous push, single or initial substance/drug" with the echocardiography procedure codes 93307 and 93308.[3]

Background

Echocardiography procedures are used to evaluate patients with known or suspected cardiac disorders. In most cases, echocardiograms can be interpreted by physicians, and the information can be used in patient management. However, in up to 20-percent of cases[4], unenhanced echocardiograms are suboptimal and repeat studies or additional testing may be required. Echocardiography contrast imaging drugs are FDA-approved intravenously-administered drugs that can enhance images in patients with suboptimal echocardiograms. Clinical studies have shown that echocardiography contrast imaging drugs can salvage up to 58-91-percent of unevaluable images.[5] Published papers have estimated that substantial cost savings can be obtained from use of contrast-enhanced echocardiography in cases with suboptimal unenhanced echocardiograms.[6]

Issue

The American Medical Association (AMA) released new Current Procedural Terminology (CPT) codes effective January 1, 2006, to report IV administration of drugs. In the notes accompanying the new codes, the AMA instructed providers not to use the new codes when an IV injection is an inherent part of a procedure. Administration of contrast in diagnostic imaging is given as an example of when the new codes should not be used because IV injection is considered part of the procedure. This limitation on use of the new codes in diagnostic imaging *generally* makes sense because—outside of echocardiography—there are specific codes for contrast-enhanced diagnostic imaging procedures which differentiate between procedures that do and do not involve IV administration of contrast. **However, this is not the case with echocardiography procedures. Echocardiography procedure codes were developed before echocardiography contrast imaging drugs were approved by the FDA, and the echocardiography procedure codes do not mention use of contrast imaging drugs.**

Consistent with the AMA instruction, CMS's CCI is now aggregating payment under the new IV injection codes into the payment for contrast-enhanced imaging procedures, when performed. Unfortunately, CCI has included echocardiography procedures under this aggregating policy. Although it may be reasonable to aggregate the new IV administration codes when there are specific contrast-enhanced diagnostic imaging procedure codes, there is no justification for aggregating the IV administration of contrast into the payment for echocardiography procedures.

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[3] 93307 "Echocardiography, transthoracic, real-time with image documentation (2D) with or without M-mode recording; complete;" 93308 "Echocardiography, transthoracic, real-time with image documentation (2D) with or without M-mode recording; follow-up or limited study"

[4] Waggoner AD, Ehler D, Adams D, et al. Guidelines for the cardiac sonographer in the performance of contrast echocardiography: Recommendations of the American Society of Echocardiography Council on cardiac sonography. *J Am Soc Echocardiogr.* 2001;14:417-20.

[5] Package insert for DEFINITY® Vial for (Perflutren Lipid Microsphere) Injectable Suspension (September 2004).

[6] Shaw LJ, Gillam L, Feinstein S, et al. Use of an intravenous contrast agent (Optison™) to enhance echocardiography: efficacy and cost implications. *Am J Man Care.* 1998;4: SP169-SP176.

Echocardiography procedure codes do not describe use of imaging drugs because these drugs are not used in the majority of procedures. Therefore, the practice expense resources involved with the IV administration of contrast imaging drugs are not included among the practice resources for the associated echocardiography procedures.

For example, the resting echocardiography code 93307 ("Echocardiography, transthoracic, real-time with image documentation (2D) with or without M-mode recording; complete") includes the following "typical" practice expenses[7].

Clinical labor—59 minutes of a cardiac sonographer's time (pre, intra and post time summed).
Equipment—50 minutes utilization of each of echocardiography ultrasound with 4 transducers, echocardiography ultrasound digital acquisition, desktop computer with monitor, color video printer, stretcher and 18 minutes utilization of each of echocardiography analyzer software and medical grade SVHS VCR video equipment.
Supplies—One each of computer media optical disk (128Mb), electrocardiograph electrode, ultrasound transmission gel, VHS video tape , minimum multi-specialty visit pack, non-sterile sheet drape (40in x 60in) and a sanitizing cloth wipe.

We would understand that the payment for this procedure would be the same whether a particular site with a specific patient used more or less of the resources identified above or used different equipment, supplies or staff than estimated by the RUC/PEAC for the typical case. However, these expenses are totally unrelated to those involved with IV administration of medical imaging drugs, which are used in a minority of echocardiography procedures.

The expenses involved with IV administration of medical imaging drugs are reflected in the practice expense inputs for code 90774.

Clinical labor—41 minutes of a nurse's time (pre, intra and post time summed)
Equipment—32 minutes utilization of an exam table
Supplies—One each of syringe with needle (OSHA compliant), alcohol swab pad, angiocatheter (14g-24g), thermometer probe cover, strip bandage (0.75in x 3in), syringe (10-12ml), syringe-needle (3ml 22-26g), non-sterile gloves, elastic, self-adherent wrap bandage (1in), non-sterile gauze (2in x 2in).

With the exception of the examination table, which contributes minimally to the practice expense inputs of 90774, all of the other expenses associated with 90774 are non-overlapping with the practice expenses for the echocardiography procedure.

In addition, it is important to note that cardiac sonographers are generally not licensed or trained to start IV lines, to administer IV medical imaging drugs or to monitor patients who have received IV drugs. Therefore, nurses, physicians or other licensed and trained technologists must be in attendance—in addition to the cardiac sonographer—to start the IV line, administer the IV contrast imaging drugs and monitor the patient following the administration of these drugs. **These resources are simply not part of the expenses paid for under the echocardiography procedure payment. Separate coding and payment are justified to cover the costs of these substantial resources.**

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[7] Taken from the practice expense input files for the 2007 MPFS Proposed Rule (inputs are taken from the non-facility amounts; minutes were not reported for equipment, but appear unchanged from the 2006 Final Rule files)(filename: 2007 NPRM Direct Practice Expense Inputs.xls accessed at http://www.cms.hhs.gov August 9, 2006).

By aggregating payment for IV administration of echocardiography contrast imaging drugs into payment for echocardiography procedures, providers will not be compensated for any of the time, skills and supplies required for the IV administration of echocardiography contrast imaging drugs. Without fair reimbursement/payment for these services, providers may avoid use of echo contrast even in suboptimal echocardiography cases where use of contrast may salvage the image and may preclude the need for repeat or additional testing.

Request

We urge CMS to remove any edits from the CCI that aggregate the IV drug injection code(s) 90774 into the codes for the associated echocardiography procedures (93307 and 93308). Deleting the CCI edits should remove financial disincentives limiting appropriate use of echocardiography contrast imaging drugs for medicare beneficiaries to help salvage images when an unenhanced echocardiography image is suboptimal.

We appreciate your consideration of our comments. Please contact Jack Slosky, Ph.D. at jack.slosky@bms.com or at 978-671-8191 if you have any questions about the comments made in this letter.

Sincerely yours,

T Ravenscroft

Timothy Ravenscroft
President, Bristol-Myers Squibb Medical Imaging

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cc: American Society of Echocardiography (ASE)
American College of Cardiology (ACC)
Medical Imaging Contrast Agent Association (MICAA)
Jack Slosky, Ph.D., BMSMI

FYI - Reg Staff

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August 21, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Administrator McClellan:

This comment letter is written in response to the proposed changes in physician fee schedules in the June 29th Federal Register. It is my understanding that under these proposed changes anesthesiology would receive a 10% cut in Medicare payments over the next four years. Any cuts to anesthesia professional reimbursements will be passed on to hospitals. Cuts to anesthesiologists will cause hospitals to pick up these costs to maintain current staffing levels. For us to continue the level of surgical services to all patients, a reduction of 10% in anesthesia payments will drastically affect our ability to recruit and maintain adequate anesthesia staffing.

In addition, the MGMA reports that 70% of hospitals in the United States are subsidizing the cost of anesthesia practices. Proposed reductions will certainly exacerbate hospital costs.

This reduction is especially egregious since anesthesia reimbursement is based on data that CMS uses to calculate overhead expenses that is outdated and appears to significantly underestimate actual expenses. These outdated data cause anesthesia reimbursements to already be drastically low compared to other specialties.

I am certainly in favor of better reimbursements for primary care specialties, however, the change in these reimbursements should not effect already low reimbursements to anesthesia.

Respectfully,

Ronald S. Owen
Chief Executive Officer

Copies to:
Representative Terry Everett
Senator Richard Shelby
Senator Jeff Sessions

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August 20, 2006

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Department of Health and Human Services
Room 443-G
Hubert H. Humphrey Building
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Washington, DC 20201

Re: Medicare Program- the "work adjuster" and proposed changes to the
Practice Expense

Dear Dr McClellan:

My name is Charles Rosenfeld, M.D. and I am the District VII Representative of the American Academy of Pediatrics, Section on Perinatal Pediatrics. This District includes Pediatricians and Neonatologists in Texas, Oklahoma, Louisiana, Mississippi and Arkansas. Therefore, I represent a large number of practitioners who care for the sick neonate delivered in each of these states.

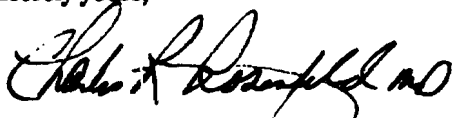
I know there was a Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology which occurred several months ago. Although many pediatric codes were increased in this Five-Year Review, the critical care and continuing intensive care neonatal codes had a "work adjuster" of 10% attached and the Practice Expense decrease.

It is my understanding that the negative "work adjuster" of 10% would be applied to all codes with physician work RVUs. In contrast to other years, CMS is utilizing this "work adjuster" to achieve budget neutrality. This approach will severely affect neonatologists in District VII as well as those throughout the remainder of the country who through Federal Government Programs receive poor remuneration. There is such variability here that a 10% reduction could lead to NICUs unwilling to accept neonates for care on the bases of insurance, thereby severely reducing access to care. I believe strongly that in years past a simpler approach would be to decrease the Conversion Factor.

In addition the thought of a transition to a new Practice Expense Methodology would also negatively affect neonatology. I have been advised that there is currently a new Physician Practice Survey available in 2008 which will offer updated information. I hope CMS will postpone this Practice Expense Methodology until the new data are available.

We all have the same goal in mind, that is, the best care for our patients at a reasonable cost. Neonatal medicine is unique in that it is all critical or intensive in nature. The babies we save today will be the leaders of the future. I hope you will consider the statements I have made in this letter and withhold the Practice Expense Methodology and eliminate the 10% "work adjuster".

Sincerely yours,



Charles R. Rosenfeld, M.D.
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As a U.S. citizen and taxpayer, I wish to voice my concern and opposition to the CMS proposal to reduce markedly the Medicare fee schedule and to change the payment structure for facility fees at ambulatory surgery centers (ASCs). I am especially concerned about CMS' attempts to create incentives to steer patients from freestanding centers back into the less cost-efficient and less patient-friendly hospital environment. **CMS should suspend its plans to implement the proposed changes and defer indefinitely the proposed new ambulatory surgery rules.**

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September 18, 2006

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Attention: CMS-1512-PN & CMS-1321-PN
P.O. Box 8014
Baltimore, Maryland 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 a 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.

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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 facility 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,

Manish Madan, MD

CC: ACH Headquarters
Bethesda, MD
Senator Hillary Clinton
Senator Charles Schumer

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September 19, 2006

Department of Health and Human Services
Attention: CMS-1502-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore. MD 21244-1850

Re: CMS1321-P proposed 2007 Physician fee schedule

To: The Centers for Medicaid and Medicare Services (CMS) Re: Proposed five year review of work components and the changes to practice expense requirements.

Dear Sir or Madam:

I am a Gynecologist in St. Petersburg Florida offering quality Dexa scanning to my patients. I have a mature practice with a substantial number of patients who need osteoporosis screening. Many of them are elderly or impaired and find that the service offered in my office is convenient and easy for them. They appreciate the personalized care which often will involve one or two employees assisting the patient on and off the table as well as the personalized expertise of their own Physician interpreting their Dexa reports on a one on one basis. The whole process can be time consuming. Many of these patients receive appropriate treatment to reduce the likelihood of a fragility fracture in the future. This treatment will protect their health and their longevity as well as reduce future costs to the health care system.

I wish to voice my objection to the five year work review in general, the practice expense methodology change, the changes offered by the deficit reduction act and the bone mass measurement test changes. I fear that the

reductions proposed for reimbursement will prevent me from continuing to perform reasonably priced and convenient Dexa scans. Certainly the Medicare portion of my practice requiring Dexa scans will be curtailed. I do note that Dexa was originally added as a preventative service. (A very smart plan) The loss of my ability to perform Dexa will result in many patients failing to get the appropriate testing.

It seems that the cuts proposed go against your own initiative to increase utilization and to prevent fragility fractures. The cuts diminish the impact of the Government's Healthy People 2010 initiative. I do not however have any problem with the steroid dosage being adjusted to 5mg.

There is substantial skill and intensity of service involved in the treatment of osteoporosis. It is not a "hands off" procedure. The counseling alone after completing the physical portion of the test can be extensive and in many cases health care providers must educate patients to accept treatment and to prevent costly and dangerous future fractures.

It seems that the assumptions used to recalculate the MPFS are inaccurate. Certainly one would not want to have a trial and error policy to experiment with a new methodology. In addition the data used to calculate densitometry is inaccurate. The majority of systems sold are fan beam not pencil beam. Finally bone densitometry equipment is not utilized simply 50% of the time.

I am asking, on behalf of my patient and myself, that the CMS1321-P proposed 2007 Physician Fee Schedule be left alone! Many of us in and outside of Government have elderly parents who deserve the appropriate screening with Dexa. A fair reimbursement to the clinician who provides such personalized intensity of service in a convenient setting, his office, to his patients who otherwise may not be able to obtain Dexa screening is appropriate.

Statement of the Manager For Section 105

Section 105. Coverage of Medical Nutrition Therapy Services for Beneficiaries With Diabetes or a Renal Disease

The provision would establish, effective January 1, 2002, Medicare coverage for medical nutrition therapy services for beneficiaries who have diabetes or a renal disease. Medical nutrition therapy services would be defined as nutritional diagnostic, therapy and counseling services for the purpose of disease management which are furnished by a registered dietician or nutrition professional, pursuant to a referral by a physician. The provision would specify that the amount paid for medical nutrition therapy services would equal the lesser of the actual charge for the service or 85% of the amount that would be paid under the physician fee schedule if such services were provided by a physician. Assignment would be required for all claims. The Secretary would be required to submit a report to Congress that contains an evaluation of the effectiveness of services furnished under this provision.

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§105. COVERAGE OF MEDICAL NUTRITION THERAPY SERVICES FOR BENEFICIARIES WITH DIABETES OR A RENAL DISEASE.

(a) Coverage.--Section 1861(s)(2) (42 U.S.C. 1395x(s)(2)), as amended by section 102(a), is amended--

(1) in subparagraph (T), by striking "and" at the end;

(2) in subparagraph (U), by inserting "and" at the end; and

(3) by adding at the end the following new subparagraph:

"(V) medical nutrition therapy services (as defined in subsection (vv)(1)) in the case of a beneficiary with diabetes or a renal disease who--

"(i) has not received diabetes outpatient self-management training services within a time period determined by the Secretary;

"(ii) is not receiving maintenance dialysis for which payment is made under section 1881; and

"(iii) meets such other criteria determined by the Secretary after consideration of protocols established by dietitian or nutrition professional organizations;".

(b) Services Described.--Section 1861 (42 U.S.C. 1395x), as amended by section 102(b), is amended by adding at the end the following:

"Medical Nutrition Therapy Services; Registered Dietitian or Nutrition Professional

"(vv)(1) The term 'medical nutrition therapy services' means nutritional diagnostic, therapy, and counseling services for the purpose of disease management which are furnished by a registered dietitian or nutrition professional (as defined in paragraph (2)) pursuant to a referral by a physician (as defined in subsection (r)(1)).

I urge you to delay the DRA until a complete and thorough analysis can be conducted using cost figures based on the proper technology. I implore Congress to intervene and stop the reduction to the conversion factor. I hope Congress will be willing to act prior to the October adjustment. I certainly will contact my Congressman and Senator from my state.

The proposed plan will be akin to "shooting oneself in the foot" with regard to protecting the health of our aging population. Are any workers in CMS aware that there are more fragility fractures across the United States than the combined numbers of strokes, breast cancer and heart attacks every year? Truly that statistic should be chilling to anyone who works in CMS. To unreasonably lower Physician reimbursement would be a tragedy since there is not a great profit in providing this personalized service in the office. However, it offers a tremendous advantage to all of our patients.

Kindly give my letter your thoughtful consideration.

Sincerely,

Gilbert A. Shamas, MD
Board Certified Gynecologist

GAS/blj

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

BACKGROUND

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

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

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

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

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

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

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

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

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

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

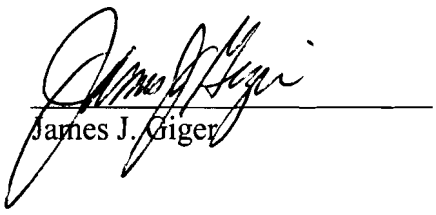
COMMENT

CMS in its Program Memorandums AB-00-099 and AB-00-108 confirms that the Department of Health and Human Services has issued a compliance program guidance for laboratory service and sets forth conditions under which a physician's order for a repeat laboratory service can quality as an order for another laboratory service.

Notwithstanding the disagreement of whether a physician's order for repeat testing on a monthly basis constitutes a "standing order", Section #4 on page 14 of the HHS Compliance Manual states that laboratory compliance programs **may** permit the use of standing orders executed in connection with an extending course of treatment; however, HHS recommends that standing orders should be periodically monitored. Further, HHS recommends that the periodic review should occur at least annually...and a Medicare facility should confirm the continued validity of all existing standing orders at that time.

Because a physician order for repeat testing is clearly provided for (allowed) and Medicare has provided the coding numbers for same tests provided to a Medicare beneficiary on the same day (i.e. modified 91) the assertions made within the proposed rule exclusively for SNFs are clearly discriminatory and the proposed rule must be withdrawn.

Submitted by:



James J. Giger

Date: September 21, 2006

Via Certified Mail
7004 1350 0004 6290 2984

[¶ 11,665] Act Sec. 4554. Law at ¶ 5265. CCH Explanation at ¶ 758.

Other Payment Provisions

Current Law—Conference Committee Report

[*Improvements in administration of laboratory services benefit*]

Significant variations exist among carriers in rules governing requirements labs must meet in filing claims for payments.

House Ways and Means Committee Report

Reason for change. Significant concerns have been raised regarding the widely varying payment policies and concomitant documentation requirements of Medicare carriers regarding claims for clinical laboratory tests. This situation is compounded because many laboratories send claims to multiple carriers. For example, for a simple cholesterol test, the carrier for one part of new York State accepts 735 different diagnosis codes, while another carrier in another part of New York accepts only 341 codes. And, in Michigan and Illinois, the carrier accepts only 9 codes for this test. The provision is intended to promote efficiency, increase uniformity, and reduce administrative burdens in claims administration and billing procedures.

Conference Committee Report

House Bill.—Section 10614. Requires the Secretary to divide the country into no more than five regions and designate a single carrier for each region to process laboratory claims (other than for independent physicians offices) no later than January 1, 1999. One of the carriers would be selected as a central statistical resource. The allocation of claims to a particular carrier would be based on whether the carrier serves the geographic area where the specimen was collected or other method selected by the Secretary.

Requires the Secretary, by July 1, 1998, to adopt uniform coverage, administration, and payment policies for lab tests using a negotiated rulemaking process. The policies would be designed to promote uniformity and program integrity and reduce administrative burdens with respect to clinical diagnostic laboratory tests in connection with beneficiary information submitted with a claim, physicians' obligations for documentation and recordkeeping, claims filing procedures, documentation, and frequency limitations. Carriers could implement changes pending implementation of uniform policies.

Permits the use of interim regional policies where a uniform national policy had not been established and there is a demonstrated need for policy to respond to aberrant utilization or provision of unnecessary services. The Secretary would establish a process under which designated carriers could collectively develop and implement interim national standards for up to 2 years.

Requires the Secretary to conduct a review, at least every 2 years, of uniform national standards. The review would consider whether to incorporate or supersede interim regional or national policies.

Specifies that before carriers implement a change in requirements (including use of interim regional and interim national policies) in the period prior to the adoption of uniform policies, they must provide advance notice to interested parties and allow a 45 day period for parties to submit comments on proposed modifications.

Requires the inclusion of a laboratory representative on carrier advisory committees. The representative would be selected by the committee from nominations submitted by national and local organizations representing independent clinical labs.

Effective date. Enactment.

Section 4614. Similar provision, except that designation of single carrier excludes tests performed in "physicians offices" rather than "independent physicians offices."

Senate Amendment.—Similar provision, except: (1) specifies that the provision designating single carriers for each of five regions would not apply to lab services furnished by independent physicians offices until such time as the Secretary determines such offices would not be unduly burdened by the application of billing requirements with respect to more than one carrier; (2) specifies that one of the goals in designing uniform policies is to "simplify administrative requirements" rather than "reduce administrative burdens"; and (3) specifies that interim and national guidelines would apply to all lab services.

Effective date. Enactment

Emergency Room Nursing Interventions/Level Charge

Patient Name _____

Account # _____

DOS _____

		Arrival			**Orthopedics**
	10	Ambulatory, wheelchair routine EMS or POV arrival		20	Crutch training and fitting
	50	Critical Transfer from other facility, mobile ICU or aircraft		15	ACE wraps, Slings, Aircasts
	10	Routine transfer in by EMS from other facility			
		Initial Nursing Assessment			**OB/GYN/GU**
	10	Triage - simple / re-check (ESI 4 & 5)		10	STD culturing
	15	Triage - complex (ESI 1, 2, & 3)		30	Newborn exam / APGAR scoring
	15	Nursing Assessment - simple (ESI 4 & 5)		80	Rape Exam
	20	Nursing Assessment - intermd/complex (ESI 1, 2, & 3)		20	Pelvic exam assist
	30	Nurse initiated protocols/directive/care paths		15	Fetal heart tone assessment
		Special Needs			
	10	Isolation and/or Latex allergy			**Point of Care**
	10	Special needs patients (sensory deficit/language)		20	Nurse monitoring pt, outside dept (CT, MRI, etc.)
	15	Patient with altered mentation		100	Conscious sedation
	50	Behavioral health		10	Glasgow coma scoring (neuro assessment)
	20	Case management/Crisis consult		15	Orthostatic vital signs
	30	Security alert		10	Specimen collection (stool, UA. Sputum/swabs)
	10	Seclusion / restraint monitoring, each 15 min		5	Visual acuity testing
		General Procedures			
	20	Bair hugger			**Discharge Instructions**
	20	SSE/ fleet enema		10	Special needs (transport/Rx needs)
	10	Dressing - simple		10	Simple discharge instructions(Rx, simple instructions sheet)
	15	Dressing - large or complex		15	Complex discharge instructions (detailed w/ follow-up)
	5	Eye exam/eye stain/ slit lamp exam			**Disposition**
	10	Eye irrigation/ morgan lens - per eye		50	DOA / expired in dept / coroner's case / post mortem care
	10	IV - simple saline lock		30	Involuntary admission / transfer
	15	IV - complex start (difficult, EJ scalp, foot, ped)		10	AMA / Elopement
	5	Medication - PO, rectal, topical, eye, ear G-tube (each)		10	Routine hospital admission
	5	O2 administration		20	Telemetry admission
	5	Phlebotomy (by nurse or lab)		30	ICU / operating room admission
	5	Ring Removal		40	Critical transfer to other facility (mobile, ICU, ALS, flight)
	20	Suctioning/ Irrigation		20	Routine transfer to other facility or nursing home
	10	Surgical Localized prep (Shave, scrub ethyl chloride)			**Critical Care**
	5	Suture/ staple removal - simple		15	Endotracheal suctioning, sterile, each time
	10	Suture / staple removal - complex, time consuming		30	Internal cardiac device care
	10	Wound cleansing or irrigation		30	Rapid infusion/fluid resuscitation
	5	X-ray - simple transport to radiology		45	Resuscitation response (non-CPR, in any room)
	10	X-ray - complex (CT, MRI, fluoro, nuclear med)		30	Specialty Alert (Stroke/MI)
		Monitoring		30	Trauma Consult, ED stat (Bethlehem Facility Only)
	20	Subsequent simple vital signs (excluding triage/discharge)		60	Trauma Alert, full team response (Bethlehem Facility Only)
	40	Continuous or complex, multi-system monitoring		30	Ventilator management
		Total Points Column 1			Total Points Column 2
		Total All Points			
	1600	99281 = 0-20 points		1642	Triage only
	1601	99282 = 21-55 points		1643	Prolonged Waiting Period (90+ minutes w/o treatment)
	1602	99283 = 56-85 points			
	1603	99284 = 86-115 points			
	1604	99285 = >116 points (does not meet Critical Care criteria)			
	1605	99291 = Critical Care (initial 30-74 minutes; direct pt care)			
	1649	99292 = Critical Care (charge each additional 30 minutes)			

Conference Agreement.—The conference agreement includes the Senate provision with amendments. The provision designating single carriers for each of five regions would not apply to those physician office laboratories which the Secretary determines would be unduly burdened by the application of billing responsibilities with respect to more than one carrier.

