

Submitter : Date & Time:

Organization :

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Issue Areas/Comments

GENERAL

GENERAL

Please see attached

CMS-1429-P-4000-Attach-1.pdf

September 24, 2004

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BY ELECTRONIC DELIVERY

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

**Re: CMS-1429-P (Medicare Program; Revisions to
Payment Policies Under the Physician Fee Schedule
for Calendar Year 2005) – Sections 303, 731(b), Impact,
Low Osmolar Contrast Media, and Coding**

Dear Administrator McClellan:

On behalf of the Association of Community Cancer Centers (“ACCC”), we appreciate this opportunity to comment on the Centers for Medicare and Medicaid Services’ (“CMS”) proposed rule regarding revisions to payment policies under the Medicare physician fee schedule, published in the Federal Register on August 5, 2004 (the “Proposed Rule”).¹ ACCC is a membership organization whose members include hospitals, physicians, nurses, social workers, and oncology team members who care for millions of patients and families fighting cancer. ACCC’s more than 700 member institutions and organizations treat 45 percent of all U.S. cancer patients. Combined with our physician membership, ACCC represents the facilities and providers responsible for treating over 60 percent of all U.S. cancer patients.

¹ 69 Fed. Reg. 47488 (Aug. 5, 2004).

ACCC supports and appreciates CMS' continued efforts to implement the Medicare Prescription Drug, Improvement, and Modernization Act ("MMA") in a timely, straightforward manner. We applaud CMS' plan to use G-codes to implement the much needed coding changes for drug² administration services in 2005. We commend CMS' logical proposals regarding the billing requirements and shipping time frames for covered immunosuppressive, oral anticancer, and oral anti-emetic drugs. We continue to be concerned, however, that the sweeping reimbursement changes required by section 303 of the MMA will disrupt patient access to cancer care. We urge the agency to use any means possible to ensure that reimbursement levels are adequate to protect beneficiaries' access to the life-saving treatments they need.

Toward this end, there are several specific provisions of the Proposed Rule that we believe should be changed or clarified. ACCC urges CMS to:

- Monitor patient access issues proactively to ensure that patient access to cancer treatment is not undermined by inadequate reimbursement;
- Provide additional guidance to physicians clarifying the appropriate use and documentation of evaluation and management codes to capture severe reaction management and clinical treatment planning services;
- Increase the proposed supplying fees for oral anticancer drugs and oral anti-emetic drugs to a level that will reimburse providers appropriately for their costs;
- Expand its support for clinical trials by issuing its long-awaited coverage criteria for trials not automatically deemed to be covered; and
- Publish reimbursement rates for all drugs administered by physicians and not assume or imply that carriers should apply least costly alternative policies.

A discussion of these recommendations is presented below.

I. Section 303 - Payment Reform for Covered Outpatient Drugs and Biologicals

A. Patient Access

ACCC members are committed to ensuring that their cancer patients receive quality care, including access to cutting-edge cancer therapies in the most

² For simplicity, we refer to drugs and biologicals collectively as "drugs" throughout our comments.

clinically appropriate setting. Provisions within the MMA have raised concerns about patient access to drugs and physician services. As CMS is in the primary stages of implementing new payment rates for drugs and drug administration services, ACCC urges CMS to continually monitor patient access. To the extent that final average sales price (“ASP”) reimbursement rates approximate those published in the Proposed Rule, some oncology practices may be unable to continue offering the full range of cancer care services.³ It is troubling that in some markets, patient access to needed therapies could be dictated by physicians’ purchasing power—based on market share and volume. This real possibility could create unintended consequences and have a ripple effect beyond community practices. In several areas, practices are contemplating reducing or eliminating infusion services, possibly require cancer patients to receive infusions in alternate—and less convenient or unfamiliar—sites, or even the more costly, inpatient setting.⁴

For example, based on a comprehensive evaluation of its cancer protocols, a three physician practice in Jupiter, Florida estimates that 40 percent of its current chemotherapy patient volume will be referred to a hospital outpatient department for treatment in 2005. The closest area hospital has a small infusion suite and may not be able to accommodate the initial surge in cancer patients. This could mean greater patient referrals to more distant hospitals or extended wait periods for patients to start chemotherapy treatment. Indeed, a patient could receive a cancer diagnosis, only to be told that treatment cannot begin for three or four weeks when a chair becomes available. Patients should not be subjected to such an edict.

Other ACCC members are echoing similar sentiments. For example, an ACCC member related information on a large urban group practice on the East coast that indicated a preliminary impact assessment may necessitate a one-third reduction in patient services. The two major hospital systems nearby have no plans to expand their infusion center capacity, however, in part due to inadequate Medicare reimbursement rates for this service in outpatient departments. This situation is exacerbated in more areas where there is less demand for these services, such as rural Pittsville, IL, population 4,000. For example, an ACCC member practicing in Springfield, Illinois fears that patients may have to travel as much as 75 to 125 miles to access needed therapies if their large group practice closes two of its satellite offices in Jacksonville and Lincoln, as is currently planned. This

³ During CMS’ Pharmaceutical, Pharmacy, and Device Manufacturers Open Door Forum teleconference on Sept. 8, 2004, a provider said that she now is sending patients to hospitals for some therapies and is deeply concerned about her ability to purchase certain drugs at ASP plus 6 percent. See also Rob Stein, Medicare Law Hurts Cancer Patients, Washington Post, Feb. 14, 2004, at A1; Sheri Hall, Reforms May Weaken Cancer Patient Care, Detroit News, Apr. 20, 2004, at A1.

⁴ Id.

possible scenario imposes undue hardships for patients who are currently able to get treatment closer to home. For patients—especially the frail elderly or very ill—losing access to community care means added inconveniences and increased pressure on their social support systems; it means unfamiliarity in nursing staff caring for them each time infusions are provided; additional time off from work; having family members or friends take time off work to drive them and/or whom are unable to provide comfort during the patient’s entire cancer treatment procedure.

In addition to basic chemotherapy services, patient access to supportive services is declining. Unless Medicare’s reimbursement methodology is changed, some providers report they will not be able to continue to provide supportive care, such as social work, nutritional care counseling, and other services, because Medicare does not currently reimburse appropriately for these services. Supportive care helps patients reap the full benefits of their drug regimens.⁵ Reductions in supportive care are extremely disruptive for patients who must subsequently rely on other, less convenient and non-patient specific, resources.

We are concerned that the negative effects on cancer patients will increase as MMA reforms are implemented and a projected \$4.2 billion is cut from the oncology drug administration infrastructure over the next decade. This cut in payments for drugs and their administration will mean that physicians will not be able to provide the same high quality services to Medicare patients, and cancer patients will struggle to find places that can provide the totality of care they need with such limited reimbursement. As CMS continues to implement the MMA’s reforms, it is critically important that the agency prepare to respond quickly to patient access problems that may arise.

In the Proposed Rule, CMS states its plan to “analyze shifts or changes in utilization patterns as the information becomes available to use once the payment changes required by the MMA go into effect.”⁶ ACCC urges CMS to begin this monitoring *before* all provisions are fully implemented. In addition to CMS’ plans to monitor patient utilization, the MMA requires the Comptroller General and the Medicare Payment Advisory Commission (“MedPAC”) to study the effect various MMA payment provisions will have on access to physicians.⁷ This study includes evaluating the effect that changes to physician reimbursement has on drug administration services and other associated oncology items and services.⁸ We

⁵ See, e.g., Sheri Hall, Reforms May Weaken Cancer Patient Care, Detroit News, Apr. 20, 2004, at A1; Ted Griggs, Medicare Change Could Make Cancer Treatment More Costly, Baton Rouge Advocate, Aug. 26, 2004, at 1D.

⁶ 69 Fed. Reg. at 47573.

⁷ MMA § 604; MMA § 303(a)(5)(A)-(C).

⁸ MMA § 303(a)(5)(A).

appreciate the statutory provision recognizing the importance of measuring the effects of payment reforms on patient access, and we encourage CMS to pay close attention to the outcomes of these reports. We remain concerned that the results of these studies will not be able to adequately protect patient access to cancer care throughout the implementation process, however.

ACCC urges CMS to begin monitoring patient access immediately, and not to wait until all MMA reforms are fully implemented. Even before the new ASP-based payment rates have gone into effect, some physicians are already struggling to provide cancer patients with access to the care and therapies they need while others are attempting to assess their ability to continue to provide services to Medicare patients in the near future. We are hopeful that CMS will develop an effective mechanism to monitor this growing access issue. At a minimum, CMS should provide a way for Medicare providers and patients to report difficulties they are encountering in providing or receiving needed services. Vehicles for reporting access and provider issues may include an option through the 1-800-MEDICARE system or providing a form on the CMS web site. In addition, the office of the Medicare Beneficiary Ombudsman, created by section 923 of the MMA, also may be an effective way to monitor and assess patient access to drugs and related services. ACCC welcomes any opportunity to work with CMS to further develop appropriate mechanisms for gathering this critical information.

B. Additional Guidance Regarding ASP Reporting

Under the new ASP-based drug reimbursement system, accurate reporting is essential to setting appropriate drug reimbursement rates that enable physicians to provide cancer therapies to their patients. In April, CMS published an Interim Final Rule ("IFR") on manufacturer submission of ASP data.⁹ Recently, CMS published the ASP Final Rule ("Final Rule") requiring manufacturers to apply a smoothing methodology for estimating certain price concessions.¹⁰ Unfortunately, the Final Rule does not fully address important ASP reporting questions, including several posed by ACCC, filed in response to the IFR.¹¹ Specifically, ACCC urged CMS to provide detailed guidance necessary to ensure that manufacturers consistently and accurately report ASP data. In our comments, we called on CMS to implement an exceptions process that would allow providers, manufacturers, and other interested parties to petition the agency for more appropriate rates if the reported ASP rate for a particular drug is not adequate. We also asked CMS to exclude certain administrative fees for legitimate services and usual and customary

⁹ 69 Fed. Reg. 17935 (Apr. 6, 2004).

¹⁰ 69 Fed. Reg. 55763 (Sept. 16, 2004).

¹¹ Letter from Patti A. Jamieson-Baker, President, ACCC, to Mark McClellan, Administrator, CMS, June 7, 2004.

prompt pay incentives from ASP, as these services reflect general business protocols that are not specific to drug purchasing. In the September final rule, CMS states, "Other issues and comments relating to the interim final rule will be addressed at a future time."¹² With only a few weeks remaining until the final filing deadline before the 2005 rates are calculated, ACCC urges CMS to address these important concerns now so manufacturers can file appropriate ASP data.

C. Payment Methodology for New Drugs

ACCC asks CMS to clarify the payment methodology for new drugs in situations in which ASP information is not available or is incomplete. Section 1847A(c)(4) of the Social Security Act ("SSA") allows the Secretary to pay for new drugs at wholesale acquisition cost ("WAC") or 95 percent of average wholesale price ("AWP") during their first calendar quarter of sales. Unfortunately, the statute and corresponding Proposed Rule do not clarify how these drugs will be paid during their second quarter of sales. CMS has stated that a new product's ASP becomes effective for use in payment at the start of its third quarter of sales. This effectively leaves a gap between the ASP reporting date after the end of the first quarter and the start of the third quarter. We request that CMS clarify how reimbursement methodologies will be applied during a product's second quarter of sales.

D. Reporting and Billing for Physicians' Services Associated with Administration of Covered Outpatient Drugs

In order to ensure that Medicare patients may access the care they need, ACCC has advocated that reductions in reimbursement for drugs should be offset by adequate increases for drug administration and other services. The MMA requires CMS to review existing drug administration codes to "ensure accurate reporting and billing for such services, taking into account levels of complexity of the administration and resource consumption."¹³ In recognition of the importance of accurate reimbursement for these services, Congress exempted any changes in reimbursement that result from this review from the budget neutrality requirements.¹⁴ In the Proposed Rule, CMS suggests using G-codes to implement drug administration coding changes, effective in 2005, recommended by the American Medical Association's ("AMA") Current Procedural Terminology ("CPT") Editorial Panel.¹⁵ ACCC supports CMS' intention to adopt the AMA recommendations and issue G-codes. In addition, we ask that CMS provide detailed

¹² 69 Fed. Reg. at 55763.

¹³ MMA § 303(a), establishing SSA § 1848(c)(2)(J).

¹⁴ MMA § 303(a)(1)(A), establishing SSA § 1848(c)(2)(B)(iv). *See also* 108th Congress, *Joint Explanation Statement of the Committee of Conference*, Report 108-391 at 580 (2003).

¹⁵ 69 Fed.Reg. at 47522.

guidance to physicians regarding the appropriate use of evaluation and management (“E&M”) codes, as well as any other codes, used to capture the following services:

- Severe reaction management;
- Clinical treatment planning; and
- Preparation of anti-neoplastic agents.

Such detailed guidance should include specific examples, such as those used by the AMA in various CPT reference books, to appropriately educate providers and carriers of the intricacies of billing for these services.

The AMA’s CPT Editorial Panel recently reviewed recommendations made by a drug administration workgroup that included representatives of the specialties that are primary users of the drug administration codes.¹⁶ The Panel accepted several recommendations made by the workgroup, including 12 new and 14 revised codes for drug infusion and administration that recognize variations in complexity among drugs and drug administration services. The RVS Update Committee (“RUC”) will meet at the end of the month to set values for these accepted codes. The value setting process is critical to CMS’ efforts to appropriately reimburse physicians for the costs of providing drug therapies. As explained above, patient access to life-extending cancer treatment will suffer unless physicians are appropriately compensated for the drugs they provide to their patients and the costs associated with drug administration. CMS is well on its way to reforming drug payments, and ACCC urges CMS to accurately and adequately adjust drug administration coding and reimbursement.

Although ACCC applauds the CPT Editorial Panel for adopting the workgroup’s recommendations for 12 new and 14 revised drug administration codes, we are concerned that the Panel rejected the workgroup’s recommendations with respect to new codes for severe reaction management, clinical treatment planning for anti-neoplastic drug administration, and physician supervision of the preparation of anti-neoplastic pharmacy supplies. AMA statements indicate that these codes were rejected primarily because Panel members believed these services could be captured by current codes, namely those for E&M and drug administration services.¹⁷ Many of our members have indicated that they are not being adequately reimbursed for these services under existing codes and have been informed by their fiscal intermediaries (“FI”) that billing E&M codes for these other specific services is inappropriate, particularly when there is no face-to-face patient encounter. Because these services are so integral to providing high quality cancer care, we ask CMS to address this issue in the final rule. Specifically, we ask CMS provide clear guidance

¹⁶ AMA, CPT Editorial Panel, August 2004 Meeting, Changes to Drug Administration Codes, available at <http://www.ama-assn.org/ama1/pub/upload/mm/362/panelactionsdruginf2.doc>.

¹⁷ Id.

on when it is appropriate to bill for these services, how to code for them, and what precisely must be documented in the medical record to support coverage and reimbursement. Overall, ACCC urges CMS to recognize the full range of services required to provide quality cancer care through new codes, improved reimbursement, and additional coding guidance to ensure that cancer patients will continue to benefit from the most appropriate and effective cancer therapy regimens.

E. Supplying Fees

ACCC applauds CMS' goal of "assur[ing] that each beneficiary who needs covered oral drugs has access to those medications"¹⁸ by paying a supplying fee for immunosuppressive drugs, oral anti-emetic drugs used as part of an anticancer chemotherapeutic regimen, and oral anticancer chemotherapeutic drugs, as required by section 303(e)(2) of the MMA. We are disappointed, however, that CMS is proposing a payment of only \$10 per prescription and we are concerned that the proposed payment will not be adequate to "cover a pharmacy's activities to get oral drugs to beneficiaries."¹⁹ In the Proposed Rule, CMS states that pharmacies recommended supplying fees ranging from \$12 to \$56 per prescription. Although we recognize that CMS expects to reduce some of the costs of filling these prescriptions through reforms to billing requirements and shipping time frames, the agency cannot assure that these savings will be sufficient to offset pharmacies' increased costs of supplying these drugs. To ensure that CMS achieves its goal of providing access to each beneficiary who needs these drugs, we encourage CMS to increase the proposed \$10 supplying fee. ACCC recommends that CMS continue working with pharmacies to better understand the costs of providing these important oral drugs.

F. Billing Requirements and Shipping Time Frames

ACCC supports the proposed reforms to the billing requirements and shipping time frames for supplying covered immunosuppressive and oral anticancer and anti-emetic drugs to Medicare beneficiaries.²⁰ Specifically, the agency proposes to allow a prescription to be dispensed based on a verbal order from the physician. A written order then must be obtained before submitting a claim, but it may be faxed, photocopied, electronic, or pen and ink.²¹ In addition, the agency proposes to eliminate the requirement to obtain an assignment of benefits form and to complete

¹⁸ 69 Fed. Reg. at 47523.

¹⁹ *Id.*

²⁰ 69 Fed. Reg. at 47523-24.

²¹ *Id.*

the DMERC Information Form.²² Finally, CMS would allow prescriptions to be refilled approximately 5 days prior to the end of the usage of the product.²³ These logical reforms will help to reduce pharmacies' costs of providing these drugs by cutting out unnecessary paperwork and reducing the costs of overnight shipping services. Most important, these reforms will benefit patients by helping to ensure that they receive their drugs in a timely manner. ACCC recommends that CMS implement these reforms in the final rule.

II. Section 731(b) – Coverage for Routine Costs of Category A Clinical Trials

In the Proposed Rule, CMS proposes to expand coverage for the routine costs of Category A clinical trials.²⁴ While CMS has turned its attention to clinical trials, we ask the agency to demonstrate its support for research and innovation by fully implementing its national coverage decision regarding routine patient care costs in other types of clinical trials. Four years have passed since CMS announced that it would cover the routine patient care costs of clinical trials; however, CMS has not fulfilled its promise to explicitly define criteria for covering additional trials. As ACCC explained in our comments concerning ways the Department of Health and Human Services can stimulate innovation,²⁵ clinical trials are vital to the continuing advancement of cancer care. Participating patients benefit from an expanded choice of therapies and gain new hope in their struggle against cancer, while even more patients benefit from the knowledge gained from trials. ACCC urges CMS to allow more beneficiaries to reap these benefits by issuing the long-awaited coverage criteria for trials not automatically deemed to be covered.

III. Impact – Need to Publish ASP-Based Rates for All Physician Administered Drugs

In the Proposed Rule, CMS failed to publish an ASP-based payment rate for J9217 (Leuprolide acetate suspension) and instead used the payment rate for J9202 (Goserelin acetate implant) because the agency “assumed that Medicare carriers are applying ‘least costly alternative’ pricing and are using the J9202 price for J9217.”²⁶ This assumption is not correct. Indeed, the Office of Inspector General (“OIG”) has identified 10 jurisdictions that do not apply least costly

²² Id. at 47524.

²³ Id.

²⁴ 69 Fed. Reg. at 47543.

²⁵ Letter from Patti A. Jamieson-Baker, President, ACCC, to Jeffrey Shuren, Assistant Commissioner for Policy, Food and Drug Administration, Aug. 20, 2004.

²⁶ Id. at 47563, 48567.

alternative (“LCA”) policies to J9217.²⁷ Moreover, several other states make exceptions to their policies when medical necessity can be shown and have “grandfathering” clauses for patients who were using Leuprolide acetate suspension prior to implementation of LCA.²⁸ During the September 8, 2004, Pharmaceuticals, Pharmacy, and Device Open Door Forum, CMS acknowledged that it had made an error and that the proper rate for J9217 should have been listed as \$249.39. ACCC applauds CMS for announcing this correction and urges the agency to publish ASP-based payment rates for all physician administered drugs in the future, including those that are subject to LCA policies. In addition, ACCC requests that CMS clarify its action in the final rule and specify that it is not mandating a national LCA policy for Leuprolide acetate suspension or any other drug.

V. Conclusion

In summary, ACCC continues to be deeply concerned that the MMA’s dramatic reductions in reimbursement could have adverse impact on patients battling cancer. Physicians simply cannot absorb the significant cuts in payment rates for cancer services without substantial ramifications for patient care. In order to ensure that Medicare patients continue to have access to necessary cancer services, we respectfully request that CMS adopt the following recommendations:

1. Proactively monitor patient access to ensure that the implementation of payment reforms do not negatively affect patient access to necessary care;
2. Issue clear guidance regarding manufacturers’ ASP reporting requirements to ensure that accurate and complete data are available for the 2005 rates;

²⁷ “OIG Draft Report: Medicare Reimbursement for Lupron,” OEI-03-03-00250, January 2004, p. i (stating “We found that carriers in 10 of 57 jurisdictions did not apply a least costly alternative policy to Lupron.”); see, e.g., Blue Cross and Blue Shield of Montana, “LMRP for Leuprolide Acetate (Lupron)”/ “Leuprolide – Lupron;” Wisconsin Physicians Services Insurance Corporation policies for Michigan, Illinois, and Wisconsin.

²⁸ See, e.g., Blue Cross and Blue Shield of Arkansas, “LCD for Leuprolide Acetate/Goserelin,” L12127; Empire Medicare Services, “LMRP for Luteinizing Hormone-Releasing Hormone (LHRH) Analogs for Treatment of Malignant Neoplasm of the Prostate,” (L3751); see, also, Memorandum from Thomas A. Scully, Administrator, CMS, to Dara Corrigan, Acting Principle Deputy Inspector General, OIG, regarding “OIG Draft Report: Medicare Reimbursement for Lupron,” p. 1 (stating “all LCA policies affecting payment for Lupron specify that full payment will be made if the physician states that the use of Lupron rather than the LCA drug is medically necessary.”); National Heritage Insurance Company (NE), “LCD for Gonadotropin-Releasing Hormone Analogs- Leuprolide Acetate (Lupron, Eligard, Viadur), Goserelin Acetate (Zoladex);” Blue Cross and Blue Shield of Arkansas, “LCD for Leuprolide Acetate/Goserelin,” L12127; Blue Cross and Blue Shield of Kansas, “LMRP for Lupron/Zoladex” (L9281).

3. Accept the CPT Editorial Panel's recommendations for new drug infusion and administration codes as G-codes in 2005 and issue additional guidance regarding the appropriate use of E&M and other codes to capture severe reaction management, clinical treatment planning, and preparation of anti-neoplastic agents services;
4. Work with pharmacies to ensure that the supplying fee required by the MMA is adequate to protect beneficiary access to covered oral drugs;
5. Fully implement the national coverage decision regarding coverage of routine patient care costs associated with clinical trials; and
6. Publish ASP-based payment rates for all drugs administered in physician offices, including those to which some carriers apply LCA policies.

ACCC appreciates the opportunity for offer these comments, and we look forward to continuing to work with CMS to address these vital issues. Please contact our staff person, Deborah Walter, at (301) 984-9496, ext. 221, if you have any questions or if ACCC can be of further assistance. Thank you for your attention to this very important matter.

Respectfully submitted,

A handwritten signature in black ink that reads "Patti Jamieson-Baker". The signature is written in a cursive style with a large initial "P".

Patti A. Jamieson-Baker, MSSW, MBA
President
Association of Community Cancer Centers
Executive Director
The Cancer Institute at Alexian Brothers
Alexian Brothers Hospital Network

CMS-1429-P-4001

Submitter : **Date & Time:**

Organization :

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Issue Areas/Comments

Issues 1-9

SECTION 611

Please see attached letter.

CMS-1429-P-4001-Attach-1.pdf

CMS-1429-P-4001-Attach-2.doc



Forest Research Institute
A Division of Forest Laboratories, Inc.

Fax: 201-427-8100
Direct Line: 201-427-8353

September 24, 2004

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention – CMS 1429-P
P.O. Box 8012
Baltimore, Maryland 21244-8042

File Code CMS – 1429-P

Re: Comments Regarding Section 611—Initial Preventive Physical Examination, (published as a Notice of Proposed Rulemaking, 69 Fed. Reg. 47488 (August 5, 2004)).

To Whom It May Concern:

Thank you for the opportunity to comment on the proposed rules implementing Section 611 of the Medicare Modernization Act (MMA) providing for coverage under Part B of an initial preventive physical examination. For new Medicare beneficiaries, this initial preventive physical examination presents a critical opportunity to promote wellness by identifying beneficiaries at risk for chronic and disabling diseases. Through early detection, patient education and treatment, we know that we can prevent or slow the progression of many chronic illnesses, saving lives and resources.

We are concerned, however, that while the proposed rule lists many services that must be included as part of the examination, the rule does not explicitly include a review of a beneficiary's mental status, cognitive function and behavioral changes, three important areas that are critical to the assessment of a beneficiary's risk for dementia and Alzheimer's disease. Absent clarification, we are concerned that physicians and other qualified non-physician practitioners may fail to include assessment of mental status, cognitive function and behavioral changes as part of the initial preventive physical examination, even when a beneficiary may be at risk for dementia or Alzheimer's disease.

Early detection for risk of dementia and Alzheimer's disease is particularly important for Medicare enrollees because these two diseases disproportionately affect the elderly.

Dementia is reported in as many as one percent of adults 60 years of age, while the frequency of dementia doubles every five years after age 60.¹ Dementia may be caused by numerous medical conditions including thyroid disease, drug toxicity, thiamine deficiency, brain injury, strokes, multiple sclerosis, brain infection, HIV infection, hydrocephalus, Pick's disease and or brain tumors.² The most common form of dementia in the elderly is Alzheimer's disease. One out of every 10 people over age 65 is a victim of Alzheimer's disease.³ Alzheimer's disease is the third most costly disease in the United States. The average lifetime cost of care for an individual with Alzheimer's disease is \$174,000, while each year, the U.S. economy spends at least \$100 billion on indirect annual costs of caring for individuals with Alzheimer's disease.⁴ By the year 2010, it is estimated that 5.1 million Americans will suffer from Alzheimer's disease.⁵

According to the Report of the Quality Standards Subcommittee of the American Academy of Neurology (AAN):

Studies indicate that individuals characterized as being cognitively impaired but not meeting clinical criteria for dementia or Alzheimer's disease (mild cognitive impairment) have a high risk of progressing to dementia or Alzheimer's disease. If the figures for incident Alzheimer's disease from the general population are used . . . one can see that the rates range from 0.2 % in the 65 to 69 year age range to 3.9% in the 85 to 89 year range. The studies of mild cognitive impairment indicate that the rate of progression to dementia or Alzheimer's disease is between 6 and 25% per year.⁶

Given the correlation between mild cognitive impairment and the development of dementia and Alzheimer's disease, the AAN recommends that "[p]atients with mild cognitive impairment should be recognized and monitored for cognitive and functional decline due to their increased risk for subsequent dementia."⁷ Furthermore, the National Guideline Clearinghouse Guidelines for Alzheimer's Disease Management make clear that comprehensive and appropriate treatment plans for patients with Alzheimer's disease can only be developed as a result of thorough assessment and that such assessment should address the patient's medical condition, including functional status (ADL and IADL) , cognitive status, other medical conditions, behavioral problems, psychotic symptoms and depression.⁸

¹ MedicineNet.com.

<http://www.medicinenet.com/script/main/art.asp?articlekey=9090&pf=3&track=qpa9090>.

² Id.

³ Alzheimer's Association. <http://www.alz.org/Resources/FactSheets/FSAzheimerStats.pdf>.

⁴ Ernst RL, Hay JW. The US economic and social costs of Alzheimer's disease revisited. *Public Health* 1994; 84:1261-1264.

⁵ Evans DA. Estimated Prevalence of Alzheimer's Disease in the United States, *Milbank Quarterly*. 1990;68:267-289.

⁶ Practice parameter: early detection of dementia: mild cognitive impairment (an evidence-based review). Report of the Quality Standards Subcommittee of the American Academy of Neurology. National Guideline Clearinghouse.

http://www.guideline.gov/summary/summary.aspx?doc_id=2816&nbr=2042&string=Alzh...

⁷ Id.

⁸ Guideline for Alzheimer's disease management. California Workgroup on Guidelines for Alzheimer's Disease Management. Los Angeles (CA): Alzheimer's Association of Los Angeles, Riverside and San

In sum, in order to ensure that Medicare beneficiaries receive a comprehensive preventive examination, we urge CMS to amend the proposed rule to make clear that screening and assessment of mental status, cognitive function and behavioral changes, when undertaken as part of such an initial preventive physical examination, are Medicare covered services.

We are also concerned that the proposed rule may not give physician's the flexibility they need to use the assessment and diagnostic tools most appropriate for each patient. Although physicians can diagnose Alzheimer's disease with a great degree of certainty, unlike some other chronic illnesses such as cancer or diabetes, there is no single test that is conclusive. Clinicians use a series of neuropsychological tests to distinguish normal aging, mild cognitive impairment, Alzheimer's disease or depression. For example, while the Mini-mental Status Exam (MMSE) is the most widely used screening instrument for cognition, it is by no means the only tool. There are also numerous tests that provide "global" assessment of the patient's overall condition, including cognitive status. Certain tests will be more appropriate than others depending on how the patient presents, the patient's history, etc. We believe that physicians and other qualified clinicians are in the best position to make clinical judgments regarding which tests and assessment tools should be used for each patient. Given the extent to which national standard setting organizations are involved in the evaluation and validation of various screening tools, we do not believe it is appropriate (or necessary) to use a National Coverage Determination (NCD) to direct physicians to a particular instrument.

Accordingly, given the discussion above, we are recommending the following changes to the proposed rulemaking:

(1) To ensure that clinicians include a screening assessment of mental status, cognitive function and behavioral changes as part of the Medicare covered initial preventive physical examination, the definition of "*Review of the individual's functional ability and level of safety*" at Section 410.16(a) should be amended to add "*mental status*" "*cognitive function*" and "*behavioral changes*" as follows:

Review of the individual's functional ability and level of safety. Review of the individual's functional ability and level of safety must include, at a minimum, a review of the following areas:

- (1) Hearing impairment.
- (2) Activities of daily living
- (3) Falls risk.
- (4) Home safety.
- (5) Mental status
- (6) Cognitive function
- (7) Behavioral changes

Bernardino Counties; 2002 Jan, 1. 52p. National Guideline Clearinghouse.
http://www.guideline.gov/summary/summary.aspx?doc_id=3157&nbr=2383&string=Alzh...

(2) To ensure that clinicians undertake a comprehensive medical history that is designed to assess a beneficiary's risk of developing dementia or Alzheimer's disease, the definition of "medical history," at Section 410.16(a) should be amended to add "head trauma" as follows:

Medical history is defined to include, at a minimum, the following:

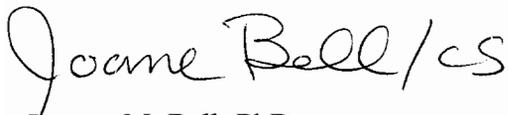
(1) Past medical and surgical history, including experiences with illnesses, hospital stays, operations, allergies, injuries (including head trauma) and treatments.

(3) Change Section 410(a)(3) to read as follows:

Review of the individual's functional and cognitive ability, and level of safety, based on the use of clinically appropriate screening and assessment instruments, which the physician or other qualified non-physician practitioner may select

Again, thank you for this opportunity to comment on the proposed rule. If you have any questions, please do not hesitate to contact me.

Yours sincerely,



Joanne M. Bell, PhD
Senior Director
CNS Medical Affairs
Forest Research Institute

September 24, 2004

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention – CMS 1429-P
P.O. Box 8012
Baltimore, Maryland 21244-8042

File Code CMS – 1429-P

Re: Comments Regarding Section 611—Initial Preventive Physical Examination, (published as a Notice of Proposed Rulemaking, 69 Fed. Reg. 47488 (August 5, 2004)).

To Whom It May Concern:

Thank you for the opportunity to comment on the proposed rules implementing Section 611 of the Medicare Modernization Act (MMA) providing for coverage under Part B of an initial preventive physical examination. For new Medicare beneficiaries, this initial preventive physical examination presents a critical opportunity to promote wellness by identifying beneficiaries at risk for chronic and disabling diseases. Through early detection, patient education and treatment, we know that we can prevent or slow the progression of many chronic illnesses, saving lives and resources.

We are concerned, however, that while the proposed rule lists many services that must be included as part of the examination, the rule does not explicitly include a review of a beneficiary's mental status, cognitive function and behavioral changes, three important areas that are critical to the assessment of a beneficiary's risk for dementia and Alzheimer's disease. Absent clarification, we are concerned that physicians and other qualified non-physician practitioners may fail to include assessment of mental status, cognitive function and behavioral changes as part of the initial preventive physical examination, even when a beneficiary may be at risk for dementia or Alzheimer's disease.

Early detection for risk of dementia and Alzheimer's disease is particularly important for Medicare enrollees because these two diseases disproportionately affect the elderly.

Dementia is reported in as many as one percent of adults 60 years of age, while the frequency of dementia doubles every five years after age 60.¹ Dementia may be caused by numerous medical conditions including thyroid disease, drug toxicity, thiamine deficiency, brain injury, strokes, multiple sclerosis, brain infection, HIV infection, hydrocephalus, Pick's disease and or brain tumors.² The most common form of dementia in the elderly is Alzheimer's disease. One out of every 10 people over age 65 is a victim of Alzheimer's disease.³ Alzheimer's disease is the third most costly disease in the United States. The average lifetime cost of care for an individual with Alzheimer's disease is \$174,000, while each year, the U.S. economy spends at least \$100 billion on indirect annual costs of caring for individuals with Alzheimer's disease.⁴ By the year 2010, it is estimated that 5.1 million Americans will suffer from Alzheimer's disease.⁵

According to the Report of the Quality Standards Subcommittee of the American Academy of Neurology (AAN):

Studies indicate that individuals characterized as being cognitively impaired but not meeting clinical criteria for dementia or Alzheimer's disease (mild cognitive impairment) have a high risk of progressing to dementia or Alzheimer's disease. If the figures for incident Alzheimer's disease from the general population are used . . . one can see that the rates range from 0.2 % in the 65 to 69 year age range to 3.9% in the 85 to 89 year range. The studies of mild cognitive impairment indicate that the rate of progression to dementia or Alzheimer's disease is between 6 and 25% per year.⁶

Given the correlation between mild cognitive impairment and the development of dementia and Alzheimer's disease, the AAN recommends that "[p]atients with mild cognitive impairment should be recognized and monitored for cognitive and functional decline due to their increased risk for subsequent dementia."⁷ Furthermore, the National Guideline Clearinghouse Guidelines for Alzheimer's Disease Management make clear that comprehensive and appropriate treatment plans for patients with Alzheimer's disease can only be developed as a result of thorough assessment and that such assessment should address the patient's medical condition, including functional status (ADL and IADL) , cognitive status, other medical conditions, behavioral problems, psychotic symptoms and depression.⁸

¹ MedicineNet.com.

<http://www.medicinenet.com/script/main/art.asp?articlekey=9090&pf=3&track=qpa9090>.

² Id.

³ Alzheimer's Association. <http://www.alz.org/Resources/FactSheets/FSAzheimerStats.pdf>.

⁴ Ernst RL, Hay JW. The US economic and social costs of Alzheimer's disease revisited. *Public Health* 1994; 84:1261-1264.

⁵ Evans DA. Estimated Prevalence of Alzheimer's Disease in the United States, *Milbank Quarterly*. 1990;68:267-289.

⁶ Practice parameter: early detection of dementia: mild cognitive impairment (an evidence-based review). Report of the Quality Standards Subcommittee of the American Academy of Neurology. National Guideline Clearinghouse.

http://www.guideline.gov/summary/summary.aspx?doc_id=2816&nbr=2042&string=Alzh...

⁷ Id.

⁸ Guideline for Alzheimer's disease management. California Workgroup on Guidelines for Alzheimer's Disease Management. Los Angeles (CA0: Alzheimer's Association of Los Angeles, Riverside and San

In sum, in order to ensure that Medicare beneficiaries receive a comprehensive preventive examination, we urge CMS to amend the proposed rule to make clear that screening and assessment of mental status, cognitive function and behavioral changes, when undertaken as part of such an initial preventive physical examination, are Medicare covered services.

We are also concerned that the proposed rule may not give physician's the flexibility they need to use the assessment and diagnostic tools most appropriate for each patient. Although physicians can diagnose Alzheimer's disease with a great degree of certainty, unlike some other chronic illnesses such as cancer or diabetes, there is no single test that is conclusive. Clinicians use a series of neuropsychological tests to distinguish normal aging, mild cognitive impairment, Alzheimer's disease or depression. For example, while the Mini-mental Status Exam (MMSE) is the most widely used screening instrument for cognition, it is by no means the only tool. There are also numerous tests that provide "global" assessment of the patient's overall condition, including cognitive status. Certain tests will be more appropriate than others depending on how the patient presents, the patient's history, etc. We believe that physicians and other qualified clinicians are in the best position to make clinical judgments regarding which tests and assessment tools should be used for each patient. Given the extent to which national standard setting organizations are involved in the evaluation and validation of various screening tools, we do not believe it is appropriate (or necessary) to use a National Coverage Determination (NCD) to direct physicians to a particular instrument.

Accordingly, given the discussion above, we are recommending the following changes to the proposed rulemaking:

(1) To ensure that clinicians include a screening assessment of mental status, cognitive function and behavioral changes as part of the Medicare covered initial preventive physical examination, the definition of "*Review of the individual's functional ability and level of safety*" at Section 410.16(a) should be amended to add "*mental status*" "*cognitive function*" and "*behavioral changes*" as follows:

Review of the individual's functional ability and level of safety. Review of the individual's functional ability and level of safety must include, at a minimum, a review of the following areas:

- (1) Hearing impairment.
- (2) Activities of daily living
- (3) Falls risk.
- (4) Home safety.
- (5) Mental status
- (6) Cognitive function
- (7) Behavioral changes

Bernardino Counties; 2002 Jan, 1. 52p. National Guideline Clearinghouse.
http://www.guideline.gov/summary/summary.aspx?doc_id=3157&string=Alzh . . .

(2) To ensure that clinicians undertake a comprehensive medical history that is designed to assess a beneficiary's risk of developing dementia or Alzheimer's disease, the definition of "medical history," at Section 410.16(a) should be amended to add "head trauma" as follows:

Medical history is defined to include, at a minimum, the following:

(1) Past medical and surgical history, including experiences with illnesses, hospital stays, operations, allergies, injuries (including head trauma) and treatments.

(3) Change Section 410(a)(3) to read as follows:

Review of the individual's functional and cognitive ability, and level of safety, based on the use of clinically appropriate screening and assessment instruments, which the physician or other qualified non-physician practitioner may select

Again, thank you for this opportunity to comment on the proposed rule. If you have any questions, please do not hesitate to contact me.

Yours sincerely,

Joanne M. Bell, PhD
Senior Director
CNS Medical Affairs
Forest Research Institute

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Therapy--"Incident to"

Dear Sirs,

I strongly support the proposed regulation that therapy services "incident to" physicians's services be provided by qualified individuals. Having served on the licensing board of the State of Maryland for Physical Therapy, I had noted many occurrences where physical therapy was provided in physicians' office by unqualified personnel. This is extremely unfair to the individuals receiving therapy, they deserve quality services. This regulation would be a step forward in preventing future incidences where Medicare patients would not be receiving quality care.

Sincerely,

William D. Hodges, PT

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I am commenting on the August 5 proposed rule on Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005.

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1429-P
P.O. Box 8012
Baltimore, MD 21244-8012

Dear Dr. McClellan,

I am a student of physical therapy at the University of Puget Sound in the final year of my DPT program. I am writing because I wish to comment on the August 5 proposed rule on "Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005." As part of my education I have received extensive education on how to make the best evidence based decisions regarding patient care. It is largely for this reason that I support CMS's proposed requirement that anyone providing physical therapy services "incident to" a physician be graduates of accredited professional physical therapist programs. Only individuals with a physical therapy education have the skills to properly choose the most effective physical therapy intervention.

Prior to physical therapy school, and early on in my program I worked as a physical therapy aide. As part of my job I administered limited physical therapy treatments under supervision. Although I was trained how to do these treatments, I did not at the time know why they were chosen. That is the problem I see with allowing unqualified persons to perform and bill for "physical therapy." They may know what to do, but they may not know why it is being done, and they will not be able to identify the best treatment for the patient. This would make care very inefficient, and greatly reduce the effectiveness of treatment.

Thank you for your consideration of these comments.

Sincerely,

Bart Hawkinson SPT

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

GENERAL

GENERAL

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

RE: CMS-1429-P

Dear Dr. McClellan:

As a hematologist who treats patients with chemotherapy and other pharmaceutical treatments in my office, I write to comment on the proposed revisions to the physician fee schedule for 2005. I am particularly concerned that in the proposed rule, CMS fails to provide hematologists and other physicians affected by the Average Sales Price (ASP) methodology with clear and reliable information upon which to make decisions about our practices for 2005 and beyond.

Section 303-Outpatient Drugs and Biologicals

I am seriously concerned that CMS has not provided affected physicians with the opportunity to comment on the proposed payment allowances for drugs in 2005. CMS has identified tentative payment allowances for only a handful of drugs omitting many of the drugs commonly used by hematologists. Why has CMS not at least provided tentative prices for all of the covered Part B drugs. If, in fact, the complexity of the calculation of ASP is the reason why data was provided only for a few drug products, it is all the more reason why comments from affected physicians are necessary. Moreover, for the limited number of drugs provided, the prices do not reflect the data for the actual period that will be used to calculate the ASP rate; i.e., the 3rd quarter of 2004 but reflects data for an earlier period.

As CMS notes in the rule, drugs constitute a very significant portion of the revenues received by oncologists, in the range of 70 percent. This would include hematologists with large oncology practices. The inability to evaluate and comment on the adequacy of the proposed payment level prior to implementation of the changes January 1, 2005, is a major deficiency of the rule. What business can possibly operate in that kind of environment? Not knowing what will be paid for the majority of our services makes it virtually impossible for a practice to plan ahead. Physicians will not truly know (1) if they can afford to continue to provide chemotherapy to Medicare patients in an office setting, (2) to what extent they will need to reduce staff, close satellite offices, etc., and (3) whether they will need to change their purchasing practices, including possibly referring patients to hospitals for these services or buy the drugs on their own and bring them to the office.

Based on a review of the hematology-related drugs for which estimated ASP prices were provided, I am concerned about my practice's ability to continue to provide all needed drugs to patients. Although I use a group purchasing organization to buy drugs, there are several drugs for which I am currently paying more than the estimated ASP. It appears that CMS is basing the ASP rate on the sales data reported by manufacturers without regard to whether the product was sold to a hospital or other large purchasing group. I understand that the Congress believes that the ASP rate should reflect the prices actually paid by practicing physicians and that the 6% increment was adequate to cover the variability in the prices paid plus other costs such as inventory costs and wastage. Unfortunately, based on my review of the ASP prices, the proposed payment rate is clearly inadequate.

I urge CMS to delay the implementation of the ASP system for at least one year. CMS needs to develop ASP data that reflects the amounts actually paid by physicians for drugs. And, before the system is finally implemented, CMS needs to provide physicians with the opportunity to comment on the proposed payment rates for the drugs that are covered under this system.

Sincerely yours,
Dr. Kelty R. Baker
Baylor College of Medicine
6565 Fannin, MS 902
Houston, Texas 77030
713-441-2127

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

GENERAL

GENERAL

see attached file



**Department of Health and Human Services
Centers for Medicare and Medicaid Services (CMS)
Offices of Strategic Operations and Regulatory Affairs**

The attachment to this document is not provided because:

1. The document was improperly formatted.
2. The submitter intended to attach more than one document, but not all attachments were received.
3. The document received was a protected file and can not be released to the public.
4. The document was not available electronically at this time. If you like to view any of the documents that are not posted, please contact CMS at 1-800-743-3951 to schedule an appointment.

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I am a physical therapist in Minnesota. We have worked as an outpatient and an inpatient service for the last 23 years. We have practiced and worked with Medicare for all types of services including orthopedic and general issues.

I would like to come out in strong support of the proposed Amendment. In particular, physical therapy has long been a supporter for health amongst the elderly. We have been well educated in these management issues and have worked within the nursing home setting to best care for these individuals. Our practice is best used for the rehabilitation of these individuals.

There are other professionals who wish to be part of this utilization of services. When physical therapy orders are often provided to clinics there has been influx of athletic trainers in that setting. All athletic trainers are very good at dealing with orthopedic type injuries and athletic type injuries. They are not provided a lot of clinical time nor school time to disease management in general, especially for an elderly population. They in effect are not the best professionals to treat these ailments. I also believe that the athletic training should be separated out to the point where they are not allowed to be part of any physical therapy type setting.

I believe the best utilization of rehab services for the elderly is with the physical therapy management as we have provided those services over the years and best understand those issues. I would strongly stay in support of the proposed rules.

In closing, I would like to thank the administrator for considering these comments, and I would be happy to continue to support this cause in the future.

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 1-9

SECTION 303

Please see attached comments

SECTION 611

Plese see attached comments

CMS-1429-P-4007-Attach-1.doc

CMS-1429-P-4007-Attach-4.doc

CMS-1429-P-4007-Attach-3.doc

CMS-1429-P-4007-Attach-2.doc

CMS-1429-P-4007-Attach-4.doc

CMS-1429-P-4007-Attach-2.doc

CMS-1429-P-4007-Attach-1.doc

CMS-1429-P-4007-Attach-3.doc



24 September 2004

Mark D. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services (CMS)
200 Independence Avenue SW
Room 214-G
Washington, DC 20201

Re: APOS Comments on the Proposed Rules for the MMA

Dear Dr. McClellan:

We are writing on behalf of our fellow members in the American Psychosocial Oncology Society (APOS) to comment on the proposed rules for the Medicare Drug, Modernization and Improvement Act (MMA). We are a non-profit professional organization, comprised of over 375 psychiatrists, psychologists, nurses, social workers and allied health professionals who specialize in assessment and treatment of the significant psychosocial burdens of cancer. More than 50% of patients who have cancer suffer from depression, anxiety and the effects of intense psychosocial distress. There is a high prevalence of co-occurring medical and psychiatric disorders among Medicare eligible citizens. Studies have shown that these individuals experience increased morbidity and mortality in their medical condition when their access to essential mental health services is limited. Conversely, when timely identification of and intervention with co-occurring psychiatric conditions are made, patients have better outcomes in the treatment of their medical disorders, reduced cost associated with chronic and disabling conditions, and higher productivity and quality of life.

Because of our concern for the patients for whom we care, we are collaborating with Treatment Effectiveness Now (TEN Project) and other professional and advocacy organizations to provide comments on two important elements of the proposed physician fee schedule for calendar year 2005: the scope of services provided as part of the initial preventive physical examination and reimbursement for chemotherapy services. We join others, including the American Psychiatric Association (APA), the National Coalition of Cancer Survivors (NCCS) and the Academy of Psychosomatic Medicine (APM) in bringing these issues to your attention.

The report of President Bush's New Freedom Commission on Mental Health cites the critical importance of Medicare and Medicaid reform to improving the quality and accessibility of mental health service delivery through support of evidence-based treatments. The Report states: "Any effort to strengthen or improve the Medicare and Medicaid programs should offer

beneficiaries options to effectively use the most up-to-date treatments and services.” Furthermore, the report calls attention to the un-met mental health needs of patients with chronic medical illnesses.¹

The MMA provides an important opportunity to provide appropriate screening and treatment for depression in the medical setting. We would like to offer comments on the proposed rule which we feel can clarify, support and strengthen the intent of the MMA in providing needed, cost-effective care to citizens with both medical and psychiatric illness, including those with cancer.

We support the comments that the TEN Project recently sent to you on the proposed MMA rules and implementation. We wish further to underscore the following points which are of high significance to our patient constituents and professional colleagues:

Comment on Section 611: Initial Preventive Physical Examination

Section 611 of the MMA provides for Medicare Part B coverage of an initial preventive physical exam for new beneficiaries for services furnished on or after 1 January 2005. CMS proposes to add a new provision that would provide coverage for certain services as part of an initial preventive physical examination in a number of settings, including in the hospital outpatient department. Among other categories, CMS has proposed to include:

- “(2) Review of the individual's potential (risk factors) for depression (including past experiences with depression or other mood disorders) based on the use of an appropriate screening instrument, which the physician or other qualified nonphysician practitioner may select from various available standardized screening tests for this purpose, unless the appropriate screening instrument is defined through the national coverage determination (NCD) process”
- “(6) Education, counseling, and referral, as deemed appropriate, based on the results of elements (1) through (5) of the proposed definition of the initial preventive physical examination.”

In support of this we would like to offer the following comments:

1. The President’s New Freedom Commission on Mental Health has stated that mental health should be treated with the same urgency as physical health and as such has made a series of recommendations acknowledging the primary care office as the “de facto” mental health system for most patients in this country. Early recognition and treatment of depression will have a positive impact on medical, mental and economic outcomes.
 - We would encourage CMS to clarify that the assessment includes consideration of both the *potential* for depression, as well as the assessment of *current depression* status. While we believe that this is the intent of the rule, the proposed language refers to assessing “potential (risk factors) for depression” but not to assessing current depression status per se.

- We concur with the recommendation that “an appropriate screening instrument” be used for the assessment of depression. However, we would suggest that a limited number of screening instruments be utilized to maximize clinical utility and transportability. For example, the 9-item Patient Health Questionnaire (PHQ-9) has now been well validated in several studies with medically ill patients as a diagnostic screen for depression.² It can provide both a diagnosis and also a severity rating, and is easy to use.
 - Furthermore, we believe that coverage for conducting and interpreting the PHQ-9 (or other appropriate depression screening tool) through the NCD process would be a critical component to assuring that physicians comply with the screening component of the preventive exam. We would welcome the opportunity to work with CMS to move forward an NCD determination for screening of depression.
2. Evidence suggests that screening for depression in and of itself does not positively impact depression outcomes. The United States Preventive Services Task Force recently reported that depression screening is primarily effective if patients who screen positive are *referred for appropriate treatment*.³ We commend CMS on including a provision that allows for counseling and referral based on the evidence of depression in the initial preventive physical examination. However, we also know that the barriers to receiving psychiatric intervention are numerous and must be considered in order to assure that patients receive appropriate treatment.
- We believe that greatest impact would occur if the rule were to include specific language stressing the importance of referring patients who screen positive for depression to appropriate treatment and the recommendation to monitor depression outcomes over time.
3. Once depression is identified, disease management, collaborative care and direct provision of appropriate psychiatric and psychosocial care are effective in improving medical and psychosocial outcomes. Furthermore, the President’s New Freedom Commission report in Recommendation 4.4 states: “Screen for mental disorders in primary health care, across the life span and connect to treatment and supports.” In addition, it states: “Collaborative care models should be widely implemented in primary health care settings and reimbursed by public and private insurers.” Currently, key elements of collaborative care-particularly nurse care management, and the collaboration between the care manager and primary and mental health specialty providers, are at best partially reimbursable under Medicare. The TEN Project, along with the American Psychiatric Association and the Academy of Psychosomatic Medicine are currently engaged in an evaluation of the current diagnostic, procedural and contractual barriers to receiving mental health services in the primary care setting, we would welcome the opportunity to share the outcome of this work with you.
- Therefore, we would recommend that CMS clarify the appropriate coding procedures to be utilized in order to be reimbursed for these services. We will be glad to provide

- additional information regarding our analysis of coding practices and reimbursement to CMS in order to address this.
- We would also encourage CMS utilize this opportunity to respond to the President's New Freedom Commission Report to develop strategies to assure that collaborative care models can be adequately reimbursed.
4. In addition, we would concur with the NCCS (see attached), which recommends that the preventive examination be expanded to include review of the individual's risk factors for cancer, including a review of the individual's past cancer diagnoses and treatment. Patients with cancer have high rates of mental disorders and distress which impair their functioning long after initial treatments end. The National Cancer Center Network, in its 2003 standards of care , addresses the need to assess and treat distress for all patients throughout and beyond their cancer illness and furthermore to utilize evidence based interventions when interventions are indicated.⁴ The Institute of Medicine in two reports, *Improving Palliative Care for Cancer*, and *Meeting Psychosocial Needs of Women with Breast Cancer*, has affirmed that available practice guidelines "should dictate the standard of care for both physical and psychosocial symptoms."^{5,6} In addition to supporting the NCCS recommendations we would also suggest:
- In addition to the depression screen, patients with a history of cancer should also be screened for cancer related distress through an appropriate screening instrument for the assessment of distress in patients with a history of cancer. Several screening instruments have been tested and validated in this patient population and can be utilized.⁷
 - We also encourage CMS to urge development of and referral to psychosocial services provided by mental health professionals who have expertise in the treatment of patients with chronic medical illnesses, such as cancer.

Section 303—Payment Reform for Covered Outpatient Drugs and Biologicals

Over 50% of cancer patients have evidence of psychiatric disorders or psychosocial distress. Only 10% receive attention to these mental health issues, much of that care is delivered in the oncology treatment setting as part of the supportive services patients receive related to chemotherapy administration. Therefore, the TEN Project is also carefully monitoring the changes in reimbursement for cancer care delivered in the physician's office that were mandated by the MMA and their potential effects on the quality of cancer care. Medicare payments for the services provided as part of chemotherapy administration must be adequate if quality care is to remain available in the community, where patients have become accustomed to receiving their treatment and prefer to be treated.

A range of services, including support services, are delivered in the oncologist's office. These services are considered a vital part of quality cancer care. These services include access to dedicated mental health professionals with expertise in the care of cancer patients who provide psychiatric and psychosocial interventions. Cancer care is a multi-disciplinary endeavor, and

elimination of any of the services that are part of the cancer care experience will have a negative impact on quality of care.

It is our hope that the modification of chemotherapy codes will yield a proposal for the addition of codes, including but not limited to a cancer management code as well as a code that could be used in the provision of psychosocial services to patients with a cancer diagnosis, which could form the basis for providing adequate reimbursement for the services that are part of chemotherapy administration. We realize that some of the services that we consider to be an integral part of cancer care have not been recognized traditionally by Medicare as covered services, but we strongly urge flexibility in establishing codes that will guarantee payment for all essential cancer care services.

In conclusion, we strongly urge you to consider the inclusion of language within the regulations that allows for these considerations in implementing this benefit. We would welcome the opportunity to meet and speak with you and to review findings that support our recommendations.

Sincerely,

A handwritten signature in cursive script that reads "Alan Valentine".

Alan Valentine, MD

President

American Psychosocial Oncology Society

References:

1. New Freedom Commission on Mental Health, *Achieving the Promise: Transforming Mental Health Care in America*. Final Report. DHHS Pub. No. SMA-03-3832. Rockville, MD: 2003.
2. Kroenke K, Spitzer RL, Williams JB. (2001). "The PHQ9: validity of a brief depression severity measure." *J Gen Intern Med*. 16(9):606-13.
3. Pignone MP, Gaynes BN, Rushton JL, Burchell CM, Orleans CT, Mulrow CD, Lohr KN (2002). "Screening for depression in adults: a summary of the evidence for the U.S. Preventive Services Task Force. *Ann Intern Med*. 2002 May 21;136(10):765-76.
4. Holland JC, Andersen B, Booth-Jones M, et al. NCCN Distress Management Clinical Practice Guidelines in Oncology. *Journal of the NCCN* 2003;1:344-74.
5. Foley KM, Gelband H, eds. *Improving Palliative Care for Cancer*, [Report of the National Cancer Policy Board/Institute of Medicine and National Research Council]. Washington, DC: The National Academies Press: 2001.
6. Hewitt M, Herdman R, Holland JC. (Eds.). *Meeting Psychosocial Needs of Women with Breast Cancer*. [Report of the National Cancer Policy Board/Institute of Medicine and National Research Council]. Washington, DC: The National Academies Press: 2004.
7. Holland JC, Andersen B, Booth-Jones M, et al. NCCN Distress Management Clinical Practice Guidelines in Oncology. *Journal of the NCCN* 2003;1:344-74.

September 24, 2004

Dr. Mark McClellan
Administrator
Centers for Medicare & Medicaid Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: CMS -1429-P; Revisions to Payment Policies Under the Physician Fee
Schedule for Calendar Year 2005

Dear Dr. McClellan:

The National Coalition for Cancer Survivorship (NCCS), an organization representing survivors of all forms of cancer, is pleased to have this opportunity to comment on two important elements of the proposed physician fee schedule for calendar year 2005: reimbursement for chemotherapy services and the scope of services provided as part of the initial preventive physical examination.

Section 303—Payment Reform for Covered Outpatient Drugs and Biologicals

Because NCCS is committed to ensuring cancer survivors access to quality cancer care, we are carefully monitoring the changes in reimbursement for cancer care delivered in the physician's office that were mandated by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and their potential effects on the quality of cancer care. Medicare payments for the services provided as part of chemotherapy administration must be adequate if quality care is to remain available in the community, where patients have become accustomed to receiving their treatment and prefer to be treated.

NCCS can offer expert commentary regarding office-based cancer care, because the vast majority of the survivors we represent received, or are receiving, their care in an oncologist's office. On the basis of our experience, we can describe the kinds of services that we receive from our oncologists as part of chemotherapy administration, as well as the range of support services that we consider a vital part of quality cancer care. Those services include: consultation with our oncologists regarding therapeutic options and modifications in treatment regimens, as well as the review of medications and interventions necessary to manage the side effects of treatment; services of oncology nurses during chemotherapy administration and in devising strategies for addressing the immediate and long-term effects of treatment; discussions with oncologists and oncology nurses regarding opportunities for enrollment in clinical trials and assistance with enrolling in a trial, if that is the best treatment option; and other professional services that may include nutritional counseling and psychosocial counseling. Cancer care is a

multi-disciplinary endeavor, and elimination of any of the services that are part of the cancer care experience will have a negative impact on quality of care. We seek a system of care that includes the appropriate management of symptoms, including palliative care, from the time of diagnosis. We believe that cancer survivors receiving well-integrated and comprehensive cancer care will be equipped to make informed decisions from the time of diagnosis to the end of life, but the reimbursement system must support such care.

We are aware of the ongoing discussions between the provider community and the Centers for Medicare & Medicaid Services (CMS) regarding additions and modification of codes for chemotherapy-related services. It is our hope that this process will yield a proposal for the addition of codes, including but not limited to a cancer management code, that could form the basis for providing adequate reimbursement for the broad range of multi-disciplinary services, as described above, which are part of providing quality cancer care. We realize that some of the services that we consider an integral part of cancer care have not been recognized traditionally by Medicare as covered services, but we strongly urge flexibility in establishing codes that will guarantee payment for all essential cancer care services.

We urge CMS to take bold action to reform the system of payment for cancer care services. The proposed rule acknowledges the possibility of coding modifications and additions, and we strongly recommend that CMS take aggressive action to reform cancer care payments, prevent immediate disruptions in access to care, and ensure a viable system of quality cancer care for the long term.

Section 611 – Initial Preventive Physical Examination

NCCS applauds the action by Congress to provide Medicare coverage of an initial preventive physical examination. This Congressional effort, necessary because of the Medicare exclusion of preventive services, ensures that beneficiaries will have access to preventive counseling and referral to appropriate Medicare Part B screening services. The proposed rule defines the initial preventive physical examination to include many, but not all, of the screening and preventive services that Medicare beneficiaries should receive at the time of program enrollment.

NCCS recommends that the examination be expanded to include review of the individual's risk factors for cancer, including a review of the individual's past cancer diagnoses and treatment. As many as 60% of cancer diagnoses are among those of Medicare age, and it is critically important that the new initial physical be utilized to identify those who may be at high risk for developing cancer as well as those, already diagnosed and treated for cancer, who may be at risk of recurrence or for late and long-term effects from their treatment.

The examination includes the development of a written plan for the individual to obtain the preventive services that are separately covered under Medicare Part B, including screening mammography, screening pap smear and screening pelvic exams, and prostate cancer screening. However, seniors are also at risk for other forms of cancer for which screening tests do not exist. For this reason, there must be a strong emphasis on the review of risk factors for all forms of cancer. In addition, this review should include an evaluation of previous cancer diagnoses and treatments. Cancer survivors may experience a wide range of late and long-term effects of

cancer and its treatment. Cancer chemotherapy and radiation may cause cancer survivors to have second malignancies, as well as pulmonary, cardiovascular, and musculoskeletal complications. Surgical treatment of cancer may also result in long-term effects.

Our key concern is guaranteeing that the initial physical examination serves as an important introduction for the Medicare beneficiary to the full range of services provided by Medicare and results in his or her referral for appropriate services; for cancer survivors that may mean referral for ongoing monitoring and treatment for the effects of cancer and its treatment. We also believe that evaluation of the patient and identification of necessary services at the time of Medicare enrollment will result in a more rational use of Medicare services.

The National Cancer Institute (NCI) is making a substantial investment in programs that are aimed at improving the timely delivery of cancer prevention, diagnosis, and treatment services to underserved populations. The NCI has identified a number of barriers to appropriate cancer care, including the delay from the time of abnormal findings to access to care. NCI-funded programs are intended to eliminate that delay.

We recommend that CMS policies be consistent with those of the NCI with regard to removing barriers to prompt and appropriate cancer care. One means of achieving this goal is to expand the services that will be available through the initial physical examination to include review of risk factors for cancer.

We recommend that the definition of the initial prevention physical examination benefit be modified by addition of the following language:

Review of the individual's risk factors for cancer (including previous diagnoses and treatment for cancer) based on an appropriate screening instrument. A core element of this review will be obtaining a full medical and social history, with special emphasis on prior treatment for cancer. The review may result in a written plan for obtaining appropriate screening and other preventive services, referral for appropriate care, or patient education regarding an ongoing monitoring plan.

Conclusion

Modification and addition of codes for chemotherapy and related support services will help ensure that payments for cancer care are adequate and that access to quality care in the community is not compromised. A modest enhancement of the activities that are part of the initial preventive physician examination has the potential to improve quality of life for cancer survivors and remove obstacles to timely access to cancer care.

Sincerely,

Ellen L. Stovall

Dr. Mark McClellan

1/28/2005

Page 4

Treatment Effectiveness Now

September 24, 2004

Mark D. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue SW
Room 214-G
Washington, DC 20201

Dear Dr. McClellan:

We are writing as Executive Board members of Treatment Effectiveness Now (the TEN Project). The TEN Project is a private, non-profit policy action organization, dedicated to educating public officials, advocates and professionals about the clinical and policy implications of evidence-based treatment for co-occurring medical and psychiatric disorders. There is a high prevalence of co-occurring medical and psychiatric disorders among Medicare beneficiaries. Consequently, the TEN Project is working with leaders of patient advocacy and professional organizations (mental and physical health), to provide comments on two important elements of the proposed physician fee schedule for calendar year 2005: the scope of services provided as part of the initial preventive physical examination and reimbursement for chemotherapy services. We join others, such as the National Coalition of Cancer Survivors (NCCS) and the American Psychiatric Association (APA) in bringing these issues to your attention.

The report of President Bush's New Freedom Commission on Mental Health (1) cites the critical importance of Medicare and Medicaid reform to improving the quality and accessibility of mental health service delivery through support of evidence-based treatments. The Report states: "Any effort to strengthen or improve the Medicare and Medicaid programs should offer beneficiaries options to effectively use the most up-to-date treatments and services." Furthermore, the report calls attention to the un-met mental health needs of patients with chronic medical illnesses.

Mental Illness in Patients with Chronic Medical Illness

Of the over 18 million adults in this country with a chronic medical condition (eg. Hypertension, diabetes, cancer etc.) more than half have evidence of a mental disorder. Patients may have evidence of mood and anxiety disorders, delirium or significant levels of psychosocial distress which greatly contribute to their health status and quality of life. Studies have shown that these patients' medical conditions appear to be worsened in the presence of mental illness and that they consequently utilize proportionately greater resources in their medical and psychiatric care. However, research indicates that when the mental illness and distress are addressed the medical conditions improve and costs are reduced. Yet, less than half of those patients presenting to their primary care physicians with evidence of a mental disorder are diagnosed, and even with diagnosis only half receive adequate treatment.

The MMA provides an important opportunity to provide appropriate screening and treatment for depression in the medical setting. We would like to offer comments on the proposed rule which we feel can clarify, support and strengthen the intent of the MMA in providing needed, cost-effective care to citizens with both medical and psychiatric illness.

Comment on Section 611: Initial Preventive Physical Examination

Section 611 of the MMA provides for Medicare Part B coverage of an initial preventive physical exam for new beneficiaries for services furnished on or after January 1, 2005. CMS proposes to add a new provision that would provide coverage for certain services as part of an initial preventive physical examination in a number of settings, including in the hospital outpatient department. Among other categories, CMS has proposed to include:

The TEN Project

In Partnership with the Department of Psychiatry, Georgetown University School of Medicine
750 17th St., NW, Washington, DC 20006 p 202.778.2373 f 202.778.2330

- “(2) Review of the individual's potential (risk factors) for depression (including past experiences with depression or other mood disorders) based on the use of an appropriate screening instrument which the physician or other qualified nonphysician practitioner may select from various available standardized screening tests for this purpose, unless the appropriate screening instrument is defined through the national coverage determination (NCD) process”
- “(6) Education, counseling, and referral, as deemed appropriate, based on the results of elements (1) through (5) of the proposed definition of the initial preventive physical examination.”

In support of this we would like to offer the following comments:

1) The President's New Freedom Commission on Mental Health has stated that mental health should be treated with the same urgency as physical health and as such has made a series of recommendations acknowledging the primary care office as the “de facto” mental health system for most patients in this country. Early recognition and treatment of depression will have a positive impact on medical, mental and economic outcomes.

- We would encourage CMS to clarify that the assessment includes consideration of both the *potential* for depression, as well as the assessment of *current depression* status. While we believe that this is the intent of the rule, the proposed language refers to assessing “potential (risk factors) for depression” but not to assessing current depression status per se.
- We concur with the recommendation that “an appropriate screening instrument” be used for the assessment of depression. However, we would suggest that a limited number of screening instruments be utilized to maximize clinical utility and transportability. For example, the 9-item Patient Health Questionnaire (PHQ-9) has now been well validated in several studies with medically ill patients as a diagnostic screen for depression (2). It can provide both a diagnosis and also a severity rating, is easy to use.
- Furthermore, we believe that coverage for conducting and interpreting the PHQ-9 (or other appropriate depression screening tool) through the NCD process would be a critical component to assuring that physicians comply with the screening component of the preventive exam. We would welcome the opportunity to work with CMS to move forward an NCD determination for screening of depression.

2) Evidence suggests that screening for depression in and of itself does not positively impact depression outcomes. The United States Preventive Services Task Force (3) recently reported, that depression screening is primarily effective if patients who screen positive are *referred for appropriate treatment*. We commend CMS on including a provision which allows for counseling and referral based on the evidence of depression in the initial preventive physical examination. Once depression is identified, disease management, collaborative care and direct provision of appropriate psychiatric and psychosocial care are effective in improving medical and psychosocial outcomes.

- We believe that in order for the depression screen to be effective, specific language needs to be included stressing the importance of appropriate treatment, including referral to mental health specialists when indicated, and the recommendation to monitor depression outcomes over time to ensure the treatment is effective.
- We also know that the barriers to receiving psychiatric care, which include but are not limited to the outpatient mental health treatment limitation which requires beneficiaries to pay more for mental health care than medical care are numerous and must addressed in order to assure that patients receive appropriate treatment.

3) Once depression is identified, disease management, collaborative care and direct provision of appropriate psychiatric and psychosocial care are effective in improving medical and psychosocial outcomes. Furthermore, the President's New Freedom Commission report in Recommendation 4.4 states: “Screen for mental disorders in primary health care, across the life span and connect to treatment and supports.” In addition it states: “Collaborative care models should be widely implemented in primary health care settings and reimbursed by public and private insurers.” Currently key elements of

collaborative care-particularly nurse care management, and the collaboration between the care manager and primary and mental health specialty providers, are at best partially reimbursable under Medicare. The TEN Project, along with the American Psychiatric Association and the Academy of Psychosomatic Medicine are currently engaged in an evaluation of the current diagnostic and procedural barriers to receiving mental health services in the primary care setting, we would welcome the opportunity to share the outcome of this work with you.

- Consequently, we recommend that CMS clarify the appropriate coding procedures to be utilized in order to be reimbursed for these services; and
- We would also encourage CMS utilize this opportunity to respond to the President's New Freedom Commission Report to develop strategies to assure that collaborative care models can be adequately reimbursed.

4) In addition, we would concur with the NCCS (see attached) which recommends that the preventive examination be expanded to include review of the individual's risk factors for cancer, including a review of the individual's past cancer diagnoses and treatment. Patients with cancer have high rates of mental disorders and distress which impair their functioning long after initial treatments end. The National Cancer Center Network, in its 2003 standards of care (4), address the need to assess and treat distress for all patients throughout and beyond their cancer illness and furthermore to utilize evidence based interventions when interventions are indicated. The Institute of Medicine in two reports, *Improving Palliative Care for Cancer*, and *Meeting Psychosocial Needs of Women with Breast Cancer* (5, 6), have both affirmed that available practice guidelines "should dictate the standard of care for both physical and psychosocial symptoms." In addition to supporting the NCCS recommendations we would also suggest:

- In addition to the depression screen, patients with a history of cancer should also be screened for cancer related distress through an appropriate screening instrument for the assessment of distress in patients with a history of cancer. Several screening instruments have been tested and validated in this patient population and can be utilized (4).
- We also encourage CMS to urge development of and referral to psychosocial services provided by mental health professionals who have expertise in the treatment of patients with chronic medical illnesses, such as cancer.

Section 303—Payment Reform for Covered Outpatient Drugs and Biologicals

Over 50% of cancer patients have evidence of psychiatric disorders or psychosocial distress. And while and only 10% receive attention to these mental health issues, much of that care is delivered in the oncology treatment setting as part of the supportive services patients receive related to chemotherapy administration. Therefore, the TEN Project is also carefully monitoring the changes in reimbursement for cancer care delivered in the physician's office that were mandated by the MMA and their potential effects on the quality of cancer care. Medicare payments for the services provided as part of chemotherapy administration must be adequate if quality care is to remain available in the community, where patients have become accustomed to receiving their treatment and prefer to be treated.

A range of services, including support services are delivered in the oncologist's office. These services are considered a vital part of quality cancer care. These services include access to dedicated mental health professionals with expertise in the care of cancer patients who provide psychiatric and psychosocial interventions. Cancer care is a multi-disciplinary endeavor, and elimination of any of the services that are part of the cancer care experience will have a negative impact on quality of care.

It is our hope that the modification of chemotherapy codes will yield a proposal for the addition of codes, including but not limited to a cancer management code as well as a code which could be used in the provision of psychosocial services to patients with a cancer diagnosis, that could form the basis for providing adequate reimbursement for the services that are part of chemotherapy administration. We realize that some of the services that we consider an integral part of cancer care have not been

The TEN Project

In Partnership with the Department of Psychiatry, Georgetown University School of Medicine
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recognized traditionally by Medicare as covered services, but we strongly urge flexibility in establishing codes that will guarantee payment for all essential cancer care services.

We respectfully request that you to incorporate these comments into the rules that will guide implementation of the MMA. We believe there is an important opportunity at hand to improve substantially the health outcomes for patients who have these co-occurring disorders, reducing morbidity, mortality and the associated productivity and treatment costs.

We thank you for your consideration and stand ready to assist you and your staff at CMS in implementation of the MMA and its associated provisions.

Sincerely,

Carol L. Alter, M.D.
Executive Director

Danna Mauch, Ph.D
President

References:

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Academy of Psychosomatic Medicine

The Organization for Consultation and Liaison Psychiatry

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September 24, 2004

Mark D. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue SW
Room 214-G
Washington, DC 20201

Dear Dr. McClellan:

We are writing on behalf of our fellow members in the Academy of Psychosomatic Medicine (the Academy) to comment on the proposed rules for the Medicare Drug, Modernization and Improvement Act (MMA). We are a private, non-profit professional organization, comprised of over 800 psychiatrists engaged in the treatment of persons who have co-morbid medical and psychiatric illnesses, within primary and specialty medical care settings. More than half, or 9 million of the over 18 million adults in this country with a chronic medical condition (e.g. hypertension, diabetes, cancer etc.), have a mental disorder which impacts on their daily life functioning and health status. There is a high prevalence of co-occurring medical and psychiatric disorders among Medicare eligible citizens. Patients may have evidence of mood and anxiety disorders, delirium or significant levels of psychosocial distress which undermine their health status and quality of life. Studies have shown that these individuals experience increased morbidity and mortality in their medical condition when their access to essential mental

health services is limited. Conversely, when timely identification of and intervention with co-occurring psychiatric conditions are made, patients have better outcomes in the treatment of their medical disorders, reduced cost associated with chronic and disabling conditions, and higher productivity and quality of life.

Because of our concern for the patients for whom we care, we are collaborating with the Treatment Effectiveness Now (TEN) Project and other professional and advocacy organizations to provide comments on two important elements of the proposed physician fee schedule for calendar year 2005: the scope of services provided as part of the initial preventive physical examination and reimbursement for chemotherapy services. We join others, including the American Psychiatric Association (APA), the National Coalition of Cancer Survivors (NCCS) and the American Psycho-oncology Society (APOS) in bringing these issues to your attention.

The Academy applauds the Report of President Bush's New Freedom Commission on Mental Health citing the critical importance of Medicare and Medicaid Reform to improving the quality and accessibility of mental health service delivery through support of evidence-based treatments. The Report states: "Any effort to strengthen or improve the Medicare and Medicaid programs should offer beneficiaries options to effectively use the most up-to-date treatments and services." Furthermore, the President's New Freedom Commission report calls attention to the un-met mental health needs of patients with chronic medical illnesses.

The President's New Freedom Commission recognized that access to and reimbursement for appropriate medical, psychiatric and other mental health services is severely limited for these doubly-burdened, co-morbidly ill patients, despite an abundance of evidence that intervention results in positive economic and clinical outcomes. The MMA provides an important opportunity to provide appropriate screening and treatment for depression in the medical setting. We offer comments on the proposed rule which we believe can clarify, support and strengthen the intent of the MMA in providing needed, cost-effective care to citizens with both medical and psychiatric illness.

We support the comments that the TEN Project recently sent to you on the proposed MMA rules and implementation. We wish further to underscore the following points which are of high significance to our patient constituents and professional colleagues:

Comment on Section 611: Initial Preventive Physical Examination

- CMS should move forward with the implementation of a one-time preventative physical examination for new Medicare beneficiaries which includes depression screening. CMS should clarify that the assessment includes consideration of both the *potential* for depression, as well as the assessment of a patient's *current depression* status.
- The Academy welcomes the opportunity to work with our colleagues and CMS on the identification of an appropriate depression screening tool(s) and advocates the consideration of such a tool(s) through the NCD process.
- CMS should include language stressing the importance of appropriate treatment, including referral to mental health specialists when indicated, and the recommendation to monitor depression outcomes over time to ensure the treatment is effective.
- CMS should specify that the initial preventive exam include an evaluation of risk factors for cancer and a review of prior cancer history. Part of that review should include a review of cancer related psychological distress. The Academy would advocate the use of a well validated tool for that purpose, and the opportunity to have such a tool reviewed through the NCD process
- CMS should work with the TEN Project, the Academy and others to identify and remove barriers to receiving psychiatric care in order to assure that patients receive appropriate treatment; addressing barriers inherent in current payment policy.

Comment on Section 303—Payment Reform for Covered Outpatient Drugs and Biologicals

- The Academy believes that CMS can and should include provision of psychiatric and psychosocial services for patients receiving chemotherapy in new coding considerations permitted in the MMA.

In conclusion, we strongly urge you to consider the inclusion of language within the regulations that allows for these considerations in implementing this benefit. We would welcome the opportunity to meet and speak with you and to review findings which support our recommendations.

Sincerely,

Ted Stern, M.D.
President
Academy of Psychosomatic Medicine

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment: letter submitted by Ronald L. Moy, President of the American Society for Dermatologic Surgery.



September 24, 2004

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1429-P, P.O. Box 8012
Baltimore, MD 21244-8012

Re: Medicare Programs Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005 (CMS-1429-P)

Dear Dr. McClellan,

On behalf of the 4,000 members of the American Society for Dermatologic Surgery (ASDS), I appreciate the opportunity to provide comments on the proposed Medicare physician fee schedule for 2005.

SGR Formula

We recommend CMS exercise its statutory authority to fix the existing flaws in the SGR formula for calculating the annual update in Medicare physician reimbursement. First, we recommend removing Medicare-covered outpatient drugs from the expenditure target or properly accounting for their cost. Second, we suggest a full accounting of the financial impact associated with the Medicare Part B spending due to changes in laws and regulations be properly addressed. These administrative changes would correct many of the problems linked to the current SGR formula.

Practice Expense Inputs for Photodynamic Therapy (PDT)

The significant decrease in payment for photodynamic therapy (PDT), CPT code 95657 is of concern to ASDS. The practice expense methodology is now using the dermatology scaling factor (0.54) for supplies instead of the all physician average (1.29), which is one of the contributing factors to the reduction in payment for this code. We request that CMS reconsider this scaling factor issue.

We also request that CMS incorporate the missing medical supply data for these codes, as there are medical supplies that are not recognized in the current practice expense inputs. The medical supplies listed are clinically necessary to lessen the reaction to the therapy and control the resulting pain. For the typical patient, these medical supplies should be recognized and included as direct practice expense inputs: Bacitracin—SJ008, quantity 0.5 of a 15gm size – to cleanse the patient's face and/or scalp with an anti-bacterial ointment to lessen any likelihood of infection; and LMX 4% Topical Anesthetic Cream, 30 gm - to control burning or stinging from the light activation procedure.

Proposed Update to Professional Liability Insurance Relative Value Units

ASDS is concerned about the proposal for the Five-Year Review of the Professional Liability Insurance (PLI) relative values. The assumptions utilized in calculating this component of Medicare physician payment are questionable. For example, the Bearing Point report has suggested a dramatic increase in the dermatology surgical risk factor by incorporating the highest major surgical data found in a rating manual. While the volume and scope of the practice of dermatologic surgery has expanded, it is inaccurate to classify all procedures performed by

dermatologic surgeons as “major surgery” and, therefore, reflect such a dramatic increase in the risk factor.

Although this component of the Resource Based – Relative Value System (RBRVS) makes up a small percentage of overall physician reimbursement, it is a critical component and deserves appropriate consideration. ASDS encourages the agency to work with physician organizations when undergoing a comprehensive review of all relative values, as stipulated in Section 1848 (C)(2)(B) of the Omnibus Reconciliation Act of 1990, to ensure the data and methodology utilized to calculate this component of Medicare physician payment are appropriate.

Addendum B Error in Practice Expense RVU for CPT 17307

The non-facility practice expense RVU for code 17307 was reduced to 2.63 from the 2004 value of 3.78. We understand the error will be corrected in the final rule, but want to ensure the appropriate PE/RVU will be inserted in the 2005 fee schedule so there are no rank order anomalies in the Mohs family of codes.

Baseline Skin Exam as Part of Medicare B

The increase in skin cancer in the U.S. has risen to epidemic proportions and the financial implications of skin cancers going undetected are substantially higher than the cost of the exam. According to the American Cancer Society, some one million new cases of skin cancer are diagnosed every year – more than all other cancers combined. Malignant melanoma accounts for just five percent of all skin cancers but leads to 75 percent of deaths from the disease. Despite constant warnings about the danger of sun exposure by ASDS and other medical specialty organizations, the incidence of skin cancer is still increasing and, worse, cases of malignant melanoma, the deadliest form of skin cancer, are increasing faster than any other cancer in America. Over 55,000 new cases will be diagnosed this year alone.

ASDS members, alone, treated 1.6 million cases of skin cancer in 2003. This figure is up 5% from 2001 and does not account for skin cancers treated by other medical practitioners or those skin cancers undetected.

While the Society supports the baseline “Welcome to Medicare” visit, it asks CMS to consider adding a baseline skin examination to the list of covered benefits under Medicare Part B. The cost of undetected skin cancers is significant. Early detection not only saves dollars, but more importantly, thousands of lives.



Payment Reform for Covered Outpatient Drugs and Biologicals

The ASDS is concerned by the lack of information in the proposed rule concerning Medicare payments for drugs and biologicals that are scheduled to take effect in 2005. We urge CMS to provide reliable 2005 drug payment information by the time the final rule is published, so that physicians can make informed decisions.

The American Society for Dermatologic Surgery appreciates the opportunity to comment on these issues of concern to our members. We thank you for considering our request.

Sincerely,

A handwritten signature in black ink that reads "Ronald J. Moy". The signature is written in a cursive style and is positioned to the left of a vertical red line.

Ronald J. Moy, MD
President
American Society for Dermatologic Surgery (ASDS)

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Please see attached file

JESSAMINE CHRISTIAN HEALTHCARE

"Family Medicine with the focus on Christ"

September 24, 2004

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1429-P
P.O. Box 8012
Baltimore, MD 21224-8012

Re: Therapy – Incident To

Dear Sir/Madam:

I am writing to express my concern over the recent proposal that would limit providers of "incident to" services in physician clinics. If adopted, this would eliminate the ability of qualified health care professionals to provide these important services. In turn, it would reduce the quality of health care for our Medicare patients and ultimately increase the costs associated with this service and place an undue burden on the health care system.

During the decision-making process, please consider the following:

- Incident to has, since the inception of the Medicare program in 1965, been utilized by physicians to allow others, under the direct supervision of the physician, to provide services as an adjunct to the physician's professional services. A physician has the right to delegate the care of his or her patients to trained individuals (including certified athletic trainers) whom the physician deems knowledgeable and trained in the protocols to be administered. The physician's choice of qualified therapy providers is inherent in the type of practice, medical subspecialty and individual patient.
- There have never been any limitations or restrictions placed upon the physician in terms of who he or she can utilize to provide ANY incident to service. Because the physician accepts legal responsibility for the individual under his or her supervision, Medicare and private payers have always relied upon the professional judgment of the physician to be able to determine who is or is not qualified to provide a particular service. It is imperative that physicians continue to make decisions in the best interests of the patients.
- In many cases, the change to "incident to" services reimbursement would render the physician unable to provide his or her patients with comprehensive, quickly accessible health care. The patient would be forced to see the physician and separately seek therapy treatments elsewhere, causing significant inconvenience and additional expense to the patient.
- This country is experiencing an increasing shortage of credentialed allied and other health care professionals, particularly in rural and outlying areas. If physicians are no longer allowed to utilize a variety of qualified health care professionals working "incident to" the physician, it is likely the patient will suffer delays in health care, greater cost and a lack of local and immediate treatment.
- Patients who would now be referred outside of the physician's office would incur delays of access. In the case of rural Medicare patients, this could not only involve delays but, as mentioned above, cost the patient in time and travel expense. Delays would hinder the patient's recovery and/or increase recovery time, which would ultimately add to the medical expenditures of Medicare.
- Curtailing to whom the physician can delegate "incident to" procedures will result in physicians performing more of these routine treatments themselves. Increasing the workload of physicians, who are already too busy, will take away from the physician's ability to provide the best possible patient care.

- To allow only physical therapists and PT assistants, occupational therapists and OT assistants, and speech and language pathologists to provide “incident to” services would improperly provide those groups exclusive rights to Medicare reimbursement. To mandate that only those practitioners may provide “incident to” care in physicians’ offices would improperly remove the states’ right to license and regulate the allied health care professions deemed qualified, safe and appropriate to provide health care services.
- CMS, in proposing this change, offers no evidence that there is a problem that is need of fixing. By all appearances, this is being done to appease the interests of a single professional group who would seek to establish themselves as the sole provider of therapy services.
- CMS does not have the statutory authority to restrict who can and cannot provide services “incident to” a physician office visit. In fact, this action could be construed as an unprecedented attempt by CMS, at the behest of a specific type of health professional, to seek exclusivity as a provider of physical therapy services.
- Independent research has demonstrated that the quality of services provided by certified athletic trainers is equal to the quality of services provided by physical therapists.
- Athletic trainers are employed by almost every U.S. post-secondary educational institution with an athletic program and every professional sports team in America to work with athletes to prevent, assess, treat and rehabilitate injuries sustained during athletic competition. In addition, dozens of athletic trainers will be accompanying the U.S. Olympic Team to Athens, Greece this summer to provide these services to the top athletes from the United States. For CMS to even suggest that athletic trainers are unqualified to provide these same services to a Medicare beneficiary who becomes injured as a result of running in a local 5K race and goes to their local physician for treatment of that injury is outrageous and unjustified.
- These issues may lead to more physician practices eliminating or severely limiting the number of Medicare patients they accept.

In summary, it is not necessary or advantageous for CMS to institute the changes proposed. This CMS recommendation is a health care access deterrent.

Sincerely,
Gregory K. Rose, MS, ATC

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Therapy--Incident To

Dear Sirs,

I strongly support the proposed regulation requiring therapy services provided incident to physicians' services be provided by qualified personnel
I urge you to adopt the proposed regulation.

Thank you,

Hilary Manges, PT

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

GENERAL

GENERAL

Please See Attached.

Ms. Janet Conneely
Senior Vice President
Novartis Nutrition Corporation
1600 Utica Avenue South
Suite 600
St. Louis Park, MN 55416

Centers for Medicare and Medicaid Services
Department of Health and Human Services
ATTENTION: CMS-1429-P
P.O. Box 8012
Baltimore, MD 21244-8012

RE: Sections 302 and 611 of CMS-1429-P

To Whom It May Concern:

The following are the comments of Novartis Nutrition Corporation (NNC) on **Sections 302 and 611 of file CMS-1429-P**, published in the Federal Register on August 5, 2004.

The mission of NNC is to improve lives, to extend lives and to save lives. We at NNC are dedicated to maintaining and improving the health and well being of consumers and patients - at home or in health care delivery settings - by fulfilling their medical nutritional needs. In partnership with health care professionals, we offer the highest quality medical nutrition products and services that improve health and quality of life. Novartis Nutrition Corporation is located in St. Louis Park, Minnesota.

Section 302

We support the efforts of CMS to identify and correct areas of current Part B coverage where clinical conditions for the use of certain DME may not be stringent enough; while continuing to ensure that quality care is provided to patients who are in true need of covered items. We are members of the National Alliance for Infusion Therapy (NAIT), and fully support the comments they submit on Section 302 of the proposed regulation and echo their concerns and perspectives. We especially concur with their arguments regarding Congressional intent concerning the scope of the face-to-face provisions of the Medicare Modernization Act. We believe that CMS was not given authority to establish face-to-face examination requirements for enteral and parenteral nutrition. The clinical conditions of coverage contained in Section 302(a)(2) of the MMA clearly apply only to durable medical equipment and **not** to therapies covered under the prosthetic device benefit.

Aside from the statutory limitation we find to be limiting the face-to-face requirement, practical reasoning argues for parenteral/enteral nutrition therapy being excluded from the proposed condition. Often times the decision to utilize enteral therapy is made in a setting and under conditions where a physician may not be immediately present or even available in short order. In addition, the decision at times may need to be implemented with great speed to improve the health and even the survivability of a patient. It is apparent that there are conditions where the face-to-face requirement, if applied to all DMEPOS including parenteral/enteral therapy, would create negative clinical consequences. Again, parenteral/enteral treatment is not conducive to abuse or proliferation – and it is maintained, without exception, for medical necessity. In fact, Part B requires sufficient medical documentation supporting a determination that an item or service is reasonable and necessary. For enteral nutrition, such documentation must generally be located in the patient's medical record and in a formal Certificate of Medical Necessity (CMN), which the patient's treating physician completes. In

completing the CMN, the treating physician certifies that the items ordered are medically necessary for the particular patient under his or her care. Because of these reasons and because of our reading of Congressional intent, NNC believe parenteral/enteral therapies should not be included with the DME that are historically associated with proliferation and, therefore, we believe the final regulation should not include face-to-face requirements for parenteral/enteral therapies.

Section 611

CMS has taken an important step by proposing an “Initial Preventative Physical Examination” to be covered by the Medicare Part B Program, as provided for in Section 611 of the Medicare Modernization Act and described in the August 5 notice. Providing coverage for preventative physical exams to new entrants into the Part B Program will allow for early detection and treatment of potentially more serious conditions before a patient might have to undergo more costly treatment later. In addition and importantly, the provisions to include assessments of nutritional needs along with medical nutrition therapy services are invaluable additions to the overall Medicare Program.

The criteria set forth for inclusion in the definition of “initial preventative physical examine” in points 1-7 are comprehensive and beneficial (Federal Register Vol. 69, No. 150, p. 47515). The scope of services to be available to new Part B enrollees under the proposal should provide CMS with a new tool to promote the public health especially in populations that heretofore may not have had the means to detect and/or prevent the onset of more serious health issues. As a result, by early screening and early referral, treatment should improve for at-risk patients and the overall costs of treatment should be reduced – a vital result considering the budget constraints faced now, and in the future, by the Medicare Program. The provisions set forth in item number seven, we believe, are especially important by providing a potentially at-risk patient with a written plan “for obtaining the appropriate screening and other preventative services, which are separately covered under Medicare Part B benefits; that is.diabetes outpatient self-management training services....medical nutrition therapy services...(Federal Register Vol. 69, No. 150, p. 47515).”

Novartis Nutrition Corporation applauds the efforts as set forth in the proposed regulation to implement the preventative care initiatives contained in the Medicare Modernization Act of 2003. We welcome the opportunity to contribute in the future as CMS moves forward toward improving care regarding the nutritional support patients’ need, both in preventative measures and in treating chronic and serious medical conditions. We believe that by covering comprehensive and quality nutritional therapy and support within the Medicare Program, CMS and the country’s health care system will benefit via lowered overall costs, shorter durations of acute care needed, and quicker recovery from serious conditions. Thank you very much for the opportunity to comment. Please feel free to contact William Hoffman III, Manager of Government Relations (952-848-6224), with Novartis Nutrition Corporation with any further questions.

Sincerely,

Ms. Janet Conneely
Senior Vice President
Novartis Nutrition Corporation

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 20-29

CARE PLAN OVERSIGHT

CARE PLAN OVERSIGHT

The American Nurses Association supports this section in the proposed rule as it clarifies that Nurse Practitioners (NPs) and Clinical Nurse Specialists (CNSs) may perform home health care plan oversight (CPO) and may bill for those services. This clarification includes the condition that an "appropriate and established relationship exists between the physician who certifies the patient for home health services and the NPP who will provide the home health CPO."

ANA appreciates that CMS is trying to resolve the seeming conflict created by letting NPPs bill for CPO when the rules don't let them certify/recertify and the statute doesn't let them do the plan of care. Although the clarification as presented in the proposed rule would be an improvement, it is still problematic, because an obstacle remains for independently practicing NPs and CNSs whose patients are receiving home health services---it requires them to maintain a relationship with a specific physician (who may or may not be the NP or CNS's collaborating physician).

ANA strongly recommends that CMS revise the rules on certification and recertification to allow NPs and CNSs to perform them, just as they can in SNFs.

THERAPY - INCIDENT TO

THERAPY- INCIDENT TO

The proposed rule as currently written allows a physician, physician assistant (PA), nurse practitioner (NP) or clinical nurse specialist (CNS) to perform occupational therapy (OT), physical therapy (PT) and speech language pathology (SLP) services, if their state scope of practice allows. But these services can only be provided incident to if the 'person who furnishes the services ... meets the standards and conditions that apply to physical therapy and physical therapists, except that a license to practice physical therapy in the State is not required.' (with the same language for OT and SLP services).

The rule as proposed appears to set up an odd situation where an NP, CNS or PA can bill directly for these services, but they (apparently) cannot be billed 'incident to?' when provided by an NP, CNS or PA. ANA is not clear if this section of the proposed rule is to be interpreted to mean that these services can be billed 'incident to' only if a PT, OT or SLP provides them. ANA maintains that if that is the case, the rule creates an odd discrepancy where an NP, CNS or PA can provide these services and can bill for them if billing directly, but the services cannot be billed incident to.

ANA recommends that proposed 410.59(iii), 410.60(iii) and 410.62(iii) be changed to read that when a PT, OT or SLP service is provided 'incident to,' it is provided by an individual who is authorized to provide it under State law or regulation or alternatively, with the addition of NP, CNS or PA acting within their State scope or practice at the end of each of these three subsections.

Submitter : Date & Time:

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Category :

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I am a PTA student and I am writing regarding cms-14-29p. I oppose this regulation for the following reasons. Physical therapists are professionally educated at the college or university level in programs accredited by the Commission on Accreditation of Physical Therapy, an independent agency recognized by the U.S. Department of Education. As of January 2002, the minimum educational requirement to become a physical therapist is a post-baccalaureate degree from an accredited education program. All programs offer at least a master's degree, and the majority will offer the doctor of physical therapy (DPT) degree by 2005. Physical therapists must be licensed in the states where they practice. As licensed health care providers in every jurisdiction in which they practice, physical therapists are fully accountable for their professional actions. Physical therapists receive significant training in anatomy and physiology, have a broad understanding of the body and its functions, and have completed comprehensive patient care experience. This background and training enables physical therapists to obtain positive outcomes for individuals with disabilities and other conditions needing rehabilitation. This education and training is particularly important when treating Medicare beneficiaries.

Submitter : Date & Time:

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Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

We beg you to NOT pass this policy whereby a physician can only refer "incident to" services to physical therapists. All qualified health care providers should be allowed to provide services to patients with a physicians prescription or under their supervision.

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

GENERAL

GENERAL

The American College of Obstetricians and Gynecologists (ACOG), an organization representing more than 45,000 physicians dedicated to improving women's health care, appreciates the opportunity to comment on the 'Medicare Program; Revision to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005; Proposed Rule' published in the Federal Register, August 5, 2004. Our primary concern in reviewing any proposal for new reimbursement policies is the potential impact these policies may have on access to and quality of health care for women.

Office of the Executive Vice President

Ralph W. Hale, MD, FACOG

Telephone: 202/863-2525

Fax: 202/863-1643

E-mail: rhale@acog.org

September 24, 2004

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

Re: Medicare Program; Revision to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005; Proposed Rule

Dear Dr. McClellan:

The American College of Obstetricians and Gynecologists (ACOG), an organization representing more than 45,000 physicians dedicated to improving women's health care, appreciates the opportunity to comment on the "Medicare Program; Revision to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005; Proposed Rule" published in the **Federal Register**, August 5, 2004. Our primary concern in reviewing any proposal for new reimbursement policies is the potential impact these policies may have on access to and quality of health care for women.

Professional Liability Insurance (PLI) Relative Value Units

ACOG has repeatedly stated since 1999 that the resource-based methodology underestimates the cost of professional liability insurance (PLI) for physicians who perform obstetric and gynecologic services. While CMS refers to Malpractice RVUs and tries to develop a risk factor associated with specific procedures, this component of the RBRVS is, in fact, based on the cost of professional liability insurance. The methodology used does not fairly include that cost in the services provided by obstetrician-gynecologists. The "risk factor" that is calculated is based on unrealistically low professional liability premiums. Eighty percent of ob-gyns perform both obstetric and gynecologic services, yet the risk factor for most services these physicians provide to Medicare beneficiaries is based on the much lower premiums paid by physicians who offer only gynecologic services. The risk factors for non-surgical services are based on the even lower premiums paid by gynecologists who do no surgery. This results in grossly inadequate PLI relative value units for services provided by ob-gyns.

A simple comparison of the surgical risk factor for general surgeons (6.13) to the risk factor for ob/gyns (5.63) illustrates the problem. The October 2003 *Medical Liability Monitor* reports that general surgeons pay from ten to over fifty percent less than ob-gyns for PLI, yet CMS calculates that the general surgeon's risk factor is eight percent higher. When the nonsurgical risk factor is also included, the discrepancy is even greater.

The Medicare Fee Schedule and Resource Based Relative Value System are used not only by CMS, but are also used as benchmarks by many insurers. Ob-gyns are commonly seeing annual increases in PLI premiums of thirty to fifty percent, with overall expenses rising by over ten percent. We are concerned that declining reimbursement in the face of rising professional liability costs will soon have serious adverse affects on women's access to care.

The proposal for the Five-Year Review of the Professional Liability Insurance (PLI) Relative Values does not address the problem. We understand that CMS is required by statute to update this component by January 1, 2005. We urge CMS to consider this an interim solution until the agency has worked with the medical community to ensure that the methodology utilized to calculate this important component of physician payment is appropriate.

ACOG understands that options to remedy the problems associated with the PLI may be somewhat limited by the budget neutrality requirement. We encourage CMS to begin working with organized medicine to advocate legislative action to address the issue of professional liability insurance. Such solutions might include removing this cost from the RBRVS altogether so that Medicare and other payers could pay their share of this cost through a more direct mechanism.

Practice Expense

In the proposed rule, CMS requests pricing information for specific equipment (E52001, E52002, and E52002) for which pricing information has not been found and documented. ACOG will forward the pricing information under separate cover.

ACOG submitted a letter to CMS on April 15, 2004, with practice expense recommendations for CPT code 58563; including documentation showing that the cost of the hysteroscopy ablation equipment system is \$19,500. An invoice from the manufacturer, Novaccept, was included with that letter. The proposed rule incorrectly identified the CPT[®] code as 56853. ACOG will present the practice expense recommendation for CPT[®] code 58563 before the RUC Committee at the February 2005 meeting.

Please contact ACOG staff person Kim Longworth at 202-863-2456 if you need additional or duplicative documentation.

Section 611-Initial Preventive Physical Examination

Effective January 1, 2005, the Medicare Modernization Act (MMA) creates coverage for an initial preventive physical examination within the first six months of the beneficiary's entrance into Medicare Part B. CMS proposes to establish a new HCPCS code, G0XX2, "Initial preventive physical examination," which includes an electrocardiogram (EKG), consistent with

Mark McClellan, MD, PhD

September 24, 2004

Page 3

the statute. Other Medicare-covered preventive services would be separately reportable using the existing codes for those services. CMS proposes to assign this code a total of 3.29 relative value units in the office setting, which is equivalent to the relative value units for a 99203 plus a complete EKG, 93000.

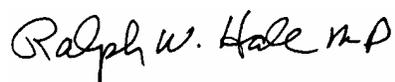
This approach may be confusing to physicians and patients alike, and may prevent patients who are eligible for the benefit from getting this service. Since Medicare beneficiaries are generally over the age of 65, the appropriate CPT code to report this service is 99387. Medicare assigns a total of 4.00 relative values to this non-covered service in the office setting, as compared to 2.58 for CPT code 99203. It should also be noted that some physicians do not perform EKGs in their office. It would then be appropriate for the physician performing the EKG, to report this service separately. Therefore, we recommend that no new code be established and that CMS direct physicians to use the existing codes 99387 and 93000 to report these services.

Physician Scarcity Areas

We appreciate CMS's effort to fairly implement the incentive payment to physicians in physician scarcity areas. We are hopeful that the 15% bonus payment will encourage physicians to provide services where the need is greatest. As this incentive is implemented, physicians must be made aware that this bonus is available, and it must be simple for them to receive the bonus.

ACOG appreciates CMS's continued willingness to work cooperatively with the physician community to assure implementation of sound policies for governing Medicare payment policy. We are eager to work with CMS to resolve the issues identified in these comments.

Sincerely,

A handwritten signature in cursive script that reads "Ralph W. Hale MD".

Ralph W. Hale, MD, FACOG
Executive Vice President

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I oppose Medicare's proposed policy to eliminate any provider except PT's from providing "incident to" medical professional's services to patients.

Submitter : Date & Time:

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Issue Areas/Comments

Issues 1-9

SECTION 303

NJSOM represents over 65 practices with 200 practicing oncologists in the state of New Jersey. We are extremely concerned with the proposed rule the Centers for Medicare and Medicaid Services plans to imposed this January 2005. As you are well aware there are severe flaws with the proposed system. The AWP system was put into place in order to allow patients to be treated out side the hospital allowing them to lead normal lives. Over the years as services became bundled into the drug codes we adjusted to these changes and relied on the drug revenue to supplement expenses. The proposed changes do not take into consideration the amount of funds needed to support the administration and disposal of the drugs as well as the amount of funding needed to comply with all the Federal and State Government regulations.

Patients who can not afford their treatments will be sent to area hospitals. This will have tremendous impact on the hospitals as well as costing the Medicare system. Patients who cannot afford their payments and do not want to be treated in the hospitals will refuse necessary treatments. Private payors will follow CMS rulings compounding this problem. Many practices will not be able to withstand these changes. At this time we are requesting that a hold be placed on the proposed changes by leaving the 2004 decision in place while we continue to work with CMS, COA and ASCO to resolve this issue without jeopardizing the future of cancer care.

Sincerely, Fran Corona, President;Luanne Lange, Vice President;Denise Johnstone,Treasurer; Jeanne McCarthy, Secretary

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I am a physical therapist assistant student. I wish to comment on the August 5 proposed rule on "Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005." I am against this regulation for the following reasons. Physical therapists and physical therapist assistants are required to be under the supervision of physical therapists. They are the only practitioners who have the education and training to perform physical therapy services. Unqualified personnel don't have the ability to perform quality services. PT's and PTA'S are educated professionals have a broad understanding of the body and its functions, and have a widespread patient care experience. This background and preparation permit physical therapists to obtain constructive results for individuals with disabilities and other conditions needing rehabilitation. PT's and PTA's expertise are particularly helpful to Medicare beneficiaries. The delivery of physical therapy services by the incompetent consists of unsubstantiated care in which all disadvantages should be strictly reviewed. Thank you for your consideration.

Submitter : Date & Time:

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Issue Areas/Comments

Issues 1-9

CODING-GLOBAL PERIOD

Comments by the American Telemedicine Association are attached

**AMERICAN TELEMEDICINE ASSOCIATION
RESPONSE TO COMMENTS
Medicare Program; Revision to Payment Policies
Under the Physician Fee Schedule for Calendar Year 2005**

**File Code: CMS-1429-P
Coding - TeleHealth**

The following comments are submitted in accordance with the published guidelines in the Federal Register, Vol. 69, No. 150: Thursday, August 5, 2004 – Proposed Rules. All comments are referenced by title, page number, column and paragraph, as there is no issue identifier number preceding the section on which we are commenting.

CMS Review (p. 47511, col 1, para 1 – 3)

Comments by CMS in the Federal Register indicate that the submission of inpatient hospital care, emergency care, hospital observation services, and inpatient psychotherapy does not meet criteria for Category 1 Services (services which are similar in nature to an office or other outpatient visit, consultation, or office psychiatry). The intent of the decision is to ensure that the roles of, and interaction among, the patient, physician, or practitioner at the distant site and telepresenter (if necessary) are similar to the current telehealth services. CMS has determined that the requested CPT codes are Category 2 services, defined as services that are not similar to an office or other outpatient visit, consultation, or office psychiatry because of the potential acuity of the patient in the hospital setting.

We would respectfully disagree with CMS's interpretation. Consultations provided via telehealth technologies mimic the traditional exam, interpretation of data, assessment criteria, and plan of care provided through an in-person office visit, ~~an in-person hospital visit, or a~~ telehealth office visit. In addition, for the proposed codes, a physician or non-physician practitioner retains control of the patient and is present or available during consultations. ~~In fact, in emergency consultations, the patient is cared for by an on-site physician, nurse practitioner, or physician assistant.~~ The telehealth link is for additional expertise, particularly in the area of trauma care, to ensure optimum clinical outcomes for the patient. [The TeleHealth consultation does not replace the on-site, in-person practitioner.](#)

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However, we also understand that the comments listed on page 47512, col 2, para 2, indicate that CMS believes that the current list of CPT codes approved for telehealth include all the codes necessary for a consulting provider who sees a patient in a hospital, emergency, or observation status. We understand CMS to say that the current list of evaluation/management and consultation codes may be used for patients in inpatient and observation status in hospitals and for patients receiving inpatient psychotherapy who receive services via telehealth. We would request that CMS comment specifically on which codes are appropriate to replace each of the requested codes for inpatient hospital, emergency department visits, hospital observation services, and inpatient psychotherapy.

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We would request clarification on [the process used to determine how a service is considered Category 1 or Category 2, as a discrepancy appears to exist in the proposed 2005 physician fee](#)

[schedule for TeleHealth](#). A large body of scientifically generated information on whether or not remote interactive dialysis care is comparable to in-person dialysis care was not submitted prior to approval of these codes. There were no large randomized clinical trials and no comparison studies submitted with the request for dialysis codes. [The same clinical evidence was submitted for dialysis as was for the other CPT code services requests](#). Yet these codes were approved in the absence of the Category 2 required empirical evidence indicating diagnostic accuracy and similar therapeutic intervention.

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End-Stage Renal Disease – Monthly Management of Patients on Dialysis (p. 47511, col 2, par 3)

ATA supports the inclusion of monthly management of patients on dialysis in the approved codes for telehealth services and acknowledges and supports the exclusion of the initial complete assessment of ESRD patients. Current practice indicates that these patients are seen in-person and it is not common practice to conduct complete evaluations by telehealth for initial visits for ESRD. We understand that current statute does not include dialysis centers as originating sites and [we](#) will pursue the inclusion of dialysis centers legislatively in the next year.

Case Management and Care Plan Oversight (p.47512, col 3, para 1-2)

CMS has determined that the codes for Case Management and Care Plan oversight cannot be added to the list of approved telehealth services as these services do not require the patient to be present. We would ask for clarification on this point. We understand CMS to say that if the patient is not present, CMS does not have the authority to add these services (codes) to the list of approved telehealth services. We are assuming that the lack of authority to add codes that do not require the patient to be present is legislated in the language of BIPA 1997 (where it is determined that services must be provided to an eligible beneficiary). Please clarify the scope of authority over decisions relating to adding codes when the patient is not present.

A second question relates to the ability of a health care team to conduct case management and care plan oversight at a distance when the patient is not present. The statement by CMS indicates that case management or care plan oversight services that includes the participation of one or more of the care plan team using telecommunications does not fall into the telehealth services category but can be billed as a covered service using normal billing procedures. This appears similar to CMS policy on remote interpretation of radiological images and other services that do not require face-to-face consultations with the patient. We would ask CMS to clarify this issue.

CMS Report to Congress (p. 47512, col 2, para 3)

Comments by CMS in the Federal Register refer to the required report to Congress (section 223(b) of BIPA). We respectfully request that CMS complete its work on this report with the inclusion in the report of the [recommendation to add Medicare eligible practitioners](#). [Specifically, we request the addition of](#) speech pathologists, speech therapists, and audiologists [as eligible practitioners](#) as well as the appropriate CPT codes that have been identified [and requested](#) by the American Speech-Language Hearing Association (ASHA). We request that CMS identify [and recommend](#) dialysis centers [be added](#) as [an](#) originating site, noting the inclusion of CPT codes, the scientific evidence used to support the inclusion of those codes, and the discrepancy of paying for a service that is delivered in a site not listed as an eligible

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originating site. This report is extremely important part of the overall work that needs to be done to eliminate the disparity that exists for access to care between Medicare beneficiaries and all other patients.

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Issue Areas/Comments

Issues 1-9

SECTION 303

Please see attached letter for detailed comments on Section 303.

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Pfizer Inc. Comments on 2005 Proposed Physician Fee Schedule Rule

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September 24, 2004

SUBMITTED ELECTRONICALLY

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

Re: **CMS-1429-P**, Comments on Medicare Program; Revisions
to Payment Policies Under the Physician Fee Schedule for
Calendar Year 2005

Dear Administrator McClellan:

Pfizer Inc. respectfully submits these comments on the Center for Medicare and Medicaid Services' proposed rule on 2005 payments for Medicare Part B drugs and revisions to the physician fee schedule ("Proposed Rule").¹

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Pfizer is a research-based, global pharmaceutical company dedicated to the discovery and development of innovative medicines and treatments that improve the quality of life of people around the world. In addition to its currently marketed therapies that are covered under Medicare Part B, Pfizer has approximately 20 new chemical entities in its oncology pipeline alone. Accordingly, we appreciate this opportunity to share our views with respect to a number of important issues that have the potential to impact significantly Medicare beneficiaries' continued access to life-enhancing drug therapies.

Pfizer's specific comments below are meant to complement, and should be read in conjunction with, the comments to the Proposed Rule submitted by the Pharmaceutical Research and Manufacturers of America ("PhRMA") and the comments submitted by the Biotechnology Industry Organization ("BIO"), both of which we broadly endorse.

¹ 69 Fed. Reg. 47488 (August 5, 2004).

SECTION 303

As a preliminary matter, Pfizer commends CMS for its recently announced revision of the methodology for estimating price concessions associated with manufacturers' average sales price ("ASP") reporting requirements.² The revised methodology, which adopts the use of a price concession percentage, will more effectively mitigate the potential for quarter-to-quarter payment rate volatility. However, we continue to believe that CMS must promptly issue clear guidance on other significant issues related to the calculation of ASPs by manufacturers to ensure accurate and consistent reporting of ASPs for the price submissions due at the end of October 2004, which will be used to establish the drug payment allowances that go into effect January 1, 2005.

To Achieve the Objective of ASP as Payment Reform, CMS Must Ensure Consistency in Price Reporting Across Manufacturers by Providing Clear Guidance on How to Calculate ASPs.

The ASP-based payment reform is a significant departure from the former Part B reimbursement system for covered drugs. Its success as *reform* will largely depend on achieving consistent price reporting *across* manufacturers, which requires clear and detailed guidance from CMS on how to calculate the ASP. The application of reasonable assumptions in the absence of specific guidance was necessary in the context of the initial data submission; however, continued reliance on manufacturer-specific assumptions clearly undermines the objective of achieving consistency in reporting across manufacturers.

Moreover, in stark contrast to the situation with best price and AMP reporting for Medicaid purposes where manufacturers face significant and continuing liability for misreporting those prices, CMS has indicated that it has very limited ability to rectify or provide meaningful relief, especially to patients, in cases where payment rates are based on erroneous ASPs. Also, to the extent that the adequacy of the ASP-based drug payment allowance may be a factor in a physician's choice of agents, manufacturers that apply more conservative assumptions may be disadvantaged largely on the basis of their ASP methodology. Under the circumstances, clear guidance up-front is the most effective way to ensure accurate and consistent price reporting.

Both PhRMA and BIO have identified various ambiguities in the guidance provided thus far that need prompt clarification. In addition to those items, we continue to believe that CMS needs to provide clearer guidance on which types of payments must be included in the ASP calculation, particularly on the issue of "administrative fees",

² See 69 Fed. Reg. 55763 (Sept. 16, 2004).

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which CMS introduced in its ASP Q&As,³ but around which there remains considerable confusion (and thus variability in treatment for ASP reporting purposes) among manufacturers. In lieu of describing the *effect* of an includable manufacturer payment, CMS should restate its guidance by clearly identifying the criteria for payments that must be included in ASP calculations as price concessions, e.g., payments related to non-exempt sales that are tied to total applicable sales and that do not constitute (or are in excess of) fair market value for actual administrative or other services rendered by the recipient. The use of bright-line tests whenever possible will minimize variability in the interpretation of ASP guidance going forward.

To Avoid Publication of Erroneous Payment Rates, CMS Should Provide Manufacturers with an Opportunity to Review Rates Prior to General Release and to Revise ASP Submissions

As part of its Regulatory Impact Analysis, the Proposed Rule published drug prices for certain high-volume drugs that CMS used to determine the drug payment impact for selected specialties. *See* Proposed Rule, Table 28, 69 Fed. Reg. at 47566. Notwithstanding that CMS included relevant disclaimers with respect to this data,⁴ the relevant specialty community reacted swiftly and unequivocally. By early September, it was widely reported that a survey conducted by the American Society of Clinical Oncology (“ASCO”) of 93 community oncology clinics found that in 2005 “[m]ore than half of the practices will have to pay more than Medicare reimburses for Pfizer’s Camptosar (irinotecan) and Lilly’s Gemzar (gemcitabine), and more than 70% of practices will not be adequately reimbursed for pamidronate (Novartis’ Aredia and generics)”.⁵ While the survey technically addresses the adequacy of payment in 2005, this kind of pronouncement by ASCO can be expected to impact *current* prescribing decisions for longer-term therapies that will continue into 2005.

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This course of events (i) demonstrates that any publication by CMS of payment rate information (including information that is disclaimed as a projection) is highly

³ *See* ASP Q&A 16:

“Q16.Should administrative fees paid to buyers be included in the ASP calculation?

A16. Administrative fees, incentives, promotional fees, chargebacks and all discounts or rebates, other than rebates under the Medicaid drug program and discounts under an endorsed discount card program, should be included in the calculation of ASP, if those sales are to an entity whose sales are included in the calculation of ASP and if they ultimately affect the price actually realized by the manufacturer.”

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⁴ The Regulatory Impact Analysis discloses that the published prices and payment impacts are based on 1st quarter 2004 ASP submissions and that actual 2005 payment rates will be based on 3rd quarter 2004 ASP submissions and updated quarterly.

⁵ *See Health News Daily*, “Procrit, Gemzar, Camptosar, At Risk Under 2005 Medicare Payment Rates, ASCO Says,” Sept. 9, 2004; *The Pink Sheet*, “Procrit, Camptosar At Risk Under 2005 Medicare Payment Rates, ASCO Says,” Sept. 13, 2004.

influential; (ii) highlights the need for CMS to permit the effected manufacturer an opportunity to review, prior to publication, any drug payment rates CMS intends to release; and (iii) supports the need for manufacturers to have an ongoing mechanism to correct honest mistakes and inadvertent errors in the ASP submission prior to publication of rates. In the present instance, the fact that CMS adopted a revised methodology for estimating certain price concessions well after the 1st quarter data was submitted, standing alone, should have signaled the need to consult with manufacturers before any payment rates based on 1st quarter data were published.

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To Ensure Access to Clinically Appropriate Treatments and Choice of Sites of Service, CMS Must Monitor the Effect of Payment Reform on Beneficiary Access

Finally, Pfizer believes that the success of the Part B payment reform must be measured in part by its impact on beneficiary access to Part B drugs. In addition to the studies mandated by Congress to monitor various factors that may impact beneficiary access (e.g., whether prices available to large-volume purchasers should be included in ASP), Pfizer urges CMS to have in place comprehensive surveillance mechanisms to ensure that timely data is collected and that potential threats to beneficiary access to the most appropriate therapies at the most appropriate sites of service can be promptly identified and appropriately addressed as they arise.

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Again, we appreciate the opportunity to comment on the Proposed Rule. We hope our suggestions are helpful to CMS in formulating and implementing these important changes to Medicare payments for Part B drugs. Thank you for considering our views.

Respectfully submitted,

W. Charles Lucas
Senior Assistant General Counsel
Legal External Affairs Group

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Pfizer Inc.
235 East 42nd Street
New York, NY 10017
Tel. 212-733-8271
Fax 212-573-1445
Email w.charles.lucas@pfizer.com

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Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 10-19

THERAPY ASSISTANTS IN PRIVATE PRACTICE

See attached file

Wisconsin Physical Therapy Association

A CHAPTER OF THE AMERICAN PHYSICAL THERAPY ASSOCIATION

802 West Broadway, Suite 208, Madison, WI 53713

Telephone 608/221-9191 Fax 608/221-9697 wpta@wpta.org www.wpta.org

September 23, 2004

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1429-P
P.O. Box 8012
Baltimore, MD 21244-8012

Subject: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005

Reference: Supervision Requirement for Private Practice Physical Therapist Offices Therapy Standards and Requirements

On behalf of the Wisconsin Physical Therapy Association's Reimbursement Committee, we would like to express our support for the proposed ruling change from personal supervision to direct supervision (in the office suite) for physical therapist assistants in physical therapy private practices (PTPP). This proposed change is both timely and necessary. Physical therapist assistants (PTAs), as defined in the regulations at 42 CFR 484.4, are already recognized as Medicare practitioners and meet the necessary requirements of a qualified provider. The Wisconsin Physical Therapy Association supports language that aligns with the Medicare supervision requirement, previously defined in CMS documents prior to 1999, for supervision of assistants in ~~an~~ independent physical therapy practices.

For almost 2 decades the Wisconsin Physical Therapist Practice Act has allowed physical therapist assistants to deliver safe and effective treatments without a physical therapist being present in the same room as the PTA. No state physical therapy practice act requires in the room or personal supervision of physical therapist assistants. CMS' proposed change brings the level of supervision of PTAs in physical therapy private practices more in line with supervision requirements in other practice settings.

As representatives of the Wisconsin Physical Therapy Association, we thank you, Dr. McClellan, for the opportunity to comment on this issue. Our 1800 members entrust the Association to offer comments to CMS on issues relevant to physical therapy services for Medicare beneficiaries.

Sincerely,

Mary Beth Geiser PT, OCS
Reimbursement Chair
Wisconsin Physical Therapy Association

Michele Thorman PT, MBA
Chapter President
Wisconsin Physical Therapy Association

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

GENERAL

GENERAL

September 21, 2004

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1429-P
P.O. Box 8012
Baltimore, MD 21244-8012

SUBJECT: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005

Dear Dr. McClellan:

I am a physical therapy student at Texas State University-San Marcos. In May of 2005 I will graduate with a MSPT degree and will begin practicing as a licensed physical therapist. As a physical therapist, I will advocate for patients to receive the most comprehensive and cost-effective care they are entitled to.

THERAPY-INCIDENT TO:

This letter is in regard to the proposed August 5th rule on a??Revision to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005a??. I am writing in strong support to the CMS proposed rule of establishing requirements for individuals who furnish outpatient physical therapy services in physiciant's offices. Individuals providing physical therapy should be graduates of an accredited professional physical therapy program. Physical therapists must be licensed in the states where they practice, and thus are held fully accountable for their professional actions. Physical therapists and physical therapy assistants under the supervision of physical therapists are the only practitioners who have the education and training to provide physical therapy service. Untrained providers hold no accountability for the services they provide. Without a license, or any type of formal training, unqualified individuals who practice physical therapy do so at a risk to patients and at an increase cost to the system.

Physical therapists have significant training in anatomy and physiology and have a broad understanding of the body and its functions. They also have comprehensive patient care experience. This background and training allow physical therapists to obtain positive cost-effective outcomes for individuals with disabilities and other conditions needing rehabilitation services. If untrained personnel provide these services patient outcomes will be negatively affected because they will not receive the comprehensive care they deserve.

Thank you for your consideration on this matter.

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

See attached file.

Wisconsin Physical Therapy Association

A CHAPTER OF THE AMERICAN PHYSICAL THERAPY ASSOCIATION

802 West Broadway, Suite 208, Madison, WI 53713

Telephone 608/221-9191 Fax 608/221-9697 wpta@wpta.org www.wpta.org

September 23, 2004

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1429-P
P.O. Box 8012
Baltimore, MD 21244-8012

Subject: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005

Reference: Therapy- Incident to

Dear Dr. McClellan:

As representatives of the Wisconsin Physical Therapy Association (WPTA), we would like to inform you of our position on the August 5 proposed rule on "Revisions to Payment Policies Under the Physician Fee Schedule for Calendar year 2005." The WPTA supports CMS's proposal that qualifications of individuals providing physical therapy services "incident to" a physician should meet the same qualifications for physical therapy services in 42 CFR 484.4, with the exception of licensure. It is essential that standards be established such that only individuals, who provide physical therapy services are those who have graduated from accredited professional physical therapy programs, fulfilled all educational requirements, are foreign-trained physical therapists or are qualified to perform physical therapy under specific grandfathering clauses.

It is our position that CMS should adopt a policy that requires physical therapists and physical therapist assistants working in a physician's office to be graduates of a CAPTE (Commission on Accreditation of Physical Therapy Education) accredited physical therapy program. CAPTE is nationally recognized by the U.S. Department of Education and the Commission on Recognition in Postsecondary Accreditation (CORPA). The accrediting body's professional curricular requirements are stringent and inclusive. A university obtains full accreditation only if core classes, which are essential for a physical therapist's education, are present in their curriculum. A typical curriculum includes course work in anatomy, physiology, patho-physiology, medical ethics, health policy, orthopedics, sports rehabilitation, industrial rehabilitation, therapeutic exercise, gait analysis, pediatrics,

electrophysiology, physical agents, wound care, cardio-pulmonary rehabilitation, neurology, neurological rehabilitation and most importantly, geriatrics and the effects of aging on all physiological systems. Physical therapists are educated on topics directly related to the elderly including changes in cognition, musculoskeletal function, nervous system function, endocrine function, and common cardio-respiratory conditions. It is a physical therapist's unique application of this knowledge base concerning the elderly that makes them *uniquely* qualified providers of physical therapy services for Medicare beneficiaries.

Presently, many physician offices employ non-qualified personnel to treat the Medicare beneficiaries. This arrangement poses an inherent risk for injury to occur when unqualified providers administer care to a Medicare beneficiary. By accepting this proposed rule, Medicare would ensure that any geriatric client receiving physical therapy in physician's office must receive their care from a qualified provider such as a physical therapist or physical therapist assistant. Physical therapists have long been respected as a qualified provider for physical therapy services. Section 1862(a) (20) of the Social Security Act clearly requires that in order for a physician to bill "incident to" for physical therapy services, those services must meet the same requirements for outpatient therapy services in all clinical settings.

It is common for physical therapists and physical therapist assistants to treat beneficiaries with ailments such as Parkinson's disease, osteoarthritis of the extremities, congestive heart failure, osteoporosis, diabetes, low back pain, spinal stenosis, cancer, multiple sclerosis, and post-polio syndrome. Although the list is not exhaustive, it represents a large subset of beneficiaries who will require physical therapy to maintain their present level of function. In a hospital based or private practice physical therapy setting these individuals would receive care from only qualified physical therapists and physical therapist assistants. In contrast, if the same client received cares in a doctor's office "incident to" the physician that individual could receive multiple sessions of "physical therapy" yet never see a qualified physical therapy provider. Imagine being treated in an oncology department without ever meeting the oncologist involved in your care. With limited CMS dollars and pending budget restrictions, Medicare would be wise to consider the potential of abuse or that could result in millions of misspent Medicare dollars when administered by unqualified providers practicing "incident to" the physician.

To further support the use of physical therapist and physical therapist assistants acting under the supervision of a physical therapist as the only providers of Physical Therapy, we would like to revisit the educational background of a physical therapist. Prior to billing Medicare for physical therapy services, each licensed physical therapist completes multiple comprehensive patient care internships. These clinical experiences provide valuable insight to the management of physical therapy services for individuals dependent on Medicare for health insurance. *How is it possible that individuals who practice "incident to" a physician are not required to have any clinical experience?* There are no regulations on their training, skill competency or knowledge base. *How can CMS justify to its beneficiaries who receive Physical Therapy "incident to" a physician that it is the same care a physical therapist or physical therapist assistant under the direction of a physical therapist, provides?* Presently there are no safeguards in place to inform beneficiaries of this discrepancy.

If the August 5 proposed rule on “Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005” is not enacted an inherent risk of increased public harm will emerge in the Medicare arena surrounding physical therapy service provided “incident to” the physician. Since January of 2002, CAPTE requires a post-baccalaureate degree for all graduating physical therapists. By 2005, a majority of all accredited programs will confer a doctor of physical therapy degree (DPT). Both the entry level and transitional DPT programs will expand the knowledge base of physical therapists. DPT level courses include study in radiology, pharmacology, evidenced-based practice, and differential diagnosing. *The WPTA urges CMS to mandate that Physical Therapy services offered “incident to” the physician be performed only by a physical therapist or a physical therapist assistant.* The WPTA voices its strong support for this proposed rule.

Finally, as January 1, 2006 approaches and the financial limitation on physical therapy service emerges again, the WPTA would like to express its concern over the resumption of the therapy cap. WPTA members repeatedly encounter barriers when a beneficiary seeks care in a privately owned physical therapy clinic. Under the present Medicare policy, which fails to include the August 5th proposed rule, a patient could exceed his/her financial cap without having a physical therapist involved in any aspect of their care. A beneficiary, who inadvertently “trusts” their physician to provide “physical therapy” under the “incident to” provision, may believe they have received the same clinical expertise of a skilled physical therapist or physical therapist assistant, under the supervision of a physical therapist. The WPTA respectfully requests that CMS examine this concern in context of the Medicare B cap.

Thank you, Dr. McClellan, for considering the WPTA’s comment on this important issue facing the physical therapists and physical therapist assistants of Wisconsin.

Sincerely,

Mary Beth Geiser PT, OCS
Reimbursement Chair
Wisconsin Physical Therapy Association

Michele Thorman PT, MBA
Chapter President
Wisconsin Physical Therapy Association

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

GENERAL

GENERAL

We beg you to NOT pass this policy whereby a physician can only refer "incident to" services to physical therapists. All qualified health care providers should be allowed to provide services to patients with a physicians prescription or under their supervision. As a massage therapist, I find many soft tissue damage patients do better with massage than with physical therapy. Please consider this, physical therapy has its roots in massage and massage has been in written records for over 3000 years. Physical therapy has only been provided by Western civilization and for less than 150 years.

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

GENERAL

GENERAL

I don't believe the Congress has accurately assessed the "damage" this new Modernization Act will bring. Most, if not all insurance companies, follow the Medicare guidelines for care and we are finding shortfalls in care already. With these new guidelines, may more patients will be finding it harder to receive care! I work in Cancer Care, and I am finding more and more necessary tests, treatments, etc. being denied by the insurance companies! Where are we heading in patient care? Will we be telling many more patients, I'm sorry we can't provide the necessary care to you because your insurance company has denied this treatment and you will be responsible for the bill. Many patient's are finding it harder and harder to afford health insurance now, with it's limiting benefits, so where is the benefit now with the pending Medicare cuts to care? Maybe members of Congress should be placed on several of the insurance policies available (HMO, EPO), and not allowed to use their ample funds, and see about getting necessary health care. Maybe then they will finally understand how bad things have become!!!!

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

As a licensed practicing physical therapist for 32 years, I strongly support the August 5 proposed rule on 'Revision Payment Policies Under the Physician Fee Schedule for Calendar Year 2005'

Outpatient physical therapy services should be provided by and billed by a licensed physical therapist who has graduated from an accredited physical therapy program. As a licensed healthcare provider I am accountable for my professional actions. If a patient is accessing physical therapy services from me they can be assured they are receiving physical therapy services rather than receiving services from an unqualified person even though it may be billed as physical therapy.

More importantly, if physical therapy services can be provided and billed by unqualified people why would you have a Physical Therapy Accreditation, a National Physical Therapy Exam, and State Licensing Requirements? I would seem superfluous and a waste of valuable resources.

Thank you for considering my comments.

Janice Culliton, P.T. #1049;
Northern Arm & Hand Center, Inc.;
1420 London Rd. Suite 102;
Duluth, MN 55805

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 1-9

SECTION 303

See attached

SECTION 611

See attached

CMS-1429-P-4027-Attach-1.doc

CMS-1429-P-4027-Attach-2.doc

CMS-1429-P-4027-Attach-2.doc

CMS-1429-P-4027-Attach-1.doc



24 September 2004

Mark D. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services (CMS)
200 Independence Avenue SW
Room 214-G
Washington, DC 20201

Re: APOS Comments on the Proposed Rules for the MMA

Dear Dr. McClellan:

We are writing on behalf of our fellow members in the American Psychosocial Oncology Society (APOS) to comment on the proposed rules for the Medicare Drug, Modernization and Improvement Act (MMA). We are a non-profit professional organization, comprised of over 375 psychiatrists, psychologists, nurses, social workers and allied health professionals who specialize in assessment and treatment of the significant psychosocial burdens of cancer. More than 50% of patients who have cancer suffer from depression, anxiety and the effects of intense psychosocial distress. There is a high prevalence of co-occurring medical and psychiatric disorders among Medicare eligible citizens. Studies have shown that these individuals experience increased morbidity and mortality in their medical condition when their access to essential mental health services is limited. Conversely, when timely identification of and intervention with co-occurring psychiatric conditions are made, patients have better outcomes in the treatment of their medical disorders, reduced cost associated with chronic and disabling conditions, and higher productivity and quality of life.

Because of our concern for the patients for whom we care, we are collaborating with Treatment Effectiveness Now (TEN Project) and other professional and advocacy organizations to provide comments on two important elements of the proposed physician fee schedule for calendar year 2005: the scope of services provided as part of the initial preventive physical examination and reimbursement for chemotherapy services. We join others, including the American Psychiatric Association (APA), the National Coalition of Cancer Survivors (NCCS) and the Academy of Psychosomatic Medicine (APM) in bringing these issues to your attention.

The report of President Bush's New Freedom Commission on Mental Health cites the critical importance of Medicare and Medicaid reform to improving the quality and accessibility of mental health service delivery through support of evidence-based treatments. The Report states: "Any effort to strengthen or improve the Medicare and Medicaid programs should offer

beneficiaries options to effectively use the most up-to-date treatments and services.” Furthermore, the report calls attention to the un-met mental health needs of patients with chronic medical illnesses.¹

The MMA provides an important opportunity to provide appropriate screening and treatment for depression in the medical setting. We would like to offer comments on the proposed rule which we feel can clarify, support and strengthen the intent of the MMA in providing needed, cost-effective care to citizens with both medical and psychiatric illness, including those with cancer.

We support the comments that the TEN Project recently sent to you on the proposed MMA rules and implementation. We wish further to underscore the following points which are of high significance to our patient constituents and professional colleagues:

Comment on Section 611: Initial Preventive Physical Examination

Section 611 of the MMA provides for Medicare Part B coverage of an initial preventive physical exam for new beneficiaries for services furnished on or after 1 January 2005. CMS proposes to add a new provision that would provide coverage for certain services as part of an initial preventive physical examination in a number of settings, including in the hospital outpatient department. Among other categories, CMS has proposed to include:

- “(2) Review of the individual's potential (risk factors) for depression (including past experiences with depression or other mood disorders) based on the use of an appropriate screening instrument, which the physician or other qualified nonphysician practitioner may select from various available standardized screening tests for this purpose, unless the appropriate screening instrument is defined through the national coverage determination (NCD) process”
- "(6) Education, counseling, and referral, as deemed appropriate, based on the results of elements (1) through (5) of the proposed definition of the initial preventive physical examination."

In support of this we would like to offer the following comments:

1. The President's New Freedom Commission on Mental Health has stated that mental health should be treated with the same urgency as physical health and as such has made a series of recommendations acknowledging the primary care office as the “de facto” mental health system for most patients in this country. Early recognition and treatment of depression will have a positive impact on medical, mental and economic outcomes.
 - We would encourage CMS to clarify that the assessment includes consideration of both the *potential* for depression, as well as the assessment of *current depression* status. While we believe that this is the intent of the rule, the proposed language refers to assessing “potential (risk factors) for depression” but not to assessing current depression status per se.

- We concur with the recommendation that “an appropriate screening instrument” be used for the assessment of depression. However, we would suggest that a limited number of screening instruments be utilized to maximize clinical utility and transportability. For example, the 9-item Patient Health Questionnaire (PHQ-9) has now been well validated in several studies with medically ill patients as a diagnostic screen for depression.² It can provide both a diagnosis and also a severity rating, and is easy to use.
 - Furthermore, we believe that coverage for conducting and interpreting the PHQ-9 (or other appropriate depression screening tool) through the NCD process would be a critical component to assuring that physicians comply with the screening component of the preventive exam. We would welcome the opportunity to work with CMS to move forward an NCD determination for screening of depression.
2. Evidence suggests that screening for depression in and of itself does not positively impact depression outcomes. The United States Preventive Services Task Force recently reported that depression screening is primarily effective if patients who screen positive are *referred for appropriate treatment*.³ We commend CMS on including a provision that allows for counseling and referral based on the evidence of depression in the initial preventive physical examination. However, we also know that the barriers to receiving psychiatric intervention are numerous and must be considered in order to assure that patients receive appropriate treatment.
- We believe that greatest impact would occur if the rule were to include specific language stressing the importance of referring patients who screen positive for depression to appropriate treatment and the recommendation to monitor depression outcomes over time.
3. Once depression is identified, disease management, collaborative care and direct provision of appropriate psychiatric and psychosocial care are effective in improving medical and psychosocial outcomes. Furthermore, the President’s New Freedom Commission report in Recommendation 4.4 states: “Screen for mental disorders in primary health care, across the life span and connect to treatment and supports.” In addition, it states: “Collaborative care models should be widely implemented in primary health care settings and reimbursed by public and private insurers.” Currently, key elements of collaborative care-particularly nurse care management, and the collaboration between the care manager and primary and mental health specialty providers, are at best partially reimbursable under Medicare. The TEN Project, along with the American Psychiatric Association and the Academy of Psychosomatic Medicine are currently engaged in an evaluation of the current diagnostic, procedural and contractual barriers to receiving mental health services in the primary care setting, we would welcome the opportunity to share the outcome of this work with you.
- Therefore, we would recommend that CMS clarify the appropriate coding procedures to be utilized in order to be reimbursed for these services. We will be glad to provide

- additional information regarding our analysis of coding practices and reimbursement to CMS in order to address this.
- We would also encourage CMS utilize this opportunity to respond to the President's New Freedom Commission Report to develop strategies to assure that collaborative care models can be adequately reimbursed.
4. In addition, we would concur with the NCCS (see attached), which recommends that the preventive examination be expanded to include review of the individual's risk factors for cancer, including a review of the individual's past cancer diagnoses and treatment. Patients with cancer have high rates of mental disorders and distress which impair their functioning long after initial treatments end. The National Cancer Center Network, in its 2003 standards of care , addresses the need to assess and treat distress for all patients throughout and beyond their cancer illness and furthermore to utilize evidence based interventions when interventions are indicated.⁴ The Institute of Medicine in two reports, *Improving Palliative Care for Cancer*, and *Meeting Psychosocial Needs of Women with Breast Cancer*, has affirmed that available practice guidelines "should dictate the standard of care for both physical and psychosocial symptoms."^{5,6} In addition to supporting the NCCS recommendations we would also suggest:
- In addition to the depression screen, patients with a history of cancer should also be screened for cancer related distress through an appropriate screening instrument for the assessment of distress in patients with a history of cancer. Several screening instruments have been tested and validated in this patient population and can be utilized.⁷
 - We also encourage CMS to urge development of and referral to psychosocial services provided by mental health professionals who have expertise in the treatment of patients with chronic medical illnesses, such as cancer.

Section 303—Payment Reform for Covered Outpatient Drugs and Biologicals

Over 50% of cancer patients have evidence of psychiatric disorders or psychosocial distress. Only 10% receive attention to these mental health issues, much of that care is delivered in the oncology treatment setting as part of the supportive services patients receive related to chemotherapy administration. Therefore, the TEN Project is also carefully monitoring the changes in reimbursement for cancer care delivered in the physician's office that were mandated by the MMA and their potential effects on the quality of cancer care. Medicare payments for the services provided as part of chemotherapy administration must be adequate if quality care is to remain available in the community, where patients have become accustomed to receiving their treatment and prefer to be treated.

A range of services, including support services, are delivered in the oncologist's office. These services are considered a vital part of quality cancer care. These services include access to dedicated mental health professionals with expertise in the care of cancer patients who provide psychiatric and psychosocial interventions. Cancer care is a multi-disciplinary endeavor, and

elimination of any of the services that are part of the cancer care experience will have a negative impact on quality of care.

It is our hope that the modification of chemotherapy codes will yield a proposal for the addition of codes, including but not limited to a cancer management code as well as a code that could be used in the provision of psychosocial services to patients with a cancer diagnosis, which could form the basis for providing adequate reimbursement for the services that are part of chemotherapy administration. We realize that some of the services that we consider to be an integral part of cancer care have not been recognized traditionally by Medicare as covered services, but we strongly urge flexibility in establishing codes that will guarantee payment for all essential cancer care services.

In conclusion, we strongly urge you to consider the inclusion of language within the regulations that allows for these considerations in implementing this benefit. We would welcome the opportunity to meet and speak with you and to review findings that support our recommendations.

Sincerely,

A handwritten signature in cursive script that reads "Alan Valentine".

Alan Valentine, MD

President

American Psychosocial Oncology Society

References:

1. New Freedom Commission on Mental Health, *Achieving the Promise: Transforming Mental Health Care in America*. Final Report. DHHS Pub. No. SMA-03-3832. Rockville, MD: 2003.
2. Kroenke K, Spitzer RL, Williams JB. (2001). "The PHQ9: validity of a brief depression severity measure." *J Gen Intern Med*. 16(9):606-13.
3. Pignone MP, Gaynes BN, Rushton JL, Burchell CM, Orleans CT, Mulrow CD, Lohr KN (2002). "Screening for depression in adults: a summary of the evidence for the U.S. Preventive Services Task Force. *Ann Intern Med*. 2002 May 21;136(10):765-76.
4. Holland JC, Andersen B, Booth-Jones M, et al. NCCN Distress Management Clinical Practice Guidelines in Oncology. *Journal of the NCCN* 2003;1:344-74.
5. Foley KM, Gelband H, eds. *Improving Palliative Care for Cancer*, [Report of the National Cancer Policy Board/Institute of Medicine and National Research Council]. Washington, DC: The National Academies Press: 2001.
6. Hewitt M, Herdman R, Holland JC. (Eds.). *Meeting Psychosocial Needs of Women with Breast Cancer*. [Report of the National Cancer Policy Board/Institute of Medicine and National Research Council]. Washington, DC: The National Academies Press: 2004.
7. Holland JC, Andersen B, Booth-Jones M, et al. NCCN Distress Management Clinical Practice Guidelines in Oncology. *Journal of the NCCN* 2003;1:344-74.

Treatment Effectiveness Now

September 24, 2004

Mark D. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue SW
Room 214-G
Washington, DC 20201

Dear Dr. McClellan:

We are writing as Executive Board members of Treatment Effectiveness Now (the TEN Project). The TEN Project is a private, non-profit policy action organization, dedicated to educating public officials, advocates and professionals about the clinical and policy implications of evidence-based treatment for co-occurring medical and psychiatric disorders. There is a high prevalence of co-occurring medical and psychiatric disorders among Medicare beneficiaries. Consequently, the TEN Project is working with leaders of patient advocacy and professional organizations (mental and physical health), to provide comments on two important elements of the proposed physician fee schedule for calendar year 2005: the scope of services provided as part of the initial preventive physical examination and reimbursement for chemotherapy services. We join others, such as the National Coalition of Cancer Survivors (NCCS) and the American Psychiatric Association (APA) in bringing these issues to your attention.

The report of President Bush's New Freedom Commission on Mental Health (1) cites the critical importance of Medicare and Medicaid reform to improving the quality and accessibility of mental health service delivery through support of evidence-based treatments. The Report states: "Any effort to strengthen or improve the Medicare and Medicaid programs should offer beneficiaries options to effectively use the most up-to-date treatments and services." Furthermore, the report calls attention to the un-met mental health needs of patients with chronic medical illnesses.

Mental Illness in Patients with Chronic Medical Illness

Of the over 18 million adults in this country with a chronic medical condition (eg. Hypertension, diabetes, cancer etc.) more than half have evidence of a mental disorder. Patients may have evidence of mood and anxiety disorders, delirium or significant levels of psychosocial distress which greatly contribute to their health status and quality of life. Studies have shown that these patients' medical conditions appear to be worsened in the presence of mental illness and that they consequently utilize proportionately greater resources in their medical and psychiatric care. However, research indicates that when the mental illness and distress are addressed the medical conditions improve and costs are reduced. Yet, less than half of those patients presenting to their primary care physicians with evidence of a mental disorder are diagnosed, and even with diagnosis only half receive adequate treatment.

The MMA provides an important opportunity to provide appropriate screening and treatment for depression in the medical setting. We would like to offer comments on the proposed rule which we feel can clarify, support and strengthen the intent of the MMA in providing needed, cost-effective care to citizens with both medical and psychiatric illness.

Comment on Section 611: Initial Preventive Physical Examination

Section 611 of the MMA provides for Medicare Part B coverage of an initial preventive physical exam for new beneficiaries for services furnished on or after January 1, 2005. CMS proposes to add a new provision that would provide coverage for certain services as part of an initial preventive physical examination in a number of settings, including in the hospital outpatient department. Among other categories, CMS has proposed to include:

The TEN Project

In Partnership with the Department of Psychiatry, Georgetown University School of Medicine
750 17th St., NW, Washington, DC 20006 p 202.778.2373 f 202.778.2330

- “(2) Review of the individual's potential (risk factors) for depression (including past experiences with depression or other mood disorders) based on the use of an appropriate screening instrument which the physician or other qualified nonphysician practitioner may select from various available standardized screening tests for this purpose, unless the appropriate screening instrument is defined through the national coverage determination (NCD) process”
- “(6) Education, counseling, and referral, as deemed appropriate, based on the results of elements (1) through (5) of the proposed definition of the initial preventive physical examination.”

In support of this we would like to offer the following comments:

1) The President's New Freedom Commission on Mental Health has stated that mental health should be treated with the same urgency as physical health and as such has made a series of recommendations acknowledging the primary care office as the “de facto” mental health system for most patients in this country. Early recognition and treatment of depression will have a positive impact on medical, mental and economic outcomes.

- We would encourage CMS to clarify that the assessment includes consideration of both the *potential* for depression, as well as the assessment of *current depression* status. While we believe that this is the intent of the rule, the proposed language refers to assessing “potential (risk factors) for depression” but not to assessing current depression status per se.
- We concur with the recommendation that “an appropriate screening instrument” be used for the assessment of depression. However, we would suggest that a limited number of screening instruments be utilized to maximize clinical utility and transportability. For example, the 9-item Patient Health Questionnaire (PHQ-9) has now been well validated in several studies with medically ill patients as a diagnostic screen for depression (2). It can provide both a diagnosis and also a severity rating, is easy to use.
- Furthermore, we believe that coverage for conducting and interpreting the PHQ-9 (or other appropriate depression screening tool) through the NCD process would be a critical component to assuring that physicians comply with the screening component of the preventive exam. We would welcome the opportunity to work with CMS to move forward an NCD determination for screening of depression.

2) Evidence suggests that screening for depression in and of itself does not positively impact depression outcomes. The United States Preventive Services Task Force (3) recently reported, that depression screening is primarily effective if patients who screen positive are *referred for appropriate treatment*. We commend CMS on including a provision which allows for counseling and referral based on the evidence of depression in the initial preventive physical examination. Once depression is identified, disease management, collaborative care and direct provision of appropriate psychiatric and psychosocial care are effective in improving medical and psychosocial outcomes.

- We believe that in order for the depression screen to be effective, specific language needs to be included stressing the importance of appropriate treatment, including referral to mental health specialists when indicated, and the recommendation to monitor depression outcomes over time to ensure the treatment is effective.
- We also know that the barriers to receiving psychiatric care, which include but are not limited to the outpatient mental health treatment limitation which requires beneficiaries to pay more for mental health care than medical care are numerous and must addressed in order to assure that patients receive appropriate treatment.

3) Once depression is identified, disease management, collaborative care and direct provision of appropriate psychiatric and psychosocial care are effective in improving medical and psychosocial outcomes. Furthermore, the President's New Freedom Commission report in Recommendation 4.4 states: “Screen for mental disorders in primary health care, across the life span and connect to treatment and supports.” In addition it states: “Collaborative care models should be widely implemented in primary health care settings and reimbursed by public and private insurers.” Currently key elements of

collaborative care-particularly nurse care management, and the collaboration between the care manager and primary and mental health specialty providers, are at best partially reimbursable under Medicare. The TEN Project, along with the American Psychiatric Association and the Academy of Psychosomatic Medicine are currently engaged in an evaluation of the current diagnostic and procedural barriers to receiving mental health services in the primary care setting, we would welcome the opportunity to share the outcome of this work with you.

- Consequently, we recommend that CMS clarify the appropriate coding procedures to be utilized in order to be reimbursed for these services; and
- We would also encourage CMS utilize this opportunity to respond to the President's New Freedom Commission Report to develop strategies to assure that collaborative care models can be adequately reimbursed.

4) In addition, we would concur with the NCCS (see attached) which recommends that the preventive examination be expanded to include review of the individual's risk factors for cancer, including a review of the individual's past cancer diagnoses and treatment. Patients with cancer have high rates of mental disorders and distress which impair their functioning long after initial treatments end. The National Cancer Center Network, in its 2003 standards of care (4), address the need to assess and treat distress for all patients throughout and beyond their cancer illness and furthermore to utilize evidence based interventions when interventions are indicated. The Institute of Medicine in two reports, *Improving Palliative Care for Cancer*, and *Meeting Psychosocial Needs of Women with Breast Cancer* (5, 6), have both affirmed that available practice guidelines "should dictate the standard of care for both physical and psychosocial symptoms." In addition to supporting the NCCS recommendations we would also suggest:

- In addition to the depression screen, patients with a history of cancer should also be screened for cancer related distress through an appropriate screening instrument for the assessment of distress in patients with a history of cancer. Several screening instruments have been tested and validated in this patient population and can be utilized (4).
- We also encourage CMS to urge development of and referral to psychosocial services provided by mental health professionals who have expertise in the treatment of patients with chronic medical illnesses, such as cancer.

Section 303—Payment Reform for Covered Outpatient Drugs and Biologicals

Over 50% of cancer patients have evidence of psychiatric disorders or psychosocial distress. And while and only 10% receive attention to these mental health issues, much of that care is delivered in the oncology treatment setting as part of the supportive services patients receive related to chemotherapy administration. Therefore, the TEN Project is also carefully monitoring the changes in reimbursement for cancer care delivered in the physician's office that were mandated by the MMA and their potential effects on the quality of cancer care. Medicare payments for the services provided as part of chemotherapy administration must be adequate if quality care is to remain available in the community, where patients have become accustomed to receiving their treatment and prefer to be treated.

A range of services, including support services are delivered in the oncologist's office. These services are considered a vital part of quality cancer care. These services include access to dedicated mental health professionals with expertise in the care of cancer patients who provide psychiatric and psychosocial interventions. Cancer care is a multi-disciplinary endeavor, and elimination of any of the services that are part of the cancer care experience will have a negative impact on quality of care.

It is our hope that the modification of chemotherapy codes will yield a proposal for the addition of codes, including but not limited to a cancer management code as well as a code which could be used in the provision of psychosocial services to patients with a cancer diagnosis, that could form the basis for providing adequate reimbursement for the services that are part of chemotherapy administration. We realize that some of the services that we consider an integral part of cancer care have not been

The TEN Project

In Partnership with the Department of Psychiatry, Georgetown University School of Medicine
750 17th St., NW, Washington, DC 20006 p 202.778.2373 f 202.778.2330

recognized traditionally by Medicare as covered services, but we strongly urge flexibility in establishing codes that will guarantee payment for all essential cancer care services.

We respectfully request that you to incorporate these comments into the rules that will guide implementation of the MMA. We believe there is an important opportunity at hand to improve substantially the health outcomes for patients who have these co-occurring disorders, reducing morbidity, mortality and the associated productivity and treatment costs.

We thank you for your consideration and stand ready to assist you and your staff at CMS in implementation of the MMA and its associated provisions.

Sincerely,

Carol L. Alter, M.D.
Executive Director

Danna Mauch, Ph.D
President

References:

1. New Freedom Commission on Mental Health, Achieving the Promise: Transforming Mental Health Care in America. Final Report. DHHS Pub. No. SMA-03-3832. Rockville, MD: 2003.
2. Kroenke K, Spitzer RL, Williams JB. (2001). "The PHQ9: validity of a brief depression severity measure." J Gen Intern Med. 16(9):606-13.
3. Pignone MP, Gaynes BN, Rushton JL, Burchell CM, Orleans CT, Mulrow CD, Lohr KN (2002). "Screening for depression in adults: a summary of the evidence for the U.S. Preventive Services Task Force. Ann Intern Med. 2002 May 21;136(10):765-76.
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5. Foley KM, Gelband H, eds. Improving Palliative Care for Cancer, [Report of the National Cancer Policy Board/Institute of Medicine and National Research Council]. Washington, DC: The National Academies Press: 2001.
6. Hewitt M, Herdman R, Holland JC. (Eds.). Meeting Psychosocial Needs of Women with Breast Cancer. [Report of the National Cancer Policy Board/Institute of Medicine and National Research Council]. Washington, DC: The National Academies Press: 2004

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 1-9

PRACTICE EXPENSE

See Attachment

SECTION 611

See Attachment

CMS-1429-P-4028-Attach-1.pdf

CMS-1429-P-4028-Attach-1.pdf



Randel E. Richner
Vice President
Government Affairs and
Reimbursement & Outcomes
Planning

1331 Pennsylvania Avenue, NW
Suite 550 South
Washington, DC 20004

BY ELECTRONIC SUBMISSION

September 24, 2004

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

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005 including Selected Provisions Implementing the Medicare Modernization Act [CMS-1429-P]

Dear Administrator McClellan:

Boston Scientific Corporation (Boston Scientific) appreciates the opportunity to present these comments and policy recommendations on CMS's Physician Fee Schedule Proposed Rule for Calendar Year 2005 (Volume 69, No. 150, August 5, 2004).

As the world's largest company dedicated to the development, manufacturing, and marketing of less-invasive therapies, Boston Scientific supplies medical devices and technologies used by physicians representing the following medical specialty areas:

- Electrophysiology;
- Endoscopy;
- Gastroenterology;
- Gynecology;
- Interventional Cardiology;
- Neurovascular;
- Oncology;
- Peripheral Interventions;
- Urology; and
- Vascular Surgery.

We are commenting on three policy issues addressed in the Calendar Year 2005 Physician Fee Schedule Proposed Rule that have important implications for physicians and their continued ability to offer Medicare beneficiaries the latest advances in clinical care safely and effectively in the lower cost setting of their offices:

1. In-Office Practice Expense Proposed RVUs for Percutaneous Thrombectomy (page 47617);
2. In-Office Practice Expense Proposed RVUs for Hysteroscopic Endometrial Ablation (“Miscellaneous Practice Expense Issues”, page 47497);
3. Initial Preventive Physical Examinations and Payment for Colorectal Cancer Screening Procedures (Provisions of the Medicare Modernization Act of 2003, A. Section 611, page 47514).

Additionally, we comment on the importance of expanding preventive care benefits to include screening for abdominal aortic aneurysms (related to Provisions of the Medicare Modernization Act of 2003, A. Section 611, page 47514).

In-Office Practice Expense RVUs for Percutaneous Thrombectomy

Thrombectomy, percutaneous, arteriovenous fistula procedures (CPT 36780) face a potential decrease of 27 percent compared to 2004 rates. Proposed in-office RVUs for 2005 are 32.39 compared to 47.27 in 2004. A dramatic reduction in physician office payment based on antiquated cost data would not be in the best interest of beneficiaries who may need timely and convenient access to this procedure in order to maintain their already disruptive treatment protocols.

To more accurately reflect in-office resource use associated with recent changes in clinical practice, we urge CMS to change the in-office practice expense RVUs for CPT 36780 in the Final Rule.

In review of the costs CMS reports for CPT code 36870, the modality of treatment was the Trerotola™ with a Fogarty™ catheter. With the advancement of technology over the last few years, the Fogarty catheter is not as widely used as a sole device. The Fogarty catheter is used to dissipate a plug, however does not allow for the removal of the debris, and is now used less than 15 percent of the time as a stand alone procedure.

Angiojet™ is an additive device that is used in over 50 percent of percutaneous thrombectomy cases to remove thrombolytic debris, preventing a potential adverse advent caused by debris capture being forced back into the body. In addition, the Angiojet device allows for multiple emboli to be freed from the graft, preventing possible future clots. With this advancement of new technology creating a safer procedure, Angiojet has gained acceptance as the standard. CMS should incorporate the cost of Angiojet to the PE expense costs.

Practice expense costs for the Fogarty Balloon as reported in the Medicare data is \$101.75. The Angiojet product manufactured by Possis has a manufacturer list price of approximately \$675-\$700. The cost of the Angiojet device needs to be added to the procedure costs to ensure physicians can continue to offer the safest procedural conditions for their patients. Therefore, we urge CMS to adjust the in-office RVU for CPT 36780 in the Final Rule to reflect the cost of the Angiojet device.

In-Office Practice Expense RVUs for Hysteroscopic Endometrial Ablation (CPT code 58563)

Based on input from the American College of Obstetricians and Gynecologists and the American Association of Gynecologic Laparoscopists, CMS assigned in-office direct cost inputs to CPT

code 58563 in the Proposed Rule. This step paved the way for establishing a proposed 2005 in-office Medicare physician payment for hysteroscopic endometrial ablation that captures the cost of performing this procedure in the office.

We applaud this step, and wish to express our appreciation to CMS for working with the gynecology specialty societies and industry on this issue to appropriately price this procedure in the office. We believe this step will help to ensure access to this less-invasive alternative to hysterectomy for Medicare-covered women suffering from abnormal uterine bleeding (UAB). The act of proposing a rate has already paved the way for greater consideration of in-office payment with private health plans, further expanding access to this proven technology to women covered through private health plans.

In our previous comments to CMS on this issue (Proposed and Final Rules for Calendar Year 2004), we urged the Agency to assign non-facility (in-office) direct cost inputs to this procedure. This procedure is a highly effective and less-invasive alternative to hysterectomy for women suffering from AUB where the primary symptom being treated is for as much as 40 to 50 percent of the nearly 700,000 hysterectomies performed annually.

In sum, we thank CMS for its efforts in establishing an appropriate in-office rate, and urge CMS to implement its proposal, as we believe that this would establish an appropriate in-office rate for CPT code 58563.

Initial Preventive Physical Examinations (Section 611) and Coverage/Payment for Colorectal Cancer Screening Procedures

Boston Scientific applauds CMS's proposal to implement Section 611 of the Medicare Modernization Act of 2003 which provides coverage and payment for an initial preventive physical examination for Part B beneficiaries. In particular, we appreciate the requirement that the examination should include education, counseling, and referral services for screening and other preventive benefits separately authorized under Part B.

However, while the screening benefits listed in Paragraph A(1) on Federal Register page 47514 (Vol. 69, No. 150) include (5) colorectal cancer screening tests, the list of screening benefits described in the same section, paragraph (7) on page 47515 does not include colorectal cancer screening. We therefore request that CMS include colorectal cancer screening in the list of screening services described on page 47515 of the Physician Fee Schedule Proposed Rule and any other section of any other proposed rule in which covered screening benefits are listed to ensure that there is no confusion regarding what services should be discussed with patients during initial preventive physical examinations.

We would also encourage CMS to expand preventive care benefits as instructed by the Medicare Modernization Act by amending the Final Rule to include coverage and payment for the performance or scheduling of as many of the procedures associated with the screening programs described in Paragraph A(1) on Federal Register 47514 as is reasonable and medically appropriate. For example, for patients for whom colonoscopy is the medically appropriate screening option for colorectal cancer, a colonoscopy appointment should be scheduled for the patient as part of the preventive physical examination.

Preventive Screening for Abdominal Aortic Aneurysms

Boston Scientific believes covering preventive care under Medicare will improve beneficiary care while saving the Medicare Program significant money over the long run. To be effective, preventive care needs to identify relevant health risks associated with the onset and progression of disease as well as take steps to reduce and mitigate those risks.

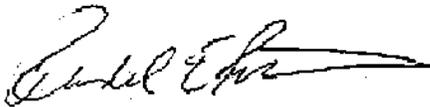
CMS's proposed implementation of new preventive benefits in the 2005 Physician Fee Schedule Proposed Rule, as mandated under the MMA of 2003, is an important first step. We look forward to working with the Agency to formulate policy and to respond to future changes in the Medicare law that would provide coverage and payment for additional preventive screening tests and procedures for which there is proven clinical benefit.

Towards that end, Boston Scientific strongly supports Medicare coverage of a one-time ultrasound screening to identify abdominal aortic aneurysms (AAA) in patients who are at the highest risk (i.e., those patients who have a family history of AAA, manifest risk factors for cardiovascular disease (such as smoking or hypertension), and have evidence of atherosclerotic vascular disease.)

When covered, we believe this screening should also be part of the "Welcome to Medicare" initial preventive physical examination. We would support keeping the term "appropriate screening instrument" undefined so that practitioners could use the instrument of choice based on current clinical practice guidelines and would discourage CMS from using the more time-consuming and burdensome National Coverage Determination (NCD) process to define these screening instruments more specifically.

We thank CMS for the opportunity to comment on the 2005 Physician Fee Schedule Proposed Rule. Please contact Sarah Wells (202-637-8021; wells1@bsci.com) in our Washington office if you have any questions.

Sincerely,



Randel E. Richner, BSN, MPH
Vice President, Government Affairs and Reimbursement & Outcomes Planning

Cc: Steve Phillips
Marc Hartstein
Carolyn Mullen
Ken Simon, M.D.

Submitter : Gillian Amador Date & Time: 09/24/2004 07:09:57

Organization : Gillian Amador

Category : Physical Therapist

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

my name is Gillian Amador. I am a PTAQ student in NVCC Springfield, Virginia. I am concerned and object to cms-1429p regulation. Some of reasons are as follow:Physical therapists and physical therapist assistants under the supervision of physical therapists are the only practitioners who have the education and training to furnish physical therapy services. Unqualified personnel should NOT be providing physical therapy services.
Thank You

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

GENERAL

GENERAL

see three attachments

CMS-1429-P-4030-Attach-3.pdf

CMS-1429-P-4030-Attach-2.pdf

CMS-1429-P-4030-Attach-1.doc

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www.bernell.com • E-Mail: amartin553@aol.com

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Regards,
Tanisha
Bernell Customer Representative

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Through the use of infra-red sensors, an individual's oculo-motor activity is recorded while he or she silently reads an appropriate text selection with the Visagraph[®] goggles. Following the reading, a brief series of questions determines whether or not the subject read with reasonable comprehension. Eye-movement characteristics are automatically analyzed, and detailed reports that provide insight as to "how" the individual reads are then generated.

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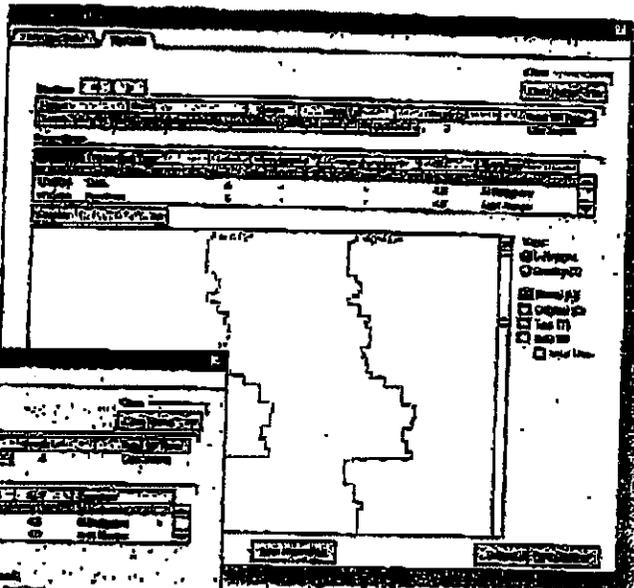


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Bob looked down the street.
 A man was riding a grey pony.
 Five pencils & six sleds the man.
 Bob got five pencils from his mother.
 He went for a ride down the street.
 Then Bob came back on the pony.
 "Stay on the pony" said the man.
 He took Bob's picture on the pony.
 Bob gave his mother the picture.

Item	Qty	Unit Price	Total Price	Comments
Apple	2	1.00	2.00	
Banana	1	1.50	1.50	
Orange	3	0.75	2.25	
Pineapple	1	2.50	2.50	
Watermelon	1	4.00	4.00	
Strawberry	1	1.00	1.00	
Blueberry	1	1.00	1.00	
Blackberry	1	1.00	1.00	
Raspberry	1	1.00	1.00	
Cherry	1	1.00	1.00	
Plum	1	1.00	1.00	
Peach	1	1.00	1.00	
Apricot	1	1.00	1.00	
Apple	2	1.00	2.00	
Banana	1	1.50	1.50	
Orange	3	0.75	2.25	
Pineapple	1	2.50	2.50	
Watermelon	1	4.00	4.00	
Strawberry	1	1.00	1.00	
Blueberry	1	1.00	1.00	
Blackberry	1	1.00	1.00	
Raspberry	1	1.00	1.00	
Cherry	1	1.00	1.00	
Plum	1	1.00	1.00	
Peach	1	1.00	1.00	
Apricot	1	1.00	1.00	

September 24, 2004

via Electronic Mail

Mark McClellan, M.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1429-P
P.O. Box 8012
Baltimore, MD 21244-8012

Federal Affairs Department

**RE: CMS-1429-P (Medicare Program; Revisions to Payment Policies
Under the Physician Fee Schedule for Calendar Year 2005)**

Dear Dr. McClellan:

On behalf of the American Academy of Ophthalmology (Academy) I am writing to comment on the Medicare Program Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005. The Academy is the world's largest organization of eye physicians and surgeons, with more than 27,500 members. Over 16,000 of our members are in active practice in the United States. We appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule.

We are pleased to note that several of the provisions contained within the proposed rule make positive strides towards promoting ophthalmic health and promoting fair reimbursement for ophthalmology procedures (i.e. the welcome to Medicare physical and the solicitation for equipment pricing information). Unfortunately, several aspects of the proposed rule could potentially have a detrimental affect on the efficacy of ophthalmology. Included among these are: the method for revising malpractice RVUs and continuing problems with the SGR. The Academy urges CMS to reconsider its current position on these issues in light of our comments.

**Practice Expense Advisory Committee (PEAC) Recommendations on CPEP Inputs
for 2005**

The Academy applauds CMS's efforts to update the supplies and equipment used in determining the practice expense values attributed to individual CPT codes. We appreciate the opportunity to provide CMS with pricing information regarding two pieces of equipment associated with ophthalmology procedures for inclusion in the data base.

Table 2- Equipment Items Needing Specialty Input for Pricing and Proposed Deletions

E71013 Computer and VDT and software (associated with 92060, 92065)-- The Visagraph unit is available through Bernell Corporation at a total cost of \$5600. This includes:

Visagraph- \$3400 (includes software and goggles)
Printer (Hewlett Packard)- \$1200
Monitor- \$350
Computer \$650

The Bernell Corporation may be contacted at:

Bernell Corporation
4016 N. Home Street
Mishawaka, Indiana 46545-4308
574-259-2070 or 800-348-2225

Drill, ophthalmology (associated with 65125)-- The ocular drill usually used in conjunction with the referenced procedure code is the titanium sleeve driver (item I-00057). The cost of the drill is \$57. This drill is available through:

Integrated Orbital Implants, Inc.
12625 High Bluff Drive, Suite 314
San Diego, CA 92130-2054
858-259-4355 or 800-424-6537

The Academy is also pleased to note that Balanced Salt Solution, ophthalmic sterile incise drapes, vicryl sutures, and other ophthalmology supplies will be added to the CMS database. Lastly, the Academy supports the decision to re-categorize and standardize the description of supplies and equipment found in the CPEP database. These changes will make the database easier to use and will promote accurate/consistent descriptions.

Ophthalmology Equipment

The proposed rule deletes the screening lane from several procedure codes that included both exam and screening lanes. In these instances CMS will now default to the exam lane only. The rule does not specifically identify the codes that were refined to reflect the screening lane deletion. It would be very helpful if CMS could identify the codes that were refined so that organizations representing ophthalmology can assure that the correct lane was deleted.

Proposed Methodology for the Revision of Resource-based Malpractice RVUS

The Academy appreciates CMS's efforts to ensure that the malpractice RVUs attributed to codes adequately reflect the malpractice risks incurred by the specialty performing the procedure. As a surgical specialty with high malpractice premiums, the Academy agrees that ophthalmology malpractice RVUs should reflect the costs incurred by the physicians performing the procedures. The Academy does not dispute its ISO risk classification nor

the premium data used by CMS. However, the Academy was curious to note that the malpractice RVUs for optometry and optician procedures were cross-walked to those for ophthalmology.

The Academy is concerned with CMS's decision to attribute its malpractice liability costs and surgical and non-surgical risk factor values to procedures done by optometrists and opticians. Ophthalmology is a surgical specialty. By contrast, optometry is a non-surgical specialty whose procedures entail a lower level of malpractice risk than ophthalmology procedures. This fact is borne out by data that suggests that the average optometrist pays malpractice premiums totaling \$780/year (see attachments), less than 6% of the average ophthalmologist's malpractice premiums of \$14,000/year. Opticians have no malpractice risks associated with their practice. The distinctions in premium rates is indicia of the malpractice risk differences incurred by ophthalmologists in comparison to optometrists and opticians and also suggests that those specialties have reduced surgical and non-surgical risk factors.

CMS cites the absence of direct premium data for optometrists or opticians as the rationale for the decision to cross-walk these specialties to ophthalmology. The Academy does not think that this rationale adequately substantiates the decision to cross-walk these specialties to one with significantly higher malpractice risk. As an alternative to the current system of cross-walking optometry and optician malpractice RVUs to those for ophthalmology, the Academy recommends cross-walking these services to a non-surgical specialty with comparable malpractice premiums, surgical and non-surgical risks.

Section 611- Initial Preventive Physical Examination

The Medicare Modernization Act of 2003 provides for Part B coverage of an initial preventive screening examination for new beneficiaries. The Academy is pleased that the definition of initial examination includes referring patients for preventive services that are not typically provided by primary care physicians, including a screening for glaucoma. The Academy believes that the definition of initial preventive physical examination developed in the proposed regulation sufficiently conveys the intent and reach of the statute and allows providers to address issues associated with vision loss that might otherwise not be addressed through a glaucoma screen (i.e. functional ability and safety).

Inclusion of a parenthetical following "falls risks" which elaborates on the factors impacting an individual's functional ability and level of safety, including vision loss, would be useful for primary care providers treating patients who may need to follow-up with a specialist. The Centers for Disease Control has cited vision loss as a major cause of falls among the Medicare beneficiary population. Injuries caused by vision loss related falls, including hip fractures, cost Medicare millions of dollars each year. It is estimated that one on every five hip fractures among the elderly is linked to vision loss. These vision loss related fractures account for approximately \$2.2 billion annually.¹

¹ American Academy of Orthopedic Surgeons website

By highlighting fall risks associated with vision loss in the final fee schedule primary care providers may be more inclined to consider this factor and to take steps to ensure that patients who report falling are seen by an ophthalmologist.

Impact- SGR

The proposed rule anticipates a 1.5 percent increase in the physician fee schedule update for 2005 based on the SGR. However, negative fee schedule updates are expected beginning in 2006 and continuing through 2009. The Academy urges CMS to strongly consider removing physician administered drug costs from the SGR pool thereby freeing up money for physician fees by reducing the gap between actual and target spending.

Drug products are not a physician service and should not be included in the SGR pool. Additionally, leaving these costs in the pool does not counter-balance incentives for over-utilization, especially in light of the significant cuts in drug payments effectuated as a result of the Medicare Modernization Act. Taking immediate steps to fix the SGR formula by removing drugs from the pool can help stabilize anticipated cuts in already diminished physician fees thereby ensuring continued beneficiary access to quality health care.

Section 303- Provisions for Appropriate Reporting and Billing for Physicians' Services Associated With the Administration of Covered Outpatient Drugs

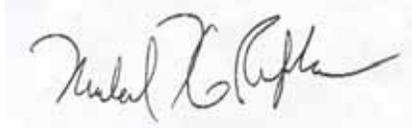
The procedure photodynamic therapy (PDT) (67221 and 67225 (second eye)) requires the administration of Visudyne, an infused drug. At the request of CMS the infusion code for PDT was bundled into the procedure. The Academy asks that, in considering our past comments on this issue in addition to recommendations from the CPT Editorial Panel, any changes in the practice expense value for the therapeutic infusion code 90780 (the infusion code currently bundled into the PDT procedure) also be reflected in the valuation for the PDT codes 67221 and 67225.

Conclusion

It is our hope that CMS will give serious consideration to the Academy's recommendations regarding the proposed fee schedule. We urge CMS to strongly consider making changes to its current system for evaluating the malpractice RVUs attributed to specialties. The modifications that we have proposed will better enable CMS to achieve its ultimate objective of fairly valuing codes based on the malpractice risks unique to the procedure. The Academy also encourages CMS to elaborate on the type of fall factors identified in the initial preventive physical examination section. We continue to urge CMS to remove physician administered drugs from the SGR. Lastly, the Academy asks that any updates to the infusion code 90780 also be reflected in the valuation for the PDT codes 67221 and 67225. The Academy appreciates the opportunity to provide additional information regarding the pricing of ophthalmology supplies and equipment. If there are additional questions and/or comments regarding the cost of ophthalmology code inputs we encourage CMS to contact us. Again, the Academy

would like to thank you for providing us with the opportunity to comment and looks forward to CMS's response to our comments in the final rule.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael X. Repka". The signature is written in a cursive style with a long, sweeping tail.

Michael X. Repka, M.D.
Chairman, Health Policy Committee

Enclosures



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RETROACTIVE DATE: N/A

INSURED:

This certificate is issued as a matter of information only. This certificate does not amend, extend or alter the coverage afforded by the policy. For details of coverage, refer to policy document.

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Type of Insurance	Policy #	Effective Date	End Date	Liability Limits Per Medical Incident/ Aggregate
Professional Liability		09/23/2003	09/23/2004	\$2,000,000/\$4,000,000
General Liability		09/23/2003	09/23/2004	\$2,000,000/\$4,000,000

Mary Jane Stuy

 Authorized Representative



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Invoice Number: 53623
 Invoice Date: 6/25/2003

CURRENT ACTIVITY

Type of Policy: Professional Liability/General Liability
 Insurance Company: NCMIC Insurance Company
 Named Insured:
 Policy Number:
 Policy Period: 09/23/2003 to 09/23/2004
 Agency: Optometric Protector Plan NC3
 Payment Plan: ANNUAL
 Reason for Invoice: Renewal

Please pay the remaining balance of: \$403.00

or

Current premium installment due: \$403.00

Pay the total current installment due: \$403.00

Please allow seven days from mailing date to process your payment. Your payment must reach us no later than: 09/23/2003

PLEASE MAKE CHECK PAYABLE TO: Optometric Protector Plan
 Your cancelled check is your receipt.

Detach and return this portion with your payment in the envelope provided.



Name:
 Policy #:
 Invoice #: 53623

Total Due: \$403.00
 Current Due: \$403.00
 Due Date: 09/23/2003
 Amount Paid: _____

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1. APPLICANT

ALL APPLICANTS MUST COMPLETE

LAST NAME FIRST NAME INITIAL

BUSINESS/CORPORATE NAME/DBA (if applicable) (COMPLETE ONLY IF YOU OWN THE BUSINESS) FEDERAL TAX I.D. # OR SOC. SEC. #

NUMBER OF OWNERS, PARTNERS, AND CORPORATE OFFICERS WHO ARE ACTIVE IN THE BUSINESS, AND THEIR PROFESSIONAL OCCUPATIONS

ADDRESS DAYTIME PHONE

CITY, STATE, ZIP COUNTY FAX NUMBER

ARE YOU A MEMBER OF YOUR STATE OPTOMETRIC ASSOCIATION YES NO

2. EMPLOYED INDIVIDUALS

See back of application for premium rates by territory. Full-Time means 20 or more hours per week. Part-Time means less than 20 hours per week.

ANNUAL LIMITS AND PREMIUMS

\$2,000,000 per incident/occurrence \$1,000,000 per incident/occurrence
\$4,000,000 aggregate \$3,000,000 aggregate

Optometrist Full-Time Rate \$ _____ \$ _____
Optometrist Part-Time Rate \$ _____ \$ _____
Optometrist 1st Year Graduate Rate \$ _____ \$ _____

3. SELF-EMPLOYED INDIVIDUALS AND BUSINESS APPLICANTS

You must pay a premium for each optometrist owner within your firm.

of Optometrist(s) X rate = premium due
see back of application for rates by territory

Optometrist owner(s) Full-Time Rate # _____ X \$ _____ = \$ _____ # _____ X \$ _____ = \$ _____
Optometrist owner(s) Part-Time Rate # _____ X \$ _____ = \$ _____ # _____ X \$ _____ = \$ _____
Optometrist owner(s) 1st Year Graduate (Individuals Only) # _____ X \$ _____ = \$ _____ # _____ X \$ _____ = \$ _____

You must pay a premium for each optometrist employee within your firm.

Optometrist employee(s) Full-Time Rate # _____ X \$ _____ = \$ _____ # _____ X \$ _____ = \$ _____
Optometrist employee(s) Part-Time Rate # _____ X \$ _____ = \$ _____ # _____ X \$ _____ = \$ _____
Optometrist employee(s) 1st Year Graduate Rate # _____ X \$ _____ = \$ _____ # _____ X \$ _____ = \$ _____

4. OPTIONAL COVERAGE SELF-EMPLOYED INDIVIDUALS AND BUSINESS APPLICANTS

Additional Insured: Premium is for each facility under contract. (List name and address of each facility on a separate sheet of letterhead.)

of Facility(s) X rate = premium due
_____ X \$183 = \$ _____ # _____ X \$156 = \$ _____

5. PREMIUM CREDITS

Subtotal Premium (sections 3 & 4): \$ _____ \$ _____

Size of Group Credit (if applicable)
This credit is based upon the size of the group at the time coverage is purchased. Credits apply as follows:
Groups of 2-9 optometrists, 4%
Groups of 10-14 optometrists, 8%
Groups of 15 or more optometrists, 12%

Less Size of Group Credit (if applicable): \$ _____ \$ _____

TOTAL DUE

(Round to Nearest Dollar): \$ _____ \$ _____

6. ALL APPLICANTS MUST ANSWER UNDERWRITING QUESTIONS

1) Have any of the following ever been revoked, suspended, refused, denied renewal, placed on probation, cancelled, or voluntarily surrendered by you or any of your employees or is such an action pending?
(If YES, please explain on a sheet of your letterhead. Include dates, allegations and amounts.) State License or Certification YES NO
Malpractice Insurance** YES NO

**Notice to Missouri Residents: this question does not apply.

2) Has any claim or suit ever been brought against you or any of your employees or are you or any of your employees aware of any incident that might reasonably lead to a claim or suit?
(If Yes, explain on a sheet of your letterhead. Please include dates, allegations and amounts.) YES NO

ALL APPLICANTS MUST COMPLETE AND SIGN THE BACK OF THE APPLICATION

COPY

How to determine your Professional Liability Premium Rate: First determine which Territory your office is located in using the Territory information below. Next, find the corresponding premium rate for your desired limits of liability from the charts on the right. All coverages must be written with the same limits of liability. Self-employed applicants have the option of purchasing additional insured coverage. Transfer the appropriate rates to the front of this application, multiply by the number of optometrists and apply the appropriate *Size of Group Premium Credit* (if applicable).
NOTE: Rates are the same for employed and self-employed optometrists. Rates differ by the number of hours worked per week: 20+ hours per week denotes Full-Time, less than 20 hours per week is considered Part-Time.

TERRITORY 1

Alabama, Alaska, Arizona, Arkansas, Delaware, Hawaii, Idaho, Indiana, Iowa, Kansas, Kentucky, Maine, Maryland, Mississippi, Montana, Nebraska, New Hampshire, New Mexico, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Rhode Island, South Carolina, South Dakota, Tennessee, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, Wyoming

TERRITORY 2

California (excluding LA County), Colorado, Florida (excluding Dade & Broward Counties), Georgia, Illinois (excluding Cook County), Massachusetts (excluding Norfolk & Suffolk Counties), Michigan (excluding Wayne County), Minnesota, Missouri, Nevada, New Jersey (excluding Camden, Hudson, Essex, Union & Mercer Counties), New York (excluding Bronx, Brooklyn, Manhattan, Queens, Staten Island, Nassau & Suffolk Counties), Pennsylvania (excluding Philadelphia County), Texas (excluding Dallas & Harris Counties)

TERRITORY 3

California (LA County), Illinois (Cook County), Louisiana, Massachusetts (Norfolk & Suffolk Counties), New Jersey (Camden, Hudson, Essex, Union & Mercer Counties), Pennsylvania (Philadelphia County), Texas (Dallas & Harris Counties)

TERRITORY 4

Connecticut, Florida (Dade & Broward Counties), Michigan (Wayne County), New York (Bronx, Brooklyn, Manhattan, Queens, Staten Island, Nassau & Suffolk Counties), Washington DC

TERRITORY 1 LIMITS & ANNUAL PREMIUM RATES	
\$2,000,000 per incident \$4,000,000 aggregate	\$1,000,000 per incident \$3,000,000 aggregate
Full-Time \$415 per Optometrist	Full-Time \$355 per Optometrist
Part-Time or 1st Year Graduate Optometrist \$311	Part-Time or 1st Year Graduate Optometrist \$266

TERRITORY 2 LIMITS & ANNUAL PREMIUM RATES	
\$2,000,000 per incident \$4,000,000 aggregate	\$1,000,000 per incident \$3,000,000 aggregate
Full-Time \$498 per Optometrist	Full-Time \$426 per Optometrist
Part-Time or 1st Year Graduate Optometrist \$374	Part-Time or 1st Year Graduate Optometrist \$320

TERRITORY 3 LIMITS & ANNUAL PREMIUM RATES	
\$2,000,000 per incident \$4,000,000 aggregate	\$1,000,000 per incident \$3,000,000 aggregate
Full-Time \$793 per Optometrist	Full-Time \$678 per Optometrist
Part-Time or 1st Year Graduate Optometrist \$595	Part-Time or 1st Year Graduate Optometrist \$509

TERRITORY 4 LIMITS & ANNUAL PREMIUM RATES	
\$2,000,000 per incident \$4,000,000 aggregate	\$1,000,000 per incident \$3,000,000 aggregate
Full-Time \$1,399 per Optometrist	Full-Time \$1,199 per Optometrist
Part-Time or 1st Year Graduate Optometrist \$1,049	Part-Time or 1st Year Graduate Optometrist \$897

I understand that I am not covered by this insurance if I am any of the following: physician (except for optometry), physician's surgeon, dentist, nurse anesthetist, chiropractor, podiatrist, osteopath, cytotechnologist, electrocardiographic technologist, perfumist or psychologist. I understand that these professional occupations are excluded from coverage. I understand that this insurance will not apply to any partner, principal or owner of a residential occupancy facility. The insurance described herein is subject to the terms, conditions and exclusions of the insurance certificate. This insurance is excess when other insurance applies to a loss.

In order to enhance the stability of this professional liability insurance program, coverage has been organized through a purchasing group, pursuant to legislation, known as the Federal Liability Risk Retention Act of 1986, enacted by Congress. Coverage is provided to the purchasing group by the Chicago Insurance Company, a member of Interstate National Corporation, one of The Fireman's Fund Insurance Companies. Once the completed application has been approved and the premium has been received, you will automatically become a member of the Allied Health Purchasing Group Association, located and domiciled in Illinois and obtain the insurance coverage afforded through the Group Policy on an annual term.

This application is subject to the underwriter's approval. Your completion of this application and premium payment does not bind coverage or obligate the insurance company to issue you insurance coverage. Coverage will become effective following the receipt of your acceptable application and premium payment. Your application cannot be processed unless it is completed in its entirety. The application is subject to the company's underwriting rules.

I declare the information contained in the application is true and that no material facts have been suppressed or misstated. I understand that incorrect information could void protection. Any person who knowingly and with intent to defraud any insurance company or other person files an application for insurance containing any false information or conceals for the purpose of misleading information concerning any fact material thereto, commits a fraudulent insurance act.

Notice to New York Applicants: any person who knowingly and with intent to defraud any insurance company or other person files an application for insurance or statement of claim containing any materially false information, or conceals for the purpose of misleading information concerning any fact material thereto, commits a fraudulent insurance act which is a crime, and shall also be subject to a civil penalty not to exceed five thousand dollars and the stated value of the claim on each such violation.

YOU MUST SIGN AND DATE THIS APPLICATION

Signature X Date _____

Enclosed is my check for \$ _____ Effective Date Desired* _____

*May not be earlier than the date the administrator receives and approves this application.

I authorize Seabury & Smith to charge my: Visa MasterCard Credit Card Number _____

Expiration Date _____ Print name exactly as it appears on card _____

Make check payable to the appropriate administrator and return with this application to the address below.

For all residents except Ohio:
 Seabury & Smith
 Joan F. O'Sullivan, Licensed Agent
 75 Remittance Drive, Suite 1788
 Chicago, IL 60675-1788
 1-800-503-9230
 www.seaburychicago.com
 CA-06-03008

For Ohio residents only:
 Maginnis & Associates
 Agency of Ohio
 P. O. Box 543
 Reynoldsburg, OH 43068-0543
 1-800-345-6917 (Ohio residents)
 1-614-866-3195 (Columbus area)

Underwritten by:
 Chicago Insurance Company,
 a member of the Interstate National Corporation, one of the Fireman's Fund Insurance Companies.

NOTE: This is only a summary of the insurance certificate provisions. If any conflict exists with the actual insurance certificate, the terms of the insurance certificate control.

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

GENERAL

GENERAL

I live in Santa Cruz County, miss-identified by CMS as rural. This designation was fixed in 1967, and a lot has changed since then. Our county is next to Santa Clara County, and many of our residents work there. Our county is part of the Consolidated Metropolitan Statistical Area that includes Santa Clara County.