The agreement would clarify that uniform policies are national uniform policies. The policies would be designed to promote program integrity and national uniformity and simplify administrative requirements with respect to lab tests in connection with beneficiary information submitted with a claim, medical conditions for which a lab test is reasonable and necessary, appropriate use of procedure codes in billing, required medical documentation, recordkeeping requirements, claims filing procedures, and limitations on frequency of coverage for the same test performed on the same individual.

The agreement would provide that recommendations from national and local organizations that represent clinical laboratories would be considered in selecting the laboratory representative on a carrier advisory committee.

``(viii) after December 31, 1997, is equal to 74 percent of such median.''.

(c) Study <<NOTE: 42 USC 13951 note.>> and Report on Clinical Laboratory Tests.--

(1) In general.--The Secretary shall request the Institute of Medicine of the National Academy of Sciences to conduct a study of payments under part B of title XVIII of the Social Security Act for clinical laboratory tests. The study shall include a review of the adequacy of the current methodology and recommendations regarding alternative payment systems. The study shall also analyze and discuss the relationship between such payment systems and access to high quality laboratory tests for medicare beneficiaries, including availability and access to new testing methodologies.

(2) Report to congress.--The Secretary shall, not later than 2 years after the date of enactment of this section, report to the Committees on Ways and Means and Commerce of the House of Representatives and the Committee on Finance of the Senate the results of the study described in paragraph (1), including any recommendations for legislation.

SEC. 4554. IMPROVEMENTS <<NOTE: 42 USC 1395u note.>> IN ADMINISTRATION OF LABORATORY TESTS BENEFIT.

(a) Selection of Regional Carriers.--

(1) In general.--The Secretary of Health and Human Services (in this section referred to as the ``Secretary'') shall--

(A) divide the United States into no more than 5 regions, and

(B) designate a single carrier for each such region, for the purpose of payment of claims under part B of title XVIII of the Social Security Act with respect to clinical diagnostic laboratory tests furnished on or after such date (not later than July 1, 1999) as the Secretary specifies.

(2) Designation.--In designating such carriers, the Secretary shall consider, among other criteria--

(A) a carrier's timeliness, quality, and experience in claims processing, and

(B) a carrier's capacity to conduct electronic data interchange with laboratories and data matches with other carriers.

(3) Single data resource.--The Secretary shall select one of the designated carriers to serve as a central statistical resource for all claims information relating to such clinical diagnostic laboratory tests handled by all the designated carriers under such part.

(4) Allocation of claims.--The allocation of claims for clinical diagnostic laboratory tests to particular designated carriers shall be based on whether a carrier serves the geographic area where the laboratory specimen was collected or other method specified by the Secretary.

(5) Secretarial exclusion.--Paragraph (1) shall not apply with respect to clinical diagnostic laboratory tests furnished by physician office laboratories if the Secretary determines that such offices would be unduly burdened by the application of billing responsibilities with respect to more than one carrier.

(b) Adoption of National Policies for Clinical Laboratory Tests Benefit.--

(1) In general.--Not later than January 1, 1999, the Secretary shall first adopt, consistent with paragraph (2), national coverage and administrative policies for clinical diagnostic laboratory tests under part B of title XVIII of the Social Security Act, using a negotiated rulemaking process under subchapter III of chapter 5 of title 5, United States Code.

(2) Considerations in design of national policies.--The policies under paragraph (1) shall be designed to promote program integrity and national uniformity and simplify administrative requirements with respect to clinical diagnostic laboratory tests payable under such part in connection with the following:

(A) Beneficiary information required to be submitted with each claim or order for laboratory tests.

(B) The medical conditions for which a laboratory test is reasonable and necessary (within the meaning of section 1862(a)(1)(A) of the Social Security Act).

(C) The appropriate use of procedure codes in

billing for a laboratory test, including the unbundling of laboratory services.

(D) The medical documentation that is required by a medicare contractor at the time a claim is submitted for a laboratory test in accordance with section 1833(e) of the Social Security Act.

(E) Recordkeeping requirements in addition to any information required to be submitted with a claim, including physicians' obligations regarding such requirements.

(F) Procedures for filing claims and for providing remittances by electronic media.

(G) Limitation on frequency of coverage for the same tests performed on the same individual.

(3) Changes in laboratory policies pending adoption of national policy.--During the period that begins on the date of the enactment of this Act and ends on the date the Secretary first implements national policies pursuant to regulations promulgated under this subsection, a carrier under such

[[Page 111 STAT. 462]]

part may implement changes relating to requirements for the submission of a claim for clinical diagnostic laboratory tests.

(4) Use of interim policies.--After the date the Secretary first implements such national policies, the Secretary shall permit any carrier to develop and implement interim policies of the type described in paragraph (1), in accordance with guidelines established by the Secretary, in cases in which a uniform national policy has not been established under this subsection and there is a demonstrated need for a policy to respond to aberrant utilization or provision of unnecessary tests. Except as the Secretary specifically permits, no policy shall be implemented under this paragraph for a period of longer than 2 years.

(5) Interim national policies.--After the date the Secretary first designates regional carriers under subsection (a), the Secretary shall establish a process under which designated carriers can collectively develop and implement interim national policies of the type described in paragraph (1). No such policy shall be implemented under this paragraph for a period of longer than 2 years.

(6) Biennial review process.--Not less often than once every 2 years, the Secretary shall solicit and review comments regarding changes in the national policies established under this subsection. As part of such biennial review process, the Secretary shall specifically review and consider whether to incorporate or supersede interim policies developed under paragraph (4) or (5). Based upon such review, the Secretary may provide for appropriate changes in the national policies previously adopted under this subsection.

(7) Requirement and notice.--The Secretary shall ensure that any policies adopted under paragraph (3), (4), or (5) shall apply to all laboratory claims payable under part B of title XVIII of the Social Security Act, and shall provide for advance notice to interested parties and a 45-day period in which such parties may submit comments on the proposed change.

(c) Inclusion of Laboratory Representative on Carrier Advisory Committees.--The Secretary shall direct that any advisory committee established by a carrier to advise such carrier with respect to coverage and administrative policies under part B of title XVIII of the Social Security Act shall include an individual to represent the independent clinical laboratories and such other laboratories as the Secretary deems appropriate. The Secretary shall consider recommendations from national and local organizations that represent independent clinical laboratories in such selection.

SEC. 4555. UPDATES FOR AMBULATORY SURGICAL SERVICES.

Section 1833(i)(2)(C) (42 U.S.C. 13951(i)(2)(C)) is amended by inserting at the end the following new sentence: ``In each of the fiscal years 1998 through 2002, the increase under this subparagraph shall be reduced (but not below zero) by 2.0 percentage points.''.

SEC. 4556. REIMBURSEMENT FOR DRUGS AND BIOLOGICALS.

(a) In General.--Section 1842 (42 U.S.C. 1395u) is amended by inserting after subsection (n) the following new subsection:

``(o)(1) If a physician's, supplier's, or any other person's bill or request for payment for services includes a charge for a drug

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
NEGOTIATED RULEMAKING ON CLINICAL DIAGNOSTIC LABORATORY TESTS

Final Agreement - 8/31/99

The Negotiated Rulemaking Committee on Clinical Diagnostic Laboratory Tests (Committee) considered issues related to national coverage and administrative policies for clinical diagnostic laboratory tests under Part B of Title XVIII (Medicare) of the Social Security Act. See sections 1861(s)(3) and 1862(a)(7) of the Social Security Act, as amended by sections 4554(b)(1) and (2) of the Balanced Budget Act of 1997.

The parties whose signatures appear on this document agree that--

1. The individual signing this agreement is authorized to commit the party to the terms of this agreement.

2. The party concurs in the following parts of the attached *Federal Register* document (version dated 8/31/99), when considered as a whole:
   A. The regulatory text;
   B. The preamble language to accompany the proposed rule;
   C. Appendix A, the Introduction to proposed national coverage policies;
   D. The negotiated sections of the proposed national coverage policies included in Appendix B. (The Reasons for Denial section in each proposed policy was not negotiated.)

   Concurrence on the policies on tumor antigens and blood glucose testing is contingent on related changes being made to procedure codes so that the procedures discussed in each policy are the only ones appropriate for the assignment of a particular procedure code.

3. The Department of Health and Human Services, through the Health Care Financing Administration, agrees to publish for comment the *Federal Register* document referred to in Article 2 above, to the maximum extent possible consistent with the Department's legal obligations.

4. Each party agrees not to file negative comments on the *Federal Register* document when published, so long as there are no changes in substance or effect from the version dated 8/31/99, except that Committee Members may comment on the definition of the "date of service" for a laboratory test under Medicare, on the issue of beneficiary notices, and on any matter that was not negotiated. Each party agrees not to comment negatively on the format of the proposed policies included in Appendix B to the *Federal Register* document.

5. The Health Care Financing Administration, consistent with its obligations under the Federal Administrative Procedure Act, will consider all relevant comments submitted on the proposed regulation, the proposed national coverage policies, or the proposed Introduction to those policies and will make such modifications as are necessary when issuing the final regulation, final policies, and final Introduction.

6. Each party agrees not to take any action to inhibit the adoption of the proposed regulation as final, to the extent the final regulation and its preamble have the same substance and effect as the *Federal Register* document referred to in Article 2 above. Each party agrees not to take action to inhibit the adoption of the proposed national coverage policies and their proposed Introduction as final, to the extent they have the same substance and effect as the Appendices to the *Federal Register* document referred to in Article 2 above.

7. The Department of Health and Human Services, through the Health Care Financing Administration, agrees further that, when the national coverage policies and their Introduction are published in final form in the *Federal Register*, they will also be included in a Department issuance.

8. No party is bound with respect to any matter that is not addressed in the attached *Federal Register* document. Moreover, Articles 4 and 6 do not apply to the issues of what the "date of service" should be and what, if any, beneficiary notices should be issued and do not apply to any part of the proposed national coverage policies that was not negotiated.

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American Association for Clinical Chemistry

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American Association of Bioanalysts

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American Society for Microbiology

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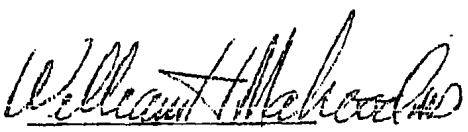

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Medicare National Coverage Decision for Blood Glucose Testing

Description

This policy is intended to apply to blood samples used to determine glucose levels.

Blood glucose determination may be done using whole blood, serum or plasma. It may be sampled by capillary puncture, as in the fingerstick method, or by vein puncture or arterial sampling. The method for assay may be by color comparison of an indicator stick, by meter assay of whole blood or a filtrate of whole blood, using a device approved for home monitoring, or by using a laboratory assay system using serum or plasma. The convenience of the meter or stick color method allows a patient to have access to blood glucose values in less than a minute or so and has become a standard of care for control of blood glucose, even in the inpatient setting.

HCPCS Codes (Alpha numeric, CPT-AMA)

Code	Descriptor
82947.....	Glucose; quantitative, blood (except reagent
82948.....	Glucose; blood, reagent strip
82962.....	Glucose, blood by glucose monitoring device(specifically for home use.

Indications

Blood glucose values are often necessary for the management of patients with diabetes mellitus, where hyperglycemia and hypoglycemia are often present. They are also critical in the determination of control of blood glucose levels in the patient with impaired fasting glucose (FPG 110-125 mg/dL), the patient with insulin resistance syndrome and/or carbohydrate intolerance (excessive rise in glucose following ingestion of glucose or glucose sources of food), in the patient with a hypoglycemia disorder such as nesidioblastosis or insulinoma, and in patients with a catabolic or malnutrition state. In addition to those conditions already listed, glucose testing may be medically necessary in patients with tuberculosis, unexplained chronic or recurrent infections, alcoholism, coronary artery disease (especially in women), or unexplained skin conditions (including pruritis, local skin infections, ulceration and gangrene without an established cause). Many medical conditions may be a consequence of a sustained elevated or depressed glucose level. These include comas, seizures or epilepsy, confusion, abnormal hunger, abnormal weight loss or gain, and loss of sensation. Evaluation of glucose may also be indicated in patients on medications known to affect carbohydrate metabolism.

Limitations

Frequent home blood glucose testing by diabetic patients should be encouraged. In stable, non-hospitalized patients who are unable or unwilling to do home monitoring, it may be reasonable and necessary to measure quantitative blood glucose up to four times annually.

Depending upon the age of the patient, type of diabetes, degree of control, complications of diabetes, and other co-morbid conditions, more frequent testing than four times annually may be reasonable and necessary.

In some patients presenting with nonspecific signs, symptoms, or diseases not normally associated with disturbances in glucose metabolism, a single blood glucose test may be medically necessary.

Repeat testing may not be indicated unless abnormal results are found or unless there is a change in clinical condition. If repeat testing is performed, a specific diagnosis code (e.g., diabetes) should be reported to support medical necessity. However, repeat testing may be indicated where results are normal in patients with conditions where there is a confirmed continuing risk of glucose metabolism abnormality (e.g., monitoring glucocorticoid therapy).

ICD-9-CM Codes Covered by Medicare Program

Code	Description
011.00-011.96	Tuberculosis
038.0-038.9	Septicemia
112.1	Recurrent vaginal candidiasis
112.3	Interdigital candidiasis
118	Opportunistic mycoses
157.4	Malignant neoplasm of Islets of Langerhans
158.0	Malignant neoplasm of retroperitoneum
211.7	Benign neoplasm of Islets of Langerhans
242.00-242.91	Thyrotoxicosis
250.00-250.93	Diabetes mellitus
251.0-251.9	Disorders of pancreatic internal secretion
253.0-253.9	Disorders of the pituitary gland
255.0	Cushing syndrome

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263.0-263.9	Malnutrition
271.0-271.9	Disorders of carbohydrate transport and meta
272.0-272-4	Disorders of lipoid metabolism
275.0	Hemochromotosis
276.0-276.9	Disorders of fluid, electrolyte and acid-bas
278.3	Hypercarotinemia
293.0	Acute delirium
294.9	Unspecified organic brain syndrome
298.9	Unspecified psychosis
300.9	Unspecified neurotic disorder
310.1	Organic personality syndrome
337.9	Autonomic nervous system neuropathy
345.10-345.11	Generalized convulsive epilepsy
348.3	Encephalopathy, unspecified
355.9	Neuropathy, not otherwise specified
356.9	Unspecified hereditary and idiopathic periph
357.9	Unspecified inflammatory and toxic neuropath
362.10	Background retinopathy
362.18	Retinal vasculitis
362.29	Nondiabetic proliferative retinopathy
362.50-362.57	Degeneration of macular posterior pole
362.60-362.66	Peripherial retinal degeneration
362.81-362.89	Other retinal disorders
362.0	Unspecified retinal disorders
365.04	Borderline glaucoma, ocular hypertension
365.32	Corticosteriod-induced glaucoma residual
366.00-366.09	Presenile cataract
366.10-366.19	Senile cataract
367.1	Acute myopia
368.8	Other specified visual disturbance
373.00	Blepharitis
377.24	Pseudopapilledema
377.9	Autonomic nervous system neuropathy
378.50-378.55	Paralytic strabiamus

379.45	Argyll-Robertson pupils
410.00-410.92	Acute myocardial infarctions
414.00-414.19	Coronary atherosclerosis and aneurysm of hea
425.9	Secondary cardiomyopathy, unspecified
440.23	Arteriosclerosis of extremities with ulcerat
440.24	Arteriosclerosis of extremities with gangren
440.9	Arteriosclerosis, not otherwise specified
458.0	Postural hypotension
462	Acute pharyngitis
466.0	Acute bronchitis
480.0-486	Pneumonia
490	Recurrent bronchitis, not specified as acute
491.0-491.9	Chronic bronchitis
527.7	Disturbance of salivory secretion (drymouth)
528.0	Stomatitis
535.50-535.51	Gastritis
536.8	Dyspepsia
571.8	Other chronic nonalcoholic liver disease
572.0-572.8	Liver abscess and sequelae of chronic liver
574.50-574.51	Choledocholitiasis
575.0-575.12	Cholecystitis
576.1	Cholangitis
577.0	Acute pancreatitis
577.1	Chronic pancreatitis
577.8	Pancreatic multiple calculi
590.00-590.9	Infections of the kidney
595.9	Recurrent cystitis
596.4	Bladder atony
596.53	Bladder paresis
599.0	Urinary tract infection, recurrent
607.84	Impotence of organic origin
608.89	Other disorders male genital organs
616.10	Vulvovaginitis
626.0	Amenorrhea
626.4	Irregular menses
628.9	Infertility--female
648.00	Diabetes mellitus complicating pregnancy, Ch puerperium, unspecified as to episode of ca
648.03	Diabetes mellitus complicating pregnancy, Ch puerperium, antipartum condition or complic

648.04	Diabetes mellitus complicating pregnancy, Ch puerperium, postpartum condition or complic
648.80	Abnormal glucose tolerance complicating preg the puerperium, unspecified as to episode o applicable
648.83	Abnormal glucose tolerance complicating preg the puerperium, antipartum condition or com
648.84	Abnormal glucose tolerance complicating preg the puerperium, postpartum condition or com
656.60-656.63	Fetal problems affecting management of mothe fetus
657.00-657.03	Polyhydramnios
680.0-680.9	Carbuncle and furuncle
686.00-686.9	Infections of skin and subcutaneous tissue
698.0	Pruritis ani
698.1	Pruritis of genital organs
704.1	Hirsutism
705.0	Anhidrosis
707.0-707.9	Chronic ulcer of skin
709.3	Degenerative skin disorders

729.1	Myalgia
730.07-730.27	Osteomyelitis of tarsal bones
780.01	Coma
780.02	Transient alteration of awareness
780.09	Alteration of consciousness, other
780.2	Syncope and collapse
780.31	Febrile convulsions
780.39	Seizures, not otherwise specified
780.4	Dizziness and giddiness
780.71-780.79	Malaise and fatigue
780.8	Hyperhidrosis
781.0	Abnormal involuntary movements
782.0	Loss of vibratory sensation
783.1	Abnormal weight gain
783.2	Abnormal loss of weight
783.5	Polydipsia
783.6	Polyphagia
785.0	Tachycardia
785.4	Gangrene
786.01	Hyperventilation
786.09	Dyspnea,
786.50	Chest pain, unspecified
787.6	Fecal incontinence
787.91	Diarrhea
788.41-788.43	Frequency of urination and polyuria
789.1	Hepatomegaly
790.2	Abnormal glucose tolerance test
790.6	Other abnormal blood chemistry (hyperglycemi
791.0	Proteinuria
791.5	Glycosuria
796.1	Abnormal reflex
799.4	Cachexia
V23.0-.9	Supervision of high risk pregnancy
V67.2	Follow-up examination, following chemotherap
V67.51	Follow up examination with high-risk medicat classified
V58.69	Long term current use of other medication

Reasons for Denial:

Note: This section was not negotiated by the Negotiated Rulemaking Committee. This section includes HCFA's interpretation of its longstanding policies and is included for informational purposes.

Tests for screening purposes that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered except as explicitly authorized by statute. These include exams required by insurance companies, business establishments, government agencies, or other third parties.

Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered according to the statute.

Failure to provide documentation of the medical necessity of tests may result in denial of claims. Such documentation may include notes documenting relevant signs, symptoms or abnormal findings that substantiate the medical necessity for ordering the tests. In addition, failure to provide independent verification that the test was ordered by the treating physician (or qualified nonphysician practitioner) through documentation in the physician's office may result in denial.

A claim for a test for which there is a national coverage or local medical review policy will be denied as not reasonable and

necessary if it is submitted without an ICD-9-CM code or narrative diagnosis listed as covered in the policy unless other medical documentation justifying the necessity is submitted with the claim.

If a national or local policy identifies a frequency expectation, a

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claim for a test that exceeds that expectation may be denied as not reasonable and necessary, unless it is submitted with documentation justifying increased frequency.

Tests that are not ordered by a treating physician or other qualified treating nonphysician practitioner acting within the scope of their license and in compliance with Medicare requirements will be denied as not reasonable and necessary.

Failure of the laboratory performing the test to have the appropriate Clinical Laboratory Improvement Amendment of 1988 (CLIA) certificate for the testing performed will result in denial of claims.

ICD-9-CM Codes Denied

Code	Description
798.0-798.9	Sudden death, cause unknown
V15.85	Exposure to potentially hazardous body fluid
V16.1	Family history of malignant neoplasm, trache
V16.2	Family history of malignant neoplasm, other intrathoracic organs
V16.4	Family history of malignant neoplasm, genita
V16.5	Family history of malignant neoplasm, urinar
V16.6	Family history of malignant neoplasm, leukem
V16.7	Family history of malignant neoplasm, other hematopoietic neoplasms
V16.8	Family history of malignant neoplasm, other neoplasm
V16.9	Family history of malignant neoplasm, unspec neoplasm
V17.0-V17.8	Family history of certain chronic disabling
V18.0-V18.8	Family history of certain other specific con
V19.0-V19.8	Family history of other conditions
V20.0-V20.2	Health supervision of infant or child
V28.0-V28.9	Antenatal screenings
V50.0-V50.9	Elective surgery for purposes other than rem
V53.2	Fitting and adjustment of hearing aid
V60.0-V60.9	Housing, household, and economic circumstanc
V62.0	Unemployment
V62.1	Adverse effects of work environment
V65.0	Healthy persons accompanying sick persons
V65.1	Persons consulting on behalf of another pers
V68.0-V68.9	Encounters for administrative purposes
V70.0-V70.9	General medical examinations
V73.0-V73.99	Special screening examinations for viral and
V74.0-V74.9	Special screening examinations for bacterial diseases
V75.0-V75.9	Special screening examination for other infe
V76.0	Special screening for malignant neoplasms, r
V76.3	Special screening for malignant neoplasms, b
V76.42-V76.9	Special screening for malignant neoplasms, (breast, cervix, and rectum)
V77.0-V77.9	Special screening for endocrine, nutrition, immunity disorders
V78.0-V78.9	Special screening for disorders of blood and
V79.0-V.79.9	Special screening for mental disorders

V80.0-V80.3	Special screening for neurological, eye, and
V81.0-V81.6	Special screening for cardiovascular, respir genitourinary diseases
V82.0-V82.9	Special screening for other conditions

ICD-9-CM Codes That Do Not Support Medical Necessity

Any ICD-9-CM code not listed in either of the ICD-9-CM sections above.

Sources of Information

AACE Guidelines for the Management of Diabetes Mellitus, Endocrine Practice (1995)1:149-157.

Bower, Bruce F. and Robert E. Moore, Endocrine Function and Carbohydrates.

Clinical Laboratory Medicine, Kenneth D. McClatchy, editor. Baltimore/Williams & Wilkins, 1994. pp 321-323.

Report of the Expert Committee on the Diagnosis and Classification of Diabetes Mellitus, Diabetes Care, Volume 20, Number 7, July 1997, pages 1183 et seq.

Roberts, H.J., Difficult Diagnoses. W. B. Saunders Co., pp 69-70.

Coding Guidelines

1. Any claim for a test listed in ``HCPCS CODES'' above must be submitted with an ICD-9-CM diagnosis code or comparable narrative. Codes that describe symptoms and signs, as opposed to diagnoses, should be provided for reporting purposes when a diagnosis has not been established by the physician. (Based on Coding Clinic for ICD-9-CM, Fourth Quarter 1995, **page** 43.)

2. Screening is the testing for disease or disease precursors so that early detection and treatment can be provided for those who test positive for the disease. Screening tests are performed when no specific sign, symptom, or diagnosis is present and the patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or exposure to communicable diseases, should be assigned, not a screening code, but the test may still be considered screening and not covered by Medicare. For screening tests, the appropriate ICD-9-CM screening code from categories V28 or V73-V82 (or comparable narrative) should be used. (From Coding Clinic for ICD-9-CM, Fourth Quarter 1996, pages 50 and 52)

3. A three-digit code is to be used only if it is not further subdivided.

[[**Page** 58850]]

Where fourth-digit and/or fifth-digit subclassifications are provided, they must be assigned. A code is invalid if it has not been coded to the full number of digits required for that code. (From Coding Clinic for ICD-9-CM. Fourth Quarter, 1995, **page** 44).

4. Diagnoses documented as ``probable,'' ``suspected,' questionable,'' ``rule-out,'' or ``working diagnosis'' should not be coded as though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD-9-CM, Fourth Quarter 1995, **page** 45).

5. When a non-specific ICD-9 code is submitted, the underlying sign, symptom, or condition must be related to the indications for the test above.

6. A diagnostic statement of impaired glucose tolerance must be evaluated in the context of the documentation in the medical record in order to assign the most accurate ICD-9-CM code. An abnormally elevated fasting blood glucose level in the absence of the diagnosis of diabetes is classified to Code 790.6--other abnormal blood chemistry. If the provider bases the diagnostic statement of impaired glucose tolerance'' on an abnormal glucose tolerance test, the condition is classified to 790.2--normal glucose tolerance test. Both conditions are considered indications for ordering glycated hemoglobin or glycated protein testing in the absence of the diagnosis of diabetes mellitus.

7. When a patient is under treatment for a condition for which the tests in this policy are applicable, the ICD-9-CM code that best describes the condition is most frequently listed as the reason for the test.

8. When laboratory testing is done solely to monitor response to medication, the most accurate ICD-9-CM code to describe the reason for the test would be V58.69--long term use of medication.

9. Periodic follow-up for encounters for laboratory testing for a patient with a prior history of a disease, who is no longer under treatment for the condition, would be coded with an appropriate code from the V67 category--follow-up examination.

10. According to ICD-9-CM coding conventions, codes that appear in italics in the Alphabetic and/or Tabular columns of ICD-9-CM are considered manifestation codes that require the underlying condition to be coded and sequenced ahead of the manifestation. For example, the diagnostic statement, ``thyrotoxic exophthalmos (376.21),'' which appears in italics in the tabular listing, requires that the thyroid disorder (242.0-242.9) is coded and sequenced ahead of thyrotoxic exophthalmos. Therefore, a diagnostic statement that is listed as a manifestation in ICD-9-CM must be expanded to include the underlying disease in order to accurately code the condition.

Documentation Requirements

The ordering physician must include evidence in the patient's clinical record that an evaluation of history and physical preceded the ordering of glucose testing and that manifestations of abnormal glucose levels were present to warrant the testing.

Key CLNRC Final Administrative Policies For Clinical Diagnostic Laboratory Tests

Below are key provisions and citations from the CLNRC Administrative Policies for Clinical Laboratory Tests published in the Federal Register (FR) dated November 23, 2001.

B. Recent Legislation (FR 11/23/01 page 58789)

Section 4554(b)(1) of the Balanced Budget Act of 1997 (BBA), Public Law 105-33, mandates use of a negotiated rulemaking committee to develop national coverage and administrative policies for clinical diagnostic laboratory services payable under Medicare Part B by January 1, 1999. Section 4554(b) (2) of the BBA requires that these national coverage policies be designed to promote program integrity and national uniformity and simplify administrative requirements with respect to clinical diagnostic laboratory services payable under Medicare Part B in connection with the following:

Beneficiary information required to be submitted with each claim or order for laboratory services.

The medical condition for which a laboratory tests is reasonable and necessary (within the meaning of section 1862(a)(1)(A) of the Act).

The appropriate use of procedure codes in billing for a laboratory test, including the unbundling of laboratory services.

The medical documentation that is required by a Medicare contractor at the time a claim is submitted for a laboratory test (in accordance with section 1833(e) of the Act).

Recordkeeping requirements in addition to any information required to be submitted with a claim, including physicians' obligations regarding these requirements.

Procedures for filing claims and for providing remittances by electronic media.

Limitations on frequency of coverage for the same services performed on the same individual.

*** (FR 11/23/01 page 58789)

II. Provisions of the March 10, 2000 Proposed Rule

The preamble to the March 10, 2000 proposed rule discussed the composition of the Committee, the guidelines the Committee following in making recommendations, and the consensus of the negotiating Committee.

*** (FR 11/23/01 page 58789)

--The policies followed a uniform format that included a narrative description of the test, panel of tests, or group of tests addressed in the NCD; clinical indications for which the test(s) may be considered reasonable and necessary.

*** (FR 11/23/01 page 58789)

The ICD-9-CM codes were displayed in one of three sections. The first section lists covered coved—those for which there is a presumption of medical necessity but the claim may be subject to review. The second section lists diagnosis codes that are never covered. The third section lists codes that generally are not considered to support a decision that the test is reasonable and necessary, but for which there are limited exceptions. Additional documentation could support a decision of medical necessity and must be submitted by the ordering provider and accompany the claim.

*** (FR 11/23/01 page 58790)

Limitation on frequency.

--We proposed to issue instructions that state February 21, 2002 that contractors may not use a frequency screen that could result in a frequency-based denial unless information published by us or our contractors includes and indication of the frequency that is generally considered reasonable utilization of that test for Medicare purposes.

*** (FR 11/23/01 page 58790)

The changes we proposed to make to Sec. 410.32 (42 CFR 410.32) are set forth as follows:

We proposed to redesignate paragraph (d) introductory test as paragraph (d)(1), and we proposed to add a heading.

We proposed to redesignate paragraphs (d)(1) through (d)(7) as paragraph (d)(1)(i) through (d)(1)(vii).

*** (FR 11/23/01 page 58790)

We proposed to add a new paragraph (d)(2) to Sec. 41032 that would outline documentation and recordkeeping requirements related to clinical diagnostic laboratory tests. The documentation and recordkeeping requirements read as follows:

++Paragraph (d)(2)(i) would specify that the physician (or qualified nonphysician practitioner) who orders the service must

*** (FR 11/23/01 page 58790)

--We proposed CFR provisions clarifying that if the documentation submitted by the entity submitting the claim is inadequate, we will seek information directly from the ordering physician.

--We clarified that we do not require the signature of the ordering physician on a requisition for laboratory tests. However, documentation that the physician ordered the test must be available upon our request.

++Paragraph (d)(2)(i) would specify that the physician or qualified nonphysician practitioner) who orders the service must maintain documentation of medical necessity for the service in the beneficiary's medical record.

++Paragraph (d)(2)(ii) would require the entity submitting the claim to maintain documentation it receives from the ordering physician and information documenting that the claim submitted accurately reflects the information it received from the ordering physician.
++Paragraph (d)(3)(i) will specify that the entity submitting the claim must provide documentation of the physician's order for the service billed, showing accurate processing and submission of the claim, and diagnostic or other medical information supplied to the laboratory by the ordering physician or qualified nonphysician practitioner, including any ICD-9-CM code or narrative description supplied.

++Paragraph (d)(3)(ii) will specify that if the documentation submitted by the laboratory does not demonstrate that the service is reasonable and necessary, we will provide the ordering physician information sufficient to identify the claim being reviewed and request from the ordering physician those parts of the beneficiary's medical record that are relevant to the claim(s) being reviewed. If the documentation is not provided timely, we will notify the billing entity and deny the claim.

++Paragraph (d)(4)(i) will state that unless indicated in paragraph (d)(4)(ii), we will not deny a claim for services that exceed utilization parameters without reviewing all relevant documentation submitted with the claim.

*** (FR 11/23/01 page 58801)

Signature on Requisition

Comment: Twelve commenters addressed the March 10, 2000 proposed rule's provision about signature requirements on requisitions.

*** (FR 11/23/01 page 58802)

Response: Regulations set forth at Sec. 410.32(a) require that diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests must be ordered by the physician who is treating the beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Some have interpreted this regulation to require a physician's signature on the requisition as documentation of the physician's order. While the signature of a physician on a requisition is one way of documenting that the treating physician ordered the test, it is not the only permissible way of documenting that the test has been ordered. For example, the physician may document the ordering of specific tests in the patient's medical record. As stated in the preamble to the March 10, 2000 proposed rule, we will publish an instruction to Medicare contractors clarifying that the signature of the ordering physician is not required for Medicare purposes on a requisition for a clinical diagnostic laboratory test.

*** (FR 11/23/01 page 58806)

Clarification that the administrative policies discussed in the preamble to the March 10, 2000 proposed rule and the NCDs in the addendum to the March 10, 2000 proposed rule apply equally to all setting (hospital and nonhospital).

*** (FR 11/23/01 page 58806)

Clarification that the signature of the ordering physician is not required for Medicare purposes on a laboratory test requisition.

*** (FR 11/23/01 page 58806)

Clarification that Medicare contractors will not use a frequency screen that could result in a frequency-based denial unless the contractor has published information about the appropriate frequency for the service or unless we have published information about the appropriate frequency in a national coverage decision.

Program Memorandum Intermediaries/Carriers

Department of Health and Human Services (DHHS)
HEALTH CARE FINANCING ADMINISTRATION (HCFA)

Transmittal AB-00-99

Date: OCTOBER 24, 2000

CHANGE REQUEST 1407

SUBJECT: Glucose Monitoring Note

This Program Memorandum (PM) briefly notes Medicare policy for glucose monitoring for a patient whose stay is not covered by Medicare Part A but who is eligible for services under Medicare Part B. Another PM will be issued, Change Request 1362, Glucose Monitoring, to describe further coverage, payment and billing instructions for this service. Glucose monitoring measures blood sugar levels for the purpose of managing insulin therapy (shots, medication, and diet). The service often involves the use of an inexpensive hand-held device to evaluate a small sample of the patient's blood acquired through a finger stick. The device(s) was added to the list of instruments that can be administered by providers registered under the Clinical Laboratory Improvement Amendments (CLIA) including providers registered with only a certificate of waiver. The Current Procedural Terminology (CPT) code that most often describes the service is 82962 *Glucose, blood by glucose monitoring device(s) cleared by the FDA (Food and Drug Administration) specifically for home use.*

Section 1862(a)(1)(A) of the Social Security Act requires the service to be reasonable and necessary for diagnosis and treatment in order to be covered by Medicare. Sections 42 Code of Federal Regulations (CFR) 410.32 and 411.15 specify that for a laboratory service to be reasonable and necessary, it must not only be ordered by the physician but the ordering physician must also use the result in the management of the beneficiary's specific medical problem. Implicitly, the laboratory result must be reported to the physician promptly so that the physician can use the result and instruct continuation or modification of patient care; this includes the physician's order for another laboratory service. Compliance program guidance for laboratory services permits, but with strict limits, the conditions under which the physician's order for a repeat laboratory service can qualify as an order for another covered laboratory service.

A national coverage policy on blood glucose monitoring has not been promulgated. Carriers and intermediaries have been responsible for making coverage determinations and many have developed a local coverage policy to assist with payment determinations. Section 541 of the Skilled Nursing Facility (SNF) Manual explains that when a reasonable and necessary laboratory service is administered for a Part B only patient, the laboratory service is separately payable either on a

The effective date for this PM is November 1, 2000.

The implementation date for this PM is November 1, 2000.

These instructions should be implemented within your current operating budget.

For questions regarding this document, contact Anita Greenberg on (410) 786-4601. For questions regarding §541 of the SNF Manual, contact Jackie Gordon on (410) 786-4517.

This PM may be discarded after December 31, 2001.

Program Memorandum Intermediaries/Carriers

Department of Health and Human Services (DHHS)
HEALTH CARE FINANCING ADMINISTRATION (HCFA)

Transmittal AB-00-108 **Date: DECEMBER 1 , 2000**

CHANGE REQUEST 1362

SUBJECT: Glucose Monitoring

This Program Memorandum (PM) reviews Medicare coverage and payment policy for glucose monitoring for a patient whose stay is not covered by Medicare Part A but who is eligible for services under Medicare Part B. During the past year, program integrity efforts have identified a significant increase in the number of claims submitted to intermediaries for glucose monitoring using a home-use device. We also have received inquiries from contractors, providers, and beneficiaries reporting encouragement of home-use glucose monitoring devices for more patients, more often and in more health care settings, specifically nursing homes and home health agencies, than in the past so that a review of the service is warranted. This PM incorporates and supplements material previously issued in a prior PM, AB-00-99, CR 1407, "Glucose Monitoring Note." It provides instructions on payment that supplement AB-00-109, CR 1377, "2001 Clinical Laboratory Fee Schedule."

Glucose monitoring measures blood sugar levels for the purpose of managing insulin therapy (shots, medication, and diet). The service often involves the use of an inexpensive hand-held device to evaluate a small sample of the patient's blood acquired through a finger stick. The device measures blood glucose values immediately on a digital display so as to permit self-administration in the home. If a physician separately orders the performance of a glucose monitoring service for a patient who can not self-administer, clinical staff generally will administer a glucose monitoring service along with their other duties.[1] Administration of the service several times a day is common in order to maintain tight control of glucose to prevent heart disease, blindness, and other complications of diabetes. This device is on the list of instruments that can be administered by providers registered under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), including providers registered with only a certificate of waiver.[2]

[1] Medicare Part B may pay for a glucose monitoring device and related disposable supplies under its durable medical equipment benefit if the equipment is used in the home or in an institution that is used as a home. A hospital or SNF is not considered a home under this benefit. §1861(h) of the Social Security Act. §42 Code of Federal Regulations (CFR) 410.38.

[2] Section 353 of the Public Health Service Act codified at §42 CFR 493. The most recent PM identifying CLIA-waived instruments under CLIA is PM AB-00-61, dated July 2000.

The Current Procedural Terminology (CPT) code that most often describes the service is 82962 *Glucose, blood by glucose monitoring device(s) cleared by the FDA (Food and Drug Administration) specifically for home use.*[3] Section 1862(a)(1)(A) of the Social Security Act requires the service to be reasonable and necessary for diagnosis and treatment in order to be covered by Medicare. Sections 42 CFR 410.32 and 411.15 specify that for a laboratory service to be reasonable and necessary, it must not only be ordered by the physician but the ordering physician must also use the result in the management of the beneficiary's specific medical problem. Implicitly, the laboratory result must be reported to the physician promptly in order for the physician to use the result and instruct continuation or modification of patient care; this includes the physician's order for another laboratory service. Compliance program guidance for laboratory services sets forth conditions under which a physician's order for a repeat laboratory service can qualify as an order for another covered laboratory service. A standing order is not usually acceptable documentation for a covered laboratory service. A national coverage policy on blood glucose monitoring has not been finalized. Carriers and intermediaries have been responsible for making coverage determinations and many have developed a local coverage policy to assist with payment determinations. However, during the past two years, experts involved in the clinical laboratory negotiated rulemaking process determined that blood glucose laboratory testing warrants a national coverage policy. These experts reached a consensus on a proposed national coverage policy, which was described in the March 10, 2000 *Federal Register*, volume 65, number 48, pages 13127-13131. This document can be obtained at the web site http://www.access.gpo.gov Intermediaries and carriers can refer to coverage policy developments at the web site http://www.hcfa.gov/quality/docs/labsd-d.htm Contractors should review their local coverage policy for glucose testing in light of the proposed national coverage policy in order to prepare for the adoption of a national coverage policy. Also, contractors should review their local coverage policy to clarify, if necessary, that a glucose monitoring laboratory service must be performed in accordance with laboratory service coverage criteria including the order and clear use of a laboratory result prior to a similar subsequent laboratory order to qualify for separate payment under the Medicare laboratory benefit.

If a glucose monitoring service is administered for a patient who is hospitalized and eligible for Medicare Part B but who is not in a Part A covered hospital stay, a Form HCFA-1450 is submitted to the intermediary using type of bill (TOB) 12x and revenue code 30x and is paid under the clinical laboratory fee schedule.[4] If a patient is eligible for Part B, but is not in a Part A covered nursing home stay, §541 of the Skilled Nursing Facility (SNF) Manual explains that a laboratory service is separately payable either on a reasonable cost basis (if the patient is in a certified bed) or under the clinical laboratory fee schedule (if the patient is in a non-certified bed). If a Part B only patient resides in a nursing home certified bed, a Uniform Bill-92 (UB92) using TOB 22x and revenue code 30x is submitted to the intermediary. The laboratory cost center of the cost report must reflect the corresponding glucose monitoring costs and charges even when the provider is registered for laboratory testing with only a certificate of waiver from CLIA. The beneficiary is liable for the deductible and coinsurance. If a Part B only patient resides in a non-certified bed, payment is made under the clinical laboratory fee schedule. Until further instructions regarding Part B only patient are implemented, a UB92 is submitted using TOB

[3] CPT code 82962 represents a method when whole blood is obtained (usually by finger stick device) and assayed by glucose oxidase, hexaokinase, or electrochemical methods and spectrophotometry using a small portable device designed for home blood glucose monitoring use. The device(s) are now also used in physician offices, nursing homes, hospitals, and during home health visits. CPT code 82947-QW describes instruments that measure quantitative glucose levels but are not cleared by the FDA for home glucose monitoring. Development of hand-held device(s) using a noninvasive biosensor or other micromethod for more rapid glucose monitoring is underway; however, to date these devices are not categorized by FDA as CLIA-waived tests. The term *continuous glucose monitoring* does not refer to CLIA-waived test but to a procedure that implants needle probes into the patient and provides measurements to a computer screen. This lengthy procedure, reviewing and interpreting the measurements is performed by a physician or appropriately licensed practitioner similar to a 24-hour electrocardiographic monitoring and payment is made under the physician fee schedule.

[4] Medicare Intermediary Manual, §§3604 and 3628.

23x and revenue code 30x to the intermediary when the SNF provides a laboratory service either directly or under arrangement with an outside laboratory. The beneficiary is not liable for a deductible or coinsurance. Nursing and physician duties, include observing, ordering, administering and interpreting the patient's health status are paid predominately under other payment systems, such as the state nursing home payment system or the physician payment system. If home-use glucose monitoring devices are used in the hospital and nursing home settings, a glucose monitoring service must be performed in accordance with laboratory coverage criteria to qualify for separate payment under the Medicare laboratory benefit. As noted above, for a laboratory service to be reasonable and necessary, it must be ordered by the physician, the ordering physician must use the result in the management of the beneficiary's specific medical problem, and the laboratory result must be reported to the physician promptly in order for the physician to use the result and instruct continuation or modification of patient care.When a glucose monitoring service meets the criteria to be a covered laboratory service for a Part B only patient, regardless of whether the nursing home patient resides in a certified or non-certified bed, payment must be made. Denial of payment for a Part B covered laboratory service cannot be made on the basis that the service is routine care. Under Medicare, routine care determinations are applicable only for Part A nursing home services.

A covered home health service requires a home health employee to supervise, assist, record, and report on the patient's daily/weekly functional and medical activities. For some patients, their daily/weekly activities include glucose monitoring, often self administered or administered with the help of a care giver who is not an employee of or affiliated with the home health provider. If the patient maintains a home-use glucose monitoring device, a home health employee's supervision and assistance of a glucose monitoring service is encompassed in the payment for the home health service. However, if a physician separately orders the employee to administer a glucose monitoring service for a Part B only patient who does not administer daily/weekly glucose monitoring and does not maintain a glucose monitoring device, the glucose monitoring service is not encompassed in the home health benefit.[5] If a home health agency receives a supplier number, a Form HCFA-1500 may be submitted to the carrier in accordance with physician and supplier billing instructions for filing Part B claims at MCM 3001.[6] Corresponding laboratory costs and charges must be reported on the cost report even when the home health agency is registered for CLIA testing with only a certificate of waiver. Sections 42 CFR 410.32 and 411.15 apply equally to a laboratory service in the home health setting. Therefore, if a home health employee carries and assists with the use of a home-use glucose monitoring device during a home health visit, a glucose monitoring service must be performed in accordance with laboratory coverage criteria to qualify for separate payment under the Medicare laboratory benefit. The blood glucose monitoring service must not only be ordered by the physician but the ordering physician must also receive and use the order's result in the management of a specific medical problem. The laboratory result must be reported to the physician promptly in order for the physician to use the result and instruct continuation or modification of patient care. Compliance program guidance for laboratory services sets forth the conditions under which a physician's order for a repeat laboratory service can qualify as an order for another covered laboratory service. Program integrity efforts should review for medical necessity a claim for a glucose monitoring laboratory service received at the same time as a claim for glucose test strips indicating the patient is maintaining a home-use device for self monitoring.

At certain times a physician may also order a separate quantitative blood glucose test to enhance a physician evaluation and management service for the patient. A specimen collection of venous blood may be sent to an independent laboratory for testing and the laboratory reports the result to the provider and the ordering physician. This is a separate laboratory service billed with a different code than a home-use glucose monitoring service and is also paid under the laboratory fee schedule. Instructions regarding the clinical diagnostic laboratory fee schedule are at §3628 of the Medicare Intermediary Manual and §5114 of the Medicare Carriers Manual.

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[5] §1861(m) of the Act governs the extent of Medicare home health services that may be provided to eligible beneficiaries by or under arrangements made by a participating home health agency (HHA).