Santa Cruz County's urban characteristics include high population density (574 people per square mile), median household income (\$54,000), home ownership (60%), median home value (\$377,500), and a low poverty rate (11.9%). [Census data from 1999 and 2000. The 2004 median house value is \$630,000.] I have taught college statistics and economics for 30 years in California. These data, plus living and working patterns, demonstrate a profound urban character to our county. Nevertheless, CMS proposes a 25% gap in payments between physicians in Santa Cruz and Santa Clara counties, based on a dated and now-false rural-urban distinction.

Economic analysis assures a serious penalty to medical care and patients in Santa Cruz from this differential. Our county has high costs of delivering care. The existing payment gap (smaller than 25%) already makes local physicians more likely to relocate to CMS-designated urban areas, and new physicians less likely to locate here. Younger physicians cannot afford to live here. Physicians are taking fewer new patients, and are less likely to take patients most in need. Emergency care will be seriously constrained, and more emergency patients will travel further to Santa Clara County, and thereby be less likely to survive. These problems will only intensify if the payment gap increases.

CMS has both the duty and the opportunity to change its classification of our county. Its duty is given by Congressional mandate ? to adjust physicians' payments based on the local cost of delivering service. Its opportunity to change county classifications is provided by the Census and strongly encouraged by the OMB. The OMB ?urges agencies to review carefully the goals of nonstatistical programs and policies to ensure that appropriate geographic entities are used to determine eligibility for and the allocation of Federal funds.? (Federal Register, 65:249, 12/27/2000, p. 82229)

I strongly encourage you to right this wrong and place Santa Cruz County in your urban classification.

Sincerely,
Suzanne Holt, Instructor
Cabrillo College

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 1-9

SECTION 303

see attached

SECTION 611

see attached

CMS-1429-P-4032-Attach-1.doc

CMS-1429-P-4032-Attach-2.doc

CMS-1429-P-4032-Attach-2.doc

CMS-1429-P-4032-Attach-1.doc



Academy of Psychosomatic Medicine

The Organization for Consultation and Liaison Psychiatry

5824 North Magnolia Avenue • Chicago, Illinois 60660 • (773) 784-2025 • Fax (773) 784-1304

E-mail: APsychMed@aol.com • Web: <http://www.apm.org>

September 24, 2004

Mark D. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue SW
Room 214-G
Washington, DC 20201

Dear Dr. McClellan:

We are writing on behalf of our fellow members in the Academy of Psychosomatic Medicine (the Academy) to comment on the proposed rules for the Medicare Drug, Modernization and Improvement Act (MMA). We are a private, non-profit professional organization, comprised of over 800 psychiatrists engaged in the treatment of persons who have co-morbid medical and psychiatric illnesses, within primary and specialty medical care settings. More than half, or 9 million of the over 18 million adults in this country with a chronic medical condition (e.g. hypertension, diabetes, cancer etc.), have a mental disorder which impacts on their daily life functioning and health status. There is a high prevalence of co-occurring medical and psychiatric disorders among Medicare eligible citizens. Patients may have evidence of mood and anxiety disorders, delirium or significant levels of psychosocial distress which undermine their health status and quality of life. Studies have shown that these individuals experience increased morbidity and mortality in their medical condition when their access to essential mental

health services is limited. Conversely, when timely identification of and intervention with co-occurring psychiatric conditions are made, patients have better outcomes in the treatment of their medical disorders, reduced cost associated with chronic and disabling conditions, and higher productivity and quality of life.

Because of our concern for the patients for whom we care, we are collaborating with the Treatment Effectiveness Now (TEN) Project and other professional and advocacy organizations to provide comments on two important elements of the proposed physician fee schedule for calendar year 2005: the scope of services provided as part of the initial preventive physical examination and reimbursement for chemotherapy services. We join others, including the American Psychiatric Association (APA), the National Coalition of Cancer Survivors (NCCS) and the American Psycho-oncology Society (APOS) in bringing these issues to your attention.

The Academy applauds the Report of President Bush's New Freedom Commission on Mental Health citing the critical importance of Medicare and Medicaid Reform to improving the quality and accessibility of mental health service delivery through support of evidence-based treatments. The Report states: "Any effort to strengthen or improve the Medicare and Medicaid programs should offer beneficiaries options to effectively use the most up-to-date treatments and services." Furthermore, the President's New Freedom Commission report calls attention to the un-met mental health needs of patients with chronic medical illnesses.

The President's New Freedom Commission recognized that access to and reimbursement for appropriate medical, psychiatric and other mental health services is severely limited for these doubly-burdened, co-morbidly ill patients, despite an abundance of evidence that intervention results in positive economic and clinical outcomes. The MMA provides an important opportunity to provide appropriate screening and treatment for depression in the medical setting. We offer comments on the proposed rule which we believe can clarify, support and strengthen the intent of the MMA in providing needed, cost-effective care to citizens with both medical and psychiatric illness.

We support the comments that the TEN Project recently sent to you on the proposed MMA rules and implementation. We wish further to underscore the following points which are of high significance to our patient constituents and professional colleagues:

Comment on Section 611: Initial Preventive Physical Examination

- CMS should move forward with the implementation of a one-time preventative physical examination for new Medicare beneficiaries which includes depression screening. CMS should clarify that the assessment includes consideration of both the *potential* for depression, as well as the assessment of a patient's *current depression* status.
- The Academy welcomes the opportunity to work with our colleagues and CMS on the identification of an appropriate depression screening tool(s) and advocates the consideration of such a tool(s) through the NCD process.
- CMS should include language stressing the importance of appropriate treatment, including referral to mental health specialists when indicated, and the recommendation to monitor depression outcomes over time to ensure the treatment is effective.
- CMS should specify that the initial preventive exam include an evaluation of risk factors for cancer and a review of prior cancer history. Part of that review should include a review of cancer related psychological distress. The Academy would advocate the use of a well validated tool for that purpose, and the opportunity to have such a tool reviewed through the NCD process
- CMS should work with the TEN Project, the Academy and others to identify and remove barriers to receiving psychiatric care in order to assure that patients receive appropriate treatment; addressing barriers inherent in current payment policy.

Comment on Section 303—Payment Reform for Covered Outpatient Drugs and Biologicals

- The Academy believes that CMS can and should include provision of psychiatric and psychosocial services for patients receiving chemotherapy in new coding considerations permitted in the MMA.

In conclusion, we strongly urge you to consider the inclusion of language within the regulations that allows for these considerations in implementing this benefit. We would welcome the opportunity to meet and speak with you and to review findings which support our recommendations.

Sincerely,

Ted Stern, M.D.
President
Academy of Psychosomatic Medicine

Treatment Effectiveness Now

September 24, 2004

Mark D. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue SW
Room 214-G
Washington, DC 20201

Dear Dr. McClellan:

We are writing as Executive Board members of Treatment Effectiveness Now (the TEN Project). The TEN Project is a private, non-profit policy action organization, dedicated to educating public officials, advocates and professionals about the clinical and policy implications of evidence-based treatment for co-occurring medical and psychiatric disorders. There is a high prevalence of co-occurring medical and psychiatric disorders among Medicare beneficiaries. Consequently, the TEN Project is working with leaders of patient advocacy and professional organizations (mental and physical health), to provide comments on two important elements of the proposed physician fee schedule for calendar year 2005: the scope of services provided as part of the initial preventive physical examination and reimbursement for chemotherapy services. We join others, such as the National Coalition of Cancer Survivors (NCCS) and the American Psychiatric Association (APA) in bringing these issues to your attention.

The report of President Bush's New Freedom Commission on Mental Health (1) cites the critical importance of Medicare and Medicaid reform to improving the quality and accessibility of mental health service delivery through support of evidence-based treatments. The Report states: "Any effort to strengthen or improve the Medicare and Medicaid programs should offer beneficiaries options to effectively use the most up-to-date treatments and services." Furthermore, the report calls attention to the un-met mental health needs of patients with chronic medical illnesses.

Mental Illness in Patients with Chronic Medical Illness

Of the over 18 million adults in this country with a chronic medical condition (eg. Hypertension, diabetes, cancer etc.) more than half have evidence of a mental disorder. Patients may have evidence of mood and anxiety disorders, delirium or significant levels of psychosocial distress which greatly contribute to their health status and quality of life. Studies have shown that these patients' medical conditions appear to be worsened in the presence of mental illness and that they consequently utilize proportionately greater resources in their medical and psychiatric care. However, research indicates that when the mental illness and distress are addressed the medical conditions improve and costs are reduced. Yet, less than half of those patients presenting to their primary care physicians with evidence of a mental disorder are diagnosed, and even with diagnosis only half receive adequate treatment.

The MMA provides an important opportunity to provide appropriate screening and treatment for depression in the medical setting. We would like to offer comments on the proposed rule which we feel can clarify, support and strengthen the intent of the MMA in providing needed, cost-effective care to citizens with both medical and psychiatric illness.

Comment on Section 611: Initial Preventive Physical Examination

Section 611 of the MMA provides for Medicare Part B coverage of an initial preventive physical exam for new beneficiaries for services furnished on or after January 1, 2005. CMS proposes to add a new provision that would provide coverage for certain services as part of an initial preventive physical examination in a number of settings, including in the hospital outpatient department. Among other categories, CMS has proposed to include:

The TEN Project

In Partnership with the Department of Psychiatry, Georgetown University School of Medicine
750 17th St., NW, Washington, DC 20006 p 202.778.2373 f 202.778.2330

- “(2) Review of the individual's potential (risk factors) for depression (including past experiences with depression or other mood disorders) based on the use of an appropriate screening instrument which the physician or other qualified nonphysician practitioner may select from various available standardized screening tests for this purpose, unless the appropriate screening instrument is defined through the national coverage determination (NCD) process”
- “(6) Education, counseling, and referral, as deemed appropriate, based on the results of elements (1) through (5) of the proposed definition of the initial preventive physical examination.”

In support of this we would like to offer the following comments:

1) The President's New Freedom Commission on Mental Health has stated that mental health should be treated with the same urgency as physical health and as such has made a series of recommendations acknowledging the primary care office as the “de facto” mental health system for most patients in this country. Early recognition and treatment of depression will have a positive impact on medical, mental and economic outcomes.

- We would encourage CMS to clarify that the assessment includes consideration of both the *potential* for depression, as well as the assessment of *current depression* status. While we believe that this is the intent of the rule, the proposed language refers to assessing “potential (risk factors) for depression” but not to assessing current depression status per se.
- We concur with the recommendation that “an appropriate screening instrument” be used for the assessment of depression. However, we would suggest that a limited number of screening instruments be utilized to maximize clinical utility and transportability. For example, the 9-item Patient Health Questionnaire (PHQ-9) has now been well validated in several studies with medically ill patients as a diagnostic screen for depression (2). It can provide both a diagnosis and also a severity rating, is easy to use.
- Furthermore, we believe that coverage for conducting and interpreting the PHQ-9 (or other appropriate depression screening tool) through the NCD process would be a critical component to assuring that physicians comply with the screening component of the preventive exam. We would welcome the opportunity to work with CMS to move forward an NCD determination for screening of depression.

2) Evidence suggests that screening for depression in and of itself does not positively impact depression outcomes. The United States Preventive Services Task Force (3) recently reported, that depression screening is primarily effective if patients who screen positive are *referred for appropriate treatment*. We commend CMS on including a provision which allows for counseling and referral based on the evidence of depression in the initial preventive physical examination. Once depression is identified, disease management, collaborative care and direct provision of appropriate psychiatric and psychosocial care are effective in improving medical and psychosocial outcomes.

- We believe that in order for the depression screen to be effective, specific language needs to be included stressing the importance of appropriate treatment, including referral to mental health specialists when indicated, and the recommendation to monitor depression outcomes over time to ensure the treatment is effective.
- We also know that the barriers to receiving psychiatric care, which include but are not limited to the outpatient mental health treatment limitation which requires beneficiaries to pay more for mental health care than medical care are numerous and must addressed in order to assure that patients receive appropriate treatment.

3) Once depression is identified, disease management, collaborative care and direct provision of appropriate psychiatric and psychosocial care are effective in improving medical and psychosocial outcomes. Furthermore, the President's New Freedom Commission report in Recommendation 4.4 states: “Screen for mental disorders in primary health care, across the life span and connect to treatment and supports.” In addition it states: “Collaborative care models should be widely implemented in primary health care settings and reimbursed by public and private insurers.” Currently key elements of

collaborative care-particularly nurse care management, and the collaboration between the care manager and primary and mental health specialty providers, are at best partially reimbursable under Medicare. The TEN Project, along with the American Psychiatric Association and the Academy of Psychosomatic Medicine are currently engaged in an evaluation of the current diagnostic and procedural barriers to receiving mental health services in the primary care setting, we would welcome the opportunity to share the outcome of this work with you.

- Consequently, we recommend that CMS clarify the appropriate coding procedures to be utilized in order to be reimbursed for these services; and
- We would also encourage CMS utilize this opportunity to respond to the President's New Freedom Commission Report to develop strategies to assure that collaborative care models can be adequately reimbursed.

4) In addition, we would concur with the NCCS (see attached) which recommends that the preventive examination be expanded to include review of the individual's risk factors for cancer, including a review of the individual's past cancer diagnoses and treatment. Patients with cancer have high rates of mental disorders and distress which impair their functioning long after initial treatments end. The National Cancer Center Network, in its 2003 standards of care (4), address the need to assess and treat distress for all patients throughout and beyond their cancer illness and furthermore to utilize evidence based interventions when interventions are indicated. The Institute of Medicine in two reports, *Improving Palliative Care for Cancer*, and *Meeting Psychosocial Needs of Women with Breast Cancer* (5, 6), have both affirmed that available practice guidelines "should dictate the standard of care for both physical and psychosocial symptoms." In addition to supporting the NCCS recommendations we would also suggest:

- In addition to the depression screen, patients with a history of cancer should also be screened for cancer related distress through an appropriate screening instrument for the assessment of distress in patients with a history of cancer. Several screening instruments have been tested and validated in this patient population and can be utilized (4).
- We also encourage CMS to urge development of and referral to psychosocial services provided by mental health professionals who have expertise in the treatment of patients with chronic medical illnesses, such as cancer.

Section 303—Payment Reform for Covered Outpatient Drugs and Biologicals

Over 50% of cancer patients have evidence of psychiatric disorders or psychosocial distress. And while and only 10% receive attention to these mental health issues, much of that care is delivered in the oncology treatment setting as part of the supportive services patients receive related to chemotherapy administration. Therefore, the TEN Project is also carefully monitoring the changes in reimbursement for cancer care delivered in the physician's office that were mandated by the MMA and their potential effects on the quality of cancer care. Medicare payments for the services provided as part of chemotherapy administration must be adequate if quality care is to remain available in the community, where patients have become accustomed to receiving their treatment and prefer to be treated.

A range of services, including support services are delivered in the oncologist's office. These services are considered a vital part of quality cancer care. These services include access to dedicated mental health professionals with expertise in the care of cancer patients who provide psychiatric and psychosocial interventions. Cancer care is a multi-disciplinary endeavor, and elimination of any of the services that are part of the cancer care experience will have a negative impact on quality of care.

It is our hope that the modification of chemotherapy codes will yield a proposal for the addition of codes, including but not limited to a cancer management code as well as a code which could be used in the provision of psychosocial services to patients with a cancer diagnosis, that could form the basis for providing adequate reimbursement for the services that are part of chemotherapy administration. We realize that some of the services that we consider an integral part of cancer care have not been

The TEN Project

In Partnership with the Department of Psychiatry, Georgetown University School of Medicine
750 17th St., NW, Washington, DC 20006 p 202.778.2373 f 202.778.2330

recognized traditionally by Medicare as covered services, but we strongly urge flexibility in establishing codes that will guarantee payment for all essential cancer care services.

We respectfully request that you to incorporate these comments into the rules that will guide implementation of the MMA. We believe there is an important opportunity at hand to improve substantially the health outcomes for patients who have these co-occurring disorders, reducing morbidity, mortality and the associated productivity and treatment costs.

We thank you for your consideration and stand ready to assist you and your staff at CMS in implementation of the MMA and its associated provisions.

Sincerely,

Carol L. Alter, M.D.
Executive Director

Danna Mauch, Ph.D
President

References:

1. New Freedom Commission on Mental Health, Achieving the Promise: Transforming Mental Health Care in America. Final Report. DHHS Pub. No. SMA-03-3832. Rockville, MD: 2003.
2. Kroenke K, Spitzer RL, Williams JB. (2001). "The PHQ9: validity of a brief depression severity measure." J Gen Intern Med. 16(9):606-13.
3. Pignone MP, Gaynes BN, Rushton JL, Burchell CM, Orleans CT, Mulrow CD, Lohr KN (2002). "Screening for depression in adults: a summary of the evidence for the U.S. Preventive Services Task Force. Ann Intern Med. 2002 May 21;136(10):765-76.
4. Holland JC, Andersen B, Booth-Jones M, et al. NCCN Distress Management Clinical Practice Guidelines in Oncology. Journal of the NCCN 2003;1:344-74.
5. Foley KM, Gelband H, eds. Improving Palliative Care for Cancer, [Report of the National Cancer Policy Board/Institute of Medicine and National Research Council]. Washington, DC: The National Academies Press: 2001.
6. Hewitt M, Herdman R, Holland JC. (Eds.). Meeting Psychosocial Needs of Women with Breast Cancer. [Report of the National Cancer Policy Board/Institute of Medicine and National Research Council]. Washington, DC: The National Academies Press: 2004

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Oppose proposed changes to "Incident to" billing regulations!
Support recognition of Certified Athletic Trainers as providers of Rehabilitation Services!

Submitter : Date & Time:

Organization :

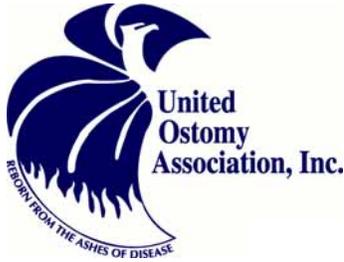
Category :

Issue Areas/Comments

Issues 10-19

SECTION 302

The United Ostomy Association feels that it is inappropriate for ostomy supplies to be included in the requirement, and further believes that the attached observations make a compelling case for their exemption.



24 September 2004

File code CMS-1429-P

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Danvers, MA

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Nancy Italia
Irvine, CA

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1429-P
P.O. Box 8012
Baltimore, MD 21244-8012

Dear Sir,

The United Ostomy Association appreciates the opportunity to comment on portions of proposed revisions to payment policies under the physician fee schedule for calendar year 2005, as published in the Federal Register.

Our comments appear on pages 2 and 3 of this document. The essence of these comments is that we feel ostomy products should be exempted from the new regulations when they become final.

Please contact me if additional information is required.

Sincerely,

Linda K. Aukett
Chair
Government Affairs Committee
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Medicare Program; Revisions to Payments Policies Under the Physician Fee Schedules for Calendar Year 2005; Proposed Rule (CMS-1429-P)

L. Section 302-Clinical Conditions for Coverage for Durable Medical Equipment (DME)

The United Ostomy Association (UOA) would like to comment on certain provisions contained in Section 302 on page 47545 of the above Proposed Rule.

The UOA represents the over half a million Americans who have undergone ostomy surgery that has resulted in the removal of part of their gastrointestinal or urinary tract. They will, therefore, have to use an external device for the collection of their bodily waste for the rest of their lives, and two-thirds of them rely on Medicare for these essential supplies.

CONCERNS REGARDING PROVISIONS OF THE PROPOSED RULE

The new rule proposes to expand the requirement for clinical conditions of coverage to all medical supplies. This would require a face-to-face physician examination at the time of any prescription renewal for all medical supplies. The rule states that CMS believes that the same level of medical intervention and skill is required for prosthetics, orthotics and supplies (POS) as for durable medical equipment (DME). However, the rule does invite specific comments as to whether specific items of DMEPOS should be exempt from the above requirement.

The UOA feels that it is inappropriate for ostomy supplies to be included in the requirement, and further believes that the following observations make a compelling case for their exemption:

- People with a permanent ostomy have had their urinary bladder or portions of their intestines surgically removed so will need to use ostomy supplies for the rest of their lives. There is no need for any confirmation of ongoing medical necessity.
- After the initial treatment period, having an ostomy becomes a way of life to be managed, rather than an ongoing treatment modality. Since the majority of people have an ostomy as the result of cancer or an inflammatory disease, they will receive frequent post-operative attention until the disease state is in remission. Once full recovery is achieved, it is possible to live well with the ostomy, without medical intervention other than recommended routine check-ups and screenings, even into advanced years.
- Unlike other products, ostomy supplies are generally ‘self-administered’ and most people manage their own ostomy or have it managed by a close family member.
- The choice of a specific ostomy system or product is usually made by the beneficiary him/herself with guidance from a Wound, Ostomy Continence (WOC) nurse who specializes in enterostomal therapy. Physicians are not routinely involved in product selection and are given no specific training in this respect.

- In the period following surgery, a stoma and its output change significantly. Selecting the optimal ostomy system is often a process involving trials of several products and combinations thereof. A requirement for a face-to-face examination with a physician every time there was to be a change in the type of ostomy supplies used would clearly be counterproductive.
- People with an established ostomy may change the type of system they use from time to time because of factors such as skin breakdown, weight gain, life style changes or an episode of diarrhea. Again, a requirement for a face-to-face physician assessment would achieve little, and could discourage patients from seeking a better-performing ostomy system.
- The UOA's goal of maximizing independence for people who live with a stoma would be severely compromised by a requirement for face-to-face contact with a physician each time an adjustment is needed to the management supplies. Physicians and WOC nurses share this goal of independence for people with a stoma.
- Durable Medical Equipment Regional Carriers (DMERCs) have developed extensive Local Medical Review Policies related to the provision of ostomy supplies. These already define medical necessity and describe the various products and their applicability. DMERCs presently require a physician's statement of medical necessity for initial orders. There is no requirement for 'renewal' of the statement aside from subsequent changes in either type or quantity of the supplies provided. In practice, initial and later change statements are normally based on the recommendations of WOC nurses.
- As physicians are ill-prepared to select the specific products that will be effective, the expenditure of additional Medicare resources to achieve a perceived improvement in "medical intervention" for this group would not be cost-effective, and would impose a needless burden on the patient and the physician. This is especially true if the patient must return to the oncologist or surgeon who was involved in creating the stoma after the acute illness has been alleviated. Primary-care and other physicians are even less-well prepared to participate in ostomy management product selection.
- Ostomy supplies represent a relatively small expenditure and an even smaller potential for fraud and abuse.

SUMMARY

The inclusion of ostomy supplies would represent a waste of time and resources and be an unnecessary burden for both physicians and beneficiaries. We would therefore urge the exclusion of ostomy supplies from this requirement.



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Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

GENERAL

GENERAL

Dear Dr. McClellan:

The Plasma Protein Therapeutics Association (PPTA) appreciates this opportunity to comment on the above-captioned proposed rule, published in the Federal Register on August 5, 2004 (the Rule). 69 Fed. Reg. 74884. As an association deeply committed to the health and safety of the patients we serve, our comments on the Rule are intended to ensure that Medicare beneficiaries have full access to the complete range of life-saving, Food and Drug Administration (FDA) approved, therapies PPTA members provide in non-hospital settings such as physician offices. We believe that the transition to a new payment system for these therapies has the potential to create access problems for the beneficiaries dependent upon these therapies and it is critical that the Centers for Medicare & Medicaid Services (CMS) be sensitive to this in the coming months.

PPTA is the association that represents the commercial producers of plasma-based and their recombinant analog therapies (plasma therapies). These therapies are used by millions of people to treat a variety of diseases and serious medical conditions. Some of the critical therapies produced by PPTA members include: blood clotting factors for people with hemophilia, intravenous immune globulins (IVIG) used to prevent infections in people with immune deficiencies and other serious conditions, and alpha-1 proteinase inhibitors used to treat people with alpha-1-antitrypsin deficiency, also known as genetic emphysema.

Our principal concern related to the Rule involves the impact of the new average sales price (ASP) methodology that will be the basis for setting payment rates for plasma therapies in 2005 and the lack of clarity in the guidance CMS has provided for manufacturer reporting of ASP information. We urge CMS to provide necessary guidance as soon as possible and to be vigilant in monitoring the effect of the new ASP system on beneficiary access to plasma therapies. In addition, we are concerned that the agency is not providing a sufficient add-on to the payment for hemophilia clotting factor, as mandated by the Medicare statute. With regard to coding for drug administration services, PPTA supports the recommendations made by the American Medical Association (AMA) and recommends that CMS implement these changes and establish payment rates accordingly. Finally, we believe that the recently added coverage for IVIG in the home setting is incomplete without payment of the supplies necessary for the effective use of IVIG in this setting and urge CMS to fully implement this benefit by covering such supplies.

PPTA RECOMMENDATIONS

For reasons discussed in detail below, PPTA recommends that CMS take the following actions:

1. Monitor beneficiary access to plasma therapies early in 2005 to assess the effects of the new payment methodology
2. Issue clear and detailed instructions for manufacturers regarding the ongoing submission of ASP information as soon as possible
3. Establish a hemophilia clotting factor add-on that will be sufficient to ensure unimpeded access to these products
4. Implement the coding changes recommended by the AMA for drug administration services and set payment rates for the new codes effective January 1, 2005
5. Cover supplies that are needed for the effective use of IVIG in the home

CONCLUSION

For the reasons stated in our comments, PPTA believes that the agency must monitor the effects of the new ASP system on access to plasma therapies and provide further clarification regarding ASP reporting. In addition, we recommend that the agency reconsider its proposal for the hemophilia clotting factor and finalize a payment rate that will ensure patient access to blood clotting factor. We also recommend that CMS adopt the recommendations on the coding for drug administration services effective January 1, 2005. Finally, we believe that CMS should consider ways in which it can make the home IVIG benefit a more meaningful one

Issues 1-9

CODING-GLOBAL PERIOD

Coding for Drug Administration Services

The Medicare statute directs CMS to evaluate the existing codes for drug administration services and work with representatives of physician specialties to determine whether coding changes should be made. SSA 1848(c)(2)(H). PPTA appreciated the flexibility CMS exhibited in the Rule with regard to implementing changes suggested by the AMA, particularly the willingness to issue G codes if needed. 69 Fed. Reg. at 47522. We understand that the AMA recently submitted its recommendations to CMS and we fully support those recommendations and ask the agency to implement them through the issuance of the necessary codes and the establishment of appropriate payment rates effective January 1, 2005.

PRACTICE EXPENSE

Hemophilia Clotting Factor Add-On

The Medicare statute requires that CMS provide for a separate payment to the entity that furnishes hemophilia clotting factor as of January 1, 2005 to compensate for items and services related to the furnishing of the product in the home. The amount of this add-on, together with the payment for the product, cannot exceed the payment rate for the product that would have been in effect if the MMA had not been enacted (i.e., 95% of average wholesale price). CMS has proposed an add-on of \$0.05 per unit. 69 Fed. Reg. at 47522-23.

The mandate for this add-on payment provides CMS with a mechanism to ensure that beneficiaries continue to have access to these critical products and PPTA is concerned that the proposed amount is not sufficient to accomplish that goal. For example, as noted earlier, the Rule indicates a \$0.37 reduction in the rate for Factor VIII recombinant. While a \$0.05 add-on would help, a reduction of \$0.32 per unit (or 25%) would still be enough of a decrease to generate concerns about beneficiary access. Thus, based on the information currently available, the proposed add-on appears insufficient. PPTA understands that other entities will provide CMS with information about the appropriate level of the add-on and we encourage CMS to consider such information carefully. We would also like to highlight concerns that have been expressed by the hemophilia community regarding the negative impact on access to high quality and clinically appropriate service caused by the \$0.05 add-on for homecare and hemophilia treatment centers. It is noteworthy that a September 2004 study conducted by The Lewin Group found that 'the costs of providing blood clotting factor to patients at home are on average \$0.20 per unit for full-service hemophilia homecare providers.'

SECTION 303

ASP Issues

Under section 1847A of the Social Security Act (SSA), the 2005 payment rates for most Part B drugs, including Plasma Therapies, in 2005 will be based on ASP. PPTA is very concerned that this new system will drastically reduce payment rates, so much so that beneficiary access to Plasma Therapies will be compromised. The Rule includes a listing of products and their ASP rates based on ASP information submitted for the first quarter of 2004, and one Plasma Therapy is included therein. According to the Rule, the ASP rate for Factor VIII recombinant would be \$0.92, which represents a 29% decrease compared to the current rate of \$1.29. 69 Fed. Reg. at 47566. Decreases of this amount are likely to diminish beneficiary access to this product and we fear that other plasma therapies could experience similar rate decreases. We believe that it is critical that CMS be highly proactive early in 2005 to ensure that these payment rate changes do not adversely affect patient care.

With regard to the quarterly manufacturer ASP reporting requirement, PPTA believes that there is a considerable degree of uncertainty that has not been resolved despite the release of two rules and some Questions and Answers. For example, the agency has not adequately indicated how manufacturers should handle discontinued National Drug Codes. In addition, we believe that there is insufficient clarity with regard to the 'smoothing methodology' announced in the recent final rule, particularly on the question of whether this methodology applies to all discounts and price concessions or only those available on a lagged basis. Accordingly, PPTA respectfully requests that CMS clarify these issues (and other issues raised in prior comments regarding ASP) in a timely fashion so that the next set of submissions from manufacturers can reflect these clarifications.

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Issues 10-19

SECTION 302

Ensuring the Adequacy of the IVIG Home Benefit

Section 642 of the MMA extended coverage of IVIG for the treatment of primary immune deficiency in the home setting effective January 1, 2004. As noted in the Rule, CMS implemented this provision through program instructions. 69 Fed. Reg. at 47525. While the statute defines IVIG for purposes of this new benefit to not include 'items and services related to the administration of the product,' PPTA believes that Congress did not intend to prevent CMS from determining that it otherwise has the authority to pay for items that are necessary for the effective use of IVIG. This situation is analogous to durable medical equipment (DME) in that the statute covers DME such as infusion pumps, but does not necessarily cover the drugs administered through such DME (e.g., insulin provided through an insulin pump). CMS has taken the position that drugs necessary for the effective use of DME are covered by Medicare. Just as the DME benefit for infusion pumps is meaningless without coverage of the drug, for those patients with primary immune deficiency that receive IVIG at home, if Medicare does not cover the infusion pump, the utility of the new IVIG home benefit will be diminished. We urge CMS to cover these items and services.

SECTION 642

Ensuring the Adequacy of the IVIG Home Benefit

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CMS-1429-P-4035-Attach-3.pdf

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CMS-1429-P-4035-Attach-3.pdf

CMS-1429-P-4035-Attach-2.pdf

September 24, 2004
Reference No.: HPSC04047

By electronic submission

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Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
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200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Comments on CMS-1562-P (Medicare Program Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005)

Dear Dr. McClellan:

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Our principal concern related to the Rule involves the impact of the new average sales price (“ASP”) methodology that will be the basis for setting payment rates for

plasma therapies in 2005 and the lack of clarity in the guidance CMS has provided for manufacturer reporting of ASP information. We urge CMS to provide necessary guidance as soon as possible and to be vigilant in monitoring the effect of the new ASP system on beneficiary access to plasma therapies. In addition, we are concerned that the agency is not providing a sufficient add-on to the payment for hemophilia clotting factor, as mandated by the Medicare statute. With regard to coding for drug administration services, PPTA supports the recommendations made by the American Medical Association (“AMA”) and recommends that CMS implement these changes and establish payment rates accordingly. Finally, we believe that the recently added coverage for IVIG in the home setting is incomplete without payment of the supplies necessary for the effective use of IVIG in this setting and urge CMS to fully implement this benefit by covering such supplies.

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1. Monitor beneficiary access to plasma therapies early in 2005 to assess the effects of the new payment methodology.
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5. Cover supplies that are needed for the effective use of IVIG in the home.

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critical that CMS be highly proactive early in 2005 to ensure that these payment rate changes do not adversely affect patient care.¹

With regard to the quarterly manufacturer ASP reporting requirement, PPTA believes that there is a considerable degree of uncertainty that has not been resolved despite the release of two rules and some “ Questions and Answers.” For example, the agency has not adequately indicated how manufacturers should handle discontinued National Drug Codes. In addition, we believe that there is insufficient clarity with regard to the “smoothing methodology” announced in the recent final rule, particularly on the question of whether this methodology applies to all discounts and price concessions or only those available on a lagged basis. Accordingly, PPTA respectfully requests that CMS clarify these issues (and other issues raised in prior comments regarding ASP) in a timely fashion so that the next set of submissions from manufacturers can reflect these clarifications.

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The mandate for this add-on payment provides CMS with a mechanism to ensure that beneficiaries continue to have access to these critical products and PPTA is concerned that the proposed amount is not sufficient to accomplish that goal. For example, as noted earlier, the Rule indicates a \$0.37 reduction in the rate for Factor VIII recombinant. While a \$0.05 add-on would help, a reduction of \$0.32 per unit (or 25 %) would still be enough of a decrease to generate concerns about beneficiary access. Thus, based on the information currently available, the proposed add-on appears insufficient. PPTA understands that other entities will provide CMS with information about the appropriate level of the add-on and we encourage CMS to consider such information carefully. We would also like to highlight concerns that have been expressed by the hemophilia community regarding the negative impact on access to high quality and clinically appropriate service caused by the \$0.05 add-on for homecare and hemophilia treatment centers. It is noteworthy that a September 2004 study conducted by The Lewin Group found that “the costs of providing blood clotting factor to

¹ PPTA recognizes that the Inspector General was charged with studying the adequacy of the ASP rates (Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (“MMA”), 303(c)(3)). However, this study is limited to certain types of products, and plasma therapies are not included. Accordingly, CMS cannot await this study to assess the impact of the new ASP rates on these products.

² SSA 1842(o)(5).

patients at home are on average \$0.20 per unit for full-service hemophilia homecare providers.”

III Coding for Drug Administration Services

The Medicare statute directs CMS to evaluate the existing codes for drug administration services and work with representatives of physician specialties to determine whether coding changes should be made. SSA 1848(c)(2)(H). PPTA appreciated the flexibility CMS exhibited in the Rule with regard to implementing changes suggested by the AMA, particularly the willingness to issue G codes if needed. 69 Fed. Reg. at 47522. We understand that the AMA recently submitted its recommendations to CMS and we fully support those recommendations and ask the agency to implement them through the issuance of the necessary codes and the establishment of appropriate payment rates effective January 1, 2005.

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CONCLUSION

For the reasons stated above, PPTA believes that the agency must monitor the effects of the new ASP system on access to plasma therapies and provide further clarification regarding ASP reporting. In addition, we recommend that the agency reconsider its proposal for the hemophilia clotting factor and finalize a payment rate that will ensure patient access to blood clotting factor. We also recommend that CMS adopt the recommendations on the coding for drug administration services effective January

³ Medicare Carriers Manual 2100.5.

1, 2005. Finally, we believe that CMS should consider ways in which it can make the home IVIG benefit a more meaningful one.

Once again, PPTA appreciates the opportunity to comment on the important issues in the Rule, and we hope that you will give consideration to our suggestions. Please feel free to contact me at (202) 789-3100 if you have any questions regarding our comments. Thank you for your attention to this very important matter.

Respectfully submitted,



Julie A. Birkofer
Acting Executive Director, North America

September 24, 2004
Reference No.: HPSC04047

By electronic submission

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Centers for Medicare & Medicaid Services
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200 Independence Avenue, S.W.
Washington, D.C. 20201

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Section 642 of the MMA extended coverage of IVIG for the treatment of primary immune deficiency in the home setting effective January 1, 2004. As noted in the Rule, CMS implemented this provision through program instructions. 69 Fed. Reg. at 47525. While the statute defines IVIG for purposes of this new benefit to not include “items and services related to the administration” of the product, PPTA believes that Congress did not intend to prevent CMS from determining that it otherwise has the authority to pay for items that are necessary for the effective use of IVIG. This situation is analogous to durable medical equipment (“DME”) in that the statute covers DME such as infusion pumps, but does not necessarily cover the drugs administered through such DME (e.g., insulin provided through an insulin pump). CMS has taken the position that drugs necessary for the effective use of DME are covered by Medicare.³ Just as the DME benefit for infusion pumps is meaningless without coverage of the drug, for those patients with primary immune deficiency that receive IVIG at home, if Medicare does not cover the infusion pump, the utility of the new IVIG home benefit will be diminished. We urge CMS to cover these items and services.

CONCLUSION

For the reasons stated above, PPTA believes that the agency must monitor the effects of the new ASP system on access to plasma therapies and provide further clarification regarding ASP reporting. In addition, we recommend that the agency reconsider its proposal for the hemophilia clotting factor and finalize a payment rate that will ensure patient access to blood clotting factor. We also recommend that CMS adopt the recommendations on the coding for drug administration services effective January

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Once again, PPTA appreciates the opportunity to comment on the important issues in the Rule, and we hope that you will give consideration to our suggestions. Please feel free to contact me at (202) 789-3100 if you have any questions regarding our comments. Thank you for your attention to this very important matter.

Respectfully submitted,



Julie A. Birkofer
Acting Executive Director, North America

September 24, 2004
Reference No.: HPSC04047

By electronic submission

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

Re: Comments on CMS-1562-P (Medicare Program Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005)

Dear Dr. McClellan:

The Plasma Protein Therapeutics Association (“PPTA”) appreciates this opportunity to comment on the above-captioned proposed rule, published in the Federal Register on August 5, 2004 (the “Rule”). 69 Fed. Reg. 74884. As an association deeply committed to the health and safety of the patients we serve, our comments on the Rule are intended to ensure that Medicare beneficiaries have full access to the complete range of life-saving, Food and Drug Administration (“FDA”) approved, therapies PPTA members provide in non-hospital settings such as physician offices. We believe that the transition to a new payment system for these therapies has the potential to create access problems for the beneficiaries dependent upon these therapies and it is critical that the Centers for Medicare & Medicaid Services (“CMS”) be sensitive to this in the coming months.

PPTA is the association that represents the commercial producers of plasma-based and their recombinant analog therapies (“plasma therapies”). These therapies are used by millions of people to treat a variety of diseases and serious medical conditions. PPTA members produce over 80% of the plasma therapies for the United States market and more than 60% worldwide. Some of the critical therapies produced by PPTA members include: blood clotting factors for people with hemophilia, intravenous immune globulins (“IVIG”) used to prevent infections in people with immune deficiencies and other serious conditions, and alpha-1 proteinase inhibitors used to treat people with alpha-1-antitrypsin deficiency, also known as genetic emphysema.

Our principal concern related to the Rule involves the impact of the new average sales price (“ASP”) methodology that will be the basis for setting payment rates for

plasma therapies in 2005 and the lack of clarity in the guidance CMS has provided for manufacturer reporting of ASP information. We urge CMS to provide necessary guidance as soon as possible and to be vigilant in monitoring the effect of the new ASP system on beneficiary access to plasma therapies. In addition, we are concerned that the agency is not providing a sufficient add-on to the payment for hemophilia clotting factor, as mandated by the Medicare statute. With regard to coding for drug administration services, PPTA supports the recommendations made by the American Medical Association (“AMA”) and recommends that CMS implement these changes and establish payment rates accordingly. Finally, we believe that the recently added coverage for IVIG in the home setting is incomplete without payment of the supplies necessary for the effective use of IVIG in this setting and urge CMS to fully implement this benefit by covering such supplies.

PPTA RECOMMENDATIONS

For reasons discussed in detail below, PPTA recommends that CMS take the following actions:

1. Monitor beneficiary access to plasma therapies early in 2005 to assess the effects of the new payment methodology.
2. Issue clear and detailed instructions for manufacturers regarding the ongoing submission of ASP information as soon as possible.
3. Establish a hemophilia clotting factor add-on that will be sufficient to ensure unimpeded access to these products.
4. Implement the coding changes recommended by the AMA for drug administration services and set payment rates for the new codes effective January 1, 2005.
5. Cover supplies that are needed for the effective use of IVIG in the home.

I ASP Issues

Under section 1847A of the Social Security Act (“SSA”), the 2005 payment rates for most Part B drugs, including plasma therapies, in 2005 will be based on ASP. PPTA is very concerned that this new system will drastically reduce payment rates, so much so that beneficiary access to plasma therapies will be compromised. The Rule includes a listing of products and their ASP rates based on ASP information submitted for the first quarter of 2004, and one plasma therapy is included therein. According to the Rule, the ASP rate for Factor VIII recombinant would be \$0.92, which represents a 29 decrease compared to the current rate of \$1.29. 69 Fed. Reg. at 47566. Decreases of this amount are likely to diminish beneficiary access to this product and we fear that other plasma therapies could experience similar rate decreases. We believe that it is

critical that CMS be highly proactive early in 2005 to ensure that these payment rate changes do not adversely affect patient care.¹

With regard to the quarterly manufacturer ASP reporting requirement, PPTA believes that there is a considerable degree of uncertainty that has not been resolved despite the release of two rules and some “Questions and Answers.” For example, the agency has not adequately indicated how manufacturers should handle discontinued National Drug Codes. In addition, we believe that there is insufficient clarity with regard to the “smoothing methodology” announced in the recent final rule, particularly on the question of whether this methodology applies to all discounts and price concessions or only those available on a lagged basis. Accordingly, PPTA respectfully requests that CMS clarify these issues (and other issues raised in prior comments regarding ASP) in a timely fashion so that the next set of submissions from manufacturers can reflect these clarifications.

II Hemophilia Clotting Factor Add-On

The Medicare statute requires that CMS provide for a separate payment to the entity that furnishes hemophilia clotting factor as of January 1, 2005 to compensate for items and services related to the furnishing of the product in the home. The amount of this add-on, together with the payment for the product, cannot exceed the payment rate for the product that would have been in effect if the MMA had not been enacted (*i.e.*, 95% of average wholesale price).² CMS has proposed an add-on of \$0.05 per unit. 69 Fed. Reg. at 47522-23.

The mandate for this add-on payment provides CMS with a mechanism to ensure that beneficiaries continue to have access to these critical products and PPTA is concerned that the proposed amount is not sufficient to accomplish that goal. For example, as noted earlier, the Rule indicates a \$0.37 reduction in the rate for Factor VIII recombinant. While a \$0.05 add-on would help, a reduction of \$0.32 per unit (or 25%) would still be enough of a decrease to generate concerns about beneficiary access. Thus, based on the information currently available, the proposed add-on appears insufficient. PPTA understands that other entities will provide CMS with information about the appropriate level of the add-on and we encourage CMS to consider such information carefully. We would also like to highlight concerns that have been expressed by the hemophilia community regarding the negative impact on access to high quality and clinically appropriate service caused by the \$0.05 add-on for homecare and hemophilia treatment centers. It is noteworthy that a September 2004 study conducted by The Lewin Group found that “the costs of providing blood clotting factor to

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Section 642 of the MMA extended coverage of IVIG for the treatment of primary immune deficiency in the home setting effective January 1, 2004. As noted in the Rule, CMS implemented this provision through program instructions. 69 Fed. Reg. at 47525. While the statute defines IVIG for purposes of this new benefit to not include “items and services related to the administration” of the product, PPTA believes that Congress did not intend to prevent CMS from determining that it otherwise has the authority to pay for items that are necessary for the effective use of IVIG. This situation is analogous to durable medical equipment (“DME”) in that the statute covers DME such as infusion pumps, but does not necessarily cover the drugs administered through such DME (e.g., insulin provided through an insulin pump). CMS has taken the position that drugs necessary for the effective use of DME are covered by Medicare.³ Just as the DME benefit for infusion pumps is meaningless without coverage of the drug, for those patients with primary immune deficiency that receive IVIG at home, if Medicare does not cover the infusion pump, the utility of the new IVIG home benefit will be diminished. We urge CMS to cover these items and services.

CONCLUSION

For the reasons stated above, PPTA believes that the agency must monitor the effects of the new ASP system on access to plasma therapies and provide further clarification regarding ASP reporting. In addition, we recommend that the agency reconsider its proposal for the hemophilia clotting factor and finalize a payment rate that will ensure patient access to blood clotting factor. We also recommend that CMS adopt the recommendations on the coding for drug administration services effective January

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Once again, PPTA appreciates the opportunity to comment on the important issues in the Rule, and we hope that you will give consideration to our suggestions. Please feel free to contact me at (202) 789-3100 if you have any questions regarding our comments. Thank you for your attention to this very important matter.

Respectfully submitted,



Julie A. Birkofer
Acting Executive Director, North America

September 24, 2004
Reference No.: HPSC04047

By electronic submission

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

Re: Comments on CMS-1429-P (Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005)

Dear Dr. McClellan:

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Our principal concern related to the Rule involves the impact of the new average sales price (“ASP”) methodology that will be the basis for setting payment rates for

plasma therapies in 2005 and the lack of clarity in the guidance CMS has provided for manufacturer reporting of ASP information. We urge CMS to provide necessary guidance as soon as possible and to be vigilant in monitoring the effect of the new ASP system on beneficiary access to plasma therapies. In addition, we are concerned that the agency is not providing a sufficient add-on to the payment for hemophilia clotting factor, as mandated by the Medicare statute. With regard to coding for drug administration services, PPTA supports the recommendations made by the American Medical Association (“AMA”) and recommends that CMS implement these changes and establish payment rates accordingly. Finally, we believe that the recently added coverage for IVIG in the home setting is incomplete without payment of the supplies necessary for the effective use of IVIG in this setting and urge CMS to fully implement this benefit by covering such supplies.

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I. ASP Issues

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Respectfully submitted,



Julie A. Birkofer
Acting Executive Director, North America

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

GENERAL

GENERAL

test

Submitter : Mrs. Deborah Brigham Date & Time: 09/23/2004 04:09:47

Organization : Mrs. Deborah Brigham

Category : Other Practitioner

Issue Areas/Comments

GENERAL

GENERAL

I would like to state my opposition to the possibility that only pt's will be allowed to administer therapy to patients of physicians. I have been a professional massage therapist for over twenty years and I can whole heartedly vouch for the value of massage and its tremendous therapeutic benefit to individuals suffering from musculoskeletal injuries and stress. The rigors of our credentialing process from state to state assures clients the highest quality and standards in our treatments. Please reconsider this issue. Thank you, Deborah Brigham

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

GENERAL

GENERAL

Continuing the trend of the last three fee schedules, the 2005 proposed rule would prolong the downward spiral of payment updates for providers paid under the Medicare physician fee schedule, if Congress had not enacted a temporary adjustment in the MMA. If the current trend remains, providers will face difficult decisions as they evaluate the economic practicability of caring for Medicare beneficiaries. The economic viability of practices is further undermined by the widespread use of the Medicare physician fee schedule as a benchmark for private insurance reimbursement rates.

MGMA has conducted extensive surveys of medical practice costs for more than 50 years. MGMA-collected data indicate that the cost of operating a group practice rose by an average 4.8 percent per year over the last 10 years. In fact, between 2001 and 2003, MGMA data show that operating costs increased more than 10.9 percent. Medicare reimbursement rates for physician services have fallen far short of the increased cost of delivering quality services to Medicare payments. Agency-initiated administrative modifications can help mitigate the anticipated cuts expected for calendar year 2006 and beyond.

Definition of ?physician services?

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

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

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

Full impact of law and regulation

The current SGR calculation fails to adequately capture the impact of changes to laws and regulations as required by law. For example, although Medicare has new screening benefits, the formula fails to account for the downstream services that will result when the screenings reveal health problems. The same is true of the Medicare prescription drug benefit, which will unquestionably lead to more medical visits, which in turn will generate additional tests and care. The SGR does not account for this inevitable spending. Additionally, the impact of CMS coverage decisions is excluded from the SGR entirely even though those decisions may have just as great an impact on patient demand for services as a statutory change. [MORE IN WRITTEN COMMENTS]

Issues 1-9

GPCI

MGMA remains opposed to CMS using inappropriate data sources to calculate the geographic practice cost indices (GPCIs). The very nature of the census data used to calculate the GPCI values render the values outdated by the time CMS is able to use the information. The decennial collection of the census means that no new data will be available on a national scale until the 2010 census data is processed. Thus, although the statute mandates updating the GPCI values every 3 years, they are in essence updated every 10 years. MGMA maintains that this is unacceptable. A separate source with more timely data must be identified to adhere to the 3-year update schedule that Congress intended.

A particular concern to MGMA is that employee wages used in the GPCI formula do not capture highly skilled professionals now considered essential for the delivery of medical services. These professionals include nurse practitioners, physician assistants, certified nurse specialists, nurse midwives, certified registered nurse anesthetists, occupational therapists, physical therapists, certified practice managers, computer professionals, transcriptionists and certified coders. While it remains true that the 2000 census definitions of certain medical professionals are more expansive than the 1990 definitions, limited improvements result for the updated 2003 GPCI values.

GPCI employee wages are included for clerical workers, registered nurses, licensed practical nurses and health technicians. The 2000 census definition of registered nurses will add wages for nurse practitioners, certified nurse specialists, nurse midwives and others. However, the wages of several prominent professions remain excluded. These professionals are physician assistants, occupational and physical therapists, certified practice managers, IT professionals, transcriptionists and certified coders. MGMA recommends that CMS revise the updated GPCIs to include these employees to ensure that the occupations used in the formula reflect the numerous categories of medical workers found in modern practices.

As in years past, the office rental indices used to calculate the practice expense GPCIs are based on the Department of Housing and Urban Development's (HUD) residential apartment rent data. While MGMA is sympathetic to the difficulty CMS has in identifying alternative sources for pricing medical office space, MGMA remains opposed to the use of residential and not commercial data for this purpose. Such use is inconsistent with the core objective of the Balanced Budget Act of 1997 to make Medicare resource based. MGMA suggests that CMS study whether actual physician office rental costs vary geographically in the same fashion as the rental index to validate the use of this proxy. Alternatively, MGMA recommends that CMS work with other government agencies like the Bureau of Labor Statistics to identify other nationally collected data sources and groups that are capable of collecting data if no such source currently exists.

The disadvantage of basing relative physician payments on indices developed for entirely different purposes is illustrated by HUD's rental floor for rural counties. This has the effect of raising the GPCIs for rural areas at the expense of urban practices. Previous fee schedules do not indicate why HUD has established this policy. Presumably it is to accomplish some HUD policy objective that has no relationship to the objectives of the GPCI in the Medicare fee schedule. Thus, it is an example of one small intervention in the system that affects physician payment which has no relationship to actual and relative costs incurred by physician practices in delivering care to Medicare beneficiaries. This is inconsistent with the broad objectives of the Medicare resource based relative value scale payment approach.

MALPRACTICE RVUs

MGMA commends CMS for updating the malpractice relative value units (RVUs) to more accurately reflect increasing liability insurance premiums. However, a great portion of today's reported catastrophic increase in insurance coverage costs was experienced in 2003, which is not fully captured in the data. Premium data for 2003 was estimated from increases in 2001 and 2002.

An informal survey taken earlier this year of our members in group practices in which over 12,750 Medicare participating physicians practice, indicates that responding practices faced an average premium increase of 37.24 percent between 2003 and 2004, on top of an average premium increase of 39.6 percent between 2002 and 2003. These updated survey results confirm that physician group practices continue to struggle with excessive medical liability premiums.

SECTION 303

MGMA has consistently expressed its concern that Medicare reimburse providers appropriately for both the cost of drugs administered in the outpatient setting and the physician administration services. The MMA dramatically altered reimbursement in both of these areas, and MGMA remains extremely concerned about the adequacy of reimbursement levels. Beginning in 2005, the cost of physician-administered drugs will be reimbursed at rates set by the Average Sales Price (ASP) + 6 percent. However, providers are now expected to prepare for an ambiguous cut for both drug administration and drug payment rates. The Aug. 5 proposed rule included preliminary estimates for drug reimbursement. These rates were then nullified by a subsequent rule published on Sept. 16 (69 FR 55763) revising drug discount calculations. CMS has not made public revised drug estimates, leaving the provider community without any guidance for the reality of Jan. 1 payment levels.

Additionally, CMS has admitted that the data the Agency has received to calculate the ASP is flawed. By the time the final rule is released, CMS will have data from 2004 Quarter Two analyzed, but very little time to work with the pharmaceutical community to ensure that the data submitted

for quarter 3 reflect actual acquisition costs. The Quarter Three data must be as accurate as possible to ensure that the ASP system is implemented as envisioned by the congressional authors.

Historically, CMS has administratively chosen to delay the implementation of payment rates when the supporting data is inadequate. This was true for the pass-through payments for the outpatient prospective payment system in 2002 (66 FR 67494) and the anesthesia services reevaluation in the 2003 physician fee schedule that delayed publication of the entire rule (67 FR 79966). MGMA strongly recommends that CMS delay the implementation of the ASP system until CMS is able to confirm the accuracy of the Quarter Three data, the affected community is provided a minimum 60 day notice and is afforded an opportunity to review and comment on the rates.

In the 2005 proposed rule, CMS suggests that providers can solve any difficulty in finding drugs at the ASP+6 percent rate by joining a group purchasing organization. However, not all specialties have group purchasing organizations and they are not available in all regions where Medicare providers practice medicine. Furthermore, it is an incorrect assumption that all group purchasing organizations can acquire drugs at or below ASP+6. MGMA practice managers report that group purchasing organizations, while helpful, were not always on track with the preliminary reimbursement rates published in the 2005 proposed rule.

Additionally, drug acquisition costs fluctuate daily. Recent research findings that MGMA, the American Medical Association (AMA) and a number of medical specialty association conducted regarding the drug reimbursement issue, found that the ability for physician practices to obtain discounts varied widely by specialty, geography and other factors. This means that reimbursement rates set quarterly will leave practices with little or no cushion for volatility.

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SECTION 413

The language of § 413 instructs CMS to identify such counties or areas as part of the proposed and final rule to implement the physician fee schedule under section 1848 for the applicable year. MGMA is disappointed that CMS was unable to meet this obligation by publishing a list of which areas will be considered primary and specialty scarcity care areas. Since the public will not have an opportunity to comment on these new areas, MGMA recommends that CMS publish the qualified scarcity areas and corresponding zip codes as an interim final rule with comment in November. This way, the public will be afforded a late opportunity for comment and critique.

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The new MMA screening exams will augment the providers' arsenal of preventive services covered by Medicare. However, the long coverage period for the cardiovascular screening blood test, decided by CMS, will make the likelihood that a provider learns about a previous exam very slim. Beneficiary memory and the transient nature of patient services leaves Medicare providers little ability for definitive coverage analysis. Instead, providers are left with virtually no choice but to give beneficiaries an advanced beneficiary notice and hope for coverage.

CMS must immediately implement a real-time electronic coverage system for providers to access. The system is already defined by the 837 standard for coordination of benefits and is an essential implementation component of this and the other new MMA benefits.

Issues 10-19

DEFINING THERAPY SERVICES

CMS solicited comments in the 2003 proposed rule from the public on qualifications for professionals performing therapy services. In the 2005 proposed rule, CMS outlines a drastic change in qualifications for professionals who perform services incident to a physician's professional service. The NPRM for the 2005 fee schedule would, if implemented, limit qualified incident to service professionals to therapists, speech language pathologists and their certified assistants. MGMA is very concerned that this proposal would leave Medicare beneficiaries with few providers in the area offering therapy services, especially in rural areas where many of the therapy professionals are outside of this very limited scope of providers. CMS failed to explain the policy rationale for the change or show evidence of any substandard services being performed by professionals outside these limited categories.

Further confusing the issue is the simple fact that nonphysician practitioners, such as nurse practitioners, clinical nurse specialists and physician assistants could perform covered therapy services under their own benefit but not as an incident to service to a physician or another nonphysician practitioner. This fact is counter-intuitive and undermines the proposed change.

MGMA recommends that CMS modify the qualification requirements for professionals performing incident to therapy services to cover services provided by persons licensed by their state to perform therapy services. Additionally, qualified professionals could include those non-licensed providers as described in the proposed rule; physical therapists, occupational therapists, speech pathologists, physical therapy assistants or occupational therapy assistants that are certified by the appropriate professional association and meet the education requirements set forth in the rule.

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Section 302 authorizes CMS to establish and implement new quality standards and requires as a condition of payment a face-to-face encounter for the prescription of the item. MGMA believes that the proposed rule exceeds the congressional mandate by applying new coverage guidelines to all categories of durable medical equipment (DME).

Section 302 of the MMA applies to a very limited subcategory of DME. Specifically, it applies to covered items (as defined in paragraph (13)) for which payment may otherwise be made under this subsection; prosthetic devices and orthotics and prosthetics described in section 1834(h)(4) [of the Social Security Act]; and items and services described in section 1842(s)(2) [of the Act]. Paragraph 13 refers to iron lungs, oxygen tents,

hospital beds and wheelchairs (Social Security Act ? 1861(n)), medical supplies and durable medical equipment (DME) used in a patient's home while the Medicare beneficiary is under a home health plan of care (Social Security Act ? 1861(m)(5)). Section 1834(h)(4) refers to prosthetics and orthotics, while section 1842(s)(2) refers to eight categories of items, notably therapeutic shoes and certain devices. The proposed condition of coverage in 42 CFR 410.36 would apply to all medical supplies, appliances and devices and not the specific categories identified in the MMA. MGMA recommends that CMS revise the proposed policy to cover only those items included in ? 302.

Furthermore, the overly restrictive requirement that providers prescribe medical supplies, appliances and devices within 30 days of a face-to-face encounter will unnecessarily restrict patient access to DME and orthotics. For many home-bound patients, a course of care is followed over a period of time via the telephone, maximizing the patient's comfort and provider's time. Prescriptions are filled over the phone when treatment is not working and may include a course of drugs and/or subsequent DME/orthotic. To require the patient to come into the office for a face-to-face encounter within a prescribed time period not only burdens the practice with a patient that they really did not need to see, but harms a patient who often requires the DME for ambulation. Furthermore, the requirement will unnecessarily result in higher utilization of services, contrary to the underlying tenants of the Medicare program. MGMA recommends that CMS revise the policy to require that the DME prescription be dated in a timely fashion following the face-to-face encounter.

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On Jan. 1, 2005, the Part B deductible will increase for the first time in many years to \$110. CMS should actively educate Medicare beneficiaries regarding this increase and possible changes in Medigap coverage. Medical group practices are very concerned that beneficiaries will be unwilling to accept this new deductible rate as a change in government policy without ample education by CMS. Beneficiary outreach should include free materials that providers can use in their practices to inform Medicare patients regarding the increases in deductible rates beginning in 2005.

SECTION 952

Physicians and nonphysician practitioners who practice in locations other than the address where Medicare payments are sent were historically unable to benefit from the simplified billing procedures available to group practices. Under this scenario, physicians (such as emergency department physicians) were left to use their individual provider numbers with a considerable hassle factor. MMA ? 952 permits these providers to apply for and use group numbers for billing purposes.

MGMA, however, is concerned by the rhetoric included in the 2005 proposed rule where CMS asserts their ill opinion of these arrangements. ?Parties should be mindful that contractual arrangements involving reassignment may not be used to camouflage inappropriate fee-splitting arrangements or payments for referrals.? The Agency further solicits comments on program ?vulnerabilities? and proposes to ?monitor reassignment arrangements for potential program abuse.? MGMA reminds CMS that nearly all physicians and nonphysician practitioners participate in the Medicare program in good faith and abide by the program's rules and regulations. It is unfortunate that CMS must cast a long shadow over these reassignment arrangements by foreshadowing fraudulent and abusive actors capitalizing on the change in policy.

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THERAPY ASSISTANTS IN PRIVATE PRACTICE

MGMA applauds the flexibility CMS proposed in the NPRM which will permit therapy assistants to perform therapy services under direct, rather than personal supervision. We see this as a welcome regulatory relief provision and support the revision.

Issues 20-29

CARE PLAN OVERSIGHT

The Medicare program has historically utilized nonphysician practitioners to extend the services of physicians and provide greater access to quality medical care for Medicare beneficiaries. The revision in the care plan oversight (CPO) policy will provide beneficiaries greater access to home health care services. MGMA supports the revision and conditions of coverage as defined in the proposed rule.

THERAPY STANDARDS AND REQUIREMENTS

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THERAPY TECHNICAL REVISIONS

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CMS-1429-P-4037-Attach-1.pdf



September 24, 2004

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1429-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005

Dear Dr. McClellan:

The Medical Group Management Association (MGMA) is pleased to submit the following comments in response to the proposed rule entitled the "Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005," as published in the Aug. 5, 2004 *Federal Register*. MGMA applauds the ongoing efforts of the Centers for Medicare & Medicaid Services (CMS) to update and clarify Medicare policies. We also recognize the substantial challenges the Agency faces in implementing the wide-ranging components of the Medicare Prescription Drug, Improvement and Modernization Act (MMA). However, MGMA has several concerns and recommendations related to this rule, as outlined below.

MGMA, founded in 1926, is the nation's principal voice for medical group practice. MGMA's 19,000 members manage and lead more than 11,000 organizations in which more than 220,000 physicians practice. Our individual members, who include practice managers, clinic administrators and physician executives, work on a daily basis to ensure that the financial and administrative mechanisms within group practices operate efficiently so physician time and resources can be focused on patient care.

Physician payment update

Continuing the trend of the last three fee schedules, the 2005 proposed rule would prolong the downward spiral of payment updates for providers paid under the Medicare physician fee schedule, if Congress had not enacted a temporary adjustment in the MMA. If the current trend remains, providers will face difficult decisions as they evaluate the economic practicability of caring for Medicare beneficiaries. The economic viability of practices is further undermined by the widespread use of the Medicare physician fee schedule as a benchmark for private insurance reimbursement rates.

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MGMA has conducted extensive surveys of medical practice costs for more than 50 years. MGMA-collected data indicate that the cost of operating a group practice rose by an average 4.8 percent per year over the last 10 years. In fact, between 2001 and 2003, MGMA data show that operating costs increased more than 10.9 percent. Medicare reimbursement rates for physician services have fallen far short of the increased cost of delivering quality services to Medicare payments. Agency-initiated administrative modifications can help mitigate the anticipated cuts expected for calendar year 2006 and beyond.

Definition of “physician services”

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

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

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

Full impact of law and regulation

The current SGR calculation fails to adequately capture the impact of changes to laws and regulations as required by law. For example, although Medicare has new screening benefits, the formula fails to account for the downstream services that will result when the screenings reveal health problems. The same is true of the Medicare prescription drug benefit, which will unquestionably lead to more medical visits, which in turn will generate additional tests and care. The SGR does not account for this inevitable spending. Additionally, the impact of CMS coverage decisions is excluded from the SGR entirely even though those decisions may have just as great an impact on patient demand for services as a statutory change. Such changes are likely to be highly beneficial for patients, but probably will contribute to negative reimbursement updates through the SGR calculation. MGMA believes CMS has the administrative authority to better account for the full impact of such changes to law and regulation, and vigorously urges CMS to assert this authority.

MEI calculation

Another component of the Medicare physician reimbursement formula that requires improvement is the Medicare Economic Index (MEI). The MEI was established in 1973 to reflect the rising cost of practicing

medicine. However, the current MEI calculation is showing its age, and fails to incorporate all of the costs a physician group practice bears to care for patients. MGMA agrees with a recommendation by the Practicing Physicians Advisory Council made to CMS earlier this year that the MEI be expanded to reflect costs such as compliance with extensive new billing regulations, including hiring new staff and increased training for current staff to comply with expanding regulations. The MEI also should reflect steps taken to improve patient safety and include those additional costs not included in the MEI in 1973, but which clearly must be a part of the calculation today.

Malpractice RVUs

MGMA commends CMS for updating the malpractice relative value units (RVUs) to more accurately reflect increasing liability insurance premiums. However, a great portion of today's reported catastrophic increase in insurance coverage costs was experienced in 2003, which is not fully captured in the data. Premium data for 2003 was estimated from increases in 2001 and 2002.

An informal survey taken earlier this year of our members in group practices in which over 12,750 Medicare participating physicians practice, indicates that responding practices faced an average premium increase of 37.24 percent between 2003 and 2004, on top of an average premium increase of 39.6 percent between 2002 and 2003. These updated survey results confirm that physician group practices continue to struggle with excessive medical liability premiums.

GPCI

MGMA remains opposed to CMS using inappropriate data sources to calculate the geographic practice cost indices (GPCIs). The very nature of the census data used to calculate the GPCI values render the values outdated by the time CMS is able to use the information. The decennial collection of the census means that no new data will be available on a national scale until the 2010 census data is processed. Thus, although the statute mandates updating the GPCI values every 3 years, they are in essence updated every 10 years. MGMA maintains that this is unacceptable. A separate source with more timely data must be identified to adhere to the 3-year update schedule that Congress intended.

A particular concern to MGMA is that employee wages used in the GPCI formula do not capture highly skilled professionals now considered essential for the delivery of medical services. These professionals include nurse practitioners, physician assistants, certified nurse specialists, nurse midwives, certified registered nurse anesthetists, occupational therapists, physical therapists, certified practice managers, computer professionals, transcriptionists and certified coders. While it remains true that the 2000 census definitions of certain medical professionals are more expansive than the 1990 definitions, limited improvements result for the updated 2003 GPCI values.

GPCI employee wages are included for clerical workers, registered nurses, licensed practical nurses and health technicians. The 2000 census definition of registered nurses will add wages for nurse practitioners, certified nurse specialists, nurse midwives and others. However, the wages of several prominent professions remain excluded. These professionals are physician assistants, occupational and physical therapists, certified practice managers, IT professionals, transcriptionists and certified coders. MGMA recommends that CMS revise the updated GPCIs to include these employees to ensure that the occupations used in the formula reflect the numerous categories of medical workers found in modern practices.

As in years past, the office rental indices used to calculate the practice expense GPCIs are based on the Department of Housing and Urban Development's (HUD) residential apartment rent data. While MGMA is sympathetic to the difficulty CMS has in identifying alternative sources for pricing medical office

space, MGMA remains opposed to the use of residential and not commercial data for this purpose. Such use is inconsistent with the core objective of the Balanced Budget Act of 1997 to make Medicare resource based. MGMA suggests that CMS study whether actual physician office rental costs vary geographically in the same fashion as the rental index to validate the use of this proxy. Alternatively, MGMA recommends that CMS work with other government agencies like the Bureau of Labor Statistics to identify other nationally collected data sources and groups that are capable of collecting data if no such source currently exists.

The disadvantage of basing relative physician payments on indices developed for entirely different purposes is illustrated by HUD's rental floor for rural counties. This has the effect of raising the GPCIs for rural areas at the expense of urban practices. Previous fee schedules do not indicate why HUD has established this policy. Presumably it is to accomplish some HUD policy objective that has no relationship to the objectives of the GPCI in the Medicare fee schedule. Thus, it is an example of one small intervention in the system that affects physician payment which has no relationship to actual and relative costs incurred by physician practices in delivering care to Medicare beneficiaries. This is inconsistent with the broad objectives of the Medicare resource based relative value scale payment approach.

Implementation of the MMA

MGMA's core purpose is to improve the effectiveness of medical group practices and the knowledge and skills of the individuals who manage and lead them. As such, we are intimately involved in the education and direction of practice managers on Medicare billing and coding rules. MGMA has questions related to the implementation of provisions under the MMA as outlined in the rule. These concerns are detailed below.

MMA section 611

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MMA section 303

MGMA has consistently expressed its concern that Medicare reimburse providers appropriately for both the cost of drugs administered in the outpatient setting and the physician administration services. The MMA dramatically altered reimbursement in both of these areas, and MGMA remains extremely concerned about the adequacy of reimbursement levels. Beginning in 2005, the cost of physician-

administered drugs will be reimbursed at rates set by the Average Sales Price (ASP) + 6 percent. However, providers are now expected to prepare for an ambiguous cut for both drug administration and drug payment rates. The Aug. 5 proposed rule included preliminary estimates for drug reimbursement. These rates were then nullified by a subsequent rule published on Sept. 16 (69 FR 55763) revising drug discount calculations. CMS has not made public revised drug estimates, leaving the provider community without any guidance for the reality of Jan. 1 payment levels.

Additionally, CMS has admitted that the data the Agency has received to calculate the ASP is flawed. By the time the final rule is released, CMS will have data from 2004 Quarter Two analyzed, but very little time to work with the pharmaceutical community to ensure that the data submitted for quarter 3 reflect actual acquisition costs. The Quarter Three data must be as accurate as possible to ensure that the ASP system is implemented as envisioned by the congressional authors.

Historically, CMS has administratively chosen to delay the implementation of payment rates when the supporting data is inadequate. This was true for the pass-through payments for the outpatient prospective payment system in 2002 (66 FR 67494) and the anesthesia services reevaluation in the 2003 physician fee schedule that delayed publication of the entire rule (67 FR 79966). MGMA strongly recommends that CMS delay the implementation of the ASP system until CMS is able to confirm the accuracy of the Quarter Three data, the affected community is provided a minimum 60 day notice and is afforded an opportunity to review and comment on the rates.

In the 2005 proposed rule, CMS suggests that providers can solve any difficulty in finding drugs at the ASP+6 percent rate by joining a group purchasing organization. However, not all specialties have group purchasing organizations and they are not available in all regions where Medicare providers practice medicine. Furthermore, it is an incorrect assumption that all group purchasing organizations can acquire drugs at or below ASP+6. MGMA practice managers report that group purchasing organizations, while helpful, were not always on track with the preliminary reimbursement rates published in the 2005 proposed rule.

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Additionally, CMS must provide clear billing guidance on the use of administration codes for non-chemotherapy drugs. Whether the codes are temporary or included in the Current Procedural Terminology (CPT) nomenclature, clear billing rules will allow providers to correctly bill and receive proper reimbursement for physician administration and drug services.

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Furthermore, the overly restrictive requirement that providers prescribe medical supplies, appliances and devices within 30 days of a face-to-face encounter will unnecessarily restrict patient access to DME and orthotics. For many home-bound patients, a course of care is followed over a period of time via the telephone, maximizing the patient's comfort and provider's time. Prescriptions are filled over the phone when treatment is not working and may include a course of drugs and/or subsequent DME/orthotic. To require the patient to come into the office for a face-to-face encounter within a prescribed time period not only burdens the practice with a patient that they really did not need to see, but harms a patient who often requires the DME for ambulation. Furthermore, the requirement will unnecessarily result in higher utilization of services, contrary to the underlying tenants of the Medicare program. MGMA recommends that CMS revise the policy to require that the DME prescription be dated in a timely fashion following the face-to-face encounter.

Therapy – incident to

CMS solicited comments in the 2003 proposed rule from the public on qualifications for professionals performing therapy services. In the 2005 proposed rule, CMS outlines a drastic change in qualifications for professionals who perform services incident to a physician's professional service. The NPRM for the 2005 fee schedule would, if implemented, limit qualified incident to service professionals to therapists, speech language pathologists and their certified assistants. MGMA is very concerned that this proposal would leave Medicare beneficiaries with few providers in the area offering therapy services, especially in rural areas where many of the therapy professionals are outside of this very limited scope of providers. CMS failed to explain the policy rational for the change or show evidence of any substandard services being performed by professionals outside these limited categories.

Further confusing the issue is the simple fact that nonphysician practitioners, such as nurse practitioners, clinical nurse specialists and physician assistants could perform covered therapy services under their own benefit but not as an incident to service to a physician or another nonphysician practitioner. This fact is counter-intuitive and undermines the proposed change.

MGMA recommends that CMS modify the qualification requirements for professionals performing incident to therapy services to cover services provided by persons licensed by their state to perform therapy services. Additionally, qualified professionals could include those non-licensed providers as described in the proposed rule; physical therapists, occupational therapists, speech pathologists, physical therapy assistants or occupational therapy assistants that are certified by the appropriate professional association and meet the education requirements set forth in the rule.

Therapy standards and requirements

MGMA applauds the flexibility CMS proposed in the NPRM which will permit therapy assistants to perform therapy services under direct, rather than personal supervision. We see this as a welcome regulatory relief provision and support the revision.

Care plan oversight

The Medicare program has historically utilized nonphysician practitioners to extend the services of physicians and provide greater access to quality medical care for Medicare beneficiaries. The revision in the care plan oversight (CPO) policy will provide beneficiaries greater access to home health care services. MGMA supports the revision and conditions of coverage as defined in the proposed rule.

Billing rules for incident-to services

Over the last several years, MGMA has sought clarification on the “incident-to” billing rules. In the 2002 final fee schedule, CMS clarified that services billed incident-to a physician’s professional service should be billed under the supervising physician’s number (66 FR 55267). This policy restricted practices from exercising their previous flexibility to bill such services under either the supervising physician’s number or the physician’s number whom the services are incident-to.

MGMA maintains that this clarification is grossly restrictive and causes confusion among beneficiaries. MGMA members report the need for widespread beneficiary education on incident-to services as the Medicare Summary Notices (MSNs) identify a physician other than the doctor who initiated a course of diagnosis or treatment. As such, some beneficiaries expressed their concern that fraudulent or abusive practices were occurring.

Carrier change requests 3138 and 3242 implemented billing changes specific to incident-to services. These instructions now require providers to identify both the supervising and ordering physician on a single claim. MGMA recommends that CMS use this information to clarify in beneficiary MSN statements which physician ordered the service instead of identifying only the supervising physician on the notice. This information will eliminate much of the reported patient confusion. However, MGMA continues to advocate that CMS retract this billing policy in 42 CFR 410.26(b)(5) and revert to the flexible policy allowing providers to bill services under either the supervising or ordering physician.

Designated health services identified in final fee schedule

For the last three Medicare physician fee schedules, CMS has included a list of Medicare services considered designated health services for the purpose of aiding provider compliance with the federal self-referral (Stark) statute. MGMA applauds these efforts and fully supports the inclusion of these codes as an appendix of each final fee schedule.

However, this list does not include CPT-4 and Healthcare Common Procedure Coding System (HCPCS) codes for services falling into six of the 11 categories of designated health services. These categories are: durable medical equipment; home health services; parenteral/enteral nutrients, equipment and supplies; prosthetics, orthotics and supplies; outpatient prescription drugs; and inpatient and outpatient hospital services. MGMA recommends that CMS clarify that the list of designated health services appearing in the appendix does not include all DHS and indicate where providers can obtain more information on the remaining categories. It is not enough to provide information in the rule’s preamble on the limitations of the table. Instead, the title and headers associated with the information must make clear that six categories of DHS are not listed by code in the table.

Additionally, MGMA continues to suggest that the CPT-4 and HCPCS codes of services falling into these six categories be included in the annually updated list of designated health services codes. These designations should also be included in the quarterly updated Microsoft Excel spreadsheet of RVU values, global periods and supervision levels for Medicare covered-services posted on the CMS Web site.

Provider education

As CMS develops new policies for the administration of the Medicare program, it is imperative that provider education be an integral aspect of implementation. Educational materials must be distributed via various media channels so that all providers have notice and access to these resources.

Additionally, carrier representatives must also be knowledgeable on these new initiatives and able to field provider questions. The recent Government Accountability Office (GAO) report, "Call Centers Need to Improve Responses to Policy-Oriented Questions from Providers" (GAO-04-669), emphasizes the continuing difficulty providers experience with the Medicare contractors. The report disturbingly states, "Only 4 percent of the responses GAO received in 300 test calls to 34 call centers were correct and complete." The GAO discovered the majority of call center responses were incorrect, or partially correct or incomplete. The GAO stated several factors accounted for the lack of incorrect and incomplete answers including "fragmented sources of information, confusing policy information and difficulties in retaining the customer service representatives (CSR) responding to calls." This is an 11 percent reduction in the accuracy rate since 2002, when the GAO reported CSRs rarely provided appropriate answers to questions, answering only 15 percent of test calls completely and accurately (GAO-02-249).

The following are specific examples of interactions our membership had with carrier call centers. Through these examples, we hope to provide additional insight into the day-to-day burdens group practice administrators face with inefficiencies in the Medicare carrier system.

1. MGMA members have found it is difficult to locate the correct individual to speak with on a given matter. Hotlines, when provided, are a "one call fits all" approach that does not adequately respond to the specifics of provider questions. We recommend carriers be required to return calls within a 24-hour period, develop a reporting mechanism for providers when staff fails to respond in a timely manner and require CMS to meet with outlier carriers to identify and enforce solutions.
2. Our members report difficulty obtaining return calls from carriers. According to one member's records, the average time it took their carrier to return calls was 2.65 working days. MGMA advocates the CMS develop a site on the Internet, similar to the Health Insurance Portability and Accountability Act section of their Web site, where Medicare providers can post questions and obtain feedback. Moreover, responses should be maintained on the Internet site for reference and inquiries must be responded to within 30 days. Additionally, carriers should be required to provide callers with either their name or unique identifier for accountability.

MGMA supports the GAO's recommendations and urges CMS to improve the responses to policy-oriented inquiries from providers. Specifically, the GAO recommends that CMS develop: a process to route policy inquiries to staff with the appropriate expertise, clear and easily accessible policy-oriented material to assist CSRs and an effective monitoring program for call centers. MGMA looks forward to collaborating with CMS to educate carriers and medical group practices on the numerous MMA policies and other upcoming program changes.

MGMA appreciates your consideration of these comments. If you should have any questions, please contact Jennifer Searfoss Miller in the Government Affairs Department at (202) 293-3450.

Sincerely,



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

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

GENERAL

GENERAL

Attached please find the University of Missouri School of Medicine's comments regarding CMS-1429-P - Coding Telehealth.

CMS-1429-P-4038-Attach-1.pdf

**Before the Centers for Medicare and Medicaid Services
Baltimore, MD
September 24, 2004**

In the Matter of:

The following comments are submitted in accordance with the published guidelines in the Federal Register, Vol. 69, No. 150: Thursday, August 5, 2004 – Proposed Rules. All comments are referenced by title, starting page number, starting column and paragraph.

File Code CMS-1429-P

“CODING – TELEHEALTH”

Comments of:

Joseph Tracy, MS, Executive Director of Telehealth, University of Missouri Columbia

Karen Edison, MD, Chair – Dermatology, Medical Director of Telehealth, University of Missouri – Columbia

Weldon Webb, MA, Director of the Office of Rural Health Programs, University of Missouri – Columbia

Barbara F. Prowant, MS, RN, CNN, Research Associate, Division of Nephrology, Department of Internal Medicine, School of Medicine, University of Missouri – Columbia

Ramesh Khanna, MD, Karl D. Nolph Distinguished Professor of Medicine, Director, Division of Nephrology, University of Missouri – Columbia

Karl Nolph, MD, Curators' Emeritus Professor of Internal Medicine, University of Missouri - Columbia

Zbylut J. Twardowski, MD. PhD, FACP, Professor Emeritus of Medicine, School of Medicine, University of Missouri - Columbia

We would like to thank the Centers for Medicare and Medicaid Services (CMS) for the opportunity to comment on the CMS' review of new telehealth services published in the Federal Register on August 5, 2004.

End Stage Renal Disease – Monthly Management of Patients on Dialysis – CMS Review (page 47511, column 3, paragraphs 1 – 7)

We concur with the recommendation that CMS should add the following to the list of Medicare telehealth services: End Stage Renal Disease (ESRD) related services with 2 or 3 visits per

months and ESRD-related services with 4 or more visits per month as described by G0308, G0309, G0311, G0312, G0314, G0315, G0317, and G0318. We also agree that the complete assessment of the ESRD beneficiary needs to be conducted in-person.

Submitted Request for Addition to the List of Telehealth Services – CMS Review
(page 47511, column 1, paragraphs 1-6)

The American Telemedicine Association, an independent practitioner and the University of Kansas submitted comments regarding the addition of services that CMS placed in a Category 2 review. CMS placed these recommendations into the Category 2 classification because of their “*potential acuity*” level. CMS suggests that because of the potential acuity level of a patient in an inpatient, emergency department or hospital observation facility, evidence that the use of a telecommunications system produces similar diagnostic findings or therapeutic interventions as would “face-to-face” delivery of the same service is required.

We respectfully disagree with CMS’ classification system in this regard. This system arbitrarily denies certain levels of care to patients who could benefit from that care if it were provided in-person in their community. Regardless of a patient’s acuity level, physicians or other eligible Medicare providers will not risk their careers by making poor medical judgements based on information provided by a telehealth system. If a provider feels uncomfortable in making a clinical judgement when using a telehealth system, the patient can be asked to come to the consulting physician’s office for further examination. On the other hand, if the provider can render an appropriate diagnosis via a telehealth system, then they have provided a timely and necessary service to an individual, who in most cases does not have ready access to specialized services. In short, the decision to use or not use telehealth needs to be in the hands of the licensed providers and not compromised by those who control the payment mechanisms.

The classification system is also flawed because CMS has a need for “evidence”, based on randomized clinical trials of telehealth, to prove that telehealth services can be delivered to “potentially acute” inpatients, emergency room patients or observation patients in a health care facility. Unfortunately, telehealth does not lend itself well to clinical trials of this nature. Telehealth is not generally deployed within a laboratory setting; it is deployed in the real world. Conducting telehealth in a laboratory setting would require multi-state evaluation efforts over a number of years before a sufficient number of clinical cases in any one diagnostic category would be amassed to produce a meaningful result. Furthermore, establishing control groups in a clinical trial of telehealth in the real world could be considered unethical and potentially unwise to conduct. Especially if a medical service, that could save a life by telehealth, is being withheld (a control group subject) just to make some future point that telehealth provides a similar level of care when compared to the same service delivered in-person.

Another issue to consider is that the “evidence” CMS currently seeks may never be obtained, because of the lack of reimbursement for providing a service. Physicians and other providers cannot afford to examine and treat a large number of patients for which there is no reimbursement. Simply put, if providers are not seeing patients because of the lack of reimbursement, then CMS will have no evaluation data to collect as “evidence”.

Speech and Audiologist Services – CMS Review
(page 47512, column 2, paragraphs 1-2)

CMS mentions that they are “exploring” issues as part of a report to Congress (required by section 223(d) of BIPA) on the addition of “originating sites and settings, geographic areas and practitioners that may be reimbursed for the provision of telehealth services.” We respectfully request that CMS complete this report as soon as possible, as it is approximately two years overdue. We strongly recommend that speech pathologists, speech therapists, and audiologists be added as eligible providers. Additionally, we recommend that the appropriate CPT codes that have been identified and requested by the American Speech-Language Hearing Association (ASHA) be added to the list of eligible Medicare telehealth services.

We also request that the report to Congress contain a recommendation from CMS to add dialysis centers to the list of originating sites and note that the CPT codes for this service have already been recommended by CMS for reimbursement.

Other Recommendations from the Commentators:

CMS should strongly consider eliminating the categorical system that is used to evaluate services for telehealth. In its place we recommend that CMS adopt a method of review that considers clinical utilization of a particular telehealth service and the opinions of providers that are rendering those services. If licensed physicians or other independent practitioners can demonstrate that a particular service is being appropriately provided by telehealth then CMS should consider that information in adding the service.

Replace the words “face-to-face” with “in-person”. We recommend that CMS replace “face-to-face” with the term “in-person”. This request is being made because whether or not you are seeing a patient “in-person” or by an interactive video telehealth system, that patient is still being seen “face-to-face”. The use of “in-person” would more accurately define an encounter in which a provider is in the same physical location as the beneficiary.

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

GENERAL

GENERAL

Please see the attached comments on behalf of the Alliance of Specialty Medicine

**Department of Health and Human Services
Centers for Medicare and Medicaid Services (CMS)
Offices of Strategic Operations and Regulatory Affairs**

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Organization :

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Issue Areas/Comments

Issues 10-19

SECTION 952

THERAPY ASSISTANTS IN PRIVATE PRACTICE

I strongly support the CMS proposal to replace the requirement that physical therapists provide personal supervision (in the room) of physical therapist assistants in the physical therapist private practice office with a direct supervision requirement. This change will not diminish the quality of physical therapy services.

In Georgia, physical therapist assistants are recognized under state licensure laws as having the education and training to safely and effectively deliver services without the physical therapist being in the same room as the physical therapist assistant.

Physical therapist assistants are recognized practitioners under Medicare and are defined in the regulations at 42 CFR 484.4. According to this provision, a physical therapist assistant is 'a person who is licensed as a physical therapist assistant by the State in which he or she is practicing, if the State licenses such assistants, and has graduated from a 2-year college-level program approved by the American Physical Therapy Association.' All physical therapist assistant programs in Georgia (Gwinnett Technical College, Athens Technical College, and Darton College) are in compliance with this regulation.

I have worked with physical therapist assistants for 25 years, and I trust them to work safely and effectively under my supervision. Their education is such that in-room supervision, under my direct sight, is unnecessary. Current laws require frequent communication and physical meetings between physical therapists and licensed assistants; removing the line-of-sight requirement will not diminish the effectiveness of current law and practice.

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Please see attached file.

**Department of Health and Human Services
Centers for Medicare and Medicaid Services (CMS)
Offices of Strategic Operations and Regulatory Affairs**

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Organization :

Category :

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I am writing to express my disapproval of your making any changes to the current "incident to" regulations, guidelines or means of reimbursing incident to services. As a person nearing Medicare age and a former competitive athlete I know about the quality services ATCs provide. I have saved considerable amounts of my money my insurance provider's money by utilizing services provided in my physician's office versus having to seek services outside of her office. Services such as therapeutic instruction, therapeutic exercise and other types of services that my physician decided I needed. Your proposal is significant in that it tends to lump totally unqualified health care providers in with qualified, though maybe limited in scope, providers. That is an absurd way to run a program, in lieu of throwing the baby out with the bath water, which this change would do, why do you not sit with the various qualified provider groups and come to a compromise. Seek a method by which all qualified providers might be able to work. Obviously you have not reviewed the statistics on the health care professional shortage that has hit, and will only worsen, the United States. I find this proposal beyond prejudicial, it is without merit, it would be allowing one provider group to hold the purse strings of Medicare, insurance companies, physicians and the Medicare beneficiaries hostage to whatever whims and fancies they might decide on. That is inanity at its apex.

I have read the regulations pointed out in your proposal and I believe that any third year law student could point out the errors in your supposed logic. I truly hope that more logical, business minded and legally astute individuals will make the final decision on this proposal and halt this onerous change from taking place.

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services

I wish to make a comment on the August 5th proposed rule on "Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005." I am a physical therapist who has been practicing in Sterling, Virginia for over 15 years. I have worked in a variety of settings including employee in a private practice, hospital and a nationwide corporation. I am currently the owner of my own physical therapy practice serving the people of Sterling and Loudoun County, Virginia.

I am in favor of the CMS's proposed requirement that physical therapists working in physicians offices be graduates of accredited professional physical therapist programs. This would set certain standards to insure appropriate, safe and effective care is being provided in these settings. A licensure requirement means that the individual providing physical therapy is a graduate of an accredited program and is required to uphold standards of professional conduct, care and maintain continued competency in the field. Failure to meet any of these standards would cause the licensed physical therapist, licensed physical therapist assistant to be answerable to their state board of physical therapy or state board of medicine for corrective and/or disciplinary actions as appropriate. Thus the licensure requirement would provide patients the proper level of security and safety in knowing that they are receiving care from a professional(licensed physical therapist or a licensed physical therapist assistant under the supervision of a physical therapist)who has completed the rigorous education and training to appropriately deliver physical therapy services.

I have had numerous patients who I have treated over the years who have had various experiences with "physical therapy". Upon their initial examination I will ask them if they have received physical therapy before and have had various replies such as "yes.....at the doctor's office..they put a heat pad on me...had ultrasound done by the receptionist or was given exercises to do on some machines or given a sheet of exercises and told to do them at home without any instruction." These kind of experiences are reported all too frequently and unfortunately this is not "real" physical therapy. Physical Therapy should include an initial evaluation and appropriate treatment plan by a licensed physical therapist and ongoing care should be administered by a physical therapist or physical therapist assistant under a P.T.'s supervision. If "physical therapy" is being provided by unqualified people it can be harmful to patients who at best may not improve their condition as they would have under the care of a licensed physical therapist and at worst may suffer serious harm due to inappropriate treatment being administered. These situations can also affect a patient's care by using all available funds for physical therapy that are available for the patient under their plan without ever receiving care from a licensed physical therapist and having treatment that would have abated or improved their condition.

I would like to thank you, Dr. McClellan for your consideration of my comments and hope that requirements are approved in the interest of public safety and to allow for safe, appropriate and cost-effective delivery of physical therapy services.

Sincerely,

Arthur C. Bronsord P.T.
Physical Therapy & Beyond
21475 Ridgetop Circle
Suite 260
Sterling, VA 20166
Ph: (703)433-0401
Fax:(703)433-0490

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 10-19

SECTION 623

please see attached. Please send a confirmation of receipt to Chris.lovell@dcinc.org

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Centers for Medicare and Medicaid Services (CMS)
Offices of Strategic Operations and Regulatory Affairs**

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Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1429-P
PO Box 8012
Baltimore, MD 21244-8012

Subject: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005

THERAPY INCIDENT TO

I am a physical therapist with 28 years practice in acute care, nursing home, home health and outpatient environments.

I strongly support CMS's proposed requirement that physical therapists working in physicians' offices be graduates of accredited professional physical therapist programs. Therapists who are licensed by the state or commonwealth in which they practice have met rigid standards for licensure, standards whose purpose are to assure patient safety in that jurisdiction.

Unqualified personnel should not be providing physical therapy services. Only physical therapists and physical therapist assistants working under the supervision of a physical therapist have the education and training to provide PT services. PT's are professionally educated at the college or university level in programs that meet the rigid standards of the Commission on Accreditation of Physical Therapy, an independent agency recognized by the U.S. department of Education. The majority of these programs will offer the doctor of physical degree (DPT) by 2005.

A thorough understanding of anatomy, physiology, and body systems and functions, which a PT possesses, is extremely important in safely treating the aging, Medicare population. An unqualified individual may not recognize adverse, and potentially dangerous, responses to treatment interventions. They may also exhaust a Medicare beneficiary's financial resources before the patient ever sees a qualified physical therapist.

Section 1862 (a) (20) of the Social Security Act clearly requires that in order for a physician to bill 'incident to' for physical therapy services, those services must meet the same requirements for outpatient therapy services in all settings. Therefore, graduates of accredited professional physical therapist education programs must perform these services.

Thank you, Dr. McClellan, for your consideration of these comments.

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 1-9

PRACTICE EXPENSE

Comments recommending that CMS work with physicians and the Immune Deficiency Foundation in determining what is an acceptable level of reimbursement for the services associated with the administration of Intravenous Immune Globulin.