[6] Home Health Manual, §465.

As stated above, the CPT code that most often describes the glucose monitoring service using a laboratory testing device designed for home use is 82962 *Glucose, blood by glucose monitoring device(s) cleared by the FDA specifically for home use.* This CPT code has been included in the clinical laboratory fee schedule since January 1, 1993. The payment amount established for this CPT code was mapped from a previously existing code representing a quantitative glucose test using a device that is not cleared by the FDA for home use. Since that time, the payment amount has been subject to the prescribed updates for the clinical laboratory fee schedule.[7] During the past year, we have reviewed the test and have determined that administering a glucose monitoring service with a home-use device is substantially different than a quantitative glucose test and therefore our earlier mapping of the CPT code 82962 for a device approved for home use to a quantitative blood glucose test was erroneous.

In order to allow Medicare to base the laboratory fee schedule payment amount for CPT code 82962 code on the best available data nationwide, carriers must gap-fill CPT code 82962 for the year 2001. To establish an appropriate gap-fill amount for 2001, carriers should receive assistance from their corresponding intermediaries to consider the cost and the charge for the service as it is administered for Part B patients in a variety of settings such as hospitals, home health agencies, nursing homes, and physician offices. Gap-filling should consider, as appropriate, the costs of professional and clerical labor, device amortization, supplies, and overhead for this service. While these costs can be difficult to distinguish from other nursing and clinical services provided to the patient, the gap-fill amount must be established to carefully reflect only the Medicare laboratory service. Carriers should also evaluate any information that may be submitted to the carrier by other interested parties in establishing the gap-fill amount. In accordance with instructions for laboratory gap-fill codes in PM AB-00-109, CR 1377, "2001 Clinical Laboratory Fee Schedule," the gap-fill amount is established by the carrier on a flow basis as claims are received for the code. For CPT code 82962, the local fee amount field and the National Limitation Amount field are zero-filled in the year 2001 clinical laboratory fee schedule date file that was issued to carriers on November 1, 2000, and to intermediaries on November 21, 2000. Carriers should establish a gap-fill amount not later that March 31, 2001, communicate the amount to the corresponding intermediary as necessary, and report the amount to their Regional Office by May 4, 2001. The gap-fill amounts establish the local laboratory fee schedule amounts for CPT code 82962 and will be used to develop the year 2002 national limitation amount for this code.

NOTE: Claims for dates of service prior to the effective date of this PM should be processed in accordance with local medical review policy in effect on the date of service. Medicare Intermediary Manual §3600.2 explains that a claim must be filed on or before December 31 of the calendar year following the year in which the service was furnished. Do not search for previously adjudicated claims, however, timely filed claims may be adjusted if brought to your attention.

The effective date for this PM is January 1, 2001.

The implementation date for this PM is January 1, 2001.

These instructions should be implemented within your current operating budget.

For questions regarding this document, contact Anita Greenberg on (410) 786-4601.

This PM may be discarded after December 31, 2001.

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[7] §1833(h) of the Act; Medicare Carriers Manual, §5114.1C.

Rheumatology and Pulmonary Clinic P.L.L.C.
421 Carriage Drive • Beckley, West Virginia 25801
Phone 304 256-0242 Fax 304 256-0244
Email wsaikali@mtneer.net

Wassim Saikali MD
Board Certified Internal Medicine and Rheumatology
Certified Clinical Densitometrist

Maria Boustani MD
Board Certified Internal Medicine, Pulmonary and Critical Care

September 26, 2006

Department of Health & Human Services
Attn: CMF-1502-P
Mail Stop C4-26-057500 Security Blvd.
Baltimore, MD 21244-1850

RE: Document #1321-P

Dear Sir or Madam:
I am writing this letter regarding the new proposal regarding coverage of bone mass measurement (BMM). I have been a practicing Rheumatologist for the last thirteen years, and definitely with the five major proposal changes I am against the reduction of reimbursement for physicians. It has been several years where there have been cuts in the reimbursement for physicians. The new one will definitely negatively impact our ability to do bone densities on patients who are a high risk for fracture. The proposed reimbursement for a bone density will barely pay for the technician fee and the time span in preparing patients and explaining the DEXA scan with them immediately after the test. It takes almost 25 to 30 minutes to run one test. How can you do prevention of fractures in treatment of patients who are at high risk without utilization of a DEXA scan?

With the proposal of cutting reimbursement, this will be against any physician or hospital purchasing a DEXA scan from leading companies that sell those machines for an average of fifty to sixty-thousand dollars. With the amount of money that the machine will generate, we will basically lose money in order to provide services to patients with Medicare and Medicaid. Keeping in mind, the bone density reimbursement is not the only service being cut down and almost all services provided by physicians across the board are being cut. At the same time, the cost of running a practice with insurance, disability and retirement for employees has been going up by 20 to 30%, with the reimbursement going down. Please keep that in mind when you make your decision regarding DEXA scans.

Sincerely,

Wassim Saikali, M.D.
Division of Rheumatology

Rheumatology and Pulmonary Clinic P.L.L.C.
421 Carriage Drive • Beckley, West Virginia 25801
Phone 304 256-0242 Fax 304 256-0244
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Wassim Saikali MD
Board Certified Internal Medicine and Rheumatology
Certified Clinical Densitometrist

Maria Boustani MD
Board Certified Internal Medicine,
Pulmonary and Critical Care

September 26, 2006

Department of Health & Human Services
Attn: CMF-1502-P
Mail Stop C4-26-057500 Security Blvd.
Baltimore, MD 21244-1850

RE: Document #1321-P

Dear Sir or Madam:
I am writing this letter regarding the new proposal regarding coverage of bone mass measurement (BMM). I have been a practicing Rheumatologist for the last thirteen years, and definitely with the five major proposal changes I am against the reduction of reimbursement for physicians. It has been several years where there have been cuts in the reimbursement for physicians. The new one will definitely negatively impact our ability to do bone densities on patients who are a high risk for fracture. The proposed reimbursement for a bone density will barely pay for the technician fee and the time span in preparing patients and explaining the DEXA scan with them immediately after the test. It takes almost 25 to 30 minutes to run one test. How can you do prevention of fractures in treatment of patients who are at high risk without utilization of a DEXA scan?

With the proposal of cutting reimbursement, this will be against any physician or hospital purchasing a DEXA scan from leading companies that sell those machines for an average of fifty to sixty-thousand dollars. With the amount of money that the machine will generate, we will basically lose money in order to provide services to patients with Medicare and Medicaid. Keeping in mind, the bone density reimbursement is not the only service being cut down and almost all services provided by physicians across the board are being cut. At the same time, the cost of running a practice with insurance, disability and retirement for employees has been going up by 20 to 30%, with the reimbursement going down. Please keep that in mind when you make your decision regarding DEXA scans.

Sincerely,

Wassim Saikali, M.D.
Division of Rheumatology

With the proposal of cutting reimbursement, this will be against any physician or hospital purchasing a DEXA scan from leading companies that sell those machines for an average

FYSE-Reg Staff

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August 18, 2006

SEP 0 6 2006

William H. Benton MD
Director Neonatal Intensive Care Unit
Baptist Health Care System
14001 Belle Pointe Drive
Little Rock, Arkansas 72212

The Honorable Mark McClellan, MD, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security, Blvd., CA-26-05
Baltimore, MD 21244

Dear Dr McClellan:

I am in receipt of The "Medicare Program, Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology".

The proposal to penalize providers 10%, if passed, will represent a disaster for the optimal health care for babies and their mothers in this country. Allow me to outline why this is:

1. Doctors working in high indigent [Medicaid]/stress areas [such as the NICU], work where the stakes are high: both medically and legally. It is, at present, difficult to attract and keep highly competent neonatologists. This will make this task even more difficult than it already is.
2. Malpractice and overhead continue to accelerate, independent of your reductions. As you know, reimbursement from all non-Medicaid payers will drop accordingly. This model eventually bankrupts our ability to survive as a viable profession.
3. This produces a negative professional-financial risk/benefit ratio for those considering neonatology; result: the movement of qualified doctors away from neonatology.
4. This produces a growing nationwide deficiency of well-trained, skilled and well educated neonatologists.
5. This reduces our ability to staff NICUs adequately, both now and into the future.
6. This produces greater ratios of patients/staff/neonatologists
7. This produces a dilution of patient care, making it, therefore, suboptimal for babies, their mothers and their families.
8. Result: a preventable disaster for babies - happens.

Summary:
Federally based financial decisions must be based upon sound public policy and forward-looking financial principles; decisions which are, therefore, investments - investments in our country's future.
This means optimizing babies and their families; optimizing not decreasing funding, no matter the effect on balanced budgets.
Decisions in this arena which are "expense-based/justified" are, therefore, intellectually, morally, medically – and therefore politically bankrupt and suicidal.
Such very-bad decisions which are counter the best interests of babies, their mothers and their care, universally make very, very bad press.

Please make the right decision for babies. Defeat this measure.

Very Respectfully Yours,

William H. Benton MD

Bill & Beth Benton
14001 Belle Pointe Dr.
Little Rock, AR 72212

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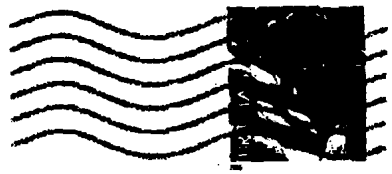

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EGERTON R. VAN DEN BERG, JR., M.D., F.A.C.C., P.A.

DIPLOMATES OF AMERICAN BOARD
OF INTERNAL MEDICINE
AND CARDIOVASCULAR DISEASES

August 21, 2006

Representative Ric Keller
605 East Robinson Street, Suite 650
Orlando, FL 32801

Dear Ric:

I am enclosing a copy of our letter to Mark B. McClellan, M.D. Ph.D. at the Centers for Medicare and Medicaid Services regarding the proposed five year review of the work relative value for physicians fee schedule payment and the changes to practice expense Methodology, notice June 29, 2006.

As you can see, the proposed cuts are unfair, extreme and will cripple our ability to perform cardiac catheterization in our outpatient catheterization lab. I am enclosing a copy of the RVU changes from 2006 which we are being paid right now to what might happen in 2007. As you can see, for the left heart catheterization (93510) the technical component is being reduced 62.22%.

The devastating impact of the proposed cuts will curtail the medicare patients access to cardiac care. As a result, we at Cardiology Consultants, feel that the CMG should freeze payments for these cardiac catheterization-related procedure codes for one year to allow time for a complete assessment of the cost profile.

It is extremely important that you bring these concerns to the attention of your fellow Congressmen and Senators. I will be calling to discuss this issue with you.

Sincerely,

Egerton K. van den Berg, Jr., M. D.

EKV/ms

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DIPLOMATES OF AMERICAN BOARD
OF INTERNAL MEDICINE
AND CARDIOVASCULAR DISEASES

August 21, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
U. S. Department of Health and Human Services
CMS-1512-PN
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

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

Dear Dr. McClellan:

On behalf of Cardiology Consultants and our four individual practicing cardiologists, we appreciate the opportunity to submit comments to the Centers for Medicare and Medicaid Services ("CMS") regarding the June 29, 2006 proposed notice ("Notice") regarding proposed changes to the Practice Expense ("PE") Methodology and its impact on our practices.

Our practice is Cardiology Consultants, 2320 N. Orange Avenue, Orlando, Florida 32084. We have our outpatient cardiac catheterization lab in which all four of our physicians perform outpatient cardiac catheterization procedures; James L. Bolen, M.D., F.A.C.C., P.A., Robert B. Boswell, M.D., F.A.C.C., P.A., Robert L. Rothbard, M.D., F.A.C.C., F.A.C.P., P.A., and Egerton K. van den Berg, Jr., M.D., F.A.C.C., P.A.

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

With regard to catheterizations, the proposed change in P E RVUs would result in a 53.1 percent reduction of payments for CPT 93510 TC. Similarly, payment for two related codes – 93555 TC and 93556 RC would be reduced substantially. In fact, under the Medicare Physician Fee Schedule ("PFS"), payment for these three codes would fall from 94 percent of the proposed 2007 APC rate for these three codes to 34 percent of the APC payment amount. These codes are representative of a range of procedures performed in cardiovascular outpatient centers.

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

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

Direct Costs

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

Even if the RUC estimates included the additional costs submitted to the RUC, the estimate is not an accurate reflection of direct costs of the resources necessary to provide the procedure because the RUC takes a narrow view of direct costs. Specifically, the RUC includes costs only if they are relevant to 51 percent of the patients. This definition of direct costs does not count the costs of supplies and the clinical labor time that may be required for the other 49 percent of the patients that may not fit the average profile. This approach is particularly inconsistent with the realities of the clinical staff needed for a catheterization facility and does not reflect the differences in clinical practice patterns. For example, some catheterization labs may use wound closure devices that will increase supply costs while lowering clinical staff time. Other labs may not use closure devices to the same extent and may allocate more staff time to apply compression to the wound. These costs would not be counted in the RUC-determined direct cost estimate unless they apply to 51 percent of the patients. Based on the PEAC Direct Input data from the CMS website, it appears that the RUC inputs assume the time that may be required if wound closures were used, but it fails to include a wound closure device in the supply list of direct costs.

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

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

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

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

A complete accounting of all of the direct costs associated with performing a cardiac catheterization procedure would result in a PE RVU that is almost two times the proposed amount, and would begin to approximate the actual costs of providing the service. There are additional improvements that can be made in the manner by which the indirect costs are estimated that are outlined below.

Indirect Costs

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

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

Solutions

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

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

We will be collaborating with our membership organization, the Cardiovascular Outpatient Center Alliance ("COCA"), to develop more accurate estimates of direct and indirect costs that may be submitted to CMS to supplement these comments either separately or as part of our comments in our response to the Proposed Rule addressing Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007. It is our understanding that CMS will accept additional data to evaluate the impact of the PE RVU methodology on our practices.

Gerald & Pat

CARDIOLOGY CONSULTANTS

JAMES L. BOLEN, M.D., F.A.C.C., P.A.
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ROBERT L. ROTHBARD, M.D., F.A.C.C., F.A.C.P., P.A.
EGERTON K. VAN DEN BERG, JR., M.D., F.A.C.C., P.A.

DIPLOMATES OF AMERICAN BOARD
OF INTERNAL MEDICINE
AND CARDIOVASCULAR DISEASES

Sincerely,

James L. Bolen, M.D.

Robert B. Boswell, M.D.

Robert L. Rothbard, M.D.

Egerton K. van den Berg, Jr., M.D.

EKV/ms

Cc: Congressman David Weldon
2725 Judge Fran Jamieson Way, Building C
Melbourne, Florida 32940

Representative Ric Keller
605 East Robinson Street, Suite 650
Orlando, Florida 32801

Congressman John Mica
668 North Orlando Avenue, Suite 208
Maitland, Florida 32751

2007 PE RVU Changes
Left Heart Cath
(93510, 93555, 93556)

2006 Physician Fee Schedule

Components	93510 TC	93510 TC	93555 TC	93555 TC	93556 TC	93556 TC	Totals
Work	0.00	$0.00	0.00	$0.00	0.00	$0.00	
PE	37.06	$1,404.48	6.29	$238.36	9.92	$375.94	
MP	2.31	$87.54	0.34	$12.89	0.51	$19.33	
	39.37	$1,492.02	6.63	$251.26	10.43	$395.27	$2,138.56
	Global	Global	Global	Global	Global	Global	
Work	4.32	$163.72	0.81	$30.70	0.83	$31.45	
PE	39.24	$1,487.10	6.61	$250.50	10.24	$388.07	
MP	2.61	$98.91	0.37	$14.02	0.54	$20.46	
	46.17	$1,749.73	7.79	$295.22	11.61	$439.99	$2,484.94
	Pro	Pro	Pro	Pro	Pro	Pro	
Work	4.32	$163.72	0.81	$30.70	0.83	$31.45	
PE	2.18	$82.62	0.32	$12.13	0.32	$12.13	
MP	0.3	$11.37	0.03	$1.14	0.03	$1.14	
	6.8	$257.70	1.16	$43.96	1.18	$44.72	$346.38

2007 Proposed PE Changes

Components	93510 TC	93510 TC	93556 TC	93555 TC	93556 TC	93556 TC	Totals	Net Change
Work	0.00	$0.00	0.00	$0.00	0.00	$0.00		
PE	[redacted]	$660.11	[redacted]	$7.15	[redacted]	$16.04		
MP	2.31	$82.40	0.34	$12.89	0.61	$20.40		TC
	19.73	$752.51	0.53	$20.04	0.91	$35.44	$807.98	-$1,330.58
								-62.22%
	Global	Global	Global	Global	Global	Global		
Work	4.32	$163.72	0.81	$30.70	0.83	$31.45		
PE	[redacted]	$788.16	[redacted]	$30.06	[redacted]	$36.81		
MP	2.61	$98.91	0.37	$14.02	0.54	$20.48		Global
	27.73	$1,060.79	1.97	$74.78	2.39	$90.73	$1,216.30	-$1,269.64
								-51.05%
	Pro	Pro	Pro	Pro	Pro	Pro		
Work	4.32	$163.72	0.81	$30.70	0.83	$31.45		
PE	[redacted]	$119.79	[redacted]	$22.44	[redacted]	$23.04		
MP	0.30	$11.37	0.03	$1.14	0.03	$1.14		Pro
	7.76	$294.88	1.43	$54.27	1.47	$56.63	$404.78	$58.40
								16.86%

2007 PE RVU Changes
Echo
(93307, 93320, 93325)

2006 Physician Fee Schedule

Components	93307	93307	93320	93320	93325	93325	Totals
	TC	TC	TC	TC	TC	TC	
Work	0.00	$0.00	0.00	$0.00	0.00	$0.00	
PE	3.87	$148.69	1.71	$64.80	2.91	$110.28	
MP	0.23	$6.72	0.12	$4.55	0.21	$7.96	
	4.1	$155.36	1.83	$69.35	3.12	$118.24	$342.97
	Global	Global	Global	Global	Global	Global	
Work	0.92	$34.87	0.38	$14.40	0.07	$2.65	
PE	4.22	$159.93	1.86	$70.49	2.94	$111.42	
MP	0.26	$9.85	0.13	$4.93	0.22	$8.34	
	5.4	$204.65	2.37	$89.82	3.23	$122.41	$416.87
	Pro	Pro	Pro	Pro	Pro	Pro	
Work	0.92	$34.87	0.38	$14.40	0.07	$2.65	
PE	0.35	$13.26	0.15	$5.68	0.03	$1.14	
MP	0.03	$1.14	0.01	$0.38	0.01	$0.38	
	1.3	$49.27	0.54	$20.46	0.11	$4.17	$73.90

2007 Proposed Transalton PE Changes

Components	93307	93307	93320	93320	93325	93325	Totals	Net Change
	TC	TC	TC	TC	TC	TC		
Work	0.00	$0.00	0.00	$0.00	0.00	$0.00		
PE	[redacted]	$141.74	[redacted]	$63.29	[redacted]	$89.06		
MP	0.23	$6.72	0.12	$4.55	0.21	$7.96		TC
	3.97	$150.45	1.79	$67.84	2.56	$97.02	$315.31	-$27.67
								-8.07%
	Global	Global	Global	Global	Global	Global		
Work	0.92	$34.87	0.38	$14.40	0.07	$2.65		
PE	[redacted]	$156.62	[redacted]	$69.35	[redacted]	$90.20		
MP	0.26	$9.85	0.13	$4.93	0.22	$8.34		Global
	5.31	$201.24	2.34	$88.68	2.67	$101.19	$391.10	-$25.77
								-6.18%
	Pro	Pro	Pro	Pro	Pro	Pro		
Work	0.92	$34.87	0.38	$14.40	0.07	$2.65		
PE	[redacted]	$14.40	[redacted]	$5.68	[redacted]	$1.14		
MP	0.03	$1.14	0.01	$0.38	0.01	$0.38		Pro
	1.33	$50.40	0.55	$20.84	0.11	$4.17	$75.42	$1.52
								2.05%

2007 PE RVU Changes
Echo
(93307, 93320, 93325)

Fully Implemented Proposed PE Changes

Components	93307 TC	93307	93320 TC	93320	93325 TC	93325	Totals	Net Change
Work	0.00	$0.00	0.00	$0.00	0.00	$0.00		
PE	[redacted]	$127.34	[redacted]	$57.98	[redacted]	$24.63		
MP	0.23	$8.72	0.12	$4.55	0.21	$7.96		TC
	3.59	$136.05	1.88	$62.53	0.86	$32.59	$231.17	-$111.80
								-32.60%
	Global	Global	Global	Global	Global	Global		
Work	0.92	$34.87	0.38	$14.40	0.07	$2.65		
PE	[redacted]	$145.53	[redacted]	$65.18	[redacted]	$25.77		
MP	0.26	$9.85	0.13	$4.88	0.22	$8.34		Global
	6.02	$190.26	2.23	$84.51	0.97	$36.76	$311.52	-$105.36
								-25.27%
	Pro	Pro	Pro	Pro	Pro	Pro		
Work	0.92	$34.87	0.38	$14.40	0.07	$2.66		
PE	[redacted]	$17.81	[redacted]	$7.58	[redacted]	$1.52		
MP	0.03	$1.14	0.01	$0.38	0.01	$0.38		Pro
	1.42	$53.81	0.59	$22.36	0.12	$4.55	$80.72	$6.82
								9.23%

51-0
(185)

Mark McClellan, MD
Centers for Medicare and Medicaid Services
Department of Health & Human Services
Attention: CMS-1506-P and CMS-1512-PN
PO Box 8014
Baltimore, Maryland 21244-8014

Dear Dr. McClellan:

As a patient, I am writing to express my concern and opposition to CMS' proposal to reduce markedly the Medicare fee schedule by virtue of the SGR, the budget neutrality aspect of Medicare fees and to the proposed change the payment structure for separate facility fees at ambulatory surgery centers (ASCs).

I am concerned that CMS' proposal would unfairly and arbitrarily shift fees with minimal objective data, and would significantly compromise the quality of care I receive. These dramatic cuts likely will result in some physicians significantly reducing (or even eliminating) Medicare patients from their practice, and reduced access for Medicare patients at ambulatory surgery centers. Some physicians may not be able to afford to spend as much time with their Medicare patients. I am especially concerned about CMS' attempts to create incentives to steer patients toward specific settings for economic reasons rather than maintaining site neutrality.

Citizens who are growing older deserve better! CMS should suspend its plans to implement the proposed changes to the five-year review, budget neutrality adjustment to the Medicare fee schedule, should defer indefinitely the ambulatory surgery rules and should revise the unfair SGR.

Very truly yours,

(Name) Ruth Mitagner

(Address) 136 Oliver St

(City, State, Zip) Torrington, CT 06790

Deborah S. Bart, M.D. & Associates
DIPLOMATE, AMERICAN BOARD OF OBSTETRICS AND GYNECOLOGY

September 26, 2006

Department of Health and Human Services
ATTN: CMS 1502-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

RE: CMS 1321-P proposed 2007 Physician fee schedule

To: The Centers for Medicaid and Medicare Services (CMS) regarding the Proposed five year review of work components and the changes to practice expense requirements.

Dear Sirs:

We are a small gynecology office in St. Petersburg, Florida with two practicing medical physicians and one nurse practitioner. This practice has been in operation for the past 50 years. Most of our patients have been coming to this office for a substantial number of those years. They rely on our office for most of their medical needs. We have furnished them with ultrasound and dexa scan in our office setting for their convenience.