SECTION 303

Comments seeking an increase to the proposed \$0.05 per unit separate payment for the administration of blood clotting factor.

CMS-1429-P-4046-Attach-1.doc

CMS-1429-P-4046-Attach-1.doc

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September 24, 2004

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

Re: CMS-1429-P (Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005)

Dear Dr. McClellan:

ZLB Behring appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule regarding revisions to payment policies under the Medicare physician fee schedule, published in the Federal Register on August 5, 2004. ZLB Behring is a wholly owned subsidiary of CSL Limited and was formed when CSL acquired Aventis Behring and combined the business with CSL's existing subsidiary, ZLB Bioplasma, in April 2004. This combined entity is the manufacturer of life-saving therapies such as hemophilia clotting factor, Von Willebrand factor, intravenous immune globulin (IVIG) and alpha₁-proteinase inhibitor.

We have specific concerns with the proposed \$0.05 add-on payment associated with the administration of blood clotting factors. Further, we are also concerned that existing reimbursement for IVIG in the home does not cover the ancillary items necessary to administer such therapy. These criteria could greatly diminish patient access to care should they be implemented in their existing manner. ZLB Behring requests the review of physician reimbursement for administering IVIG, also a concern regarding patient access to care. Further, ZLB Behring requests that CMS exempt blood clotting factors and alpha₁-proteinase inhibitor from the competitive acquisition model of Medicare Part B that will be implemented in January 2006. Lastly, we ask CMS to issue very specific guidelines for the submission of Average Sales Price (ASP) so as to remove uncertainty and confusion.

Payment of Items and Services Associated with the Administration of Blood Clotting Factor

This separate payment provision recognizes the unique costs associated with the administration of blood clotting factors and ZLB Behring is strongly supportive of providing an additional payment. However, CMS proposes to make only a \$0.05 per unit separate payment to hemophilia treatment centers and homecare companies for the items and services necessary in administering blood clotting factor. This amount does not sufficiently protect beneficiary access to these life-saving therapies, especially in light of the payment rate reductions for clotting factor therapies taking place in 2005. This is the second consecutive year in which CMS has proposed the same separate payment rate of \$0.05 per unit and, as noted in the proposed rule, many commenters responded that the payment was too low and would “severely impact beneficiaries access to clotting factor.” After reviewing a January 2003 General Accounting Office (GAO) report, as instructed by the MMA, CMS proposes the same \$0.05 rate, which is still inadequate to cover the costs associated with constituting, storing, and delivering clotting factors, supplies, and patient training. We urge CMS to examine more recent data than the 2000-2001 data in the GAO study and propose a new rate that will appropriately reimburse providers and better ensure patient access to life-saving blood clotting factor.

In addition, ZLB Behring would urge that the beneficiary’s 20% co-pay not be applicable to this separate payment. The beneficiary co-pay is overwhelming as it is and needs to be addressed, but requiring an additional beneficiary co-pays only adds additional financial burden.

Extension of Coverage of IVIG for the Treatment of Primary Immune Deficiency Diseases in the Home

CMS proposes to implement section 642 of the MMA, which expands Medicare coverage for IVIG administered in the home. ZLB Behring appreciates CMS’ efforts to implement this provision in a timely manner, but we are concerned that the items and services related to the administration of IVIG in the home are excluded from coverage. We urge CMS to extend coverage for the important items and services necessary to administer IVIG. This can be done through Medicare’s proposed rule on Part D. ZLB Behring supports the view put forward by CMS in the Part D regulations that Part D should wrap around Part B coverage filling “any gaps in existing Part B coverage” – such as the need for beneficiaries to have access to the items and services necessary to administer IVIG in their homes. By having such ancillary

“wrap-around” coverage under part D, coverage of the IVIG therapy under Part B can then be effectively utilized.

An alternate solution would be to treat the ancillary items and services as Medicare treats a drug administered through a piece of durable medical equipment (DME). Medicare may not always cover a drug but CMS has taken the position that such drugs necessary for the effective use of DME are to be covered. A similar policy would be ideal for the ancillary supplies and services necessary to administer IVIG in the home. Such a provision would comply with the spirit of the IVIG home infusion provision and allow patients access to the care they so desperately need.

IVIG Physician Service Fees

There is great concern within the medical community that with the implementation of Average Sales Price plus 6% in 2005, physicians will no longer be properly reimbursed for their services. ZLB Behring recognizes that CMS has gone to great lengths to examine physician reimbursement separate from reimbursement of the therapy. Therefore, we ask CMS to specifically review the physician payment rates for those professionals who prescribe and administer IVIG in coordination with such professionals and the Immune Deficiency Foundation (IDF) to determine appropriate reimbursement for these professional services. A CMS study in collaboration with the IDF on the physician fee rates associated with administering IVIG, similar to the January 2003 General Accounting Office report on blood clotting factors, would provide a better understanding of reimbursement needs associated with administering IVIG to ensure continued access for beneficiaries.

As there is great fear within the immune deficient community over the ability of medical professionals to be adequately reimbursed when treating Medicare beneficiaries and administering a high complexity therapy, there would need to be a separate payment, such as with blood clotting factor, or some other type of redress, as was done with physician fee schedule upward adjustments for oncologists.

Exemption of Blood Clotting Factors and Alpha₁-Proteinase Inhibitor from Part B Competitive Acquisition in 2006

While this topic is not specific to the Physician Fee Schedule for 2005, competitive acquisition is a looming issue for 2006. ZLB Behring would like to bring to your attention concerns shared by the plasma industry and the patient advocacy organizations regarding competitive acquisition for blood clotting factors and alpha₁-proteinase inhibitor.

Both therapies should also be excluded from the competitive acquisition model as was done with IVIG. Since blood clotting factors are used to treat hemophilia, a rare condition affecting a miniscule percentage of Medicare beneficiaries there is fear that regional bidders will not carry all brands or will artificially limit choice. As blood clotting factor is a biological derived from human blood plasma, one brand of factor may not be as effective in obtaining hemostasis as another. There is also the possibility of allergic reactions and increased inhibitor development in some cases for certain individuals where one brand is used over another. Similarly, these points also apply for alpha₁-proteinase inhibitor in the treatment of alpha₁ antitrypsin deficiency. For biologics, and especially plasma-derived therapies, one brand does not work in all cases and different brands may work best in different situations. Thus it is essential that access to all brands of therapies be maintained, which the competitive acquisition model will not likely result in nor guarantee.

The Average Sales Price model does provide access to all brands of therapy, allowing beneficiaries to obtain the brand that the patient and physician believe will work best. ZLB Behring asks that Secretary Thompson use his exclusion authority to exempt blood clotting factors and alpha₁-proteinase inhibitor from competitive acquisition and maintain the ASP model for these life-saving therapies, as is being done with IVIG.

Submission of Average Sales Price to Determine Payment Rates in 2005 and Beyond

In the new ASP-based reimbursement system, access to drugs and biologicals will depend on the rates calculated using manufacturers' ASP data. It is essential, therefore, that manufacturers obtain the guidance they need to submit accurate data. CMS issued an Interim Final Rule on ASP data submissions in April 2004 and a final rule specific to price concessions on September 16, 2004. Although we appreciate CMS' recent guidance regarding the use of a smoothing methodology for estimating rebates and chargebacks in order to prevent dramatic swings in ASP, the agency has not addressed many other important issues including a clarification as to which drugs and biologicals are subject to the reporting requirements and which sales are exempted from ASP calculations. The final filing deadline before the 2005 rates are calculated is approaching, yet CMS says in the September final rule that it will address other issues "at a future time." ZLB Behring urges CMS to provide manufacturers with detailed instructions immediately to ensure that payments rates for January 2005 and beyond are based on the most complete data possible so payment rates will be accurate.

ZLB Behring recognizes the complexity of implementing the many regulations needed in order to comply with the MMA. We look forward to working with CMS on the issues we have raised in addition to the reimbursement of all plasma-derived and recombinant analog therapies. Thank you for your consideration of our comments and if ZLB Behring may be of any assistance, please feel free to contact me directly.

Sincerely,

A handwritten signature in cursive script, appearing to read "Dennis Jackman".

Dennis Jackman
Senior Vice President, Public Affairs

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

GENERAL

GENERAL

Issues 1-9

SECTION 303

Please see the attached file.

CMS-1429-P-4047-Attach-1.doc

CMS-1429-P-4047-Attach-1.doc



John M. Gray, President and CEO
Eric Schuss, Chairman of the Board

September 24, 2004

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1429-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Via Electronic Submission

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005, Section 303 [CMS-1429-P]. 69 Fed. Reg. 47488 (August 5, 2004).

Dear Dr. McClellan:

The Healthcare Distribution Management Association submits the following comments in response to the Centers for Medicare and Medicaid Services (CMS) proposed rule, *Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005*. 69 Fed. Reg. 47488 (August 5, 2004). I am writing to express the concerns of the HDMA membership regarding the manufacturers' average sales price (ASP) calculation used to establish fee schedule amounts for Part B drugs and biologicals.

HDMA is the national trade association representing full-service distribution companies responsible for ensuring that billions of units of medication are safely distributed to retail pharmacies, hospitals, nursing homes, clinics, and other provider sites across the United States. Healthcare distributors manage drug distribution, ensure product safety and provide the vital link between pharmaceutical manufacturers and healthcare providers by providing a wide array of important services including warehousing finished products, processing orders, keeping records, managing inventory, supplying inventory and sales data, supplying information systems and software, offering marketing support and services, processing recalls and returns, providing accounting services and extending credit.

Healthcare Distribution Management Association
Formerly National Wholesale Druggists' Association (NWDA)

On behalf of our distributor members, HDMA seeks clarification from CMS regarding calculation of manufacturers' ASP data, which will serve as the basis for Part B drug pricing beginning in January 2005. When Congress enacted payment policy reforms for Part B drugs under the Medicare Prescription Drug Benefit, Improvement, and Modernization Act of 2003 (MMA) its intent was that reimbursement rates adequately reflect the costs incurred by providers for these specialty products¹. In order to achieve that goal, HDMA believes that CMS must provide clarification to manufacturers that recognizes the following:

1. The ASP calculation should exclude any *bona fide* fees for services provided to manufacturers by pharmaceutical distributors; and
2. Prompt pay discounts reflect the time value of money rather than a true discount on the cost of the drug. Prompt pay discounts offered to the distributor by the manufacturer should not be included within the ASP calculation.

By issuing clear guidance for manufacturers' calculation of ASP data, CMS will ensure that the resulting fee schedule amounts reflect accurate acquisition costs for Medicare Part B providers while not erecting regulatory barriers to distributors' compensation for their valuable services in those situations where manufacturers and distributors agree to such compensation in their individual discussions.

I. Section 303 – Payment Reform for Covered Outpatient Drugs and Biologicals.

A. Congress intended that payment policy reforms result in fee schedule amounts that adequately reflect providers' acquisition costs.²

The revisions to Part B payment policy for drugs and biologicals were enacted by Congress as a means of adequately reflecting transactions that occur in the marketplace and ensure that reimbursement rates fairly provide for the costs incurred by providers of Part B products. Further, prior to the enactment of the MMA, “. . . the GAO urged CMS to take steps to begin reimbursing providers for Part B-covered drugs and related services at levels reflecting providers' acquisition costs using information about actual market transaction prices.”³

In order to ensure affordable access and comprehensive coverage for important, life saving pharmaceutical products in the outpatient setting, it is imperative that reimbursement rates for Part B drugs accurately reflect the true cost to the provider. The interim final rule

¹ H.R. Rep. No. 108-391 at 583 (2003) available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=108_cong_reports&docid=f:hr391.108.pdf.

² Id.

³ Id. In 2001, a General Accounting Office (GAO) study found that Medicare's payments for doctor-billed drugs were at least \$532 million higher than providers' acquisition costs in 2000. Medicare Part B Drugs: Program Payments Should Reflect Market Prices, U.S. Government Accounting Office (September 21, 2001).

published by CMS on April 6, 2004 outlined the methodology for manufacturer calculations of ASP for Part B drugs⁴. While the ASP formula is not specifically addressed in this proposed rule, the fee schedule amounts and payment policies reflected here result from the first quarter data submissions from manufacturers. As such, we believe that this is an appropriate and necessary forum to express HDMA's concerns.

Congress intended that the formula used to calculate manufacturers' ASP should result in reimbursement rates that represent the true acquisition cost of the product. If this goal is reached, HDMA believes that access for beneficiaries and efficiency in the supply chain will both be preserved.

While pharmaceutical distributors neither establish drug prices nor receive Medicare reimbursement for services, they serve as a conduit for manufacturers to move products through the supply chain to providers and pharmacies. In doing so, HDMA members provide valuable services and play an important role in the drug supply chain.

HDMA believes that the intent of the reimbursement methodology outlined in the proposed rule should result in fair reimbursement rates that accurately reflect the true costs of the drugs to the providers who dispense them. To fully realize the congressional intent of the MMA and achieve accurate fee schedule amounts, the ASP calculation should exclude *bona fide* fees for services provided to manufacturers by pharmaceutical distributors. Further, since standard prompt pay discount arrangements also reflect the value of distributors' services and the time value of money, they too should not be included in the ASP calculations.

1. **The ASP calculation should exclude *bona fide* fees for services provided to manufacturers by pharmaceutical distributors**

HDMA requests that CMS provide clear guidance to manufacturers which clarifies that the calculation of ASP data should exclude any consideration of *bona fide* fees rendered at fair market value for distribution services. While the statute and the recent CMS rulemakings do not mention *bona fide* service fees, we are calling attention to this issue due to perceived confusion among manufacturers. It is my understanding that Part B drug manufacturers have received inconsistent information and varying advice on this issue, which may yield inconsistent reporting of ASP data.

Upon submission of data for all NDCs across a particular HCPCS code, if ASP amounts are not calculated consistently across the board the end result will be a fee schedule with inaccurate reimbursement rates that do not reflect the true cost to providers for each drug. Moreover, such inconsistencies in calculations and submissions could ultimately create imbalanced or inadequately valued HCPCS codes.

⁴ Medicare Program; Manufacturer Submission of Manufacturer's Average Sales Price (ASP) Data for Medicare Part B Drugs and Biologicals, 69 Fed. Reg. 17935, 17938 (April 6, 2004).

One reason for the existing confusion is a recent guidance issued by CMS for manufacturers that are required to submit ASP data⁵. In its *Average Sales Price Reporting Requirements Questions and Answers*, when asked whether administrative fees paid to buyers should be included in the ASP calculation, CMS provided the following answer:

A16. Administrative fees, incentives, promotional fees, chargebacks and all discounts or rebates, other than rebates under the Medicaid drug program and discounts under an endorsed discount card program, should be included in the calculation of ASP, if those sales are to an entity whose sales are included in the calculation of ASP and if they ultimately affect the price actually realized by the manufacturer⁶.

HDMA believes that the direction provided by CMS in this guidance is confusing to manufacturers regarding whether *bona fide* fees for services provided by distributors to manufacturers should be included in the calculation. Our interpretation of the above directive is that by its failure to mention service fees, CMS has indicated that *bona fide* service fees for distribution services would *not* be included in the ASP calculation. Although CMS has not spoken directly to this issue, it appears that CMS intended for inclusion only of “administrative fees” and “all discounts or rebates,” when they “. . . ultimately affect the price realized by the manufacturer.”⁷

Currently, Medicare Part B does not reimburse distributors for services to manufacturers and delivery of products to providers. Historically, distributors have been compensated through a combination of (1) prompt pay discounts; (2) inventory inflation; and (3) some service fees. In the healthcare distribution industry, an individual distributor may agree with an individual manufacturer on service fees for legitimate and commercially reasonable services that are provided by the distributor to the manufacturer. *Bona fide* service fees are not price concessions on the products purchased by the distributor, nor are they to be confused with administrative fees, as listed by CMS above. In addition, other government health care programs, such as Medicaid, support this approach of distinguishing between *bona fide* service fees that do not affect the price ultimately realized on the drug and price concessions.

Manufacturers may pay *bona fide* fees for services provided by distributors. Such services broadly include logistics management, administrative functions, and financial services. For example, through the use of distributors, manufacturers are able to ship product to a smaller number of distribution centers vs. thousands of provider sites. Distributors also provide inventory and sales data, perform customer service functions, and sell and market manufacturers’ products to a variety of provider and pharmacy customers. Financial services provided to manufacturers include maintenance of working inventories to meet

⁵ *Average Sales Price Reporting Requirements Questions and Answers* Centers for Medicare and Medicaid Services (April 22, 2004) at http://www.cms.hhs.gov/providers/drugs/aspqa_web_042204.pdf.

⁶ *Average Sales Price Reporting Requirements Questions and Answers* Centers for Medicare and Medicaid Services (April 22, 2004) at http://www.cms.hhs.gov/providers/drugs/aspqa_web_042204.pdf.

⁷ *Id.*

high service level requirements, management of credit risk, and billing and collections. Other examples of distribution services performed for manufacturers in return for *bona fide* fees include:

- Complex pricing maintenance;
- Chargeback administration;
- Recalls and returns processing;
- Electronic order systems;
- Product launch support;
- Data collection and management; and
- Just in time delivery.

Today's pharmaceutical distributors provide important services that go far beyond the traditional "pick, pack, and shipping" of healthcare products and contribute significantly to the efficiency of the drug supply chain. For example, if manufacturers were to assume responsibility for these services without distributors, the cost of drugs may increase. Manufacturers do not have the specialized expertise or operational systems in place to assume these tasks. Therefore, it is important that manufacturers' use of experienced distributors be recognized by CMS as a valuable part of the drug delivery system, and any fees for such services excluded from calculation of ASP data submissions.

While HDMA recognizes that the MMA directs CMS to reimburse Medicare Part B drugs through the ASP definition, HDMA is also concerned that states and other payors will quickly adopt the ASP definition. In July, the state of California passed budget language that mandates ASP reporting by manufacturers and will use ASP as one metric for MediCal reimbursement. Other states will likely follow quickly. Inclusion of *bona fide* service fees in the ASP calculation would inappropriately reduce reimbursement rates for providers. That outcome could potentially deter manufacturers from paying fair and reasonable compensation to distributors. HDMA is confident that Congress did not intend to erect barriers to fair compensation for distributors when constructing the new ASP model.

The ultimate intent of the ASP methodology is to capture the actual acquisition price/cost to the practitioner or specialty pharmacy. By asking CMS to issue this clarification HDMA is simply requesting that the resulting ASP calculation represent fair and accurate reimbursement for the provider, thereby ensuring adequate access for beneficiaries. Additional guidance is necessary to show that any *bona fide* service fees paid by manufacturers to distributors are distinct from the administrative fees mentioned in the previous guidance and should be excluded from the ASP methodology.

2. Standard prompt pay discounts reflect the time value of money and should not be deducted from manufacturers' ASP data submissions.

HDMA also seeks clarification from CMS regarding prompt pay discounts and their role in the calculation of ASP data submissions. We recognize that unlike *bona fide* distribution

service fees, “prompt pay discounts” are explicitly named in both the statute and the ASP interim final rule as a deductible item in the methodology. However, ASP should exclude prompt pay discounts to distributors.

Prompt pay discounts are provided to distributors by manufacturers as a function of the time value of money. Such discounts are standard financing incentives used to encourage customers to process and pay their invoices faster. Traditionally, pharmaceutical distributors have received prompt pay discounts for the vast majority of drug products. Prompt pay discounts are not related to, nor do they affect the true price of the drug. Rather, they are dependent on a distributor’s ability to remit payment in an accelerated rate and they are completely unrelated to the cost of pricing the drug.

Prompt payment is a concept that is widely accepted across many industries and recognized by federal and state agencies. When a prompt pay discount is provided by the seller, the true price of the product is not actually affected, but rather the “discount” serves as a fee to the purchaser for assuming the burden of rendering payment in advance. When such prompt pay discounts are received by distributors from their suppliers, these discounts in essence pay for the time value of money and cover capital costs for the time lapsed between payment to the manufacturer and the time the distributor receives payment from the provider. These discounts also help defray a portion of the costs of picking, packing and shipping the drugs.

Most Part B drugs are “specialty” products that carry with them handling and storage requirements that are far more complex than those associated with other products. Examples of these specialty pharmaceuticals include injectables, infusion therapy drugs and other drugs used with durable medical equipment, and biotech drugs used by patients with serious, chronic conditions needing intensive and often expensive treatment. When these types of products are channeled through the supply chain, the costs of handling such drugs escalate to meet their unique storage and handling needs. For example, most of the products covered under Part B require special conditions such as refrigeration, exact temperature control, special packaging, and complex shipping requirements. Part B drugs often have short shelf-lives, require on-site refrigeration, freezing or exact temperature controls, and are accompanied by special inventory carrying costs.

Healthcare distributors serve manufacturers by meeting these critical specialty drug handling needs to protect the efficacy of the product. Additionally, they accelerate and streamline the drug ordering, transaction and shipping processes, thereby enabling providers to concentrate on the function they do best -- direct patient care.

HDMA has concerns that handling and storage costs of these specialty medicines are not fairly reflected in the ASP calculation. We contend that when Congress included “prompt pay discounts” in the statute, its intent was clearly to make sure that price concessions were deducted from the ASP data submissions. Again, Congress’ intent was to ensure that resulting reimbursement rates accurately reflect providers’ acquisition costs. Prompt pay discounts offered by manufacturer to distributor reflect the time value of money rather than

a discount on the cost of a drug and, therefore, should not be included within the ASP calculation.

II. Conclusion

HDMA hopes to work with you on these issues as the agency continues to develop the new Medicare prescription drug benefits and revise current payment policies. We want to ensure that manufacturers' ASP calculations, upon which fee schedule amounts for Part B drugs will be based, are accurate and consistent. More importantly, it is HDMA's position that the resulting rates should provide adequate reimbursement for Part B drugs in order to ensure that beneficiaries have access to the medications they need.

While HDMA acknowledges that pharmaceutical distributors neither establish drug prices nor serve Medicare beneficiaries directly, our members provide valuable services as described above, and serve an important function in the supply chain. It is imperative that CMS recognize these services and ensure that any *bona fide* fees that are paid for such services are excluded from the reporting requirements for manufacturers.

HDMA also supports the elimination of prompt pay discounts from the ASP methodology outlined in the rule because this type of "discount" reflects the time value of money rather than a true discount on the cost of a drug. Such discounts are standard financing incentives used to encourage customers to process and pay their invoices faster and they are not a factor in determining the price of a drug. Prompt pay discounts are dependent on a distributor's ability to remit payment at an accelerated rate and should not be included as a deduction in manufacturers' ASP calculation.

HDMA appreciates this opportunity to provide CMS with its comments regarding Part B drug payment policy. Please contact me or Elizabeth Gallenagh, Manager, Regulatory Affairs at 703-787-0000 ext. 234 should you have any questions or need additional information.

Sincerely,

A handwritten signature in black ink that reads "Scott Melville". The signature is written in a cursive style. To the right of the signature is a vertical red line.

Scott Melville
Sr. Vice President of Government Relations

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Please do NOT pass this policy whereby a physician can only refer "incident to" services to physical therapists. All qualified health care providers should be allowed to provide services to patients with a physicians prescription or under their supervision. It should be the patients right to have this available to them. Please do not limit their care to obtain optimum health.

Submitter : Mrs. LOIS CHAPPELL Date & Time: 09/24/2004 08:09:45

Organization : BOSOM FRIEND

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

I FEEL MASTECTOMY PRODUCTS SHOULD BE EXCLUDED FROM THE FACE TO FACE PRESCRIPTION REQUIREMENTS. THE EFFECTS OF A MASTECTOMY ARE PERMANENT. THE LADIES WHO ARE MEDICARE AGE DO NOT WANT RECONSTRUCTION. MEDICARE ALREADY HAS PARAMETERS IN PLACE FOR THESE ITEMS.THE FACE TO FACE PRESCRIPTION REQUIREMENT WOULD PLACE UNDUE HARDSHIPS ON THE MEMBER AND OFTEN FAMILY MEMBERS.PHYSICIANS AND SUPPLIERS AND MEDICARE AS WELL. THE FACE TO FACE PRESCRIPTION REQUIREMENT WILL REQUIRE THE INCONVIENCE OF A VISIT TO THE PHYSICIAN,THE PHYSICIAN'TIME FOR THE VISIT AND MEDICARE'S PAYMENT FOR THE VISIT. PLEASE LEAVE AS IS.THANK YOU.

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Please see attached file.

Heather Bristol, MS,ATC,CSCS
1921 Rock Street #6
Mountain View, CA 94043

September 23, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1429-P
P.O. Box 8012
Baltimore, MD 21244-8012

Re: Therapy – Incident To

Dear Sir/Madam:

I am writing alongside my colleagues, to request you consider all aspects of the recent proposal that would limit providers of “incident to” services in physician clinics. If adopted, this would eliminate the ability of qualified health care professionals to provide these important services. In turn, it would reduce the quality of health care for our Medicare patients and ultimately increase the costs associated with this service and place an undue burden on the health care system.

I am confident that you have seen the letters drafted by representatives of the National Athletic Trainers’ Association and would like to highlight a few points I feel are of vital importance to our profession as well as the decision-making process regarding this proposal.

- To allow only physical therapists and PT assistants, occupational therapists and OT assistants, and speech and language pathologists to provide “incident to” services would improperly provide those groups exclusive rights to Medicare reimbursement. To mandate that only those practitioners may provide “incident to” care in physicians’ offices would improperly remove the states’ right to license and regulate the allied health care professions deemed qualified, safe and appropriate to provide health care services. Please note, that the education level of physical and occupational therapy assistants is only an Associates degree. Certified athletic trainers ALL possess a minimum of a Bachelors degree and over half possess Masters degrees or higher. Physical therapists have only recently required Masters degrees to practice and many practicing physical therapists hold only Bachelors degrees. Additionally, the National Athletic Trainers’ Association requires continuing education to maintain certification. Physical therapists require no such continuing education. Even physicians are required to obtain continuing education and take regular exams to practice medicine.
- **For these professions to suggest that Certified Athletic Trainers are in the same category as “a high school student or another individual with no training in anatomy, physiology, neuromuscular reeducation or other techniques to furnish services in a physician’s office without the physician actually observing the provision of these services” is asinine and ignorant.**
- The United States Olympic Training Centers Sports Medicine facilities are staffed and directed by Certified Athletic Trainers and physicians. The most elite athletes in the world have entrusted their medical needs to Certified Athletic Trainers. To make a law that certain health professions are unable to treat a population based on the age of the population is absurd. A human body is a human body regardless of age and Certified Athletic Trainers ARE educated to understand the human body. For CMS to concur that Certified Athletic Trainers are capable to render care to professional, elite, collegiate and high school athletes, yet are unqualified to provide the same

- services to a Medicare beneficiary who becomes injured as a result of running in a local 5K race and goes to their local physician for treatment of that injury is outrageous and unjustified.
- Delays in medical care often result in increased cost to the patient and insurance companies, not even to mention the medical aspects of delayed treatment. If physicians are no longer allowed to utilize a variety of qualified health care professionals working “incident to” the physician, it is likely the patient will suffer delays in health care, greater cost and a lack of local and immediate treatment.
 - Independent research has demonstrated that the quality of services provided by certified athletic trainers is equal to the quality of services provided by physical therapists.
 - These issues may lead to more physician practices eliminating or severely limiting the number of Medicare patients they accept.
 - In summary, it is not necessary or advantageous for CMS to institute the changes proposed. This CMS recommendation is a health care access deterrent.

If you have read this far, I would like to give you some insight into my personal education and experience, which is not atypical for a Certified Athletic Trainer. I have a Bachelor of Science degree in Exercise Physiology with a German minor from the University of California at Davis, a Master of Science degree in Sports Health Care from A.T. Still University’s Arizona School of Health Sciences and am currently a Physician Assistant student at the latter school. As a Certified Athletic Trainer, I have worked with Stanford University, Santa Clara University, the NFL-Europe league, Phoenix College and at a physical therapy clinic. I am confident that I provide elite medical services within my scope of practice and value the contributions of other medical professionals. Sadly, the American Physical Therapy Association does not reciprocate respect and professionalism towards Certified Athletic Trainers, and instead, tries only to define their profession based on the exclusion and insult of other professions.

Sincerely,

Heather Bristol, MS, ATC, CSCS
1921 Rock Street #6
Mountain View, CA 94043

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 10-19

SECTION 302

National Association for Home Care and Hospice
228 7th Street, SE
Washington, DC 20003

September 24, 2004

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8012
Baltimore, MD 21244-8012

Attn: CMS-1429-P Medicare Program: Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005 (69 Federal Register 47488 (August 5, 2004)

Ref: Section 302

Dear Dr. McClellan:

The National Association for Home Care and Hospice (NAHC) appreciates the opportunity to comment on the 2005 Physician Fee Schedule proposed rule. NAHC represents home health, hospice, and durable medical equipment providers (DME) and their patients and is interested in federal policy that impacts all of these parties. Of particular interest are the provisions of the Physician Fee Schedule that implements Section 302(2)(a) of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003. NAHC is especially concerned that the Centers for Medicare and Medicaid Services (CMS) has exceeded its authority in development of the durable medical equipment regulation for implementation of MMA 302(2)(a) in some areas and failed to provide clarity in others.

1. ISSUE: Section 410.38 (g)(2) requires a physical examination at the time of initial order and renewal of continued need items. The regulation reads: "conduct a face-to-face examination to determine the medical necessity of each item of durable medical equipment." Neither the regulation nor the preamble defines "face-to-face examination." Examination could range from a cursory review of a patient's status during a routine visit to a complete physical examination.

a. RECOMMENDATION: Define "face-to-face examination" as an evaluation sufficient to determine beneficiaries' equipment needs.

RATIONALE: The term "examination" has different connotations ranging from complete physical to a cursory evaluation during a routine office visit. An examination justifying a cane or walker would differ significantly from an examination to justify intravenous therapy. Although a definition is needed to provide guidance for physicians and other practitioners it should be non-prescriptive in light of the variety of durable medical equipment items and individual beneficiary characteristics.

b. RECOMMENDATION: Amend the regulatory language for face-to-face examination to: "The physician or prescribing practitioner must determine the medical necessity of durable medical equipment during a face-to-face examination."

RATIONALE: The proposed regulation contradicts the language in the preamble which discourages examinations for the sole purpose of determining the necessity of durable medical equipment. Furthermore, the determination of equipment need can be done during the course of examination for other reasons.

c. RECOMMENDATION: Limit physical examination requirements to initial orders.

RATIONALE: MMA does not include face-to-face examinations for equipment renewal. To require repeated exams that are timed to coincide with equipment renewals would be burdensome to Medicare beneficiaries. Office visits solely for equipment need determination could be costly if equipment renewals do not coincide with physician visits for other medically necessary services. In addition, beneficiaries who are homebound could be put in jeopardy of losing on-going coverage of their equipment if they are unable to get to their physicians' offices for these exams. Finally, the cost of medical transportation will be an added burden for bed-bound beneficiaries in need of renewals of hospital beds.

ISSUE: Section 410.38(g)(4) requires a signed and dated order within 30 days of after the face-to-face examination. A 30-day time limit assumes that the ordering physician makes all equipment need determinations immediately and independently.

RECOMMENDATION: Extend the time limit for physician's

CMS-1429-P-4051-Attach-1.doc

CMS-1429-P-4051-Attach-2.doc



Ruth L. Constant, EdD
Chairman of the Board

NATIONAL ASSOCIATION FOR HOME CARE & HOSPICE
228 Seventh Street, SE, Washington, DC 20003 • 202/547-7424 • 202/547-3540 fax

Val J. Halamandaris, JD
President

National Association for Home Care and Hospice
228 7th Street, SE
Washington, DC 20003

September 24, 2004

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8012
Baltimore, MD 21244-8012

Attn: CMS-1429-P Medicare Program: Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005 (69 Federal Register 47488 (August 5, 2004))

Ref: Section 302

Dear Dr. McClellan:

The National Association for Home Care and Hospice (NAHC) appreciates the opportunity to comment on the 2005 Physician Fee Schedule proposed rule. NAHC represents home health, hospice, and durable medical equipment providers (DME) and their patients and is interested in federal policy that impacts all of these parties. Of particular interest are the provisions of the Physician Fee Schedule that implements Section 302(2)(a) of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003. NAHC is especially concerned that the Centers for Medicare and Medicaid Services (CMS) has exceeded its authority in development of the durable

medical equipment regulation for implementation of MMA 302(2)(a) in some areas and failed to provide clarity in others.

1. **ISSUE:** Section 410.38 (g)(2) requires a physical examination at the time of initial order and renewal of continued need items. The regulation reads: “conduct a face-to-face examination to determine the medical necessity of each item of durable medical equipment.” Neither the regulation nor the preamble defines “face-to-face examination.” Examination could range from a cursory review of a patient’s status during a routine visit to a complete physical examination.

a. **RECOMMENDATION:** Define “face-to-face examination” as an evaluation sufficient to determine beneficiaries’ equipment needs.

RATIONALE: The term “examination” has different connotations ranging from complete physical to a cursory evaluation during a routine office visit. An examination justifying a cane or walker would differ significantly from an examination to justify intravenous therapy. Although a definition is needed to provide guidance for physicians and other practitioners it should be non-prescriptive in light of the variety of durable medical equipment items and individual beneficiary characteristics.

b. **RECOMMENDATION:** Amend the regulatory language for face-to-face examination to: “The physician or prescribing practitioner must... determine the medical necessity of durable medical equipment during a face-to-face examination.”

RATIONALE: The proposed regulation contradicts the language in the preamble which discourages examinations for the sole purpose of determining the necessity of durable medical equipment. Furthermore, the determination of equipment need can be done during the course of examination for other reasons.

c. **RECOMMENDATION:** Limit physical examination requirements to initial orders.

RATIONALE: MMA does not include face-to-face examinations for equipment renewal. To require repeated exams that are timed to coincide with equipment renewals would be burdensome to Medicare beneficiaries. Office visits solely for equipment need determination could be costly if equipment renewals do not coincide with physician visits for other medically necessary services. In addition, beneficiaries who are homebound could be put in jeopardy of losing on-going coverage of their equipment if they are unable to get to their physicians’ offices for these exams. Finally, the cost of medical transportation will be an added burden for bed-bound beneficiaries in need of renewals of hospital beds.

ISSUE: Section 410.38(g)(4) requires a signed and dated order within 30 days of after the face-to-face examination. A 30-day time limit assumes that the ordering physician makes all equipment need determinations immediately and independently.

RECOMMENDATION: Extend the time limit for physician's signed and dated orders to "within 90 days after the face-to-face examination."

RATIONALE: Equipment specifications are more often determined by practitioners other than the ordering physicians. For example, physicians refer patients to physical and occupational therapists to determine whether beneficiaries need canes versus walkers, as well as the most appropriate types of walkers or canes. In addition, ordering of equipment is often delayed until a course of therapy has progressed to the point where the most appropriate equipment for long term use is identified, thus avoiding unnecessary expenditures. In many cases, the determination of the right piece of equipment might not be made for one to two months after the examination.

Another example where outside information is needed before equipment needs can be determined is intravenous therapy (IV). IV drug therapy is the last recourse in treatment of infections. Decisions to initiate intravenous drug therapy are based upon laboratory test results, including blood tests and cultures. IV drug therapy is not started until and unless oral antibiotic regimens, some lasting several weeks, have proven to be unsuccessful. Such decisions may not require an additional face-to-face examination.

Finally, other factors can impact beneficiaries' equipment needs besides their physical conditions. Changes in home environment and/or caregiver access can have a profound impact on equipment needs. However, a physical examination would not be appropriate to verify these changes.

ISSUE: Section 410.38(g)(4) states that the beneficiary's medical record must include verification of the face-to-face examination, while 410.38(g)(5) imposes a requirement for the physician or prescribing practitioner to document, in the beneficiary's medical record, the need for the durable medical equipment being ordered. Specific content of documentation of face-to-face examination is not defined and could be interpreted differently by contractors.

RECOMMENDATION: Eliminate documentation requirements that are duplicative.

RATIONALE: Any documentation of physician encounters with patients presumes "face-to-face examinations". Therefore, to require a specific notation that a face-to-face examination took place would be duplicative. Furthermore, documentation in a beneficiary's medical record of the need for medical equipment is duplicative of the information found in Certificates of Medical Necessity, creating an unnecessary regulatory burden. Finally, to hinge Medicare payment on even more documentation by a party who is not paid for these services could create a barrier to beneficiary access to services. Since there are no financial consequences for physicians who fail to provide documentation verifying examinations there is no incentive for them to do so. Thus, the end result will be denial of equipment needed by Medicare beneficiaries, rather than better documentation

ISSUE: Section 41038(h) Prohibition of payment for face-to-face examinations for the sole purpose of the beneficiary's obtaining the physician's or prescribing practitioner's order for durable medical equipment creates a new cost-sharing responsibility for beneficiaries by requiring them to incur an expense in order to access their durable medical equipment benefit.

RECOMMENDATION: Pay for face-to-face examinations for the sole purpose of determining the need for durable medical equipment if medically necessary services are not indicated at the time and failure to provide examinations could result in delay in the provision of needed durable medical equipment.

RATIONALE: Refusal of Medicare payment for physician examinations solely for the purpose of meeting durable medical equipment requirements will result in a new cost-sharing responsibility and patient liability. Creation of this new cost-sharing responsibility is not authorized by MMA. Therefore, there is no legislative authorization for CMS to exclude payment to physicians for these services.

Thank you again for the opportunity to comment on this proposed regulation.

Sincerely,
Mary St.Pierre

Mary St.Pierre
Vice President for Regulatory Affairs



Ruth L. Constant, EdD
Chairman of the Board

NATIONAL ASSOCIATION FOR HOME CARE & HOSPICE
228 Seventh Street, SE, Washington, DC 20003 • 202/547-7424 • 202/547-3540 fax

Val J. Halamandaris, JD
President

National Association for Home Care and Hospice
228 7th Street, SE
Washington, DC 20003

September 24, 2004

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8012
Baltimore, MD 21244-8012

Attn: CMS-1429-P Medicare Program: Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005 (69 Federal Register 47488 (August 5, 2004))

Ref: Section 302

Dear Dr. McClellan:

The National Association for Home Care and Hospice (NAHC) appreciates the opportunity to comment on the 2005 Physician Fee Schedule proposed rule. NAHC represents home health, hospice, and durable medical equipment providers (DME) and their patients and is interested in federal policy that impacts all of these parties. Of particular interest are the provisions of the Physician Fee Schedule that implements Section 302(2)(a) of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003. NAHC is especially concerned that the Centers for Medicare and Medicaid Services (CMS) has exceeded its authority in development of the durable

medical equipment regulation for implementation of MMA 302(2)(a) in some areas and failed to provide clarity in others.

1. **ISSUE:** Section 410.38 (g)(2) requires a physical examination at the time of initial order and renewal of continued need items. The regulation reads: “conduct a face-to-face examination to determine the medical necessity of each item of durable medical equipment.” Neither the regulation nor the preamble defines “face-to-face examination.” Examination could range from a cursory review of a patient’s status during a routine visit to a complete physical examination.

a. **RECOMMENDATION:** Define “face-to-face examination” as an evaluation sufficient to determine beneficiaries’ equipment needs.

RATIONALE: The term “examination” has different connotations ranging from complete physical to a cursory evaluation during a routine office visit. An examination justifying a cane or walker would differ significantly from an examination to justify intravenous therapy. Although a definition is needed to provide guidance for physicians and other practitioners it should be non-prescriptive in light of the variety of durable medical equipment items and individual beneficiary characteristics.

b. **RECOMMENDATION:** Amend the regulatory language for face-to-face examination to: “The physician or prescribing practitioner must... determine the medical necessity of durable medical equipment during a face-to-face examination.”

RATIONALE: The proposed regulation contradicts the language in the preamble which discourages examinations for the sole purpose of determining the necessity of durable medical equipment. Furthermore, the determination of equipment need can be done during the course of examination for other reasons.

c. **RECOMMENDATION:** Limit physical examination requirements to initial orders.

RATIONALE: MMA does not include face-to-face examinations for equipment renewal. To require repeated exams that are timed to coincide with equipment renewals would be burdensome to Medicare beneficiaries. Office visits solely for equipment need determination could be costly if equipment renewals do not coincide with physician visits for other medically necessary services. In addition, beneficiaries who are homebound could be put in jeopardy of losing on-going coverage of their equipment if they are unable to get to their physicians’ offices for these exams. Finally, the cost of medical transportation will be an added burden for bed-bound beneficiaries in need of renewals of hospital beds.

ISSUE: Section 410.38(g)(4) requires a signed and dated order within 30 days of after the face-to-face examination. A 30-day time limit assumes that the ordering physician makes all equipment need determinations immediately and independently.

RECOMMENDATION: Extend the time limit for physician's signed and dated orders to "within 90 days after the face-to-face examination."

RATIONALE: Equipment specifications are more often determined by practitioners other than the ordering physicians. For example, physicians refer patients to physical and occupational therapists to determine whether beneficiaries need canes versus walkers, as well as the most appropriate types of walkers or canes. In addition, ordering of equipment is often delayed until a course of therapy has progressed to the point where the most appropriate equipment for long term use is identified, thus avoiding unnecessary expenditures. In many cases, the determination of the right piece of equipment might not be made for one to two months after the examination.

Another example where outside information is needed before equipment needs can be determined is intravenous therapy (IV). IV drug therapy is the last recourse in treatment of infections. Decisions to initiate intravenous drug therapy are based upon laboratory test results, including blood tests and cultures. IV drug therapy is not started until and unless oral antibiotic regimens, some lasting several weeks, have proven to be unsuccessful. Such decisions may not require an additional face-to-face examination.

Finally, other factors can impact beneficiaries' equipment needs besides their physical conditions. Changes in home environment and/or caregiver access can have a profound impact on equipment needs. However, a physical examination would not be appropriate to verify these changes.

ISSUE: Section 410.38(g)(4) states that the beneficiary's medical record must include verification of the face-to-face examination, while 410.38(g)(5) imposes a requirement for the physician or prescribing practitioner to document, in the beneficiary's medical record, the need for the durable medical equipment being ordered. Specific content of documentation of face-to-face examination is not defined and could be interpreted differently by contractors.

RECOMMENDATION: Eliminate documentation requirements that are duplicative.

RATIONALE: Any documentation of physician encounters with patients presumes "face-to-face examinations". Therefore, to require a specific notation that a face-to-face examination took place would be duplicative. Furthermore, documentation in a beneficiary's medical record of the need for medical equipment is duplicative of the information found in Certificates of Medical Necessity, creating an unnecessary regulatory burden. Finally, to hinge Medicare payment on even more documentation by a party who is not paid for these services could create a barrier to beneficiary access to services. Since there are no financial consequences for physicians who fail to provide documentation verifying examinations there is no incentive for them to do so. Thus, the end result will be denial of equipment needed by Medicare beneficiaries, rather than better documentation

ISSUE: Section 41038(h) Prohibition of payment for face-to-face examinations for the sole purpose of the beneficiary's obtaining the physician's or prescribing practitioner's order for durable medical equipment creates a new cost-sharing responsibility for beneficiaries by requiring them to incur an expense in order to access their durable medical equipment benefit.

RECOMMENDATION: Pay for face-to-face examinations for the sole purpose of determining the need for durable medical equipment if medically necessary services are not indicated at the time and failure to provide examinations could result in delay in the provision of needed durable medical equipment.

RATIONALE: Refusal of Medicare payment for physician examinations solely for the purpose of meeting durable medical equipment requirements will result in a new cost-sharing responsibility and patient liability. Creation of this new cost-sharing responsibility is not authorized by MMA. Therefore, there is no legislative authorization for CMS to exclude payment to physicians for these services.

Thank you again for the opportunity to comment on this proposed regulation.

Sincerely,
Mary St.Pierre

Mary St.Pierre
Vice President for Regulatory Affairs

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

GENERAL

GENERAL

Please see attached comments



A Coalition of 14 Medical Societies Representing more than 200,000 Specialty Physicians in the United States

John D. Barnes, Chair
jbarnes@aad.org
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(202) 728-0610

September 24, 2004

Mark B. McClellan, MD, Ph.D. Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201
Attention: CMS-1429-P

RE: CMS-1429-P: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005

Dear Dr. McClellan:

On behalf of the undersigned members of the Alliance of Specialty Medicine, a coalition of 14 medical societies representing more than 200,000 specialty physician in the United States, we would like to comment on the Centers for Medicare and Medicaid Services' (CMS) *Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005 Proposed Rule*, published August 6, 2004 in the *Federal Register*.

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

The Alliance appreciates CMS' implementation of the 1.5 percent update to the physician fee schedule as mandated by Congress in the Medicare Modernization Act of 2003 (MMA). Without the positive update, physicians would have received an estimated 3.7 percent reduction for 2005. However, the Alliance continues to believe that significant problems exist with the current methodology used for reimbursing physicians, and urges CMS to address the problems within its statutory authority in the upcoming final rule. We outline these problems below.

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Sustainable Growth Rate Formula

The Alliance of Specialty Medicine would like to address concerns related to the Sustainable Growth Rate (SGR) Formula. The SGR is used by the agency to calculate physician payment, however, this formula has several flaws. We are aware that Congress, not CMS, created the flawed formula, however, we continue to believe that CMS has the statutory authority to make some key administrative changes, which would alleviate several problems associated with the SGR.

We describe below some problematic areas of the SGR formula, which must be changed and are within the purview of the agency.

Removal of Physician-Administered Medicare-Covered Drugs

The Alliance of Specialty Medicine is, once again, disappointed that Medicare-covered outpatient drugs continue to be included in the expenditure target. The cost of these drugs are not controlled by physicians, and yet each year they account for a greater portion of the actual costs incurred by the Medicare program. In fact, the Congressional Budget Office (CBO) has predicted that spending for Medicare-covered outpatient drugs will continue to grow at a rate more rapidly than allowed by the expenditure target.

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In addition, we believe that Medicare-covered outpatient drugs must be removed from the expenditure target in order to more accurately reflect “true” physician payments for “true” physician services. CMS has noted previously that Medicare-covered drugs are not a physician service, and that the agency has the authority to remove these drugs from the SGR. We, therefore, believe that CMS must assure the physician community and Congress that it is committed to fixing the problems with the SGR by removing Medicare-covered outpatient drugs from the physician payment pool.

Changes in Medicare Spending Due to Law and Regulation

The Alliance continues to be concerned with CMS’ continued refusal to assess the cost effects of the addition of Medicare benefits that are attributable to national coverage decisions made by the Agency. The SGR includes a component to reflect changes in law and regulation, however, CMS only includes program benefits attributable to legislation in this component. As a result, CMS neglects to include costly Medicare spending increases that result from regulatory changes. Coverage decisions, including the services they may require and generate, which have been added to the Medicare program, must be included in the expenditure target. Calculating the SGR without including the impact of coverage decisions is unfair, as coverage decisions have an impact on utilization by increasing the volume of physician services and, therefore, increasing the probability that cost of physician services will exceed the expenditure target.

Furthermore, any change in Medicare coverage adopted by CMS pursuant to formal or informal rulemaking constitutes a regulatory change as contemplated by the SGR. Accordingly, as CMS calculates the 2005 SGR, the Alliance urges CMS to ensure that the estimates used take into account both legislative and regulatory effects.

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Medicare Modernization Act of 2003 – Sections 611, 612, and 613

The Alliance supports the creation of a "Welcome to Medicare" physical for new beneficiaries. In addition, we support the creation of screening benefits, such as the Diabetes Screening Test and the Cardiovascular Screening Blood Test. These benefits, which were included in the Medicare Modernization Act of 2003, will provide Medicare beneficiaries with additional opportunities to receive high quality healthcare. However, we urge CMS to provide more information on the assumptions used to forecast costs estimated at \$65 million in 2005 alone. We are concerned that these costs may be underestimated and will have a significant impact on the annual physician fee schedule update calculations. The proposed rule states that payment for these physicals will be made to physicians and other practitioners who provide these examinations, including any medically necessary follow-up tests,

counseling, or treatment that may be required as a result of the coverage of the screening examination. In the proposed rule, CMS estimates that this new benefit will cost \$65 million next year. This new benefit will create many more referrals to specialists and, again, we are concerned that CMS did not take this into account when estimating the fiscal impact of this new benefit.

Payment Reform for Covered Outpatient Drugs and Biologicals – Section 303

The Alliance is concerned about the lack of information in the proposed rule on Medicare drug payments that are scheduled to go into effect in 2005. The proposed rule does not provide a complete list of estimated 2005 drug payments, therefore, providing no opportunity to comment formally on many of the drugs. CMS has been continually urged to provide information for 2005 drug payments as soon as possible so that physicians can decide on the best course of action for their patients and their practices.

We are aware that first-quarter drug payments for 2005 will be based on 2004 third-quarter ASP data provided by drug manufacturers. In addition, we understand that third-quarter data is not due to the agency until October 30, 2004. Once the data has been reviewed by CMS and made publicly available, there will be little time before the new drug prices are scheduled for implementation. The Alliance is concerned that medical societies will not have adequate time to review and comment on the new drug payment amounts prior to the publication of the final rule. We urge CMS to seriously consider whether the payment system based on ASP will truly be ready for implementation on January 1, 2005 and to delay implementing the new payment system if necessary to avoid patient access problems and confusion. At the very least, CMS should phase in the more dramatic cuts by establishing a floor over the next few years. Most major changes to the Medicare fee schedule have been phased in to mitigate impacts on physicians, 95 percent of which are small business owners according to CMS.

We would also urge the agency to consider publishing the final rule as “interim final with comment” to allow medical societies, especially those who are heavily impacted by this change, time to review and comment on the new drug payment amounts before they are implemented January 1, 2005. Furthermore, we would encourage the agency to consider any comments submitted on the updated drug prices as quickly as possible.

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Professional Liability RVU Revisions

The Alliance is disappointed by the counter intuitive results of the CMS proposed methodology for “revising” the professional liability RVUs, with some of the specialties most in crisis receiving decreases in payment to account for PLI costs. CMS is required by law to consult with organizations representing physicians in the creation of fee schedule values. CMS accomplishes this for physician work and practice expense by participating with the AMA Relative Value Update Committee (RUC). However, CMS has not given the medical community the same opportunity for input for the professional liability component. Although this component is much smaller than work or practice expense, it is vitally important, especially to the high-risk specialties that have been disproportionately affected.

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In order to have a sense of understanding of how CMS derived the PLI values, one must read the report of the company contracted to conduct the data analysis, Bearing Point. We contend that CMS should have provided more information in the NPRM from the contractor’s report in order to elucidate their conclusions and make clear the implications of proposed alternative methodologies. Without an opportunity for physician organizations to see the data used, it is difficult to be sure that major errors have not occurred.

We believe that CMS has not proposed an adequate methodology or rationale for meeting the requirements for the scheduled update of the PLI component of the Medicare Fee Schedule. The RBRVS system is based on resources and all physician specialties have had to devote more resources to professional liability insurance premiums in recent years. However, CMS has not given serious consideration to recommendations made by the medical community regarding this important issue. Our position is that any values issued in the final rule should be considered “interim” until physician organizations have adequate opportunity to review the data and have meaningful input.

Conclusion

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In conclusion, the Alliance of Specialty Medicine would ask that CMS make the following changes in the final rule:

- CMS is urged to use its statutory authority and remove Medicare-covered drugs from the physician payment pool.
- CMS is urged to ensure that it accurately accounts for changes in law and regulation when calculating the expenditure target. Specifically, changes due to coverage decisions, especially those that require certain diagnostic tests to be performed in conjunction with the procedure(s) or service(s) being addressed by the coverage decision, must be accurately accounted for in the SGR.
- CMS is urged to ensure that it not only accounts for the “Welcome to Medicare” physical and the newly added screening benefits in the SGR, but that it also accounts for the additional items, services, diagnostic tests, imaging services, procedures and office visits these new benefits will generate.
- CMS is urged to delay implementation of the new drug payment system to avoid patient access problems and confusion, and at the very least consider publishing the final rule as “interim final with comment” to allow medical societies impacted by the payment reform for covered outpatient drugs and biologicals, time to review and comment on the new drug payment amounts before they are implemented January 1, 2005. Furthermore, we would encourage the agency to consider any comments submitted on the updated drug prices as quickly as possible.
- CMS is urged to work more closely with the medical societies through the AMA Relative Value Update Committee (RUC) process on the professional liability component of the RBRVS system. In addition, CMS is urged to provide all available data, including contractor report findings, for review and analysis by medical societies in the future. Furthermore, CMS is urged to make any PLI values “interim with comment” in the upcoming final rule, and provide medical societies and the AMA RUC with adequate time to review the values and provide meaningful input.

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The Alliance of Specialty Medicine appreciates the opportunity to comment on these important issues impacting Medicare beneficiaries and the physician community. The undersigned organizations thank CMS for considering our views on these important matters. Please do not hesitate to contact Nancy McCann at nmcann@ascrs.org or 703-591-2220 or Ann LaBelle at alabelle@acep.org or 202-728-0610 if you have any questions regarding our comments and recommendations.

Sincerely,

American Academy of Dermatology Association
American Association of Neurological Surgeons/Congress of Neurological Surgeons
American Academy of Orthopaedic Surgeons
American College of Emergency Physicians
American College of Obstetricians and Gynecologists
American Urological Association
American Society of Cataract and Refractive Surgery
Society of Thoracic Surgeons

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American College of Emergency Physicians¶
American Society of Cataract and Refractive Surgery¶

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 1-9

SECTION 611

See attachment

SECTION 612

See Attachment

Issues 10-19

SECTION 302

See Attachment

SECTION 512

See Attachment

CMS-1429-P-4053-Attach-1.pdf

CMS-1429-P-4053-Attach-1.pdf

CMS-1429-P-4053-Attach-1.pdf

CMS-1429-P-4053-Attach-1.pdf

**Department of Health and Human Services
Centers for Medicare and Medicaid Services (CMS)
Offices of Strategic Operations and Regulatory Affairs**

The attachment to this document is not provided because:

1. The document was improperly formatted.
2. The submitter intended to attach more than one document, but not all attachments were received.
3. The document received was a protected file and can not be released to the public.
4. The document was not available electronically at this time. If you like to view any of the documents that are not posted, please contact CMS at 1-800-743-3951 to schedule an appointment.

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

GENERAL

GENERAL

Please do not pass this policy that requires that physicians only pass "incident to" therapy to physical therapists. ALL qualified health care providers should be allowed to perform this therapy. Many of us have had extensive training in areas that physical therapists have had less. This limits significantly the range of choices for medicare recipients. Thank you for your consideration.

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

GENERAL

GENERAL

Comments relating sections 413, 611, as well as other issue areas can be found in the PDF attachment.

Issues 1-9

PRACTICE EXPENSE

VIII. PRACTICE EXPENSE ISSUES

A. Equipment Items Needing Specialty Input

In Table 3, CMS requested specialty input for pricing of certain equipment. We agree with the pricing of items used in our practices. Additionally, there is no cost listed for a bronchogram tray. This procedure is seldom performed and, when performed, it is always in a facility. Therefore, there would be no physician practice expense.

B. Proposed Changes to Equipment Pricing

ACCP is in agreement with CMS? pricing data except for E55003, Pulse oximeter with printer. CMS prices it at \$1,207.18. We believe the price should be \$1,295.00. The item is sold by CritiCare.

C. Methacholine Used in CPT Code 95070

The RUC made changes to the direct practice expense inputs for 95070. One of these changes was to move the cost of the Methacholine administered from code 94070 to 95070. In the NPRM, however, we note that there is no change to the practice expense for 95070. ACCP believes that this omission should be corrected in the final rule.

SECTION 413

See attachment

SECTION 611

See attachment

Issues 10-19

SECTION 302

VII. SECTION 302 ? CLINICAL CONDITIONS OF COVERAGE FOR DURABLE MEDICAL EQUIPMENT (DME)

ACCP shares the CMS concern regarding the fraudulent provision of DME items and recognizes that the physician has a primary role in assuring DME is furnished based on the needs of the beneficiary. A blanket requirement, however, that all DME prescriptions and renewals require a face-to-face visit is excessive as it has the potential to diminish beneficiary access to medically necessary DME. ACCP recommends that CMS refrain

from implementing its proposal to require a face-to-face visit for all DME prescriptions and renewals.

The CMS proposal to implement this MMA provision by requiring that a physician furnish a face-to-face service with the patient in order to order an initial prescription and to renew a previous prescription order is unnecessary and impractical. The additional requirement that the face-to-face examination should be for the purpose of evaluating and treating the patient's medical condition and not for the sole purpose of obtaining the prescribing physician's or practitioner's order for the DMEPOS that the prescribing physician conduct a sufficient examination of the patient's medical condition to ascertain the appropriate overall treatment plan and to order the DMEPOS as only one aspect of that treatment plan makes it even more unworkable. In addition, ACCP recommends that CMS consider the following as a way to balance fraud concern against ensuring that beneficiaries have timely access to necessary DME:

? Consider developing additional clinical criteria for the DME items for which there is a demonstrated need, as demonstrated by a CMS, a Government Accountability Office (GAO) or the HHS OIG analysis.

? Determine whether the DMERC can access carrier claims processing system data to ascertain whether the prescribing physician has furnished a face-to-face visit to the beneficiary who is to receive the DME item within a reasonable period of time.

CMS stated that the prescribing physician be independent from the supplier and may not be a contractor or an employee of the supplier. ACCP is seeking clarification about the physician who has the supplier number and, therefore, cannot have an arms-length away relationship.

CMS-1429-P-4055-Attach-1.pdf

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CMS-1429-P-4055-Attach-1.pdf

CMS-1429-P-4055-Attach-1.pdf

CMS-1429-P-4055-Attach-1.pdf

AMERICAN COLLEGE OF CHEST PHYSICIANS

September 24, 2004

Mark B. McClellan, PhD, MD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert Humphrey Building
Room 443-G
200 Independence Avenue, SW
Washington, DC 20201

ATTENTION: CMS-1429-P

Dear Dr. McClellan:

I am writing on behalf of the American College of Chest Physicians (ACCP). The ACCP's membership is comprised of over 16,000 physicians and allied health professionals, whose everyday practice involves diseases of the chest in the specialties of pulmonology, cardiology, thoracic and cardiovascular surgery, critical care medicine, 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. We appreciate the opportunity to submit comments to be considered as CMS finalizes its rule regarding Medicare's Revisions to Payment Policies under the Physician Fee Schedule for CY2005 based upon proposals set forth in the Notice of Proposed Rulemaking (NPRM) published on August 5, 2004.

I. SUSTAINABLE GROWTH RATE FORMULA

The 2004 physician fee schedule conversion factor is \$37.3374. The 2004 CF represents a 1.5% increase from the 2003 CF. Congress, through the Medicare Modernization Act (MMA), mandated that CF increase a minimum of 1.5% in 2004 and 2005. The MMA averted the 4.5% CF cut that was scheduled to be implemented in 2004. CMS projects that the MMA mandated 1.5% minimum increase will be implemented January 1, 2005 because it is currently projecting a cut under the update formula.

The law requires CMS to set the physician fee schedule update under the sustainable growth rate (SGR) system. For 2004 and 2005, the MMA requires the update to be no less than 1.5 percent. The Medicare Trustees have projected that physicians will be facing a crisis of a 5 percent cut. If action is not taken to replace the SGR, the results of these cumulative cuts will be a reduction in physician payment rates by nearly a third. CMS is currently forecasting payment reductions under the SGR system for 2006 and later years. CMS will include a complete discussion of its methodology for calculating the SGR in the final rule. As discussed below, ACCP reiterates its previous comments that CMS should, at a minimum, remove the cost of physician-administered drugs from the SGR and recognize the true cost of new Medicare benefits resulting from changes to the law, regulations or CMS policies.

A. Appropriate Accounting for Changes in Law and Regulation

The statute also does require that CMS make adjustments to the SGR to reflect increases or decreases in the cost of physician services that are expected to result from changes in law(s) and regulation(s). ACCP believes it is imperative that CMS account for the full impact of changes in law(s) and regulation(s) in the SGR formula. The following discussion in numbers 1. and 2. are examples of increased costs that adversely impact the SGR. ACCP believe that these changes must be recognized; failure to do so inappropriately penalizes physicians for appropriate, expected increases in utilization.

1. *New, Preventive Medicare Benefits*

Congress encourages increased utilization through establishment of new, preventive Medicare benefits. It is imperative that CMS appropriately account for the increased direct spending associated with new benefits in the SGR formula. Further, new, preventive benefits have ancillary costs in addition to direct expenditure for the newly covered service(s). Newly covered preventive services will trigger additional medically necessary services, in the form of increased visits, increased laboratory and other tests, and/or procedures. While Congress' adding such preventive services to the Medicare benefit structure is laudable, CMS's subsequent omitting or understating the cost of the medically necessary physician services will penalize physicians and patients for the resulting increase in volume through reductions to the annual Medicare fee schedule update. CMS must fully account for the direct and ancillary costs associated with new benefits in the SGR formula.

2. *Medicare National Coverage Decisions*

CMS encourages increased utilization through National Coverage Decisions (NCDs) that establish Medicare coverage for a new service or expand the conditions for which Medicare covers a service. It is imperative that CMS appropriately account for the increased spending associated with NCDs in the SGR formula. ACCP is concerned that CMS has omitted or underestimated costs associated with NCDs. CMS must fully account for the costs associated with NCDs in the SGR formula.

An example of these types of costs would be those associated with CMS' decision to cover lung volume reduction services (LVRS). There will be expenses related to the hospitalization for the surgery, the surgeon's fee, and mandatory pre- and post-operative monitoring of these ill patients.

B. Removing Drugs from the SGR Formula

ACCP recommends that CMS exercise its discretionary authority and reverse its policy of including the costs of Medicare-covered physician-administered drugs in determining whether Medicare spending has exceeded the SGR target. Reconsideration of the CMS policy is especially warranted in light of changes made by MMA. CMS officials have argued that including the cost of the drugs and biological products is necessary to counter-balance for over-utilization in the drug reimbursement system. CCP rejects this premise as MMA reform of the drug and biological payment methodology diminishes such an incentive even if it had existed.

CMS action to remove drug and biological costs is imperative as they have risen rapidly and are expected to continue to increase. In its proposed rule on payment reform of Medicare covered drugs, CMS estimated the 2002 allowed charges for the approximately 450 Medicare-covered drugs to be \$8.4 billion, compared to \$3.3 billion in allowed charges in 1998. A study for the Medicare Payment Advisory Commission (MedPAC) that determined there are over 650 drugs in development is an indication that drug costs will continue to escalate.

Inclusion of the cost of drugs and biologicals in the expenditure target provides further example of how the SGR formula is not in concert with our public policy decisions aimed at improving health. The federal government has supported the development of life-saving and quality-of-life-enhancing physician administered drugs through actions such as increased funding for the National Institutes of Health (NIH) and streamlining the Food and Drug Administration (FDA) drug approval process. Further, the Department of Health and Human Services (HHS) 2003 action plan and a May 2003 Interagency Agreement between the National Cancer Institute (NCI) and the FDA indicate that the administration strives to accelerate drug development. In its statement announcing the May 2003 agreement, NCI and FDA officials described it as "an important step toward NCI's goal to eliminate suffering and death due to cancer by 2015" and stated the collaboration "holds great promise for getting better cancer drugs to patients sooner." ACCP believes that the CMS policy to include the cost of drugs and biologicals in the SGR formula threatens to undermine these laudable goals. Continued CMS inclusion of drug costs in the SGR is likely to penalize physicians for administering drugs beneficial to beneficiaries by resulting/contributing to payment reductions—reductions that jeopardize the financial viability of treating Medicare patients.

Furthermore, physician-administered drugs are clearly not "physician services" as the term is defined in the Medicare statute.

II. SECTION 305 – PAYMENT FOR INHALATION DRUGS

In this NPRM, CMS states that for the first quarter of 2005, the Medicare payment for albuterol sulfate and ipratropium will be the Average Sales Price (ASP) plus 6 percent which is estimated to be \$0.04 per milligram for albuterol sulfate and \$0.30 per milligram for ipratropium bromide. While these figures represent estimated reductions from 2004 payment levels of about 90 percent, they are not necessarily the actual payment amounts for the first quarter of 2005. The actual payment amounts will be based on ASPs calculated from the manufacturer to be submitted for the third quarter of 2004.

Further, CMS has signaled its desire to pay for less nebulizers citing the fact that it believes that MDIs are just as effective at delivering medications as nebulizers. While the efficacy of the delivery method may be almost equal on a short-term basis based on a “snapshot,” clinicians have found that, over longer periods of time, this is not true as patients become non-compliant with the use of MDIs. This is because many of these patients lack manual dexterity and the ability to comprehend/retain/apply instructions without constant reinforcement.

The disadvantages of MDIs are that:

- Coordination of breathing and actuation is needed.
- Device actuation is required.
- High pharyngeal deposition occurs.
- Upper limit to unit dose content is realized.
- Remaining doses in canister difficult to determine.

The disadvantages of holding chambers or spacers are:

- Inhalation can be more complex for some patients.
- If not used properly, drug dosage may be reduced.
- More expensive than MDI alone.
- Less portable than MDI alone

The delivery method should be a matter of physician judgment after assessing several factors such as:

- Patient’s ability to use the device correctly;
- Preferences of patient for the device;
- Lack of time or skills to instruct properly the patient in the use of the device or monitor its appropriate use;
- Unavailability of an appropriate drug/device combination; and
- Compatibility between the drug and delivery device.

ACCP is concerned that during CY 2005 there may be significant disruptions to access for beneficiaries who require albuterol sulfate and ipratroium bromide to manage their respiratory disease. We fear that the severity of the cuts will result in significant changes in both how the DME companies supply inhalation drugs and their willingness to supply the drugs and related

services. Additionally, CMS proposes changes to the dispensing fee. The changes listed in the NPRM appear to move DME suppliers to a model of service that is primarily based on mail order delivery of drugs and, therefore, does not include the availability and use of technically trained staff, calling into question the quality of services offered to Medicare beneficiaries. Therefore, ACCP strongly urges CMS to delay the implementation of these severe cuts until CY 2006 when the Medicare prescription drug benefit is implemented and leave the delivery method of choice, just as with the correct medication(s) to prescribe, to the physician's assessment,

III. CODING – RESPIRATORY THERAPY

In the 2001 final rule, CMS created three HCPCS “G” codes for respiratory therapy services. CMS assigned total RVUs of 0.49 to one of the codes (G0237 – *Therapeutic procedures to increase strength or endurance of respiratory muscles, one-on-one*), and indicated that the other two codes (G0238 – *Therapeutic procedures to improve respiratory function other than the ones described in G0237, one-on-one* and G0239 – *therapeutic procedures to improve respiratory function or increase strength, two of more patients*) would be carrier priced.

Because the services represented by these codes are frequently being performed in outpatient departments of hospitals or comprehensive outpatient rehabilitation facilities paid by fiscal intermediaries, there has been some uncertainty surrounding the payment for the carrier priced services. CMS believes assigning RVUs to G0238 and G0239 would alleviate some of this uncertainty. Therefore, they are proposing to value these services using the nonphysician work pool and assigning total RVUs of 0.49 to G0238 due to its similarity to G0237 and total RVUs of 0.34 to G0239, roughly a third less because of the group session.

ACCP continues to believe that the RVUs assigned are too low. We question where CMS obtained the data about the expensive equipment investments (e.g., various exercise equipment, EKG monitoring devices, etc.).

IV. AVERAGE SALE PRICE

Effective January 1, 2005, payment for many covered prescription drugs will be based on the manufacturer's average sales price (ASP). On July 27, 2004, CMS released proposed ASP reimbursement rates for certain physician-administered drugs. While ACCP appreciates this preliminary data, the proposal fails to provide physicians with clear and reliable information upon which to make decisions about their practices for 2005 and beyond. Moreover, the proposal did contain a list of only 31 affected drugs. For example, none of the drugs used to treat infectious diseases were included.

We urge CMS to ensure that the physician community be notified early of the ASP for all impacted drugs as well as be given the opportunity to comment of the appropriateness of the ASPs. This information is vital for physicians for planning purposes so that physicians will be able to maintain inventory, and patients will not suffer serious access problems.

ACCP urges CMS to establish a system for monitoring access to drugs affected by this new ASP methodology. CMS should continually evaluate whether:

- physicians are able to afford the purchase and administration of drugs that are needed for appropriate treatment of their patients;
- physicians have to lay off medical and/or administrative staff in response to lower drug and administration payments;
- physicians have to close satellite offices or discontinue or limit the types of treatment they are able to offer;
- patients have to travel further to get medical treatment if their physicians' office can no longer afford to provide it;
- patients have higher out-of-pocket costs at hospital-based facilities;
- alternative medical facilities, such as a hospital outpatient department, have the proper medical infrastructure in place — including drug inventory, adequate medical staff, and medical equipment and facilities — to provide quality medical treatment, especially in rural areas; and
- these alternative medical facilities are able to absorb additional patients

V. SECTION 611 – INITIAL PREVENTIVE PHYSICAL EXAMINATION

A. Initial Preventive Physical Exam Definition and Billing Code

CMS proposes the establishment of a new HCPCS code, G0XX2 with a total physician work value of 1.51. This value is based upon the determination that the new service has equivalent resources and work intensity to the ones found in CPT's E/M code 99203, a mid-level new patient, office or other outpatient visit plus CPT code 93000, complete electrocardiogram. The total RVUs for the new code would be 2.58 after factoring in practice expense and malpractice costs. ACCP strongly opposes the mandatory assignment of a Level 3 E/M code. Many of these patients would require a Level 4 or 5 E/M visit. We do not believe that an averaging concept should be used as a rationale; i.e., some visits involve more and some less work, thus averaging to a Level 3 visit.

ACCP recommends that CMS revise its proposal to specify that physicians report the covered initial preventive physical examination using the appropriate CPT Preventive Medicine Service new or established patient code, CPT 99381-99397, and an EKG code, such as CPT 93000, with physicians indicating that it is the covered initial preventive physical examination by using the appropriate "V" diagnosis code, e.g., V70.0. To avoid paying for an initial new patient preventive medicine service to a beneficiary more than six months after the beneficiary enrolled in Medicare Part B, carriers could program their claims processing system to only pay for CPT 99387, 99397, or other new patient preventive medicine service codes within six months of the beneficiary's Part B enrollment date.

The CPT new patient preventive medicine service code descriptors are purposely vague to allow the physician to tailor the service to the patient's needs, as determined by gender and age. The introductory text to the CPT preventive medicine service codes states that extent of the focus of

the services depends largely on the patient's age and that the comprehensive nature of the service codes reflects an age and gender appropriate physical exam.

Physicians generally follow the United States Preventive Services Task Force (USPSTF) age-specific recommended interventions when furnishing a preventive medicine service. While the USPSTF recommended interventions are generally consistent with the CMS proposed definition of an initial preventive physical examination, the CMS proposal is too proscriptive and the establishment of a HCPCS G code, G0XX2, only complicates the coding system.

Further, instructing physicians to use the appropriate CPT new patient preventive medicine service code supported by a diagnosis code to indicate screening would be consistent with the agency's proposed implementation of the new benefits for cardiovascular screening blood tests and diabetes screening tests, which instructs physicians to bill the new benefits using a CPT code supported by an ICD-9 code that indicates screening.

1. *Inclusion of EKG in Definition of Initial Preventive Physical Examination.*

It is not clear what happens to the EKG component if the physician cannot do one in his or her office. In that case, is the physician prohibited from providing the initial preventive physical examination? CMS needs to address this point in the final rule.

2. *Inclusion of Counseling Services in Definition*

CMS states that "counseling" is one of the bundled services included in the definition of an initial preventive physical examination. ACCP is opposed to use of the term "counseling" in the definition. Counseling entails varying amounts of time depending upon the type of counseling, ability of the patient to comprehend, etc. For example, we applaud CMS for recently posting a request for coverage of smoking cessation counseling. This type of counseling is labor-intensive as it involves an addiction of many years duration.

3. *Separate Reporting of Screening-Related Service Already Covered by Medicare*

ACCP agrees with CMS proposal that Medicare will pay for all Medicare covered screening services separately and will not implement edits to bundle payment for these separately payable services into the payment for the initial preventive service.

B. Payment for Initial Preventive Physical Exam

1. *Payment for Initial Preventive Physical Exam as a Stand-alone Service*

ACCP believes that CMS has undervalued the non-EKG portion of its proposed payment for the initial preventive physical examination. Consistent with our previously recommendation that CMS instruct physicians to report the initial preventive physical examination using the existing CPT Preventive Medicine Service new and established patient

codes, 99381-99397, ACCP recommends that CMS pay for the initial preventive physical examination service using the RVUs that are currently assigned to the CPT 99381-99397. Although these codes are currently assigned non-covered status in the fee schedule, RVU are assigned and maintained for these services. The RVUs were developed with input from the RUC, and the RUC recommended values are based on a clinical vignette describing the typical service provided for each age-specific code.

ACCP recommends that CMS designate CPT 99381-99397 as “active” codes in the fee schedule—thus eligible for separate payment—when the service is provided to a beneficiary within six months of enrollment. CMS should publish the existing RVUs that are maintained for 99381-99397 and make payment for eligible services.

Further, ACCP recommends that CMS ask the RUC to review the RVUs assigned to 99381-99387 in the context of the CMS initial preventive physical examination. CMS should utilize the RUC’s expertise because the extent to which preventive services for which Medicare makes separate payment are typically provided during an initial preventive physical exam is difficult to tease out, e.g. a pelvic and clinical breast exam is recommended for women.

2. *Payment for Medically Necessary E/M Service Furnished on the Same Date as an Initial Preventive Physical Exam*

CMS proposes to limit payment for a medically necessary E/M service on the same date to a level 2 office visit. CMS also restricts the coverage of and payment for the second E/M visit to a medically necessary visit **to treat the patient’s illness or injury**. It is especially unwarranted in light of its proposal to link payment for the non-EKG portion to CPT 99203, which requires a detailed history, detailed examination, and medical decision making of low complexity. Once again, ACCP is opposed to any such restriction on the Level of the visit reported. As stated above, many of these patients will require interventions/care planning far in excess of the Level 2 code. The CMS proposal effectively limits physicians to treating an acute or chronic (i.e. medically necessary) problem that is self-limited or minor (in the case of established patients) or of low to moderate severity (in the case of new patients) during an initial preventive physical examination even though that the agency believes the preventive exam is of low-to-mid complexity. This is unreasonable considering that many beneficiaries, even those new to Medicare, have multiple chronic conditions.

ACCP recommends that CMS review its proposal to remove the restriction on the level of service that a physician can bill for a medically necessary E/M service furnished on the same date as an initial preventive physical exam. CPT allows physicians to report a problem-oriented E/M service in conjunction with a preventive medicine service without regard to the level of problem-oriented E/M service. The CMS current Medicare policy pertaining to billing of a medically

necessary E/M on the same date as a Medicare non-covered comprehensive preventive examination includes no restriction on the level of service.

C. Record Documentation Expected for Initial Preventive Physical Exam

If CMS decides to finalize its creation of the HCPCS G code, G0XX2, it should specify the documentation that a physician who billed for this service would be expected to maintain. To not offer such an explanation places the physician at risk and leaves the carriers without guidelines for direction.

VI. SECTION 413 – PHYSICIAN SCARCITY AREAS AND HEALTH PROFESSIONAL SHORTAGE AREAS INCENTIVE PAYMENTS

A. Improvement to Medicare HPSA Incentive Payment Program

Medicare pays a 10 percent bonus to physicians for each services furnished in an area designated as a Health Professional Shortage Area (HPSA). Since the inception of the incentive program, physicians have been responsible for indicating their eligibility for the incentive payment of the claim form with the use of a modifier. The MMA mandated that CMS automate payment to eligible physicians by requiring carriers identify qualified HPSAs by the zip code of the physician’s office shown on the claim form. CMS also states the physicians will be required to continue to use the billing modifiers ACCP recommends that CMS clarify the extent to which automation will not be feasible in the final rule.

B. Physician Scarcity Areas (PSAs)

The MMA provides a new 5 percent incentive payment to physicians furnishing services in physician scarcity areas FROM January 1, 2005, through December 31, 2007. The new incentive payment would apply to the professional services performed by physicians, including evaluation and management, surgery, consultation, and home, office and institutional visits. The technical component of physicians' services is not eligible.

The Congress created the new 5 percent incentive payment program to make it easier to recruit and retain both primary and specialist care physicians for furnishing services to Medicare beneficiaries in PSAs. The MMA provides for paying the 5 percent incentive payment to primary care physicians furnishing services in a primary care scarcity county and specialty physicians furnishing services in a specialist care scarcity county. ACCP is pleased that there is a distinction allowing recognition of counties where primary care physicians are in abundant supply but specialist physicians are in short supply.

C. CMS Proposal to Identify PSAs

CMS will identify PSAs by their 5-digit zip code area for the purpose of automatically providing the 5 percent incentive payment to eligible physicians. The zip code of the place of service is the only data element reported on the Medicare claim form that would

allow automation. For zip codes that cross county boundaries, the statute specifically requires the use of the dominant county of the postal zip code (as determined by the U.S. Postal Service).

The statute requires CMS to publish a list of the PSA counties and areas that would be “primary care scarcity areas” and “specialist care scarcity counties” as part of the proposed and final fee schedule rules for the years for which these counties are identified or revised and to post a list of these counties on the CMS website. The proposed rule does not include a list of these counties, as required by law, and the ACCP urges CMS to publish a list of these counties immediately.

Failure to publish timely in the NPRM a list of eligible counties undermines the purpose of this important MMA provision in helping to recruit and retain physicians in underserved communities. ACCP advocates that physicians must have advance notice of any bonus payments that are available to them, especially as physicians make long-range decisions about where to practice and whether to continue practicing in certain areas. Further, ACCP urges that CMS provide physicians with advance notice of these scarcity counties and an opportunity to comment meaningfully on any proposed list before it is finalized. Otherwise, physicians in certain counties that are not included on the list, but perhaps should have been included, have no ability to seek corrections. This would be extremely inequitable as well as in contravention of section 413(a) of the MMA.

D. Primary Care

The MMA specifies that primary care scarcity areas are determined by the ratio of primary care physicians to Medicare beneficiaries. The MMA defines a primary care physician as a general practitioner, family practice practitioner, general internist, obstetrician, or gynecologist. CMS proposes to identify eligible primary care scarcity counties by ranking each county by its ratio of primary care physicians to Medicare beneficiaries. From the list of primary care scarcity counties, only those counties with the lowest primary care ratios that represent 20 percent of the total number of Medicare beneficiaries residing in the counties will be considered eligible for the 5 percent incentive payment.

E. Specialist Care

The MMA specifies that specialist care scarcity areas are determined by the ratio of specialty care physicians to Medicare beneficiaries. The MMA defines specialist care as all care provided by physicians who are not identified as primary care physicians. From the list of specialist care scarcity counties, only those counties with the lowest ratios that represent 20 percent of the total number of Medicare beneficiaries residing in the counties will be considered eligible for the 5 percent incentive payment. ACCP is pleased that there is a distinction allowing recognition of counties where primary care physicians are in abundant supply but specialist physicians are in short supply, creating an inequity that has now been corrected with this new provision,

F. Eligibility for Both HPSA Bonus and PSA Incentive Payment

Eligible physicians furnishing services in an area qualified as a physician scarcity area (PSA) and HPSA would be entitled to receive both incentive payments, that is, a 15 percent bonus payment. Eligibility for receiving both incentive payments is time limited (January 1, 2005 to January 1, 2008) because the 5 percent PSA bonus is scheduled to sunset on December 31, 2007.

VII. SECTION 302 – CLINICAL CONDITIONS OF COVERAGE FOR DURABLE MEDICAL EQUIPMENT (DME)

ACCP shares the CMS concern regarding the fraudulent provision of DME items and recognizes that the physician has a primary role in assuring DME is furnished based on the needs of the beneficiary. A blanket requirement, however, that all DME prescriptions and renewals require a face-to-face visit is excessive as it has the potential to diminish beneficiary access to medically necessary DME. ACCP recommends that CMS refrain from implementing its proposal to require a face-to-face visit for all DME prescriptions and renewals.

The CMS proposal to implement this MMA provision by requiring that a physician furnish a face-to-face service with the patient in order to order an initial prescription and to renew a previous prescription order is unnecessary and impractical. The additional requirement that the face-to-face examination should be for the purpose of evaluating and treating the patient's medical condition and not for the sole purpose of obtaining the prescribing physician's or practitioner's order for the DMEPOS—that the prescribing physician conduct a sufficient examination of the patient's medical condition to ascertain the appropriate overall treatment plan and to order the DMEPOS as only one aspect of that treatment plan—makes it even more unworkable. In addition, ACCP recommends that CMS consider the following as a way to balance fraud concern against ensuring that beneficiaries have timely access to necessary DME:

- Consider developing additional clinical criteria for the DME items for which there is a demonstrated need, as demonstrated by a CMS, a Government Accountability Office (GAO) or the HHS OIG analysis.
- Determine whether the DMERC can access carrier claims processing system data to ascertain whether the prescribing physician has furnished a face-to-face visit to the beneficiary who is to receive the DME item within a reasonable period of time.

CMS stated that the prescribing physician be independent from the supplier and may not be a contractor or an employee of the supplier. ACCP is seeking clarification about the physician who has the supplier number and, therefore, cannot have an arms-length away relationship.

VIII. PRACTICE EXPENSE ISSUES

A. Equipment Items Needing Specialty Input

In Table 3, CMS requested specialty input for pricing of certain equipment. We agree with the pricing of items used in our practices. Additionally, there is no cost listed for a bronchogram tray. This procedure is seldom performed and, when performed, it is always in a facility. Therefore, there would be no physician practice expense.

B. Proposed Changes to Equipment Pricing

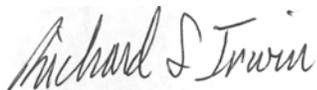
ACCP is in agreement with CMS' pricing data except for E55003, Pulse oximeter with printer. CMS prices it at \$1,207.18. We believe the price should be \$1,295.00. The item is sold by CritiCare.

C. Methacholine Used in CPT Code 95070

The RUC made changes to the direct practice expense inputs for 95070. One of these changes was to move the cost of the Methacholine administered from code 94070 to 95070. In the NPRM, however, we note that there is no change to the practice expense for 95070. ACCP believes that this omission should be corrected in the final rule.

As always, ACCP believes that CMS should solicit input from practicing physicians prior to implementing these or any other initiatives. Once again, thank you for allowing us to comment about these issues. Should you or your staff have any questions, please do not hesitate to contact me or Lynne Marcus at lmarcus@chestnet.org or (847) 498-8331.

Sincerely,



Richard S. Irwin, MD, FCCP
President

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Please see attached file

Anthony C. Catsaros, MS, ATC/L
27 Red Haw Lane
Lake Zurich, IL 60047

September 23, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1429-P
P.O. Box 8012
Baltimore, MD 21244-8012

Re: Therapy – Incident To

Dear Sir/Madam:

I am writing to express my concern over the recent proposal that would limit providers of "incident to" services in physician clinics. If adopted, this would eliminate the ability of qualified health care professionals to provide these important services. In turn, it would reduce the quality of health care for our Medicare patients and ultimately increase the costs associated with this service and place an undue burden on the health care system.

During the decision-making process, please consider the following:

- Incident to has, since the inception of the Medicare program in 1965, been utilized by physicians to allow others, under the direct supervision of the physician, to provide services as an adjunct to the physician's professional services. A physician has the right to delegate the care of his or her patients to trained individuals (including certified athletic trainers) whom the physician deems knowledgeable and trained in the protocols to be administered. The physician's choice of qualified therapy providers is inherent in the type of practice, medical subspecialty and individual patient.
- There have never been any limitations or restrictions placed upon the physician in terms of who he or she can utilize to provide ANY incident to service. Because the physician accepts legal responsibility for the individual under his or her supervision, Medicare and private payers have always relied upon the professional judgment of the physician to be able to determine who is or is not qualified to provide a particular service. It is imperative that physicians continue to make decisions in the best interests of the patients.
- In many cases, the change to "incident to" services reimbursement would render the physician unable to provide his or her patients with comprehensive, quickly accessible health care. The patient would be forced to see the physician and separately seek therapy treatments elsewhere, causing significant inconvenience and additional expense to the patient.
- This country is experiencing an increasing shortage of credentialed allied and other health care professionals, particularly in rural and outlying areas. If physicians are no longer allowed to utilize a variety of qualified health care professionals working "incident to" the physician, it is likely the patient will suffer delays in health care, greater cost and a lack of local and immediate treatment.
- Patients who would now be referred outside of the physician's office would incur delays of access. In the case of rural Medicare patients, this could not only involve delays but, as mentioned above, cost the patient in time and travel expense. Delays would hinder the patient's recovery and/or increase recovery time, which would ultimately add to the medical expenditures of Medicare.
- Curtailing to whom the physician can delegate "incident to" procedures will result in physicians performing more of these routine treatments themselves. Increasing the workload of physicians, who are already too busy, will take away from the physician's ability to provide the best possible patient care.
- To allow only physical therapists and PT assistants, occupational therapists and OT assistants, and speech and language pathologists to provide "incident to" services would improperly provide those groups exclusive rights to Medicare reimbursement. To mandate that only those practitioners may provide "incident to" care in physicians' offices would improperly remove the states' right to license and regulate the allied health care professions deemed qualified, safe and appropriate to provide health care services.

- CMS, in proposing this change, offers no evidence that there is a problem that is need of fixing. By all appearances, this is being done to appease the interests of a single professional group who would seek to establish themselves as the sole provider of therapy services.
- CMS does not have the statutory authority to restrict who can and cannot provide services "incident to" a physician office visit. In fact, this action could be construed as an unprecedented attempt by CMS, at the behest of a specific type of health professional, to seek exclusivity as a provider of physical therapy services.
- Independent research has demonstrated that the quality of services provided by certified athletic trainers is equal to the quality of services provided by physical therapists.
- Athletic trainers are employed by almost every U.S. post-secondary educational institution with an athletic program and every professional sports team in America to work with athletes to prevent, assess, treat and rehabilitate injuries sustained during athletic competition. In addition, dozens of athletic trainers had accompanied the U.S. Olympic Team to Athens, Greece this summer to provide these services to the top athletes from the United States. For CMS to even suggest that athletic trainers are unqualified to provide these same services to a Medicare beneficiary who becomes injured as a result of running in a local 5K race and goes to their local physician for treatment of that injury is outrageous and unjustified.
- These issues may lead to more physician practices eliminating or severely limiting the number of Medicare patients they accept.

In summary, it is not necessary or advantageous for CMS to institute the changes proposed. This CMS recommendation is a health care access deterrent.

Sincerely,

Anthony C. Catsaros, MS, ATC/L

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Please see attached file

Donna M. Dugas, ATC
UPMC Sports Medicine
3200 South Water Street
Pittsburgh, PA 15203

September 24, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1429-P
P.O. Box 8012
Baltimore, MD 21244-8012

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In summary, it is not necessary or advantageous for CMS to institute the changes proposed. This CMS recommendation is a health care access deterrent.

Sincerely,

Donna M. Dugas, ATC

Certified Athletic Trainer, UPMC Sports Medicine

Head Athletic Trainer, Chatham College

Pittsburgh, PA

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 1-9

PRACTICE EXPENSE

See Section 303 comments.

SECTION 611

I am the Reimbursement Coordinator for a small oncology practice with urban and suburban practice locations. I am extremely worried about the impact this piece of legislation will have on our ability to continue to serve the needs of cancer patients, survivors, and families. We have great concerns regarding the ASP methodology and its accuracy with regard to actual prices available to small clinics and practices, in spite of group purchasing/buying group contracts. Additionally, CMS has released only limited ASP data to date. This has limited our ability to conduct an accurate analysis of our actual losses in drug revenues. Coupled with the expiration of the 'transitional' 32% increase in drug administration code payments, we are facing losses in the range of \$300,000- \$650,000. While I recognize that coding changes are being considered to compensate community oncologists for unreimbursed practice expenses, it is unrealistic to think that these changes will occur in sync with the ASP transition. Further more, what CMS is considering a 32% 'transitional' payment increase on drug administration services should actually be perceived as a correction. The true expense of delivering chemotherapy in the office setting is finally being recognized after extensive research on the part of the GAO and ASCO. Salaries for qualified personnel, unreimbursed supply costs, and the complexity of the service itself must be factored in. Operating budgets were extensively reviewed and trimmed with the last round of drug reimbursement cuts. The proposed cuts in this regulation will force us to slash additional patient programs and amenities that make cancer treatment a less daunting experience for patients and families. We will need to direct patients on a more regular basis to hospital outpatient departments that have already expressed an unwillingness to accommodate our patients. Patients will have less flexibility in scheduling treatments and will lose out on the more personalized care and attention they now receive in the office setting. I strongly appeal to CMS to maintain the drug administration payment rates as they stand currently in 2004. With the inherent uncertainty of the ASP system, small community oncologists need the stability of these payments to react to the unknown of ASP.

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Please see attached file

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- CMS does not have the statutory authority to restrict who can and cannot provide services "incident to" a physician office visit. In fact, this action could be construed as an unprecedented attempt by CMS, at the behest of a specific type of health professional, to seek exclusivity as a provider of physical therapy services.
- Independent research has demonstrated that the quality of services provided by certified athletic trainers is equal to the quality of services provided by physical therapists.
- Athletic trainers are employed by almost every U.S. post-secondary educational institution with an athletic program and every professional sports team in America to work with athletes to prevent, assess, treat and rehabilitate injuries sustained during athletic competition. In addition, dozens of athletic trainers will be accompanying the U.S. Olympic Team to Athens, Greece this summer to provide these services to the top athletes from the United States. For CMS to even suggest that athletic trainers are unqualified to provide these same services to a Medicare beneficiary who

becomes injured as a result of running in a local 5K race and goes to their local physician for treatment of that injury is outrageous and unjustified.

- These issues may lead to more physician practices eliminating or severely limiting the number of Medicare patients they accept.

In summary, it is not necessary or advantageous for CMS to institute the changes proposed. This CMS recommendation is a health care access deterrent.

Sincerely,

Jill Nelson- Ramirez, ATC/L, K.T.

121 East Woodlawn Road

New Lenox, IL 60451

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 1-9

GPCI

CODING-TELEHEALTH

As the CMD for Alaska, Hawaii and the Pacific territories, I am very familiar with some of the problems in delivering ESRD Monthly Management for Patients on Dialysis across very wide geographic distances (American Samoa, Guam, outlying Alaska) as well as Medicare's need to assure service quality, some of which were dealt a fairly severe blow with the changes last year. We and the nephrology community in several of these areas applaud your proposed changes in adding a number of these services to the telehealth possibilities. This will definitely help! I also understand, and generally agree with your reasoning for not adding the 'comprehensive assessment with appropriate clinical exam' to the telehealth list, since '...a clinical examination of the vascular access site can be adequately performed only with a face-to-face, 'hands on' examination of the patient' (p. 47511). Having seen first hand, however, how the dialysis care is coordinated in some of these remote sites, I'd like to recommend that there be an exception, allowing telehealth also of the 'comprehensive assessment and appropriate clinical examination visit' where the originating (transmitting) site is by a physician/surgeon skilled in the management, servicing and repair of hemodialysis vascular access. There are vascular surgeons at some of these locations who are skilled in and responsible for at least a portion of the vascular access management, and 'IN A SITUATION WHERE SUCH AN ON-SITE PHYSICIAN IS PRESENT', the ESRD management, if done in coordination, really can be very well performed by telemedicine capabilities. Where there are distances of over a thousand miles, and severe geographic and weather separations, this additional option would enable continued quality services to Medicare beneficiaries that are otherwise seriously threatened. At the very least, please allow such arrangements at the contractor's discretion to enable a means to deal with severe geographic or weather situations, where the contractor feels quality of care can be assured. Thank you for considering, and for the other additions to the telehealth capabilities for ESRD.

Dick Whitten (206 979-5007). CMD, AK, HI, WA and Pacific Territories

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Please See Attached File

Dear Sir/Madam:

I am writing to express my concern over the recent proposal that would limit providers of "incident to" services in physician clinics. If adopted, this would eliminate the ability of qualified health care professionals to provide these important services. In turn, it would reduce the quality of health care for our Medicare patients and ultimately increase the costs associated with this service and place an undue burden on the health care system.

During the decision-making process, please consider the following:

- Incident to has, since the inception of the Medicare program in 1965, been utilized by physicians to allow others, under the direct supervision of the physician, to provide services as an adjunct to the physician's professional services. A physician has the right to delegate the care of his or her patients to trained individuals (including certified athletic trainers) whom the physician deems knowledgeable and trained in the protocols to be administered. The physician's choice of qualified therapy providers is inherent in the type of practice, medical subspecialty and individual patient.
- There have never been any limitations or restrictions placed upon the physician in terms of who he or she can utilize to provide ANY incident to service. Because the physician accepts legal responsibility for the individual under his or her supervision, Medicare and private payers have always relied upon the professional judgment of the physician to be able to determine who is or is not qualified to provide a particular service. It is imperative that physicians continue to make decisions in the best interests of the patients.
- In many cases, the change to "incident to" services reimbursement would render the physician unable to provide his or her patients with comprehensive, quickly accessible health care. The patient would be forced to see the physician and separately seek therapy treatments elsewhere, causing significant inconvenience and additional expense to the patient.
- This country is experiencing an increasing shortage of credentialed allied and other health care professionals, particularly in rural and outlying areas. If physicians are no longer allowed to utilize a variety of qualified health care professionals working "incident to" the physician, it is likely the patient will suffer delays in health care, greater cost and a lack of local and immediate treatment.
- Patients who would now be referred outside of the physician's office would incur delays of access. In the case of rural Medicare patients, this could not only involve delays but, as mentioned above, cost the patient in time and travel expense. Delays would hinder the patient's recovery and/or increase recovery time, which would ultimately add to the medical expenditures of Medicare.
- Curtailing to whom the physician can delegate "incident to" procedures will result in physicians performing more of these routine treatments themselves. Increasing the workload of physicians, who are already too busy, will take away from the physician's ability to provide the best possible patient care.
- To allow only physical therapists and PT assistants, occupational therapists and OT assistants, and speech and language pathologists to provide "incident to" services would improperly provide those groups exclusive rights to Medicare reimbursement. To mandate that only those practitioners may provide "incident to" care in physicians' offices would improperly remove the states' right to license and regulate the allied health care professions deemed qualified, safe and appropriate to provide health care services.
- CMS, in proposing this change, offers no evidence that there is a problem that is need of fixing. By all appearances, this is being done to appease the interests of a single professional group who would seek to establish themselves as the sole provider of therapy services.
- CMS does not have the statutory authority to restrict who can and cannot provide services "incident to" a physician office visit. In fact, this action could be construed as an unprecedented attempt by CMS, at the behest of a specific type of health professional, to seek exclusivity as a provider of physical therapy services.
- Independent research has demonstrated that the quality of services provided by certified athletic trainers is equal to the quality of services provided by physical therapists.
- Athletic trainers are employed by almost every U.S. post-secondary educational institution with an athletic program and every professional sports team in America to work with athletes to prevent, assess, treat and rehabilitate injuries sustained during athletic competition. In addition, dozens of athletic trainers will be accompanying the U.S. Olympic Team to Athens, Greece this summer to provide these services to the top athletes from the United States. For CMS to even suggest that athletic trainers are unqualified to provide these same services to a Medicare beneficiary who

becomes injured as a result of running in a local 5K race and goes to their local physician for treatment of that injury is outrageous and unjustified.

- These issues may lead to more physician practices eliminating or severely limiting the number of Medicare patients they accept.

In summary, it is not necessary or advantageous for CMS to institute the changes proposed. This CMS recommendation is a health care access deterrent.

Sincerely,

Jill Nelson- Ramirez, ATC/L, K.T.

121 East Woodlawn Road

New Lenox, IL 60451

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Dear Dr. McClellan;

I am a PT in Springfield, Illinois and wish to comment on the August 5th proposed rule on 'Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005.' I strongly support the proposed rule CMS has discussed and believe PT and PTA's (under the supervision of PT's) are the only practitioners who have the education and training to furnish PT services. I believe the quality of assessment, treatments and outcomes for the patients are the reason that one should meet the personnel qualifications for physical therapy in 42 CFR 484.4.

I have had the opportunity to review medical cases and know there are many patients who have met the 'therapy cap' without being seen by a PT. Those individuals treating patients do not have the same educational back ground and are not able to provide the same quality treatment.

I believe there are needs for the non PT/PTA healthcare professionals though in the own field of service. I believe it is a disservice to the patient to be receiving physical therapy services from an unqualified provider. I believe that licensure sets a standard of practice that is measurable and that quality of care is provided for the Medicare patient.

Thank you for your time and consideration.

Theresa Delvo, PT

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

We beg you to NOT pass this policy whereby a physician can only refer "incident to" services to physical therapists. All qualified health care providers should be allowed to provide services to patients with a physician's prescription or under their supervision. I am a massage therapist, and although this does not affect me directly at this time, the passage of this bill DOES affect my chosen profession and many of my colleagues. Thank you for your time.

Submitter : Mrs. nicole longwell Date & Time: 09/24/2004 08:09:47

Organization : Mrs. nicole longwell

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I am a Licensed Massage Therapist, currently working with Medicaid clients. It has been noted by many, including the clients themselves that massage therapy, along with other complimentary therapies, has been very effective in treating various conditions. However, many can not otherwise afford therapy. Denying the option of additional therapies may hinder or deny recovery and maintainance of health and wellbeing.

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 10-19

SECTION 623

please see attachment

CMS-1429-P-4065-Attach-1.pdf



DIALYSIS CLINIC, INC.

A Non-Profit Corporation

H. Keith Johnson, M.D., Chairman of the Board
James Perry, President
Ed Attrill, Secretary and Treasurer

1633 Church Street
Suite 500
Nashville, TN 37203
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Fax: (615) 329-2513

September 24, 2004

Centers for Medicare and Medicaid Services
Department Health and Human Services
Attention: CMS-1429-P, Section 623
P.O. Box 8012
Baltimore, MD 21244-8012

Re: Regulations for Section 623 of the Medicare Modernization Act

Dear Sirs:

Dialysis Clinic, Inc. (DCI) is a non-profit provider of dialysis care founded in 1971, with rehabilitation of the ESRD patient and constant improvement of the patient's care as the principal thrust of its efforts. DCI presently operates 190 free-standing dialysis clinics in 27 states, and serves more than 12,300 patients. Approximately 80% of our patients are Medicare recipients. DCI is pleased to have the opportunity to submit this comment letter to the Centers for Medicare and Medicaid Services (CMS) in response to the Medicare Modernization Act (MMA), Section 623 – Payment for Renal Dialysis Services.

DCI has the following reservations about the proposed rules:

- 1) It would be unreasonable to reimburse drug acquisition cost at 3 percent below the manufacturer's Average Sale Price (ASP);
- 2) It is improper to apply a single add-on methodology;
- 3) The case-mix adjustment proposal is not budget neutral;
- 4) Pediatric patients are costly, widely dispersed, and merit reimbursement adjustment to all facilities treating them;
- 5) We do not routinely test patients for HIV, and the laws of many states prohibit us from disclosing HIV status without patient consent;
- 6) The proposed adjustment to reimbursement on the basis of case mix lacks face validity, and the analyses on which this proposal is based are not reproducible.

1) It would be unreasonable to reimburse drug acquisition cost at 3 percent below the manufacturer's Average Sale Price (ASP)

The Office of the Inspector General found that drug manufacturers report an average sale price (ASP) exceeding the acquisition cost reported by dialysis providers. This discrepancy resulted in the determination that acquisition cost is 3% below the ASP. However, the presumption that a dialysis provider's drug acquisition cost could be lower than the manufacturer's average sale price defies logic. Acquisition costs exceed ASP because drug purchases are largely conducted through wholesalers. The wholesalers incur costs in handling and distributing the products; these costs are passed on to the facility purchasing the drugs. Finally, most of the 10 drugs identified are used primarily in the ESRD market; ESRD providers should thus obtain the most efficient pricing and their acquisition cost should strongly influence the ASP. This consideration casts further doubt on the conclusion that the ASP is measurably different from ESRD providers' acquisition cost.

It is not clear how the Office of the Inspector General reached the conclusion that dialysis providers' drug acquisition cost was lower than ASP, but this error may reflect inconsistent accounting practices in reports from manufacturers and providers regarding transactions such as rebates, charge backs and cash discounts. Rebates are paid on a quarterly basis, but in the fourth quarter of the year, reconciliation typically takes place, reflecting overall purchases for the year. This reconciliation determines the cumulative rebate for the year, which may be several percent higher or lower than rebates paid in the first three quarters. The final rebate payment, reflecting the reconciliation, will be made in the first quarter of the following year. If the manufacturer's report to the OIG of 2003 transactions was made on the basis of cash accounting, it would not include the rebate for the fourth quarter, because it was not paid until 2004. If, on the other hand, the dialysis provider's 2003 report was based on accrual accounting, it would include the rebate for the fourth quarter. Thus, a mismatch between the methodology used by drug manufacturers to report sales and by dialysis providers to report rebates and discounts may explain part of the discrepancy reported by the OIG between ASP and acquisition cost.

Furthermore, the OIG report incorrectly included cash discounts from manufacturer to wholesalers in their calculation of dialysis providers' acquisition cost. There is no reason to presume that wholesalers pass such discounts on to providers and indeed they rarely do so. Finally, the methodology makes no allowance for wastage, spoilage, insurance, inventory acquisition costs and freight costs.

Although CMS intends the new rule to remove a perceived incentive to over-utilize drugs, the OIG report shows that some providers will continue to profit from drug administration, while others will lose money on drugs. Those providers who continue to profit will have no incentive to control drug administration. Those facilities that must pay more for these drugs than they are reimbursed will have a significant incentive to under-utilize the drugs. Thus, the rule will create two classes of patients, depending on financial incentives to individual providers. This new disparity will further complicate efforts to achieve quality improvement by the development and application of practice guidelines. DCI does not believe that CMS intended its reimbursement policies to exacerbate disparities in patient outcomes.

The proposed rule will unfairly and unreasonably penalize dialysis providers when drug prices increase. Because reimbursement is recalculated only quarterly, adjustments may occur only 6 to 9 months following a price increase. For example, if a general price increase occurs on February 15, it

will not be fully reflected in the ASP until June 30, at the end of the following quarter; the data will be submitted to CMS only another 30 days later, on July 30. It is CMS’s current practice to use such data to update reimbursement for the following quarter. Thus, a price increase occurring February 15 would not be fully reflected in reimbursement adjustment until October 1. It is not financially possible to provide drugs at or below cost for such prolonged periods.

Recent experience shows that drug manufacturers’ price increases can be significant. The OIG reports that erythropoietin accounts for two-thirds of drug expenditures. The manufacturer of erythropoietin has no competition; thus, normal market forces cannot be expected to control prices. (Competition in the intravenous iron and vitamin D analog markets is also limited.) Under the proposed rule, an increase in the price of erythropoietin alone would result in a substantial loss to the dialysis provider. The cause of the loss would be the delay in incorporating the price increase into the reimbursement rate.

The table below shows an additional loss as a consequence of the proposed rule over five years for a drug initially costing \$10.00, the price of which increases 3.5% annually. At the beginning of the five year period, the provider loses \$0.30/treatment; at the end, the provider loses \$0.36/treatment, a 20% increase in the loss.

<u>Year</u>	<u>ASP</u>	<u>Reimbursement</u>	<u>Loss</u>
start	\$10.00	\$9.70	-\$0.30
1	\$10.35	\$10.04	-\$0.31
2	\$10.71	\$10.39	-\$0.32
3	\$11.09	\$10.75	-\$0.33
4	\$11.48	\$11.13	-\$0.34
5	\$11.88	\$11.52	-\$0.36

It is not reasonable to postulate that ESRD providers can influence drug acquisition costs by usual market mechanisms. Drug manufacturers largely dictate prices, and have no incentive to control these. Drug reimbursement of dialysis providers at 3% below the ASP will create an incentive to shift drug treatment to physicians’ offices, where reimbursement would be 9% higher than that to the dialysis provider. Patients and families would be inconvenienced, care would be fragmented, and cost to CMS would increase.

Because the methodology for determining ASP has changed, and because the OIG analysis did not take account of the considerations outlined above, DCI recommends that dialysis providers be reimbursed for drugs at ASP plus a reasonable percentage to cover the wholesaler’s fee, and a percentage to cover wastage, spoilage, insurance, inventory acquisition cost and freight. This would ensure that all providers will be able to cover the cost of drugs, will assure that all patients have access to appropriate drug treatment, and will level the playing field on which patient outcomes are determined.

2) It is improper to apply a single add-on methodology

The OIG study “Medicare Reimbursement for Existing End-Stage Renal Disease Drugs” attempts to determine how much money should be added to the composite rate to compensate for the loss of profit on drugs. This study relies exclusively on data from independent facilities, and excludes data from hospital-based facilities. The Scope section of the report states that

“We limited the focus to independent dialysis facilities because drugs that they provide are currently reimbursed at a percentage of published average wholesale prices. Other types or facilities are reimbursed for separately billable drugs based on Medicare principles of reasonable cost.”

It is therefore inappropriate to include the total number of dialysis procedures performed by both independent and hospital-based facilities in the denominator in calculating the amount paid per treatment to independent facilities for drugs other than erythropoietin. The correct denominator would be the number of treatments at independent facilities. The quotient of this calculation would be approximately \$7.15/treatment higher, as set forth below.

Erythropoietin alone accounts for almost 70% of estimated 2005 payments for items billed separately by dialysis units. On the basis of our contract with the manufacturer and on the erythropoietin reimbursement presently proposed, DCI expects to lose approximately \$5,600,000 annually on erythropoietin alone. We purchase erythropoietin at a cost substantially higher than the proposed reimbursement; a one-time increase in the composite rate cannot make good this ongoing loss.

Furthermore, the proposal to apply a single methodology to calculate the “add-on” for all facility types unfairly penalizes independent facilities with respect to the cost of separately billable drugs other than erythropoietin, accounting for about 30% of estimated 2005 payments. This is not an insignificant consequence. According to Section 623, the estimated 2005 reimbursement to independent facilities for billable drugs other than erythropoietin is \$1,096,000,000. Since 31,400,000 treatments are projected in 2005, reimbursement to independent facilities for billable drugs other than erythropoietin will be \$34.90/treatment. If the \$1,096,000,000 is inappropriately divided by the 39,500,000 treatments projected to be delivered by both independent and hospital-based facilities, facility reimbursement for billable drugs other than erythropoietin would be calculated at \$27.75/treatment. This incorrect calculation results in a \$7.15 reduction in estimated drug revenue to independent providers. This error should be corrected so that the appropriate offsetting increase in dialysis reimbursement can be calculated.

By contrast, hospital-based facilities will continue to receive drug reimbursement on the basis of reasonable rates. They will not experience the volatility of ASP, and it is unlikely that they will be reimbursed at rates lower than acquisition cost. If all facilities are given the same add-on to the treatment rate methodology, hospital-based facilities stand to gain \$11.38 per treatment, experiencing an extraordinary 8.6% increase in revenue. It should be noted that the hospital composite rate already exceeds that for independent facilities by 4%. Furthermore, hospital-based units have received annual industry updates to account for inflation. Over the past 14 years, the Medical Hospital Operating Update has yielded a total increase of 32.15%. In comparison, independent dialysis facilities have received a total increase of 3.6% over the past 14 years. The method of payment to hospital-based facilities is clearly differentiated from that to independent facilities. Reimbursement for separately billable drugs other than erythropoietin should be calculated separately on the basis of the number of treatments performed by each type of facility. Independent facilities and hospital-based facilities should receive separate and distinct add-ons.

3) The case-mix adjustment proposal is not budget neutral.

DCI has a very robust electronic information system, and incorporates comorbidity assessment into routine data collection. Our problem-based medical record allows physicians and nurses to relate physician orders and other records and events to the relevant medical condition. We have demonstrated the quality and completeness of our data in our recent work with CMS to transfer Form 2728 data, Vision EAI data, Fistula First data, CPM data and E-Lab data directly from our information system to CMS computers.

We used two particularly high quality data sets collected using this system to examine the implications of the case-mix adjustment proposal. Our Kansas City-area facilities recently used our information system to conduct the Dialysis Risk Factor Intervention Trial (DRFIT), designed to reduce cardiovascular risk among ESRD patients. A pharmacist conducted regular patient interviews and chart reviews, and updated the computer record of patients' in-center and home medications. Each medication was linked to one or more problems, which were coded using ICD-9 codes. Within this group of dialysis units, case mix data are particularly accurate. We analyzed data from patients who received regular in-center hemodialysis treatment (cost code 1110) billed to Medicare in July 2004. This cohort included 291 Medicare patients. Among these patients, we looked for active problems coded using the ICD-9 code 042 (AIDS) and all of the ICD-9 codes listed for PVD in the MMA. Four patients (1.4%) carried the diagnosis of AIDS. Seventy-four, or 25.4% carried the diagnosis of PVD.

A group of DCI facilities in western Pennsylvania offers another example of especially high quality data collection over many years. At these clinics, in a cohort of 321 Medicare patients, none had an AIDS diagnosis. Sixty, or 18.7%, had PVD by the MMA definition. Across DCI as a whole, we find AIDS in 1.3% of patients and PVD by the MMA definition in 15%.

We calculated the proportion of DCI's Medicare patients that would have to carry diagnoses of AIDS or PVD if the proposed case mix adjustments are to maintain budget neutrality for DCI. We think that the estimate that 1.3% of patients have AIDS is reliable, because it is confirmed by the Kansas City data. Assuming this AIDS prevalence, **budget neutrality would require that approximately 75% of our patients have PVD.** The Kansas City and western Pennsylvania clinics meticulously track case mix statistics, and their patient populations are otherwise comparable to DCI as a whole. In Kansas City, PVD is present in 25.4% of patients, and in western Pennsylvania, in 18.7%. These numbers are not far from the overall prevalence of 15%, suggesting that the quality of data across the company is quite high. They are far below 75%. This proposal will not be budget neutral to DCI. We cannot imagine that it will be budget neutral to any other provider.

4) Pediatric patients are costly, widely dispersed, and merit reimbursement adjustment to all facilities treating them

Many DCI facilities treat pediatric patients. Our experience thus differs from that reported by the MMA, which asserts that "pediatric patients are generally treated in specialized pediatric facilities." As of July 31, 2004, DCI provided care to 92 patients younger than 19 years; they comprised less than 3% of our entire population. These patients were dialyzed in 20 of DCI's 190 facilities. Only one (5%) of these facilities would meet the criterion that 50% of its patients were younger than 19 years, and it provided care to only 10 of the 92 pediatric patients. Fifteen facilities (75%) treated 5 or fewer pediatric patients, and many of the facilities treat only one pediatric patient. These facilities'

efficiencies are directed toward adult patients. With introduction of pediatric patients, the dialysis staff has to provide continuity of care to mitigate the adverse long-term physical, developmental, educational and psychosocial consequences of ESRD. Ongoing care often involves coordination with other health care professionals, which may include other medical specialists, surgical subspecialists, nutritionists, genetic counselors, public health and school nurses, physical therapists, occupational therapists, speech therapists, audiologists, psychologists, social workers and transplant centers. Dialysis staff help the patient and family with coping skills, and participate in educational planning with the local school district. Increased vigilance by the dialysis staff is necessary during key periods of transition when new and sometimes difficult adjustments must be made by the child and family. Examples include the start of school, a job or an intervention program, and the changes faced during puberty and adolescence. Our pediatric ESRD patients generally have less access than adults to needed general preventive health care services because of their families' financial and socioeconomic status, the limited availability of child care services, and limited access to transportation.

All these services make the care of each individual pediatric patient higher than the care of each individual adult patient. But the presence of pediatric patients has a further effect: it increases the cost of treating adult patients, because it impairs the facility's ability to maximize efficiencies for adult patients. DCI is pleased that the MMA recognizes that "pediatric patients are more costly to treat." However, it is incorrect to assume that these increased costs only affect dialysis facilities treating large numbers of pediatric patients. The costs to all facilities treating children are too high not to try to make an educated estimate. Such an estimate could later be revised on the basis of further data.

5) We do not routinely test patients for HIV, and the laws of many states prohibit us from disclosing HIV status without patient consent;

Ideally, previously untested patients with risk factors for HIV would undergo HIV testing by the dialysis facility to allow appropriate treatment. However, many patients still do not wish to undergo HIV testing, despite high risk behaviors or obvious symptoms of AIDS, because of the stigma associated with HIV and AIDS, and the potential for discrimination in many facets of their lives¹.

In nearly every state, patients have the absolute right to refuse HIV testing. Most states require that health care providers obtain specific consent for HIV testing². If the patient refuses testing, health care providers are unable to make the diagnosis definitively. Although empiric antiretroviral treatment is theoretically possible, it is probably hardly ever given; providers treating patients who refuse HIV testing must restrict themselves to treating the manifestations of AIDS as they arise. Under the proposed regulations, dialysis providers treating these complex patients will also be denied increased payment for patients who refuse to be tested for HIV.

If a patient does agree to HIV testing, facilities will have to disclose the AIDS diagnosis to CMS on billing records. Although the Health Insurance Portability and Accountability Act ("HIPAA") authorized the release of medical information to payers for payment purposes, state law pre-empts

¹ Health Care Ethics Critical Issues, John F. Monagle and David C. Thomasma, Aspen 1994, pgs 189-197. .

² Id., page 189-197.

the provisions of HIPAA³. HIPAA mandates that if a state law is more stringent than the HIPAA requirement for use or disclosure, then state law shall be followed, to afford the individual even greater privacy protection. For instance, California law prohibits the disclosure of HIV status to anyone who is not a health care provider giving direct patient care without specific written authorization from the patient for each disclosure of test results, including specification of the recipient of the information⁴. State law regarding the disclosure of AIDS diagnoses varies, even for payment purposes.

The American Health Information Management Association indicates states that a facility should obtain specific consent from the patient to disclose the diagnosis of AIDS for the purpose of obtaining insurance benefits⁵. Therefore, a general authorization for disclosure of medical information for payment purposes would be insufficient. The facility would be required to obtain specific consent from the patient carrying a diagnosis of AIDS in order to disclose this particular condition to CMS for payment purposes. Again, if the patient refuses to consent to disclosure of the AIDS diagnosis for payment purposes, the facility must forgo the payment adjustment for that patient.

DCI does not currently suggest to patients that they have HIV testing. The proposed case mix adjustment would require us to change our practices in order to obtain appropriate payment. We will have to balance the patient's right to be free of unwarranted intrusion into highly personal information with the need to seek payment commensurate with services provided.

Historically, the health care industry has avoided blanket requests that patients be tested for AIDS/HIV, because such testing is not necessary to reduce the risk of HIV exposure by health care workers, and because such testing should not be substituted for rigorous adherence to universal precautions⁶. The American Hospital Association indicates that there are certain situations in which HIV testing is appropriate; these do not include payment. The Association states that HIV testing is appropriately performed for the purpose of making the diagnosis of AIDS, answering a patient's question about whether or not he or she is infected, screening blood, organs, or other substances prior to donation, or conducting follow-up after a potential exposure to HIV⁷. We believe that the proposed policy should be revised to avoid this very real potential for invasion of patient privacy. One possible solution would be to make an estimated adjustment to each provider based on the estimated number of AIDS patients being treated by that provider, using national estimates of AIDS prevalence in the ESRD population.

- 6) The proposed adjustment to reimbursement on the basis of comorbid disease lacks face validity, and the analyses on which this proposal is based are not reproducible.

DCI recommends that if case-mix adjustment of reimbursement is to be implemented now, without further study, that adjustment should include the proportion of patients with body mass

³ U.S. Department of Health and Human Services Office for Civil Rights, Standards for Privacy of Individually Identifiable Health Information, 45 CF Parts 160, Sections 160.2010160.205.

⁴ California Health and Safety Code, section 120980.

⁵ HIV and Confidentiality, Guidelines for Managing Health Information Related to HIV Infection, Mary D. Brandt, American Health Information Management Association (1997), page 13.

⁶ The American Hospital Association, Special Committee on AIDS/HIV Infection Policy, AIDS/HIV Infection Policy: Ensuring a Safe Hospital Environment (August 1987).

⁷ Id.

index exceeding 30 kg/m², the proportion of patients having received ESRD treatment for more than 3 years (“vintage”), the proportion of patients having diabetes requiring insulin treatment (not diabetes as the cause of ESRD), the proportion of male patients and the proportion of black patients. Our recommendations are based on a sample of limited size, but one that we believe to be unbiased, analyzed using a well-established measure of comorbidity.

DCI has been systematically collecting data on comorbid disease since 1997. As noted earlier, we use the Index of Coexistent Disease (ICED). ICED methodology requires a careful review of the medical record. It is thus considerably more rigorous than the methods used by clinicians completing Form 2728. Appendix A summarizes our findings. These unfortunately do not include pediatric patients; they do include patients from 63 units. The paragraphs that follow summarize univariate and multivariate analyses of our data.

We find considerable variability in case mix across dialysis facilities. Furthermore, the diagnoses correlated with cost in our data set are not the same as those identified by the CMS analyses. In particular, we did not find the proportion of patients carrying a diagnosis of AIDS or of peripheral vascular disease by the CMS definition to be significantly related to a unit’s cost per treatment. Case-mix adjusted reimbursement based on faulty methodology could be very dangerous: it would create random disparities in reimbursement, financially destabilizing some units and subsidizing others; it would discourage outpatient facilities from accepting complex patients, and would encourage them to seek pretenses to discharge such patients; it would corrupt future data by promoting misleading patient classification.

In our data set, multivariate analysis showed few factors to be significantly related to treatment cost. The presence in a dialysis unit of patients having a) body mass index exceeding 30 kg/m², or b) ESRD treatment for more than 3 years (“vintage”) or c) diabetes requiring insulin treatment (not diabetes as the cause of ESRD) was associated with increased cost. The presence of male patients or of black patients was associated with decreased cost. The morbidity associated with extreme overweight lends credence to our finding regarding body mass index. The acceleration of cardiovascular disease with prolonged dialysis treatment might be responsible for a vintage effect. The finding that the proportion of insulin-requiring diabetics in a dialysis unit is related to cost corresponds to the clinical impression that these are particularly ill patients.

In addition to the findings in multivariate analysis, univariate analysis showed erythropoietin cost to increase with the presence of patients having had a diagnosis of cancer in the last year, having frequent intradialytic hypotension, low-predialysis systolic blood pressure, and peripheral vascular disease, where peripheral vascular disease is defined by the presence of amputation, recurrent cellulitis or gangrene. It is important to note that the more broadly defined ICED item “any history of PVD” did not correlate significantly with cost (either erythropoietin or total cost) in univariate nor in multivariate analysis. By contrast, the narrower definition of peripheral vascular disease, taking account of severity, was significant in univariate analysis. The finding that the cost of erythropoietin was related to these factors makes sense, because of the erythropoietin resistance caused by inflammation and malnutrition.

Although our data set did not allow us to test these hypotheses, we think it likely that several other variables are also related to the cost of dialysis treatment. These include the use of translators, treatment of nursing home patients, treatment of patients who cannot walk, treatment of patients who are less adherent to treatment or medication recommendations, treatment of patients having

psychiatric disease, treatment of patients anticoagulated with warfarin, and treatment of patients who are at high risk for infection. The presence of PVD and/or AIDS seems unlikely to us to capture this last risk.

DCI currently collects principal diagnoses for more than 99% of its patients' hospitalizations. We recently enhanced our electronic problem list to improve the accuracy of clinical problem lists and of information regarding comorbid disease. We anticipate that these, in combination with laboratory and physiologic variables, will enable us to derive a more robust and accurate case-mix adjusted model of cost. We welcome questions from CMS regarding our experience. As CMS considers how to case-mix adjust dialysis reimbursement, we at DCI would be pleased to participate in and provide data to enhance these discussions. We respectfully suggest that the currently proposed case-mix adjustment of reimbursement is inadequate. If case-mix adjustment of reimbursement is to be implemented without further study, it should at minimum include the factors we found to be significant in multivariate analysis.

Thank you for the opportunity to comment on this Draft Policy. Please call either one of us if you have any question.

Sincerely,



H. Keith Johnson, M.D.
Chairman of the Board



James Perry
President

APPENDIX A

Purpose:

We sought to determine the relationship of case-mix factors with costs of dialysis care in a representative sample of DCI patients, in whom detailed co-morbidity information had been collected as part of another study. The unique aspect of this work is our access to detailed co-morbidity information that was collected as part of a feasibility project using the Index of Coexistent Diseases. We have the ability to examine additional co-morbidities over those present on the Form 2728 and these are also defined more specifically to capture severity of each condition of interest.

Study Population:

DCI is a non-profit dialysis provider with 190 dialysis units nationwide. All are independent facilities. In recognition of the importance of collecting co-morbidity data and the insensitivities of the Form 2728, several dialysis units have collected detailed co-morbidity information through medical record review and scored it using the Index of Coexistent Disease. This effort was on a voluntary basis and since 1997, 46 units conducted detailed co-morbidity reviews on their patients. These facilities serve as the study population for the present analyses. Facilities were excluded if co-morbidity assessments were performed in fewer than 50% of the unit census (defined at the end of the fiscal year) or the unit census was less than 20.

Statistical Analyses:

The proportion of subjects with each factor of interest was summarized for each facility. Two outcomes were examined:

- i) Total cost per treatment reported to CMS/ Composite Rate (the division by composite rate is to standardize for differences in area wage index).
- ii) Epogen Costs per treatment

The patient-specific factors, summarized for each facility, were regressed against total cost per treatment (from cost report data) using log linear regression. The result is interpreted as a relative risk of cost (E.g. 1.2= 20% increase in cost for a person with vs. without the factor). Differential lengths of follow-up of case-mix factors were weighted by the fraction of time exposure in the fiscal year. The epogen cost per treatment was calculated as the total reported epogen costs/ total number of treatments reported to Medicare. The variable was normally distributed and linear regression was used to relate factors to it. Thus, the regression coefficient is the change in cost of epogen per treatment for a subject with vs. without the factor of interest.

Results:

There were 63 dialysis facility-year units that serve as the study population. Some units contributed more than once to the study population. There is considerable variability in the case-mix burden of each facility, as shown in Table 1. This table describes the frequency of factors within the facilities (n=63). We have examined various demographics, co-morbidities and laboratory factors that have been shown to be strong prognostic markers for death and resource use.

Table 1: Large Variability in the Burden of Comorbidity and Other Case-Mix Factors across Dialysis Facilities

Patient Factors		Mean	Median	10 th percentile	90 th percentile
Age	< 50 yr	0.21	0.16	0.08	0.41
	> 80 yr	0.13	0.13	0.04	0.22
Cause ESRD: Diabetes	DM	0.41	0.39	0.29	0.55
Body Mass Index (kg/msq)	BMI > 30	0.14	0.13	0.06	0.23
	BMI < 20	0.24	0.23	0.15	0.34
Pre-dialysis Systolic BP (mm Hg)	SBP < 120	0.79	0.07	0.16	0.14
	SBP > 180	0.08	0.06	0.00	0.16
Serum albumin	< 3.0	0.06	0.06	0.01	0.11
	≥ 4.0	0.03	0.31	0.12	0.45
Comorbidity					
Disease Severity					
	MI, CABG or angioplasty in past yr	0.29	0.33	0.07	0.46
	Frequent intradialytic hypotension	0.01	0.00	0.00	0.02
	Severe CHF	0.04	0.06	0.00	0.10
	Diabetes requiring insulin: Type 1 or	0.02	0.00	2.07	0.05
	Any history of PVD	0.19	0.20	0.07	0.30
	Amputation, active gangrene	0.09	0.09	0.02	0.16
Physical Impairments					
	Walks with assistance	0.03	0.24	0.15	0.38
	Wheelchair or bedridden	0.14	0.14	0.06	0.22
Total Cost (outcome)*		1.21	1.19	1.05	1.41
Epogen (dollars per treatment)		54.64	54.58	36.64	70.04

* outcome interpretation: 1.2 = 20% above composite rate per treatment

Relationships of Patient-Specific Factors with Total Cost Per Tx/ Composite Rate

Table 2A: UNIVARIATE

Patient Factors		Relative Risk	Standard Error	p value
Age	<50	0.93	0.12	0.57
	50-65	1.00	Reference	
	65-80	1.32	0.22	0.21
	>80	0.90	0.25	0.68
Cause ESRD DM vs. Non-DM		1.18	0.13	0.21
Race	White	1.00	Reference	
	Black	0.96	0.05	0.40
	Other	1.11	0.09	0.24
Male vs. Female		0.86	0.15	0.33
Dialysis Vintage	<1 yr	0.85	0.17	0.35
	1-3y		Reference	
	>3	0.96	0.19	0.85
Serum Albumin	<3.0	0.70	0.38	0.35
	3.0-3.5	1.12	0.16	0.49
	3.6-3.9	0.86	0.19	0.44
	≥4.0	1.00	Reference	
Pre-dialysis Systolic BP mm Hg	<120	1.05	0.27	0.86
	120-140	1.03	0.21	0.90
	141-180	1.00	Reference	
	>180	1.06	0.27	0.83
Serum Phosphate mg/dl	<3.5	0.87	0.25	0.57
	3.5-5.5	1.00	Reference	
	5.5-8.0	0.81	0.16	0.21
	>8.0	1.01	0.37	0.99
Body Mass Index kg/msq	<20	0.78	0.27	0.36
	20-24.9	1.00	Reference	
	25-29.9	0.96	0.20	0.85
	≥30	1.18	0.22	0.45
Comorbidities				
MI, CABG or angioplasty in past yr		1.05	0.11	0.62
Hospitalized for CHF once/ past yr		1.36	0.14	0.03
Severe CHF *		1.32	0.24	0.27
Frequent Intradialytic hypotension		0.71	1.03	0.74
>2 hospitalizations for CHF/ past yr		1.60	0.36	0.19
Arrhythmia requiring meds		0.80	0.19	0.25
Stroke (any history)		1.23	0.21	0.33
Diabetes requiring insulin (I or II)		1.88	0.46	0.18
Severe Liver Disease		1.12	0.32	0.72
AIDS		0.55	0.46	0.20
Cancer in the past year		0.65	0.57	0.46
Vasculitis or SLE (+/- active disease)		1.91	0.40	0.11
Peripheral neuropathy		1.03	0.14	0.82
PVD- prior bypass, anticoagulated		1.27	0.20	0.23
Amputation, active gangrene		1.01	0.30	0.96
Any history of PVD		1.05	0.15	0.76

Physical Impairments			
Walks with Assistance	1.13	0.17	0.46
Wheelchair or bedridden	0.78	0.19	0.19

*Severe CHF=>2 admissions in past yr for CHF, intradialytic hypotension or EF<30% on Echocardiogram
 Study Population: 63 dialysis units in which co-morbidity was collected using the ICD in more than half the units census for that fiscal year. Includes units from 1998-2003. The exposure time for each factor was weighted according to the time at risk for each subject.

Table 2B: MULTIVARIATE

Variable	Relative Standard				
	B	Risk	Error	t	p value
BMI >30	0.72617	2.07	0.17	18.62	<.0001
Vintage >3 years	0.26668	1.31	0.13	4.28	0.0441
Diabetes on Insulin (Type 1 or 2)	1.4326	4.19	0.51	7.92	0.0071
Black Race	-0.15218	0.86	0.05	8.71	0.0049
Male	-0.26766	0.77	0.13	4.29	0.0439

RELATIONSHIPS OF PATIENT-SPECIFIC FACTORS WITH EPOGEN COSTS

Table 3A: UNIVARIATE

Patient Factors		B (Difference in Cost)	Standard Error	p value
Age	<50	-14.75	18.39	0.43
	50-65	-13.11	34.22	0.70
	65-80	0.00	Reference	
	>80	13.02	39.25	0.74
Cause ESRD DM vs. Non-DM		16.33	19.71	0.41
Race	White	0.00	Reference	
	Black	-14.94	7.35	0.05
	Other	-21.21	13.42	0.12
Male vs. Female		8.63	23.40	0.71
Dialysis Vintage	<1 yr	-0.17	25.77	0.99
	1-3y	0.00	Reference	
	>3	-16.86	29.71	0.57
Serum Albumin	<3.0	-4.40	54.17	0.94
	3.0-3.5	58.53	22.46	0.01
	3.6-3.9	-28.10	27.13	0.30
	≥4.0	0.00	Reference	
Pre-dialysis Systolic BP mm Hg	<120	67.83	38.55	0.08
	120-140	25.82	30.25	0.40
	141-180	0.00	Reference	
	>180	-22.60	38.38	0.56
Serum Phosphate mg/dl	<3.5	-47.23	37.85	0.22
	3.5-5.5	0.00	Reference	
	5.5-8.0	22.60	24.32	0.36
	>8.0	40.30	55.31	0.47
Body Mass Index kg/msq	<20	-40.30	40.74	0.33
	20-24.9	0.00	Reference	
	25-29.9	-37.39	29.29	0.21
	≥30	-75.23	32.74	0.03
Comorbidities				
MI, CABG or angioplasty in past yr		23.05	16.00	0.15
Hospitalized for CHF once/ past yr		3.52	22.43	0.88
Severe CHF *		-12.14	37.63	0.75
Frequent Intradialytic hypotension		486.96	143.70	0.001
>2 hospitalizations for CHF/ past yr		-29.64	55.15	0.59
Arrhythmia requiring meds		41.67	29.51	0.16
Stroke (any history)		-2.16	32.88	0.95
Diabetes requiring insulin (I or II)		100.16	70.13	0.16
Severe Liver Disease		-9.24	48.98	0.85
AIDS		-121.93	69.14	0.08
Cancer in the past year		82.18	87.16	0.35
Vasculitis or SLE (+/- active disease)		88.28	61.39	0.16
Peripheral neuropathy		6.88	21.06	0.75
PVD- prior bypass, anticoagulated		38.38	31.93	0.24

Amputation, active gangrene	113.13	44.01	0.01
Any history of PVD	3.05	22.77	0.89
Physical Impairments			
Walks with Assistance	-2.31	25.40	0.93
Wheelchair or bedridden	69.57	27.34	0.01

Interpretation: The epogen costs of a subject with "PVD: amputation or active gangrene" costs 113.13 per treatment vs. a subject without this co-morbidity.

Study Population: 63 dialysis units in which co-morbidity was collected using the ICED in more than half the unit census for that fiscal year. Includes units from 1998-2003. The exposure time for each factor was weighted according to the time at risk for each subject.

Table 3B: MULTIVARIATE

Variable	Parameter Standard		t Value	Pr > t
	Estimate	Error		
Vintage >3 years	25.29	18.64	1.36	0.1805
Male	-31.88	20.25	-1.57	0.1212
Systolic BP <120	62.63	33.69	1.86	0.0685
Systolic BP 120-140	42.56	23.26	1.83	0.0728
Phosphate <3.5	-49.30	33.00	-1.49	0.141
PVD: amputation, recurrent gangrene	134.94	36.02	3.75	0.0004
Cancer in past year	127.14	81.00	1.57	0.1224
Frequent Intradialytic Hypotension	516.36	131.45	3.93	0.0002

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

See attached file comment from the Northeast Ohio Academy of Chiropractic.

THERAPY STANDARDS AND REQUIREMENTS

See attached file comment from the Northeast Ohio Academy of Chiropractic.

CMS-1429-P-4066-Attach-1.pdf

CMS-1429-P-4066-Attach-1.pdf

NORTHEAST OHIO ACADEMY OF CHIROPRACTIC

September 24, 2004

Submitted Electronically at <http://www.cms.hhs.gov/regulations/ecomments>

Mark McClellan, M.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Baltimore, MD 21244

Re: Comments on Revisions to Medicare Physician Fee Schedule for Calendar Year 2005
File Code: CMS-1429-P
Therapy—Incident To
Therapy—Standards and Requirements

Dear Dr. McClellan:

On behalf of the patients of its members, the Northeast Ohio Academy of Chiropractic (NOAC) respectfully comments on the Centers for Medicare and Medicaid Services (CMS) proposed changes to the Medicare benefit for physical therapy services provided "incident to" a physician services. NOAC believes that this restriction on Medicare coverage would impose additional hardship for beneficiaries requiring physical medicine services.

The mission of the NOAC is to promote the highest level of quality of chiropractic practice for the protection of the public welfare, to promote and upgrade the practice of chiropractic and the education and knowledge of chiropractic practitioners, and to expose fraudulent, unethical and unaccredited practices in the chiropractic art and education.

NOAC is dedicated to serving as spokesman and voice of the chiropractic profession in regards to political, legal and socioeconomic welfare of the chiropractic profession in northeastern Ohio. We have special qualifications to address the merits of this issue as members are licensed to practice physical therapy as doctors of chiropractic in the state of Ohio.

Background on Proposed Rule Change

CMS proposes to restrict Medicare coverage to allow only those individuals to provide physical therapy incident to the services of a physician who graduated from a physical therapy curriculum approved by (1) the American Physical Therapy Association (APTA); (2) the Committee on Allied Health Education and Accreditation of the American Medical Association (AMA), or (3) the Council on Medical Education of the AMA or APTA.

Essentially the current Medicare incident to rule, codified at 42 C.F.R. §410.26, would be changed effective with the CY 2005 Fee Schedule to require training in physical therapy school for all physical medicine services furnished under a physician's direction and control. CMS would do so by adding section 410.26(c) (2) to the "incident to" physician services rule which cross references to new sections on the therapy rules governing outpatient physical therapy

providers.¹ This change would effectively negate the ability of Medicare beneficiaries to receive physical medicine services incident to physician services from chiropractors.

A substantive change of this magnitude should be based on empirical data and a solid statutory foundation given Medicare's long-standing policy of covering this type of services. A November 21, 1994, letter from Bernadette Schumaker, Acting Director of the HCFA Office of Physician and Ambulatory Care Policy to Bill Maruca specifically states that despite the restrictions on Medicare coverage for chiropractic services at §1861(r)(5) of the Social Security Act, a chiropractor may furnish physical therapy services or any other service he or she is authorized to perform under the incident to benefit. Correspondence and communication from HCFA officials in 1996 and 1997 specifically addresses this issue and recognized continued coverage of physical therapy provided by doctors of chiropractic incident to the services of a physician.²

The "incident to" statutory benefit at Social Security Act §1861(s)(2)(A) contains no educational qualification conditions.³ The statutory basis CMS offers for this change is §1862(a)(20) of the Social Security Act enacted in 1997 stating that Medicare does not cover "outpatient physical therapy services furnished as an incident to a physician's professional services that do not meet the standards and conditions (other than any licensing requirement)... as such standards and conditions would apply to such therapy services if furnished by a therapist."

CMS is proposing to adopt a limitation on Medicare incident to benefits it consistently has rejected subsequent to enactment of the 1862(a)(20) provisions. Instead, current Medicare rules deliberately rely on state scope of practice laws to establish qualifications for the incident to statutory benefit under both §1862(s)(2)(A) and §1862(a)(20). When CMS reviewed and revised the Incident to Physician Services rule in 2001, CMS made clear that "any individual" could qualify subject to scope of practice laws as follows:

We have not further clarified who may serve as auxiliary personnel for a particular incident to service because the scope of practice of the auxiliary personnel and the supervising physician (or other practitioner) is determined by State law. We **deliberately used the term any individual** so that the physician (or other practitioner), under his or her discretion and license, may use the service of anyone ranging from another physician to a medical assistant. In addition, it is impossible to exhaustively list all incident to services and those specific auxiliary personnel who may perform each service.

¹ The person furnishing the service would be required to meet the standards and conditions that apply to physical therapy and physical therapists, except for a license to practice physical therapy in the State. See proposed §410.60(a)(3)(iii). The proposal adopts the definition of "physical therapist" for home health agencies at 42 C.F.R. §484.4 which contains the educational requirement.

² Copies of these documents are being sent in a pdf file to Dorothy Shannon at CMS.

³ 42 U.S.C. §1395x(s)(1), (2)(A) ("services...furnished as an incident to a physician's professional service, of kinds which are commonly furnished in physicians' offices and are commonly either rendered without charge or included in the physicians' bills.").

Medicare Program; Revisions to Payment Policies and Five-Year Review of and Adjustments to the Relative Value Units Under the Physician Fee Schedule for Calendar Year 2002, 66 Fed. Reg. 55246, 55268 (Final Rule) (Nov. 1, 2001) (emphasis added).

In 1998, CMS specifically rejected the idea that §1862(a)(20) requires the qualifications that it now intends to impose. Instead, CMS implemented the §1862(a)(20) terms through a manual instruction that required the physician whose services the therapy was incidental to be licensed to practice physical therapy. In responding to comments in the final CY 1999 Physician Fee Schedule rule, CMS stated:

Comment: One commenter stated that verification should be provided in the final rule that section 1861(p) of the Act requires a physician to have services furnished by a licensed physical therapist or under the supervision of such a therapist when billing for physical therapist services incident to the physician's professional services.

Response: Section 1861(p) of the Act does not set forth the requirements as specified by the commenter. As previously stated, section 4541(b) of the BBA 1997 amended section 1862(a) of the Act to require that outpatient physical therapy services (including speech-language pathology services) and occupational therapy services furnished "incident to" a physician's professional services meet the standards and conditions (other than any licensing requirement specified by the Secretary) that apply to therapy services furnished by a therapist. In May 1998, we issued Transmittal No. 1606 of the Medicare Carriers Manual, Part 3—Claims Process which implemented this provision that was effective January 1, 1998. Section 2218(A) of the Medicare Carriers Manual requires that physical therapy services provided by a physician or by an incident to employee of the physician in the physician's office or the beneficiary's home must be provided by, or under the direct supervision of, a physician (a doctor of medicine or osteopathy) who is legally authorized to practice physical therapy services by the State in which he or she performs such function or action.

Medicare Program; Revisions to Payment Policies and Adjustments to the Relative Value Units under the Physician Fee Schedule for Calendar Year 1999, 63 Fed. Reg. 58863, 58870 (Final Rule) (Nov. 2, 1998).

Last year, when CMS considered the implementation of §1862(a)(20), it once again rejected national standards for therapy services. 68 Fed. Reg. 49030, 49059 (CY 2004 proposed rule) (August 15, 2003). Current CMS manual instructions applicable to Physical Therapy and Occupational Therapy Provided by Physicians and Physician Employees, are in accord stating that that "[t]he services must be provided by, or under the direct supervision of, a physician (a doctor of medicine or osteopathy) who is legally authorized to practice physical therapy services by the State in which he performs such function or action." *Medicare Benefit Policy Manual*, Pub. 100-2, Chapter 15, 220.2, Rev. 1, 10-01-03.⁴

⁴ To the extent any CMS manual instructions or local medical review policies adopted by carriers paying physician claims currently seek to impose additional qualifications in contradiction to §410.26, those interpretations are not

While previous government studies⁵ have suggested that physical medicine services provided by unlicensed or unqualified personnel should be addressed, doctors of chiropractic are both licensed and qualified to provide physical therapy. To equate chiropractors with untrained, unlicensed, unqualified staff is repugnant, and lacks a sound empirical basis. Indeed, the Federal Employees' Workers Compensation Program has developed special rules for chiropractors to include both treatment to correct a spinal subluxation (paralleling the Medicare benefit) as well as "services in the nature of physical therapy under the direction of a qualified physician." Department of Labor, Office of Workers' Compensation Programs (OWCP) Rules, 20 C.F.R. §10.311. Likewise, the Blue Cross Blue Shield Service Benefit Plan for federal employees does not cover chiropractic services, but covers physical therapy provided by chiropractors. Medicare beneficiaries should have access to at least the same therapy services as federal employees who are injured in the workplace and the CMS staff.

Conflict with other Laws

There are numerous legal reasons the proposed rule should not be adopted in its present form. Besides the separate statutory benefit at §1861(S)(2)(A), as discussed above, the proposed rule directly conflicts with other federal laws. First, this additional requirement interferes with the practice of medicine, the authority of state licensing boards, and Medicare beneficiary freedom of choice. The very first section of the Medicare Act, Section 1801 prohibits federal interference in the practice of medicine. Public Law 89-97, 1965, codified at 42 U.S.C. §1395. ("Nothing in this title shall be construed to authorize any federal officer or employee to exercise any supervision or control over the practice of medicine").

The restriction interferes with state licensing authority. Under the incident to rule, therapy services are an integral part of the physician's professional services and the physician is immediately available to furnish assistance and direction while the therapy is performed. The definition of Medicare "physician services" at 42 C.F.R. §440.50(a) unquestionably includes supervisees other than the physician and services provided by employees supervised by the physician can only be conditioned on *the scope of the practice of medicine* as defined by state law. *Yapalater v. Bates*, 494 F. Supp. 1349, 1363-64 (S.D.N.Y. 1980), *aff'd*, 644 F.2d 131 (2d Cir. 1981), *cert. denied*, 455 US 908 (1982).

For example, in Ohio, the state medical board rule for delegation requires a physician to determine that the delegation is appropriate and conforms to minimal standards of care of similar physicians under same or similar circumstances considering various factors. *See* Ohio State Medical Board Rule on delegation of medical tasks at Ohio Rev. Code §4731-23-02.

The restriction also interferes with Section 1802 of the Medicare Act providing Medicare beneficiaries with the freedom of choice for qualified providers, "Any individual entitled to insurance benefits under this title may obtain health services from any institution, agency, or

binding. *See, e.g., Christensen v. Harris County*, 529 U.S. 576, 587 (2000) ("Interpretations such as those in opinion letters – like interpretations contained in policy statements, agency manuals, and enforcement guidelines, all of which lack the force of law – do not warrant *Chevron*-style deference."); *see also United States v. Ward*, 2001 U.S. Dist. LEXIS 15897 (E.D. Pa. Sept. 5, 2001).

⁵ *See e.g.,* OIG Report on Physical Therapy in Physician Offices, OEI-02-90-00590 (March 1994); DynCorp Report to CMS at www.medlearn/therapy/dyncorprpt@asp.

person qualified to participate under this title if such institution, agency, or person undertakes to provide him such services." 42 U.S.C. §1395a(a).

Second, the imposition of qualifications on the physical medicine codes used by physician offices contradicts the uniform coding system established by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Transaction and Code Set Rule. Under that rule, the Current Procedural Terminology®, 4th Edition, as maintained and distributed by the American Medical Association, ("CPT-4 Manual") was adopted as the official coding system for both physician and physical therapy services⁶ electronically billed by covered entities. See 45 C.F.R. §162.1002.

Federal law requires providers who submit claims electronically and payors covered by HIPAA, including CMS, to follow CPT guidance. The American Medical Association publishes the *CPT Assistant* to provide official CPT coding advice, and that publication refers coders of physical therapy services to state licensing laws, stating:

These codes are not restricted to use by a specific specialty. No distinction is made concerning the licensure or professional credentials of the provider. State and institutional authorities should be consulted regarding the appropriate provision of these services by health care professionals.

CPT Assistant, Physical Medicare and Rehabilitation Service, Part I, Dec. 2003, at 4.

Third, this a major substantive change to Medicare policy. As CMS acknowledged last year in requesting comments on this issue, "There are currently no national standards for qualifications of individuals providing outpatient physical therapy services incident to physicians' services...we are not proposing a change at this time..." 68 Fed. Reg. 49030, 49059 (CY 2004 proposed rule) (August 15, 2003).

To the extent that CMS would implement this change retroactively, 903(b) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 ("The Medicare Modernization Act") prohibits the retroactive application of substantive changes in Medicare regulations, manual instructions, interpretive rules, policy statements or guidelines unless the Secretary determines that retroactive application is necessary to comply with the statute.⁷ This proposed change is not necessary as other alternatives exist.

Alternatives for Consideration

The primary policy reason the proposed change should not be adopted because it will negatively impact Medicare beneficiary access to quality physical medicine services. This proposed change needs further study of physical therapy provided by doctors of chiropractic

⁶ Physical therapy services are those procedures found in the Physical Medicine and Rehab Section of the CPT-4 Manual. Medicare *Benefit Policy Manual*, Pub. 100-2, Chapter 15, 220.2, Rev. 1, 10-01-03

⁷ Section 903(b) of the Medicare Modernization Act also provides that no action shall be taken against providers or suppliers for noncompliance with a substantive change for items and services furnished before the effective date of the change.

incident to a physicians services because these services can and do meet the standards and conditions of services provided by physical therapists.

As CMS acknowledged in its specific call for comments from physicians and others who would be affected by this change, the issue is one of whether CMS can identify alternatives "to ensure that qualified staff are providing 'incident to' therapy services." 68 Fed. Reg. 49030, 49059 (CY 2004 proposed rule) (August 15, 2003). Thus, the State of Ohio has already determined that doctors of chiropractic can meet the standards and qualifications to provide physical therapy services. Ohio chiropractors are specifically trained in physical medicine in addition to chiropractic manual therapy. Indeed, Ohio doctors of chiropractic must pass the physiotherapy section of their national board exam and graduate from a chiropractic college with a minimum of 120 hours of education in rehabilitation procedures. Ohio has addressed the issue of whether the provision of physical therapy services is within the scope of practice of chiropractic in Ohio. The Ohio Attorney General concluded that chiropractors may perform physical therapy services included within the scope of chiropractic services and within the chiropractor's education, training and experience. See 1987 Op. Atty. Gen. Ohio 492.

One alternative is to specifically add doctors of chiropractic to the rule as the OWCP has done. Medicare coverage and benefit rules are replete with examples of where training and qualifications of one licensed discipline is deemed to be equivalent when provided by another discipline, *e.g.*, coverage of physician services by osteopathic and allopathic physicians. A second alternative would be to allow any individual authorized by the state where the services are provided to perform physical medicine services. Either of these rules would defer to state licensing authorities to set standards and conditions as is currently done for most Medicare covered services.

Third, Medicare could follow the rule for physician services that allows licensed physicians to decide "under his or her discretion and license" whether the standard is met. This alternative would place the burden on the physician whose billing number is used to ensure that the local standard of care and state medical board rules have been met. Other requirements set forth in the Incident to Physician Services would rule further protect Medicare beneficiaries. The requirements that the service be an integral part of the physician's professional services and be billed under the physician's member establishes accountability and malpractice liability for the physician and licensure sanction for services outside the scope of the delegate's license.

This third alternative is consistent with the proposed changes to the rules at 42 C.F.R. §410.60 expressly allowing physical therapy assistants to provide physical therapy if they do so under a physical therapists' direct supervision. In other words, while denying licensed and qualified individuals such as doctors of chiropractic to provide physical therapy under the direct supervision of a physician, CMS proposes to allow lesser trained individuals such as physical therapist assistants to provide the same services if a physical therapist supervises. To codify this delegation by physical therapists while prohibiting physicians from delegating to doctors of chiropractic inappropriately places therapists above physicians in implementing plans of care for physical medicine services. NOAC further believes that CMS should consider the restrictions on delegation under the supervision of physical therapists in conjunction with this rule and revise it as well.

We support the Medicare benefit for our patients and would be please to discuss these issues further with your staff. You may contact me at tdisalvatore@adelphia.net.

Sincerely,

**Thomas DiSalvatore, President
NOAC**

cc: Dorothy Shannon, CMS (by email at DShannon2@cms.hhs.gov w/PDF attachments)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

REFER TO: FKA43

6325 Security Boulevard
Baltimore, MD 21207 - 5187

NOV 21 1994

Mr. William H. Maruca
Kabala and Geeseman
The Waterfront
200 First Avenue
Pittsburgh, PA 15222-1575

Dear Mr. Maruca:

I am responding to your inquiry concerning Medicare coverage of physical therapy services when provided by a chiropractor incident to the services of a physician.

You stated in your inquiry that the Pennsylvania Chiropractic Practice Act permits chiropractors to perform additional services including some physical therapy procedures. This being the case, you have asked whether Medicare covers the services of a chiropractor who performs physical therapy services incident to the services of a physician, when the physician and chiropractor are both employed by the same professional corporation.

As you mentioned in your inquiry, Medicare Part B pays for only one service furnished by a licensed and Medicare approved chiropractor. Under section 1861(r)(5) of the Social Security Act (the Act), that one service is treatment by means of manual manipulation of the spine to correct a subluxation that is demonstrated by an X-ray to exist.

It is important to emphasize, that a chiropractor, as such, is authorized by the Act and coverage and separate payment is available when he or she furnishes subluxation of the spine. However, if a chiropractor furnishes services incident to the services of a physician, different rules apply.

For the services of a chiropractor or any other auxiliary personnel's services to be covered under the "incident to" benefit, the services must be of the kind that are commonly furnished in physicians' offices or clinic and are generally rendered without charge or included in the physician's bill. The physician must perform the initial service for the patient and subsequent services of a frequency that reflects his or her active participation in and management of the patient's course of treatment. Additionally, the physician must provide direct personal supervision to the chiropractor.

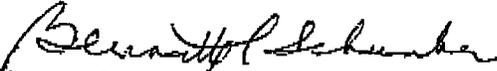
This means that the physician must be present in the office suite and immediately available to provide assistance and direction throughout the time the chiropractor is performing his or her services. The services provided by the chiropractor must be furnished as an integral, although incidental, part of the physician's personal professional service provided in the course of diagnosing or treating the patient for an injury or illness. These requirements and other requirements pertaining to the "incident to" benefit are described at section 2050 of the Medicare Carriers Manual (MCM).

In conclusion, when a chiropractor furnishes a physical therapy service or any other service that he or she is authorized to perform by the State in which the services are furnished, and all other "incident to" requirements are met, then the services furnished by the chiropractor can be covered under the "incident to" benefit.

With respect to the employment requirement, when a chiropractor (or any other auxiliary personnel) furnishes services incident to the services of a physician, and both the physician and the Chiropractor are employed by the same legal entity, then, the employment requirement is considered to be met. An employer employee relationship is considered to be established between a physician and the chiropractor when the physician has the right to control and direct the personnel who performs the service, not only as to the results to be accomplished, but as to the details and means by which that result is accomplished.

I hope this information clarifies your concerns.

Sincerely,


Bernadette S. Schumaker
Acting Director
Office of Physician and
Ambulatory Care Policy
Bureau of Policy Development

R

REMARKS: Per our telephone conversation I am faxing you some information on chiropractor—MD Hixon. For further clarification you can contact Grant Bagley in our Bureau of Policy Development (410) 786-4509. His mail stop is C4-04-26. Another policy contact on chiropractor services is Ms. Dorothy Honemann, (410) 786-5702. Her mail stop is also C4-04-26.

10 1149467457 ID: 7149467457 FROM HART KING & COLDREN

M E M O R A N D U M

FROM: MJS
BJD
DATE: January 17, 1997
RE: New Info From HCFA - Billing of DC's Services in MD/DC Facility

See the attached FAX from Patricia Gill, who is with the Office of Program Requirements ("OPR"). OPR is a section of the the Practitioner Claims Processing Requirements Department of HCFA

OPR gets policy from the Bureau of Policy Development. OPR then translates policy into operational carrier instructions to distribute to state carriers, providers, etc.

The attached FAX is pursuant to my prior telephone conversation with Ms. Gill. I spoke to Ms. Gill again on 1/17/97 regarding the attached FAX.



Gill consulted with Grant Bagley, M.D., who is a medical adviser to the Bureau of Policy Development.

Per Dr. Bagley, PT or rehab prescribed by MD, performed by a DC (if w/in DC's state scope of practice), and properly supervised by MD under the "incident to" supervision requirements may be billed and reimbursed by Medicare as services incident to the MD's services. In other words, the services are billed as medical services by the individual MD or group practice.

With respect to use of RPT, Ms. Gill consulted with another PT expert in her office while we were on the phone. Per Ms. Gill, PT services that are either performed by an "independent" RPT (i.e., not an EE of medical entity) or by an aide who is supervised by the independent RPT will be billed by and reimbursable to the independent RPT. In the case of rehab performed by a DC as incident to an MD's services, there is no requirement that a PT be involved in order the services to be reimbursable.

10 1149467457 ID: 7149467457 FROM HART KING & COLDREN

HART, KING & COLDREN
200 E. Sandpointe, Fourth Floor
Santa Ana, California 92707
Telephone 714-432-8700
Facsimile 714-546-7457

FACSIMILE TRANSMISSION COVER SHEET

FAX NO. (714) 546-7457

DATE: August 22, 1997 **FILE NO:** 71371.003
FAX #: 757-523-9457
TELEPHONE #: 757-523-2333
TO: Michael Concessi, D.C.
FROM: Barbara J. Dibble, Esq.

To: Grant Bagley, 1/17/97
Patricia Gill, 1/17/97

I received a phone call from a billing agency for a group of physicians who is in the process of starting a practice together. This group of docs has a chiropractor on its staff. The billing agency understands Medicare rules regarding chiropractor services, however, they have pose the following question:

Medicare reimburse a MD for an office ancillary service performed by a chiropractor that the MD is supervising? In other words, if the chiropractor acting as an unlicensed physician performs some type of service, such as a rehab service, with the MD directing, can the MD bill for this services as an in office ancillary service?

From: Grant Bagley, 1/9/97
To: Pat Gill

In the case of the chiropractor-MD liaison the following possibilities exist.

1. Chiropractor performs chiropractor service (manual manipulation of the spine). This service is Medicare covered and can be billed by the chiropractor but cannot be performed or billed for by the MD since most State statutes limit chiropractic treatment to holders of a chiropractic license.
2. Chiropractor performs other service such as PT, E&M, rehab, etc. that is permitted under the state chiropractor statute. These services generally fall within the scope of chiropractor and MD licensure but is only Medicare covered if done by the MD. When done by the chiropractor and reported as incident to the MD it would be subjected to the usual incident to requirements.

4/4 PAGE 474 ID: 7145487487 MBRDIO 2 ONIX 1248-1248 11 14 11 FROM: HART KING & COLDREN 410 786 1297 P. 01 02



HEALTH CARE FINANCING ADMINISTRATION
7500 Security Boulevard
BALTIMORE, MARYLAND 21244-1850

January 17, 1997
Pages: 2



O: Ms. Barbara Dibble, (714) 432-8700
ext 714-546-7457

Patricia Gill, Office of Program Requirements, BPO

com: (410) 786-1297
Fax: (410) 786-4047 or 786-7585

US81

Refer to: R3-18 (17)
File Code: Chiro-Carr Spec-b

Robert S. Muscalus, D.O., F.A.A.F.P.
Medical Director
Xact Medicare Services
1800 Center Street
Camp Hill, PA 17011-0632



February 23, 1996-

Dear Dr. Muscalus:

This is in response to the issue you raised in your letter dated January 18, 1996 concerning business arrangements which were proposed by chiropractors to expand the types of chiropractic services reimbursed by Medicare. You indicated that several groups of M.D.s, D.O.s, and chiropractors recently incorporated under Pennsylvania Law and are requesting provider numbers from Xact. There is nothing in our guidelines that would preclude Xact from issuing provider numbers to these entities. We agree with you that this issue could have a significant impact on Medicare, however, under current guidelines Medicare would pay for the services of a chiropractor under the "incident to" benefit as described in Medicare Carriers Manual (MCM) Section 2050. To be covered as "incident to" the services of a physician, the chiropractors' services must meet all of the requirements of MCM 2050.

You asked what services other than physical therapy, which was referenced in a HCFA directive, would a chiropractor be allowed to perform under "incident to". The HCFA directive (a letter to William Maruca dated November 21, 1994 from Bernadette Stumaker) describes our policy concerning Medicare coverage of physical therapy services when provided by a chiropractor "incident to" the services of a physician. When a chiropractor furnishes a service that he or she is licensed to perform by the state and all "incident to" requirements are met, the services furnished by the chiropractor can be covered by Medicare. These "incident to" requirements which chiropractors must meet are:

- An integral, although incidental, part of the physician's professional service (see MCM 2050.1, first paragraph)
- Commonly rendered without charge or included in the physician's bill (see MCM 2050.1, second paragraph)
- Of a type that are commonly furnished in a physician's office or clinic (see MCM 2050.2)
- Furnished under the physician's direct personal supervision (see MCM 2050.2) and
- Furnished by the physician or an individual that qualifies as an employee of the physician

06-18-1998 05:21PM FROM 229 State Street

TO

6223599 P.03

Page 2

Xact must carefully consider how each of these corporate entities meets all of the above requirements for Medicare and that the services provided by the chiropractors are within the scope of their state license and are reasonable and medically necessary.

You are concerned about the financial impact to Medicare as the number of M.D./D.O./D.C. corporations increase since services performed by chiropractors under "incident to" a physician would now be paid and how you should ensure that these services meet "incident to" guidelines. We recommend that you contact the principals of these physician/chiropractor corporate entities that are requesting provider numbers and thoroughly explain the "incident to" and medical necessity requirements under Medicare. We also suggest that you review utilization, perhaps by comparing volume and mix of services by these entities to an average "all M.D./D.O." entity with appropriate action based on your findings. After six months or sooner if there is a problem, we would like you to provide us with your utilization analysis of these M.D./D.O./D.C. entities.

Thank you for bringing this matter to our attention. We appreciate the proactive position you have taken to identify issues that could have a significant impact on Medicare. Please do not hesitate to contact Jim Throne at (215) 596-0575 with any questions regarding this letter.

Sincerely,

is/
Catherine McCoy, Chief
Operations Branch
Division of Medicare

cc: RSM
C Lentz

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

GENERAL

GENERAL

Department of Health and Human Services
Centers for Medicare and Medicaid Services
42 CFR Parts 405, 410, 411, 414, 418,424,484, and 486
[CMS-1429-P]
RIN 0938-AM90
Medicare Program; Revisions to Payment Policies Under the
Physician Fee Schedule for Calendar Year 2005

File Code: CMS-1429-P

Section 302

Issue Identification: Clinical Conditions for Coverage of Durable Medical Equipment

?Section 302? Comment

This is a Section 302 Comment. We are commenting about a proposed rule that the Department of Health and Human Services (HHS) has proposed that would, among other things, require face-to-face physician visits as a prerequisite for all Medicare payment for DMEPOS renewals. We represent a business which is in the business of providing DMEPOS renewals and which will thus be substantially affected by the new rule. Our client is in a good position to appreciate the future effects of the proposed rule and to comment on it. Please accept this comment on our client's behalf.

Your proposal states that you believe that ?it is good clinical practice for the beneficiary to be seen by the physician for their medical condition and the physician to decide whether or not an item of DMEPOS is appropriate during the face-to-face examination of the beneficiary.? You also say that, since you expect that a beneficiary will be seen by their physician for a specific medical condition, that you do not believe that a requirement for a face-to-face examination for initial orders and at the time of prescription renewal for the items would place a burden on the physician or beneficiary, as it would be part of a necessary examination.

You discuss the fact that your focus, in adding the face-to-face requirement, is to eliminate fraud, avoid the prescription of unnecessary DMEPOS and encourage quality care. You believe that the face-to-face requirement will help you reach that goal. However, you recognize that perhaps this requirement should not be applied across the board. You seek ?specific comments about whether specific items of DMEPOS should be exempt from the face-to-face examination requirement.? We share your concern that this proposed new requirement may not be necessary in all situations. We would like to comment on one such specific situation: the provision of replacement breast prostheses and related supplies. We suggest that this situation should be specifically exempted from your proposed rule.

We believe the final rule should make it clear that face-to-face physician examinations should not be required in order for beneficiaries to obtain replacement DMEPOS items (such as breast prosthesis, mastectomy bras, etc.) where the initial physician order satisfies coverage criteria for lifetime, because the medical condition requiring the DMEPOS item will not change. Our client, a supplier of breast prosthesis and related accessories, is concerned about application of the new requirement to the replacement of items that it provides in this area. The initial physician order for a breast prosthesis, mastectomy bra, etc. is generally sufficient for lifetime because the patient's physical condition will remain the same. These patients will need to replace items due to normal wear and tear. If an additional physician examination is required prior to each replacement order, the beneficiary would have to attend an unnecessary physician visit, as well as incur a needless expense, in the form of the Medicare co-payment for each visit. Requiring doctor visits for replacement orders under these circumstances will not further the Secretary's stated goal of encouraging quality care, mitigating any proliferation of use of these products, and ensuring that only patients that need items of DMEPOS receive them.

Respectfully Submitted,

Shutts & Bowen LLP
Michael Gennett, Esq.

201 South Biscayne Blvd.
Suite 1500
Miami, FL 33131
(305)358-6300



Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

GENERAL

GENERAL

Re: CMS-1429-P -- Carl Zeiss, Inc. Comments on the Proposed Rule for Calendar Year 2005 Payment Policies Under the Physician Fee Schedule

To Whom It May Concern:

Enclosed please find comments submitted on behalf of Carl Zeiss, Inc. regarding the proposed rule revising payment policies under the Medicare Physician Fee Schedule for Calendar Year 2005. These comments also have been submitted via hand delivery. Please contact me at michael_ruggiero@aporter.com, 202-942-6365 with any questions.

Sincerely,

Michael J. Ruggiero
Arnold & Porter

September 24, 2004

Carl Zeiss, Inc.
2005 Physician Fee Schedule Comments

September 24, 2004

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

VIA ELECTRONIC SUBMISSION AND HAND DELIVERY

Re: CMS-1429-P -- Comments on the Proposed Rule for Calendar Year 2005
Payment Policies Under the Physician Fee Schedule

Dear Administrator McClellan:

These comments are submitted by Carl Zeiss, Inc., a global leader in visualization technologies. Carl Zeiss remains committed to developing innovative radiation cancer therapies to be used in a wide range of contexts, including the Intrabeam® system, which is used in the treatment of early-stage breast cancer.

Carl Zeiss appreciates this opportunity to submit comments regarding the payment under the Physician Fee Schedule for Intrabeam Intra-Operative Radiation Therapy. Under current policy, the Intrabeam procedure must be reported using CPT 77776, a brachytherapy code that does not accurately describe or reflect the unique and distinct surgical and radiation therapy components of performing this procedure. Accordingly, we request that CMS create new HCPCS codes for each of the two physician services that are provided in connection with Intrabeam. This will enable CMS to establish appropriate valuation of the physician services and practice expenses associated with the Intrabeam procedure as well as ensure appropriate payment.

Treatment of breast cancer varies case-by-case and depends upon a range of factors, but generally includes a lumpectomy or mastectomy as well as adjuvant therapy, such as radiation, to decrease the likelihood of recurrence. The most common forms of radiotherapy are external beam radiation and brachytherapy. Both of these conventional forms of radiation occur as a separate treatment following a lumpectomy and require multiple treatments. External beam radiation delivers high energy x-ray beams to the entire affected breast from outside of the body. Brachytherapy, on the other hand, involves the placement of radioactive seeds or pellets near the cancer site, using numerous plastic catheters or needles. Brachytherapy is used as a sole source of radiation, or to deliver a “boost” of radiation following external beam radiation therapy.

Intrabeam intra-operative therapy gives to women diagnosed with early-stage breast cancer a treatment option that is more efficient and convenient than conventional radiation techniques. Currently, Intrabeam therapy is used either as a boost replacement or as single-dose radiotherapy as part of the international TARGIT trial. Both form of Intrabeam therapy substantially reduce the overall number of treatment days for early stage breast cancer patients, providing numerous quality of life benefits for patients and significant cost savings for the health care system.

For purposes of the Physician Fee Schedule, the principal distinction between Intrabeam therapy and more conventional methods of radiotherapy is that the Intrabeam procedure is performed intra-operatively, and thus requires the services of both a breast surgeon and a radiation oncologist. The procedure occurs as follows:

Immediately following tumor resection, the surgeon measures the tumor site and selects a spherical Intrabeam applicator that will fill the tumor cavity. The surgeon then places the appropriate resposable applicator onto the probe of the Intrabeam's miniature x-ray source and inserts the ensemble directly into the tumor cavity, using surgical closure techniques to ensure contact between the breast tissue and the x-ray source. The placement of the applicator usually takes approximately five to ten minutes. The surgeon also shields the skin and muscle from the x-ray source at this time. The radiation oncologist then determines the prescribed dose of radiation and enters the information into the Intrabeam's control console. The Intrabeam radiation source is activated and delivers a high dose of low level energy (50KeV) radiation directly to the tumor site. The radiation is delivered over a period of time determined by the size of the tumor cavity, usually ranging from 25 to 45 minutes. After the radiation treatment is complete, the surgeon removes the applicator/radiation ensemble and closes the surgical wound, ending the procedure.

The two physician services that comprise Intrabeam therapy fundamentally differentiate it from conventional radiation methods. The procedure requires both a breast surgeon and a radiation oncologist, and thus has two distinct relative values—one that describes the surgeon's services and one that describes the radiation oncologist's services. These two values are different in terms of the work provided and the practice expense, and thus, require different codes in order to report the service accurately.

Currently, no code exists to describe the services performed by a breast surgeon during the Intrabeam procedure. As a result, breast surgeons must use CPT 14999, an unspecified surgical code to report the Intrabeam procedure. Radiation oncologists, on the other hand, use CPT 7776 to describe the services they perform during Intrabeam therapy. CPT 7776 is a brachytherapy code used to describe brachytherapy procedures. As explained above, however, Intrabeam therapy is not brachytherapy in that it requires different physician services and different practice expenses.

Therefore, we request that CMS create two new HCPCS codes with the following descriptors for the physician services that comprise the Intrabeam procedure until CPT can provide adequate codes:

1. Surgical placement and removal of intra-operative direct application x-ray source using surgical closure techniques.
2. Administration of radiation therapy by intra-operative direct application of x-ray source.

Because CMS does not have accurate data regarding the practice expense associated with the Intrabeam procedure, we recommend that CMS seek such information from stakeholders over the next year. In the meantime, CMS should leave the codes unpriced and allow the individual carriers to price the two services.

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

see attachment

September 23, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1429-P
P.O. Box 8012
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: **COMMENTS TO PHYSICAL THERAPY-INCIDENT TO
RULE PROPOSED REGULATION**

Dear Sir/Madam:

Please treat this correspondence as our state association's comments and recommendations for modifications to proposed regulations published at 69 *Federal Register* 47550-47552 (8/5/04).

By way of introduction, the Pennsylvania Chiropractic Association represents more than 3,000 Doctors of Chiropractic in the Commonwealth of Pennsylvania. Our goal is to improve upon the profession of chiropractic by being the full time spokesperson before businesses, insurance companies, legislators, peer review organizations, health maintenance organizations as well as the general public. We represent hundreds of doctors who provide chiropractic care and adjunctive therapy services in their chiropractic practices as well as those who operate multispecialty/multidisciplinary practices including medical or osteopathic along with chiropractic and/or physical therapy. These doctors have serious policy, clinical and practical concerns about the proposed regulations affecting outpatient therapy services performed "incident to" physicians' services, and the qualification standards and supervision requirements in therapy private practice settings. Each will be addressed separately.

COMMENTS TO THERAPY-INCIDENT TO PROPOSED REGULATION

At 69 *Federal Register* 47550-47551 (8/5/04), CMS proposes to revise 42 C.F.R. § 410.26, § 410.59, § 410.60 and § 410.62 to reflect that physical therapy provided "incident to" a physician's professional services are subject to the limitations of § 1862(a)(20) of the Act. The proposed regulation contemplates application of the standards set forth in 42 C.F.R. § 484.4 as a condition to bill for therapy services "incident to" a physician's services. The proposal raises serious clinical, statutory, relational, access and quality of care issues.

The standards set forth at 42 C.F.R. § 484.4 would require the person performing therapy "incident to" a physician to graduate from an approved physical therapy

curriculum or a physical therapy assistant curriculum. As a matter of practical reality, the number of PT or PTA graduates who are not licensed are few and far between. In our members' experiences, virtually every person who has graduated from an approved PT or PTA curricula as set forth in § 484.4 is a licensed PT or certified PTA. Therefore, incorporation by reference of the § 484.4 standards to qualify for performance of therapy services billed "incident to" a physician is a de facto licensing requirement.

We respectfully submit this is contrary to the Congressional intent of § 1862(a)(20) of the Act. Under that general coverage exclusion provision, covered outpatient physical therapy services furnished "incident to" must meet the standards and conditions under the second sentence of § 1861(p), which essentially requires services to be performed under the supervision of a provider, and repeats the provision relating to regulations promulgated by the Secretary. The cross-reference to § 1861(p) is not helpful to the analysis. What is helpful to the analysis is that the specific terms of § 1862(a)(20) ***specifically exclude any licensing requirement*** and contain a conditional clause explicitly contemplating therapy services covered by a non-therapist, drawing the comparison to services "if furnished by a therapist." 42 U.S.C. § 1395y(a)(20).

Commonly accepted principles of statutory construction compel the following conclusions. First, even therapy services performed "incident to" a physician need not be performed by a licensed individual. Second, the standards and conditions relating to the "if" clause demonstrate that ***someone other than the therapist*** may perform therapy services "incident to" a physician. Therefore, read in its entirety, § 1862(a)(20) statutorily contemplates "incident to" coverage for therapy services performed by someone who is (a) not licensed and (b) not a therapist.

Nevertheless, the proposal to mandate the § 484.4 qualifications results in a standard that **only therapists** can meet. Accordingly, this proposed regulation reads the final clause of § 1862(a)(20) out of existence, improperly renders it surplusage and is inconsistent with the statutory permissive authority established by Congress. Further, as a *de facto* matter, virtually every person who satisfies the PT and PTA curricula requirements *is* a licensed PT or PTA, thereby severely undermining the statutory authority that expressly allows non-licensed persons to perform therapy under the "incident to" rule.

Access to care is also a serious issue. Since the proposed regulations were published in August 2004, we notified our doctors throughout the state of the impending problem that may exist. There are two specific access problems that have arisen. In a multidisciplinary practice involving a psychiatrist and a chiropractic physician in northeastern Pennsylvania, the practice has attempted to recruit a licensed PT and/or PTA, or an unlicensed person with PT and PTA

educational experience consistent with the § 484.4 guidelines. The practice has been completely unsuccessful in getting even a candidate to interview in two months of efforts. Similarly, a well-recognized neurologist in Mississippi who also provides physical therapy services for his severely impaired patients and who has achieved outstanding clinical results has likewise attempted to recruit a licensed PT, licensed PTA or a person who has satisfied the PT or PTA equivalent curriculum standards. This practice has “struck out” as well. Adopting the proposed regulation will create an access to care problem.

Competition will be negatively affected as well. If medical and multidisciplinary practices are unable to recruit licensed PTs or PTAs, or the arguably non-existent person who is not licensed but nevertheless has completed the PT or PTA educational curricula, these patients will be forced to be referred to free-standing physical therapy clinics. This will have a negative impact on competition. Because our doctors are providing high quality therapy services with well-trained supportive personnel and other individuals such as exercise physiologists, there is nothing other than a professional turf-based reason to preclude medical, osteopathic and chiropractic physicians from being involved in the delivery of physical therapy in stand-alone medical practices or multidisciplinary practices through well-trained but unlicensed individuals.

For the same reasons, the forced referrals that will occur will have a substantial impact on the **physician-patient relationship**. Rather than being able to constantly monitor physical therapy, physicians will lose immediate oversight, resulting in an impairment to or interference in the physician-patient relationship.

Quality of care under the current paradigm is simply not an issue. The proponents of the regulatory change, likely organized physical therapy associations, can point to no malpractice cases in Pennsylvania, or in any other jurisdiction that we have seen. On the contrary, our chiropractors deliver high quality therapeutic interventions to Medicare beneficiaries, all of whom are regularly satisfied and who receive excellent clinical care and results.

The proposed regulation further **interferes with state law** that is developing on this subject. Some commercial insurers are taking aggressive positions (albeit unsuccessfully in the courts) to preclude unlicensed but well-trained auxiliary personnel from performing physical therapy services. We have been directly involved in one of these cases and present the following for CMS’ careful consideration.

The Pennsylvania Insurance Department has specifically addressed this issue and decided that chiropractic physicians may delegate physical therapy procedures to unlicensed personnel, which would run contrary to the § 484.4 standards being proposed, and stated as follows:

The recent decision of the Supreme Court affirming the Commonwealth Court's Opinion in *Kleinberg v. Southeastern Penn. Transp. Auth.*, 765 A.2d 405 (Pa. Cmwlth. 2000), *aff'd* 810 A.2d 635 (Pa. 2002) has **not changed the Department's interpretation of the MVFRL**. In *Kleinberg*, the Commonwealth Court held that SEPTA was not required by [the MVFRL] to reimburse an osteopathic physician for physical therapy modalities delegated to unlicensed assistants. **Kleinberg has nothing to do with either chiropractors or adjunctive procedures**. The Supreme Court has explicitly recognized that adjunctive procedures performed by chiropractors in physical therapy are not legally the same. See *Bureau of Professional and Occupational Affairs v. State Board of Physical Therapy*, 556 Pa. 269, 728 A.2d 340 (1999). **Therefore, the Kleinberg decision does not change the Department's long-standing position that the MVFRL requires automobile insurers to pay first party claims involving those aspects of adjunctive procedures that may be properly delegated by chiropractors to unlicensed assistants**. The Department has discussed its interpretation with BPOA. The BPOA has confirmed that its interpretation has not changed post *Kleinberg*. However, the Department is not the proper forum to determine which aspects of adjunctive procedures may be properly delegated to unlicensed support personnel under the Act.

33 *Pa. Bulletin* 5888 (November 29, 2003) (emphasis added). The Notice also requires the chiropractic physician to make the diagnosis and evaluation, specify the treatment regimen, and perform any aspects of the adjunctive procedures that may not be delegated because they require the professional skill and education of a licensed chiropractic physician. *Id.* State Farm recently asserted a challenge to this delegation authority in federal court litigation against one of our doctors. The U.S. District Court for the Eastern District of Pennsylvania, on reconsideration, addressed State Farm's issues in great detail, analyzed the extensive legislative history surrounding § 601 of the Act, and held as follows:

As § 601's legislative history makes clear, the General Assembly **intended to authorize chiropractors to delegate adjunctive procedures to unlicensed supportive personnel**. There is

nothing in that legislative history to suggest another conclusion, and the contemporaneous statements of

legislators only support it. Senator Afflerbach's floor statement, which incorporates the May 22, 1996 letter by reference, plainly reveals that **the General Assembly intended for chiropractors to be able to delegate adjunctive procedures to unlicensed supportive personnel, and the fairest reading of Representative Civera's comments also supports this conclusion. Thus, we predict the Pennsylvania Supreme Court would interpret § 601 to permit licensed chiropractors to delegate adjunctive procedures to unlicensed supportive personnel under their direct on-premises supervision.**

State Farm v. All-Care, et al., 2004 WL 1446033 (E.D. Pa. 2004), pp. 4-5 (emphasis added). As the Eastern District Court's Opinion in State Farm illustrates, chiropractic physicians clearly can delegate adjunctive physical therapy procedures to unlicensed personnel.

Similarly, a Florida Court of Appeals, in another unsuccessful challenge by State Farm, concluded unequivocally that physicians may delegate physical therapy services to unlicensed personnel. State Farm v. Universal Medical Center of South Florida, ___ So. 2d ___ (Fla. Ct. App. 3rd Dist. 2004). On a similar note, a federal court in Minnesota dismissed a *qui tam* relator's complaint, concluding that physical therapy services could in fact be delegated to athletic trainers under the state regulatory paradigm. U.S. ex rel Lee v. Fairview Health System, 2004 WL 1638252 (D. Minn. 2004).

These decisions illustrate the fact that Pennsylvania and other states specifically authorize therapy services to be performed by unlicensed personnel. Commercial insurers, particularly State Farm, have endeavored to reduce their therapy costs by eradicating this long-standing protocol. Those efforts have been completely unsuccessful in the courts, which have interpreted state laws to specifically allow such delegation and supervision of therapy.

Based upon the statutory analysis outlined above, and in light of the quality, access, competition, physician-patient relationship and legal issues, it is not sound policy for Medicare beneficiaries to be deprived of these therapy services performed by well-trained, albeit unlicensed, therapy personnel under the direction and control of their treating physician. Retention of higher priced PTs and PTAs will also increase medical overhead costs, which is just the opposite of what is needed in this economic climate of rising costs, lower reimbursements, and the medical practice crisis and its attendant costs.

Based upon the foregoing, we respectfully request CMS withdraw the proposed regulation and not publish it in final form. Instead, CMS could develop a regulatory approach similar to that taken by the Pennsylvania Insurance Department, as follows:

- Physicians must render the diagnosis and evaluation of the patient (already required by the “incident to” rule);
- Physicians must specify, determine and order (in documentation contained in the medical record) the precise therapy treatment regimen to include the exact parameters of the treatment, technique to be applied, muscle location, amount of force (if relevant, i.e. in the context of a manual therapy procedure), and duration of the service;
- No discretion should be given to the auxiliary personnel;
- The unlicensed person must merely implement the rudimentary functions of the detailed regimen established by the physician under the physician’s on-premises supervision; and
- The physician’s documentation must support each of these criteria, as well as the criteria inherent to other aspects of the treatment including coding, documentation of service rendered for timed physical therapy codes, etc.

Were CMS to adopt these alternative standards, it would ensure that the requisite physician involvement would occur and be documented. It would be consistent with the statutory parameters under § 1862(a)(20) for “incident to” therapy services. Quality of care would be preserved. Potential problems relating to access to care, reduced competition, and interference with the physician-patient relationship would all be avoided.

Moreover, although chiropractors are physicians for purposes of spinal subluxation generally under the Medicare statute, 42 U.S.C. § 1395x(r)(5), a 2003 law created a Demonstration Project under which the full range of chiropractic services (including physical therapy which is within the scope of practice the vast majority of jurisdictions in the United States) are covered. This appears to allow therapy services to be performed and billed under the “incident to” rules (even CRNPs and PAs can bill therapy under the current “incident to”

regulations) via chiropractic physician supervision. Therefore, the issue is directly relevant to chiropractic physicians and the compelling analysis outlined above should result in CMS not publishing the proposed regulation in final form.

In the event CMS would reject this approach, our doctors would need express guidance from the federal government with respect to the type of person who would satisfy these criteria. For example, we request the following questions be addressed and answered:

1. Would a Doctor of Chiropractic satisfy the § 484.4 standards? All accredited chiropractic colleges throughout the United States require 4-year educational courses. Unlike PTs, virtually all states allow patients direct access to Doctors of Chiropractic. Under virtually all state laws, Doctors of Chiropractic have the duty, not just the authority, to render differential diagnoses on patients. Based upon our analysis, the chiropractic education is more extensive than the PTs'. Therefore, the § 484.4 standard would be satisfied, and a physician could delegate a therapy service and have it performed and billed under the "incident to" rules if a Doctor of Chiropractic performed the service and the physician otherwise satisfied each of the "incident to" rules.
2. Does a person such as an exercise physiologist, who has graduated from institutions such as Pennsylvania State University, West Chester University, and other universities renown for athletic training and exercise physiology programs qualify under the § 484.4 standards? It would appear the answer to that question would also be in the affirmative, but express guidance is needed in the event the proposed regulation becomes final.

We present one final public policy basis to preclude adoption of the proposed regulation. While we fully recognize CMS is concerned with the Medicare program, the reality is that many payors in many jurisdictions are either statutorily mandated or as a practical matter adopt new Medicare payment guidelines. In Pennsylvania for example, auto insurers and workers compensation insurers are mandated to follow Medicare guidelines. If Medicare adopts this regulation, other carriers will follow suit, which would have the result of a federal regulation disrupting, interfering or conflicting with current state laws. It is quite foreseeable that auto insurers and workers compensation insurers would immediately take the position that, in light of the § 484.4 standards, it would no

Centers for Medicare & Medicaid Services

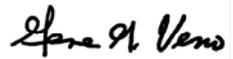
January 28, 2005

Page 8

longer have to pay for any therapy services performed “incident to” a physician or Doctor of Chiropractic that were performed by unlicensed, albeit well-qualified, well-trained and well-supervised individuals. This unintended consequence could be avoided if the regulation were not published in final form.

Thank you for your careful consideration of these important policy and legal issues.

Sincerely,

A handwritten signature in black ink that reads "Gene G. Veno". The signature is written in a cursive style and is enclosed in a thin black rectangular border.

Gene G. Veno
Executive Vice President

GGV/mab

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

See Attached letter.

Rae Emrick, MS, ATC, CSCS
MSC 1789
West Virginia Wesleyan College
59 College Ave.
Buckhannon, WV 26201

September 24, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1429-P
P.O. Box 8012
Baltimore, MD 21244-8012

Re: Therapy – Incident To

Dear Sir/Madam:

I am writing to express my concern over the recent proposal that would limit providers of “incident to” services in physician clinics. If adopted, this would eliminate the ability of qualified health care professionals to provide these important services. In turn, it would reduce the quality of health care for our Medicare patients and ultimately increase the costs associated with this service and place an undue burden on the health care system.