I would like to make an objection to the five year work review in general, but in particular to the practice expense methodology and the changes offered by the deficit reduction act and the bone mass measurement test changes.

The dexa scan machine was installed in our office 4 years ago at great expense for the convenience of our many older gynecological patients. We do not advertise this service; it is used solely for our patients. It is a fan beam unit made by Aloka. There is substantial skill and service involved in the treatment of osteoporosis. The counseling of patients is also an integral part of our dexa scan service. It is necessary to prevent dangerous fractures in our elderly population. Because we use this dexa scan solely for our own patients, it would pose a financial hardship to our office for you to enact the reimbursement policy you propose. We only do an average of 10 – 12 scans per week and the cost of the equipment, tech, and physician, and office personnel would not be compensated fairly with your proposed rate of reimbursement. Your new rate which is approximately ¼ of the current rate would pose a real hardship for us. I believe that any physician office that has a unit, for the sole use of their patients, would be burdened by this reduction in like manner.

3055 5th Avenue North • St. Petersburg, FL 33713-6799
(727) 323-3838 • Fax (727) 323-4520

Deborah S. Bart, M.D. & Associates
DIPLOMATE, AMERICAN BOARD OF OBSTETRICS AND GYNECOLOGY

Department of Health and Human Services
Attn: CMS – 1502-P

Page Two

Please reconsider a fair reimbursement for this personalized intense service supplied not only by the technician, and physician, but also includes the nurse, billing and office personnel, all of whom are involved in this procedure in our office setting.

Thank you for your kind consideration in this matter.

Sincerely,

Deborah S Bart MD

Deborah S. Bart, M.D.

3055 5th Avenue North • St. Petersburg, FL 33713-6799
(727) 323-3838 • Fax (727) 323-4520

St Luke's HOSPITAL
ALLENTOWN CAMPUS

1736 Hamilton Street
Allentown, PA 18104
610-770-8300

53

August 30, 2006

To Whom it May Concern,

Our ED staff has reviewed the proposed changes to E&M coding guidelines. We have found the changes to be confusing and somewhat awkward.

We have recently implemented a new point system which we find more "user friendly" that what is being proposed.

Thank you for allowing us to send in our comments.

Faith Ring BSN

Faith Ring
Nurse Manager, Emergency Department
St. Luke's Hospital- Allentown Campus

Rick Neas

Rick Neas
Clinical Coordinator, Emergency Department
St. Luke's Hospital- Allentown Campus

Denise Stein RN, MSN, CENP, CEN

Denise Stein
Clinical Nurse Specialist, Emergency Department
St. Luke's Hospital- Allentown Campus

Emergency Room Nursing Interventions/Other Charges

Patient Name _____
Account # _____
DOS _____

		Diagnostic Tests
	1628	ABG Collection (36600)
	2998	Breath Alcohol, Legal (82075)
	2997	Breath Alcohol, Medical (82075)
	1619	EKG 12-lead by nurse or tech (93005)
	1627	Glucometer reagent strip (82948)
	1626	Hemoccult, feces (82272)
	5004	Pulse ox spot check (94760)
	5005	Pulse ox monitoring, continuous (94762)
	1614	Updraft, Aerosol/Vapor Inhl Tx (94640)
	1625	Urinalysis, Dip w/o micros (81002) (Atown/Beth/ Miners)
		Lab SIM Department
	0075	ED Legal Urine Drug Screen (NIDA)
	3618	ED Pregnancy, Urine HCG testing (81025) (+) (-)
		Therapeutic Treatments
	1618	Cardioversion (92960)
	1620	CPR - initial multi-disciplinary response (92950)
	5002	Cardiac pacing external (92953)
	1654	IV Hydration, 1st Hour (90760)
	1655	IV Hydration, Ea Addl Hour (90761)
	1610	IV Drug Therapy, 1st Hour (90765)
	1611	IV Drug Therapy, Ea Addl Hour (90766)
	1656	IV Drug Therapy, Addl, Sequential (90767)
	1657	IV Drug Therapy, Concurrent(90768) **NA for MC/MA/SP**
	1621	IV Thrombolytic Coronary Infusion Therapy (92977)
	1612	Transfusion Therapy, Blood/Blood Products (36430)
	1633	Medication Injection, Tx/Dx, IM/Subcu (90772)
	1634	Medication Injection, Intra-arterial (90773)
	1635	Medication Injection, IV Push (90774)
	1658	Med Injection, IV Push, Ea Addl, Seqntl, New Rx (90775)
		Vaccine Administrations
	1630	TD Adult
	1631	DT Peds
	1632	Tetanus toxoid
	1629	Rabies IM
	1637	Rabies ID
	1638	Immune Globulin IM
	1639	Immune Globulin Rabies
	1640	Immune Globulin Rabies Ht Trtd
	1641	Immune Globulin Tetanus IM

Instructions for Choosing a Procedure Charge Code

If only one item is checked, then the corresponding charge code is entered.

If multiple Simple Procedures (1606) are checked off, all Simple Procedures included under Charge Code 1607

	1607	Multiple Simple procedures

If multiple Simple/Intermd Procedures (1606 & 1607) are checked off, all procedures included under Charge Code 1608

	1608	Simple &/or Multiple Intermediate procedures

If multiple Simple-Cmplx Procedures (1606-1608) are checked off, all procedures included under Charge Code 1609

	1609	Simple/Intermed &/or Multiple Complex procedures

If no Trauma Alert is Called and Critical Care Level is Checked, all Procedures Included Under Charge Code 1609

	1609	Medical Procedures, complex, multiple

If a Trauma Alert is Called all Procedures Included Under Charge Code 1255

	1255	Trauma Alert, team response (Bethlehem Facility Only)

If Multiple Items Are Checked In This Box, Please Refer to Specific Instructions for Choosing the Appropriate Charge.

		Medical Procedure Charges
	1606	Arthro,Aspir/Injection (20600, 20605, 20610)
	1606	Aspiration, Absc/Hema/Cyst/Bulla (10160)
	1606	Burn Care Simple, w/o ansth (16000, 16020)
	1607	Burn Care Intrmd, w/o ansth (16025, 16030)
	1607	Central line placement assist (36555, 36556)
	1606	Closed Treatment of Fracture, Simple
	1607	Closed Treatment of Fracture, Intermediate
	1608	Closed Treatment of Fracture, Complex
	1606	Closed Trmt Nursemaid Elbow w/Manipulation (24640)
	1606	Ear irrigation (69210)
	1606	Epistaxis Control, anterior (30901, 30903)
	1607	Epistaxis Control, posterior (30905)
	1606	Foley Catheter insertion (51702, 51703)
	1606	Foreign Body Rmvl, Subcu ,Simple (10120)
	1607	Foreign Body Rmvl, Subcu, Complicated (10121, 28190)
	1606	Foreign Body Rmvl, Eye w/wo Lamp(65205, 65220, 65222)
	1606	Gastric lavage/ GI decontamination (91105)
	1606	I&D Simple, single (10060)
	1607	I&D Complicated, multiple (10061)
	1608	I&D Ischiorectal/Perirectal Abscess (46040)
	1607	I&D Peritonsillar Abscess (42700)
	1606	Intraosseous infusion, needle placement (36680)
	1607	Intubation, endotracheal assist (31500)
	1606	Laceration repair assist, simple 1- 10 min
	1607	Laceration repair assist intermediate 10-20 min
	1608	Laceration repair assist, complex >20 min
	1606	Nails, (trimming, debridement, avulsion, evacuation)
	1607	Nails, Excision of nail and nail matrix (11750)
	1606	Paracentesis assist (49080)
	1607	Pericardiocentesis, Initial (33010)
	1609	Precipitous newborn delivery
	1606	Spinal Puncture, Lumbar, Diagnostic (62270)
	1606	Splinting & strapping (splints, immobilizers)
	1606	Thoracentesis assist (32000)
	1608	Thoracostomy, w/wo water seal (Chest tube 32020)
	1609	Thoracotomy assist (32110)
	1608	Tracheostomy assist (31603, 31605)
	1606	Trigger Point Injection (20550)
	1606	Tube Placement NG or OG w/fluoroscopy (43752)
	1608	Tube Placement Gastrostomy (43750)
	1606	Tube Change Gastrostomy (43760)
	1606	Wound Debridement, simple (skin/subcutaneous tissue)
	1607	Wound Debridement, intermed (skin/subcu/muscle)
	*	**Unlisted Procedure (Check off this item if the procedure performed is not listed above. Include a description in the space below. Enter all other charges & forward to the CDM dpt.)**

Revised 08/24/2006
R:\CDM\ER\08-24-06 SLHN 2 PG TSystm ER Points & Charges

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MIDTOWN NUTRITION CARE
119 WEST 57TH STREET
NEW YORK, NY 10019
(212) 333-4243

September 11, 2006

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

Re: August 22, 2006 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

Issue Identifier: PROVISIONS—MEDICAL NUTRITION THERAPY SERVICES, CPT 97802-4, G0270-1 (II. Provisions of the Proposed Rule, A. Resource-Based Practice Expenses (PE) RVU Proposals for CY 2007, 3. Medical Nutrition Therapy Services, 71 FR 48987)

Dear Sir or Madam:

Midtown Nutrition Care (Midtown), a single specialty nutrition group practice with 7 registered dietitians, respectfully submits the following comments.

Table of Contents

Attachment B—July 2000 HCPAC Recommendations and August 1, 2000 transmittal memo (4 pages)

Attachment C—January 3, 2006 letter from ADA to CMS (4 pages)

Attachment D—March 24, 2006 letter from ADA to CMS (3 pages)

Attachment E—Section 105 of BIPA and Statement of the Manager For Section 105 (2 Pages)

Attachment F—March 2000 RUC Update Survey (24 pages)

Summary of Points

The work RVUs for the three individual 15-minute medical nutrition therapy codes CPT 97802, 97803 and G0270 should all be the same. The work RVUs for the medical nutrition therapy codes should be based on the 15-minute consultation code CPT 99241 rather than on the 15-minute and 30-minute physical therapy codes CPT 97110 and 97150.

Inadequate Reimbursement = Lack of Access

1. Last year, in the Calendar Year 2006 Proposed Rule, CMS proposed eliminating the nonphysician work pool, formerly known as the zero-work pool, and stated: "We recognize that there are still some outstanding issues that need further consideration, as well as input from the medical community. For example, although we believe that the elimination of the nonphysician work pool would be, on the whole, a positive step, some practitioner services, such as audiology and medical nutrition therapy, would be significantly impacted by the proposed change.... We, therefore, welcome all comments on these proposed changes..." (70 FR 45777, second column).

2. As members of the medical community Midtown submitted comments dated September 22, 2005 from our group and from the original sponsor of the medical nutrition therapy benefit bills, Congressman Jose Serrano. Comments were also submitted by our professional society, the American Dietetic Association (ADA).

3. These comments showed that even without further reduction current reimbursement rates are inadequate, and urged that appropriate work RVUs be assigned to the Medical Nutrition Therapy codes in order to give effect to the intention of Congress to provide adequate payment for these services, so that access to these services would become generally available to the Medicare beneficiaries entitled thereto, namely, patients with diabetes or renal disease.

4. That the access to care envisioned by Congress does not exist is shown by the following three items. First, prior to passage of the medical nutrition therapy benefit the Congressional Budget Office estimated the annual cost of medical nutrition therapy services to be 60 million dollars, but only a few million dollars have been spent annually since the benefit became available in 2002. Second, this represents visits by only about 250,000 beneficiaries out of an estimated 8 million beneficiaries with diabetes or renal disease. Third, only about 10% of dietitians (7,000 out of 65,000 nationwide) have become Medicare providers, compared with over 90% of physicians. For a discussion of these three items, see Journal of the American Dietetic Association, June 2005, p. 990 and p. 995 (footnote references).

5. In our case, as our September 22, 2005 comment showed, Medicare pays less than half the fees paid by insurers in our area that have independently valued these codes. Medicare's fees are well below our break-even level. Therefore we cannot afford to treat Medicare patients and none of us has become a Medicare provider. We turn away a couple of Medicare patients every day and most of these patients are unable to obtain medical nutrition therapy services because virtually none of the dietitians in our area accept Medicare.

6. In the Calendar Year 2006 Physician Fee Schedule Final Rule no decision was made regarding medical nutrition therapy work RVUs; that decision was put off to this year: "Because we are maintaining the NPWP for 2006, we are deferring our decision regarding work RVUs for audiology, speech language pathology and medical nutrition pending further discussions with the specialties." (70 FR 70134, first column).

7. In the Calendar Year 2007 Proposed Rule CMS stated it would establish work RVUs and remove clinical labor time in the practice expense direct input database: "Because we propose to add the work RVUs to these services, the MNT clinical labor time in the direct input database would be removed with the adoption of this proposal." (71 FR 48987, third column).

8. The assignment of work RVUs coupled with the removal of clinical labor time from the practice expense direct input database would raise the fully implemented non-facility total RVU of the 15-minute new patient visit code CPT 97802 from **0.48** to **0.58**, leave the 15-minute established patient visit codes CPT 97803 and G0270 total RVU of **0.48** unchanged, and raise the 30-minute group codes CPT 97804 and G0271 total RVU from **0.19** to **0.32**. (70 FR 70457, 70462; 71 FR 49231, 49235).

9. Given the approximately 10% adjustment required to preserve budget neutrality (71 FR 37241, first-second columns), this means that the new patient visit code would pay about 5% more than currently, the established patient visit codes would pay about 5% less than currently, and the group codes would pay about 50% more than currently. Although the group fees would be adequate, neither our practice nor the practices or employment settings of other dietitians have many group visits compared to individual visits. Therefore if these RVUs are carried over to the Final Rule our practice and other dietitians will still be unable to afford to treat Medicare patients, allowing the lack of access to care to continue.

The Work RVUs Should Be the Same for the Individual Codes

10. The proposed work RVUs are those recommended on an interim basis by HCPAC in July 2000, transmitted to CMS by memo dated August 1, 2000, a copy of which is attached as Attachment B.

11. These recommendations were based on a RUC survey conducted in March 2000 (Attachment F) for seven proposed, but never adopted, Medical Nutrition Therapy codes, 3 initial visit codes, 3 follow-up visit codes and 1 group visit code, modeled after the office visit code series CPT 99201-99205, 99211-99215.

12. Unlike the time-based codes that were adopted, these 7 codes were based on level-of-complexity. Thus the survey data showed that follow-up visits would have lower RVUs because at the same level of complexity the follow-up visit will take less time than the initial visit.

13. But because a shorter visit will take less time, it will also have fewer 15-minute increments. Therefore there is no need to value the 15-minute follow-up visit increment less than the 15-minute initial visit increment. In fact doing so amounts to a double reduction of the fee, first for fewer 15-minute increments, and then a lower RVU for the each increment.

14. HCPAC stated at the bottom of the first page of the July 2000 Recommendations (Attachment B): "This recommendation maintains the relativity of CPT code 97803 and 97804 as presented by the survey data and original work relative value recommendations from the American Dietetic Association." Somehow HCPAC overlooked the fact that the survey data was based on the never adopted level-of-complexity codes, while the adopted codes were purely time-based codes.

15. Using the survey data, HCPAC valued the15-minute follow-up increment 73% less than the 15-minute initial visit increment, estimating that the typical CPT 97802 visit would take 75 minutes (pre, intra and post visit time), while the typical CPT 97803 visit would take 55 minutes (pre, intra and post visit time), or 73% less time ($55 \div 75 = 73\%$).

16. All of the CPT codes that are time-based, other than the Medical Nutrition Therapy codes, use the same code for their initial and follow-up visits, so their initial and follow-up time increments will pay the same. See, for example, the preventive medicine counseling codes CPT 99401-99412 and the psychiatric therapeutic psychotherapy codes CPT 90804-90829.

17. In fact, were it not for CMS's need to use CPT 97803 and G0270 to keep track of the number of follow-up visits and change-of-diagnosis follow-up visits, it would need only one code for all individual visits. But just because CMS needs to use two additional follow-up visit codes is no reason to value the 15-minute increments of those codes less than the 15-minute increment of the initial visit code.

18. CMS recognized that initial and follow-up time-based medical nutrition therapy codes should be valued the same when CMS valued the later-created group change-of-diagnosis 30-minute follow-up code G0271 the same as the CPT 30-minute group code CPT 97804. (70 FR 70457, 70462).

19. But more to the point, the question of whether the individual 15-minute codes would be valued the same or differently was an issue once before, in the preparation of the Calendar Year 2002 Physician Fee Schedule. The Calendar Year 2002 Proposed Rule had proposed a lesser value for the 15-minute follow-up increments. The issue was fully discussed in the Proposed Rule, in comments thereto, and in the Final Rule, which concluded that all of the time-based Medical Nutrition Therapy codes should have the same hourly rate: "A commenter representing dietitians asked us to review the relativity of payment across the three medical nutrition CPT codes. The commenter indicated that payment for CPT code 97803 was set at 72.9 percent of proposed RVUs for CPT 97802 and 97804 was set at 31 percent of CPT code 97802. The commenter argues that, because reassessments are shorter than initial assessments, the proposed RVUs are actually discounted twice (that is, less payment per 15 minutes of time as well as less total time). They believe the value of CPT codes 97802 and 97803 should be identical.... We have reviewed the payments for CPT codes 97802 and 97803 and agree with the commenter that these two codes should have the same values. The essential difference between an initial and follow up medical nutrition therapy service is the time spent performing the service. Initial visits will be longer than follow-up visits and will likely involve Medicare payment for more increments of service. We will pay less for follow up visits because they will typically involve fewer 15-minute increments of time than an initial visit. The payment rate we are establishing in this final rule for CPT code 97803 will be the same as the proposed rate for CPT code 97802. We have also changed the payment rate for CPT code 97804 assuming that the code will normally be billed for 4 to 6 patients with the average of 5. Using the revised values, the payment rate for group medical nutrition therapy would approximate the hourly rate paid for other medical nutrition therapy services." (68 FR 55280, first-second columns).

20. That reasoning was sound and remains sound and should continue to be followed, rather than create a **0.08** less work RVU for CPT code 97803 and G0270 (0.45 – 0.37 = 0.08). (71 FR 49231, 49235).

Use the Work RVU of the 15-Mintue Consultation Code

21. CMS may accept or reject HCPAC work RVU recommendations. (71 FR 37173, third column). In this instance we submit that CMS should reject the July 2000 HCPAC interim recommendations, which base the medical nutrition therapy work RVUs on the 15-minute and 30-minute physical therapy codes CPT 97110 and 97150, and instead base the work RVUs on the 15-mnute consultation code CPT 99241.

22. The July 2000 HCPAC interim recommendations regarding the new Medical Nutrition Therapy codes were unusual in that they were initially submitted for the Calendar Year 2001 Physician Fee Schedule before CMS had the statutory authority to

value these codes for Medicare payment (71 FR 48987, first-second columns), because the law that created the medical nutrition therapy benefit was not enacted until later, in December 2000, and created the benefit for these services starting in the Calendar Year 2002. See PL 106-544, Appendix F, the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), Section 105, Coverage of Medical Nutrition Therapy Services for Beneficiaries With Diabetes or a Renal Disease, and the published legislative history set forth in the Statement of the Manager For Section 105, both attached as Attachment E.

23. When HCPAC was making its interim work recommendations, HCPAC did not know what the statute would eventually contain. Therefore HCPAC looked solely to the text of the Medical Nutrition Therapy codes CPT 97802-4 which describe medical nutrition therapy services in bare-bones terms as "assessment [or re-assessment] and intervention, individual [or group], face-to-face with the patient, each 15 [or 30] minutes." On the other hand the statute defines medical nutrition therapy services much more comprehensively as "diagnostic, therapy and counseling services for the purpose of disease management", Section 105(b) of BIPA, 42 U.S.C. 1395x(vv)(1), and provides that payment of 85% to dietitians be determined "for the same services if furnished by a physician." Section 105(c)(2) of BIPA, 42 U.S.C. 1395l(a)(1)(T).

24. Since HCPAC was recommending work RVUs when it was not even cognizant of what the statutory definition would be, HCPAC was able to compare the15- and 30-minute individual and group medical nutrition therapy codes to "other modality or treatment codes" (middle of the first page of the July 2000 Recommendations, Attachment B), in this case the 15- and 30-minute individual and group physical therapy codes CPT 97110 and 97150.

25. These treatment codes are poor comparisons given the (now known) statutory definition of medical nutrition therapy in Section 105(b), 42 U.S.C. 1395x(vv)(1), which includes diagnosis and counseling as well as therapy.

26. In the 2002 Physician Fee Schedule Proposed and Final Rules CMS had compared medical nutrition therapy services to the 15-minute preventive medicine counseling code CPT 99401: "Commenters...believe that medical nutrition therapy payment should not be based on comparison to a preventive medicine code (CPT code 99401) in the zero-work pool methodology. The commenters indicated that preventive medicine services omit the problem-oriented components of the comprehensive history, as well as other essential assessment points, such as the patient's chief complaint and history of present illness." (66 FR 55279, third column-55280, first column).

27. In prior submissions to CMS Midtown had also proposed that the work RVUs for the Medical Nutrition Therapy codes could be based on the 15-minute preventive medicine counseling code CPT 99401. However Section 105(b), 42 U.S.C. 1395x(vv)(1), defines medical nutrition therapy services as services provided "for the purpose of disease management", that is, for patients with established illness. So a crosswalk to CPT 99401 would not be appropriate, because the CPT text prior to Sections 99401-99429 states (third paragraph of text): "These codes [preventive medicine counseling codes] are not to

be used to report counseling and risk factor reduction interventions provided to patients with symptoms or established illness. For counseling individual patients with symptoms or established illness, use the appropriate office, hospital or consultation or other evaluation and management codes [emphasis supplied]."

28. A more appropriate crosswalk, according to the text quoted above, would be to the work RVU of an office visit or consultation code.

29. Section 105(b), 42 U.S.C. 1395x(vv)(1), provides that a medical nutrition therapy visit be "pursuant to a referral by a physician", to whom a report is sent post-visit. Therefore the visit could be considered a consultation. If so, the work RVU could be that of the 15-minute consultation code CPT 99241, which has a work RVU of **0.64** as of the 2006 Physician Fee Schedule, and the same **0.64** is proposed for the 2007 Physician Fee Schedule. (71 FR 37218, second-third columns; 71 FR 49232).

30. The medical nutrition therapy visit could also be considered an office visit. If so, the work RVU could be that of the 15-minute established patient office visit code CPT 99213, which has a work RVU of **0.67** as of the 2006 Physician Fee Schedule (70 FR 70458) and a proposed work RVU of **0.92** for the 2007 Physician Fee Schedule. (71 FR 37218, second-third columns; 71 FR 49232).

31. CMS could use either the work RVU of CPT 99241 or the work RVU of CPT 99213 as the work RVU for the 15-minute individual Medical Nutrition Therapy codes CPT 97802, 97803 and G0270; and as the basis for the work RVU for the 30-minute group codes CPT 97804 and G0271 in the same manner as was done in the Calendar Year 2002 Physician Fee Schedule Final Rule; that is, by multiplying the CPT 97802 RVU by 2 then dividing by 5. (66 FR 55281, first column).