During the decision-making process, please consider the following:

- Incident to has, since the inception of the Medicare program in 1965, been utilized by physicians to allow others, under the direct supervision of the physician, to provide services as an adjunct to the physician’s professional services. A physician has the right to delegate the care of his or her patients to trained individuals (including certified athletic trainers) whom the physician deems knowledgeable and trained in the protocols to be administered. The physician’s choice of qualified therapy providers is inherent in the type of practice, medical subspecialty and individual patient.
- There have never been any limitations or restrictions placed upon the physician in terms of who he or she can utilize to provide ANY incident to service. Because the physician accepts legal responsibility for the individual under his or her supervision, Medicare and private payers have always relied upon the professional judgment of the physician to be able to determine who is or is not qualified to provide a particular service. It is imperative that physicians continue to make decisions in the best interests of the patients.
- In many cases, the change to “incident to” services reimbursement would render the physician unable to provide his or her patients with comprehensive, quickly accessible health care. The patient would be forced to see the physician and separately seek therapy treatments elsewhere, causing significant inconvenience and additional expense to the patient.
- This country is experiencing an increasing shortage of credentialed allied and other health care professionals, particularly in rural and outlying areas. If physicians are no longer allowed to utilize a variety of qualified health care professionals working “incident to” the physician, it is likely the patient will suffer delays in health care, greater cost and a lack of local and immediate treatment.
- Patients who would now be referred outside of the physician’s office would incur delays of access. In the case of rural Medicare patients, this could not only involve delays but, as mentioned above, cost the patient in time and travel expense. Delays would hinder the patient’s recovery and/or increase recovery time, which would ultimately add to the medical expenditures of Medicare.
- Curtailing to whom the physician can delegate “incident to” procedures will result in physicians performing more of these routine treatments themselves. Increasing the workload of physicians, who are already too busy, will take away from the physician’s ability to provide the best possible patient care.
- To allow only physical therapists and PT assistants, occupational therapists and OT assistants, and speech and language pathologists to provide “incident to” services would improperly provide those groups exclusive rights to Medicare reimbursement. To mandate that only those practitioners may provide “incident to” care in physicians’ offices would improperly remove the states’ right to license

and regulate the allied health care professions deemed qualified, safe and appropriate to provide health care services.

- CMS, in proposing this change, offers no evidence that there is a problem that is need of fixing. By all appearances, this is being done to appease the interests of a single professional group who would seek to establish themselves as the sole provider of therapy services.
- CMS does not have the statutory authority to restrict who can and cannot provide services “incident to” a physician office visit. In fact, this action could be construed as an unprecedented attempt by CMS, at the behest of a specific type of health professional, to seek exclusivity as a provider of physical therapy services.
- Independent research has demonstrated that the quality of services provided by certified athletic trainers is equal to the quality of services provided by physical therapists.
- Athletic trainers are employed by almost every U.S. post-secondary educational institution with an athletic program and every professional sports team in America to work with athletes to prevent, assess, treat and rehabilitate injuries sustained during athletic competition. In addition, dozens of athletic trainers will be accompanying the U.S. Olympic Team to Athens, Greece this summer to provide these services to the top athletes from the United States. For CMS to even suggest that athletic trainers are unqualified to provide these same services to a Medicare beneficiary who becomes injured as a result of running in a local 5K race and goes to their local physician for treatment of that injury is outrageous and unjustified.
- These issues may lead to more physician practices eliminating or severely limiting the number of Medicare patients they accept.

In summary, it is not necessary or advantageous for CMS to institute the changes proposed. This CMS recommendation is a health care access deterrent.

Sincerely,

Rae Emrick, MS, ATC, CSCS

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 1-9

PRACTICE EXPENSE

I'm a physician practicing in San Antonio for 30 yrs. & co-chair the Legislative/Socio-economics committee for Bexar County Medical Society representing over 3,700 Doctors. I have seen a gradual decrease in health care availability for Medicare patients in my city because other physicians are closing their practices to them--the reason being low reimbursement. Medicare patients are usually sicker and more complex requiring greater physician time and work. Anything that would improve reimbursement might result in better access for these patients by bringing more Doctors back as Medicare providers. Correcting the unfair classification of San Antonio in the GPCI category of 'Rest of Texas' would be a good start. This classification results in my reimbursement being 12% - 20% less than physicians in the other major Texas cities for the same medical service. May I add that San Antonio is the 2nd largest city in the state and the 8th largest in the nation and yet CMS continues to classify San Antonio with towns like Sweetwater, Navasota, and Beeville, just to name a few--get real! The cost of running my practice is the same if not more than my colleagues practicing in Austin, Beaumont, Brazoria, Dallas, Fort Worth, Galveston, and Houston. Yet for reasons that are not clear to me, they receive a higher GPCI category of reimbursement. I request that CMS designate San Antonio as a separate payment area (distinct locality) and recalculate the artificially low GPCI values for my city. I want to continue to provide care to my Medicare patients and yet be able to run a profitable practice where I can continue to employ qualified personnel and offer them benefits such as health insurance, retirement plans, etc. However, without some type of revision to my Medicare reimbursement, this may not continue to be a reality.

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

GENERAL

GENERAL

Please see the attached documents.

CMS-1429-P-4072-Attach-2.rtf

CMS-1429-P-4072-Attach-1.rtf



American Pharmacists Association

Improving medication use. Advancing patient care.

September 24, 2004

Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-1429-P
PO Box 8012
Baltimore, MD 21244-8012

RE: CMS-1429-P

Dear Sir/Madam:

Thank you for the opportunity to comment on the proposed rule making revisions to payment policies under the physician fee schedule payments for calendar year 2005. The American Pharmacists Association (APhA), founded in 1852 as the American Pharmaceutical Association, represents more than 50,000 practicing pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in advancing the profession. APhA, dedicated to helping all pharmacists improve medication use and advance patient care, is the first-established and largest association of pharmacists in the United States.

The proposed rule addresses several provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), including several of interest to the Association and its members: coverage of an initial preventive physical examination; coverage of cardiovascular screening blood tests; coverage of diabetes screening tests; payment for covered outpatient drugs and biologicals; and clinical conditions for payment of covered items of durable medical equipment. The Act is the most significant change to the Medicare program since its inception, and APhA commends the Administration and Congress for their efforts to provide prescription drug coverage for Medicare beneficiaries. However, APhA has concerns with the some of these provisions, and our comments will specifically focus on: The role of pharmacists in the provision of preventive benefits such as diabetes screening tests, cardiovascular screening blood tests, pneumococcal, influenza and hepatitis B vaccines and their administration, and bone mass measurements,

1. The adequacy of the proposed supplying fee for pharmacies which provide covered Part B medications,
2. The clinical conditions for coverage of durable medication equipment and prosthetics, orthotics and supplies (DMEPOS) , and
3. The omission of payment for valuable medication therapy management services that help ensure appropriate medication use.

Section 611: Initial Preventive Physical Examination

The MMA provides for coverage under Medicare Part B of an initial preventive exam for new beneficiaries, effective on or after January 1, 2005. This valuable new benefit may yield earlier diagnosis and treatment of chronic diseases, such as cardiovascular disease and diabetes. Under the MMA an

“initial preventive physical examination” consists of physicians’ and certain qualified non-physician practitioners’ services including, among others, education, counseling and referral with respect to screening and other preventive benefits separately authorized under Part B, such as:

- pneumococcal, influenza and hepatitis B vaccines and their administration
- diabetes outpatient self-management and training services
- bone mass measurements
- cardiovascular screening blood tests
- diabetes screening tests

The proposed rule allows for the practitioner providing the initial preventive physical examination to refer beneficiaries for services such as those listed above. However, the proposed rule defines a “qualified non-physician practitioner” as a physician assistant, nurse practitioner, or clinical nurse specialist. This definition fails to recognize that pharmacists are also qualified to provide many of these services. Pharmacists provide valuable medication-related services in conjunction with the screenings and preventive benefits noted above. Pharmacists are currently recognized and paid by Medicare Part B for the provision and administration of pneumococcal and influenza vaccines, and the MMA recognized pharmacists as providers of medication therapy management services under Medicare Part D. Pharmacists who meet the requirements of the Medicare diabetes self-management and training services are also currently reimbursed for these activities under Medicare Part B. Many pharmacists currently provide bone density and cholesterol screenings in their practice as well. As the goal of including these new preventive services is earlier diagnosis and treatment, it would seem logical to include pharmacists—the medication expert on the health care team—as an “other qualified non-physician practitioner” for those services within the pharmacist’s scope of practice. APhA encourages CMS to include pharmacists as qualified non-physician practitioners for the purposes of providing these valuable preventive benefits.

Section 303: Payment Reform for Covered Outpatient Drugs and Biologicals

The proposed rule implements modifications to the payment methodology for Part B covered drugs that are not paid on a cost or prospective payment basis (including immunosuppressive drugs, oral cancer medications, and oral anti-emetic drugs). Beginning in 2005, the MMA requires a new Average Sales Price (ASP) payment system for these drugs. APhA continues to be concerned that inadequate reimbursement for Part B drugs could have significant adverse effects. If pharmacists and other suppliers are unable to provide Part B products at the new reimbursement rate, many suppliers will choose to discontinue providing these drug products to physicians and their patients. This is especially concerning because Part B drugs such as immunosuppressants – drugs that can make the difference between life and death for transplant patients. Although pharmacists are dedicated to helping their patients, pharmacies may be forced to stop providing these drugs and accompanying services if the reimbursement rates do not cover their costs.

The Medicare Part B payment revisions contained in the MMA establish a new payment methodology intended to more accurately reimburse providers for their true costs associated with providing Part B drugs. The revisions attempt to create a reimbursement system that moves away from using the “spread” between estimated product cost and actual product cost to provide adequate payment, to a system that provides appropriate reimbursement for the cost to acquire the product and a separate reimbursement for the costs associated with administering and/or supplying the product.

Section 303(e)(2) of the MMA requires the Secretary to pay a pharmacy supplying fee for immunosuppressive drugs, oral anti-cancer agents, and oral anti-emetics used as part of a chemotherapy

regimen. The inclusion of this provision is of great significance to pharmacy suppliers. Traditionally, Medicare's payment policies for delivering pharmacy supplied drugs have been uneven. Pharmacists who billed Medicare only received a dispensing fee for one type of drug – inhalation therapy drugs. Similar to the increase in the drug administration fee for physicians, the new pharmacy supplying fee was included in the Act in recognition that current supply payments were inadequate to cover a pharmacy's costs.

The proposed rule includes a pharmacy supplying fee of \$10 effective January 2005. APhA is pleased that the Agency revised its stance from the interim final rule which did not include the pharmacy supplying fee, but we have concerns that the proposed level of reimbursement is inadequate. CMS asks for comments on the appropriateness of the supplying fee amount to assure beneficiary access to oral drugs. Because the law requires the establishment of a pharmacy supplying fee, it is the Agency's responsibility to determine – based on a sound economic analysis – the amount of the supplying fee necessary to cover costs associated with a pharmacy supplying the product. This fee may vary based on the product and the variables associated with its provision. CMS does not provide in the proposed rule a basis or rationale for the \$10 fee.

The supplying fee is intended to cover a pharmacy's activities to deliver oral medications to beneficiaries and is seeking comments on additional services pharmacists provide in conjunction with these medications. In addition, the Agency seeks comment on whether the fee should be higher during the initial month following a Medicare beneficiary's transplant. APhA supports the proposal for higher fees during the initial month following a transplant and encourages the Agency to explore this option. Examples of pharmacist's professional services provided to Medicare patients receiving Part B covered drugs include:

- Confirming the patient understands how to use the medication and is compliant with the medication regimen. This can involve face-to-face consultations and/or phone calls to the patient on a monthly or more frequent basis to assess compliance.
- Screening new prescriptions to make sure they do not interact with immunosuppressive medications. Some drug-drug interactions may lead to a decrease in effectiveness of the immunosuppressive medication's ability to prevent organ rejection.
- Maintaining an adequate inventory of extremely expensive medications to ensure convenient patient access to these vital medications.
- Individualized case management to ensure patients adhere to adjunct medications that prevent side effects and decrease risk factors, such as serious infections, hyperlipidemia, and hypertension.

CMS also fails to address issues related to administrative costs associated with filing Medicare claims. Unlike Medicaid claims, Medicare does not have a real time, point-of-service claims filing process. Medicare payment can often take weeks to process, and much longer if there is a problem with the claim submission. CMS recognized concerns with billing requirements and the proposed rule does make some changes and clarifications to billing requirements, including

- Clarifying the requirement for an "original signed order" by allowing durable medical equipment, including drugs, to be dispensed based on an oral order. A written order must be obtained before submitting a claim, but it may be faxed, photocopied, electronic or pen and ink.
- Elimination of the use of the Assignment of Benefits for Part B covered oral drugs
- Elimination of the DMERC Information Form

The proposed \$10 supplying fee is inadequate to cover both pharmacists' professional fees as well as administrative costs with the delivery of the drug and claims submission. APhA recommends the Agency undertake a careful review and study of the costs to provide these medications and services to Medicare beneficiaries. CMS should look at the various cost-to-dispense studies done across the country.

Section 305: Payment for Inhalation Drugs

Medicare Part B currently pays for nebulizers and inhalation drugs. The MMA allows coverage of metered dose inhalers (MDIs) and the inhalation drugs they furnish beginning January 2006. CMS believes there will be a substantial shift to MDIs because they are less expensive, portable, and easier to use. Medicare currently pays a monthly dispensing fee of \$5 for each covered inhalation drug or combination of drugs used in a nebulizer. The Agency is seeking comments about an appropriate amount for a dispensing fee that would assure beneficiary access to inhalation medications provided through nebulizers. Additionally, CMS proposes a separate dispensing fee to pharmacies that furnish inhalation drugs to Medicare beneficiaries and is concerned about beneficiary access to these drugs given the overall reduction in payment for inhalation drugs. CMS notes that because shipping, handling, compounding and other pharmacy activities would usually exceed the 6% payment above the drug acquisition costs, the Agency believes it is appropriate for Medicare to continue to pay a separate dispensing fee to pharmacies. This separate dispensing fee will be in addition to the difference between the supplier's acquisition cost and the Medicare payment for the drug. The Agency is seeking comments on an appropriate dispensing fee amount to cover these pharmacy activities.

APhA supports the Agency's desire to include a separate dispensing fee for inhalation drugs. As stated earlier, the Association is concerned that a reduction in the reimbursement for covered Part B drugs may hinder patient access to medications. A dispensing fee that covers the cost to provide the medication to the patient and provides a reasonable return to the pharmacy should be established. APhA recommends the Agency work with pharmacist and pharmacy organizations to establish an appropriate dispensing fee.

CMS also proposes to allow physicians to prescribe inhalation drugs for a 90-day period instead of the current one-month supply restriction. The Agency believes that significant savings will be achieved by mail order of 90-day supply. Savings can also be achieved by allowing non-mail service pharmacies to dispense 90-day supplies of medications. Any beneficiary cost-sharing for these products should not economically disadvantage beneficiaries who wish to receive their medications, including a 90-day supply, from their pharmacist of choice.

Medication Therapy Management Services

CMS also failed to recognize an important service to Medicare Part B beneficiaries. Through the revisions to the Part B reimbursement system, Congress attempted to create the "appropriate" reimbursement for drugs and biologics. Under the MMA, appropriate reimbursement includes payment for the cost to acquire the product, payment for physicians to administer the product, and payment for pharmacists to supply the product. However, both Congress and the Agency fail to recognize another component crucial to the provision of Medicare Part B products – medication therapy management services.

Modifications to the payment system must consider the role of pharmacists in ensuring appropriate medication use. Pharmacists provide services such as case management, disease management, patient training and education, and resolution of medication-related problems, as well as programs that enhance patient understanding of medication utilization, improve compliance, and reduce the potential for adverse drug events. APhA recently led efforts by the profession to define "medication therapy management services". This definition (attached) is supported by eleven national pharmacy organizations. These

services are essential to long-term survival of the Medicare program. If Medicare continues to pay for drugs without also paying for the services to ensure appropriate use, the government wastes its investment in those drugs. Paying for drugs which do not cure a disease or an infection because of inappropriate use costs the health care system more money due to hospitalizations, emergency room visits, and other procedures. Paying pharmacists to provide valuable medication therapy management services will actually save Medicare money in the long term. Part B payment should be expanded to include compensation for pharmacist-provided medication therapy management services.

In conclusion, APhA reiterates our support for efforts to create a more transparent system of paying for medications. We support a system that provides appropriate and adequate payment to cover pharmacists' costs to acquire a product that also includes a separate fee for costs associated with supplying the product. However, we have significant concerns with the revisions to the Medicare Part B reimbursement system. If pharmacies are unable to cover their costs, many will be forced to discontinue providing these products to Medicare beneficiaries. We encourage the Agency conduct an ongoing assessment to determine whether the reduced reimbursement rates are adequate for pharmacist and physician suppliers. Additionally, the Association encourages CMS to include pharmacists as a "qualified non-physician practitioner" in the preventive benefit provision for services provided within a pharmacist's scope of practice.

APhA offers our assistance in working with the Agency to determine the appropriate amount of this fee for Medicare Part B drugs, and the appropriate payment for pharmacist-provided medication therapy management services.

Thank you for your consideration of the views of the nation's pharmacists. Please contact Susan C. Winckler, Vice President, Policy & Communications and Staff Counsel, at 202-429-7533 or SWinckler@APhAnet.org, or Susan K. Bishop, Senior Manager, Regulatory Affairs & Political Action, at 202-429-7538 or SBishop@APhAnet.org with any questions.

Sincerely,



John A. Gans, PharmD
Executive Vice President

cc: Susan C. Winckler, RPh, Esq, Vice President, Policy & Communications and Staff Counsel
Susan K. Bishop, MA, Senior Manager, Regulatory Affairs & Political Action
Kristina E. Lunner, Director, Federal Government Affairs

Medication Therapy Management Services

Definition and Program Criteria

Medication Therapy Management is a distinct service or group of services that optimize therapeutic outcomes for individual patients. Medication Therapy Management Services are independent of, but can occur in conjunction with, the provision of a medication product.

Medication Therapy Management encompasses a broad range of professional activities and responsibilities within the licensed pharmacist's, or other qualified health care provider's, scope of practice. These services include but are not limited to the following, according to the individual needs of the patient:

- a. Performing or obtaining necessary assessments of the patient's health status;
- b. Formulating a medication treatment plan;
- c. Selecting, initiating, modifying, or administering medication therapy;
- d. Monitoring and evaluating the patient's response to therapy, including safety and effectiveness;
- e. Performing a comprehensive medication review to identify, resolve, and prevent medication-related problems, including adverse drug events;
- f. Documenting the care delivered and communicating essential information to the patient's other primary care providers;
- g. Providing verbal education and training designed to enhance patient understanding and appropriate use of his/her medications;
- h. Providing information, support services and resources designed to enhance patient adherence with his/her therapeutic regimens;
- i. Coordinating and integrating medication therapy management services within the broader health care-management services being provided to the patient.

A program that provides coverage for Medication Therapy Management services shall include:

- a. Patient-specific and individualized services or sets of services provided directly by a pharmacist to the patient*. These services are distinct from formulary development and use, generalized patient education and information activities, and other population-focused quality assurance measures for medication use.
- a. Face-to-face interaction between the patient* and the pharmacist as the preferred method of delivery. When patient-specific barriers to face-to-face communication exist, patients shall have equal access to appropriate alternative delivery methods. Medication Therapy Management programs shall include structures supporting the establishment and maintenance of the patient*-pharmacist relationship.
- b. Opportunities for pharmacists and other qualified health care providers to identify patients who should receive medication therapy management services.
- c. Payment for Medication Therapy Management Services consistent with Contemporary provider payment rates that are based on the time, clinical intensity, and resources required to provide services (e.g., Medicare Part A and/or Part B for CPT & RBRVS).
- d. Processes to improve continuity of care, outcomes, and outcome measures.

* In some situations, Medication Therapy Management Services may be provided to the caregiver or other persons involved in the care of the patient.

Approved July 27, 2004 by the Academy of Managed Care Pharmacy, the American Association of Colleges of Pharmacy, the American College of Apothecaries, the American College of Clinical Pharmacy, the American Society of Consultant Pharmacists, the American Pharmacists Association, the American Society of Health-System Pharmacists, the National Association of Boards of Pharmacy*, the National Association of Chain Drug Stores, the National Community Pharmacists Association and the National Council of State Pharmacy Association Executives.

* Organization policy does not allow NABP to take a position on payment issues.

Submitter : Mrs. Patricia Naylor Date & Time: 09/24/2004 08:09:19

Organization : Mrs. Patricia Naylor

Category : Physical Therapist

Issue Areas/Comments

GENERAL

GENERAL

Comments submitted related to issues 20-29.

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1429-P
P.O. Box 8012
Baltimore, MD 21244-8012

September 24, 2004

Subject: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005

To Whom It May Concern:

I am writing this letter in response to the August 5th proposed rule on the “Therapy-Incident To” revisions. I am a physical therapist in rural Southern Illinois. I have been licensed as a physical therapist for 12 years, and my background includes experience in acute care, neurorehabilitation, long-term care/skilled nursing, home health, and physical therapy education. I fully support the requirement that individuals providing physical therapy services “incident to” a physician should meet all of the qualifications required of individuals providing physical therapy services in any other setting.

The practice of physical therapy is now regulated at the state level in all 50 states. In order to be licensed as a physical therapist, an individual must be professionally educated at the post-baccalaureate level. All services that are represented as “physical therapy” must be provided by a licensed PT or a licensed physical therapist assistant under the direction of a licensed PT when provided in a hospital, nursing home, or outpatient clinic. In Illinois there are many examples of physician and chiropractic offices that provide “physical therapy” by on-the-job trained employees. The current incident to rule makes this circumvention of professional licensure possible in the physician’s office.

Physical therapy treatment provided by unqualified personnel results in less consistent health outcomes, and may result in injury to the patient. Professional licensure exists to protect the public from being harmed due to treatment by unqualified personnel. It is the type of care provided that determines who is qualified to provide it, not where it occurs, and therefore, the definition of who is “qualified” to provide a certain type of care should not change from one type of setting or one type of building to another. It is not possible to substitute on-the-job training for graduate level education and clinical experience in *any* setting. The proposed rule is an important and necessary step in improving the consistency and quality of care available to Medicare beneficiaries, and toward improving overall physical therapy outcomes.

Thank your for your consideration of these comments.

Sincerely,

Patricia Y. Naylor, PT, MS
3535 Pierland Drive
Pocahontas, IL 62275

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

GENERAL

GENERAL

In response to the section dealing with certified athletic trainers

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn.: CMS-1429-P
P.O. Box 8012
Baltimore, MD 21244-8012

Friday, September 24, 2004

Re: Therapy—Incident To Services

To Whom It May Concern:

I am writing in response to the recently issued document concerning “incident to” billing of outpatient therapy services to Medicare and Medicaid recipients. It is to my understanding that you wish to discontinue the allowance of billing of “incident to” outpatient therapy services by certified athletic trainers. I find this to be outrageous and degrading to myself as a medical professional.

As a certified athletic trainer currently employed in the clinical setting, I treat members of the physically active population, ranging in age from young children to older adults, some of which can be classified as high profile athletes/patients. In addition, I graduated from a four year university (Minnesota State University, Mankato, class of 2003) with a bachelor’s degree in athletic training in an extremely intense and high profile program. I have worked long and hard to achieve the knowledge and training that I currently possess, so for the federal government to not consider those in my profession qualified to care for our senior population is an insult.

We, as certified athletic trainers, have worked long and hard to get where we are and to show we deserve the recognition and responsibility we get. We have been trained to provide the services to which you are trying to revoke our privileges. We deserve to have the ability to provide services to all members of the physically active population, no matter how young or old they may be. Let’s keep the future of certified athletic trainers in the medical profession heading uphill, not down.

Thank you for your time and consideration.

Sincerely,

Jessica M. Van Handel, ATC/R
Orthopaedic and Fracture Clinic
Physical Therapy and Sports Medicine
Mankato, MN 56001

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

GENERAL

GENERAL

Re: CMS-1429-P -- Medical Metrx Solutions, Inc. Comments on the Proposed Rule for Calendar Year 2005 Payment Policies Under the Physician Fee Schedule

To Whom It May Concern:

Enclosed please find comments submitted on behalf of Medical Metrx Solutions, Inc. regarding the proposed rule revising payment policies under the Medicare Physician Fee Schedule for Calendar Year 2005. These comments also have been submitted via hand delivery. Please contact me at michael_ruggiero@aporter.com, 202-942-6365 with any questions.

Sincerely,

Michael J. Ruggiero
Arnold & Porter

CMS-1429-P-4075-Attach-1.pdf

CMS-1429-P-4075-Attach-2.pdf

CMS-1429-P-4075-Attach-3.pdf

CMS-1429-P-4075-Attach-4.pdf



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August 20, 2004

Mark B. McClellan, M.D.
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, S.W.
Room 314-G
Washington, DC 20201

Dear Dr. McClellan:

I write on behalf of the Society for Vascular Surgery (SVS) to underscore the need to revise the APC code descriptor for G0288 ("Reconstruction, computed tomographic angiography of aorta for preoperative planning and evaluation post vascular surgery"). Specifically, the descriptor for G0288 should be revised so that it requires the use of three-dimensional pre-operative and post-operative computer-aided measurement planning and simulation ("3-D CAMPS") technologies that are capable of providing the anatomic measurements recognized by the FDA as sufficient for pre-operative planning and post-surgical monitoring in connection with the treatment of abdominal aortic aneurysms (AAAs).

The development of 3D-CAMPS was driven largely by FDA's concerns about serious complications reported with stent grafts. On April 27, 2001, FDA issued a Public Health Notification expressing concerns about reports of serious adverse events with stent grafts thought to be associated with sub-optimal graft placement, endoleak, graft migration, problems with device integrity, and aneurysm anatomy.¹ In the notification, the FDA said it is "critical that physicians who evaluate and treat AAA patients have the information needed to make informed decisions on patient selection, device selection, and follow-up management." The FDA said it would work with manufacturers to "obtain relevant data that will help us understand how these problems affect the overall risk/benefit assessment of this product."

Shortly after issuing the 2001 public notification on stent grafts, the FDA began consultations with representatives from SVS, Medical Metrx Solutions (MMS, a developer of 3D-CAMPS technology), and stent graft manufacturers to develop a system that would enable post-surgical monitoring of AAA patients. Through this collaborative process, a suite of anatomical

¹ See Food and Drug Administration, "FDA Public Health Notification: Problems with Endovascular Grafts for Treatment of Abdominal Aortic Aneurysm (AAA)" (April 27, 2001); See also Food and Drug Administration, "FDA Public Health Notification: Updated Data on Mortality Associated with Medtronic AVE AneuRx® Stent Graft System" (December 17, 2003).

measurements was developed that was deemed by FDA to be the standard of care for post-operative monitoring of stent graft implantation, including to assess the need to correct graft migration or loss of exclusion of aortic pressure from the aneurysm sac. This list of measurements is attached.

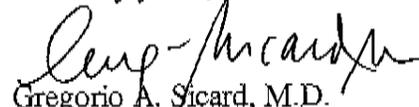
These measurements became the basis for Preview®, the first 3D-CAMPS technology, which was developed by MMS, and also enabled the establishment of the Patient Evaluation and Management System (PEMS), an Internet-based postmarketing surveillance database that catalogues the therapeutic outcomes of AAA patients. PEMS provides a powerful tool to conduct the postmarketing surveillance FDA requires for stent graft implantation.

In addition to its central role in AAA postmarketing surveillance, we also consider 3D-CAMPS to be the standard of care for pre-surgical treatment planning and the most effective means of meeting the stent graft labeling requirements for pre-operative measurement. The precise measurements provided by this technology greatly enhance a surgeon's ability to plan the intervention, and thereby minimize the incidence of complications attributable to improper patient or graft selection and incorrect graft placement. Surgical planning for AAAs also can benefit significantly from the PEMS database; physicians can use the information in PEMS to determine the relative suitability of patients for particular modes of treatment based on the outcomes data available in the database.

Last year, CMS expired the APC code C9708 ("Preview Treatment Planning Software"), which theretofore had been used to bill for 3D-CAMPS, and replaced this code with G0288. Our main concern with G0288 is that its descriptor does not restrict its use to those technologies that are capable of providing the critical measurements that are the essence of 3D-CAMPS technology. In order to ensure appropriate payment for and rapid adoption of 3D-CAMPS technology, CMS should revise the G0288 descriptor to ensure that it can only be used for products that are true 3D-CAMPS technologies, and not for less sophisticated and less costly technologies that do not achieve the standard of care for pre-operative planning and post-surgical monitoring of AAA interventions. These measurements are currently provided by the MMS Preview® and PEMS product, but can be produced on any properly operated 3-D CT workstation. The SVS is therefore not endorsing a single commercial provider, but rather pointing out the importance of including a requirement for these measurements within the G0288 descriptor.

We would be pleased to meet with you or your staff to discuss the importance of 3D-CAMPS, and to provide you with any additional information that might assist in your consideration of this matter.

Sincerely yours,



Gregorio A. Sicard, M.D.

President

Society for Vascular Surgery

Preoperative			Postoperative	
Measurement	Rationale		Measurement	Rationale
VOLUME			VOLUME	
1. AAA Sac Volume (cc)	Assess Risk of Rupture		1. AAA Sac Volume 1(cc)	Assess Effectiveness of Graft
2. AAA + Iliac Volume(cc)	Assess Risk of Rupture		2. AAA + Iliac 2(cc)	Assess Effectiveness of Graft
			3. Endoleak Volume (cc)	Assess Progress of Endoleak for Possible Intervention
AORTIC DIAMETERS			AORTIC DIAMETERS	
3. Maximum AAA Diameter (mm)	Assess Risk of Rupture		4. Maximum AAA Diameter (mm)	Assess Effectiveness of Stent-Graft
4. Minimum Suprarenal Aortic Diameter (mm)	Sizing Proximal Diameter for Suprarenal Fixation Stent-Graft		5. Aortic Diameter at Renals (mm)	Assess Possible Changes to Aorta Diameter that Could Lead to Graft Failure
5. Aortic Diameter at Renals (mm)	Sizing Proximal Diameter for Infrarenal Fixation Stent-Graft		6. Aortic Diameter at Top of Stent-graft (mm)	Assess Possible Changes to Aorta Diameter that Could Lead to Graft Failure
6. Aortic Diameter 15mm Below Renals (mm)	Assessing Proximal Neck Diameter for Stent-Graft Suitability		7. Aortic Diameter 10mm Below Top of Stent-graft (mm)	Assess Possible Changes to Aorta Diameter that Could Lead to Graft Failure
7. Aortic Diameter at Distal End of Proximal Neck (mm)	Assessing Proximal Neck Diameter for Stent-Graft Suitability		8. Aortic Diameter at Most Proximal Stent-graft Apposition (mm)	Assess Possible Changes to Aorta Diameter that Could Lead to Graft Failure
8. Diameter of Distal Aorta (mm)	Assessing Aorta Diameter for Passing Stent-Graft Distal Limbs		9. Aortic Diameter at Most Distal Stent-graft Apposition (mm)	Assess Possible Changes to Aorta Diameter that Could Lead to Graft Failure
			10. Aortic Diameter 15mm Below Renals (mm)	Assess Possible Changes to Aorta Diameter that Could Lead to Graft Failure
ILIAC DIAMETERS			ILIAC DIAMETERS	
9. Diameter at Right Common Iliac Landing Zone (mm)	Assessing Iliac Diameter for Stent-Graft Distal Limb Suitability		11. Diameter at Right Iliac Proximal Stent-graft Apposition (mm)	Assess Possible Changes to Iliac Diameter that Could Lead to Graft Failure
10. Diameter at Left Common Iliac Landing Zone (mm)	Assessing Iliac Diameter for Stent-Graft Distal Limb Suitability		12. Diameter at Right Iliac Distal Stent-graft Apposition (mm)	Assess Possible Changes to Iliac Diameter that Could Lead to Graft Failure

Preoperative		Postoperative	
Measurement	Rationale	Measurement	Rationale
11. Minimum Access Diameter of Right External Iliac (mm)	Assessing Approach for Stent-Graft Delivery System	13. Diameter at Left Iliac Proximal Stent-graft Apposition (mm)	Assess Possible Changes to Iliac Diameter that Could Lead to Graft Failure
12. Minimum Access Diameter of Left External Iliac (mm)	Assessing Approach for Stent-Graft Delivery System	14. Diameter at Left Iliac Distal Stent-graft Apposition (mm)	Assess Possible Changes to Iliac Diameter that Could Lead to Graft Failure
VESSEL LENGTHS		GRAFT APPPOSITION LENGTHS	
13. Proximal Neck Length (mm)	Assessing Proximal Neck Seal Zone for Stent-Graft	15. Proximal Neck Graft Apposition Length (mm)	Assess Possible Loss of Seal that Could Lead to Stent-Graft Failure
14. Renal to Aortic Bifurcation Length (mm)	Determining Size of Stent-Graft	16. Right Iliac Graft Apposition Length (mm)	Assess Possible Loss of Seal that Could Lead to Stent-Graft Failure
15. Renal to Right Internal Iliac Length (mm)	Determining Size of Stent-Graft	17. Left Iliac Graft Apposition Length (mm)	Assess Possible Loss of Seal that Could Lead to Stent-Graft Failure
16. Renal to Left Internal Iliac Length (mm)	Determining Size of Stent-Graft	PROXIMAL NECK ANGULATION	
ANGULATION / TORTUOSITY		18. Angle Proximal Neck to AAA Body (degrees)	Assess Morphology Changes that Could Lead to Graft Failure
17. Angle Proximal Neck to AAA Body (degrees)	Determining Suitability of Aorta for Stent-Graft	19. Angle Suprarenal Aorta to Proximal Neck (degrees)	Assess Morphology Changes that Could Lead to Graft Failure
18. Angle Suprarenal Aorta to Proximal Neck (degrees)	Determining Suitability of Aorta for Suprarenal Stent-Graft	DEVICE MIGRATION	
19. C-Arm Gantry Correction Angle (degrees)	Proper Intra-operative Placement of C-Arm to Prevent Parallax Error in Placing Stent-Graft Proximally	20. Distance From Distal Renal to Top of Graft (mm)	Assess Possible Device Migration

Endovascular Aneurysm Repair: 3-D Computer Aided Measuring and Planning Software (CAMPS) and Conventional Angiography
by Dr. Mark Fillinger

The advent of endovascular repairs of abdominal aortic aneurysms (AAA) in the early 1990's has had a profound effect on the management of this disease. AAA's represent a progressive, localized degeneration and concomitant enlargement of the aorta. Although debated, an enlargement greater than 50% of the adjacent aorta is generally considered to define an aneurysm. In clinical practice, this usually correlates with an aortic diameter of 3 cm. The etiology of this degeneration is multi-factorial, likely secondary to a combination of genetic predisposition, environmental conditions and risk factors including tobacco use, hypercholesterolemia and hypertension. The actual incidence of AAA's is difficult to assess because of a lack of formal surveillance data. It is estimated that the likelihood of developing a AAA varies from 3 to 117 per 100,000 person years.¹ The 1-year risk of aneurysm rupture increases with increasing aortic diameter and is estimated at approximately 9.4% for AAA's measuring between 5.5 and 5.9 cm, but increases to 32.5% for aneurysm's greater than 7 cm.²

In 1991 Parodi introduced the medical community to the endovascular technique for the repair of AAA's.³ Since then, there have been progressive advancements in the devices and techniques used to perform these endovascular aneurysm repairs. This has resulted in a significant shift in the management of aneurysms. Although open surgical replacement of the aneurismal segment used to account for almost all of the nearly 40,000 AAA repairs performed annually, approximately 36% of all current aneurysm repairs are being performed via an endovascular approach.⁴ Ongoing improvements, the introduction of FDA approved devices and recent studies demonstrating effectiveness will likely continue to fuel the shift towards the endovascular management of AAA's.⁴⁻⁹

Although the fundamental principle of endovascular aneurysm repairs is similar to open surgical repair, to isolate the aneurismal segment of aorta from the systemic blood flow, the technique is significantly different. It is dependent on the precise, intra-vascular placement of an expandable stent graft that excludes the aneurysm. Successful exclusion mandates that there is an adequate region of seal between the aortic wall and the proximal and distal extents of the stent. If the stent-graft fails to make a complete seal with the aortic wall, the aneurysm sac remains subject to the systemic blood pressure and, therefore, susceptible to aneurysm rupture. Since these endovascular systems are delivered via an endovascular deployment system, only minimal changes can be made to its size and position once the device is in place. Furthermore, although there are exceptions, the device is usually deployed between the level of the renal arteries and the bifurcation of the hypogastric vessels in the pelvis. Obviously, the inadvertent deployment of the device across the renal or hypogastric arteries could result in substantial patient morbidity.

In order to ensure the accurate placement of endovascular grafts, meticulous pre-operative planning is necessary. Inappropriate or incorrect planning can result in catastrophic consequences for the patient. Several morphologic measurements are needed in order to select the appropriate device. Furthermore, specific characteristics of the patient's vascular anatomy directly impact the deployment approach and the final

success of the actual device. Figure 1 lists the necessary preoperative measurements and calculations for successful pre-operative planning.

<u>Mandatory Pre-operative Measurements</u>
Diameter of Aortic Neck at Renals
Maximal Aortic Diameter
Diameter at the Aortic Bifurcation
Common Iliac and External Iliac maximum diameters
Common Iliac and External Iliac minimum diameters
Length of Infra-renal Aortic Neck
Length from renal arteries to aortic bifurcation
Length from renal arteries to hypogastric bifurcation
Length of iliac seal zones
Angulation of Aortic neck
Amount of thrombus at the infra-renal aortic neck

Figure 1
Necessary AAA
morphologic
measurements
for pre-
operative
endovascular
planning

Each of these is used for the of a patient's an

measurements determination eligibility for endovascular

repair as well as the actual planning of the repair. If any one of these measurements do not meet specified requirements, the patient may not be an appropriate candidate for the specific device. For example, at this time, the two commercially available endograft systems (Gore Excluder and Cook Zenith) are limited to aneurysms that have a proximal aortic neck diameter ranging between 18mm and 28mm. If the actual aortic diameter exceeds this range by only 1-2 mm, there is a strong likelihood of an inadequate seal between the stent-graft and the aortic wall with a resulting persistent leak into the aneurysm sac. This failure to exclude the aneurysm would require an adjunctive means of treatment. The importance of accurate measurements can not be over emphasized.

These morphologic measurements can be obtained via a number of different imaging modalities. Figure 2 lists the available imaging alternatives.

<u>Imaging Modalities</u>
Computed Tomography (CT)
Computed Tomographic Angiography (CTA)
Magnetic Resonance Imaging (MRI)
Magnetic Resonance Angiography (MRA)
Conventional Angiography
Transabdominal Ultrasound
Intravascular Ultrasound

Figure 2 Imaging Modalities

Historically, open AAA repairs were all preceded by conventional angiography.^{10, 11} As non-invasive means of evaluating the aorta became more reliable and available, the trend moved away from angiography. At first, axial and then later, spiral CT scans became the mainstay of pre-operative evaluation for aneurysm repairs. The use of MRI/MRA and ultrasound has also been discussed and advocated by some, but the resolution, availability and consistency are not equivalent to the results obtained with CT and CTA. The trend began to swing back towards the use of contrast angiography with the introduction of

endovascular repair systems. This requirement stemmed predominantly from the need for accurate and spatially oriented 3-D evaluations of the aneurysm morphology. At this time in the 1990's, 3-D Computer Aided Measurement and Planning Software (CAMPS) was in its initial phase of development. The lower resolution, thicker slice (5-10mm/slice) axial CT scans could not provide all the necessary information for obtaining the required measurements listed in Figure 1. Although the CT and contrast-enhanced CTA were significantly more specific than angiography for determining vessel diameters, lumen diameters and identifying intra-luminal thrombus and calcifications, the coarse slice thickness and axial orientation of the scans made accurate length and angle determinations difficult. Therefore, routine pre-operative aortic and pelvic angiograms were performed to fill the voids left by the CT scans. With the addition of a graduated marker catheter during the angiography, these additional views facilitated a more accurate representation of the true center-line anatomic lengths, neck and iliac angulation and overall vessel tortuosity, thereby compensating for the deficiencies of the CT scans. These combined imaging modalities allowed more accurate pre-operative planning for the endovascular repairs—the critical part of all such repairs.

The added use of angiography, however, did not come without an additional cost. Angiography is an invasive procedure requiring arterial access and the passage of guidewires and catheters throughout the vascular anatomy. The potential complications of angiography are widespread.¹² Additionally, the nephrotoxic and allergic potential of the contrast used during the procedure carry a small, but real risk for the patient.¹³ In an earlier study of 190 patients undergoing angiography for evaluation of abdominal aortic aneurysms, Brewster et al reported complications, albeit rare, including puncture-site hematoma (1), localized dissections(2) and transient renal dysfunction(1) for an overall complication rate of 2 percent.¹⁴ In a later evaluation of arteriography-related complications, AbuRahma et al evaluated 707 consecutive patients undergoing angiograms for any reason.¹⁵ The minor complication rate, major complication rate and mortality were 7.9%, 7.1% and 0.7%, respectively, for an overall complication rate of 14.3%. These complications included hematomas(9.8%), thrombo-embolic events(0.6%), vessel thrombosis, neurologic injuries of the femoral nerve(transfemoral approach) and brachial plexus(transaxillary approach), puncture-site infections(0.3%), myocardial infarctions(0.3%), angina and cardiac arrhythmias(1.1%), acute renal failure(1.7%) and allergic reactions(0.14%). Thus, it is evident that angiography carries a moderate amount of risk. Clearly, a non-invasive means of conducting a thorough pre-operative evaluation of patients who are candidates for an endovascular repair of their aneurysm would be preferable.

The development of 3-D CAMPS systems has progressed rapidly. These Computer Aided Measuring and Planning Software systems utilize the raw data generated by a standard CT scan to develop an interactive, 3-D reconstruction capable of multiple-angle viewing and manipulation, spatial orientation, vessel centerline and distance measurements, vessel and lumen diameter determinations and angle calculations. Therefore, by nature of their 3-D capabilities, these systems offer a potential modality that is capable of negating the requirement for pre-operative angiograms in patients being evaluated for endovascular repairs of their AAA. Their successful use for this indication however, is predicated on their ability to accurately and precisely replace these former imaging protocols.

In order to review the potential of CAMPS based systems, a Medline search using OVID was performed from 1966 to March 2004. 76 articles were initially returned. There was a paucity of data in the pre-1990 era, likely secondary to the relative novelty of CT scanners at that time. Articles addressing either the use of CT scans for the evaluation of AAA, or comparing the use of CT scans with or without concurrent angiography were selected for further review. Articles were selected according to their specific relevance to AAA or endovascular repairs, their study design, patient sample size and timeliness.

A total of 32 articles were selected. These are listed in Table 1.

Author	Title	Year	N (cases)	Enrollment	Study Type	Tech nique	CT w/ 3-D reco	CT only	Angio Only	CT c/w Angio	CT c/w Surg	Path/Morph ID	EVAR planning	Sole use for EVAR	Measurements	Accuracy	Notes
Van der Laan, et al ¹⁶	Preprocedural Imaging	2002	--	--	D		x			x							
Fillinger ¹⁷	Imaging of the Thoracic and...	2000	--	--	D	x	x	x				x	x		x		
Fillinger ¹⁸	Advances in Imaging for Vascular and Endovascular Surgery		--	--	D		x			x		x	x		x		1
Beebe, et al ¹⁹	Imaging modalities for Aortic Endografting	1997	--	--	D		x			x			x		x		
Costello, et al ²⁰	Spiral CT Angiography of AAA	1995	28	U	RR	x	x			x		x			x		
Diethrich ²¹	Will contrast aortography become obsolete...	1997	--		D		x			x							
Shin, et al ²²	Preoperative neck measurements for endovascular aortic	1999	--		A	x		x							x	x	2
Bradshaw, et al ²³	Multiplanar reformatting and three-dimensional ...	1998	53	U	RR	x	x				x	x			x		
Fillinger, et al ²⁴	The "Virtual" Graft: Preoperative simulation	1997	--		A	x	x	x					x		x	x	

Author	Title	Year	N (cases)	Enrollment	Study Type	Tech nique	CT w/ 3-D reco	CT only	Angio Only	CT c/w Angio	CT c/w Surg	Path/Morph ID	EVAR planning	Sole use for EVAR	Measurements	Accuracy	Notes
Fillinger, et al ²⁵	Utility of Spiral CT in the Preoperative evaluation...	1997	--		D	x	x			x		x	x		x	x	
Balm, et al ²⁶	Spiral CT—Angiography of the aorta	1994	17	U	RR	x	x	x				x	x		x	x	
Rubin, et al ²⁷	Three-dimensional spiral CTA...	1993	35	C	RR	x	x			x		x			x	x	
Rubin, et al ²⁸	Measurement of the Aorta and its....	1998	4	C	PS	x		x							x	x	2
Moritz, et al ²⁹	Infrarenal AAA: Implications of CT evaluation of size...	1996	77	C	RR	x		x				x			x		
Bayle, et al ³⁰	Morphologic assessment of abdominal aortic...	1997	86	C	PR	x	x	x				x	x		x		
Deaton ³¹	Endovascular aortic reconstruction	2003	--		D		x	x					x		x		
Brown, et al ³²	Is Aortic angio...	2003	54	C	PR	x	x			x		x	x		x	x	12
Aziz, et al ³³	Accuracy of Three dim...	2003	85	U	RR	x	x	x				x	x		x	x	3
Beebe et al ³⁴	Aortic Aneurysm ..	1995	50	C	RR		x			x		x	x		x	x	4
Broeders, et al ³⁵	Pre-operative Sizing of...	1997	21	C	PR	x	x			x		x	x		x		5
Wyers, et al ³⁶	Endovascular repair of ...	2003	196	C	RR	x	x	x				x	x	x	x	x	6
Shin, et al ³⁷	Can Preop spiral CT	2000	31	N	RR					x					x		7
Beebe, et al ³⁸	Endograft Planning...	2000	25	C	PR	x	x	x				x	x	x	x		
Resch, et al ³⁹	Abdominal Aortic...	1999	133	U	RR	x				x		x	x		x		
L Van Hoe, et al ⁴⁰	Supra- and juxta...	1996	38	U	A		x			x		x					
Armon, et al ⁴¹	Spiral CT angiography	1998	108	U	RR	x				x		x	x		x	x	8

Author	Title	Year	N (cases)	Enrollment	Study Type	Tech nique	CT w/ 3-D reco	CT only	Angio Only	CT c/w Angio	CT c/w Surg	Path/Morph ID	EVAR planning	Sole use for EVAR	Measurements	Accuracy	Notes
Cikrit, et al ⁴²	Comparison of Spiral CT	1996	32	U	RR	x	x			x		x					9
Salaman, et al ⁴³	Intravenous digital sub...	1994	127	U	RR	x				x	x	x				x	10
Gomes, et al ⁴⁴	Preoperative assessment...	1994	32	U	RR	x	x			x		x					
Simoni, et al ⁴⁵	Helical CT for the Study...	1996	33	U	RR	x				x	x	x					
Rieker, et al ⁴⁶	CT Angio...	1997	30	C	PR	x				x		x					11
Whittaker, et al ⁴⁷	Prediction of Altered Endo..	2004	50	C	RR		x					x	x	x	x	x	

Table 1: Selected literature

(RR, Retrospective review; PR, prospective review; PS, Prospective study; D, discussion; U, unknown; A, abstract; C, consecutive; N, non-consecutive

Notes: 1.volume measurements; 2. Use of phantoms; 3. comparison w/ conventional CT and IVUS; 4. Complimentary use of CT and CA; 5. Curved linear reformats, not 3-D; compared with conventional 2-D CT; 6, Best study; 7. 2-D spiral CT only; 8. 2-D CT; 9. Predominantly visceral and renal vessels; 10. 2-D CT; 11. Aorto-occlusive dx, no AAA's; 12. CT underestimates iliac vessel tortuosity;)

Definitions: *Accuracy:* comparison to phantoms, operative measurements or other imaging modalities; *Measurements:* obtaining numerical distances and diameters.

Ideally, the evaluation of CAMPS based systems in the management of AAA's requires a careful assessment of the CT's potential to completely replace the need for adjunctive imaging modalities. The literature in Table 1 can be evaluated and used as a means to that end. Table 1 lists the individual manuscripts and classifies them based on a number of different criteria. Although there were no randomized, controlled, prospective studies found in this literature search, there were 20 prospective or retrospective reviews. The remainder of the manuscripts were divided into 7 discussions, 3 abstracts and one study by Rubin, GD et al that prospectively compared actual phantom models with the resultant CT images to determine the accuracy of CT's evaluation of luminal diameter and curvature.

As the table depicts, each of these papers focused on different patient populations with different study endpoints. The earlier studies were clearly performed before endovascular AAA's were an accepted treatment modality. These studies tended to forego actual measurements in lieu of aortic morphology and spatial relationships with surrounding structures. The progression of time and technology from the 1990's to the present has allowed more CT imaging alternatives, increased resolution and enhanced post-processing capabilities. Together, these earlier studies have served as a foundation

for the most recent, stand-alone studies demonstrating the efficacy of CT alone in the pre-operative evaluation of patients for endovascular AAA repair. Many of the inaccuracies attributed to CT AAA evaluations in the earlier years have been eradicated by the new technologies of the current generation CT scanners.

The papers by Beebe et al and Wyers et al represent the most recent evidence in support of the use of 3-D CAMPS based CT images as the sole source of pre-operative planning for treatment of AAA patients with EVAR techniques.

In Wyers et al's paper from 2003, his group from Dartmouth Hitchcock Medical Center performed EVAR's on 196 patients between 1996 and 2001 using only 3-D CAMPS as the sole preoperative planning software. For a smaller subset of patients, the 3-D reconstructions were more accurate than comparative angiography in determining endograft length and iliac access. Their in-hospital patient mortality rate was 0% and 94% were free from secondary procedures at 1 year—a strong indication of successful, accurate and well designed pre-operative planning of the appropriate endograft type and size for the specific aneurysm. Furthermore, they had no known measurement related complications in this series.

Beebe's cohort was smaller than Wyer's, but the results were as equally impressive. This study evaluated 25 consecutive patients with AAA who were evaluated for EVAR by spiral CT and 3-D CAMPS. They reported no graft-related complications or deaths. All endografts were deployed as planned using the 3-D CAMPS reconstructions and virtual grafts.

It is clear that there is a definite relationship between the generation of CT scans used, the type of CAMP software employed during the 3-D reconstructions and the results obtained. The earlier validation studies based on 2-D axial CT scans lack the same accuracy and stand-alone capability demonstrated by the later generation spiral CT's with CAMPS based 3-D reconstructions.

With the recent advances in 3-D reconstructions and the ongoing improvements in CT imaging, the evidence appears to support a trend toward the use of CT scans with 3-D reconstructions and measuring capabilities as the sole requirement in pre-operative imaging for patients with AAA being considered for repair with an endovascular system. The reduced morbidity of the CT scans in comparison to angiography coupled with CT's enhanced measurement and planning capabilities make this the modality of choice. There is, however, a current lack of Level I evidence supporting this logical claim. At the time of this review, there have been no randomized, controlled studies evaluating the sole use of 3-D CT's and CAMP based software in the planning for EVAR.

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September 24, 2004

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VIA ELECTRONIC SUBMISSION AND HAND DELIVERY

Re: CMS-1429-P -- Comments on the Proposed Rule for Calendar Year 2005
Payment Policies Under the Physician Fee Schedule

I. INTRODUCTION

MMS appreciates this opportunity to submit comments to the Centers for Medicare and Medicaid Services (“CMS”) concerning the proposed rule revisions to the payment policies under the Medicare Physician Fee Schedule for calendar year 2005 (the “Proposed Rule”).¹ Specifically, we wish to comment on the Proposed Rule’s treatment of three-dimensional pre-operative and post-operative computer-aided measurement planning and simulation (“3D-CAMPS”) technology, which currently is reported by physicians under G0288, “Reconstruction, computed tomographic angiography of aorta for preoperative planning and evaluation post vascular surgery.”

As we have conveyed to CMS in a number of other contexts, “3D-CAMPS” refers to a specific and unique type of health information technology service that enables vascular surgeons to deliver the highest form of treatment for abdominal aortic aneurysms (“AAAs”) and thoracic aortic aneurysms (“TAAs”). Our product Preview® was the first commercially marketed 3D-CAMPS service. Significantly, 3D-CAMPS and Preview are not synonymous; rather, 3D-CAMPS is a non-proprietary generic term that refers to a software technology that delivers precise anatomical measurements and three-dimensional modeling in conformance with a specific suite of measurements endorsed by the Society for Vascular Surgery and recognized by the Food and Drug Administration as adequate for postmarketing surveillance of stent grafts.

¹ See Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for the Calendar Year 2005, 69 Fed. Reg. 47,488 (proposed August 5, 2005).

We have two principal concerns with the Proposed Rule. First, the descriptor for G0288, the creation of which CMS announced in the calendar year 2003 Physician Fee Schedule final rule, fails to describe 3D-CAMPS technology with adequate specificity and accuracy. Second, the valuation for G0288 is not based on any meaningful analysis of the practice expense associated with providing this service, and thus produces an inadequate payment level. We therefore urge CMS to adopt appropriate measures to address these problems so that Medicare beneficiaries and their physicians can continue to benefit from the use of 3D-CAMPS technology.

II. BACKGROUND ON 3D-CAMPS

Before the development of 3D-CAMPS technology, the primary tool for surgical planning and post-procedure monitoring for AAAs and TAAs was an angiogram, which is a costly, invasive procedure that presents significant health risks to Medicare patients. 3D-CAMPS provides physicians with detailed anatomic measurements and a far more accurate picture of a patient's condition compared to angiograms, at significantly less cost to the health care system. 3D-CAMPS's measurements, along with its highly accurate multi-model object planning tool, are the basis for physicians to execute AAA and TAA surgical planning and post-operative evaluation.

The development of 3D-CAMPS was driven largely by FDA's concerns with serious complications reported with stent grafts.² Shortly after issuing a public notification on these devices in 2001, FDA began consultations with representatives from the Society for Vascular Surgery ("SVS"), MMS, and stent graft manufacturers to develop a system that would enable post-surgical monitoring of AAA patients. Through this collaborative process, a suite of anatomical measurements was developed that was deemed by FDA to be the standard of care for post-operative monitoring of stent graft implantation, including to assess the need to correct graft migration or loss of exclusion of aortic pressure from the aneurysm sac. This suite of measurements, along with other functionality specifications (including the ability to perform multi-object three-dimensional modeling), became the basis of 3D-CAMPS technology, which was first developed by MMS in the form of its Preview product.³ (The 3D-CAMPS measurement suite is attached.)

² On April 27, 2001, FDA issued a Public Health Notification expressing concerns with reports of serious adverse events with stent grafts thought to be associated with sub-optimal graft placement, endoleak, graft migration, problems with device integrity, and aneurysm anatomy. See Food and Drug Administration, "FDA Public Health Notification: Problems with Endovascular Grafts for Treatment of Abdominal Aortic Aneurysm (AAA)" (April 27, 2001); see also Food and Drug Administration, "FDA Public Health Notification: Updated Data on Mortality Associated with Medtronic AVE AneuRx® Stent Graft System" (December 17, 2003). In the notification, FDA said it is "critical that physicians who evaluate and treat AAA patients have the information needed to make informed decisions on patient selection, device selection, and follow-up management." FDA said it would work with manufacturers to "obtain relevant data that will help us understand how these problems affect the overall risk/benefit assessment of this product."

³ Because of the expense of establishing an information technology infrastructure capable of performing 3D-CAMPS, most physicians currently obtain this service on a contract basis with MMS. Nevertheless, a

Footnote continued on next page

In addition to its central role in AAA and TAA postmarketing surveillance, 3D-CAMPS also has emerged as the standard of care for pre-surgical treatment planning, and the most effective means of meeting the stent graft labeling requirements for pre-operative measurement. The precise measurements provided by 3D-CAMPS greatly enhance a surgeon's ability to plan the intervention, and thereby minimize the incidence of complications attributable to improper patient or graft selection and incorrect graft placement.⁴

III. PROBLEMS WITH PROPOSED RULE AND RECOMMENDATIONS

A. Descriptor for G0288

Since 2003, physicians have reported 3D-CAMPS using G0288, "Reconstruction, computed tomographic angiography of aorta for preoperative planning and evaluation post vascular surgery."⁵ The descriptor for this code does not describe 3D-CAMPS technology accurately or with adequate specificity. First, and most importantly, the code should specify that it may be used only for 3D-CAMPS technologies capable of generating the measurements and modeling deemed essential by SVS. In addition, the code descriptor should not be limited to services that use computed tomography angiography (CTA). Many hospitals do not perform CTA on-site, and some patients who must undergo vascular surgery of the aorta cannot tolerate the contrast material used to generate a CTA. Under such circumstances, 3D-CAMPS can process data from computed tomography (CT) or magnetic resonance (MR) images.

Accordingly, CMS should revise the descriptor so that it reads as follows:

"Three-dimensional pre-operative and post-operative computer-aided measurement planning and simulation in accordance with measurements and modeling specifications of the Society for Vascular Surgery."

Footnote continued from previous page

small (and we expect increasing) number of larger institutions are capable of providing genuine 3D-CAMPS services in-house, and it is a distinct possibility that another entity will emerge to compete with MMS in providing 3D-CAMPS on a contract basis.

⁴ For further information on 3D-CAMPS, see Dr. Mark Fillinger, "Endovascular Aneurysm Repair: 3-D Computer Aided Measuring and Planning Software (CAMPS) and Conventional Angiography" (attached); Dr. Omaid C. Velasquez, "Decreased use of iliac extensions and reduced graft junctions with software-assisted centerline measurement in selection of endograft components for endovascular aneurysm repair" (attached).

⁵ Upon its introduction, the code was described as "Reconstruction, computed tomographic angiography of aorta for surgical planning for vascular surgery." In response to comments by MMS, CMS subsequently changed the descriptor to encompass use of the code for post-operative monitoring.

B. Valuation for G0288

CMS proposes a non-facility total relative value of 10.78 units for G0288, which yields a payment for the service of \$408.56 (10.78 [RVUs] x \$37.90 [CF]). Because most practices purchase 3D-CAMPS from an outside entity, the practice expense for G0288 should approximate physicians' actual acquisition cost for the service. According to MMS's sales data (which currently comprise the majority of the market for 3D-CAMPS), however, the known physicians' median acquisition cost for 3D-CAMPS is \$575.00, which exceeds the proposed physician fee schedule payment for G0288 by \$166.44, or 29 percent.

The discrepancy between the valuation of G0288 and the actual cost for physicians to obtain this service is not surprising, because G0288 has of yet not been subject to a meaningful valuation analysis. Accordingly, we urge CMS to base the practice expense relative value of G0288 on appropriate external cost data so that an adequate valuation of this service can be established.

* * *

We appreciate the opportunity to provide these comments and are eager to work with CMS to ensure that physicians and patients continue to realize the clinical benefits offered by 3D-CAMPS. Please let me know if I can be of further assistance.

Sincerely,

M. Weston Chapman
Chairman and Chief Executive Officer

From the Society for Clinical Vascular Surgery

Decreased use of iliac extensions and reduced graft junctions with software-assisted centerline measurements in selection of endograft components for endovascular aneurysm repair

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Objective: The purpose of this study was to determine the impact of using computerized software-assisted centerline measurements for extensions and graft junctions during the selection of endograft components for modular aortic endografts in endovascular repair of abdominal aortic aneurysms.

Methods: From April 1998 to December 2002, 289 modular aortic endografts were implanted at our institution. These included 248 grafts (prior to 2002, group 1) with components selected on the basis of manual caliper measurements from combined contrast computed tomography (CT) and marker-catheter arteriography data, and 41 grafts (2002, group 2) with components selected with the use of computerized software that allowed for centerline measurements on 3-dimensional reconstructions based on CT data. These 2 groups were compared for the number and type of extensions required per case. Seventeen other relevant variables were analyzed for their potential influence on selection of endograft components. These variables included age, gender, maximum aneurysm size, level of distal fixation, length and diameter at the fixation points, endograft manufacturer (make), and configuration. The significance of the observed differences was analyzed with a multivariate regression model, adjusting for potentially confounding preoperative measures.

Results: Multivariate analysis demonstrated that the number of right iliac extensions, left iliac extensions, total extensions, and total graft junctions was significantly reduced by the use of computerized software-assisted centerline measurements (group 2) compared with caliper measurements (group 1), independent of all other 17 preoperative variables. Notably, the mean number of required right iliac extensions was double in group 1 versus group 2.

Conclusions: Centerline software-assisted measurements can significantly reduce the need for iliac extensions and, concomitantly, the number of required endograft junctions. On average, twice as many extensions were required for right iliac fixation when the manual caliper measurements were used compared with software-assisted measurements. These findings are highly relevant to issues of total endograft cost and long-term endograft integrity and focus attention on the tools that may need to be considered standards of care rather than optional for selection of endograft components. (*J Vasc Surg* 2004;■■■■.)

Until recently, the radiographic imaging evaluation used for selection of endograft components in endovascular repair (EVAR) of abdominal aortic aneurysms has traditionally consisted of thin-cut contrast spiral computer tomography (CT) and marker catheter arteriography.^{1,2} CT data has been most commonly used for gathering outer-to-outer cross-sectional diameters, and the marker catheter arteriogram has been employed to measure lengths and estimate angles. Recently, several groups have reported their encouraging experience with various post-imaging software systems that use helical CT angiography data to

accurately obtain 3-dimensional views, volumetric data, and centerline length measurements.^{1,3-8} The Preview (Medical Media Systems), used for this study, was validated as accurate in preoperative and postoperative assessment of aneurysm anatomical features and aortoiliac measurements when compared with intravascular ultrasound and axial CT scan data.⁹ To date, 2 large studies have been reported in which CT data plus software systems have completely eliminated the need for preoperative calibrated arteriography, thereby averting any of its associated morbidity, expense, and exposure to nephrotoxic contrast agents.^{1,2} However, a large number of community centers continue the standard use of CT plus marker catheter arteriography for selection of endograft components in EVAR.

The impact of any of these software-assisted methods on the need for endograft extensions in modular stent grafts has not been previously studied, although the specific selection of components greatly affects total endograft cost and long-term endograft integrity. Modular components are costly and need to be individually purchased. Separations of the modular graft components, resulting in a type III endoleak (at the graft junction), have been reported

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Competition of interest: none.

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ed.¹⁰⁻¹⁵ These type III endoleaks increase the risk for repeat interventions, open conversion, or aneurysm rupture. In this article, we report our experience with the routine use of software-assisted centerline measurements in our standard protocol for stent-graft selection of endograft components, specifically evaluating the use of extension modules and, thus, the total resulting stent-graft junctions.

METHODS

Two hundred and eighty-nine modular stent grafts for EVAR were implanted at our institution from April 1998 to December 2002 to treat 268 men and 21 women. The endografts implanted included 83 AneuRx (Medtronic, Minneapolis, Minn), 50 Zenith (Cook, Bloomington, Ind), 7 Cordis (Johnson & Johnson Inc, New Brunswick, NJ), 14 Lifepath (Edwards Lifesciences, Irvine, Calif), 33 Lo-Pro (Low Profile Talent, World Medical Inc, Jacksonville, Fla), and 102 Talent (World Medical Inc). The selection of endograft components included 253 aortobiliac (ABG), 34 aortouniliac, and 2 tube stent grafts. Data were gathered prospectively into a data bank and analyzed retrospectively by querying the data bank, with formal consultation from our center's Division of Biostatistics. Our main objective was to determine the impact of software-assisted centerline measurements on the need for extensions to achieve successful aneurysm exclusion. Prior to 2002, 248 grafts (group 1, noncenterline) were implanted with components selected on the basis of manual caliper measurements from combined contrast computed tomography (CT) and marker-catheter arteriography data. In 2002, 41 grafts (group 2, centerline) were implanted with components selected with the use of computerized software that allowed for highly accurate centerline measurements of 3-dimensional reconstructions based on CT data (the software used was from Medical Media Systems [MMS], West Lebanon, NH). These two groups were compared for the number and type of extensions required per case, while seventeen other relevant variables with potential confounding influence on selection of endograft components were analyzed. The significance of the observed differences was analyzed by using a multivariate regression model, adjusting for all potentially confounding preoperative measures. The data were analyzed and F-statistics were generated and interpreted in consultation with a biostatistician.

Definitions

The specific main outcome measures studied were (1) number of proximal extensions, (2) number of right iliac extensions, (3) number of left iliac extensions, (4) total iliac extensions (right + left iliac extensions), (5) total number of extensions used (proximal extensions + total iliac extensions), and (6) total graft junctions.

The 17 preoperative variables evaluated were (1) age, (2) gender, (3) maximum antero-posterior abdominal aortic aneurysm diameter (max AAA D), (4) renal-to-aortic bifurcation length (RBL), (5) proximal neck length (L1), (6) proximal neck diameter (D1), (7) proximal neck angle, (8) level for planned right landing zone (common iliac

versus external iliac), (9) right common iliac artery diameter (R CIA D), (10) right common iliac artery length (R CIA L), (11) right external iliac diameter (R EIA D), (12) level for planned left landing zone, (13) left common iliac diameter (L CIA D), (14) left common iliac artery length (L CIA L), (15) left external iliac diameter (L EIA D), (16) device type (make), and (17) device configuration (tube, aortouniliac, or ABG).

Options for the length of the iliac limb docking segments were fixed or varied depending on the endograft make (more details follow). The statistics performed on endograft configuration and make were aimed to encompass these issues (and other device-related issues) since these docking length features are by definition device-specific.

Statistical analysis

Analysis of main outcome measures. The two-sample *t* test was employed using the SAS/STAT User's Guide (Version 8; SAS Institute Inc, Cary, NC) software package to compare the group effects on each of the main outcomes. Diagnostic tests were performed to check for significant violations in the distribution assumptions. As a means of validating the results from the *t* tests, the non-parametric Wilcoxon rank sum test was also implemented to assess whether there was a difference between the groups regarding outcome. The Wilcoxon test requires no distribution assumptions.¹⁶

Analysis on distributions of preoperative variables. The Wilcoxon rank sum statistic was used to evaluate the group association with all of the continuous preoperative measures, and a Fisher χ^2 exact test (SAS) was used for all categorical preoperative measures.

Adjusting for preoperative confounders. A multivariate logistic regression model, based on use or non-use of an extension in each case and then evaluation of those distributions across the 2 groups (rather than the number of extensions per patient across groups) was used to assess the association between groups and each of the main outcome variables, while adjusting for all preoperative measures (confounders) found to be associated with each group. This was done to determine whether the group effect on the outcome measures might actually be a consequence of some preoperative difference between the 2 groups. The general linear model procedure in SAS (1999) was employed to generate the F-statistic¹⁶ and used to test the hypothesis that there was no group association after adjusting for preoperative confounders.

RESULTS

Main outcome measures. On average, the group with centerline measurements required significantly lower right iliac extensions and left iliac extensions, total iliac extensions, and overall total extensions. Table I summarizes the statistic evaluation after regression analysis and after adjusting for any potential confounding variable (details follow). Most notably, the centerline measurement group had a 2-fold decrease in mean number of required right iliac

Table I. F statistics of the multiple regression analysis showing outcome measures that were significantly affected by computerized software-assisted centerline measurements

Outcome measures	Ratio of mean extensions in group 1/group 2	F statistic	P
Right iliac extensions	2	$F_{108,1} = 8.89$.0037
Left iliac extensions	1.4	$F_{93,1} = 4.29$.0042
Total iliac extensions	1.6	$F_{89,1} = 8.77$.0041
Total extensions	1.35	$F_{89,1} = 5.36$.0233

Table II. Effect of computerized software-assisted centerline measurements on the mean number of required right iliac extensions

Accurate centerline measurement?	Mean (SEM)	Sample size	Pooled SD	P*
No	0.74 (0.045)	248	0.700	.0005
Yes	0.37 (0.109)	41		

*Calculated with Wilcoxon-test.

extensions (Table II). As expected, given the findings on the number of iliac and total extensions, receiving the accurate centerline measurement was associated with significantly lower total number graft junctions (Table III). Those who received the software-assisted centerline measurements on average had a larger number of proximal extensions (Table IV), but there was no evidence that this difference is statistically significant. Statistical evaluation of the residual values from the 2-sample *t* test on all the main outcome variables revealed no outliers, influential points, or significant violations in the constant variance assumption.

Preoperative variables. The Figure provides summary statistics for each of the continuous preoperative variables, by group. There was no significant association ($P > .05$) between groups for any of the following preoperative measures: age, gender, max AAA D, D1, L1, RBL, right landing zone level, left landing zone level, R CIA D, L CIA D, or L EIA D.

However, the group that received the accurate centerline measurement had, on average, a significantly larger LCIA L ($z = 4.69$; $P < .0001$), RCIA L ($z = 5.58$; $P < .0001$), and neck angle ($z = 2.06$; $P = .042$). Furthermore, the group that received the accurate centerline measurements had, on average, a significantly lower R CIA D ($z = -2.63$; $P = .009$) than the group that did not receive it.

The Fisher χ^2 test results suggested a significant association between group and device type (make) ($\chi^2 = 15.7$; $P = .0007$) and device configuration ($\chi^2 = 97.98$; $P < .0001$) (Tables V, VI). Specifically, those who received the centerline measurements tended to get the ABG more often (Table V). In addition, those who received the cen-

Table III. Impact of centerline measurements on total graft junctions

Accurate centerline measurement?	Mean (SEM)	Sample size	Pooled SD	P*
No	2.38 (0.079)	248	1.199	.0386
Yes	2.02 (0.187)	41		

*Calculated with Wilcoxon test.

Table IV. Impact of centerline measurements on number of proximal extensions

Accurate centerline measurement?	Mean (SEM)	Sample size	Pooled SD	P*
No	0.16 (0.027)	248	0.425	.1147
Yes	0.27 (0.066)	41		

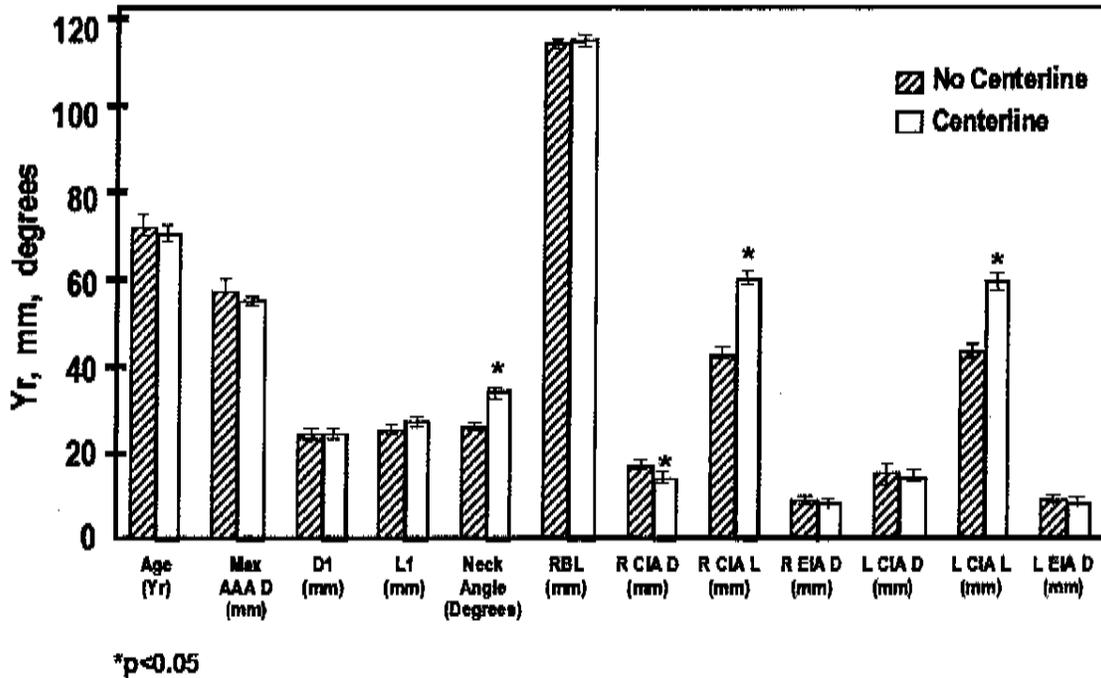
*Calculated with Wilcoxon test.

terline measurement tended to get Edwards' Lifepath at a higher rate, while those who did not get the centerline measurement tended to get AneuRx, Zenith, and Lo-Pro at a higher rate (Table VI). After adjustment for all these preoperative differences, using multivariable regression analysis, the centerline group retained its significant association with the all the evaluated outcome measures as detailed in Table I. Lastly, after adjusting for preoperative differences, the regression analysis demonstrated that there was no evidence of a significant association between accurate centerline measurements and the number of proximal extensions ($F_{107,1} = 0.65$; $P = .4226$).

The rate of extension use, expressed as the percentage of patients requiring extensions who were evaluated with MMS (centerline, group 2) versus percentage of patients requiring extensions who were not evaluated with MMS (noncenterline, group 1), for proximal, right, and left extensions were 24% versus 16%, 22% versus 62%, and 22% versus 43%, respectively. As detailed earlier, these differences were statistically significant even after accounting for some preoperative differences in some of the relevant evaluated values.

DISCUSSION

This work has demonstrated that the use of centerline measurements significantly affects the utilization of iliac extensions and consequently leads to a significantly lower total number of graft junctions. While we used rigorous statistical methods to determine significance and 17 relevant potential confounding variables were excluded as reasons for the observed differences, this was not a randomized trial; therefore, the possibility of selection bias cannot be completely ruled out. For instance, the patients that received the accurate centerline measurement might have also received some other unique care, which may actually



Summary of continuous preoperative measures across groups. Data expressed as mean ± SEM.

Table V. Distribution of device make across centerline (MMS, group 2) versus noncenterline (caliper measurements, group 1)

Device	Noncenterline	Centerline	Total
AneuRx	76	7	83
Zenith	47	3	50
Cordis	4	3	7
Lifepath	0	14	14
Lo-Pro	32	1	33
Talent	89	13	102
Total	248	41	289

MMS, Medical Media Systems.

account for the observed group differences. However, that possibility is unlikely, and thus our data strongly indicate that centerline measurements result in more accurate endograft length predictions. For the right iliac fixation zone, although the right common iliac artery length in the centerline group was significantly longer ($P < .0001$), this group required on average half the number of extensions of the noncenterline group. In consultation with our biostatistics team, the authors feel strongly that the regression analysis performed has served to determine if preoperative group differences accounted for or eliminated the significant differences in extension use across the 2 groups.

Iliac extensions were added for 3 indications: (1) to treat a distal type I endoleak not resolved by balloon angioplasty, (2) to extend the length of the iliac artery fixation zone for a sufficient distance to ensure long term

Table VI. Distribution of endograft configuration across centerline (MMS, group 2) versus noncenterline (caliper measurements, group 1)

Configuration	Noncenterline	Centerline	Total
ABG	215	38	253
AIG	32	2	34
Tube	1	1	2
Total	248	41	289

MMS, Medical Media Systems; ABG, aortobiliac; AIG, aortouniiliac.

scaling, and (3) to achieve the preoperative planned optimal distal fixation zone, beyond any segment of iliac disease (aneurysm, stenosis, thrombus-lined, or severe angulation). We do not have specific data as to the proportions for these indications among the groups since this data was not prospectively captured in the data bank. However, regression analysis did not identify the level of the distal fixation zone (common versus external iliac) as an independent variable with any significant impact on the use of extensions. In addition, multivariate logistic regression showed that the preoperative differences between the groups in device configuration and make (as well as other detailed differences) did not remove (or confound) the significance of the differences in extension use between the 2 groups. This suggests that accurate preoperative length measurements were more important in the determination of the need for extensions. This is believed to be particularly so, since the authors involved aimed, as a matter of standard of

practice, to minimize the use of extensions in every case, to decrease cost and number of endograft junctions. Therefore, each case was planned by selecting the components that would yield optimal endovascular exclusion while minimizing the use of extra components.

For most preoperative variables, the groups were fairly evenly distributed. However, those who received the centerline measurements more frequently tended to get an ABG design or an Edward's Lifepath endograft. This was not surprising since the Lifepath endograft trial exclusively used MMS centerline measurements as part of the protocol² and the ABG design tends to be most frequently used in general (thus group 2, being smaller, randomly accumulated more ABG designs). The centerline group on average had increased proximal neck angulation. This likely explains the observed trend toward increase use of proximal extensions in that group. However, this trend was not statistically significant. Multivariable regression analysis strongly indicated that, after accounting for any unevenly distributed variables across the groups, the differences on our evaluated outcomes were still highly significant (Table I).

Learning curve may be considered a potential confounder, but is difficult to formally evaluate this variable in this retrospective design. However, the first group included 248 patients over 3 years and 8 months of EVAR experience. The authors feel that that is a large enough experience to be far beyond the acute phase of the learning curve and also a large enough number of patients to dilute out any potential "learning curve issues" that could have played a role in the observed use of extensions for group 1.

No prior reports have compared the use of modular extensions with and without software-assisted centerline measurements, but the high accuracy and clinical usefulness of software-assisted centerline measurements has been documented for MMS^{2,9} and several other software systems.^{1,7,8} Our findings are thus consistent with previously reported studies. Most reports have confirmed that centerline measurements are most accurate in predicting aortoiliac length measurements for the selection of components in EVAR.^{1,7-9} However, 1 group reported higher accuracy with the shortest aortoiliac path length (SP), maintaining at least 1 radius distance from the vessel wall, than with the median luminal centerline lengths.¹⁷ These authors attempted to predict the aortoiliac stent-graft length by their own software on the basis of helical CT data, calculating either the SP or the median luminal centerline and comparing it with intravascular ultrasonographic withdrawal length measurements in 31 AneuRx and 2 Excluder cases. They determined that the preprocedural prediction of the postprocedural aortoiliac length was more accurate with the SP (shortest path) formula. Most other reports, however, have validated the standard software-assisted centerline length measurements from helical CT angiogram data as highly accurate and clinically effective.^{1,2,7-9,18} Aziz et al⁹ examined the accuracy of 3-dimensional simulation generated from spiral CT data by MMS software when compared with intravascular ultrasound and axial CT scan.

Eighty-five patients undergoing EVAR (43 Talent and 42 AneuRx) were studied. Linear regression and Bland-Altman agreement analysis were used to compare the measurements, using the various modalities. The software was found to be highly accurate with 95% confidence interval between MMS and intravascular ultrasound.⁹ The software is now widely used and was exclusively used during the EVAR multicenter trial of the Lifepath system, which reported a zero incidence of type III endoleaks.² Other software has indicated equally promising accuracy.

Isokangas et al⁸ demonstrated accuracy of their computer-aided centerline measurements in EVAR planning by using an experimental model with 2 phantoms. Coenegrachts et al⁷ compared multislice CT (MSCT) in combination with their semiautomated software program with calibrated aortography in 7 patients undergoing EVAR. Using phantoms, the authors generated strong regression analysis data indicating that the semiautomated software program was likely more accurate than calibrated aortography for length measurements. Wyers et al¹ reported the use of a 3-dimensional reconstruction and computer-aided measurement, planning, and simulation software (3-D CAMPS) based on CT or magnetic resonance imaging, to eliminate the need for preoperative arteriography. In a significant subset of patients who also underwent calibrated aortography, 3-D CAMPS was superior to angiography for prediction of endograft length.

This work represents strong clinical evidence that software-assisted centerline measurements are not only accurate and useful for EVAR selection of endograft components but also in fact are associated with a significant reduction in the overall use of iliac extension modules, thus reducing total graft junctions. The potential impact on cost and long-term endograft integrity are important enough to warrant reconsidering the clinical role of this technology and whether it should be a luxury or routine standard of care.

The study was not intended to be a formal cost-analysis study, particularly since many of these cases were performed as part of ongoing clinical trials. However, the average cost for our center to purchase extensions for the devices used in this study was approximately \$2,000 per iliac limb extension (although this figure varies widely per device and does not take into account whether the device is FDA-approved versus purchased as part of clinical trial). In contrast, the cost of 1 MMS study is significantly more modest. The cost of an MMS study (the software used in this work) depends on the local reimbursement level. The Medicare reimbursement level in our region is \$473. The national MMS reimbursement average is \$450 for Medicare. In addition, the use of MMS software-assisted reconstruction(s) has eliminated the need for diagnostic arteriogram (with its added cost and potential complications.) Lastly, it is difficult to gauge the potential long-term impact on endograft durability of the reduction of total graft junctions.

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Submitted Jan 28, 2004; Apr 13, 2004.

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

See attachment.

**Department of Health and Human Services
Centers for Medicare and Medicaid Services (CMS)
Offices of Strategic Operations and Regulatory Affairs**

The attachment to this document is not provided because:

1. The document was improperly formatted.
2. The submitter intended to attach more than one document, but not all attachments were received.
3. The document received was a protected file and can not be released to the public.
4. The document was not available electronically at this time. If you like to view any of the documents that are not posted, please contact CMS at 1-800-743-3951 to schedule an appointment.

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 1-9

CODING-GLOBAL PERIOD

Dr. Mark McClellan
 Administrator
 Centers for Medicare and Medicaid Services
 Department of Health and Human Services
 P.O. Box 8012
 Baltimore, MD 21244-8012

RE: CMS-1429-P

Dear Dr. McClellan:

The Society for Vascular Surgery (SVS) is pleased to accept the opportunity to submit the following comment. SVS is the largest and oldest national medical specialty society representing vascular surgeons in the United States. Our 2300 members provide a full spectrum of medical, surgical and interventional services to Medicare beneficiaries who suffer from arterial and venous disorders. SVS will address the following issues regarding the 2005 NPRM:

- ? Proposed G-code (GOXX3) for venous mapping prior to hemodialysis access placement
- ? Refinement of Equipment inputs for noninvasive vascular diagnostic codes
- ? Comments on PE RVU relativity, PE \$ rate/hour, & outliers for office-priced codes

Proposed G-code for Venous Mapping Prior to Hemodialysis Access Placement

SVS appreciate CMS' support for venous mapping because it will bring an improvement in the efforts to create fistulae for hemodialysis access. We view this proposal as closely related to the "Fistula First" initiative sponsored by CMS. We know that an arteriovenous (AV) fistula is the preferred vascular access for patients with end stage renal disease. AV fistulae have significantly lower rates of complications (such as infection and clotting), and longer patency compared to other access methods, resulting in fewer hospitalizations and lower costs. We have several comments on the proposal as it is now written.

The proposal includes a newly created G code for the operating surgeon to report venous mapping. We are concerned that restricting the use of the G code to the operating surgeon may be impractical. We note the following:

- ? The mapping is often performed before the surgeon meets the patient. One of the documents CMS is distributing as part of Fistula First is the Fistula First Change Package that describes the best practices for increasing the use of AV fistulas. Step three of that document talks about early referral to a surgeon for an "AVF only" evaluation and timely placement. In it the following statement appears: "Nephrologist refers for vessel mapping where feasible, ideally prior to surgery referral".
- ? The process of scheduling vascular mapping is such that the operating surgeon may not be available to interpret the mapping. Most vascular laboratories have more than one physician performing the professional interpretations on a regularly scheduled basis. The patient is usually given a choice of times to have the vascular mapping performed, and it may be done at a time when the operating surgeon is not assigned or available to perform the interpretation.
- ? While surgeons who perform hemodialysis fistula placement regularly have the best concept of what constitutes an adequate vein for successful fistula creation, we believe appropriately qualified non-operating physicians can safely interpret vascular mapping. Medical literature provides minimally adequate vein diameters for wrist and more central fistulas as well as guidelines regarding evaluation for adequacy of arterial inflow and deep venous outflow. Accredited laboratories or credentialed technologists following these guidelines should provide the high quality studies needed to guide the surgeon in creating the best possible fistula.

Submitter : Mrs. Starlyn Tyree Date & Time: 09/24/2004 08:09:05

Organization : Mrs. Starlyn Tyree

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

I am submitting an attached letter urging CMS to reconsider the NPRM proposed recommendation for a separate add-on of \$.05 per unit for items and services related to the supply of blood-clotting factor.

September 24, 2004

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

Re: File Code CMS-1429-P (69 Fed. Reg. 47488, August 5, 2004)

Dear Dr. McClellan:

I am writing to encourage CMS to reconsider the NPRM's proposed separate add on payment of \$.05 to cover the cost of items and services for Medicare beneficiaries receiving life-saving blood-clotting factor.

I have worked within the bleeding disorders community for the past 18 years. I served 12-years as the Executive Director of Hemophilia of Indiana. The past 6 years I have worked within the community as a Resource Coordinator providing guidance to education, resources and advances in treatment and research. Based upon my level of involvement and compassion for this community I am certain the proposed NPRM recommendation will have a negative impact upon those individuals who want and need the specialized service that is provided them via full-service homecare companies.

The services that are provided by full-service homecare companies are essential and necessary to make hemophilia and related bleeding disorders a chronic manageable disorder rather than a devastating and catastrophic disease. Before the availability of home infusion and homecare services, lives were tied to hospitals and emergency rooms. Individuals with clotting disorders were prisoners to these expensive, time-consuming healthcare services. Full-service homecare is not just the delivery of blood-clotting factor it includes but is not limited to education, nursing, waste disposal services, RX management and much more.

If homecare services are reduced or eliminated which is more than a probability under the NPRM recommendation, I believe that any Medicare cost-savings will be at best short term. It is more costly to have to go to an emergency room, pay physician's fees, E.R. fees in addition to the costs of factor and supplies, which can be administered at home. The increase would certainly be more than the current proposed \$.05 and greater than the recommended \$.20 add-on payment.

I encourage you to reconsider the NPRM's current proposal and consider the long-term Medicare cost savings afforded by full-service homecare providers.

This community has struggled and overcome many obstacles including HIV/AIDS, Hepatitis infections and more. Please do not turn back the clock in an effort to "contain" costs by eliminating services that have improved quality of life.

Sincerely,
Starlyn L. Tyree

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 20-29

OTHER - INCIDENT TO

? Patients who would now be referred outside of the physician's office would incur delays of access. In the case of rural Medicare patients, this could not only involve delays but, as mentioned above, cost the patient in time and travel expense. Delays would hinder the patient's recovery and/or increase recovery time, which would ultimately add to the medical expenditures of Medicare.

? Curtailing to whom the physician can delegate 'incident to' procedures will result in physicians performing more of these routine treatments themselves. Increasing the workload of physicians, who are already too busy, will take away from the physician's ability to provide the best possible patient care.

? To allow only physical therapists and PT assistants, occupational therapists and OT assistants, and speech and language pathologists to provide 'incident to' services would improperly provide those groups exclusive rights to Medicare reimbursement. To mandate that only those practitioners may provide 'incident to' care in physicians' offices would improperly remove the states' right to license and regulate the allied health care professions deemed qualified, safe and appropriate to provide health care services.

? CMS, in proposing this change, offers no evidence that there is a problem that is need of fixing. By all appearances, this is being done to appease the interests of a single professional group who would seek to establish themselves as the sole provider of therapy services.

? CMS does not have the statutory authority to restrict who can and cannot provide services 'incident to' a physician office visit. In fact, this action could be construed as an unprecedented attempt by CMS, at the behest of a specific type of health professional, to seek exclusivity as a provider of physical therapy services.

? Independent research has demonstrated that the quality of services provided by certified athletic trainers is equal to the quality of services provided by physical therapists. Certified athletic trainers take most if not all of the same courses that physical therapists take.

? Athletic trainers are employed by almost every U.S. post-secondary educational institution with an athletic program and every professional sports team in America to work with athletes to prevent, assess, treat and rehabilitate injuries sustained during athletic competition. In addition, dozens of athletic trainers will be accompanying the U.S. Olympic Team to Athens, Greece this summer to provide these services to the top athletes from the United States. For CMS to even suggest that athletic trainers are unqualified to provide these same services to a Medicare beneficiary who becomes injured as a result of running in a local 5K race or in the health club and goes to their local physician for treatment of that injury is outrageous and unjustified.

? These issues may lead to more physician practices eliminating or severely limiting the number of Medicare patients they accept.

In summary, it is not necessary or advantageous for CMS to institute the changes proposed. This CMS recommendation is a health care access deterrent.

Sincerely,

Andrea Brezill MS, ATC/L

CMS-1429-P-4079-Attach-2.doc

CMS-1429-P-4079-Attach-1.doc

Andrea Brezill MS, ATC/L
17712 Stonebridge Drive
Hazel Crest, IL 60429

September 22, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1429-P
P.O. Box 8012
Baltimore, MD 21244-8012

Re: Therapy – Incident To

Dear Sir/Madam:

I am writing to express my concern over the recent proposal that would limit providers of “incident to” services in physician clinics. If adopted, this would eliminate the ability of qualified health care professionals to provide these important services. In turn, it would reduce the quality of health care for our Medicare patients and ultimately increase the costs associated with this service and place an undue burden on the health care system. Certified and Licensed athletic trainers are required to take the following courses in their undergraduate curriculum: human physiology, human anatomy, kinesiology/biomechanics, nutrition, acute care of injury and illness, statistics and research design, and exercise physiology. Many athletic trainers take high level science courses such as: organic chemistry, biochemistry, microbiology, pharmacology, and gross anatomy. Seventy (70) percent of all athletic trainers have a master’s degree or higher. This is comparable to the credentials of other healthcare professionals including: physical therapists, occupational therapists, and registered nurses. Many certified and licensed athletic trainers graduate with thousands of hours of observation and physician shadowing hours under their belts. On a more personal note, I have grand-parents who have been denied access to physical therapy, if it weren’t for my expertise in assisting, monitoring, and instructing them in proprioception, range-of –motion exercises, strengthening exercises and correct and incorrect body position they would still be unable to perform simple daily activities. In addition, I have treated high caliber athletes that have competed in the Olympics and have even gone on to compete in professional leagues. It is an insult that the federal government feels as though I am unqualified and untrained to treat our older population.

During the decision-making process, please consider the following:

- Incident to has, since the inception of the Medicare program in 1965, been utilized by physicians to allow others, under the direct supervision of the physician, to provide services as an adjunct to the physician’s professional services. A physician has the right to delegate the care of his or her patients to trained individuals (including certified athletic trainers) whom the physician deems knowledgeable and trained in the protocols to be administered. The physician’s choice of qualified therapy providers is inherent in the type of practice, medical subspecialty and individual patient.
- There have never been any limitations or restrictions placed upon the physician in terms of who he or she can utilize to provide ANY incident to service. Because the physician accepts legal responsibility for the individual under his or her supervision, Medicare and private payers have always relied upon the professional judgment of the physician to be able to determine who is or is not qualified to provide a particular service. It is imperative that physicians continue to make decisions in the best interests of the patients.
- In many cases, the change to “incident to” services reimbursement would render the physician unable to provide his or her patients with comprehensive, quickly accessible health care. The patient would be forced to see the physician and separately seek therapy treatments elsewhere, causing significant inconvenience and additional expense to the patient.
- This country is experiencing an increasing shortage of credentialed allied and other health care professionals, particularly in rural and outlying areas. If physicians are no longer allowed to utilize a variety of qualified health care professionals working “incident to” the physician, it is likely the patient will suffer delays in health care, greater cost and a lack of local and immediate treatment.

- Patients who would now be referred outside of the physician's office would incur delays of access. In the case of rural Medicare patients, this could not only involve delays but, as mentioned above, cost the patient in time and travel expense. Delays would hinder the patient's recovery and/or increase recovery time, which would ultimately add to the medical expenditures of Medicare.
- Curtailing to whom the physician can delegate "incident to" procedures will result in physicians performing more of these routine treatments themselves. Increasing the workload of physicians, who are already too busy, will take away from the physician's ability to provide the best possible patient care.
- To allow only physical therapists and PT assistants, occupational therapists and OT assistants, and speech and language pathologists to provide "incident to" services would improperly provide those groups exclusive rights to Medicare reimbursement. To mandate that only those practitioners may provide "incident to" care in physicians' offices would improperly remove the states' right to license and regulate the allied health care professions deemed qualified, safe and appropriate to provide health care services.
- CMS, in proposing this change, offers no evidence that there is a problem that is need of fixing. By all appearances, this is being done to appease the interests of a single professional group who would seek to establish themselves as the sole provider of therapy services.
- CMS does not have the statutory authority to restrict who can and cannot provide services "incident to" a physician office visit. In fact, this action could be construed as an unprecedented attempt by CMS, at the behest of a specific type of health professional, to seek exclusivity as a provider of physical therapy services.
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Sincerely,

Andrea Brezill MS, ATC/L

Andrea Brezill MS, ATC/L
17712 Stonebridge Drive
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September 22, 2004

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Sincerely,

Andrea Brezill MS, ATC/L

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

GENERAL

GENERAL

The Ohio State Chiropractic Association hereby agrees to and ratifies the comments as submitted by the Northeast Ohio Academy of Chiropractic. It is imperative that chiropractors be allowed to continue to provide therapy services to patients. Adoption of this new rule would deny patients quality services from qualified physicians. The Ohio State Chiropractic Association and its members support this medicare benefit and would be happy to discuss this issue further.

NORTHEAST OHIO ACADEMY OF CHIROPRACTIC

September 24, 2004

Submitted Electronically at <http://www.cms.hhs.gov/regulations/ecomments>

Mark McClellan, M.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Baltimore, MD 21244

Re: Comments on Revisions to Medicare Physician Fee Schedule for Calendar Year 2005

File Code: CMS-1429-P
Therapy—Incident To
Therapy—Standards and Requirements

Dear Dr. McClellan:

On behalf of the patients of its members, the Northeast Ohio Academy of Chiropractic (NOAC) respectfully comments on the Centers for Medicare and Medicaid Services (CMS) proposed changes to the Medicare benefit for physical therapy services provided "incident to" a physician services. NOAC believes that this restriction on Medicare coverage would impose additional hardship for beneficiaries requiring physical medicine services.

The mission of the NOAC is to promote the highest level of quality of chiropractic practice for the protection of the public welfare, to promote and upgrade the practice of chiropractic and the education and knowledge of chiropractic practitioners, and to expose fraudulent, unethical and unaccredited practices in the chiropractic art and education.

NOAC is dedicated to serving as spokesman and voice of the chiropractic profession in regards to political, legal and socioeconomic welfare of the chiropractic profession in northeastern Ohio. We have special qualifications to address the merits of this issue as members are licensed to practice physical therapy as doctors of chiropractic in the state of Ohio.

Background on Proposed Rule Change

CMS proposes to restrict Medicare coverage to allow only those individuals to provide physical therapy incident to the services of a physician who graduated from a physical therapy curriculum approved by (1) the American Physical Therapy Association (APTA); (2) the Committee on Allied Health Education and Accreditation of the American Medical Association (AMA), or (3) the Council on Medical Education of the AMA or APTA.

Essentially the current Medicare incident to rule, codified at 42 C.F.R. §410.26, would be changed effective with the CY 2005 Fee Schedule to require training in physical therapy school for all physical medicine services furnished under a physician's direction and control. CMS would do so by adding section 410.26(c) (2) to the "incident

to" physician services rule which cross references to new sections on the therapy rules governing outpatient physical therapy providers.^[1] This change would effectively negate the ability of Medicare beneficiaries to receive physical medicine services incident to physician services from chiropractors.

A substantive change of this magnitude should be based on empirical data and a solid statutory foundation given Medicare's long-standing policy of covering this type of services. A November 21, 1994, letter from Bernadette Schumaker, Acting Director of the HCFA Office of Physician and Ambulatory Care Policy to Bill Maruca specifically states that despite the restrictions on Medicare coverage for chiropractic services at §1861(r)(5) of the Social Security Act, a chiropractor may furnish physical therapy services or any other service he or she is authorized to perform under the incident to benefit. Correspondence and communication from HCFA officials in 1996 and 1997 specifically addresses this issue and recognized continued coverage of physical therapy provided by doctors of chiropractic incident to the services of a physician.^[2]

The "incident to" statutory benefit at Social Security Act §1861(s)(2)(A) contains no educational qualification conditions.^[3] The statutory basis CMS offers for this change is §1862(a)(20) of the Social Security Act enacted in 1997 stating that Medicare does not cover "outpatient physical therapy services furnished as an incident to a physician's professional services that do not meet the standards and conditions (other than any licensing requirement)... as such standards and conditions would apply to such therapy services if furnished by a therapist."

CMS is proposing to adopt a limitation on Medicare incident to benefits it consistently has rejected subsequent to enactment of the 1862(a)(20) provisions. Instead, current Medicare rules deliberately rely on state scope of practice laws to establish qualifications for the incident to statutory benefit under both §1862(s)(2)(A) and §1862(a)(20). When CMS reviewed and revised the Incident to Physician Services rule in 2001, CMS made clear that "any individual" could qualify subject to scope of practice laws as follows:

We have not further clarified who may serve as auxiliary personnel for a particular incident to service because the scope of practice of the auxiliary personnel and the supervising physician (or other practitioner) is determined by State law. **We deliberately used the term any individual** so that the physician (or other practitioner), under his or her discretion and license, may use the service of anyone ranging from another physician to a medical assistant. In addition, it is impossible to exhaustively list all incident to services and those specific auxiliary personnel who may perform each service.

Medicare Program; Revisions to Payment Policies and Five-Year Review of and Adjustments to the Relative Value Units Under the Physician Fee Schedule for Calendar Year 2002, 66 Fed. Reg. 55246, 55268 (Final Rule) (Nov. 1, 2001) (emphasis added).

In 1998, CMS specifically rejected the idea that §1862(a)(20) requires the qualifications that it now intends to impose. Instead, CMS implemented the §1862(a)(20) terms through a manual instruction that required the physician whose

services the therapy was incidental to be licensed to practice physical therapy. In responding to comments in the final CY 1999 Physician Fee Schedule rule, CMS stated:

Comment: One commenter stated that verification should be provided in the final rule that section 1861(p) of the Act requires a physician to have services furnished by a licensed physical therapist or under the supervision of such a therapist when billing for physical therapist services incident to the physician's professional services.

Response: Section 1861(p) of the Act does not set forth the requirements as specified by the commenter. As previously stated, section 4541(b) of the BBA 1997 amended section 1862(a) of the Act to require that outpatient physical therapy services (including speech-language pathology services) and occupational therapy services furnished "incident to" a physician's professional services meet the standards and conditions (other than any licensing requirement specified by the Secretary) that apply to therapy services furnished by a therapist. In May 1998, we issued Transmittal No. 1606 of the Medicare Carriers Manual, Part 3—Claims Process which implemented this provision that was effective January 1, 1998. Section 2218(A) of the Medicare Carriers Manual requires that physical therapy services provided by a physician or by an incident to employee of the physician in the physician's office or the beneficiary's home must be provided by, or under the direct supervision of, a physician (a doctor of medicine or osteopathy) who is legally authorized to practice physical therapy services by the State in which he or she performs such function or action.

Medicare Program; Revisions to Payment Policies and Adjustments to the Relative Value Units under the Physician Fee Schedule for Calendar Year 1999, 63 Fed. Reg. 58863, 58870 (Final Rule) (Nov. 2, 1998).

Last year, when CMS considered the implementation of §1862(a)(20), it once again rejected national standards for therapy services. 68 Fed. Reg. 49030, 49059 (CY 2004 proposed rule) (August 15, 2003). Current CMS manual instructions applicable to Physical Therapy and Occupational Therapy Provided by Physicians and Physician Employees, are in accord stating that that "[t]he services must be provided by, or under the direct supervision of, a physician (a doctor of medicine or osteopathy) who is legally authorized to practice physical therapy services by the State in which he performs such function or action." Medicare *Benefit Policy Manual*, Pub. 100-2, Chapter 15, 220.2, Rev. 1, 10-01-03.^[4]

While previous government studies^[5] have suggested that physical medicine services provided by unlicensed or unqualified personnel should be addressed, doctors of chiropractic are both licensed and qualified to provide physical therapy. To equate chiropractors with untrained, unlicensed, unqualified staff is repugnant, and lacks a sound empirical basis. Indeed, the Federal Employees' Workers Compensation Program has developed special rules for chiropractors to include both treatment to correct a spinal subluxation (paralleling the Medicare benefit) as well as "services in the nature of physical therapy under the direction of a qualified physician." Department of

Labor, Office of Workers' Compensation Programs (OWCP) Rules, 20 C.F.R. §10.311. Likewise, the Blue Cross Blue Shield Service Benefit Plan for federal employees does not cover chiropractic services, but covers physical therapy provided by chiropractors. Medicare beneficiaries should have access to at least the same therapy services as federal employees who are injured in the workplace and the CMS staff.

Conflict with other Laws

There are numerous legal reasons the proposed rule should not be adopted in its present form. Besides the separate statutory benefit at §1861(S)(2)(A), as discussed above, the proposed rule directly conflicts with other federal laws. First, this additional requirement interferes with the practice of medicine, the authority of state licensing boards, and Medicare beneficiary freedom of choice. The very first section of the Medicare Act, Section 1801 prohibits federal interference in the practice of medicine. Public Law 89-97, 1965, codified at 42 U.S.C. §1395. ("Nothing in this title shall be construed to authorize any federal officer or employee to exercise any supervision or control over the practice of medicine").

The restriction interferes with state licensing authority. Under the incident to rule, therapy services are an integral part of the physician's professional services and the physician is immediately available to furnish assistance and direction while the therapy is performed. The definition of Medicare "physician services" at 42 C.F.R. §440.50(a) unquestionably includes supervisees other than the physician and services provided by employees supervised by the physician can only be conditioned on *the scope of the practice of medicine* as defined by state law. *Yapalater v. Bates*, 494 F. Supp. 1349, 1363-64 (S.D.N.Y. 1980), *aff'd*, 644 F.2d 131 (2d Cir. 1981), *cert. denied*, 455 US 908 (1982).

For example, in Ohio, the state medical board rule for delegation requires a physician to determine that the delegation is appropriate and conforms to minimal standards of care of similar physicians under same or similar circumstances considering various factors. See Ohio State Medical Board Rule on delegation of medical tasks at Ohio Rev. Code §4731-23-02.

The restriction also interferes with Section 1802 of the Medicare Act providing Medicare beneficiaries with the freedom of choice for qualified providers, "Any individual entitled to insurance benefits under this title may obtain health services from any institution, agency, or person qualified to participate under this title if such institution, agency, or person undertakes to provide him such services." 42 U.S.C. §1395a(a).

Second, the imposition of qualifications on the physical medicine codes used by physician offices contradicts the uniform coding system established by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Transaction and Code Set Rule. Under that rule, the Current Procedural Terminology®, 4th Edition, as maintained and distributed by the American Medical Association, ("CPT-4 Manual") was adopted as the official coding system for both physician and physical therapy services^[6] electronically billed by covered entities. See 45 C.F.R. §162.1002.

Federal law requires providers who submit claims electronically and payors covered by HIPAA, including CMS, to follow CPT guidance. The American Medical

Association publishes the *CPT Assistant* to provide official CPT coding advice, and that publication refers coders of physical therapy services to state licensing laws, stating:

These codes are not restricted to use by a specific specialty. No distinction is made concerning the licensure or professional credentials of the provider. State and institutional authorities should be consulted regarding the appropriate provision of these services by health care professionals.

CPT Assistant, Physical Medicare and Rehabilitation Service, Part I, Dec. 2003, at 4.

Third, this a major substantive change to Medicare policy. As CMS acknowledged last year in requesting comments on this issue, "There are currently no national standards for qualifications of individuals providing outpatient physical therapy services incident to physicians' services...we are not proposing a change at this time..." 68 Fed. Reg. 49030, 49059 (CY 2004 proposed rule) (August 15, 2003).

To the extent that CMS would implement this change retroactively, 903(b) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 ("The Medicare Modernization Act") prohibits the retroactive application of substantive changes in Medicare regulations, manual instructions, interpretive rules, policy statements or guidelines unless the Secretary determines that retroactive application is necessary to comply with the statute.¹⁷ This proposed change is not necessary as other alternatives exist.

Alternatives for Consideration

The primary policy reason the proposed change should not be adopted because it will negatively impact Medicare beneficiary access to quality physical medicine services. This proposed change needs further study of physical therapy provided by doctors of chiropractic incident to a physicians services because these services can and do meet the standards and conditions of services provided by physical therapists.

As CMS acknowledged in its specific call for comments from physicians and others who would be affected by this change, the issue is one of whether CMS can identify alternatives "to ensure that qualified staff are providing 'incident to' therapy services." 68 Fed. Reg. 49030, 49059 (CY 2004 proposed rule) (August 15, 2003). Thus, the State of Ohio has already determined that doctors of chiropractic can meet the standards and qualifications to provide physical therapy services. Ohio chiropractors are specifically trained in physical medicine in addition to chiropractic manual therapy. Indeed, Ohio doctors of chiropractic must pass the physiotherapy section of their national board exam and graduate from a chiropractic college with a minimum of 120 hours of education in rehabilitation procedures. Ohio has addressed the issue of whether the provision of physical therapy services is within the scope of practice of chiropractic in Ohio. The Ohio Attorney General concluded that chiropractors may perform physical therapy services included within the scope of chiropractic services and within the chiropractor's education, training and experience. See 1987 Op. Atty. Gen. Ohio 492.

One alternative is to specifically add doctors of chiropractic to the rule as the OWCP has done. Medicare coverage and benefit rules are replete with examples of

where training and qualifications of one licensed discipline is deemed to be equivalent when provided by another discipline, *e.g.*, coverage of physician services by osteopathic and allopathic physicians. A second alternative would be to allow any individual authorized by the state where the services are provided to perform physical medicine services. Either of these rules would defer to state licensing authorities to set standards and conditions as is currently done for most Medicare covered services.

Third, Medicare could follow the rule for physician services that allows licensed physicians to decide "under his or her discretion and license" whether the standard is met. This alternative would place the burden on the physician whose billing number is used to ensure that the local standard of care and state medical board rules have been met. Other requirements set forth in the Incident to Physician Services would rule further protect Medicare beneficiaries. The requirements that the service be an integral part of the physician's professional services and be billed under the physician's member establishes accountability and malpractice liability for the physician and licensure sanction for services outside the scope of the delegate's license.

This third alternative is consistent with the proposed changes to the rules at 42 C.F.R. §410.60 expressly allowing physical therapy assistants to provide physical therapy if they do so under a physical therapists' direct supervision. In other words, while denying licensed and qualified individuals such as doctors of chiropractic to provide physical therapy under the direct supervision of a physician, CMS proposes to allow lesser trained individuals such as physical therapist assistants to provide the same services if a physical therapist supervises. To codify this delegation by physical therapists while prohibiting physicians from delegating to doctors of chiropractic inappropriately places therapists above physicians in implementing plans of care for physical medicine services. NOAC further believes that CMS should consider the restrictions on delegation under the supervision of physical therapists in conjunction with this rule and revise it as well.

We support the Medicare benefit for our patients and would be please to discuss these issues further with your staff. You may contact me at tdisalvatore@adelphia.net.

Sincerely,

**Thomas DiSalvatore, President
NOAC**

cc: Dorothy Shannon, CMS (by email at DShannon2@cms.hhs.gov w/PDF attachments)

^[1] The person furnishing the service would be required to meet the standards and conditions that apply to physical therapy and physical therapists, except for a license to practice physical therapy in the State. See proposed §410.60(a)(3)(iii). The proposal adopts the definition of "physical therapist" for home health agencies at 42 C.F.R. §484.4 which contains the educational requirement.

^[2] Copies of these documents are being sent in a pdf file to Dorothy Shannon at CMS.

^[3] 42 U.S.C. §1395x(s)(1), (2)(A) ("services...furnished as an incident to a physician's professional service, of kinds which are commonly furnished in physicians' offices and are commonly either rendered without charge or included in the physicians' bills.").

^[4] To the extent any CMS manual instructions or local medical review policies adopted by carriers paying physician claims currently seek to impose additional qualifications in contradiction to §410.26, those interpretations are not binding. See, e.g., *Christensen v. Harris County*, 529 U.S. 576, 587 (2000) ("Interpretations such as those in opinion letters – like interpretations contained in policy statements, agency manuals, and enforcement guidelines, all of which lack the force of law – do not warrant *Chevron*-style deference."); see also *United States v. Ward*, 2001 U.S. Dist. LEXIS 15897 (E.D. Pa. Sept. 5, 2001).

^[5] See e.g., OIG Report on Physical Therapy in Physician Offices, OEI-02-90-00590 (March 1994); DynCorp Report to CMS at www.medlearn/therapy/dyncorprpt.asp.

^[6] Physical therapy services are those procedures found in the Physical Medicine and Rehab Section of the CPT-4 Manual. Medicare *Benefit Policy Manual*, Pub. 100-2, Chapter 15, 220.2, Rev. 1, 10-01-03

^[7] Section 903(b) of the Medicare Modernization Act also provides that no action shall be taken against providers or suppliers for noncompliance with a substantive change for items and services furnished before the effective date of the change.

Submitter : **Dr. Roger Litwiller** Date & Time: **09/24/2004 08:09:59**

Organization : **American Society of Anesthesiologists**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Issues 10-19

SECTION 952

American Society of Anesthesiologists
Office of Governmental Affairs
1101 Vermont Ave., N.W., Suite 606
Washington, D.C. 20005

September 24, 2004

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

Attention: CMS-1429-P

Submitted electronically to <http://www.cms.hhs.gov/regulations/ecomments>

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005 (69 Fed. Reg. 47488, August 5, 2004)

Section 952 Revisions to Reassignment Provisions

Dear Administrator McClellan:

The American Society of Anesthesiologists appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' proposals regarding the implementation of Section 952 of the Medicare Modernization Act.

We agree that the program integrity safeguards recommended in the Conference Agreement and incorporated in the February 2004 change to the Medicare Manual are appropriate. The physician (or nonphysician practitioner) who performs the service being billed in his or her name, by an entity to which the physician has reassigned payment, must clearly have access to the billing records if he or she is liable for any overpayment. We would ask you to consider issuing instructions on how the independent contractor physician who has reassigned payment rights to a medical group or other entity might enforce the right of unrestricted access stated in proposed ?424.80(d)(2). One can envision disputes that become complicated through the group's use of an independent billing agency, for example. Guidance on the nature and extent of the effort that the physician must make in order to protect himself from liability on a suspected overpayment to the group, or pattern of overpayment, would be helpful.

Conversely, although the regulations are silent on this point, the duty of full disclosure should be reciprocal. The group filing the claim must have access to the independent contractor physician's records on services for which Medicare payment has been reassigned to the group.

The pre-MMA prohibition on reassignment of the payment rights of independent contractor anesthesiologists seemed to us to be a solution in search of a problem. We are still not aware of the ways in which facilitating the use of independent contractor anesthesiologists might give rise to fraud and abuse. This is particularly true since it has long been lawful for nurse anesthetists to reassign their billing rights to an entity with which they have a contract, and no allegations of fraud regarding such arrangements have come to our attention. We do have recommendations regarding the monitoring that the Agency intends to conduct, however. Focused reviews of the arrangements or contracts of groups that submit a truly exceptionally large number of reassigned claims could serve the purpose well, as long as the number of such claims is the numerator and the total number of claims submitted by the group is the denominator. Given that nothing in the MMA reassignment rule changes suggests to us a potential for fraud and abuse, we would urge that the Agency not monitor the independent contractor reassignment arrangements aggressively.

Thank you for your consideration of our comments. If you have any questions, please contact Karin Bierstein of our Washington office, k.bierstein@asawash.org or 202.289.2222.

Sincerely,

Roger W. Litwiller, M.D.
President

cc: Eugene P. Sinclair, M.D.
Orin F. Guidry, M.D.
Ronald A. Bruns
Michael Scott, Esq.
Karin Bierstein, Esq.

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

GENERAL

GENERAL

See attached document.

CMS-1429-P-4082-Attach-1.doc



55th Anniversary

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9111 Old Georgetown Rd.
Bethesda, MD 20814-1699
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President
Michael J. Wolk, MD

September 24, 2004

President-Elect
Pamela S. Douglas, MD

Mark McClellan, MD, PhD
Administrator

Immediate Past President
Carl J. Pepine, MD

Centers for Medicare and Medicaid Services
Department of Health and Human Services

Vice President
Steven E. Nissen, MD

Attention: CMS-1479-P
P.O. Box 8012

Secretary
James W. Fasules, MD

Baltimore, MD 21244-8012

Treasurer
James T. Dove, MD

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005

Chair, Board of Governors
James W. Fasules, MD

Dear Dr. McClellan:

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Douglas P. Zipes, MD
William A. Zoghbi, MD

The American College of Cardiology (ACC) is a 31,000 member nonprofit professional medical society and teaching institution whose purpose is to foster optimal cardiovascular care and disease prevention through professional education, promotion of research, and leadership in the development of standards and formulation of health care policy. The College represents more than 90 percent of the cardiologists practicing in the United States.

The ACC appreciates the opportunity to submit our comments on the proposed changes for physicians for 2005. Our comments are limited to the issues below and we appreciate the consideration that you and your staff have provided on these and many other issues.

Practice Expense

The ACC recently submitted supplemental practice expense data to CMS for consideration in updating cardiology's practice expenses per hour based to reflect better the increased costs of cardiovascular practice. We are pleased that Lewin has recommended approval of this data to CMS.

ACC is also pleased that CMS has decided not to eliminate the non-physician work pool (NPWP) for 2005 until methodological issues are addressed and we support delay in implementation of the new practice expense data submitted by cardiology and other specialties until that occurs.

ACC, however interprets the Lewin report as suggesting that CMS consider blending the data. We think that their suggestion is invalid for two reasons. First, their suggestion that

Chief Executive Officer
Christine W. McEntec

Letter to Dr. Mark McClellan, MD - (cont'd)

Page 2

September 24, 2004

"similar changes (increased use of more expensive technology) may also have occurred throughout the physician services industry" is an unfounded speculation. Few other specialties are as technologically driven as cardiology, so any increase in practice expense due to increased use of expensive technology is likely to be disproportionately greater in cardiology. Second, other specialties have the opportunity to provide survey data if they feel that their practice expenses have risen faster than the normal rate of inflation. It is best to use this up-to-date data wherever possible, instead of diluting it with obsolete data. Additionally, CMS is not blending the data that has been provided by other specialties and CMS should treat all specialties consistently.

Recommendation:

ACC requests that CMS utilize our practice expense data submitted in March 2004 as submitted without blending it with older SMS data.

ACC also recommends that CMS work with the affected specialties to determine an appropriate solution to the elimination of the non-physician work pool.

Other Practice Expense Issues

External Counterpulsation

CMS has proposed several changes to the direct practice expense inputs for external counterpulsation. Those changes are generally reasonable but it may be more appropriate to maintain the 5-year amortization schedule for ECP machines. Additionally, the expense of providing this service in cardiologist's offices is very similar to the costs of providing many in-office diagnostic services. Payments for most of those procedures are not subject to the resource based practice expense methodology because of the NPWP. It may be appropriate for CMS to delay changes on practice expense inputs for external counterpulsation until 2006 when the NPWP will probably be eliminated and the newer practice expense per hour figures are used for cardiology.

Cardiac Event Monitoring

ACC sought unsuccessfully to gather direct practice expense information from a variety of physician and industry sources prior to making direct practice expense recommendations to the PEAC on cardiac monitoring services. Our recommendations to the PEAC were based largely on input from the Mayo Clinic, which is one of the few physician groups that provides full 24 hour monitoring in-house. The Mayo clinic's operations may or may not reflect the direct practice expenses of the typical provider of cardiac event monitoring.

Equipment and Supply Costs

CMS is seeking pricing information for several cardiology-related equipment and supplies.

We are pleased to provide the following input:

Equipment:

1. Ambulatory blood pressure monitors

CMS has a current price listed of \$3,000. Pricing for the top three ambulatory blood pressure monitoring companies ranges approximately \$2,800 to \$3,500. ACC supports CMS' current pricing.

2. E53005 Camera system, cardiac nuclear

CMS has a current price listed of \$675,000 for use with CPT code 78414. Cardiology bills an extremely low percentage of CPT code 78414 and defers to anesthesiology for input on this pricing.

3. Detector (Probe). This equipment is used by radiology. ACC has no comment on the pricing.

4. E55035 ECG signal averaging system

Signal averaging system software is added to the ECG machines. ACC is unaware of any stand-alone SAECG machines. A base ECG machine ranges from \$9,700-\$12,000 and the SAECG software, based on GE Medical/Marquette current price, is an additional \$3,500.

5. E55013 Programmer/pacemaker

The ACC, in consultation with the Heart Rhythm Society, recommends that CMS delete E55013 Programmer/pacemaker from the list of equipment used for pricing practice expense inputs. During the ACC and the Heart Rhythm Society's submission to the Practice Expense Advisory Committee (PEAC) in 2004, pricing information for the E55013 Programmer/pacemaker was specifically deleted due to current practice patterns. Physician offices are required to obtain numerous programmers from different manufactures in order to provide pacemaker analysis and reprogramming services for their patients. However, it is the current industry practice to provide these programmers without any cost to the physician's office.

6. E52007 Ultrasound, echocardiography digital acquisition (Novo Microsonics, Tom Tec)

Letter to Dr. Mark McClellan, MD - (cont'd)

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September 24, 2004

The ACC recommends that CMS delete E52007 from the list of equipment used for pricing practice expense inputs. This piece of equipment does not exist in the marketplace anymore. A digital workstation would now be used (i.e. GE echo PAC, Siemens Kinetdx, Philips Xcelera). We recommend that an appropriate CMS equipment code be available for these products. For a digital echo reading station that can read stress, the price range for the GE, Phillips and Siemens models is from \$25,000-\$30,000.

Supply items:

1. Blood pressure recording form, average

CMS is proposing a price of \$.31. Welch Allyn, one of the leading companies providing ambulatory blood pressure equipment, has a current price of \$1.55 each.

2. Pressure bag

Bag, Infuser Disposable both 500cc and 1000 cc, 5/box are \$14.29 each (source McKesson).

3. Tubing sterile, non-vented (fluid administration)

Set, IV Basic 15 DP 67" LL Non-Vented 50/case is \$.075 each (source McKesson).

Section 612-Cardiovascular Screening

CMS proposes coverage of the following three screening blood tests for conditions associated with cardiovascular disease:

1. A total cholesterol test.
2. A cholesterol test for high-density lipoproteins.
3. A triglycerides test.

These tests should be performed as part of a panel and should be done after a 12-hour fast. CMS is proposing coverage of each of these tests once every 5 years. In the future, CMS will use the National Coverage Process to add other cardiovascular screening tests.

CMS is proposing to pay for the screening cardiovascular disease tests at the same amounts paid for these tests when they are performed to diagnose an individual with signs and symptoms of cardiovascular disease. Medicare will pay for the tests under the clinical laboratory fee schedule.

Recommendation:

ACC is pleased that CMS will be offering this important screening benefit to beneficiaries. As CMS collects data on the effectiveness of this benefit and possible savings to the Medicare program in the future, we recommend it re-evaluate the five-year time frame of screening for a more frequent screening interval.

Drug Administration

The ACC is concerned that the CPT Editorial Panel Workgroup on Drug Administration may have inadvertently restricted the categories of biological therapies included under their proposed revisions to the infusion procedure codes. We understand that the CPT Editorial Panel has identified monoclonal antibodies and biological response modifiers as candidates for inclusion under the revised chemotherapy infusion codes.

ACC is aware of a class of biological products, neurohormones, used to treat advanced heart failure. We believe this class of therapies should be included under the revised chemotherapy infusion codes. These products are complex to administer, requiring reconstitution, mixing/dilution and calculation of patient-specific dosing regimens. Furthermore, these products require intensive monitoring because of side effect risks. However, this class of products are neither monoclonal antibodies nor biological response modifiers.

Recommendation:

The ACC recommends that a third term be added to include this new class of heart failure therapies, recombinant hemodynamic hormones.

As an alternative, CMS may wish to replace more specific terms mentioned above with a single, more inclusive term that references the full range of complex biologicals. As a result, the focus would move from the class of biological to the nature and complexity of the associated infusion procedure. ACC recommends CMS consider the term recombinant therapeutic proteins.

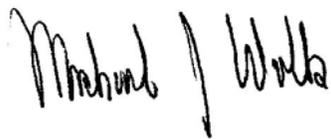
Letter to Dr. Mark McClellan, MD - (cont'd)

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September 24, 2004

We appreciate the opportunity to comment on this proposed rule. Please contact Anne Marie Bicha, ACC Regulatory and Legal Affairs, at (301) 493-2384 or abicha@acc.org with any questions or for additional information. Thank you.

Sincerely,

A handwritten signature in black ink that reads "Michael J. Wolk". The signature is written in a cursive style with a vertical line separating the first and last names.

Michael J. Wolk, MD, FACC
President

Submitter : Lydia Blanchard Date & Time: 09/24/2004 09:09:14

Organization : Lydia Blanchard, LMFT

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

Please redraw the map of California that has defined Santa Cruz County as rural. It is no longer definable as rural, in my informed opinion, especially since it is a bedroom community of Santa Clara County, has a major university, and many large businesses, including high technology ones.

Santa Cruz County's median home cost is \$630,000, which is higher than that of Santa Clara County, which is classified correctly as an urban county by CMS. (My two-bedroom town house is worth now about \$450,000, with a fine view across Monterey Bay.)

One of my doctors has recently decided no longer to accept Medicare. I am 70 years old.

PLEASE ALLOW OUR DOCTORS TO AFFORD TO LIVE HERE, WITH ADEQUATE MEDICARE AND MEDICAID COMPENSATION.

PLEASE MAKE IT POSSIBLE FOR SANTA CRUZ RESIDENTS TO HAVE A SUFFICIENT NUMBER OF *GOOD* DOCTORS, rather than having them leave for Santa Clara County.

CMS' classification of this county is affecting private insurance plans' payments to its doctors, as well.

The county is subject to regular natural disasters. My history of service to the Santa Cruz Red Cross Disaster Mental Health Team attests to that. We need adequate and well-funded medical and mental health care.

We have the same economic changes as Santa Clara County. Please do not ignore them. PLEASE DO NOT UNINTENTIONALLY, SLOWLY, AND SURELY DESTROY THE SANTA CRUZ COUNTY HEALTH CARE SYSTEM. LAST WEEK WE LOST ACCESS BY HELICOPTER TO SANTA CLARA COUNTY HOSPITALS FOR SPECIALIZED MEDICAL EMERGENCIES. THE SITUATION IS VERY SERIOUS.

AS A MENTAL HEALTH PROFESSIONAL I ASSERT THAT LOW QUALITY MEDICAL CARE IS A COMMUNITY MENTAL HEALTH ISSUE, AS WELL AS AN URGENT MEDICAL ONE. I AM FAMILIAR WITH MANY PARTS OF THE THIRD WORLD. PLEASE DO NOT LOWER SANTA CRUZ COUNTY'S STANDARDS TO THOSE OF THE THIRD WORLD.

Thank you for immediate action. --Lydia Blanchard, licensed marriage and family therapist #MFC34603

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

GENERAL

GENERAL

RE:CMS-1429-P

Dear Dr. McClellan:

The Society for Vascular Surgery (SVS) is pleased to accept the opportunity to submit the following comment. SVS is the largest and oldest national medical specialty society representing vascular surgeons in the United States. Our 2300 members provide a full spectrum of medical, surgical and interventional services to Medicare beneficiaries who suffer from arterial and venous disorders. SVS will address the following issues regarding the 2005 NPRM:

Proposed G-code (GOXX3) for venous mapping prior to hemodialysis access placement

Refinement of Equipment inputs for noninvasive vascular diagnostic codes

Comments on PE RVU relativity, PE \$ rate/hour, & outliers for office-priced codes

Proposed G-code for Venous Mapping Prior to Hemodialysis Access Placement

SVS appreciate CMS support for venous mapping because it will bring an improvement in the efforts to create fistulae for hemodialysis access. We view this proposal as closely related to the Fistula First initiative sponsored by CMS. We know that an arteriovenous (AV) fistula is the preferred vascular access for patients with end stage renal disease. AV fistulae have significantly lower rates of complications (such as infection and clotting), and longer patency compared to other access methods, resulting in fewer hospitalizations and lower costs. We have several comments on the proposal as it is now written.

The proposal includes a newly created G code for the operating surgeon to report venous mapping. We are concerned that restricting the use of the G code to the operating surgeon may be impractical. We note the following:

The mapping is often performed before the surgeon meets the patient. One of the documents CMS is distributing as part of Fistula First is the Fistula First Change Package that describes the best practices for increasing the use of AV fistulas. Step three of that document talks about early referral to a surgeon for an AVF only evaluation and timely placement. In it the following statement appears:

Nephrologist refers for vessel mapping where feasible, ideally prior to surgery referral.

The process of scheduling vascular mapping is such that the operating surgeon may not be available to interpret the mapping. Most vascular laboratories have more than one physician performing the professional interpretations on a regularly scheduled basis. The patient is usually given a choice of times to have the vascular mapping performed, and it may be done at a time when the operating surgeon is not assigned or available to perform the interpretation.

While surgeons who perform hemodialysis fistula placement regularly have the best concept of what constitutes an adequate vein for successful fistula creation, we believe appropriately qualified non-operating physicians can safely interpret vascular mapping. Medical literature provides minimally adequate vein diameters for wrist and more central fistulas as well as guidelines regarding evaluation for adequacy of arterial inflow and deep venous outflow. Accredited laboratories or credentialed technologists following these guidelines should provide the high quality studies needed to guide the surgeon in creating the best possible fistula.

We enthusiastically support the references to the need for appropriate quality standards being put in place in connection with the pre-HD access vein mapping procedure. In this regard, we strongly encourage CMS to adopt a requirement that the service only be payable where the technical component service is provided by an individual who is credentialed by an appropriate national credentialing body in vascular technology or by a

laboratory that has been accredited by an appropriate national accreditation body. We note that the clear majority of Medicare carrier jurisdictions require this standard to be met in connection with all other vascular ultrasound services.



Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 1-9

SECTION 611

See attached for comment on preventive office visit

CMS-1429-P-4085-Attach-1.pdf

CMS-1429-P-4085-Attach-2.doc



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*Society of Clinical Vascular Surgery
Washington, D.C.*

Kerry Stewart, Ed.D.
*American Association for Cardiovascular and
Pulmonary Rehabilitation
Baltimore, Maryland*

September 24, 2004

Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

Re: File Code CMS-1429-P
Section 611 and Section 612 of the Provisions of the Medicare
Modernization Act of 2003

The Vascular Disease Foundation appreciates the opportunity to offer comment regarding implementation of Sections 611 and 612 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

SECTION 611 Comment:

The goal of an initial preventive physical examination as defined in the proposed rules is for health promotion and disease detection. The patient's height, weight and brachial blood pressure, along with the electrocardiogram, are all elements to achieve that goal. However, this simple description omits a critical assessment tool that has been well-demonstrated to achieve these preventive goals. Specifically, the standard physical examination does not provide a sensitive assessment of vascular health and a large fraction (at least half) of individuals with peripheral arterial disease cannot now be detected by a standard office examination alone. However, the standard physical examination can be supplemented by performance of the ankle-brachial index (ABI) measurement. The value of this assessment tool is well established, but cannot be, and is not currently being, performed as a component of the office examination.¹ The Vascular Disease Foundation recommends that the wording of the ruling be modified to state, "along with the electrocardiogram and the ankle-brachial index."

This revised Medicare Modernization Act can serve public health by specifically identifying this test and its high preventive value, and thus achieve its mandated goal of health promotion and disease detection. This test serves as the internationally recognized diagnostic tool to identify peripheral arterial disease (PAD). PAD is associated with a very high proximate risk of cardiovascular morbidity and mortality, as individuals with PAD are known to suffer a near six-fold increased mortality due to preventable heart attack and stroke. As well, PAD directly causes lower extremity ischemic symptoms that markedly impair quality of life. "Claudication" represents the leg muscle pain that is caused by inadequate blood

flow during even minimal exercise (such as walking one block). This symptom threatens functional independence and causes a detrimental impact on personal and family life that is comparable to that suffered by individuals with severe heart failure. PAD is present in approximately 8-12 million Americans. Many more individuals are at short-term risk to develop PAD due to the presence of classical atherosclerosis risk factors. PAD that is not promptly diagnosed is more likely to progress to more severe stages, requiring use of health care resources. PAD is the major cause of preventable amputation in the United States. The ankle-brachial index is the only cost-effective objective diagnostic assessment that is practical to deploy in office-based settings. The ankle-brachial index is the only cost-effective objective diagnostic assessment that is practical to deploy in office-based settings. The ABI, however, as a test that requires significantly greater effort than any component of the physical examination, should not be considered simply as “part of” the office-based examination. Rather, recognition of the ABI as a distinct test is based on overt experience from epidemiologic surveys, study of office based practice, and an expanded research database. The ABI is akin to the “ECG for arterial disease”.

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SECTION 612 COMMENT:

The proposed rule lists specific tests for (10) Cardiovascular screening blood tests. The Vascular Disease Foundation recommends the word “blood” be omitted from the final rule. The narrow focus of this Act on blood testing alone restricts the potential benefit that could be accrued to the American public if more robust cardiovascular risk markers (e.g., the ABI) were included in this definition. Indeed, the ABI is the single most direct measurement of preventable cardiovascular risk, and its predictive value far exceeds that of any current blood test, providing a powerful rationale for including the ankle-brachial index as an integral component of Section 611. The rationale to not define “appropriate screening instrument” for screening individuals for depression, would equally apply to the cardiovascular screening tests. As with depression screening, the examining physician will want to use the appropriate screening tests “based on current clinical practice

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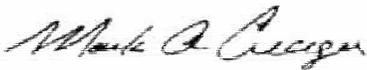
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Please do not hesitate to contact us if you have any questions regarding these data or public health implications of our recommendation.

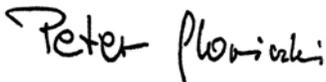
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Associate Professor of Epidemiology
University of Minnesota School of Public Health
Immediate Past President, Vascular Disease Foundation



Mark A. Creager, MD
Professor of Medicine
Harvard Medical School
Treasurer, Vascular Disease Foundation



Peter Gloviczki, MD
Professor of Surgery, Mayo Medical School
Director, Gonda Vascular Center, Mayo Clinic
President, Vascular Disease Foundation

Alain T. Drooz, MD
President-Elect, Vascular Disease Foundation



September 24, 2004

Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

Re: File Code CMS-1429-P
Section 611 and Section 612 of the Provisions of the Medicare
Modernization Act of 2003

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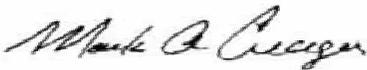
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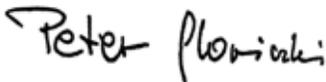
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President-Elect, Vascular Disease Foundation

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 1-9

PRACTICE EXPENSE

September 24, 2004

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1429-P

Via electronic transmittal

Dear Sirs:

I am a medical oncologist, practicing in a large group specialty practice (16 medical oncologists) in Northwest Georgia. Our practice serves Medicare beneficiaries from approximately 6 metropolitan counties in Northwest Georgia and adjacent rural counties. In 2004, we project to serve over 4,900 Medicare beneficiaries. I would like to comment on the adverse effect this proposed rule may have on these beneficiaries.

SECTION 303

1. ASP Payment Methodology

The implementation of this methodology, as proposed, will have immediate and severe adverse effects on Medicare beneficiaries' access to cancer care.

a. Insufficient information is contained in the proposed rule to calculate the specific drug allowances that will be in effect on January 1, 2005. This

is due to the fact that the methodology for determining ASP itself, described in other rule-making documents, is still being revised and tested. The methodology is insufficiently refined and not adequately validated to be implemented with this rule.

2. Provision for Appropriate Reporting and Billing for Physician Services Associated with the Administration of Covered Outpatient Drugs.

Despite the requirement of Section 1848(c) (2) (J) of the Act discussed in this section, it is noted that no additional codes, or revised codes, have been included in the proposed rule. It is, therefore, impossible to comment on the effect of any changes this provision may engender. However, without substantive changes in billing and coding provisions as required by the Act, practice expenses related to the provision of complex chemotherapy services will continue to be under recognized and under reimbursed. Any proposed changes under this section should have additional time for development, review, analysis, and comment prior to implementation, none of which are provided in the proposed rule.

IMPACT

VII Regulatory Impact Analysis

Based upon the limited information available in the proposed rule (tables 24, 25, 26, 27, and 28), I have calculated the potential impact on our group practice as follows:

Calculated Impact of Proposed Rule compared to 2004 % Change Change from 2004
Reimbursement Effects on E&M Codes - Table 24 1.59% \$37,467
Reimbursement Effects on Admin Codes - Table 25 (21.13%) (\$417,507)
Reimbursement Effects on Drug Codes - Table 28 (11.69%) (\$1,009,833)

Proposed 2005 Reimbursement Changes (10.72%) (\$1,389,872)

Calculated Impact of Proposed Rule on Practice Expenses and Physician Compensation

Projected 2005 Medicare Receipts \$ 14,993,825
Projected 2005 Medicare Drug Costs \$ 10,805,741
Projected Net Practice Receipts \$ 4,188,084
Projected 2005 Medicare Practice Expense \$ 5,060,648
NGOC 2005 Medicare Loss prior to Physician Compensation \$ 872,563
Medicare Patients 4,882

Proposed Changes as a percent of Projected Net Practice Receipts (33.19%)

Based upon this analysis, it is clear that we will not be able to provide Medicare beneficiaries the same level of services that we were able to provide in 2004. The cuts in allowable charges for expensive pharmaceuticals are so drastic that we will not be able to furnish these services for all Medicare beneficiaries. For many rural patients, alternative treatment facilities may not be available. Particularly disturbing is the fact that the most needy Medicare patients may be the most adversely affected. These include the indigent and poor, who are unable to afford premiums for Medi-gap co-insurance, the disabled, for whom Medi-gap co-insurance is not available; and Medicaid beneficiaries for whom no payment is made for deductible or co-insurance under current Georgia Medicaid Law. As the Medicare p

Northwest Georgia Oncology Centers, P.C.

“for the care of cancer and blood disorders”

Michael B. Andrews, MD
Bruce J. Gould MD
Richard G. Gray, MD
Hillary A. Hahn MD, PhD
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Carlos A. Osmon, MD
Raul H. Oyola, MD
Suzanne E. Patton, MD, PhD
Randall E. Pierce, MD
Don W. Shaffer, II, MD

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Page 1 of 4

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NOTES/COMMENTS:

Thank you for your referral to our practice. This report is being sent to you by facsimile to assist in the coordination of care of our mutual patient. Please do not hesitate to call me with any questions that you may have. If this is not the preferred fax number to receive patient information such as consultations, progress notes or other correspondence between our offices; please contact our privacy officer at (770) 281-5122.

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Northwest Georgia Oncology Centers, P.C.

“for the care of cancer and blood disorders”

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1/28/2005

Page 2 of 4

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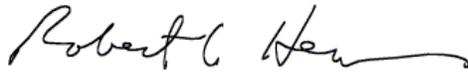
Proposed Changes as a percent of Projected Net Practice Receipts **(33.19%)**

Based upon this analysis, it is clear that we will not be able to provide Medicare beneficiaries the same level of services that we were able to provide in 2004. The cuts in allowable charges for expensive pharmaceuticals are so drastic that we will not be able to furnish these services for all Medicare beneficiaries. For many rural patients, alternative treatment facilities may not be available. Particularly disturbing is the fact that the most needy Medicare patients may be the most adversely affected. These include the indigent and poor, who are unable to afford premiums for Medi-gap co-insurance, the disabled, for whom Medi-gap co-insurance is not available; and Medicaid beneficiaries for whom no payment is made for deductible or co-insurance under current Georgia Medicaid Law. As the Medicare payments are inadequate to cover the cost of the pharmaceutical drugs for these patients, medically necessary cancer treatment may not be available to them.

While appropriate reform of the Medicare payment system for cancer services is needed, the proposed rule will undermine the ability of Medicare beneficiaries to receive these services in 2005. A transitioning of the payment program is needed in 2005 to allow the adequate implementation of the needed revisions for billing and coding of services, and to stabilize the new, untested, ASP system. Transition payment levels should be adopted to avoid abrupt, severe, and drastic discounts in payment that would otherwise adversely impact the delivery system.

I appreciate your attention to these comments, and hope that they will be understood in your analysis of the final rule.

Sincerely,

A handwritten signature in black ink, appearing to read "Robert C. Hermann". The signature is fluid and cursive, with a long horizontal flourish extending to the right.

Robert C. Hermann, MD

RCH/kjc

Northwest Georgia Oncology Centers, P.C.

“for the care of cancer and blood disorders”

Michael B. Andrews, MD
Bruce J. Gould MD
Richard G. Gray, MD
Hillary A. Hahn MD, PhD
Robert C. Hermann, MD
Bradley J.G. Larson, MD
Kathleen A. Long, MD
Frank P. McCoy, MD, PhD

Steven L. McCune, MD, PhD
Satyen R. Mehta, MD
Debra R. Miller, MD
Carlos A. Osmon, MD
Raul H. Oyola, MD
Suzanne E. Patton, MD, PhD
Randall E. Pierce, MD
Don W. Shaffer, II, MD

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Page 1 of 4

Sender's Fax Number:
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Re:
Referring Physicians: Patient Information

Sender's Reference Number:
MRN.0

NOTES/COMMENTS:

Thank you for your referral to our practice. This report is being sent to you by facsimile to assist in the coordination of care of our mutual patient. Please do not hesitate to call me with any questions that you may have. If this is not the preferred fax number to receive patient information such as consultations, progress notes or other correspondence between our offices; please contact our privacy officer at (770) 281-5122.

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Northwest Georgia Oncology Centers, P.C.

“for the care of cancer and blood disorders”

55 Witcher Street, Suite 300
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Don W. Shaffer, II, MD

September 24, 2004

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1429-P

Via electronic transmittal

Dear Sirs:

I am a medical oncologist, practicing in a large group specialty practice (16 medical oncologists) in Northwest Georgia. Our practice serves Medicare beneficiaries from approximately 6 metropolitan counties in Northwest Georgia and adjacent rural counties. In 2004, we project to serve over 4,900 Medicare beneficiaries. I would like to comment on the adverse effect this proposed rule may have on these beneficiaries.

SECTION 303

1. ASP Payment Methodology

The implementation of this methodology, as proposed, will have immediate and severe adverse effects on Medicare beneficiaries' access to cancer care.

- a. Insufficient information is contained in the proposed rule to calculate the specific drug allowances that will be in effect on January 1, 2005. This is due to the fact that the methodology for determining ASP itself, described in other rule-making documents, is still being revised and tested. The methodology is insufficiently refined and not adequately validated to be implemented with this rule.

2. Provision for Appropriate Reporting and Billing for Physician Services Associated with the Administration of Covered Outpatient Drugs.

1/28/2005

Page 2 of 4

Despite the requirement of Section 1848(c) (2) (J) of the Act discussed in this section, it is noted that no additional codes, or revised codes, have been included in the proposed rule. It is, therefore, impossible to comment on the effect of any changes this provision may engender. However, without substantive changes in billing and coding provisions as required by the Act, practice expenses related to the provision of complex chemotherapy services will continue to be under recognized and under reimbursed. Any proposed changes under this section should have additional time for development, review, analysis, and comment prior to implementation, none of which are provided in the proposed rule.

IMPACT
VII Regulatory Impact Analysis

Based upon the limited information available in the proposed rule (tables 24, 25, 26, 27, and 28), I have calculated the potential impact on our group practice as follows:

<u>Calculated Impact of Proposed Rule compared to 2004</u>	% Change	Change from 2004
<u>Reimbursement Effects on E&M Codes - Table 24</u>	<u>1.59%</u>	<u>\$37,467</u>
<u>Reimbursement Effects on Admin Codes - Table 25</u>	<u>(21.13%)</u>	<u>(\$417,507)</u>
<u>Reimbursement Effects on Drug Codes - Table 28</u>	<u>(11.69%)</u>	<u>(\$1,009,833)</u>
<u>Proposed 2005 Reimbursement Changes</u>	<u>(10.72%)</u>	<u>(\$1,389,872)</u>

Calculated Impact of Proposed Rule on Practice Expenses and Physician Compensation

<u>Projected 2005 Medicare Receipts</u>	<u>\$ 14,993,825</u>
<u>Projected 2005 Medicare Drug Costs</u>	<u>\$ 10,805,741</u>
<u>Projected Net Practice Receipts</u>	<u>\$ 4,188,084</u>
<u>Projected 2005 Medicare Practice Expense</u>	<u>\$ 5,060,648</u>
<u>NGOC 2005 Medicare Loss prior to Physician Compensation</u>	<u>\$ 872,563</u>
<u>Medicare Patients</u>	<u>4,882</u>

Proposed Changes as a percent of Projected Net Practice Receipts **(33.19%)**

Based upon this analysis, it is clear that we will not be able to provide Medicare beneficiaries the same level of services that we were able to provide in 2004. The cuts in allowable charges for expensive pharmaceuticals are so drastic that we will not be able to furnish these services for all Medicare beneficiaries. For many rural patients, alternative treatment facilities may not be available. Particularly disturbing is the fact that the most needy Medicare patients may be the most adversely affected. These include the indigent and poor, who are unable to afford premiums for Medi-gap co-insurance, the disabled, for whom Medi-gap co-insurance is not available; and Medicaid beneficiaries for whom no payment is made for deductible or co-insurance under current Georgia Medicaid Law. As the Medicare payments are inadequate to cover the cost of the pharmaceutical drugs for these patients, medically necessary cancer treatment may not be available to them.

While appropriate reform of the Medicare payment system for cancer services is needed, the proposed rule will undermine the ability of Medicare beneficiaries to receive these services in 2005. A transitioning of the payment program is needed in 2005 to allow the adequate implementation of the needed revisions for billing and coding of services, and to stabilize the new, untested, ASP system. Transition payment levels should be adopted to avoid abrupt, severe, and drastic discounts in payment that would otherwise adversely impact the delivery system.

I appreciate your attention to these comments, and hope that they will be understood in your analysis of the final rule.

Sincerely,

A handwritten signature in cursive script, appearing to read "Robert C. Hermann".

Robert C. Hermann, MD

RCH/kjc

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

SEE ATTACHMENT.

**Department of Health and Human Services
Centers for Medicare and Medicaid Services (CMS)
Offices of Strategic Operations and Regulatory Affairs**

The attachment to this document is not provided because:

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2. The submitter intended to attach more than one document, but not all attachments were received.
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Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

See attached



September 23, 2004

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1429-P
P.O. Box 8012
Baltimore, MD 21244-8012

VIA E-MAIL ONLY

Re: Therapy---Incident To

Dear Sir/Madam:

I am the past-President of the Minnesota Athletic Trainers Association (“MATA”). I am writing this letter on behalf of MATA regarding the August 5th proposed rule on “Revisions to Payment Policies Under the Physician Fee Schedule for the Calendar Year 2005.” This proposal seeks to restrict payment for “incident to” services furnished in physicians offices and clinics. I am writing to urge the Center for Medicare and Medicaid Services (“CMS”) to withdraw this proposal. Limiting providers of “incident to” services to only physical therapists and physical therapy aides will adversely affect Medicare beneficiaries’ access, quality and cost of care.

It is clear to both MATA and CMS that the demand represented by the increasing size of the aging population, when compared to the supply represented by the number of physical therapists expected available in the near future will produce a shortage of physical therapists.¹ The field is plagued by difficulty in recruiting, retaining and competitively compensating physical therapists. The shortage of physical therapists is especially felt in rural areas. The aging population will intensify this problem. Eliminating Medicare payments where athletic trainers could provide “incident to” services will only exacerbate this problem. Predictable consequences include delays in receiving treatment due to greater demand than supply, greater travel time to meet with a physical therapist, and physicians may perform more physical therapy services in their offices in order to treat their patients needs due to the unavailability of physical therapists.

Not only will Medicare beneficiaries suffer challenges in access to health care, they will also face higher costs of health care. A basic economic principle is that in cases where demand is greater than supply, costs will rise. First, travel expenses incurred while commuting to therapy

¹ See generally, U.S. Department of Labor, Bureau of Labor Statistics, Occupational Outlook Handbook, Physical Therapists, Mar. 21, 2004 available at: <http://stats.bls.gov/oco/oco2001.htm#emply> (discussing the projected demand for physical therapists due to the growing elderly population, the increasing needs of the baby-boom generation, developing medical technology increasing demand for rehabilitative care and health promotion among employers).

will add to the beneficiaries' cost of physical therapy services. Second, if physicians perform more physical therapy services in their offices, the costs will also increase. Likewise, costs will increase if providers are required to employ a specific population of clinicians to provide services when the supply of clinicians is already short. These costs will ultimately be passed on to Medicare beneficiaries.

Finally, this change will not produce higher quality of care. There is no scientifically supportable evidence that the use of athletic trainers produces substandard care. Second, athletic trainers have qualifications and training similar to those required of physical therapists. The American Physical Therapy Association ("APTA") has claimed that "under the current policy it is possible for a high school student or another individual with no training in anatomy, physiology, neuromuscular reeducation or other techniques to furnish services in the physician's office without the physician actually observing the provision of these services."² As a result, the APTA seeks a drastic overhaul of the current policy to permit only physical therapists and physical therapist assistants from performing such functions. APTA argues that this reform will ensure that individuals performing these services are adequately educated and accountable.

Whatever is the validity of the APTA concern regarding untrained individuals performing "incident to" services under the current version of the policy, these concerns simply cannot involve certified or licensed athletic trainers. Like physical therapists, all certified or licensed athletic trainers must have a bachelor's or master's degree from an accredited college or university. Many athletic trainers possess a master's degree or higher educational credentials; in Minnesota the number is as high as 70% in clinical settings. Athletic trainer programs are accredited through an independent process by the Commission on Accreditation of Allied Health Education Programs via the Joint Review Committee on Education Programs in Athletic Training. Foundation courses include human physiology, human anatomy, kinesiology/biomechanics, nutrition, acute care of injury and illness, statistics and research design, and exercise physiology. In addition, athletic trainers are regulated by a significant number of states. For example, the state of Minnesota requires that registered athletic trainers complete an approved education program, have a baccalaureate degree from an accredited college or university and earn a qualifying score on a credentialing examination. MINN. STAT. § 148.7808, subd. 1(2), (4), and (9). As a result, both types of professionals are accountable for their actions.³

In conclusion, the proposed changes would result in the elimination of athletic trainers as an affordable and quality means of health care to Medicare beneficiaries. Furthermore, this restriction would result in increased costs and decreased access to "incident to" services. Both Medicare beneficiaries and athletic trainers will suffer significant harm if the proposed regulations are passed. Please consider these concerns and withdraw this proposal.

Sincerely,

Scott H. Kulstad, M.Ed., ATC/R

² Letter from Dave Mason, Vice President, Government Affairs, American Physical Therapy Association, to Thomas A. Scully, Administrator, Centers for Medicare and Medicaid Services of 10/6/2003 at 2, *available at* http://www.apta.org/documents/public/fee_sche.pdf.

³ Not only state legislatures, but federal courts, have recognized the legitimacy of the athletic trainer profession. *Cf. United States of America, ex rel., Toni Lee v. Fairview Health System*, Civ. No. 02-270, (D. Minn. July 22, 2004).

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

GENERAL

GENERAL

See Attached Letter

CMS-1429-P-4089-Attach-1.pdf

**Department of Health and Human Services
Centers for Medicare and Medicaid Services (CMS)
Offices of Strategic Operations and Regulatory Affairs**

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Submitter : Date & Time:
Organization :
Category :

Issue Areas/Comments**Issues 1-9**

PRACTICE EXPENSE

Comments on PE RVU relativity, PE \$ rate/hour, & outliers for office-priced codes

SVS appreciates CMS efforts to add true relativity to the MFS PE RVUs. We understand the methodology, we appreciate the complexity of the system, and we are extremely impressed by the massive amount of hard work required of CMS staff to bring this to fruition. Nevertheless, we remain very concerned about wide variations in PE RVUs derived in some instances by this methodology. We suggest that some outliers require additional focus to determine whether there are errors in direct inputs or whether the examples reflect larger problems with the methodology. The following are some examples derived from sorting the MFS by ratio of non-facility to facility PE RVUs. This approach tends to identify services with expensive disposables that must be purchased by office practices, but in some cases the combination of inputs, PE/hr, and PE RVU methodology result in troublesome values:

CPT 20225 Biopsy bone, trocar, needle, deep. This code is a one-hour physician service with 26.72 non-facility PE RVUs when performed in office. According to the database information we have available there appears to be no major or expensive disposable inputs. We suspect this may somehow represent an error.

CPT 45303 Sigmoidoscopy with Dilation. This service has 19.32 non-facility PE RVUs. The major PE input is a dilation balloon, supposedly requiring 3 balloons at \$498. If the typical service actually requires 3 balloons, then the non-facility payment of \$721 may be reasonable, but this example demonstrates the crucial dependence of PE payment on accurate item pricing and total number of items required for the typical service.

CPT 20982 Ablate bone tumor, percutaneous, includes a radiofrequency probe that reportedly costs \$1,950 for a practice to purchase. This service garners 109.89 PE RVUs, and the service pays \$4,401 in the office setting. Other office supplies and physician work do not appear to close the large gap between the single expensive supply item and the total non-facility PE RVU assignment. We were not able to determine if this service derives from the physician-no-work pool, or PE RVUs were determined from the standard PE methodology. Assuming the latter, we are concerned that methodology scaling factors combined with very high PE/hr rates combined to produce a payment that is not truly resource-based.

CPT 52214 and 52224, cystoscopy procedures, and CPT 36516 apheresis procedures are high outliers for non-facility PE RVUs at 37.93, 36.30, and 84.13 respectively. For the cystoscopy procedures, these values that are 12.5 and 13.5 fold greater than their in-facility counterparts. These services are newly valued on the non-facility side, and we have not yet been able to identify the cost of disposable items that would be purchased by an office practice. Nevertheless, we believe these would be excellent tests of the PE methodology including aggregate impact of PE/hr and scaling factors. If aggregate actual costs approach \$1500 for the cystoscopies and \$3,100 for the apheresis, then we could conclude the system is working well. If not, SVS suspects PE/hr and scaling are the culprits.

SVS appreciates the opportunity to comment. We do not want these latter observations to reflect any bias against the individual specialties involved with the identified procedures, nor any criticism of the hard work of CMS staff in creating and implementing the methodology. We do believe that PE/hr rates are suspect based on a number of deficiencies in the original SMS data collection tool, and we fear these problems are magnified by the PE methodology. In this circumstance we recommend consideration of alternative methodologies for reimbursement of high-priced single-use items in the non-facility setting.

September 24, 2004

VIA ELECTRONIC DELIVERY

Dr. Mark McClellan
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8012
Baltimore, MD 21244-8012

RE: CMS-1429-P

Dear Dr. McClellan:

The Society for Vascular Surgery (SVS) is pleased to accept the opportunity to submit the following comment. SVS is the largest and oldest national medical specialty society representing vascular surgeons in the United States. Our 2300 members provide a full spectrum of medical, surgical and interventional services to Medicare beneficiaries who suffer from arterial and venous disorders. SVS will address the following issues regarding the 2005 NPRM:

- Proposed G-code (GOXX3) for venous mapping prior to hemodialysis access placement
- Refinement of Equipment inputs for noninvasive vascular diagnostic codes
- Comments on PE RVU relativity, PE \$ rate/hour, & outliers for office-priced codes

Proposed G-code for Venous Mapping Prior to Hemodialysis Access Placement

SVS appreciate CMS' support for venous mapping because it will bring an improvement in the efforts to create fistulae for hemodialysis access. We view this proposal as closely related to the "Fistula First" initiative sponsored by CMS. We know that an arteriovenous (AV) fistula is the preferred vascular access for patients with end stage renal disease. AV fistulae have significantly lower rates of complications (such as infection and clotting), and longer patency compared to other access methods, resulting in fewer hospitalizations and lower costs. We have several comments on the proposal as it is now written.

The proposal includes a newly created G code for the operating surgeon to report venous mapping. We are concerned that restricting the use of the G code to the operating surgeon may be impractical. We note the following:

- The mapping is often performed before the surgeon meets the patient. One of the documents CMS is distributing as part of Fistula First is the Fistula First Change Package that describes the best practices for increasing the use of AV fistulas. Step three of that document talks about early referral to a surgeon for an "AVF only" evaluation and timely placement. In it the following statement appears:

“Nephrologist refers for vessel mapping where feasible, ideally prior to surgery referral”.

- The process of scheduling vascular mapping is such that the operating surgeon may not be available to interpret the mapping. Most vascular laboratories have more than one physician performing the professional interpretations on a regularly scheduled basis. The patient is usually given a choice of times to have the vascular mapping performed, and it may be done at a time when the operating surgeon is not assigned or available to perform the interpretation.
- While surgeons who perform hemodialysis fistula placement regularly have the best concept of what constitutes an adequate vein for successful fistula creation, we believe appropriately qualified non-operating physicians can safely interpret vascular mapping. Medical literature provides minimally adequate vein diameters for wrist and more central fistulas as well as guidelines regarding evaluation for adequacy of arterial inflow and deep venous outflow. Accredited laboratories or credentialed technologists following these guidelines should provide the high quality studies needed to guide the surgeon in creating the best possible fistula.
- We enthusiastically support the references to the need for appropriate quality standards being put in place in connection with the pre-HD access vein mapping procedure. In this regard, we strongly encourage CMS to adopt a requirement that the service only be payable where the technical component service is provided by an individual who is credentialed by an appropriate national credentialing body in vascular technology or by a laboratory that has been accredited by an appropriate national accreditation body. We note that the clear majority of Medicare carrier jurisdictions require this standard to be met in connection with all other vascular ultrasound services. Because these services are so operator-dependent, the services simply are not reasonable and necessary in the absence of credentialing or accreditation.

If CMS continues to restrict the code to the operating surgeon, language to that effect needs to be included in the code descriptor. Then the operating surgeon will use the new G code and all other physicians will continue to use CPT code 93971, *Duplex scan of extremity veins including responses to compression and other maneuvers; unilateral or limited study*, and ICD-9 CM diagnostic code 585, *Chronic renal failure*.

Our second concern with the proposal is that the study described by the proposed G code, which CMS considers similar to code 93971, does not reflect pre-dialysis imaging protocols now being performed. Many existing thorough vascular laboratory protocols include a Doppler evaluation to assure adequacy of arterial inflow, including, at minimum, recorded arterial Doppler waveform morphology and Doppler based brachial artery pressure (example protocol in

Appendix 1). This means that assigning technical and professional RVUs to the new G-code equivalent to the limited venous duplex scan will undervalue a study that evaluates both veins and arteries in the proposed extremity. The technical component will be undervalued more than the professional component.

In view of this second concern with the proposed G code, we would like to suggest a different G code descriptor. modeled after CPT code 93990, *Duplex scan of hemodialysis access (including arterial inflow, body of access and venous outflow)*. We suggest the following descriptor: *Duplex scan for proposed hemodialysis access including superficial venous mapping, evaluation of deep veins to exclude central vein obstruction, and evaluation of arterial inflow to ensure adequacy, one extremity*. We would suggest the additional work of searching for a new access involves at least 20 percent more technical and physician work than evaluation of an established access since more veins need to be mapped. We expect this approach would help surgeons choose the optimal fistula site. With CMS support for the concept, it is likely that several specialty societies will have interest in cooperatively submitting a Category I CPT code application for this service. The CPT process will permit dialogue among physicians to arrive at the best possible coding solutions and the RUC process will allow physicians from many specialties to participate in the relative value recommendation.

Finally, it appears that CMS is searching for a means to reward surgeons who create AV fistulas. This is not possible in the regular Medicare physician fee schedule because, by statute, it is resource-based. However, we believe this would be a good place to test a pay-for-performance (P4P) quality measure. We are aware that there are a number of demonstration opportunities to create a higher quality of care for Medicare beneficiaries. We are enthusiastic about P4P but believe we will both benefit from testing the concept on a small scale before moving forward with national implementation across all of surgery.

Our proposal calls for surgeons to track initial proportion of new hemodialysis access placed as fistulas (rather than synthetic AV grafts); perioperative complications; and functional fistula patency after maturation (two to four months postoperatively), either by physical examination by the operating surgeon, a physical examination and a report from the nephrologist, or an evaluation by duplex scan (CPT code 93990, *Duplex scan of hemodialysis access (including arterial inflow, body of access and venous outflow)*). Those physicians meeting quality thresholds would be rewarded with a lump sum payment. We will be happy to discuss details of our proposal at any time.

Refinement of Equipment inputs for noninvasive vascular diagnostic codes

We thank CMS for implementing a long-needed update in equipment inputs for noninvasive vascular diagnostic services, incorporated in Equipment code E52018. This refinement is most welcome and ensures a much more accurate payment for our services. However, we note that CMS has not yet adopted the additional refinements that we suggested for the other ancillary equipment present in a vascular ultrasound room. These additional expenses should be reflected in CMS's practice expense calculation for vascular ultrasound services, CPT codes 93875-93979, and 93990. We understand that the CMS equipment and supply contractor has inputs for

“ultrasound room, vascular”. We ask that these additional refinements be undertaken and made effective for January 1, 2005 if at all possible.

Comments on PE RVU relativity, PE \$ rate/hour, & outliers for office-priced codes

SVS appreciates CMS efforts to add true relativity to the MFS PE RVUs. We understand the methodology, we appreciate the complexity of the system, and we are extremely impressed by the massive amount of hard work required of CMS staff to bring this to fruition. Nevertheless, we remain very concerned about wide variations in PE RVUs derived in some instances by this methodology. We suggest that some outliers require additional focus to determine whether there are errors in direct inputs or whether the examples reflect larger problems with the methodology. The following are some examples derived from sorting the MFS by ratio of non-facility to facility PE RVUs. This approach tends to identify services with expensive disposables that must be purchased by office practices, but in some cases the combination of inputs, PE/hr, and PE RVU methodology result in troublesome values:

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Sincerely yours,

Robert M. Zwolak, M.D.
Chair, Government Relations
Society for Vascular Surgery

Submitter : Mrs. Marcey Keefer Hutchison Date & Time: 09/24/2004 08:09:02

Organization : Therapeutic Associates

Category : Physical Therapist

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

To: Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1429-P
P.O. Box 8012
Baltimore, MD 21244-8012

Dear Dr. McClellan,

I am a physical therapist and certified athletic trainer with 13 years experience in physical therapy private practice. I am writing in support of the August 5th proposed rule on 'Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005'. It has been my privilege to work with both physical therapists and certified athletic trainers over the years. I myself hold both credentials and believe this allows me to view this topic from both sides of the fence. Both professions are well trained and qualified to provide health care in very distinct and different areas. Only the education and training a physical therapist has qualifies that practioner to provide physical therapy services. It is vitally important to the well being of our Medicare patients that physical therapy be delivered by a therapist as they are highly trained in the areas of neurology and pathology so commonly associated with the needs of Medicare patients. This area of rehabilitation training is unique to the physical therapy profession. Other health care providers may have some knowledge of general physical medicine principles but lack the critical knowledge essential in providing safe, effective and appropriate physical therapy.

Thank you so much for taking your time to read my email and for your thoughtful consideration of the points I've made.

Sincerely,

Marcey Keefer Hutchison, MS, PT, ATC

Submitter :

Date & Time:

09/24/2004 08:09:24

Organization :

Category :

Health Care Professional or Association

Issue Areas/Comments**Issues 20-29**

THERAPY - INCIDENT TO

I strongly support the August 5 proposed rule on "Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005" discussed by CMS, which establishes the requirements and qualifications of individuals who perform patient physical therapy services in physician's offices.

My comments aren't the intention of discrediting non-PT/PTA healthcare professionals currently providing physical therapy services under "incident to," but to express the need to match educational background to scope of services provided, in the best interest of the patient, especially the Medicare patient.

I have been a licensed Physical Therapist in Illinois for 17 years. I have served many roles within the physical therapy community such as Supervisor of Physical Therapy, Manager of Physical Therapy, and Director of Physical Therapy. I have provided managed care for patients (inpatient and outpatient) needing rehabilitation to include spinal cord injury and brain injury patients. Accomplishing a degree and accreditation has equipped me with advanced training in anatomy and physiology along with a detailed understanding of pathology and disease processes, as well as the impact they have on movement disorder and function. This training enables physical therapists to obtain positive results for individuals with disabilities and other conditions requiring rehabilitation.

I am an active advocate of professional and accredited healthcare services within my community, with a shared goal of providing the best care for the patient. Along with my accomplished degree and accreditation, I have instructed a college level Physical Therapy Program course for 4 years. I share my background because not only do I fully support CMS's stance that individuals providing physical therapy in a physician office must be graduates of an accredited professional physical therapist program, but also because I stand by the belief that a common educational standard of practice should exist amongst individuals who provide physical therapy services.

In the best interest of the Medicare patient, I strongly feel that unqualified personnel should not be providing physical therapy services. Lack of educational background toward the needs of the patients receiving physical therapy, most importantly the Medicare patient, is a disservice to the patient who receives physical therapy services from an unqualified provider. Other individuals who qualify to provide services "incident to" physicians, who are not PTs or PTAs under the supervision of a PT, do not have the same educational background and therefore are not able to furnish the best quality of assessment, treatment, and outcome the patient deserves.

Sincerely,

Teresa Reiser, PT

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

GENERAL

GENERAL

The American Nephrology Nurses Association (ANNA) thanks you for the opportunity to provide comments about the Proposed Rule for the Calendar Year 2005 Physician Fee Schedule (Proposed Rule). ANNA is a professional organization representing some 11,000 nephrology nurses whose main patient population is the hemodialysis population. ANNA is a member of the Kidney Care Partners (KCP) and these comments should be considered as additional to their response and not in conflict

We have four areas of specific interest:

1. Nephrology nurses love what they do best ? direct patient care. Our concern with the financial aspects of this rule is that there will be a net reduction in the overall reimbursement for the dialysis treatment and dialysis related drugs that will impact decisions that are made by providers and that this, in turn, will further impede our ability to recruit and retain qualified, experienced nurses into our specialty to work in dialysis units. Because dialysis facilities lack an annual update, we are challenged to compete with hospitals that can offer nurses so much more in terms of appropriate workload, training, administrative support as well as salary. Nephrology nurses want to be appropriately compensated but we value even more the benefits of having proper training and experienced supervision of all the staff.

2. The venous mapping rule should be revised to include arterial studies because it has been clearly shown through the work of leaders in the National Vascular Access Improvement Initiative (Fistula First) that at times arterial studies are necessary to ensure the success of fistula creation. We therefore suggest renaming the studies vascular mapping.

We further recommend that reimbursement for these studies be extended to nephrologists and interventional radiologists who frequently perform the studies prior to surgical creation of the fistula.

3. We applaud the expansion of the telehealth services to include the monthly management visits for dialysis patients with end-stage renal disease (ESRD).

As proposed, ANNA supports the standard that every ESRD dialysis patient have a face-to-face comprehensive assessment as part of their monthly care plan. This face-to-face visit can be completed by either a physician or practitioner (nurse practitioner, clinical nurse specialist, or physician assistant). The other 2 to 3 monthly visits could be made either in-person or electronically, with an inexpensive interactive audio and video telecommunications system which are now readily available commercially. We support the proposed new G-codes for ESRD-related services to be added to the list of telehealth services.

To meet the August 5, 2004 NRPM regarding ESRD patients, nephrologists and practitioners (NPs, CNSs, and PAs) would complete the once a month comprehensive in-person visit to the ESRD patient. The other 2 or 3 monthly visits could be completed by setting up a satellite office in a distant dialysis facility, and completing telehealth visits via telecommunications technologies for an audio and video-conference.

4. We trust that nurse practitioners will be included in all areas that describe physicians as medical care providers. We believe that nurse practitioners in collaboration with nephrologists provide high quality care to the hemodialysis patient care population. Indeed it is our sincere hope that when ESRD Disease Management is a reality for all hemodialysis patients that nurse practitioners will play an integral role in the day to day management of this patient population.

ANNA members sincerely appreciate your request for, and review of, our input into this most important rule. We hope that you will not hesitate in contacting us if you have questions regarding these comments (Lesley Dinwiddie, (919) 859-0994) or if we can be of any help in the future.

September 24, 2004

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

Re: CMS-1429-P; Comments on Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2005; Proposed Rule

Dear Administrator McClellan:

The American Nephrology Nurses Association (ANNA) thanks you for the opportunity to provide the Centers for Medicare and Medicaid Services (CMS) with comments about the Proposed Rule for the Calendar Year 2005 Physician Fee Schedule (Proposed Rule).¹ ANNA is a professional organization representing some 11,000 nephrology nurses whose main patient population is the hemodialysis population. ANNA is a member of the Kidney Care Partners (KCP) and these comments should be considered as additional to their response and not in conflict

We have four areas of specific interest:

1. Nephrology nurses love what they do best – direct patient care. Our concern with the financial aspects of this rule is that there will be a net reduction in the overall reimbursement for the dialysis treatment and dialysis related drugs that will impact decisions that are made by providers and that this, in turn, will further exacerbate the recruitment and retention of qualified, experienced nurses into our specialty to work in dialysis units. Because dialysis facilities lack an annual update, we are challenged to compete with hospitals that can offer nurses so much more in terms of appropriate workload, training, administrative support as well as salary. Nephrology nurses want to be appropriately compensated but we value even more the benefits of having proper training and experienced supervision of all the staff. It is the stress of not having these, if reimbursement is compromised, that make new nurses leave and more experienced nurses move to positions that have less liability and stress attached.
2. The venous mapping rule should be revised to include arterial studies because it has been clearly shown through the work of leaders in the National Vascular Access Improvement Initiative (Fistula First) that at times arterial studies are necessary to ensure the success of fistula creation. We therefore suggest renaming the studies vascular mapping.

¹ 69 Fed. Reg. 47488 (2004).

We further recommend that reimbursement for these studies be extended to nephrologists and interventional radiologists who frequently perform the studies prior to surgical creation of the fistula.

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As proposed, ANNA supports the standard that every ESRD dialysis patient have a face-to-face comprehensive assessment as part of their monthly care plan. This face-to-face visit can be completed by either a physician or practitioner (nurse practitioner, clinical nurse specialist, or physician assistant). The other 2 to 3 monthly visits could be made either in-person or electronically, with an inexpensive interactive audio and video telecommunications system which are now readily available commercially. We support the proposed new G-codes for ESRD-related services to be added to the list of telehealth services.

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4. In addition to the inclusion of nurse practitioners in the rule on telehealth, we trust that nurse practitioners will be included in all areas that describe physicians as medical care providers. We believe that nurse practitioners in collaboration with nephrologists provide high quality care to the hemodialysis patient care population. Indeed it is our sincere hope that when ESRD Disease Management is a reality for all hemodialysis patients that nurse practitioners will play an integral role in the day to day management of this patient population.

ANNA members sincerely appreciate your request for, and review of, our input into this most important rule. We hope that you will not hesitate in contacting us if you have questions regarding these comments (Lesley Dinwiddie, 919- 859-0994) or if we can be of any help in the future.

Sincerely,



Lesley Dinwiddie, MSN, RN, FNP, CNN
President
American Nephrology Nurses' Association

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

GENERAL

GENERAL

See attached.

CMS-1429-P-4094-Attach-1.pdf

CMS-1429-P-4094-Attach-2.pdf

Center for Telemedicine Law

Overcoming Barriers to Telehealth

September 21, 2004

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services, HHS
7500 Security Blvd.
Baltimore, MD 21244-1850

Dear Dr. McClellan:

Thank you for the opportunity to provide the Centers for Medicare & Medicaid Services with **CODING – TELEHEALTH** comments pertaining to CMS-1429-P: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar year 2005.

As you know the telehealth field is growing and is certainly a part of the health care solution in a variety of areas:

- Providing health care access particularly in rural, remote, and frontier areas;
- Providing patients with access to care and specialists when they need it;
- Ameliorating provider burn out in rural areas or specialty areas;
- Addressing professional nursing shortages;
- Providing health care services to incarcerated or non-ambulating populations at a fraction of the cost of transporting and treating the patient; and,
- Providing disease management and monitoring for high risk and high cost populations, such as diabetics.

Over the past 10 years HRSA's Office for Advancement of Telehealth (OAT) has provided millions of dollars to launch successful telehealth projects. These early days of providing research grant funding for telehealth projects has made telehealth more mainstream. Both audio and video consults have become standard health care practices and joins the world of the Internet-based health information, email communications, electronic health records, and "smart cards", which allow consumers to carry their health records with them on what is essentially a credit card device. Certainly, the patients and health care staff, including nurses, physicians, and other health professionals, are taking advantage of a variety of health tools to both increase the efficiency and continuity of care to for patients. CMS can further these efforts by enacting reimbursement policies that support telehealth.

On behalf of the Center for Telemedicine Law and our telehealth colleagues, we provide the following comments:

END-STAGE RENAL DISEASE

CTL and the American Nephrology Nurses Association (ANNA) fully support expanding the list of Medicare telehealth services to include the monthly management visits for dialysis patients with end-stage renal disease (ESRD).

We support the standard that every ESRD dialysis patient has a face-to-face comprehensive assessment as part of his or her monthly care plan. This face-to-face examination can be performed by either by a physician or practitioner, nurse practitioner, clinical nurse specialist, or physician assistant. The other two to three monthly follow-up visits could be made either in-person or electronically from a satellite office in a dialysis facility. We support CMS' recommendation to add the following to the list of Medicare telehealth services: End Stage Renal Disease (ESRD) related services with two or three visits per months and ESRD-related services with four or more visits per month as described by G0308, G0309, G0311, G0312, G0314, G0315, G0317, and G0318.

Today, technology is allowing patients to receive health care services without leaving home. Small "webcam" cameras connected to a television, or desk or laptop computer can be purchased for less than \$80 at any local computer store. While "peripherals", such as blood pressure cuffs, scales, vital sign measuring devices, glucometers and so on are readily available from telecommunications vendors, and connected by computer technicians. Just as grandparents are using web cameras to talk and see their children and grandchildren, they can also be utilized for communications between a nephrologists' office, thus, connecting the provider and patient electronically. The amount of time, money, and energy spent by patients and providers alike can be reduced by better utilizing technology.

Using telehealth technologies does not require vast sums of capitol expenditures, and can be accomplished inexpensively. Certainly, the shortage of nephrologists requires us to find creative ways in which to serve these patients -- telehealth is one of solutions.

SPEECH LANGUAGE HEARING

In North Dakota, for example, both Blue Cross Blue Shield and Medicaid pay for speech therapy services that are reimbursable on a face-to-face basis. Medicare has not yet agreed to cover speech therapy services via telehealth as therapists are not permitted under current law to provide and receive payment for Medicare telehealth services at a distant site.

This policy creates undue hardship on patients. At St. Alexius Medical Center, for example, they had been providing patients with speech therapy services via telemedicine. As you are aware, it is a hardship for many of patients to leave the nursing home to obtain health services because of the type or severity of their health problems, a majority of whom are post-stroke patients. For those with Alzheimer's disease or other dementias, transporting patients disrupts their routine resulting in

adverse reactions. St. Alexius no longer has the funding to provide these services and has notified new Medicare patients and their families that they will no longer provide speech therapy services via telemedicine unless they have insurance coverage through another payer or are willing to pay for the services out-of-pocket. Their only alternative would be to travel for a face-to-face visit. Later this year we will request that CMS expand the reimbursement codes to provide services to Medicare nursing home patients, as provided below. In the meantime, however, we request that CMS recommend in their report to Congress (as required under BIPA) that speech therapists may be reimbursed for providing telehealth services. We also request that this report be completed as soon as possible.

Evaluation	92506GT / 92506	Speech Language Evaluation: Evaluation of speech, language, voice, communication, auditory processing, and/or aural rehabilitation status
Evaluation	96105GT / 96105	Aphasia Evaluation: Assessment of aphasia (includes assessment of expressive and receptive speech and language function, language comprehension, speech production ability, reading, spelling, writing, (i.e., Boston Diagnostic Aphasia Examination) with interpretation and report, per hour
Evaluation	92610GT / 92610	Bedside Swallow Evaluation: Evaluation of oral and pharyngeal swallowing function (clinical or bedside evaluation)
Therapy	92507GT / 92507	Speech Language (Individual) Therapy: Treatment of speech, language, voice, communication, auditory processing disorder, and/or aural rehabilitation status, individual
Therapy	97532GT / 97532	Cognitive Perceptual Treatment: Development of cognitive skills to improve attention, memory, problem solving (includes compensatory training), direct (one-on-one) patient contact by the provider, each 15 minutes
Therapy	92526GT / 92526	Swallowing Treatment: Treatment of swallowing dysfunction and/or oral function or feeding
Therapy	43742	Supplies (often therapists purchase coloring book sheets or use other types of materials that can be faxed or put on projector to show the patient objects for identification or words for repetition)

The Center for Telemedicine Law is a non-profit organization committed to overcoming the legal and regulatory barriers to telehealth since 1996. CTL and members of the telehealth community would be delighted to work with CMS on expansion of telehealth services and/or on identifying appropriate pilot projects to demonstrate the value of telehealth.

Thank you for your consideration our comments. The telehealth community looks forward to continuing to improve access to affordable care for patients.

Sincerely,



Jackie Eder-Van Hook
Executive Director
Center for Telemedicine Law

Center for Telemedicine Law

Overcoming Barriers to Telehealth

September 21, 2004

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services, HHS
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Sincerely,



Jackie Eder-Van Hook
Executive Director
Center for Telemedicine Law

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 1-9

PRACTICE EXPENSE

Refinement of Equipment inputs for noninvasive vascular diagnostic codes

We thank CMS for implementing a long-needed update in equipment inputs for noninvasive vascular diagnostic services, incorporated in Equipment code E52018. This refinement is most welcome and ensures a much more accurate payment for our services. However, we note that CMS has not yet adopted the additional refinements that we suggested for the other ancillary equipment present in a vascular ultrasound room. These additional expenses should be reflected in CMS's practice expense calculation for vascular ultrasound services, CPT codes 93875-93979, and 93990. We understand that the CMS equipment and supply contractor has inputs for ?ultrasound room, vascular?. We ask that these additional refinements be undertaken and made effective for January 1, 2005 if at all possible.

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

GENERAL

GENERAL

DATE: September 24, 2004

TO: CMS REFERENCE: CMS-1429-P

The Impact on My Businesses Of Reduction in Reimbursement for Respiratory Medications by the 2003 Medicare Drug Bill

The Corporate office of Home Care Pharmacy is in Halifax and employs 7 people, plus a pharmacist and a pharmacy technician at each of the two pharmacy sites. This is a total of 11 employees, not including myself as the managing partner.

Staff duties:

- ? Patient intake and data entry ? 2
- ? Billing ? 2
- ? Collections ? 1
- ? Patient services ? 1
- ? Business operations and payables ? 1
- ? Pharmacist ? 2
- ? Pharmacy Techs ? 2

Home Care Pharmacy serves over 1200 Medicare patients each month by supplying their respiratory drugs directly to them at home. These medications are not covered by Medicare under any other program.

- ? We are required by regulation to contact each patient each month to monitor their status and determine if they need refills on their drugs.
- ? We also must obtain written orders and certifications and have proof of delivery with an adult signature.
- ? We must also comply with the 21 Medicare supplier standards, the HIPAA privacy and security standards, and the OIG compliance guidelines to participate in the Medicare/Medicaid program.
- ? Beginning in 2006, we will also have to be accredited by an approved accrediting body.

Current billing rules required us to identify the supplier of the equipment used to administer the medication, as does it require the equipment provider to identify the medication provider. Most retail pharmacies do not provide these medications to Medicare beneficiaries since they do not have NSC provider numbers.

The following is the financial impact of this legislation on my business.

Currently ? AWP ?5% - 2003

Attachment 1, Column 1 ? a profit and loss statement for December 2003.

? As you can see, we are a profitable business but do not have the extreme profits implied by the GAO and CBO. Most of the profit is used to expand the business to provide this needed service.

Unit Dose Reduction from AWP ?5% to AWP ?20% - 2004

Attachment 1, Column 2 ? a profit and loss statement from that same month adjusted for the 15% reduction.

? Again you can see that we are profitable, but the margins are thinner and the added cost of accreditation will consume most of this.

Change to ASP +6% - Beginning 1/12005

Attachment 1, Column 3 ? a profit and loss statement from that same month adjusted to ASP +6%, assuming that ASP is my current cost for the drugs.

? As you can see, we are now operating at a huge loss and will have no choice but to close the doors on January 1, 2005, putting 11 people and myself out of work.

This is just one part of this bill that will have a serious impact on small business, but an even more serious impact on access to these necessary medications to insure that the Medicare patient is able to remain healthy.

My father used these medications before his death; as does my wife use them now. Without them he would have died much sooner and my wife would likely require hospitalization three or four times a year to treat lung infections caused by the respiratory distress.

What will happen if this goes forward?

? Thousands of small businesses across the country will close or stop providing these medications.

? Millions of Medicare patients will not be able to obtain these medications resulting in increased in-patient expense to Medicare.

? A few, likely three of four, large national medical equipment providers with a pharmacy subsidiary will take these patients and will ship drug in from other states at a loss since they will make profits from the oxygen and other medical equipment. By marketing this to the physicians and being the only companies doing this, they will capture the related medical equipment business from the local DME provider that is no longer able to compete.

? This lack of competition will drive up costs and reduce a

CMS-1429-P-4096-Attach-1.doc

CMS-1429-P-4096-Attach-2.doc



HOME CARE PHARMACY, Inc.

Unit Dose Respiratory Medications

DATE: September 24, 2004

TO: CMS

REFERENCE: CMS-1429-P

The Impact on My Businesses Of Reduction in Reimbursement for Respiratory Medications by the 2003 Medicare Drug Bill

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The following is the financial impact of this legislation on my business.

Currently – AWP –5% - 2003

Attachment 1, Column 1 – a profit and loss statement for December 2003.

- As you can see, we are a profitable business but do not have the extreme profits implied by the GAO and CBO. Most of the profit is used to expand the business to provide this needed service.

Unit Dose Reduction from AWP –5% to AWP –20% - 2004

Attachment 1, Column 2 – a profit and loss statement from that same month adjusted for the 15% reduction.

- Again you can see that we are profitable, but the margins are thinner and the added cost of accreditation will consume most of this.

Change to ASP +6% - Beginning 1/12005

Attachment 1, Column 3 – a profit and loss statement from that same month adjusted to ASP +6%, assuming that ASP is my current cost for the drugs.

- As you can see, we are now operating at a huge loss and will have no choice but to close the doors on January 1, 2005, putting 11 people and myself out of work.

This is just one part of this bill that will have a serious impact on small business, but an even more serious impact on access to these necessary medications to insure that the Medicare patient is able to remain healthy.

My father used these medications before his death; as does my wife use them now. Without them he would have died much sooner and my wife would likely require hospitalization three or four times a year to treat lung infections caused by the respiratory distress.

What will happen if this goes forward?

- Thousands of small businesses across the country will close or stop providing these medications.
- Millions of Medicare patients will not be able to obtain these medications resulting in increased in-patient expense to Medicare.
- A few, likely three of four, large national medical equipment providers with a pharmacy subsidiary will take these patients and will ship drug in from other states at a loss since they will make profits from the oxygen and other medical equipment. By marketing this to the physicians and being the only companies doing this, they will capture the related medical equipment business from the local DME provider that is no longer able to compete.
- This lack of competition will drive up costs and reduce access to care.

What should be done to correct this?

- Eliminate the provision in the law that reduces the payment to ASP +6% to Medicare Part B providers and keep the reimbursement at the reduced level of AWP –20%.

As you can see, this action will have a tremendous impact of me and my staff, leaving all except two unemployed. The remaining provisions of the law, specifically the FEHEP provisions, the cap on fees and the competitive bidding provisions will have a similar effect on my two small DME companies and will likely force me to close both of those since I may not be able to remain profitable under the FEHEP reimbursement and will not be able to secure a winning bid under the competitive bidding. Based on just conservative estimates, more than 100 small medical equipment providers in Virginia will close.

Sincerely,

Wayne E. Stanfield
President
Home Care Pharmacy, Inc.

BUSINESS OFFICE:

5037 Halifax Road, Suite V, Halifax, VA 24558
(434)-572-4274
Fax: (434) 572-3033

DISPENSING OFFICE:

518 South Sycamore Street, Petersburg, VA 23803
1-888-733-4122
Fax: (804) 862-1254

Toll Free: 1-888-NEB-MEDS (632-6337)



HOME CARE PHARMACY, Inc.