32. The Calendar Year 2002 Physician Fee Schedule Final Rule, however, had rejected a valuation crosswalk to E/M codes, making the following analysis for the first time in the Final Rule, though not in the Proposed Rule (so no comments may have been received questioning such analysis): "We do not believe that it is appropriate to compare medical nutrition therapy provided by a registered dietitian to an E/M service provided by a physician. Registered dietitians do not take medical histories, they are not trained and do not perform physical examinations, nor do they make medical decisions. Furthermore, when physicians use an E/M code, they typically have also performed a medical history, physical examination, and engaged in medical decision making as part of that service. If such an individual performed a service that met the requirements of an E/M service, then it would be appropriate for him or her to report an E/M service [emphasis supplied]." (66 FR 55278, third column).

33. This analysis misread the statute, which specifies that the amount paid be determined by comparing medical nutrition therapy services provided by a physician, not by comparing medical nutrition therapy services provided by a registered dietitian. Section 105(c)(2), 42 U.S.C. 1395l(a)(1)(T), states "the amount paid shall be...85 percent of the amount determined ... for the same services if furnished [i.e., provided] by a physician".

(See the third sentence of the Statement of the Manager For Section 105, Attachment E, "... if such services were provided by a physician [emphasis supplied].")

34. CMS has acknowledged that: "Physicians will occasionally meet the statutory qualifications to be considered a registered dietitian or nutrition professional who can bill Medicare for medical nutrition therapy services. (66 FR 55279, second column).

35. If a physician who is also a dietitian has a medical nutrition therapy visit "for the purpose of disease management" the physician will perform the 3 key components, taking a medical history, performing a physical examination and engaging in medical decision making, as part of the service. In fact, the text following CPT 97802-4 states: "For medical nutrition therapy assessment and/or intervention performed by a physician, see Evaluation and Management or Preventive Medicine service codes." (As noted above, since the Section 105(b), 42 U.S.C. 1395x(vv)(1), requires Medicare-covered visits to be for patients with established illness, only the office visit/consultation codes, not the preventive medicine codes, could be used for a Medicare-covered visit.)

36. To qualify for CPT 99241 or CPT 99213 these 3 components do not need to be at high levels. CPT 99241 is a level one E/M code that has the following, a problem focused history, a problem focused examination, and straightforward medical decision making; CPT 99213 is a level three E/M code that has the following, an expanded problem focused history, an expanded problem focused examination, and medical decision making of low complexity. (71 FR 37211, 37214).

37. Similarly, a registered dietitian who is not a physician will take a problem focused or expanded problem focused medical history, reviewing labs and other reports from the referring physician and interviewing the patient; will perform a limited medical examination, which will include anthropometric measurements, and could also include additional examination such as taking blood pressure or blood glucose, or examining affected body areas such as the skin for diabetic acanthosis nigricans, or for pressure ulcers that may be connected with protein-calorie malnutrition; and engage in straightforward or low complexity medical decision making, which will include prescribing or modifying nutrient and/or micronutrient intake, administration or supplementation, and could include additional medical decision making such as modifying insulin doses to match carbohydrate intake using carbohydrate counting/insulin ratios.

38. Because the levels of the history taking, physical examination and decision making in the visit (whether by a physician who is also a dietitian, or by a dietitian who is not a physician) are often low, the lower levels of medical history, physical examination and decision making contained in the 15-minute consultation code CPT 99241 make the work RVU of that code (current and proposed work RVU of **0.64**) more appropriate than the work RVU of CPT 99213, which has higher levels of history taking, physical examination and decision making (current work RVU of **0.67**, proposed work RVU of **0.92**). Therefore we recommend using the work RVU of CPT 99241.

39. It is also appropriate to use the work RVU of CPT 99241 because time may be the determining factor in assigning the level of the service. When time is the determining factor, the work RVU of CPT 99241 generates the lowest (and therefore most modest) work RVUs for visits lasting 15 minutes, 30 minutes or one hour.

40. The Evaluation and Management Service Guidelines state, under the heading "Levels of E/M Services": "The descriptors for the levels of E/M services recognize seven components, six of which are used in defining the levels of E/M services. These components are: History, Examination, Medical decision making, Counseling, Coordination of care, Nature of presenting problem, Time. The first three of these components (history, examination, and medical decision making) are considered the key components in selecting a level of E/M services."

41. However the Evaluation and Management Service Guidelines state later, under the heading "Select the Appropriate Level of E/M Services Based on the Following", "3. When counseling and/or coordination of care dominates (more than 50%) the physician/patient and/or family encounter (face-to-face time in the office or other outpatient setting or floor/unit time in the hospital or nursing facility), then time may be considered the key or controlling factor to qualify for a particular level of E/M services."

42. Although the definition of medical nutrition therapy services, Section 105(b), 42 U.S.C 1395x(vv)(1), includes three services, "diagnostic, therapy, and counseling services", counseling services will almost always dominate (more than 50%) the encounter. Therefore, time may be considered the key or controlling factor.

43. The following chart compares CPT 99241 to all other office visit/consultation codes that are 15 minutes or divisible by 15 minutes (all other codes are either less than 15 minutes or not divisible by 15 minutes). The chart shows that for both the current and proposed RVUs, the work RVU of CPT 99241 generates the lowest (most modest) work RVUs for visits lasting 15 minutes, 30 minutes or one hour. (70 FR 70458; 71 FR 37218, second-third columns; 71 FR 49232):

CPT Code	15-Minute RVU	30-Minute RVU	One-Hour RVU
99241	**0.64** Current	**1.28** (2 increments)	**2.56** (4 increments)
	0.64 Proposed	**1.28** (2 increments)	**2.56** (4 increments)
99213	**0.67** Current		
	0.92 Proposed		
99242		**1.29** Current	
		1.34 Proposed	
99203		**1.34** Current	
		1.34 Proposed	
99244			**2.58** Current
			3.02 Proposed
99205			**2.67** Current
			3.00 Proposed

The ADA Prefers Using an E/M Code RVU

44. All of the registered dietitians at Midtown are members of our professional society, the American Dietetic Association, and we have observed over the past 6 years that the ADA has consistently communicated its preference for work values based on E/M codes, in particular the level three, 15-minute and 30-minute, office visit codes CPT 99213 and 99203. As CMS observed, "the ADA compared work associated with their services to physician E/M services of CPT 99203 and 99213, which have respective work values of **1.34** and **0.67**." (71 FR 48987, second column).

45. Because CMS stated in the Calendar Year 2006 Final Rule that it was "deferring our decision regarding work RVUs for audiology, speech language pathology and medical nutrition pending further discussion with the specialties", ADA submitted a January 3, 2006 letter (Attachment C). In the letter ADA stated, at page 3, "there is external support for a far more transparent approach to MNT RVUs. AMA indicates in the CPT 2005 publication, 'for medical nutrition therapy assessments and/or intervention performed by a physician, see Evaluation and Management or Preventive Medicine service codes.' If CMS believes the MNT statute for payment must be followed, then the agency should base the RD payment rate on 85% of the total physician RVUs for these codes (eg. E&M code 99203)." Nowhere in that letter are the HCPAC interim recommendations even mentioned.

46. In its March 24, 2006 follow-up letter to CMS (Attachment D), ADA again states its preference for E/M work values (bottom of page 1-top of page 2): "The most straightforward way to correct this anomaly is to establish work values for codes 97802, 97803 and 97804. CMS could crosswalk the work RVU from either the Evaluation and Management codes, or Preventive Medicine codes; the codes physicians are directed to use when they provide MNT services.... Alternatively, CMS could use the HCPAC interim work RVUs for the MNT codes. These values could be used but only with caution since they were not valued as physician services and therefore reflect a discounted service [emphasis supplied]."

47. CMS stated in the Calendar Year 2007 Proposed Rule: "More recently, the ADA requested us to reconsider our decision not to accept the HCPAC recommended work RVUs [emphasis supplied]." (71 FR 48987, second column). A more accurate statement would be: "More recently, the ADA requested us to reconsider our decision not to accept work RVUs."

48. When ADA wrote its March 24, 2006 letter it was not clear whether CMS would establish work values, so in an effort to make CMS comfortable with the concept ADA demonstrated to CMS that there were several sources upon which to base work values. ADA listed four such sources in the following order, first ADA's preference, an E/M code, then a preventive medicine code, then the 2000 RUC survey data, then the HCPAC interim recommended RVUs, if CMS "would adjust the HCPAC work professional services upward to recapture the value of the remaining 15%".

49. The HCPAC recommended work RVUs not increased by 15% were not even one of the alternatives! And the difference in compensation by not increasing by 15% (i.e. dividing by 0.85) is significant because the HCPAC recommended base RVU of **0.45** ÷ 0.85 = **0.53**, or **0.08** RVUs higher.

50. But even if increased by 15%, we submit that physical therapy code-based RVUs are not statutorily appropriate because the statute says that payment to dietitians should be 85% of the amount determined for the same services if provided by a physician.

CMS Not HCPAC Should Determine the Value of the Work RVUs

51. ADA has clearly expressed its preference for a comparison to E/M codes. However, even if ADA had no preference, we submit that CMS has the duty to make a reasoned analysis of whether E/M codes rather than physical therapy codes best describe what a physician who is also a dietitian would report for the service: "we retain the responsibility for analyzing any comments and recommendations received, developing the proposed rule, evaluating the comments on the proposed rule, and deciding whether and how to revise the work RVUs for any given service." (71 FR 37172, first–second columns).

52. If after a reasoned analysis CMS determines that medical nutrition therapy services are closer to physical therapy services than to office visit/consultation services, then so be it. But Midtown respectfully submits that CMS owes the public, the beneficiaries entitled to medical nutrition therapy services, and the registered dietitians and nutrition professionals who may provide such services, a thorough, reasoned analysis of the issue.

53. If CMS allows the HCPAC physical therapy code-based work RVU recommendations to become part of the Final Rule, the ADA will be forced to take the issue back to HCPAC. However, we strongly urge CMS to avoid this situation.

54. First, this will delay by at least one year the establishment of adequate work RVUs. And there is no guarantee that HCPAC will act in time for the 2008 Physician Fee Schedule. HCPAC may take 2 or even 3 years to act, prolonging the lack of access to care for 8,000,000 beneficiaries with diabetes or renal disease.

55. Second, now that these services are recognized as physician services there may be a jurisdictional question as to whether the regular RUC or RUC/HCPAC should decide the issue.

56. Third, CMS is fully competent to make its own determination.

57. Congressman Jose Serrano, the original sponsor of the medical nutrition therapy benefit bills, has reviewed this Comment and joins with our request that "you [CMS] perform a prompt, thorough, reasoned analysis of the appropriateness of the work value to be assigned, so that better access to care may be made available as soon as possible." (Attachment A).

Conclusion

58. The current and proposed malpractice RVU for all 5 Medical Nutrition Therapy codes is **0.01**. When added to the current practice expense RVUs, this makes the total current RVUs **0.48** and **0.19** for the individual codes and groups codes, respectively. (70 FR 70458, 70462; 71 FR 49231, 49235).

59. Midtown submits that the assignment of appropriate work RVUs to these codes should be based on the 15-minute consultation code CPT 99241, using its current and proposed RVU of **0.64** for the individual codes and 40% of that amount (multiply by 2 then divide by 5), or **0.25**, for the group codes. (66 FR 55281, first column).

60. If the proposed practice expenses of **0.12**, **0.10**, and **0.04**, for the individual initial visit, the individual follow-up visits, and the group visits (71 FR 49231, 49235), are added to work RVUs based on CPT 99241 (**0.64** and **0.25**), this would create (including the malpractice RVUs), total RVUs of **0.77**, **0.75** and **0.30**.

61. This would increase provider reimbursement rates for medical nutrition therapy services by about 50%, or perhaps a little less due to adjustments to preserve budget neutrality. (71 FR 37241, first-second columns).

62. With a 50% increase Medicare reimbursement would still be about 25% less than existing market rates but should be sufficient to allow us, and, we believe, the majority of other registered dietitians, to afford to become Medicare providers, and this should provide access to care for the Medicare beneficiaries entitled to these services.

Sincerely yours,

Robert Howard, RD, JD
Managing Partner

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Congress of the United States
House of Representatives
Washington, DC 20515-3216

September 11, 2006

COMMITTEE:
APPROPRIATIONS

SUBCOMMITTEES:
SCIENCE, STATE, JUSTICE, AND COMMERCE
HOMELAND SECURITY

MEMBER, CONGRESSIONAL
HISPANIC CAUCUS

VICE CHAIR
DEMOCRATIC STEERING
COMMITTEE

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

Dear Dr. McClellan:

I was the sponsor of the original medical nutrition therapy benefit bills in the mid-90's and cosponsor of the 1999 bill that eventually became the law, as Section 105 of PL 106-544, entitled "Coverage of Medical Nutrition Therapy Services for Beneficiaries with Diabetes or Renal Disease."

As you review the rule pertaining to medical nutrition therapy benefits, please be aware of Congress' intent that payment be sufficient to provide access to care for the beneficiaries of the service. Establishing an appropriate work value for nutrition therapy based upon "the same services if furnished by a physician" would promote access to these services and thus comply with the intent of the law. Therefore I ask that you perform a prompt, thorough, reasoned analysis of the appropriateness of the work values to be assigned so that better access to care may be made available as soon as possible.

I have reviewed the comments of Midtown Nutrition Care and would ask that they be given every consideration as the rule in question is reviewed.

Sincerely,

Jose E. Serrano

Jose E. Serrano
Member of Congress

Attachment A page 1 of 1

Memo to: Paul Rudolf, MD, JD

From: Don E Williamson, OD, Co-Chair, HCPAC

Date: August 1,2000

Subject: HCPAC Review Board Recommendations for Medicare Fee Schedule 2001

It is with pleasure that I submit to the Health Care Financing Administration (HCFA), on behalf of the RUC Health Care Professional Advisory Committee (HCPAC) Review Board, work relative value and direct practice expense inputs for new and revised codes for CPT 2001. This year, the HCPAC will be submitting two sets of recommendations, the first represent recommendations for Sensory Integrative Technique Procedures and the second, Medical Nutrition Therapy. At this time, we are forwarding interim recommendations for the Medical Nutrition Therapy procedures as the American Dietetic Association may choose to bring additional data forward to the HCPAC.

We appreciate the Health Care Financing Administration (HCFA)'s representatives' participation in the HCPAC process.

Should you have any questions regarding the material contained herein, please contact Sherry Smith at (312) 464-4308 or Dawn K. Gonzalez at (312) 464-4308.

cc: Rick Ensor
Carolyn Mullen
Terry Kay

Attachment B page 2 of 4

RUC HEALTH CARE PROFESSIONALS ADVISORY COMMITTEE REVIEW BOARD SUMMARY OF RECOMMENDATIONS

July 2000

Medical Nutrition Therapy

CPT Code 97802

Work Relative Value Recommendation

New code 97802 *Medical nutrition therapy; initial assessment and intervention, individual, face-to-face- with the patient, each 15 minutes* was created to describe both the assessment as well as intervention which regularly includes behavior components requiring advanced skills and knowledge by a registered dietician. In addition, these patients are usually very sick and complex due to the shift of patients receiving treatment from the inpatient to the outpatient setting. This new code,combines Medical Nutrition Therapy assessment/evaluation and intervention/treatment, and both of these services are included in the Medical Nutrition Therapy provided to the patient during the first visit. The 15 minute time value is similar to many other modality or treatment codes. For example, the pre- intra- and post-service times of 97802 (3 minutes,15 minutes,5 minutes) are comparable to CPT code 97110 *Therapeutic procedure, one or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility* (5 minutes,20 minutes,5 minutes) work RVW of .45. Another comparable CPT code is 97001 *Physical therapy evaluation* (pre-5 minute, intra- 30 minutes, and post-service –15 minutes)(work RVW-1.20) which is not a timed procedure but usually represents 30-45 minutes of work. This new MNT code usually is reported in four increments (50 minutes spent fact-to-face with patient or a total time (pre, intra and post) of 75 minutes) for the medical nutrition therapy assessment/evaluation and patient intervention and self-management training. **Based on these reference procedures, the Review Board agreed to an interim work relative value of .45 for CPT Code 97802.** The American Dietetic Association may gather additional data and develop further proposals with the CPT Editorial Panel.

Practice Expense Recommendation

The HCPAC agrees to the attached list of practice expenses for CPT Code 97802.

CPT Code 97803

Work Relative Value Recommendation

The HCPAC Review Board agreed that the new code 97803 *reassessment and intervention, individual, face-to-face- with the patient, per 15* should be valued at .37 work relative value units. This recommendation maintains the relativity of CPT code 97803 and 97804 as presented by the survey data and original work relative value recommendations from the American Dietetic Association. This new code usually is reported in two to three increments (30 minutes face-to-face time with the patient or a total time (pre, intra and post) of 55 minutes) for the patient reassessment

and intervention. **Therefore, the Review Board recommends an interim work relative value of .37 for CPT 97803**. The American Dietetic Association may gather additional data and develop future proposals with the CPT Editorial Panel.

Practice Expense Recommendation
The HCPAC agreed that the attached list of practice expenses represent the resources necessary to perform the procedure in a non-facility setting.

CPT Code 97804

Work Relative Value Recommendation
The new code 97804 *Medical Nutrition therapy group (2 or more individuals), per 30 minutes* was compared to CPT Code *97150 Therapeutic procedures(s), group (2 or more individuals)* work RVW =.27. This new code usually is reported in two increments (60 minutes face-to-face time or a total (pre, intra, and post-time of 90 minutes for a group or a hour for a group setting of 4-6 while CPT Code 97150 is usually reported in three increments (45 minutes) for a group setting of 5 individuals. **Based on this comparison, the HCPAC Review Board agreed that this new code 97804 should be valued at an interim work RVW of .25.** The American Dietetic Association may gather additional data and develop further proposals with the CPT Editorial Panel.

Practice Expense Recommendation
The HCPAC agreed that the attached list of in office direct inputs represent the practice cost to perform this procedure.

CPT Code (●New) (▲Revised) (D Deleted) (E Editorial)	CPT Descriptor	Global Period	Work RVU Recommendation
●97802	Medical nutrition therapy; initial assessment and intervention, individual, face-to-face- with the patient, each 15 minutes	XXX	0.45 (Interim)
●97803	reassessment and intervention, individual, face-to-face- with the patient, per 15 minutes	XXX	0.37 (Interim)
●97804	group (2 or more individuals(s)), each 30 minutes (For medical nutrition therapy assessment and/or intervention performed by a physician, see **Evaluation and Management** or **Preventive Medicine** service codes)	XXX	0.25 (Interim)

*The HCPAC Review Board agreed that these three Medical Nutrition Therapy Codes should be valued at interim work RVWs while the American Dietetic Association gathers additional data and considers code restructure for discussion at the HCPAC and/or the CPT Editorial Panel's upcoming meeting(s).

Attachment B - page 4 of 4

American Dietetic Association
Your link to nutrition and health.[sm]

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800/877-1600
www.eatright.org

Policy Initiatives and Advocacy
1120 Connecticut Avenue, Suite 480
Washington, DC 20036-3989
202/775-8277 FAX 202/775-8284

January 3, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-FC
7500 Security Lane
Baltimore, MD 21244-8017

RE: 42 CFR Parts 405, 410, 411, 413, 414, 424, 426 [CMS-1502-FC].
Medicare Program: Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2006.

Dear Dr. McClellan:

The American Dietetic Association (ADA) appreciates this opportunity to re-affirm our comments on the Notice of Final Rule for the CY 2006 Physician Payment Schedule published November 21, 2005 (70 FR 70116) . We urge you to consider this information as you refine the Final Rule for CY 2006 and initiate procedures to revise methodology for relative values for the following year's rule.

The ADA represents nearly 65,000 food and nutrition professionals working to improve the nutritional status of Americans. As primary prevention, strong evidence indicates that nutrition helps promote health and functionality and affects each individual's quality of life. As secondary and tertiary prevention, medical nutrition therapy (MNT) is a cost-effective disease management strategy that lessens chronic disease risk, and which slows disease progression and reduces symptoms. Medicare Part B covers MNT provided by registered dietitians (RDs) for diabetes and chronic renal disease.

Telehealth for Individual MNT

ADA supports the final rule decisions to add individual MNT to the Medicare list of services that can be provided via telehealth, and recognize registered dietitians (RDs) and nutrition professionals as qualified healthcare professionals who can submit claims for individual MNT provided via telehealth. ADA welcomes the opportunity to assist CMS in educating Medicare RD providers on telehealth services and to inform and encourage physician practitioners and beneficiaries of this new service delivery option.

PE Methodology and Elimination of the Non-Physician Work Pool
ADA agrees with CMS' decision to withdraw the entire PE methodology proposal and to refine the process for the CY 2007 proposed rule.

We ask to participate in the process as a full partner when CMS considers how to revise the methodology to calculate CPT code relative values. When CMS convenes a meeting with interested medical societies to discuss the direct and indirect PE methodology and elimination of the non-physician work pool, as well as meet individually with groups to discuss their particular concerns, ADA representatives need to cover our unique experience and knowledge along with the other interested medical societies. We also request to meet separately with CMS to discuss the medical nutrition therapy CPT code RVUs, including the direct and indirect PE inputs for the codes.

The current methodology and the proposed bottom-up methodology for MNT services fail to appropriately recognize RD work. With the proposed CY 2006 RVUs for MNT CPT codes, the agency once again has overlooked the intent of Congress regarding the implementation (and payment) for medical nutrition therapy services. In particular:

- *MNT code PE inputs are not valid.*
  RD work should be fully recognized and accounted for in the code RVUs.
  The current direct inputs do not accurately reflect the RD's full clinical labor and professional service that is required to provide MNT. The inputs fail to represent the RD's pre-, intra-, and post-work times to provide this service as the current values significantly underestimate, or omit certain pre- and post-service activities.

  ADA recommends PE time be allocated consistently within the three MNT codes for pre-services, such as reviewing medical records and laboratory data, equipment set-up, and other clinical activities (greeting the patient, treatment room set-up); and for post-services such as dismantling and storing equipment and educational materials such as food models; documentation and conducting follow-up communications with the referring physicians, patients and family members as appropriate and necessary. CMS has not accurately represented these activities in the direct input data used to calculate the MNT RVUs.

  PE data that ADA discussed with the AMA PEAC in February 2005 indicates that the following minutes of clinical labor are accurate:

  - 39 minutes total clinical labor time, including RD professional work for 97802 and 97803 per unit code;
  - 28 minutes total clinical labor time, including RD professional work for 97804 per unit code.

  These work data are significantly different from the arbitrary direct input values that CMS has used in the proposed PE calculation of RVU for the MNT codes -- 25 minutes 97802; 22 minutes for 97803, and 9 minutes for 97804. (See accompanying table).

- *The RVUs for initial MNT (97802) and follow-up MNT (97803) should be the same.*
  Since the MNT codes are time-based, the complexity and amount of time spent completing the pre-, intra-, and post-service times will be reflected in the number of

units used for each code. Therefore, the four-minute difference that the agency currently used in the direct PE values for determining the total RVUs is not appropriate. Both initial and follow-up MNT for individual encounters should have the same direct PE RVUs.

- *CMS should pay RDs and qualified nutrition professionals 100% of the MNT code RVUs or pay 85 percent of designated physician codes.*
  While current policy is inconsistent with the authorizing statute, it also lacks intellectual integrity. In the agency's determination that there is no physician work for MNT services, and its policy to take 85 percent of the physician fee schedule values for the MNT CPT codes, the agency has created an unfair payment anomaly towards registered dietitians and nutrition professionals who provide and bill for the services using the MNT CPT codes. If the agency continues to support the premise that there is no physician work for the MNT codes, this 'double discount' can be corrected by paying RDs 100% of the physician fee schedule.

  Alternatively, there is external support for a far more transparent approach to MNT RVUs. AMA indicates in the CPT 2005 publication, "for medical nutrition therapy assessments and/or intervention performed by a physician, see Evaluation and Management or Preventive Medicine service codes." If CMS believes the MNT statute for payment must be followed, then the agency should base the RD payment rate on 85% of the total physician RVUs for these codes (eg. E&M code 99203). CMS has established a precedent of paying a percentage of the physician fee schedule for codes used by other non-physician practitioners. For example, social workers, certified nurse midwives, physician assistants, and certified nurse specialists are paid a percentage of the physician's fee schedule when providing services that otherwise would have been performed by the physician. The payment amount is based on the physician code to provide the service, not other non-physician practitioner codes for the service.

- *CMS should establish work RVUs for MNT codes provided by RDs.*
  ADA asks the agency to work with our professional association to determine appropriate values and methodology that accurately reflects the professional work of RDs for MNT services.

  If a work RVU cannot be established, ADA asks CMS to consider establishing a new PE category that specifically references the professional's work effort. This would be a separate calculation to the current PE that accounts for clinical labor to support the RD in providing MNT services.

Physician Liability Insurance (PLI) Calculation for RDs

ADA agrees with CMS and the PLI workgroup's decision that nonphysician professionals, such as RDs, incur PLI costs similar to the lowest cost physician specialty; the lowest current risk factor of 1.0. While ADA realizes that CMS was unable to identify all Medicare providers in the proposed and final rule, we note that reference to liability insurance for registered dietitians continues to be omitted in the agencies' comments.

Recognition of RD Medicare Providers by CMS

In closing, in future Federal Register notices and general communications that relate to Medicare Part B providers, ADA urges the agency to include registered dietitians in the printed list of Medicare Part B providers. RDs were omitted in all tables included in CMS-1502-P and CMS-1502-FC, in the list of providers eligible to "opt-out" of Medicare, and other references to

Medicare Part B providers in the proposed rules for the CY 2006 physician fee schedule (70 FR 45764).

ADA looks forward to partnering with CMS in the development of the RVUs for CY 2007 final rule and education on new changes for the 2006 calendar year. Please do not hesitate to call Mary Hager, PhD, RD, Senior Manager, Regulatory Affairs, (202) 775-8277, ext. 1007 or Pam Michael, Director of Nutrition Services Coverage Team, 312-899-4747, with any questions or requests for additional information.

Best regards,

Pam Michael, MBA, RD
Director of Quality, Outcomes and Coverage

Mary H. Hager, PhD, RD
Senior Manager, Regulatory Affairs

American Dietetic Association
www.eatright.org | *Your link to nutrition and health℠*

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March 24, 2006

Terry Kay
Deputy Director, Hospital and Ambulatory Policy Group
Centers for Medicare & Medicaid Services
7500 Security Boulevard, C4-01-15
Baltimore, Maryland 21244

As a follow up to the CMS February 15th Practice Expense Town Hall meeting, the American Dietetic Association (ADA) submits the following comments to questions addressed by the agency.

In multiple written and verbal communications ADA has asserted that CMS incorrectly valued the medical nutrition therapy (MNT) codes and ignored Congress' intent in establishing fair and equitable policies for the covered MNT services provided by registered dietitians (RDs). As a result of the agencies' current non-physician work pool methodology and the discount applied to the MNT codes, the services are not only undervalued but will be unfairly penalized with even larger reductions using any of the new bottom-up methodologies that have been suggested.

While ADA agrees strongly with CMS' intent to eliminate the non-physician work pool, any bottom up methodology which significantly and unjustly reduces the MNT code RVUs will result in severe provider shortages from RD Medicare providers who will have no choice but to leave Medicare.

The adoption of a new practice expense methodology is an opportunity for CMS to acknowledge and correct the payment inequities previously applied to the MNT codes. We believe a solution should be applied that will allow any methodology selected by CMS to fairly value MNT codes. The obvious solution is one that recognizes the need to use professional work to allocate practice expense.

Recognition of Work
CMS has acknowledged the problems with policies used in valuing the MNT codes. The fair way to correct previous inequities is adopt professional work values for MNT services.

ADA believes the agency has undervalued the MNT CPT codes by refusing to recognize and properly account for the professional work of registered dietitians who perform MNT services. This work is currently imbedded in the PE RVU and as such is valued based solely on time rather than Relative Value which considers time, intensity, training and other factors.

The most straightforward way to correct this anomaly is to establish work values for codes 97802, 97803 and 97804. CMS could crosswalk the work RVU from either the Evaluation and Management codes, or Preventive Services codes; the codes physicians are directed to use when

they provide MNT services. ADA also submitted survey data that identified work RVUs for the three MNT codes (see Appendix 1).

Alternatively, CMS could use the HCPAC interim work RVUs for the MNT codes. These values could be used but only with caution since they were not valued as physician services and therefore reflect a discounted service. When the HCPAC valued the codes, they acknowledged the work as the professional services of the RD. If CMS uses these work values, the agency should increase the values since currently they represent 85% of physician work as RD professional services, not physician work. The agency should adjust the HCPAC work recommendation upward to recapture the value of the remaining 15%, so as to reflect the equivalent level of physician work. Then for actual payment to the RD, this work value could be adjusted to 85% of the physician rate by Medicare payment contractors processing the claims.

ADA realizes that creation of a work RVU for the MNT codes will impact the PE RVUs. While the professional service component from the current PE RVU will be removed, the revised PE direct costs must still include labor time for support services, supplies and equipment. ADA previously submitted PE data to the AMA PEAC at their April 2005 meeting to gather preliminary feedback on revised PE data for the MNT codes. ADA will provide this revised data to you to assist in the re-alignment of the MNT work and PE values.

Proxy Work for direct and indirect PE allocation is an alternative methodology option
While ADA believes establishing a work RVU is the most sound and fair solution for determining RVUs for the MNT codes, if CMS denies this change, an alternative is to establish a proxy work value to determine the direct and indirect PE RVUs for the MNT codes.

In this case, CMS can use the professional work RVUs as described above. Alternatively, CMS could use the time component of professional service multiplied by an appropriate intra-service work per unit of time (IWPUT) value. This methodology would be relevant for codes previously included in the NPWP where the service includes a defined professional component, such as MNT and audiology services. The professional time and IWPUT methodology would not apply to NPWP codes where a procedure has work values associated for interpretation but has zero work by virtue of being a technical component only.

Direct cost utilization rate, particularly for high cost equipment
ADA recommends the agency consider different utilization rates for high end equipment beyond the current 50%; perhaps considering methodology that allows quartile use of equipment, eg. 25%, 50%, 75%, 100% utilization rates. Additionally, ADA requests the agency reconsider the generic 50% utilization rate that is applied to equipment used for MNT services. In some cases, the equipment/supplies are used by RDs throughout the whole patient encounter.

Transition of new methodology
Because the new methodology will negatively impact many codes, ADA recommends CMS transition the changes over several years. Additionally, because the MNT codes may be significantly impacted, such that providers may exit Medicare and leave beneficiaries in a critical state unable to access MNT services, we recommend that CMS implement limits to the potential practice expense payment changes.

Supplemental Surveys
ADA would like to conduct a survey to gather PE data specific to MNT services provided by RDs since there are no data pools available to CMS at this time. Yet the agency has indicated it does not plan to accept any new supplemental survey data.

ADA strongly believes a new survey process is necessary in order to verify data used in CMS calculations, to replace older SMS survey data, and make data available where it is currently missing. By allowing all groups -- physician and non-physician societies -- to gather PE data in a systematic, consistent approach, CMS can create a data base that more accurately represents current PE for the various healthcare groups. This new survey data would also replace the faulty non-physician work pool or CMS' current crosswalks to inappropriate codes. ADA supports this initiative and would participate in future discussions with AMA and CMS on future SMS type surveys.

Conclusions
While ADA recognizes that many medical societies have suggested that the AMA RUC discuss methodology and specific allocation methods at the April 26-30, 2006 RUC meeting, it is imperative that any discussions include alternatives for the NPWP.

To avoid the disastrous impact of the proposed PE methodology to the 2007 physician fee schedule, CMS should recognize professional work for the MNT codes. This is a fair and equitable solution that will offset previous payment inconsistencies for the MNT codes.

ADA requests additional face-to-face meetings with the agency to further discuss our recommended methodologies that will impact future fee schedules. We will contact you to arrange a meeting at your offices.

Regards,

Pam Michael, MBA, RD
Director of Nutrition Services Coverage
312-899-4747

Mary H. Hager, PhD, RD
Senior Manager, Regulatory Affairs
202-775-8277

Statement of the Manager For Section 105

Section 105. Coverage of Medical Nutrition Therapy Services for Beneficiaries With Diabetes or a Renal Disease

The provision would establish, effective January 1, 2002, Medicare coverage for medical nutrition therapy services for beneficiaries who have diabetes or a renal disease. Medical nutrition therapy services would be defined as nutritional diagnostic, therapy and counseling services for the purpose of disease management which are furnished by a registered dietician or nutrition professional, pursuant to a referral by a physician. The provision would specify that the amount paid for medical nutrition therapy services would equal the lesser of the actual charge for the service or 85% of the amount that would be paid under the physician fee schedule if such services were provided by a physician. Assignment would be required for all claims. The Secretary would be required to submit a report to Congress that contains an evaluation of the effectiveness of services furnished under this provision.

****

§105. COVERAGE OF MEDICAL NUTRITION THERAPY SERVICES FOR BENEFICIARIES WITH DIABETES OR A RENAL DISEASE.

(a) Coverage.--Section 1861(s)(2) (42 U.S.C. 1395x(s)(2)), as amended by section 102(a), is amended--

(1) in subparagraph (T), by striking "and" at the end;

(2) in subparagraph (U), by inserting "and" at the end; and

(3) by adding at the end the following new subparagraph:

"(V) medical nutrition therapy services (as defined in subsection (vv)(1)) in the case of a beneficiary with diabetes or a renal disease who--

"(i) has not received diabetes outpatient self-management training services within a time period determined by the Secretary;

"(ii) is not receiving maintenance dialysis for which payment is made under section 1881; and

"(iii) meets such other criteria determined by the Secretary after consideration of protocols established by dietitian or nutrition professional organizations;".

(b) Services Described.--Section 1861 (42 U.S.C. 1395x), as amended by section 102(b), is amended by adding at the end the following:

"Medical Nutrition Therapy Services; Registered Dietitian or Nutrition Professional

"(vv)(1) The term 'medical nutrition therapy services' means nutritional diagnostic, therapy, and counseling services for the purpose of disease management which are furnished by a registered dietitian or nutrition professional (as defined in paragraph (2)) pursuant to a referral by a physician (as defined in subsection (r)(1)).

Attachment E page 1 of 2

"(2) Subject to paragraph (3), the term 'registered dietitian or nutrition professional' means an individual who–

"(A) holds a baccalaureate or higher degree granted by a regionally accredited college or university in the United States (or an equivalent foreign degree) with completion of the academic requirements of a program in nutrition or dietetics, as accredited by an appropriate national accreditation organization recognized by the Secretary for this purpose;

"(B) has completed at least 900 hours of supervised dietetics practice under the supervision of a registered dietitian or nutrition professional; and

"(C)(i) is licensed or certified as a dietitian or nutrition professional by the State in which the services are performed; or

"(ii) in the case of an individual in a State that does not provide for such licensure or certification, meets such other criteria as the Secretary establishes.

"(3) Subparagraphs (A) and (B) of paragraph (2) shall not apply in the case of an individual who, as of the date of the enactment of this subsection, is licensed or certified as a dietitian or nutrition professional by the State in which medical nutrition therapy services are performed.".

(c) Payment.--Section 1833(a)(1) (42 U.S.C. 1395l(a)(1)) is amended--

(1) by striking "and" before "(S)"; and

(2) by inserting before the semicolon at the end the following: ", and (T) with respect to medical nutrition therapy services (as defined in section 1861(vv)), the amount paid shall be 80 percent of the lesser of the actual charge for the services or 85 percent of the amount determined under the fee schedule established under section 1848(b) for the same services if furnished by a physician".

(d) Application of Limits on Billing.--Section 1842(b)(18)(C) (42 U.S.C. 1395u(b)(18)(C)) is amended by adding at the end the following new clause:

"(vi) A registered dietitian or nutrition professional.".

(e) Effective Date.--The amendments made by this section shall apply to services furnished on or after January 1, 2002.

(f) Study.--Not later than July 1, 2003, the Secretary of Health and Human Services shall submit to Congress a report that contains recommendations with respect to the expansion to other medicare beneficiary populations of the medical nutrition therapy services benefit (furnished under the amendments made by this section).

Attachment E page 2 of 2

March 14, 2000

The American Medical Association/Specialty Society RVS Update Committee

PHYSICIAN/PROVIDER WORK RVS Update Survey

Tracking Numbers; New CPT Codes; and Descriptors

K1	978X1	Medical nutrition therapy initial assessment and intervention, low complexity
K2	978X2	Medical nutrition therapy initial assessment and intervention, moderate complexity
K3	978X3	Medical nutrition therapy initial assessment and intervention, high complexity
K4	978X4	Medical nutrition therapy reassessment and intervention, low complexity
K5	978X5	Medical nutrition therapy reassessment and intervention, moderate complexity
K6	978X6	Medical nutrition therapy reassessment and intervention, high complexity
K7	978X7	Medical nutrition therapy reassessment and intervention, low Complexity, group setting

Global Period: XXX for all seven codes

INTRODUCTION

Why should I complete this survey?

The AMA/Specialty Society RVS Update Committee (RUC) and The American Dietetic Association, the American Association of Clinical Endocrinologists, American Gastroenterological Association, and the Society of American Gastrointestinal Endoscopy needs your help to assure relative values will be accurately and fairly presented to HCFA during this revision process. This is important to you and other physician/providers because these values determine the rate at which Medicare and other payers reimburse for procedures.

What if I have a question?

Contact: Pam Michael, MBA, RD, LD; The American Dietetic Association, Director Health Care Financing Team; 800-877-1600, ext. 4844 or email: pmichae@eatright.org

How is this survey organized?

Each new code must be surveyed, there are 7 medical nutrition therapy (MNT) codes that are included in this one survey document. There are 7 questions in the survey relating to physician/provider work.

START HERE

The following information must be provided by the Physician/Provider responsible for completing the questionnaire.

Physician/Provider Name: [illegible]
Business Name: [illegible]
Business Address: [illegible]
City: [illegible]
State: NY
Zip: 10019
Business Phone: (212) 333 4243
Business Fax: (212) 333 3768
E-mail Address:
Physician/Provider Specialty: [illegible]
Years Practicing Specialty: 6

Primary Geographic Practice Setting: Rural___ Suburban___ Urban ✓

Primary Type of Practice:
Solo Practice___
Single Specialty Group ✓
Multispecialty Group___
Medical School Faculty Practice Plan___

Attachment F - page 2 of 24

PHYSICIAN/PROVIDER WORK

INTRODUCTION

"Physician/Provider work" includes the following elements:

- Physician/Provider time it takes to perform the service
- Physician/Provider mental effort and judgment
- Physician/Provider technical skill and physical effort, and
- Physician/Provider psychological stress that occurs when an adverse outcome has serious consequences

All of these elements will be explained in greater detail as you complete this survey.

"Physician/Provider work" does **not** include the services provided by support staff who are employed by your practice and cannot bill separately, including registered nurses, licensed practical nurses, medical secretaries, receptionists, and technicians; these services are included in the practice cost relative values, a different component of the RBRVS.

Medical Nutrition Therapy (MNT) Vignettes

The AMA RUC has indicated the following definitions apply to medical nutrition therapy initial assessment and reassessment codes (978X1-978X7)

K1 978X1 Medical nutrition therapy initial assessment and intervention, low complexity

Definition
Therapy with patient with one diagnosis, limited data to be reviewed, and low risk of nutrition-related complications.

Description of Procedure(s)/Service(s):
Review of the patient's medical record for medical diagnosis. Nutrition history from the patient, evaluation of use of nutrition supplements, identification of nutrition problems. Obtaining of physical measurements, calculations related to body size. Nutrition assessment to evaluate patient's current nutrition needs, appropriateness of weight in relation to desirable body weight and goal weight, adequacy of present diet, potential drug-nutrient interactions, exercise patterns; psychosocial food patterns; and patient's knowledge and willingness to implement nutrition interventions. Formulation of a nutrition prescription specific to patient's diagnosis, translation of nutrition prescription into an individualized meal plan and menu guidelines. Self-management training, review of techniques for self-monitoring, identification of self-management goals, and scheduling of a follow-up appointment. Documentation of nutrition assessment, nutrition prescription, and instructions provided in the patient's medical record.

A 42-year-old male has been diagnosed with hypertension. Initial medical nutrition therapy assessment and intervention is being initiated prior to a decision on whether to prescribe medication.

K2 978X2 Medical nutrition therapy initial assessment and intervention, moderate complexity

Definition
Therapy with patient with one or more medical diagnoses and comorbidities, with moderately complex data to be reviewed, and a high risk of nutrition-related complications.

Description of Procedure(s)/Service(s):
Thorough review of the patient's medical record for medical diagnosis, past medical history, history of present illness, and pertinent lab data. Nutrition history from the patient, thorough evaluation of nutrient intake and use of nutrition supplements, identification of nutrition problems. Obtaining of physical measurements, calculations related to body size. Intensive nutrition assessment to evaluate nutrient requirements, appropriateness of weight in relation to desirable body weight and goal weight, adequacy of present diet, potential drug-nutrient interactions, exercise patterns, psychosocial food patterns, and patient's knowledge of and willingness to implement nutrition interventions. Review of clinical data and lab information and evaluation of patient's ability to perform self-monitoring. Formulation of a complex nutrition prescription specific to patient's diagnosis, translation of nutrition prescription into an individualized meal plan and menu guidelines. Self-management training, review of techniques for self-monitoring, identification of self-management goals, identification of barriers to adherence and strategies to overcome barriers, and scheduling of follow-up appointment(s). Documentation of nutrition assessment, nutrition prescription, and self-management training provided in the patient's medical record, with notation of communication with other health care providers and any referrals made.

A 66-year-old female with pre-existing osteoporosis has been diagnosed with type 2 diabetes and hyperlipidemia. Initial medical nutrition therapy assessment and intervention is being initiated, in addition to oral medication for treatment of diabetes.

K3 978X3 Medical nutrition therapy initial assessment and intervention, high complexity

Definition
Therapy with patient with one or more medical diagnoses and comorbidities of a highly complex nature, with highly complex data to be reviewed, and a high risk of nutrition-related complications.

Description of Procedure(s)/Service(s):
Comprehensive review of the patient's medical record for diagnosis, past medical history, history of present illness, review of systems, medications, and lab data. Collaboration with physician and other health care providers. Comprehensive nutrition history from the patient, in-depth evaluation of nutrient intake, use of nutrition supplements, weight history, and identification of nutrition problems. Obtaining of physical measurements, physical assessment, calculations related to body size. Comprehensive nutrition assessment to evaluate nutrient requirements, appropriateness of weight in relation to desirable body weight and goal weight, adequacy of present diet or nutrition regimen, potential drug-nutrient interactions, exercise patterns, psychosocial food patterns, and patient's knowledge of and willingness to implement nutrition interventions. Review of clinical data and lab information and evaluation of patient's ability to perform self-monitoring. Formulation of a highly complex nutrition prescription from multiple nutrition management options and specific to patient's diagnosis, translation of nutrition prescription into an individualized meal plan and menu guidelines, or nutrition regimen. In-depth self-management training, review of techniques for self-monitoring, identification of self-management goals, identification of barriers to adherence and strategies to overcome barriers, and scheduling of follow-up appointment(s). Documentation of nutrition assessment, nutrition prescription, treatment protocol, and self-management training provided in the patient's medical record, with notation of communication with other health care providers and referrals made.

A 15-year-old female patient with uncontrolled non-insulin-dependent diabetes recently diagnosed with bulimia of 6 months' duration, who has experienced a 25-pound weight loss and has expressed a fear of getting fat. Patient purges 2 to 3 times per week, generally following a binge day. She is experiencing projectile vomiting, over which she no longer has control. Comprehensive medical nutrition therapy assessment and intervention are initiated for the patient.

K4 978X4 Medical nutrition therapy reassessment and intervention, low complexity

Definition
Therapy with patient with one diagnosis, limited data to be reviewed, and low risk of nutrition-related complications.

Description of Procedure(s)/Service(s):
Review of the patient's medical record. Nutrition history from patient, identification of changes in physician orders, identification of nutrition problems. Nutrition assessment to evaluate patient's adherence to nutrition prescription and meal plan, effectiveness of dietary modifications in medical management of diagnosis, changes in weight status, and need for additional nutrition interventions. Reinforcement self-management training on nutrition prescription, menu guidelines, and self-monitoring procedures. Definition of schedule for follow-up. Documentation of nutrition history, nutrition assessment, and reinforcement instructions provided in patient's medical record.

A 45-year-old woman with confirmed lactose intolerance who has received prior self-management training on a low lactose is seen for follow-up self-management training.

K5 978X5 Medical nutrition therapy reassessment and intervention, Moderate complexity

Definition
Therapy with patient with one or more medical diagnoses and comorbidities, with moderately complex data to be reviewed, and a high risk of nutrition-related complications.

Description of Procedure(s)/Service(s):
Review of the patient's medical record. Intensive nutrition history from patient, identification of changes in physician orders, identification of nutrition problems. Intensive nutrition assessment to evaluate patient's adherence to nutrition prescription and meal plan, barriers to adherence, medication schedule and lab data, effectiveness of dietary modifications in medical management of diagnoses, changes in weight status, and need for additional nutrition interventions. Reinforcement self-management training on nutrition prescription, menu guidelines, and self-monitoring procedures. Definition of schedule for follow-up. Documentation of nutrition history, nutrition assessment, reinforcement instructions provided, collaboration with other health care providers, and referrals made in patient's medical record.

A 67-year-old man with congestive heart failure with decreased cardiac output and edema who has received prior nutrition self-management training is receiving follow-up and more detailed self-management training to address co-morbidities.

K6 978X6 Medical nutrition therapy reassessment and intervention, high Complexity

Definition
Therapy with patient with one or more medical diagnoses and comorbidities of a highly complex nature, with highly complex data to be reviewed, and a high risk of nutrition-related complications.

Description of Procedure(s)/Service(s):
Review of the patient's medical record. Collaboration with physician or other health care providers. Comprehensive nutrition history from patient, identification of changes in physician orders, identification of nutrition problems, physical assessment of patient. Comprehensive nutrition assessment to evaluate patient's adherence to nutrition prescription, nutrition regimen, and meal plan, barriers to adherence, medication schedule and lab data, effectiveness of dietary modifications in medical management of diagnoses, changes in weight status, and need for additional nutrition interventions. Reinforcement self-management training on nutrition prescription and nutrition regimen, menu guidelines, medication schedule and administration, and self-monitoring procedures. Definition of schedule for follow-up. Documentation of nutrition history, nutrition assessment, reinforcement instructions provided, collaboration with other health care providers, and referrals made in the patient's medical record.

A 35-year-old female with gestational diabetes mellitus with excess weight gain during pregnancy who has received prior medical nutrition therapy intervention and requires highly comprehensive reassessment and complex intervention including the review of her nutrition prescription and diet guidelines and evaluation of her ability to make needed adjustments in her food selection and preparation.

K7	978X7	Medical nutrition therapy reassessment and intervention, low complexity, group setting

Definition
Therapy with patient with one diagnosis, limited data to be reviewed, and low risk of nutrition-related complications, group setting.

Description of Procedure(s)/Service(s):
Review of the patient's medical record. Nutrition history from the patient, identification of changes in physician orders, identification of nutrition problems. Nutrition assessment to evaluate patient's adherence to nutrition prescription and meal plan, effectiveness of dietary modifications in medical management of diagnosis, changes in weight status, and need for additional nutrition interventions. Skill development/self-management training in a small group setting on nutrition prescription, menu guidelines, and self-monitoring procedures. Definition of schedule for follow-up. Documentation of nutrition history, nutrition assessment, and instructions provided in patient's medical record.

A 55-year-old man with hyperlipidemia and obesity who has received prior face-to-face self-management training is receiving follow-up self-management training in a small group setting.

Background for Question 1

Attached is a list Reference Services that have been selected for use as comparison services for this survey because their relative values are sufficiently accurate and stable to compare with other services. The "2000 Work RVU" column presents current Medicare RBRVS work RVUs (relative value units). Select one code which is most similar to the new/revised CPT code descriptor and typical patient/service described on the cover of this questionnaire.

Note: The American Medical Association advised that the global period for medical nutrition therapy codes is XXX and reference service list global periods are XXX.

It is very important to consider the global period when you are comparing the new code to the reference services. A service paid on a global basis includes:

- visits and other physician/provider services provided within 24 hours prior to the service;
- provision of the service; and
- visits and other physician/provider services for a specified number of days after the service is provided.

The global periods listed on the cover of the survey refer to the number of post-service days of care that are included in the payment for the service as determined by the Health Care Financing Administration for Medicare payment purposes.

Categories of *Global Period:*

090 90 days of post-service care are included in the work RVU

010 10 days of post-service care are included in the work RVU

000 0 days of post-service care are included in the work RVU

ZZZ This code is reported in addition to a primary procedure and only the additional intra-service work to perform this service is included in the work RVU

XXX A global period does not apply to the code and evaluation and management and other diagnostic tests or minor services performed, may be reported separately on the same day

QUESTION 1: Which of the Reference Service List, see Attachment #1, is most similar to the new CPT Code Descriptor and Typical Patient Service described on the cover of this questionnaire?

K1 978X1 Medical nutrition therapy initial assessment and intervention- Low complexity: CPT Code 97244
K2 978X2 Medical nutrition therapy initial assessment and intervention- Moderate complexity: CPT Code 97245
K3 978X3 Medical nutrition therapy initial assessment and intervention- High complexity: CPT Code 97245 AND 97354
K4 978X4 Medical nutrition therapy reassessment and intervention- Low complexity: CPT Code 97213
K5 978X5 Medical nutrition therapy reassessment and intervention- Moderate complexity: CPT Code 97214
K6 978X6 Medical nutrition therapy reassessment and intervention- High complexity: CPT Code 97215
K7 978X7 Medical nutrition therapy reassessment and intervention- Low complexity, group setting: CPT Code 97214

BACKGROUND FOR QUESTION 2
SERVICE PERIOD DESCRIPTIONS

OFFICE

PRE-SERVICE PERIOD

The pre-service period includes services provided before the service and may include preparing to see the patient, reviewing records, and communicating with other professionals.

INTRA-SERVICE PERIOD

The intra-service period includes the services provided while you are with the patient and/or family. This includes the time in which the physician obtains the history, performs an evaluation, and counsels the patient.

POST-SERVICE PERIOD

The post-service period includes services provided after the service and may include arranging for further services, reviewing results of studies, and communicating further with the patient, family, and other professionals which includes written and telephone reports.

HOSPITAL

PRE-SERVICE PERIOD

The pre-service period includes services that are **not performed on the patient's hospital unit or floor**, including: communications with other professionals and the patient's family; obtaining and/or reviewing the results of diagnostic and other studies; and written and telephone reports.

INTRA-SERVICE PERIOD

The intra-service period includes the services provided while you are present on the patient's hospital unit or floor, including: reviewing the patient's chart; seeing the patient, writing notes, and communicating with other professionals and the patient's family.

POST-SERVICE PERIOD

The post-service period includes services that are not provided on the patient's hospital unit or floor, including: communicating further with other professionals and the patient's family; obtaining and/or reviewing the results of diagnostic and other studies; and written and telephone reports.

QUESTION 2: How much of your own time is required per patient treated for each of the following steps in patient care related to this procedure? Indicate your time for both the new code on the front cover and the reference you chose in Question 1. ***(Refer to pre-, intra- and post-service definitions on page 11.)***

K1 978X1 Medical nutrition therapy initial assessment and intervention- Low complexity :

Day of Procedure

	New Code	Reference Code
Pre-service time:	٥ min	٥ min
Intra-service time:	٦٠ min	٦٠ min
Post-service time:	١٥ min	١٥ min

K2 978X2 Medical nutrition therapy initial assessment and intervention- Moderate complexity:

Day of Procedure

	New Code	Reference Code
Pre-service time:	١٥ min	١٥ min
Intra-service time:	٤٥ min	٤٥ min
Post-service time:	١٥ min	١٥ min

K3 978X3 Medical nutrition therapy initial assessment and intervention- High complexity:

Day of Procedure

	New Code	Reference Code
Pre-service time:	١٥ min	١٥ min
Intra-service time:	١٢٠ min	١٢٠ min
Post-service time:	١٥ min	١٥ min

K4 978X4 Medical nutrition therapy reassessment and intervention- Low complexity:

Day of Procedure

	New Code	Reference Code
Pre-service time:	٥ min	٥ min
Intra-service time:	١٥ min	١٥ min
Post-service time:	٥ min	٥ min

QUESTION 2, continued:

K5 978X5 Medical nutrition therapy reassessment and intervention- Moderate complexity:		
Day of Procedure	New Code	Reference Code
Pre-service time:	5 min	5 min
Intra-service time:	25 min	25 min
Post-service time:	5 min	1 min

K6 978X6 Medical nutrition therapy reassessment and intervention- High complexity:		
Day of Procedure	New Code	Reference Code
Pre-service time:	5 min	5 min
Intra-service time:	45 min	45 min
Post-service time:	1 min	5 min

K7 978X7 Medical nutrition therapy reassessment and intervention- Low complexity, group setting:		
Day of Procedure	New Code	Reference Code
Pre-service time:	5 min	1 min
Intra-service time:	25 min	25 min
Post-service time:	5 min	1 min

QUESTION 3: For the New CPT codes and for the reference services you chose, rate the AVERAGE pre-, intra-, and post service *complexity/intensity* on a scale of 1 to 5 (circle one: 1 = low; 3 medium 5 = high)

K1 978X1 Medical nutrition therapy initial assessment and intervention- Low complexity:		
	New CPT:	Reference Service CPT:
PRE-service	1 2 (3) 4 5	1 2 (3) 4 5
INTRA-service	1 2 (3) 4 5	1 2 (3) 4 5
POST-service	1 2 (3) 4 5	1 2 (3) 4 5

K2 978X2 Medical nutrition therapy initial assessment and intervention- Moderate complexity:		
	New CPT:	Reference Service CPT:
PRE-service	1 2 3 (4) 5	1 2 3 (4) 5
INTRA-service	1 2 3 (4) 5	1 2 3 (4) 5
POST-service	1 2 3 (4) 5	1 2 3 (4) 5

K3 978X3 Medical nutrition therapy initial assessment and intervention-High complexity :		
	New CPT:	Reference Service CPT:
PRE-service	1 2 3 4 (5)	1 2 3 4 (5)
INTRA-service	1 2 3 4 (5)	1 2 3 4 (5)
POST-service	1 2 3 4 (5)	1 2 3 4 (5)

K4 978X4 Medical nutrition therapy reassessment and intervention-Low complexity:		
	New CPT:	Reference Service CPT:
PRE-service	1 2 (3) 4 5	1 2 (3) 4 5
INTRA-service	1 2 (3) 4 5	1 2 (3) 4 5
POST-service	1 2 (3) 4 5	1 2 (3) 4 5

K5 978X5 Medical nutrition therapy reassessment and intervention-Moderate complexity:		
	New CPT:	Reference Service CPT:
PRE-service	1 2 3 (4) 5	1 2 3 (4) 5
INTRA-service	1 2 3 (4) 5	1 2 3 (4) 5
POST-service	1 2 3 (4) 5	1 2 3 (4) 5

QUESTION 3, continued:

K6 978X6 Medical nutrition therapy reassessment and intervention- High complexity:		
	New CPT:	Reference Service CPT:
PRE-service	1 2 3 4 (5)	1 2 3 4 (5)
INTRA-service	1 2 3 4 (5)	1 2 3 4 (5)
POST-service	1 2 3 4 (5)	1 2 3 4 (5)

K7 978X7 Medical nutrition therapy reassessment and intervention- Low complexity, group setting:		
	New CPT:	Reference Service CPT:
PRE-service	1 2 3 (4) 5	1 2 3 (4) 5
INTRA-service	1 2 3 (4) 5	1 2 3 (4) 5
POST-service	1 2 3 (4) 5	1 2 3 (4) 5

Background for Question 4

In evaluating the work of a service, it is helpful to identify and think about each of the components of a particular service. Focus only on the work that you perform during each of the identified components. The descriptions below are general in nature. Within the broad outlines presented, please think about the specific services that you provide.

Physician/Provider work includes the following:

Time it takes to perform the service.

Mental Effort and Judgment necessary with respect to the amount of clinical data that needs to be considered, the fund of knowledge required, the range of possible decisions, the number of factors considered in making a decision, and the degree of complexity of the interaction of these factors.

Technical Skill required with respect to knowledge, training and actual experience necessary to perform the service.

Physical Effort can be compared by dividing services into tasks and making the direct comparison of tasks. In making the comparison, it is necessary to show that the differences in physical effort are not reflected accurately by differences in the time involved; if they are, considerations of physical effort amount to double counting of physician/provider work in the service.

Psychological Stress – Two kinds of psychological stress are usually associated with physician/provider work. The first is the pressure involved when the outcome is heavily dependent upon skill and judgment and an adverse outcome has serious consequences. The second is related to unpleasant conditions connected with the work that are not affected by skill or judgment. These circumstances would include situations with high rates of mortality or morbidity regardless of the physician/provider's skill or judgment, difficult patients or families, or physician/provider physical discomfort. Of the two forms of stress, only the former is fully accepted as an aspect of work; many consider the latter to be a highly variable function of physician/provider personality.

QUESTION 4: For the New CPT codes and for the reference services you chose, rate the intensity for each component listed on a scale of 1 to 5. (circle one: 1= low; 3 medium 5 = high)

K1 978X1 Medical nutrition therapy initial assessment and intervention- Low complexity		
Mental Effort and Judgment	**New CPT:**	**Ref. Service CPT:**
The range of possible diagnoses and/or management options that must be considered	1 2 (3) 4 5	1 2 (3) 4 5
The amount and/or complexity of medical records, diagnostic tests, or other information that must be analyzed	1 2 (3) 4 5	1 2 (3) 4 5
Urgency of medical decision making	1 2 (3) 4 5	1 2 (3) 4 5
Technical Skill/Physical Effort		
Technical skill required	1 2 (3) 4 5	1 2 (3) 4 5
Physical effort required	1 2 (3) 4 5	1 2 (3) 4 5
Psychological Stress		
The risk of significant complications, morbidity and/or mortality	1 2 (3) 4 5	1 2 (3) 4 5
Outcome depends on skill and judgment of Physician/Provider	1 2 (3) 4 5	1 2 (3) 4 5
Estimated risk of malpractice suit with poor outcome	1 2 (3) 4 5	1 2 (3) 4 5

K2 978X2 Medical nutrition therapy initial assessment and intervention- Moderate complexity		
Mental Effort and Judgment	**NEW CPT:**	**Ref. Service CPT:**
The range of possible diagnoses and/or management options that must be considered	1 2 3 (4) 5	1 2 3 (4) 5
The amount and/or complexity of medical records, diagnostic tests, or other information that must be analyzed	1 2 3 (4) 5	1 2 3 (4) 5
Urgency of medical decision making	1 2 3 (4) 5	1 2 3 (4) 5
Technical Skill/Physical Effort		
Technical skill required	1 2 3 (4) 5	1 2 3 (4) 5
Physical effort required	1 2 3 (4) 5	1 2 3 (4) 5
Psychological Stress		
The risk of significant complications, morbidity and/or mortality	1 2 3 (4) 5	1 2 3 (4) 5
Outcome depends on skill and judgment of Physician/Provider	1 2 3 (4) 5	1 2 3 (4) 5
Estimated risk of malpractice suit with poor outcome	1 2 3 (4) 5	1 2 3 (4) 5

Question 4, continued

K3 978X3 Medical nutrition therapy initial assessment and intervention-High complexity		
Mental Effort and Judgment	**NEW CPT:**	**Ref. Service CPT:**
The range of possible diagnoses and/or management options that must be considered	1 2 3 4 (5)	1 2 3 4 (5)
The amount and/or complexity of medical records, diagnostic tests, or other information that must be analyzed	1 2 3 4 (5)	1 2 3 4 (5)
Urgency of medical decision making	1 2 3 4 (5)	1 2 3 4 (5)
Technical Skill/Physical Effort		
Technical skill required	1 2 3 4 (5)	1 2 3 4 (5)
Physical effort required	1 2 3 4 (5)	1 2 3 4 (5)
Psychological Stress		
The risk of significant complications, morbidity and/or mortality	1 2 3 4 (5)	1 2 3 4 (5)
Outcome depends on skill and judgment of Physician/Provider	1 2 3 4 (5)	1 2 3 4 (5)
Estimated risk of malpractice suit with poor outcome	1 2 3 4 (5)	1 2 3 4 (5)

K4 978X4 Medical nutrition therapy reassessment and intervention-Low complexity		
Mental Effort and Judgment	**New CPT:**	**Ref. Service CPT:**
The range of possible diagnoses and/or management options that must be considered	1 2 (3) 4 5	1 2 (3) 4 5
The amount and/or complexity of medical records, diagnostic tests, or other information that must be analyzed	1 2 (3) 4 5	1 2 (3) 4 5
Urgency of medical decision making	1 2 (3) 4 5	1 2 (3) 4 5
Technical Skill/Physical Effort		
Technical skill required	1 2 (3) 4 5	1 2 (3) 4 5
Physical effort required	1 2 (3) 4 5	1 2 (3) 4 5
Psychological Stress		
The risk of significant complications, morbidity and/or mortality	1 2 (3) 4 5	1 2 (3) 4 5
Outcome depends on skill and judgment of Physician/Provider	1 2 (3) 4 5	1 2 (3) 4 5
Estimated risk of malpractice suit with poor outcome	1 2 (3) 4 5	1 2 (3) 4 5

Question 4, continued

K5 978X5 Medical nutrition therapy reassessment and intervention-Moderate complexity		
Mental Effort and Judgment	**New CPT:**	**Ref. Service CPT:**
The range of possible diagnoses and/or management options that must be considered	1 2 3 (4) 5	1 2 3 (4) 5
The amount and/or complexity of medical records, diagnostic tests, or other information that must be analyzed	1 2 3 (4) 5	1 2 3 (4) 5
Urgency of medical decision making	1 2 3 (4) 5	1 2 3 (4) 5
Technical Skill/Physical Effort		
Technical skill required	1 2 3 (4) 5	1 2 3 (4) 5
Physical effort required	1 2 3 (4) 5	1 2 3 (4) 5
Psychological Stress		
The risk of significant complications, morbidity and/or mortality	1 2 3 (4) 5	1 2 3 (4) 5
Outcome depends on skill and judgment of Physician/Provider	1 2 3 (4) 5	1 2 3 (4) 5
Estimated risk of malpractice suit with poor outcome	1 2 3 (4) 5	1 2 3 (4) 5

K6 978X6 Medical nutrition therapy reassessment and intervention-High complexity		
Mental Effort and Judgment	**New CPT:**	**Ref. Service CPT:**
The range of possible diagnoses and/or management options that must be considered	1 2 3 4 (5)	1 2 3 4 (5)
The amount and/or complexity of medical records, diagnostic tests, or other information that must be analyzed	1 2 3 4 (5)	1 2 3 4 (5)
Urgency of medical decision making	1 2 3 4 (5)	1 2 3 4 (5)
Technical Skill/Physical Effort		
Technical skill required	1 2 3 4 (5)	1 2 3 4 (5)
Physical effort required	1 2 3 4 (5)	1 2 3 4 (5)
Psychological Stress		
The risk of significant complications, morbidity and/or mortality	1 2 3 4 (5)	1 2 3 4 (5)
Outcome depends on skill and judgment of Physician/Provider	1 2 3 4 (5)	1 2 3 4 (5)
Estimated risk of malpractice suit with poor outcome	1 2 3 4 (5)	1 2 3 4 (5)

Question 4, continued

K7 978X7 Medical nutrition therapy reassessment and intervention-Low complexity, group setting

Mental Effort and Judgment	New CPT:	Ref. Service CPT:
The range of possible diagnoses and/or management options that must be considered	1 2 3 (4) 5	1 2 3 (4) 5
The amount and/or complexity of medical records, diagnostic tests, or other information that must be analyzed	1 2 3 (4) 5	1 2 3 (4) 5
Urgency of medical decision making	1 2 3 (4) 5	1 2 3 (4) 5
Technical Skill/Physical Effort		
Technical skill required	1 2 3 (4) 5	1 2 3 (4) 5
Physical effort required	1 2 3 (4) 5	1 2 3 (4) 5
Psychological Stress		
The risk of significant complications, morbidity and/or mortality	1 2 3 (4) 5	1 2 3 (4) 5
Outcome depends on skill and judgment of Physician/Provider	1 2 3 (4) 5	1 2 3 (4) 5
Estimated risk of malpractice suit with poor outcome	1 2 3 (4) 5	1 2 3 (4) 5

QUESTION 5: How many times have you personally performed these procedures in the past year?

K1 978X1 Medical nutrition therapy initial assessment and intervention- Low complexity: How many times have you personally performed these procedures in the past year? New Code: 0 Reference Service Code: 0
K2 978X2 Medical nutrition therapy initial assessment and intervention- Moderate complexity: How many times have you personally performed these procedures in the past year? New Code: 100 Reference Service Code: 100
K3 978X3 Medical nutrition therapy initial assessment and intervention- High complexity: How many times have you personally performed these procedures in the past year? New Code: 300 Reference Service Code: 300
K4 978X4 Medical nutrition therapy reassessment and intervention- Low complexity: How many times have you personally performed these procedures in the past year? New Code: 0 Reference Service Code: 0
K5 978X5 Medical nutrition therapy reassessment and intervention- Moderate complexity: How many times have you personally performed these procedures in the past year? New Code: 100 Reference Service Code: 100
K6 978X6 Medical nutrition therapy reassessment and intervention- High complexity: How many times have you personally performed these procedures in the past year? New Code: 300 Reference Service Code: 300
K7 978X7 Medical nutrition therapy reassessment and intervention-Low complexity, group setting: How many times have you personally performed these procedures in the past year? New Code: 0 Reference Service Code: 0

Question 6: Is your typical patient for this procedure similar to the medical nutrition therapy vignette, found on pages 3-7, in the survey?

K1 978X1 Medical nutrition therapy initial assessment and intervention- Low complexity Is your typical patient for this procedure similar to the medical nutrition therapy vignette, found on pages 3-7, in the survey? Yes ? (No ?) If no, please describe your typical patient for this procedure: DO NOT SEE LOW-COMPLEXITY PATIENTS
K2 978X2 Medical nutrition therapy initial assessment and intervention- Moderate complexity Is your typical patient for this procedure similar to the medical nutrition therapy vignette, found on pages 3-7, in the survey? (Yes ?) No ? If no, please describe your typical patient for this procedure:
K3 978X3 Medical nutrition therapy initial assessment and intervention-High complexity Is your typical patient for this procedure similar to the medical nutrition therapy vignette, found on pages 3-7 in the survey? (Yes ?) No ? If no, please describe your typical patient for this procedure:
K4 978X4 Medical nutrition therapy reassessment and intervention-Low complexity Is your typical patient for this procedure similar to the medical nutrition therapy vignette, found on pages 3-7 in the survey? Yes ? (No ?) If no, please describe your typical patient for this procedure: DO NOT SEE LOW-COMPLEXITY PATIENTS
K5 978X5 Medical nutrition therapy reassessment and intervention-Moderate complexity Is your typical patient for this procedure similar to the medical nutrition therapy vignette, found on pages 3-7 in the survey? (Yes ?) No ? If no, please describe your typical patient for this procedure:
K6 978X6 Medical nutrition therapy reassessment and intervention-High complexity Is your typical patient for this procedure similar to the medical nutrition therapy vignette, found on pages 3-7 in the survey? (Yes ?) No ? If no, please describe your typical patient for this procedure:
K7 978X7 Medical nutrition therapy reassessment and intervention-Low complexity, group setting Is your typical patient for this procedure similar to the medical nutrition therapy vignette, found on pages 3-7 in the survey? Yes ? (No ?) If no, please describe your typical patient for this procedure: DO NOT SEE PATIENTS IN GROUP SETTINGS

**********VERY IMPORTANT**********

QUESTION 7:

K1 978X1 Medical nutrition therapy initial assessment and intervention- Low complexity **Based on your review of all previous steps, please provide your Estimate work RVU for the new CPT code:** SAME
K2 978X2 Medical nutrition therapy initial assessment and intervention- Moderate complexity **Based on your review of all previous steps, please provide your Estimate work RVU for the new CPT code:** SAME
K3 978X3 Medical nutrition therapy initial assessment and intervention-High complexity **Based on your review of all previous steps, please provide your Estimate work RVU for the new CPT code:** SAME
K4 978X4 Medical nutrition therapy reassessment and intervention-Low complexity **Based on your review of all previous steps, please provide your Estimate work RVU for the new CPT code:** SAME
K5 978X5 Medical nutrition therapy reassessment and intervention-Moderate complexity **Based on your review of all previous steps, please provide your Estimate work RVU for the new CPT code:** SAME
K6 978X6 Medical nutrition therapy reassessment and intervention-High complexity **Based on your review of all previous steps, please provide your Estimate work RVU for the new CPT code:** SAME
K7 978X7 Medical nutrition therapy reassessment and intervention-Low complexity, group setting **Based on your review of all previous steps, please provide your Estimate work RVU for the new CPT code:** SAME

For example, if the new/revised code involves the same amount of physician/provider work as the reference service you choose, you would assign the same work RVU. If the new/revised code involves twice as much (or half as much) work as the reference service, you would calculate and assign a work RVU value that is twice as much (or half as much) as the work RVU of the reference service. This methodology attempts to set the work RVU of the new or revised service relative to the work RVU of comparable and established reference services.

Attachment F - Page 24 or 24