Unit Dose Respiratory Medications

September 24, 2004

COMMENTS – CMS1429-P

Dear Sir,

I ask you to eliminate the ASP+6% provision of the MMA 03 or at least delay implementation until a reasonable study can be done. My drug cost will not change after Jan 1, 2005 and in the face of an 89% reduction in reimbursement after the 15% in January, there is little I can do to continue to serve my patients. That is an 95% reduction in just 12 months.

I currently pay \$0.056 per milligram and CMS is proposing to pay \$0.04. My cost is based on bulk buying drugs direct from the manufacturer to serve thousands of patients per month. Where is the cost of a pharmacist, a building, liability insurance, a billing staff, accreditation, administration, and shipping going to fit into this equation? The ASP figures used to support this must be seriously flawed.

I suggest that in an attempt to provide a drug benefit, the government has failed to see the consequences of including these drugs in with drugs provided by physicians in their office. These drugs are NEVER supplied in the physician's office. They are supplied only by specialty pharmacy providers that have jumped through all of the hoops to meet the NSC and CMS requirements to be a supplier.

For CMS to arrogantly suggest that they may pay a transitional payment to "encourage providers to stay in business until 2006" is insulting to me and thousands of other small businesses founded on the principle that the government would not deliberately put us out of business in the name of politics.

There is a grave misunderstanding of how these products are covered by CMS and in the draft regulations, CMS clearly does not understand even its own rules that are currently in effect. I cannot accept that this is just the way it is when my livelihood is being taken away. Home care is the solution to high cost institutional care and yet we are the only segment of the Medicare budget that was targeted for huge cuts to accomplish the prescription drug coverage.

Sincerely,
Wayne E. Stanfield
President

BUSINESS OFFICE:
5037 Halifax Road, Suite V,
Halifax, VA 24558
(434)-572-4274
Fax: (434) 572-3033

DISPENSING OFFICE:
518 South Sycamore Street,
Petersburg, VA 23803
1-888-733-4122
Fax: (804) 862-1254

Toll Free: 1-888-NEB-MEDS (632-6337)

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

GENERAL

GENERAL

September 24, 2004

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

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005; Proposed Rule. File Code CMS-1429-P (69 Fed. Reg. 47488, August 5, 2004)

Dear Dr. McClellan,

I am a 43 year old man with severe hemophilia factor IX (nine) deficiency. When I was very young, my bleeding episodes had an extreme impact on my health and ability to function. Those bleeding episodes are still affecting me today in that I have severe joint damage in both my ankles, right knee and elbow and limit my abilities.

The reasons for my joint damage goes beyond the fact that I don't clot properly. The damage is extreme (I am in need of a knee replacement) because of the delays that kept me from getting enough factor nine replacement to stop my bleeding. These delays, over the years, were such things as;

Time until notifying parents of hemorrhage, time to travel to the hospital, hospital administrative red tape, doctor diagnosis and understanding of hemophilia, pharmacy delivery times, receiving enough whole blood or factor concentrate to form a clot, proper follow up therapy.

Once the clotting factor was available as a concentrate and we were able to bring this life sustaining medicine home to self infuse, my joint crippling began to end. I was able to infuse as soon as I knew I was starting to hemorrhage and avert severe damage in healthy joints. Being able to have this medicine at home and with me when I travel has a major impact in my health and well being. It also eliminates an tremendous amount of wasted monies on hospital visits and all the associated cost.

I used to get my clotting factor from the hospital and now am able to get it from a speciality homecare company. The differences in the to two delivery options are vast. I gain support and understanding from my homecare company and didn't from the hospital. I also receive personal care in that the homecare representative knows and understands my needs.

I am 1st Vice President of the Hemophilia Federation of American, a national non-profit advocacy organization of people with blood clotting disorders. Our population on Medicare and Medicaid will be drastically affected if they are forced to receive their medications from a limited number of providers, because homecare companies could no longer afford to do business with those with hemophilia.

Please be fair in the reimbursement amounts given to the homecare companies so I and we can continue to have a choice in and participation in our health care.

Thank you,

Carl Weixler

859-245-0519
1745 Farmview Drive
Lexington, KY 40515



Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

GENERAL

GENERAL

I encourage the adoption of the proposed rule which would require that "incident to" therapy services provided by physicians must have providers meet the same minimal standards as licensed physical therapists when providing outpatient physical therapy. The current laxity of the personnel standards allows for physicians to delegate therapy services to untrained individuals, with minimal to no oversight provided. As a reviewer of insurance claims, I see daily the abuses that occur when untrained individuals perform "physical therapy" under the current "incident to" regulation. The proposed changes would bring physician offices under the same minimal standard which applies to physical therapist offices. It would require that physicians, if providing physical therapy in their offices, hire and utilize actual physical therapists. More importantly, the patient will know that physical therapy means services by a physical therapist, educated in providing physical therapy.

I also strongly support the revision of the Therapy Standards and Requirements, specifically the changes that would remove the personal "in-room" supervision requirement to that of direct supervision for physical therapist assistants (PTA). PTA's are educated in providing skilled physical therapy services under the supervision of a physical therapist. In many settings, including home health where I am involved mostly, this allows for off-site supervision to occur. It makes no sense that in the outpatient setting the supervision requirement is more stringent and limiting than in other settings. The proposed changes would bring in line the outpatient physical therapy clinic with other settings, and is very much overdue. Physical therapists are fully accountable to their state licensing agencies, as well as the review of payers, to insure that when delegating tasks to PTA's, that they are appropriately supervised and quality care is delivered. It is time to align the outpatient Medicare standards for supervision with those in other treatment settings.

Thank you for their consideration of these comments.

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 1-9

CODING-GLOBAL PERIOD

The proposed new G-code for vein mapping prior to hemodialysis access leads SVS to the impression that CMS is searching for a means to reward surgeons who create AV fistulas. This is not possible in the regular Medicare physician fee schedule because, by statute, it is resource-based. However, we believe this would be a good place to test a pay-for-performance (P4P) quality measure. We are aware that there are a number of demonstration opportunities to create a higher quality of care for Medicare beneficiaries. We are enthusiastic about P4P but believe we will both benefit from testing the concept on a small scale before moving forward with national implementation across all of surgery. Our proposal calls for surgeons to track initial proportion of new hemodialysis access placed as fistulas (rather than synthetic AV grafts); perioperative complications; and functional fistula patency after maturation (two to four months postoperatively), either by physical examination by the operating surgeon, a physical examination and a report from the nephrologist, or an evaluation by duplex scan (CPT code 93990, Duplex scan of hemodialysis access (including arterial inflow, body of access and venous outflow). Those physicians meeting quality thresholds would be rewarded with a lump sum payment. We will be happy to discuss details of our proposal at any time.

CMS-1429-P-4100

Submitter : **Date & Time:**

Organization :

Category :

Issue Areas/Comments

Issues 1-9

GPCI

Attached document from CHRISTUS Santa Rosa Health Care

CMS-1429-P-4100-Attach-1.pdf



September 24, 2004

Mark B. McClellan, M.D., Ph.D.
Administrator, Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1429-P
P.O. Box 8012
Baltimore, MD 21244-8012

Re: GPCI

Dear Dr. McClellan:

CHRISTUS Santa Rosa Health Care Regional System of San Antonio, Texas submits the following comments on the proposed Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2005 contained in the Federal Register of August 5, 2004. Section 1848 (e) (1) (C) of the Social Security Act, requiring that payments be made using the physician fee schedule must be adjusted in each geographic area to reflect variation in local resource costs as measured by the Geographic Practice Cost Indices (GPCIs) and this adjustment is to be reevaluated every three years.

The San Antonio metropolitan area, currently the second largest city in the state and eighth largest in the nation according to the 2004 U.S. Census Bureau, has surpassed Dallas metropolitan area in population. Yet San Antonio has been included in the GPCI value "Rest of Texas" category since 1997 and is far below those of the Dallas metropolitan area values. The latest American Chamber of Commerce Researchers Association (ACCRA) tabulation of cost of living indices places San Antonio's cost of living index on par with or above the other major metropolitan areas of Dallas, Houston and Austin in Texas.

The formulas and data used by the Centers for Medicare and Medicaid Services (CMS) to calculate the GPCIs may be the root cause. There is a significant, unwarranted disparity between San Antonio and the seven distinct Texas metropolitan localities in CMS' consideration of practice expense costs. We bring this to your attention and urge that there be an opportunity to discuss the CMS 2005 GPCI formulas and data in detail before the final rule is determined.

The practice of medicine in San Antonio is among the best in the nation as evidenced by awards to many of our major health care organizations. CHRISTUS Santa Rosa received the 2004 Health Grade Award for Clinical Excellence and is rated in the top 5% of hospitals in the nation. San Antonio uses the same expensive, state-of-the-art medical equipment as other large Texas cities.

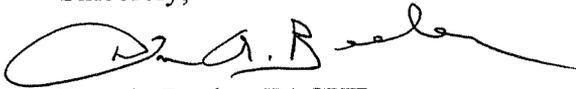
Dr. Mark B. McClellan
September 24, 2004
Page Two

San Antonio competes with those large Texas cities for medical professionals as well. Reimbursing healthcare providers in San Antonio at a lower rate than other equivalent cities severely taxes the ability of current providers in San Antonio to meet local needs.

CHRISTUS Santa Rosa Health Care support and call CMS' attention to the disparities in the formula-driven GPCI. As one of the community partners of Cancer Therapy and Research Center (CTRC), we urge your reconsideration of the formulas and data used to set these resource costs for our area in Texas.

Thank you for your attention to this matter.

Sincerely,

A handwritten signature in black ink, appearing to read "Don A. Beeler", with a long horizontal flourish extending to the right.

Don A. Beeler, FACHE
Regional President and CEO

cc: Congressman Henry Bonilla, 2458 Rayburn House Office Building
Washington, DC 20515 www.house.gov/writerep
U.S. Senator Kay Bailey Hutchison, 284 Russell Senate Office Building,
Washington, DC 20510 casework@hutchison.senate.gov

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

GENERAL

GENERAL

Please see attached comments

CMS-1429-P-4101-Attach-1.doc

CMS-1429-P-4101-Attach-2.pdf

CMS-1429-P-4101-Attach-3.pdf



cUL classification
UL classification
ISO 9002

19799 SW 95th Place, Suite B
Tualatin, OR 97062

503/612-6780 FAX 503/612-6542
sales@mectacorp.com
techsupport@mectacorp.com

DATE: 9-23-04

TO: Becky Yowell

COMPANY: APA

DEPARTMENT:

FAX#: 703-907-1089

COMMENTS:

Becky,

Attached is the quote for the mid-range priced spECTrum. The majority of our customers pay in this price range as this system has all the pertinent features in it. Customers who pay the base price usually end up upgrading later anyway.

Also attached see a price sheet for supplies.

I estimated monthly supplies at 8 treats per day, 3 x's per week, or approximately 120 treatments per month, which is pretty average for the major facilities. Consumable supplies are as follows:

ITEM	QTY / MONTH @ 24 TREATMENTS PER WK	COST / MONTH/ 120 TREATMENTS
Disposable EEG Pads	8 bags / mo (20 pkts/bag)	\$48 / bag x 8 = \$384
Disposable ECG Pads	8 boxes/ mo (10 pkg/box)	\$24 / box x 8 = \$192
Chart Paper	6 rolls per month x \$9 /roll	\$54
Electrode Gel	2-3 tubes per month	3 x \$7 tb = \$21
Electrode Paste	1 tube	\$7
Bite Blocks (1 per Patient) some patients keep for next treatment; other hospitals use the Mouth Prop below.	\$18 each x 120 treats/mth	\$2,160
- OR -		
Mouth Prop (Reusable)	2 (a spare is required) \$66	2 @ \$66 = \$132

Hope this helps in your estimates!


Wendi Butler
General Manager
MECTA Corporation

To: ** FOR APA USE IN MEDICARE/MEDICAID
EXPENSE STUDY ONLY **

From: MECTA Corporation
19799 SW 95th Place, Ste B
Tualatin, OR 97062
Phone (503) 612-6780
Fax (503) 612-6542

QUOTATION # - Special Package Offer (TYPICAL PACKAGE PURCHASED)

Quantity	Description	Total Price
1 each	MECTA spECTrum 5000Q with EEG/EEG channels	\$14,995.00
1 each	EEG Data Analysis	
1 each	ECG Channel OR Optical Motion Sensor	
1 each	Remote Monitor Software (RMS) Remote Display and Data Logging	
1 each	RMSManager Database Software (use with RMS)	
Total (Save \$2,800):		\$14,995.00
	Freight charges	\$150.00

Following items included at no additional cost:

• 2 each	Instruction Manuals	• 1 box	Chart Paper (10 rolls per box)
• 2 each	Service Manuals	• 1 each	Bite Block
• 1 each	MECTA Videotape (technical)	• 1 tube	Electrode Gel
• 1 each	Textbook: The Practice of Electroconvulsive Therapy, APA, 2 nd Ed.	• 1 tube	Electrode Paste
• 1 each	Patient Stimulus Cable	• 2 each	Fuse - 4 Amp
• 1 each	Patient Safety Monitor Cable	• 2 box	EEG Disposable Pads
• 1 each	Adjustable Headband	• 1 set	Flat Stimulus Electrodes
• 1 set	EEG Safety Leads	• 1 set	Concave Stimulus Electrodes
• 1 set	ECG Safety Leads	• 1 each	Dynamic Load Box
• 1 each	Mouth Prop	• 1 each	Sensor Strip
		•	

OPTIONAL FEATURES:

1 each	Computer system for Remote PC Software	\$2,000.00
1 set	Hand-held electrodes:	\$400.00
	• Choose with OR without remote when ordering	
	• Choose dual or single when ordering	
NEW!	Patient and Family videotape - produced by Dartmouth/Hitchcock University Hospital, sold exclusively by MECTA. 2003.	\$175.00

* Optional Features include all additional cables, leads, educational materials, etc.


Wendi Butler, Sales Manager

To: ** FOR APA USE IN MEDICARE/MEDICAID
EXPENSE STUDY ONLY **

From: MECTA Corporation
19799 SW 95th Place, Suite B
Tualatin, OR 97062
Phone (503)612-6780
Fax (503)612-6542

QUOTATION #WB

Quantity	Description	Total Price
1 each	*MECTA spECTrum 5000Q (4 Stimulus Parameter Knobs) **with ECG/EEG OR EEG/EEG channels	\$13,495.00
	OR	
1 each	*MECTA spECTrum 5000M (Single Stimulus Dial) **with ECG/EEG OR EEG/EEG channels	\$13,495.00

* Please choose between the Q and the M models.

** Base price includes 2 channels of monitoring. Please choose either ECG/EEG or EEG/EEG. If choosing ECG/EEG, 1 add'l EEG may be purchased (making ECG/2EEG) or 3 add'l EEG may be purchased (ECG/4EEG). See optional features below for pricing.

Following items included at no additional cost:

• 2 each	Instruction Manuals	• 1 box	Chart Paper (10 rolls per box)
• 2 each	Service Manuals	• 1 each	Bite Block
• 1 each	MECTA Videotape (technical)	• 1 tube	Electrode Gel
• 1 each	Textbook: The Practice of Electroconvulsive Therapy, APA, 2 nd Ed.	• 1 tube	Electrode Paste
• 1 each	Patient Stimulus Cable	• 2 each	Fuse - 4 Amp
• 1 each	Patient Safety Monitor Cable	• 1 box	EEG Disposable Pads
• 1 each	Adjustable Headband	• 1 box	ECG Disposable Pads
• 1 set	EEG Safety Leads	• 1 set	Flat Stimulus Electrodes
• 1 set	ECG Safety Leads	• 1 set	Concave Stimulus Electrodes
• 1 each	Mouth Prop	• 1 each	Dynamic Load Box
		• 1 each	Sensor Strip

Freight charges

\$150.00

Trade-in of older MECTA ECT device

(\$500.00)

OPTIONAL FEATURES AVAILABLE:

1 each	Additional EEG Monitoring Channel (must choose EEG/ECG)	\$850.00
3 each	Additional EEG Monitoring Channels (must choose EEG/ECG)	\$2,550.00
1 each	Optical Motion Sensor with OMS cable and sensor	\$850.00
1 each	EEG Data Analysis (2 EEG Channels Required) Save \$450 Limited Time Only!	\$500.00
1 each	Remote Monitor Software for Remote Display and Data Logging	\$2,000.00
NEW!	RMSManager Database (works with RMS above) Save \$500 Limited Time Only!	\$000.00
1 each	Computer System for Remote PC Software	\$2,000.00
1 set	Hand-held electrodes with or without remote button, dual or single handle	\$400.00
NEW!	Patient and Family Videotape <i>Electroconvulsive Therapy</i> Produced by Dartmouth/Hitchcock Univ. Hospital	\$175.00

* Optional Features include all additional cables, leads, educational materials, etc.


Wendi Butler, Marketing

American Psychiatric Association

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Arlington, VA 22209
Telephone 703.907.7300
Fax 703.907.1085
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September 24, 2004

Mark McClellan, M.D., PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1429-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Dr. McClellan:

On behalf of the American Psychiatric Association (APA), a medical specialty society representing over 35,000 psychiatric physicians nationwide, I am pleased to submit our comments on the Center for Medicare and Medicaid Services (CMS) proposed rule, published in the Federal Register on August 5, 2004, relating to revised payment policies under the physician fee schedule for calendar year 2005.

The APA will comment on the following issues:

- Sustainable Growth Rate
- Practice Expense
- Section 611 – Initial Preventative Physical Examination
- Section 413 - Incentive Payment for Physician Scarcity
- Diagnostic Psychological Tests

Sustainable Growth Rate

The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) has ensured a positive SGR update of 1.5% in lieu of the projected payment cut of 3.7% under the sustainable growth rate (SGR) formula. For the third year in a row (2003 to 2005) a projected reduction in payments has been avoided due to congressional intervention to correct a flawed formula. However, projections show the trend of negative updates as a result of the SGR system will continue in 2006 and beyond, widening the gap between the cost to practice medicine and payments to physicians and to other health care providers.

The APA is concerned that continuing payment cuts could restrict access to care for Medicare beneficiaries. The MMA has made significant strides in improving the overall system for Medicare beneficiaries, including broad-scale improvements for care furnished to patients in rural areas as well as important new benefits. These critical improvements must be supported by an adequate payment structure for physicians' services. Without a long term solution, access to care is compromised.

The APA requests that CMS take additional action in the 2005 payment rule to help ease problems created by the Medicare physician payment formula and lead the way for congressional intervention down the road. With payment cuts slated to begin in 2006, it is critical for CMS to move as quickly as possible to send Congress and physicians the message that the Administration does not intend to sit idly by while Medicare payments to physicians tumble to levels that the Medicare Trustees have acknowledged are politically unsustainable.

Practice Expense

According to the proposed rule, CMS continues the process of repricing the clinical practice expense inputs for equipment. CMS, in conjunction with a consultant, has been working closely with specialty societies to identify equipment and the applicable prices. CMS notes that there are specific items of equipment for which pricing information has not yet been found (Table 2 – Equipment Items Needing Specialty Input for Pricing and Proposed Deletions). The rule requests that those submitting comments, in particular relevant specialty groups, provide the needed information pertaining to price for those items identified in Table 2.

At the request of CMS, the APA has secured pricing information on the cost of an Electroconvulsive Therapy (ECT) machine which is associated with CPT code 90870 (Electroconvulsive Therapy). Pricing information provided by MECTA Corporation and Somatics, L.L.C., the only two ECT device distributors in the United States is attached to this submission. The MECTA devices range from \$13,495 to \$14,995 while the Somatics, LLC device is priced at \$13,995, a price that includes some start up supplies. The attached documentation includes itemized figures. The APA would be happy to work with CMS to further define this information if necessary.

Section 611-Initial Preventive Physical Examination

Effective January 1, 2005, the Medicare Modernization Act (MMA) creates coverage for an initial preventive physical examination within the first six months of the beneficiary's entrance into Medicare Part B. The APA submits comments on two of the seven identified by CMS as components of this exam, which is known as the "Welcome to Medicare Visit" (WMV):

- (2) Review of the individual's potential (risk factors) for depression (including past experiences with depression or other mood disorders) based on the use of an appropriate screening instrument which the physician or other qualified nonphysician practitioner may select from various available standardized screening tests for this purpose, unless the appropriate screening instrument is defined through the national coverage determination (NCD) process.



(6) Education, counseling, and referral, as appropriate, based on the results of the previous five elements of the initial preventive physical examination.

The APA commends CMS for its efforts in implementing this new Medicare initial preventative physical examination as mandated by the MMA. This benefit, if implemented properly, has the potential to help beneficiaries adopt healthier lifestyles and to substantially enhance the health of the Medicare population.

We are especially pleased by the inclusion of a depression screen in this process and see this as acknowledgement by CMS of the value of identification and treatment of mental disorders. As noted in the report of the President's New Freedom Commission on Mental Health¹, mental health should be treated with the same urgency as physical health and as such the Commission has made a series of recommendations acknowledging the primary care office as the "de facto" mental health system for most patients in this country. Furthermore, the presence of depression and other mental health conditions is accompanied by significantly greater morbidity of medical illnesses and increased costs of care. Early recognition and treatment of depression will have a positive impact on medical, mental and economic outcomes.

As it relates to the issue of depression screening, the APA encourages CMS to clarify and restate that the assessment includes consideration of both the *potential* for depression, as well as the assessment of a patient's *current depression* status. While we believe that this is the intent of the rule, the proposed language refers to assessing "potential (risk factors) for depression" but not to assessing current depression status.

APA concurs with the recommendation that "an appropriate screening instrument" be used for the assessment of depression and that practitioners are encouraged to utilize a screening instrument that is recognized as best practice. We would, however, suggest that a limited number of screening instruments be utilized to maximize clinical utility and transportability. While there is no commonly accepted screening tool for depression, the 9-item Patient Health Questionnaire (PHQ-9) is currently thought by many, including the APA, Robert Wood Johnson Foundation and the MacArthur Foundation, to be the most practical choice in terms of its coverage of Diagnostic and Statistical Manual of Mental Disorders (DSM) identified depression symptoms, the self administered format, its brevity and the ease of administration, scoring and interpretation for busy primary care practices. The PHQ-9 was identified by the APA, American Academy of Family Physicians and the American College of Physicians as the screening tool designated for use with their Depression Management Project; a collaborative effort to address mental illness in primary care settings. This particular tool has now been well validated in several studies with medically ill patients.² It can provide both a diagnosis and also a severity rating, and is easy to use.

¹ New Freedom Commission on Mental Health, *Achieving the Promise: Transforming Mental Health Care in America*. Final Report. DHHS Pub. No. SMA-03-3832. 2003.

² Kroenke K, Spitzer RL, Williams JB. (2001). "The PHQ9: validity of a brief depression severity measure." *J Gen Intern Med*. 16(9):606-13.



APA believes there are both positive and negative implications of a National Coverage Determination (NCD) pertaining to a depression screening instrument, however we do not have sufficient information to provide substantive comment on a proposal. We would welcome the opportunity to work with CMS to determine if an NCD is an appropriate mechanism.

APA also applauds the inclusion of the CMS provision on “Education, counseling, and referral, as appropriate, based on the results of the previous five elements of the initial preventive physical examination.” Evidence suggests that screening for depression in and of itself does not positively impact depression outcomes. The National Preventive Services Task Force ³ recently reported that depression screening is primarily effective if patients who screen positive are *referred for appropriate treatment*. Once depression is identified, disease management, collaborative care and direct provision of appropriate psychiatric and psychosocial care are effective in improving medical and psychosocial outcomes.

APA believes that in order for the depression screen to be effective, specific language needs to be included stressing the importance of appropriate treatment which includes a referral to mental health specialists when indicated, and to recommend that practitioners monitor depression outcomes over time to ensure the treatment is effective.

We also know that the financial barriers to receiving psychiatric care, such as the outpatient mental health treatment limitation which requires beneficiaries to pay more for mental health care than medical care are numerous and must be addressed in order to ensure that patients receive appropriate treatment. In addition to recommending screening and referral for mental health disorders in primary health care settings, the report of the President’s New Freedom Commission states “Collaborative care models should be widely implemented in primary health care settings and reimbursed by public and private insurers.” Currently key elements of collaborative care-particularly nurse care management, and the collaboration between the care manager and primary and mental health specialty providers, are at best partially reimbursable under Medicare.

Section 413 - Incentive Payment for Physician Scarcity Areas and Health Professional Shortage Areas Incentive Payments

Section 413(a) of the MMA provides a new 5% incentive payment to physicians furnishing services in physician primary care and specialist care scarcity areas. This new incentive plan is in addition to the existing plan, established in 1989, that is currently paying qualifying clinicians practicing in Health Professional Shortage Areas (HPSA) an additional 10%. The intent of both provisions is to provide a means for incentive payments that would translate in to increased recruitment and retention of both primary and specialty care physicians for furnishing services to Medicare Beneficiaries.

³ Pignone MP, Gaynes BN, Rushton JL, Burchell CM, Orleans CT, Mulrow CD, Lohr KN (2002). “Screening for depression in adults: a summary of the evidence for the U.S. Preventive Services Task Force. *Ann Intern Med.* 2002 May 21;136(10):765-76.



APA strongly supports the policy of incentive payments for physicians, including psychiatrists, practicing in what are defined as physician scarcity areas (PSA) and Health Professional Shortage Areas (HPSA). The APA also commends CMS for its clarification of the role of psychiatrists in Mental Health HPSAs. APA urges CMS to count only those practicing physicians who treat Medicare patients when determining the ratio of beneficiaries to practicing physicians. To count all practicing physicians, including those who do not treat Medicare patients would undermine the intent of the provision.

E. Diagnostic Psychological Tests

The APA opposes CMS amending Section 410.32(b)(2)(iii), to expand the supervision requirements regarding who can supervise diagnostic psychological testing services. The regulations currently provide an exception to the physician supervision requirement for clinical psychologists and independently practicing psychologists to personally perform diagnostic psychological testing services without physician supervision. However, diagnostic psychological tests performed by anyone other than a clinical psychologist must be provided under the general supervision of a physician. CMS proposes to expand this requirement by allowing clinical psychologists to supervise those individuals, such as ancillary staff, to perform psychological and neuropsychological testing without physician supervision.

CMS states the primary reasons for expanding these supervision requirements is that it will potentially relieve burdens on physician and healthcare facilities as well provide greater access to beneficiaries in rural areas based on the lack of physicians to supervise tests. The APA contends that in those rural areas referenced by CMS, there may exist both a scarcity of clinical psychologists and physicians to perform and supervise those diagnostic tests. Expanding the ability of non-qualified individuals to perform psychological and neuropsychological tests without physician supervision would not remedy the problem. We must note that CMS has proposed a major reimbursement and public policy decision absent any supporting documentation. The APA requests that CMS provide data that illustrate that physicians and healthcare facilities will be less burdened by expanding the supervision requirements for these psychological tests. We would also welcome an opportunity to work with CMS and others to more fully explore shortage issues and potential solutions.

Conclusion

In summary, the APA makes the following recommendations:

- CMS needs to address the development of a remedy to the flawed SGR system.
- CMS should move forward with the implementation of a one-time preventative physical examination for new Medicare beneficiaries which includes depression screening. CMS should clarify that the assessment includes consideration of both the *potential* for depression, as well as the assessment of a patient's *current depression* status.



- APA welcomes the opportunity to work with CMS on the definition of an appropriate depression screening tool(s) such as the PHQ-9.
- CMS should include language stressing the importance of appropriate treatment, including referral to mental health specialists when indicated, and the recommendation to monitor depression outcomes over time to ensure the treatment is effective.
- CMS should work with APA to identify and remove barriers to receiving psychiatric care in order to assure that patients receive appropriate treatment; addressing barriers inherent in current payment policy.
- APA supports the policy of incentive payments for physicians, including psychiatrists, practicing in what are defined as physician scarcity areas (PSA) and Health Professional Shortage Areas (HPSA).
- APA opposes CMS amending Section 410.32(b)(2)(iii), to expand the supervision requirements regarding who can supervise diagnostic psychological testing services and requests that CMS provide data that illustrate that physicians and healthcare facilities will be less burdened by expanding the supervision requirements for these psychological tests.

We hope these recommendations and comments are helpful and we urge you to act on them before the publication of the final rule. As always, we are prepared to assist CMS. Please contact Andrew Whitman, J.D., Deputy Director, Regulatory Affairs, at 703-907-7842 if you have questions or need additional information relating to our comments.

Sincerely,



James H. Scully, Jr., MD
Medical Director

Enclosures





SOMATICS, L.L.C.

910 SHERWOOD DRIVE
LAKE BLUFF, ILLINOIS 60044

Makers of The Thymatron®
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FAX

Date September 21, 2004

Number of pages including cover sheet

TO: Becky Yowell
American Psychiatric Association
1000 Wilson Blvd., Suite 1825
Arlington, VA 22209

Phone 703-907-8593 / 888-357-7924 x8593
Fax Phone 703-907-1089
E-Mail

FROM: Christine Tadish

Somatics, LLC.
Phone (847) 234-6761
Fax Phone (847) 234-6763
E-Mail accounts@thymatron.com

CC: byowel@psych.org

REMARKS: Urgent For your review Reply ASAP Please Comment

Thank you for your inquiry on our Thymatron® System IV ECT Instrument. Enclosed are the information and pricing sheets for your review. Also, let me know at anytime if you develop a need for our color brochures and a 6 minute video about the system.

We are currently offering two specials. First we are offering a trade in for old ECT units. If your facility is interested, please provide the model and serial number so we can quote a trade in value. We are also offering the video, "Technique of ECT" by Drs. Abrams & Swartz, a \$360.00 value, for free, if the System IV will be used to train residents.

We recommend that you consider the EctoBrain™ II training / testing device. This simulates a patient's response so the medical people can practice before actually treating the patients. The EctoBrain™ II can be used for a rapid and precise check on the System IV by anyone in the ECT area, or by a Biomedical Technician. It is also an excellent training tool for doctors, nurses, residents and medical students.

Please note the discount offered for prompt payment. Also, please note the Special Pricing on the EctoBrain™ II and the Extended Warranty when ordered with the System IV.

We look forward to serving your needs and if you have any future questions please contact us at the numbers above or visit us at the web site www.thymatron.com.

Sincerely,

Christine Tadish



SOMATICS, LLC

910 SHERWOOD DRIVE
LAKE BLUFF, ILLINOIS 60044

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TOLL FREE ORDER LINE
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<http://www.thymatron.com>
e-mail: sales@thymatron.com

QUOTATION

To: **Becky Yowell**
American Psychiatric Association
1000 Wilson Blvd., Suite 1825
Arlington, VA 22209

Date: September 21, 2004

Terms: 2.85% 30, Net 31 Days*

Prices Quoted Are: F.O.B. Lake Bluff, IL

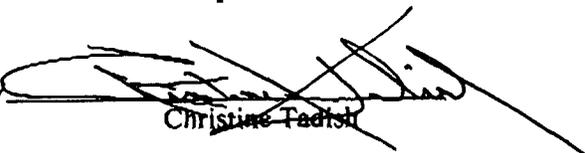
Delivery: Available for delivery within 30 days, ARO

THE PRICES QUOTED HEREIN ARE GOOD THROUGH OCTOBER 31, 2004

Quantity	Description	Advance Order Price
1	Thymatron® System IV ECT Instrument	\$13,995.00 *USD

Includes: built-in 4-channel hard-copy monitor/printer (dual EEG, ECG, true EMG); ~~front panel~~
FlexDial™ programmer; 2 pads of thermal recording paper; 1 ECT Treatment cable; ~~1 set~~
EEG/ECG/EMG monitoring cable; 1 set monitoring leads (new clip style); 1 set 60" monitoring
leads (new clip style); 1 ea. MouthGuard™ oral protector (large); 1 ea. MouthGuard™ oral
protector (small); 50 pair Thymapad® disposable treatment electrodes; 200 count disposable
EEG/ECG/EMG recording electrodes; 1 ea. Drs. Abrams and Swartz' In-Service videotape; 2 ea.
ECT instruction manuals; 1 ea. service manual; and 1 ea. Fuse. Made in the USA. CSA
Approved. - includes continuous heart rate display printout, Krystal-Weiner EEG pattern
analysis, patented auto EEG/EMG endpoint detection, the most efficient charge rate program,
and 0.25 msec pulse width.

Please advise us if you are interested in the trade in or the video specials.

By 
Christine Padish

Thymatron® System IV *Deduction if paid before due date: \$398.86 USD
Shipping Prepaid & Added to Invoice via UPS Ground Service, \$70.00



SOMATICS, LLC
 910 SHERWOOD DRIVE
 LAKE BLUFF, ILLINOIS 60044

Makers of The Thymatron®
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 e-mail: sales@thymatron.com

COMPLETE PARTS AND SUPPLIES
INCLUDED WITH THE
THYMATRON® SYSTEM IV INTEGRATED ECT INSTRUMENT

- 1) 1 each audio cassette tape "The Audible EEG™ of the Thymatron®" #EAUD
- 2) 2 pads of thermal recording paper (fan-fold) #EP4 @ \$9.50 ea
- 3) 1 each ECT treatment cable #ECET @ \$110.00 ea
- 4) 1 each EEG/ECG/EMG monitoring cable #ECEP @ \$280.00 ea
- 5) 1 set of 24" monitoring lead wires #ELDSC-9 @ \$42.75 ea
- 6) 1 set of 60" monitoring lead wires #ELDS-BR @ \$19.70 ea
- 7) 1 each large Somatics MouthGuard™ (autoclavable) #EMGD @ \$29.85 ea
- 8) 1 each small Somatics MouthGuard™ (autoclavable) #EMGS @ \$29.85 ea
- 9) 50 pair (2 Boxes) Thymapad® adherent stimulus electrodes #EPAD (Detailed Instructions Enclosed in each box @ \$74.00/box. 1 bottle #EPTAC Pre-Tac Adherent Solution enclosed in each box of Thymapads® @ \$4.95 ea. Please follow instructions included for Pre-Tac use with Detailed Instruction sheet for Thymapads®.
- 10) 200 each EEG/ECG/EMG self-stick disposable recording electrodes #EEDS @ \$36.00 box/100
- 11) 1 each Foam pressure applicator handle #EHAN-S @ \$10.00 ea
- 12) 1 each videotape "Inservice Demonstration of the Thymatron® System IV"
- 13) 2 each Thymatron® System IV Instruction Manuals
- 14) 1 each Thymatron® System IV Maintenance/Service Manual with schematics
- 15) 1 spare fuse for Thymatron® System IV @ \$1.00 ea
- 16) 1 each Power Cord for Thymatron® System IV @ \$20.00 ea
- 17) VENTIL-A™ Disposable Oral Protector Samples (25 each)
- 18) Genie Software
- 19) Customer Survey Form

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

GENERAL

GENERAL

We appreciate this opportunity to comment on the CMS proposed physician fee schedule for 2005. The National Coalition for Quality Diagnostic Imaging Services (NCQDIS) represents more than 2,400 outpatient diagnostic imaging centers and departments in the United States. The Coalition was formed to organize the radiology industry in an effort to safeguard the integrity of the specialty by supporting policies that promote quality diagnostic imaging services. We understand that there are concerns among policy makers regarding the appropriate use of diagnostic imaging tests. Therefore, we are proposing that CMS incorporate policies into its

September 22, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1429-P
P.O. Box 8012
Baltimore, MD 21244-8012

Re: Comments on the Proposed Physician Fee Schedule for CY 2005: CMS-1429-P

Dear Sir or Madam:

We appreciate this opportunity to comment on the CMS proposed physician fee schedule for 2005. The National Coalition for Quality Diagnostic Imaging Services (NCQDIS) represents more than 2,400 outpatient diagnostic imaging centers and departments in the United States. The Coalition was formed to organize the radiology industry in an effort to safeguard the integrity of the specialty by supporting policies that promote quality diagnostic imaging services. We understand that there are concerns among policy makers regarding the appropriate use of diagnostic imaging tests.¹ Therefore, we are proposing that CMS incorporate policies into its final rule that would ensure appropriate access to these vital services for Medicare patients.

I. Overview of Issues Related to Diagnostic Imaging

NCQDIS shares the concerns of CMS about the appropriate use of diagnostic imaging tests among Medicare beneficiaries. In March 2003, the Medicare Payment Advisory Commission (MedPAC) presented a report to Congress which reviewed growth in Medicare services between 1999 and 2002 in four broad categories: evaluation and management (E&M), procedures, tests, and imaging. Average annual growth during that period was 1.8% for E&M services, 4.1% for procedures, and 5.6% for tests, and a more substantial 9.0% for imaging. Needless to say, this has raised considerable concern among those responsible for paying for health care, and particularly among radiologists as the ones who provide imaging services and are held accountable for the cost escalation. However, there is strong evidence in the Medicare databank and in commercial

¹ Senate Finance Committee staff, Liz Fowler, suggested that imaging services were a concern that could be addressed as part of a deficit reduction bill when addressing the Academy of Molecular Imaging and Institute for Molecular Technologies on September 8, 2004. In addition, the New York Times published an editorial by Dr. David C. Levin entitled, "Me and My MRI" on July 6, 2004, discussing the rapid increase in imaging equipment in non-radiologist physician offices.

payer data that radiologists, who do not refer patients for imaging, are not primarily responsible for the increasing utilization of diagnostic imaging tests among Medicare beneficiaries. Research also shows better quality of care when radiologists performed services, reducing the need for duplicate scans or expensive therapy based on incomplete or misdiagnosis.

A. Utilization of Diagnostic Imaging Services in Medicare

We are aware of concerns among policy-makers regarding utilization of diagnostic imaging tests. As you may know, there is an extensive body of literature seeking to identify the cause of this trend, in addition to the research described in our comments below. Though radiologists are precluded from self-referring patients for diagnostic imaging tests, they are often looked to for an explanation of rising utilization rates of these services. It is important to note that, in effect, radiologists act as a check and balance in situations where physicians refer patients to diagnostic imaging centers. The radiologist is given the opportunity to review the physician's orders, confirm that the test ordered is correct, and consult with the physician to ensure that the patient is receiving the best treatment possible. Unfortunately, in situations where the referring physician is equipped to run the diagnostic imaging test by self-referral, the second opinion of the radiologist is not available.

Research has compared nationwide trends in noninvasive diagnostic imaging (NDI) practice patterns of radiologists and of non-radiologists among the Medicare population during the 6 years from 1993 to 1999 to determine the overall utilization rates and relative value unit (RVU) rate changes between 1993 and 1999 among radiologists and non-radiologists.² Medicare Part B claims files from 1993, 1996, and 1999 were analyzed for all procedure codes related to NDI. NDI codes were classified into 22 diagnostic categories within seven imaging modality groups. For each NDI code, physicians performing the services were classified as radiologists or non-radiologists by using the provider specialty code designated in claims in the files.

As a result, it was found that in 1993, the overall NDI utilization rate per 100,000 Medicare fee-for-service beneficiaries was 215,652 for radiologists and 79,942 for non-radiologists. In 1999, the rate was 207,270 for radiologists and 100,059 for non-radiologists, which is a 3.9% decrease among radiologists and a 25.2% increase among non-radiologists. In the 6-year interval from 1993 to 1999, the overall RVU rate increased 6.9% among radiologists and 32.4% among non-radiologists. The percentage of NDI performed by radiologists decreased from 73.0% in 1993 to 67.4% in 1999.

B. Quality of Care

To define quality in practical terms, we can turn to the IOM "Crossing the Quality Chasm" report which calls on us to collectively assure that care is:

² Matino, Radiology, 2003; 228:795

- **Safe**, avoiding injuries that can come from untrained staff using imaging equipment inappropriately;
- **Effective**, assuring that evidence-based procedures are followed, from the type of imaging equipment used to the amount of contrast ordered.
- **Patient-centered** and responsive to patient preferences.
- **Timely**, reducing waits and harmful delays for those who receive and give care.
- **Efficient**, avoiding waste by offering the “right test at the right time, done right” and
- **Equitable**, meaning there is no variation in consistency – a goal that is now obviously not being achieved for Medicare patients.

NCQDIS believes that the self-referral trend is troubling not only for its effect on the Medicare budget, but its implications for quality of care to Medicare patients. A quality assessment of 562 imaging sites by health plans found significant deficiencies related to imaging services in non-radiologist physician offices.³ The designation of a problem as a deficiency required the unanimous agreement of the panel members. The following chart reflects the failure rates upon inspection:

³ Orrison, Radiology 2002; 225(P):550

**TABLE
4-1**

Outpatient imaging failure rates vary by specialty

Practitioner or physician specialist	Number of sites inspected	Failures	
		Number	Percent
Chiropractor	144	70	49%
Podiatrist	49	22	45
Family or general practitioner	72	31	43
Internist	20	8	40
Urologist	14	5	36
Surgeon	12	3	25
Orthopedist	43	7	16
Obstetrics and gynecology	41	3	7
Radiologist	77	1	1

Source: Orrison and Levin 2002..

The failure rates described above raise concerns about the technical component of diagnostic imaging services provided by non-radiologist physicians. Though the American College of Radiology (ACR) has full accreditation programs for many diagnostic procedures, physician offices are not required to become accredited to provide these services (provided that the service is defined by statute as an in-office ancillary service excluded from the ban on physician self-referral⁴). The accreditation requirements of ACR typically include standards for equipment and for qualifications of technologist's performing the test. Entities that can meet these standards are able to produce a better diagnostic image for interpretation by a physician. Unfortunately, physicians that are not part of an accredited entity often are not able to produce the same quality images.

Not only is NCQDIS concerned about the quality of supervision and equipment associated with diagnostic imaging services, we are also concerned about the professional component of these services. In 2000, one research group used a standardized set of chest radiographs to compare the accuracy of interpretation of radiologists and non-radiologists. A standardized set of 60 chest radiographs was presented to 162 study participants. Each participant reviewed the radiographs and recorded his or her diagnostic impression by using a fixed five-point scale. These

⁴ 42 C.F.R. §411.355(b)

response data were used to generate receiver operating characteristic curves and to establish performance benchmarks. The variations in performance were tested for statistical significance.⁵

The research identified significant differences between radiologists and non-radiologist. The composite group of board-certified radiologists demonstrated performance far superior to that of non-radiologist physicians. Even radiology residents in training out-performed non-radiologist physicians. The superior performance by radiologists raises significant concerns within the health care industry.

II. Medicare Payment Advisory Commission Analysis

As you know, MedPAC's June 2004 Report identified diagnostic imaging as an area where Medicare could decrease costs and potentially improve quality. MedPAC described several purchasing strategies currently in place in the private sector and examined the feasibility of applying them in the fee-for-service Medicare program. The report acknowledged the problems with physician self-referral in diagnostic imaging services and identified the loophole in the Stark law. Though no recommendations were made, MedPAC discussed several potential strategies to administratively address the Commission's concerns about diagnostic imaging services, including:

- **Physician privileging.** In the June 2004 Report, MedPAC identified physician privileging as the "private sector response" to close the Stark loophole on physician self-referral.
- **Quality.** MedPAC also found that some private insurers have implemented safety and quality standards for imaging equipment in response to concerns about safety and technical quality of outpatient imaging facilities.

III. Privileging

Restricting the number of doctors eligible for reimbursement for certain procedures such as diagnostic imaging services would reduce over-utilization of diagnostic imaging tests by physicians that may financially benefit from providing a high volume of these services. In addition, such action could increase the overall quality of diagnostic imaging services by avoiding the provision of low-quality images, interpreted by inadequately trained non-radiologists using sub-standard technology. We support a privileging policy that addresses the professional and technical components of diagnostic imaging services.

Use of privileging and credentialing strategies has been effective in the private sector. For example, the Massachusetts Blue Cross/Blue Shield program has implemented technical and professional privileging policies for outpatient radiology providers in the form of quality

⁵ Potchen, RADIOLOGY, 2000; 217:456

standards.⁶ For technical privileging, an application must be filled out detailing the technologist's qualifications and the equipment being used to perform diagnostic tests. A subsequent site inspection is then performed, including a questionnaire with 100 questions related to quality. The professional privileging policy requires verification of the physician's specialty and Board status, and involves a list of CPT codes for which a physician may bill based on whether imaging is part of the practice, training is available to residents in that specialty, and they are credentialed at imaging at a local hospital.

In addition, Cigna Healthcare of Connecticut led its own quality standards program in 1996 that limited the imaging procedures that could be performed by specialty. In addition, technology assessments were performed, and 92 non-radiologists offices were inspected that performed x-ray services. Overall, 78% of non-radiologist physician offices had at least one major deficiency identified. As a result, the number of non-radiologists performing outpatient x-ray services decreased dramatically. Many were unwilling or unable to get accreditation to perform the service, and therefore were dropped by Cigna.⁷

A. Statutory Authority

We believe that CMS has sufficient administrative authority to implement a privileging policy for diagnostic imaging services based on the inefficient over-utilization of certain diagnostic imaging services by non-radiologists. In establishing the fee schedule for radiologist services, Congress gave the following authority to CMS:

- (3) CONSIDERATIONS.—In developing the relative value scale and fee schedules under paragraph (1), the Secretary—
- (A) shall take into consideration variations in the cost of furnishing such services among geographic areas and among different sites where services are furnished, and
 - (B) may also take into consideration such other factors respecting the manner in which physicians in different specialties furnish such services as may be appropriate to assure that payment amounts are equitable and designed to promote effective and efficient provision of radiologist services by physicians in the different specialties.⁸

As demonstrated by studies described above, non-radiologists are unable to perform diagnostic imaging services at the same level of proficiency as physicians specializing in radiology (e.g., you can't diagnose what you can't see because of the poor quality image done on low-strength equipment or because you don't recognize what you are seeing.) Therefore, the effective and efficient provision of diagnostic imaging services requires that diagnostic imaging providers be formally and appropriately trained.

⁶ Verrilli, *Radiology*, 1998; 208:385.

⁷ Moskowitz, *AJR* 2000; 175: 9

⁸ S.S.A. § 1834(b)(3)

B. Precedent for Wheelchairs

CMS instituted a privileging policy in response to perceived widespread abuse of power wheelchair (scooter) coverage. CMS now precludes payment by Medicare for a motorized wheelchair, unless ordered by a physician with a specialty in physical medicine, orthopedic surgery, neurology, or rheumatology. CMS addressed the complexities of this policy for rural areas by creating an exception to this policy when a specialist is not reasonably accessible (e.g., more than a day's round trip travel from the patient's home or the patient's condition precludes travel to a specialist). In this circumstance, an order from the patient's physician may be acceptable. CMS implemented this policy by rulemaking using the agency's statutory authority governing durable medical equipment (DME).⁹ We believe that CMS should use the statutory authority described above for radiology services to accomplish a similar goal for diagnostic imaging services as part of the agency's final physician fee schedule rule to be issued in the fall of 2004.

C. Quality

CMS should also address its concerns about quality and utilization in diagnostic imaging by implementing a quality initiative for diagnostic imaging services modeled after existing standards for certification that have been implemented in the private sector or by bodies such as the ACR. It is important to note that CMS initially implemented certain standards for Independent Diagnostic Testing Facilities (IDTFs) in its final physician fee schedule rule for FY 1998. IDTFs were defined by that final rule as entities not associated with hospitals or physicians offices through which non-physician personnel furnish diagnostic procedures under physician supervision.¹⁰

We propose that CMS apply quality standards to all physicians providing diagnostic imaging services as part of the final physician fee schedule rule for FY 2005. Conditions of coverage could require that a physician become certified by CMS as a qualified diagnostic imaging provider in order to bill Medicare for diagnostic imaging tests. We suggest that CMS address the technical component of services by implementing standards for equipment quality. An image produced by a poor quality piece of equipment will inevitably lead to errors, misdiagnoses, and the need for repeat testing.

A. Statutory Authority

We believe that Section 1834(b)(3) also provides authority to CMS to develop quality standards for diagnostic imaging providers. The effective and efficient provision of services is

⁹ 42 C.F.R. § 410.38(c)

¹⁰ 42 C.F.R. § 410.33

enhanced if quality and/or certification standards are established that all providers of imaging services under Part B must meet.

It is also important to note that, in the final rule creating IDTFs in 1997, several commenters requested that the same rules applicable to IDTFs should apply to all settings. They expressed concern about the exemption of physicians' offices, group practices, and multi-specialty groups from the rules governing IDTFs. Commenters raised both the potential for abuse, quality and safety concerns, as well as the competitive disadvantage of IDTFs with hospitals and physician offices. CMS justified its decision by stating that hospitals are currently regulated and physicians must have State licensure to perform services. CMS did not state that it did not have statutory authority to impose the same requirements on physicians.¹¹ We believe that this response demonstrates that CMS itself believed it had authority to extend the same standards to physician offices. Unfortunately, the potential abuses described by commenters in 1997 have now become a reality. We recommend that CMS alter its policy to impose IDTF requirements and other quality standards in all settings where diagnostic imaging services are performed.

D. Conclusion

NCQDIS encourages CMS to implement standards for diagnostic imaging that apply to all providers of services. We want to work with the agency to improve quality of care in diagnostic imaging services. Privileging and quality standards are two options available to CMS as part of its final rule implementing the physician fee schedule for 2005. We believe that all providers should be accountable for providing high quality diagnostic imaging tests – as a coalition of diagnostic imaging centers, we are willing to be accountable to meet these standards ourselves.

Diagnostic imaging has revolutionized physicians' ability to diagnose and properly treat patients. Therefore, we encourage CMS to develop quality monitoring in an effort to assure appropriate access to diagnostic imaging services for all Medicare beneficiaries. Nevertheless, as authorized by the Medicare statute, it is also important that Medicare policies promote the most effective and most efficient provision of radiologist services among the specialties. Medicare patients would benefit from better, higher quality services, and the Medicare program would experience significant cost savings.

We look forward to working with CMS on these issues, and would be happy to provide you with additional data and information to help address the effective and efficient utilization of diagnostic imaging services.

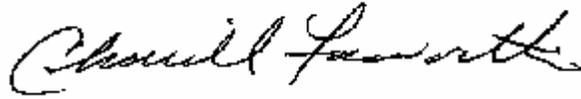
¹¹ Medicare: Physician Prospective Payment System for Calendar Year 1998, 62 *Fed. Reg.* 59,047, 59,073 (Final Rule, October 31, 1997).

Centers for Medicare & Medicaid Services

January 28, 2005

Page 9

Best regards,

A handwritten signature in black ink, reading "Cherrill Farnsworth". The signature is written in a cursive style with a large initial 'C'.

Cherrill Farnsworth

Chairperson

NCQDIS

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

GENERAL

GENERAL

I would like to respectfully comment on the proposed limitations being considered that would restrict clinicians who can bill "incident to" in a physician's office to a certain group of ancillary clinicians, excluding certified athletic trainers. As a provider who practices sports medicine, I have found that athletic trainers are simply the most qualified office staff available for what I do. Most have post-graduate training, they get consistently good patient feedback, and they are uniquely trained for injury evaluation. In Illinois, our trainers can even provide rehabilitation services for sport injury, and bill independently. We have never had a problem. Excluding certified athletic trainers from Medicare reimbursement will not accomplish anything except limit patient access to proper care, and decrease patient choice. Please amend this regulation to allow inclusion for athletic trainers. Thank you.

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

GENERAL

GENERAL

These comments are submitted on behalf of Fairview Rehabilitation Services

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 1-9

GPCI

CONTINUED FROM PREVIOUS 'GPCI' COMMENT SECTION
ASSEMBLYMEMBER JOHN LAIRD, 27TH DISTRICT
CALIFORNIA STATE ASSEMBLY

It is my understanding that the California Medical Association supports this proposal in concept and is currently working internally to reach a mutually beneficial and acceptable resolution to the GAF issue. Recognizing that this alternative proposal is still a work-in-progress, I'm both supportive of this effort and optimistic that a solution will be reached soon. It is a viable proposal to address an urgent issue that cannot face another delay as it has in previous years. The physician vacuum is a threat to Santa Cruz and Monterey County healthcare and if not addressed soon they will face dire financial and healthcare consequences.

I appreciate having this opportunity to share with you my thoughts and concerns. If you have any questions please do not hesitate to contact me at (916) 319-2027 or via email at Assemblymember.Laird@assembly.ca.gov.

Sincerely,

JOHN LAIRD
Assemblymember, 27th District

E-mailed from the desk of

J O H N L A I R D

A S S E M B L Y M E M B E R

2 7 T H D I S T R I C T

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DISTRICT OFFICES

SANTA CRUZ COUNTY 701 OCEAN STREET, SUITE 318B SANTA CRUZ, CA 95060 PHONE: (831) 425-1503 FAX: (831) 425-2570	MONTEREY AND SANTA CLARA COUNTIES 99 PACIFIC STREET, SUITE 555-D MONTEREY, CA 93940 PHONE: (831) 649-2832 FAX: (831) 649-2935
--	--

September 22, 2004

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

File Code CMS-1429-P
Re: Proposed Geographic Practice Cost Indices for 2005

To Whom It May Concern:

I am writing to share with you my opposition to the Proposed Geographic Practice Cost Indices (GPCI) for 2005, as printed in the Federal Register of August 5, 2004.

The proposed changes would have a significant negative affect on practicing physicians in the 27th California State Assembly District, which encompasses portions of southern Santa Clara County and the counties of Monterey and Santa Cruz. The latter two counties fall into the assessment category titled 'Locality 99,' which are defined as rural even though their economic growth and metropolitan identities prove to the contrary. Over the last decade the costs associated with medical treatment and physician care have increased tremendously, including the cost of living, which has skyrocketed in the last decade along the central coast and in the Bay Area. Medicare reimbursement rates, however, have not grown with these costs and have fallen far below the standard under which physicians can afford to treat Medicare beneficiaries. This has placed an expensive burden on physicians who choose to continue treating Medicare patients and jeopardizes the ability of Medicare patients in our region to receive care.

If adopted, the proposed GPCI changes would make a bad situation worse. They fail to address the reimbursement reform needed in the California counties of Santa Cruz, Sonoma, Monterey, San Diego, Sacramento, Santa Barbara and El Dorado, where medical costs exceed the statewide average by more than five percent, known as the 105 percent rule. Additionally, these counties as part of the category 'Locality 99' are afforded the rural reimbursement formula when they clearly should be provided the similar rates as their urban counterparts.

This inequity makes quality physician retention and recruitment increasingly difficult, placing an undue burden upon both physicians and residents alike who seek quality healthcare in their community. Furthermore, if these seven counties were re-qualified as their own locality and thus no longer a part of Locality 99, if the Geographic Adjustment Factor (GAF) is recalculated for

Locality 99, Placer and San Luis Obispo Counties would also rise above the five percent threshold.

I am aware that an alternative proposal has been presented to the Center for Medicare and Medicaid Services (CMS) that would provide an in-state, whole state fix that would create new localities for each of the nine counties mentioned previously. I am further aware, however, that if these nine counties were placed into their own locality, the remaining rural counties in Locality 99 would experience a decrease in their Medicare reimbursement rate due to the budget neutrality provision as mandated by Federal Law. This is not an attractive solution in a state where rural healthcare is a priority, which is why I'm pleased that the alternative proposal also includes a corresponding minimum reimbursement rate that would keep remaining Locality 99 counties reimbursed at a sufficient and satisfactory level.

It is my understanding that the California Medical Association supports this proposal in concept and is currently working internally to reach a mutually beneficial and acceptable resolution to the GAF issue. Recognizing that this alternative proposal is still a work-in-progress, I'm both supportive of this effort and optimistic that a solution will be reached soon. It is a viable proposal to address an urgent issue that cannot face another delay as it has in previous years. The physician vacuum is a threat to Santa Cruz and Monterey County healthcare and if not addressed soon they will face dire financial and healthcare consequences.

I appreciate having this opportunity to share with you my thoughts and concerns. If you have any questions please do not hesitate to contact me at (916) 319-2027 or via email at Assemblymember.Laird@assembly.ca.gov.

Sincerely,

JOHN LAIRD
Assemblymember, 27th District

Submitter : Mrs. connie creighton Date & Time: 09/24/2004 09:09:12

Organization : Mrs. connie creighton

Category : Physician Assistant

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Please do NOT pass the policy whereby a physician can only refer "incident to" services to patients with a physicians perscription or under their supervision.

Submitter :

Date & Time:

09/24/2004 09:09:58

Organization :

Category :

Physical Therapist

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I am proud to be a board-certified sports physical therapist & athletic trainer. I have been the director of two large outpatient physical therapy clinics. I am now faculty at one of the top 5 physical therapy programs (according to US News & World Report) & occasionally teach into the highly regarded athletic training program at this University. CONSEQUENTLY, I BELIEVE THAT MY PERSPECTIVE ON THE 'INCIDENT TO' ISSUE IS ESPECIALLY PERTINENT.

I know this is a hot issue because I have received at least 12 solicitations to sign form letters from the NATA or associated grassroots efforts & two from the APTA's grassroots efforts (I am a member of both associations). ALTHOUGH MANY PEOPLE WOULD LIKE TO MAKE THIS A COMPLICATED ISSUE, IT IS ACTUALLY QUITE SIMPLE, DESPITE THE OVERWHELMING, PASSIONATE RESPONSE.

Let me start by saying that as an athletic trainer & physical therapist, I firmly believe that there are many athletic trainers that are qualified to see the YOUNG, ATHLETIC POPULATION independently in a physician's office. With that said, YOUR OBLIGATION IS TO ENSURE THAT MEDICARE ELIGIBLE PATIENTS ARE TREATED BY QUALIFIED PROVIDERS, THEREBY ENSURING THAT TAX PAYERS DOLLARS ARE WELL SPENT. As an athletic trainer, I know that most athletic trainers, while sharp people and good clinicians, ARE NOT TRAINED TO SEE THE TYPICAL MEDICARE PATIENT (certainly they can perform range of motion, apply a modality, or teach an exercise, but these are just a small component of physical therapy services and do not account for the complexity of treating the typical Medicare patient). In my experience, most Medicare eligible patients are on SEVERAL MEDICATIONS AND OFTEN HAVE SEVERAL COMORBIDITIES ALONG WITH THE ORTHOPAEDIC... COMPLAINT THEY ARE BEING TREATED FOR. This is beyond the scope of the typical athletic trainer. I believe that nearly all of my athletic training faculty colleagues would agree with this.

WHY IS THE NATA & ATHLETIC TRAINING COMMUNITY VIGOROUSLY ASKING YOU TO RECONSIDER? Because insurance companies generally follow the lead of CMS. If CMS rules that only physical therapists can provide physical therapy services, then insurance companies may not reimburse athletic trainers for rehabilitation services. While, as an athletic trainer, I am sympathetic the athletic trainers' current situation, that does not change the fact that they are NOT TRAINED TO CARE FOR THE TYPICAL MEDICARE PATIENT. Certainly, there are older athletes who are injured while participating in recreational or athletic events and are otherwise healthy. But, this is not the Norm. It is more common to see someone scheduled for a knee replacement that is a little overweight and has a heart condition and diabetes. In this situation, a WORKING KNOWLEDGE of the COMORBIDITIES (diabetes, heart disease) is imperative.

As an educator & clinician in both athletic training and physical therapy, I could provide you with a detailed description of the STARK DIFFERENCES in the BACHELOR'S LEVEL training of most athletic trainers & the MASTER'S OR DOCTORAL TRAINING that is the standard in physical therapy. Each program is appropriate for the patient population treated. Because the therapist treats a broader range of patients with a broader spectrum of medical conditions, their training requires a more advanced degree. Because the athletic trainer generally treats people who are young, active, and without comorbidities, a bachelor's level education is satisfactory, although not ideal.

THE PATIENT SHOULD BE THE CENTER OF THIS DECISION. In that context your proposed ruling is absolutely correct. Physical Therapists and those under their supervision should be the only clinicians authorized to provide 'incident to' physical therapy services to the MEDICARE ELIGIBLE PATIENT.

IT IS IMPORTANT THAT YOU KEEP THE CURRENT WORDING BECAUSE IT IS IN THE BEST INTEREST OF THESE PATIENTS.

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

GENERAL

GENERAL

This policy will severely limit a patient's RIGHT to choose who they want to provide their care. This is a direct infringement on a patient's right to a qualified rehabilitation specialist. If this bill passes the consumer will have no choice as to whom they see for their care. This will severely limit the quality of rehabilitative care given in the United States today. It will continue to tighten the grip around the throat of a patient's right to choose who to see for their care. Not only is this policy bad for the patient but also it is an outrageous violation of Anti-Trust Laws. The organizations that are backing law this are trying to monopolize the rehabilitation market. For the good of the ever-increasing elderly population as well as everyone else, this policy must be defeated and never to be resurrected.

Thank you,
David C. Heyel

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 1-9

PRACTICE EXPENSE

September 23, 2004

Mark McClellan, MD, Ph.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1429-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW.
Washington, DC 20201

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005; Proposed Rule

Dear Dr. McClellan:

Possis Medical appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) notice of proposed rulemaking governing revisions to payment policies under the Physician Fee Schedule for calendar year 2005, published in the Federal Register on August 5, 2004 (69 Fed. Reg. 47488). We are pleased with the agency's decision to increase the overall payment to physicians and to provide an opportunity to comment on the proposed changes.

Our reason for commenting relates to the non-facility practice expense RVU for CPT code 36870 Thrombectomy, percutaneous, arteriovenous fistula, as published on page 47617 of the rule. The non-facility RVU has been decreased by 27% from the 2004 RVU level. The proposed non-facility RVU is 32.39, compared to 47.27 in 2004. In reviewing the cost data as reported by Medicare for CPT code 36870, only one modality of treatment was reflected in the data - The Trerotola[®] with a Fogarty catheter. Although this particular product is used in approximately 50% of the percutaneous thrombectomy procedures, devices such as the Angiojet[®] rheolytic[®] thrombectomy catheter or lytic agents are used in the other 50%. The Medicare data reflects a cost of the Fogarty balloon of \$101.75 and Trerotola cost of \$487.50. The Angiojet[®] thrombectomy catheter, which is manufactured by Possis Medical, is \$ 450. In addition, a pump set is required for the procedure with a cost of \$250.

Based on the aforementioned, we would like to recommend that CMS consider using the AngioJet List Price in the development of the non-facility practice expense RVU for this procedure. By doing so, the costs will more accurately reflect the true costs of performing the percutaneous thrombectomy procedure in the non-facility setting.

Possis Medical appreciates the opportunity to comment on the Proposed Rule. If you have any questions regarding our comments, please feel free to contact Faith Salchert at 763-717-1167. We thank you for your attention to this very important matter.

Respectfully submitted by,

Faith Salchert
Marketing Manager

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

GENERAL

GENERAL

I WOULD LIKE TO COMMENT IN SUPPORT OF THE INCIDENT TO RULE BEING PROPOSED TO INSURE THAT INDIVIDUALS PROVIDING THERAPY SERVICES IN PHYSICIAN OFFICES BE GRADUATES OF APPROVED PROGRAMS, (APTA, AMA COMMITTEE ON ALLIED HEALTH EDUCATION AND ACCREDITATION, ETC.) AS THESE INDIVIDUALS WILL HAVE GOAL DRIVEN AND FUNCTION FOCUSED SERVICE FOR THE CLIENTEL THAT THEY SERVE, WHEREAS THE NON-PROFESSIONAL MAY PROVIDE ONLY PALLIATIVE CARE AND SERVICE. WE FREQUENTLY SEE AND ARE TOLD BY PATIENTS IN SITUATIONS WHERE THEY WERE TREATED BY NON-PROFESSIONALS, THAT THEY DID NOT SEE THE PHYSICIAN SUPERVISING THEIR CARE NOR WERE THEY GIVEN COMPREHENSIVE TREATMENT. THEY COMMENT THAT THEY WERE OFTEN TOLD WHAT TO DO ONLY TO HAVE THE PERSONNEL WALK AWAY FROM THEIR TREATMENT AREA AND GO TO OTHER INDIVIDUALS AND NOT RETURN FOR SOME TIME. SOME STATED THAT THEY FELT LIKE THEY WERE CATTLE BEING RUSHED THROUGH THE TREATMENT SETTING. THIS TYPE OF SITUATION I FEEL IS NOT PRODUCTIVE FOR THE INDIVIDUAL BEING TREATED. THE PHYSICAL THERAPIST OR PHYSICAL THERAPIST ASSISTANT WOULD PROVIDE MORE GOAL DIRECTED AND COMPREHENSIVE SERVICE GIVEN THEIR PRIOR TRAINING. AGAIN I AM IN FAVOR OF THIS RULE AS IN THE LONG RUN IT WOULD BE MORE COST EFFECTIVE TO THE PATIENT AND CMS. THANK YOU.

JAMES T. MAIER,PT,MS

Submitter : Mrs. sherly arthur Date & Time: 09/24/2004 09:09:19

Organization : Mrs. sherly arthur

Category : Physician Assistant

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I beg you not to pass this policy whereby a physician can only refer "incident to" services to physical therapists. All qualified healthcare providers SHOULD be allowed to provide services to patients with a physicians prescription or under their supervision. The patient should be allowed to seek care with whomever they chose. They should not be forced to have their care performed by someone not of their choice.

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 10-19

SECTION 629

My name os Rimvydas Veitas. I am a physical therapist, with 10 years of experience in orthopedic physical therapy, currently licensed and working in Seattle Washington.

I would like to comment on the August 5 proposed rule on 'Revisions to payment policies under the physician fee schedule for calendar year 2005.' I strongly support the proposed standards of reimbursement for physical therapy service only when performed by a physical therapist, or a physical therapy assistant under the direct supervision of a physical therapist. I strongly oppose the use of unqualified personel to provide physical therapy services.

Physical therapy is a specialized medical field for which there is a rigorous course of study at the postgraduate university level, including clinical and residency. We are also expected to continue our education after graduation and licensure, through professionally sponsored courses. This makes us highly qualified to provide physical therapy services, or to supervise trained physical therapy assistants. By allowing unqualified individuals to perform these services puts patients at risk for injury or even death.

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I implore you not to pass this policy whereby a physician can only refer "incident to" services to physical therapists. All qualified healthcare providers should be allowed to provide services to patients with a prescription or under there supervision. They should be able to get care performed by the best possible source which is not always the pt

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Do not pass this policy whereby a physician can only refer "incident to" services to physical therapists. All qualified healthcare providers should be allowed to provide services to patients with a prescription or under our supervision.

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

We hope that you do not pass this policy whereby a physician can only refer "incident to" service to physical therapists. All qualified health care providers should be allowed to provide services to patients with a physicians prescription or under their supervision.

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

9/24/04

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1429-P
P.O. Box 8012
Baltimore, MD 21244-8012

Re: Therapy ? Incident To

Dear Sir/Madam:

I am writing to express my concern over the recent proposal that would limit providers of "incident to" services in physician clinics. If adopted, this would eliminate the ability of qualified health care professionals to provide these important services. In turn, it would reduce the quality of health care for our Medicare patients and ultimately increase the costs associated with this service and place an undue burden on the health care system.

I am a physical therapist in addition to an athletic trainer. I feel athletic trainers are qualified to treat orthopedic and athletic injuries in the clinical setting. Athletic trainers are required to take extensive course work in the evaluation and treatment of several orthopedic conditions. I feel that athletic trainers are qualified to treat orthopedic patients secondary to their education.

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Please do not pass this bill. People should be able to get the best care, and this is not always from a physical therapist.

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Let it be known, that I am opposed to the passing of this policy whereby a physician can only refer "incident to" services to physical therapists. All qualified health care providers should be allowed to provide services to patients with a physicians prescription or under their supervision. Thank you.

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

GENERAL

GENERAL

I am a licensed physical therapist in the state of Washington, and have been providing outpatient physical therapy services since 1994. I would like to ask for your support of the proposed rule on "Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2005." The proposed change would provide for better quality of physical therapy services to be rendered to patients.

A few years ago I had the following experience with a patient that came into my office after having received "physical therapy" from a physicians' office. This individual came into my office and asked that I help her understand her physical therapy bill. I did not recognize this individual and asked if they had been seen in my clinic. They responded no they had been seen in a doctor's office in town and had "physical therapy" services there.

The question she wanted answered was why she received a bill for over \$100 dollars when the appointment had only been for 25-30 minutes. I told them I could not explain the bill and they would need to take it up with the doctor. She told me that she laid down on a table that provided heat, vibrated, and had mechanical traction for the neck. She was also told "move your neck" for exercises, by someone in the doctors office. She was seen several times with this same type of treatment.

I explained to her that I was sorry she had a bad experience with this doctor and explained to her that patients in my clinic were evaluated and treated by licensed physical therapist, instructed in a personalized treatment/exercise plan and progressed as appropriate to meet their physical needs and abilities.

I love my job as a physical therapist and helping patients return to their best ability. It bothers me to hear of peoples bad experiences with physical therapy related services. Licensed physical therapists have undergone extensive education and training in the services they provide. What this woman received was not physical therapy but was billed for modalities that allowed this particular doctors office to earn more money.

I hope that CMS will Support Proposed Personnel Standards for Medicare "Incident To" Physical Therapy Services rules change.

If you have any further questions and would like to talk with me I would encourage you to call the American Physical Therapy Association or feel free to contact me, 509-783-1962.

Sincerely,

Kenneth S. Call, MSPT

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I strongly encourage the support of having only qualified personnel (physical therapists and physical therapist assistants) providing services delineated as "physical therapy"- physical therapists and assistants go through a formal education process and licensure to specifically provide "physical therapy" which is not a loose term whose services can be effectively or correctly provided by just any person who is staff in a physician's office. The physical therapist and assistant use their education and unique experiences to guide them in their decisions, rationale and reasoning for using/providing each physical therapy service. To have someone providing the physical therapy service without the education/training/etc or the understanding of a physical therapist, is doing a disservice to the patient and to the physical therapy profession and may not actually be providing that service, no matter how it is billed.

I strongly encourage the support of having only qualified personnel (physical therapists and physical therapist assistants) providing services delineated as "physical therapy"- physical therapists and assistants go through a formal education process and licensure to specifically provide "physical therapy" which is not a loose term whose services can be effectively or correctly provided by just any person who is staff in a physician's office. The physical therapist and assistant use their education and unique experiences to guide them in their decisions, rationale and reasoning for using/providing each physical therapy service. To have someone providing the physical therapy service without the education/training/etc or the understanding of a physical therapist, is doing a disservice to the patient and to the physical therapy profession and may not actually be providing that service, no matter how it is billed.

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

9/24/04

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1429-P
P.O. Box 8012
Baltimore, MD 21244-8012

Re: Therapy ? Incident To

Dear Sir/Madam:

I am writing to express my concern over the recent proposal that would limit providers of "incident to" services in physician clinics. If adopted, this would eliminate the ability of qualified health care professionals to provide these important services. In turn, it would reduce the quality of health care for our Medicare patients and ultimately increase the costs associated with this service and place an undue burden on the health care system.

In the clinical setting I work in, the athletic trainers are a valuable asset with regard to their knowledge and skills. They also help to fill staffing needs with skilled individuals. I believe there should be limitations set on various professions, but keeping an ATC out of the clinic entirely is not one of them.

Sincerely,
Chad Hatayama
2687 Brookline Pl
Decatur, IL 62521

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I strongly support CMS's proposed requirement that physical therapy services in a physician's office be provided only by a physical therapist, or physical therapist assistant under the supervision of a physical therapist. In addition, a licensed physical therapist should be a graduate of an accredited professional program, or have met the grandfathering clauses, or specific requirements if they are a foreign-trained physical therapist. Physical therapists possess an unique body of knowledge regarding rehabilitation acquired through specialized education that is approved by the Commission of Accreditation of Physical Therapy. Consequently, physical therapy services should only be provided by these qualified personnel to ensure safety and quality care of patients.

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

All qualified health care providers should be allowed to provide services to patients with a physicians prescription or under their supervision. We submit that you to NOT pass this policy whereby a physician can only refer "incident to" services to physical therapists. Thank You!

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

We ask that you NOT pass this policy whereby a physician can only refer "incident to" services to physical therapists. All qualified health care providers should be allowed to provide services to patients with a physicians prescription or under their supervision.
Thank you for your help!

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

GENERAL

GENERAL

as a certified athletic trainer, i am concerned with the potential changes that are being considered to the definition of who can provide therapy. while physical therapists are highly skilled a the rehabilitation of injuries, they are not the only ones. certified athletic trainers are highly skilled in the prevention, evaluation, and rehabilitation of athletic and non-athletic injuries alike. with a certification system in place for both the undergraduate curriculums that teach athletic training and also for the licensure and certification the parameters are in place to regulate a highly skilled profession. if things change and these services are restricted even more, it will not only be limiting the usefulness of an entire segment of the health care population, but it would also limit the opportunities for those who require such services. please carefully consider all the potential ramifications of this decision and the lives of those who will be affected--both health care professionals and patients who require therapy.

Submitter : Mrs. Beth Agami Date & Time: 09/25/2004 12:09:20

Organization : A FITTING EXPERIENCE MASTECTOMY SHOPPE, INC.

Category : Home Health Facility

Issue Areas/Comments

GENERAL

GENERAL

Mastectomy products should be excluded from the face-to-face prescription requirements. The effects of a mastectomy are permanent. Based on that fact, mastectomy products are necessary throughout the life of the recipient. Medicare already has parameters in place for the dispensation these items. These parameters should be sufficient. The face-to-face prescriptions requirement would place an undue burden on all affected Medicare beneficiaries, physicians, suppliers and Medicare as well. The face-to-face prescription requirement will require the recipient the inconvenience of a visit to the physician, the physician's time for the visit, and Medicare's payment for the visit. How is that cost effective? If a breast cancer survivor was in need of code L8000 (surgical mastectomy bra), will she need to schedule an appointment with her physician for the request of a bra? This is will be an unnecessary emotional burden on the breast cancer survivor. I appreciate the opportunity to express this opinion.

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Please do not pass this policy whereby a physician can only refer "incident to" services to physical therapists. All qualified health care providers should be allowed to provide their services to patients with a physician's prescription or under their supervision.

-Thank You, Ms. Citelli

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I am writing to you today concerning CURRENT PLANNED POLICY THAT RESTRICTS WHO PHYSICIANS CAN HIRE TO PROVIDE OUTPATIENT THERAPY SERVICES. This will severely discriminate against a group of healthcare providers recognized by the American Medical Association, and one that each of you are likely now familiar, ATC's. Certified Athletic Trainers are qualified trained individuals that have consistently treated patients under the direct supervision of physicians for a number of years, and should be allowed to bill for their services as an "incident to" service.

Adopting new policy that restricts who physicians can hire to provide rehabilitation therapy services to their patients, as noted in the proposed rule issued on August 5, will exclude such highly qualified individuals as those certified by the National Athletic Trainer's Association.

I am one such certified athletic trainer, having 2 master's degrees, and being an active healthcare administrator. To provide such regulation, you will further harm the physical therapy profession by limiting the supply of highly qualified individuals, particularly as the demand for caregivers increases.

I strongly encourage you to study the background of athletic trainers, their education, and particularly recommend that you visit with those individuals who have a dual credential in both physical therapy and athletic training (PT/ATC). Those individuals can attest to the expertise that ATC's have brought to the physical therapy profession.

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I am writing to express my concern over the recent proposal that would limit providers of "incident to" services in physician offices and clinics. If adopted, this would eliminate the ability of qualified health care professionals to provide these important services. In turn, it would reduce the quality of health care for our Medicare patients and ultimately increase the costs associated with this service and place an undue burden on the health care system.

During the decision-making process, please consider the following:

"Incident to" has, since the inception of the Medicare program in 1965, been utilized by physicians to allow others, under the direct supervision of the physician, to provide services as an adjunct to the physician's professional services. A physician has the right to delegate the care of his or her patients to trained individuals (including certified athletic trainers) whom the physician deems knowledgeable and trained in the protocols to be administered. The physician's choice of qualified therapy providers is inherent in the type of practice, medical subspecialty and individual patient.

There have never been any limitations or restrictions placed upon the physician in terms of who he or she can utilize to provide ANY "incident to" service. Because the physician accepts legal responsibility for the individual under his or her supervision, Medicare and private payers have always relied upon the professional judgment of the physician to be able to determine who is or is not qualified to provide a particular service. It is imperative that physicians continue to make decisions in the best interests of the patients.

In many cases, the change to "incident to" services reimbursement would render the physician unable to provide his or her patients with comprehensive, quickly accessible health care. The patient would be forced to see the physician and separately seek therapy treatments elsewhere, causing significant inconvenience and additional expense to the patient.

This country is experiencing an increasing shortage of credentialed allied and other health care professionals, particularly in rural and outlying areas. If physicians are no longer allowed to utilize a variety of qualified health care professionals working "incident to" the physician, it is likely the patient will suffer delays in health care, greater cost and a lack of local and immediate treatment.

Patients who would now be referred outside of the physician's office would incur delays of access. In the case of rural Medicare patients, this could not only involve delays but, as mentioned above, cost the patient in time and travel expense. Delays would hinder the patient's recovery and/or increase recovery time, which would ultimately add to the medical expenditures of Medicare.

Curtailing to whom the physician can delegate "incident to" procedures will result in physicians performing more of these routine treatments themselves. Increasing the workload of physicians, who are already too busy, will take away from the physician's ability to provide the best possible patient care.

Athletic trainers are highly educated. ALL certified or licensed athletic trainers must have a bachelor's or master's degree from an accredited college or university. Foundation courses include: human physiology, human anatomy, kinesiology/biomechanics, nutrition, acute care of injury and illness, statistics and research design, and exercise physiology. Seventy (70) percent of all athletic trainers have a master's degree or higher. This great majority of practitioners who hold advanced degrees is comparable to other health care professionals, including physical therapists, occupational therapists, registered nurses, speech therapists and many other mid-level health care practitioners. Academic programs are accredited through an independent process by the Commission on Accreditation of Allied Health Education Programs

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

GENERAL

GENERAL

Dear Mr. McClellan,

I am writing to you to encourage endorsement of the "Incident To" provision which specifies that Medicare will only make payment for physical therapy service provided incident to physician services if they are furnished by an individual meeting the requirements in current regulations for a physical therapist. I am recommending it is included in the final rule for the agency's "Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2005".

I am strongly in support of CMS' rule that individuals who furnish physical therapy services must be graduates of an accredited professional physical therapy program (or meet certain grandfathering clauses or special rules for foreign trained physical therapists). As Physical therapists our educational programs are quite intensive and include, but are not limited to the following areas: Anatomy, Physiology, Histology, Radiology, Pharmacology, Psychology, Neuroscience, Orthopedics, Human growth and Development, Medical Ethics and Differential Diagnosis. In addition to classroom activity an extensive amount of time is spent in the clinical setting working under licensed physical therapists and developing proficiency in the delivery of physical therapy services. Training in the rehabilitation of individuals from neonatal to geriatrics is encompassed within the educational and clinical settings.

I understand and appreciate the rationale for the ruling in outpatient physical therapy clinics that care will only be reimbursed if it is provided by a physical therapist or a physical therapist assistant under the direction of the physical therapist. Based on this ruling, it appears CMS is in agreement with the physical therapy profession that physical therapists and physical therapist assistants are best trained to provide these services to the Medicare population. I therefore think it is necessary for consistency in rulings and that physical therapy services in a physician's office should also be provided by physical therapists and physical therapist assistants under the direction of a physical therapist. In order to best serve the rehabilitation needs of Medicare beneficiaries requiring physical therapy these individuals should be properly educated and trained in this specialized field of practice. Only Physical therapists and physical therapist assistants under the direct supervision of a physical therapist are trained to provide this service.

I hope you will carefully consider the importance of consistency in rulings in addition to what is the most optimum and safe care for Medicare beneficiaries.

Sincerely,

Audrey Waldron, PT

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

GENERAL

GENERAL

I am attaching our comments for Docket CMS-1429-P.
Thank you,
Jim Elkin
Novartis Corporation
202 638 7429

CMS-1429-P-4131-Attach-2.rtf

CMS-1429-P-4131-Attach-1.rtf

September 24, 2004

BY HAND DELIVERY

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

Re: [CMS-1429-P] Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005

Dear Dr. McClellan:

I am pleased to submit the following comments on behalf of a Novartis Corporation affiliate, Novartis Pharmaceuticals Corporation (“Novartis”), regarding the above-referenced rule (the “Rule”). 69 Fed. Reg. 47488 (Aug. 5, 2004). We provide a broad portfolio of innovative, effective, and safe products in diversified treatment areas, including oncology, primary care, transplantation, and ophthalmics. In addition, Novartis aims to harness the latest advances in biomedical research and technology to develop new therapies with the potential to benefit millions of patients throughout the world.

Novartis supports the comments on the Rule submitted by the Pharmaceutical Research and Manufacturers of America (“PhRMA”) on behalf of the pharmaceutical industry. We write separately, however, to highlight issues that are of particular concern to Novartis. We are extremely concerned that the upcoming changes to the 2005 Medicare payment rates for Part B drugs and biologicals (hereinafter, “drugs”) and the reduced payment rates for administering such drugs will lead to diminished access to critical treatments for Medicare beneficiaries. Moreover, many questions remain unanswered regarding the average sales price (“ASP”) mechanism that will be used to determine the payment rates for drugs in 2005, and we urge the Centers for Medicare & Medicaid Services to provide much needed clarification on the issues discussed below in a timely manner. With regard to drug administration services, we believe that CMS should adopt the recommendations recently made by the American Medical Association (“AMA”) regarding new codes for such services and establish appropriate payment rates for these new codes. Finally, we believe that it is critical for the Centers for Medicare and Medicaid Services (“CMS”) to revise the proposed

pharmacy supply fee paid to entities that provide immunosuppressive agents to ensure that Medicare beneficiaries have continued access to these critical products.¹

I. The Need for Guidance on Average Sales Price

As noted above, Novartis is very concerned that the new method of setting payment rates based on ASP in 2005 will lead to beneficiaries not having the necessary access to Part B drugs through physicians and suppliers to treat their ailments. We encourage CMS to monitor access closely and appreciate the agency's statement recognizing this responsibility. 69 Fed. Reg. at 47573 (discussing plans to study drug utilization patterns). At the same time, we believe that the validity of the ASP-based ratesetting mechanism depends on clear and considered guidance on how to report ASP correctly. Notwithstanding the release of a recent final rule related to ASP reporting, there are a number of other areas for which guidance is needed but has not been provided. We address such issues below.

A. Ensuring the Propriety of ASP Rates

Novartis believes that CMS needs to establish a mechanism that would provide the public with an opportunity to identify errors in the calculation of ASP-based payment rates before the start of the calendar quarter in which the rates are effective. The agency's experience to date indicates that errors in both reporting and computing ASP-based rates may occur. CMS could minimize the impact of such calculation errors by posting the payment rates weeks before they become effective. For example, since the first quarter 2005 rates are based on third quarter 2004 information reported by manufacturers, CMS would obtain that information at the end of October. If CMS were to compute the rates and release them to the public within a few weeks, the public could identify possible mistakes and report them to CMS in time for the agency to make any appropriate changes before the rates go into effect. Novartis urges CMS to take such an approach each calendar quarter beginning with the first quarter 2005 payment rates.

B. Payment for New Drugs

The statute provides for payment for new drugs based on wholesale acquisition cost or methodologies in effect on November 1, 2003, but only for a maximum of a calendar quarter. Social Security Act ("SSA") § 1847A(c)(4). While this provision addresses payment through the first full calendar quarter, it is silent as to the payment rate for a new drug in its second calendar quarter.² Novartis recommends that CMS

¹ All of our comments pertain to "Section 303."

² For example, if a new product is first sold on January 1, 2005, the statute provides a distinct method for establishing payment in the first quarter of 2005 only. The second quarter 2005 rates for most drugs will be based on ASP information reported for the fourth quarter of 2004, but there will be no information to report for the new drug from that time period. The first set of ASP information that could

provide clear guidance on how the payment rate for a new drug in its second calendar quarter will be determined. In our view, given the lack of available ASP information for determining the payment rate, CMS should use the same methodology for the second quarter payment as for the first quarter.

C. Clarification Regarding Reporting

Novartis believes that CMS has failed to provide sufficient guidance to manufacturers regarding certain aspects of the ASP information they must report. For instance, there is a lack of guidance on the duration of the reporting requirement for a National Drug Code (“NDC”) that has been discontinued. Novartis recommends that CMS require manufacturers to report ASP through the shelf life date of the last lot distributed of the discontinued NDC. In addition, we request that CMS identify how a manufacturer is supposed to report ASP information when the calculated ASP is a negative number. Since the next deadline for submitting information is at the end of October, we urge CMS to provide the needed guidance well in advance of that deadline.

D. Removal of Certain Items from the ASP Calculation

As noted above, Novartis is very concerned that this untested system of setting payment rates based on reported average sales price information may result in payment rates that are inadequate to ensure that beneficiaries have continued access to drugs and biologicals furnished by physicians and suppliers. We believe that some of the components (*i.e.*, prompt pay incentives, certain administrative fees paid to wholesalers and distributors) required by CMS to be included in the ASP calculation in the interim final rule should not be included in the calculation.

Many manufacturers, including Novartis, offer prompt pay incentives to wholesalers and distributors in order to motivate them to make payment for products they purchase within a set time period. In our view, these incentives are not discounts on the product, but represent standard business arrangements that reflect the time value of money. We note also that the Office of the Inspector General has taken the position that these arrangements are not discounts designed to induce purchase, when it decided not to include prompt pay incentives in the discount safe harbor.³ Accordingly, we recommend that CMS exclude these incentives from the calculation of ASP.

Similarly, we recommend that CMS consider excluding some administrative fees that are paid by manufacturers in return for services provided by wholesalers and distributors. CMS recently addressed this issue in its “Average Sales Price (ASP) Reporting Requirements Questions and Answers” (“Q & As”), stating in response to

be reported for this new drug would be from the first quarter of 2005, which would be used to establish the payment rate for the third quarter of 2005.

³ 56 Fed. Reg. 35952, 35979 (Jul. 29, 1991).

question 16 that administrative fees should be included in the calculation of ASP if “they ultimately affect the price actually realized by the manufacturer.”⁴ We suggest that CMS clarify that its statement that administrative fees should be included if they affect the price actually realized by the manufacturer was not intended to include all administrative fees, and instead make clear that administrative fees for real services provided by the purchaser for the benefit of the manufacturer would not be included in the ASP calculation. We ask that CMS address this issue before the third quarter 2004 ASP information is due to CMS.

E. Treatment of Price Concessions Available on a Lagged Basis

We appreciate the recent guidance on a revised methodology to handle “lagged” price concessions, 69 Fed. Reg. 55763 (Sept. 16, 2004), and generally believe the revised methodology is an improvement over the prior methodology. However, we believe that there are some ambiguities in the revised methodology that need to be clarified prior to the next deadline for reporting ASP information. In particular, Novartis requests that CMS clarify whether the revised methodology applies to all price concessions or only those price concessions for which data are lagged. In addition, we request that CMS clarify how (if at all) the revised methodology applies to a price concession category (e.g., chargebacks), where some, but not all, of the data to be used in the ASP calculation are available on a lagged basis.

II. Payments for Drug Administration Services in 2005

Novartis believes that it is extremely important that physicians and suppliers furnishing drugs to Medicare beneficiaries be properly paid for performing these services. We are concerned that the significantly lower transition adjustment in 2005 (3%) compared to 2004 (32%) will adversely impact patient care, and we believe that this also should be monitored by CMS. We commend CMS for the flexibility that it displayed in the Proposed Rule with regard to a willingness to create new codes to accommodate suggested changes in the coding for drug administration services. The AMA has submitted its recommendations for changes to the codes for drug administration services and we fully support those recommendations. Accordingly, we urge CMS to adopt these recommended changes, issue the necessary codes to implement the changes on January 1, 2005, and establish appropriate payment rates for these new codes.

III. Ensuring Access to Immunosuppressive Agents

After failing to provide for any pharmacy supplying fee for immunosuppressive drugs in 2004 despite a requirement to do so, *see* SSA § 1842(o)(6), Novartis was pleased to see that the agency has proposed such a fee for 2005. 69 Fed. Reg. at 47523. However, we are troubled by the proposed amount for this fee - \$10 per prescription.

⁴ The Q & As are available at http://www.cms.hhs.gov/providers/drugs/aspqa_web_042204.pdf.

While the agency reports that it was presented with a variety of information and suggested fees, CMS provides no explanation as to why it chose the lowest of any of the figures that it was provided. *See* 69 Fed. Reg. at 47523. Given the critical nature of these products to Medicare beneficiaries receiving them, it is imperative that beneficiaries have access to them. With the change in the methodology for determining payment rates for these products in 2005 and the possibility of reduced rates, ensuring a proper supplying fee is especially important. We encourage CMS to consider additional information provided regarding an appropriate supplying fee and to finalize a rate that will ensure that beneficiaries continue to have access to immunosuppressive drugs.

IV. Conclusion

For the reasons discussed above, Novartis urges CMS to be vigilant about ensuring beneficiary access to drugs as the new ASP payment mechanism is implemented. While monitoring access is important in this regard, CMS also should ensure that the determined payment rates are accurate by establishing a process that it will follow in each calendar quarter to provide the public with sufficient opportunity to review the rates and raise issues to CMS before the rates go into effect. Novartis also recommends that CMS adopt the AMA's suggested coding changes for drug administration services and fully implement these changes effective January 1, 2005. Finally, we urge the agency to establish an appropriate pharmacy supplying fee for immunosuppressive products in the final rule.

We thank CMS in advance for its serious consideration of these comments, as well of those submitted by PhRMA, as the new payment methodology for Part B drugs continues to take shape.

Sincerely,

Jim Elkin
Vice President
Federal Government Relations
Novartis Corporation
701 Pennsylvania Ave. NW, Suite 725
Washington, D.C. 20004
Phone 202 638 7429

September 24, 2004

BY HAND DELIVERY

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

Re: [CMS-1429-P] Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005

Dear Dr. McClellan:

I am pleased to submit the following comments on behalf of a Novartis Corporation affiliate, Novartis Pharmaceuticals Corporation (“Novartis”), regarding the above-referenced rule (the “Rule”). 69 Fed. Reg. 47488 (Aug. 5, 2004). We provide a broad portfolio of innovative, effective, and safe products in diversified treatment areas, including oncology, primary care, transplantation, and ophthalmics. In addition, Novartis aims to harness the latest advances in biomedical research and technology to develop new therapies with the potential to benefit millions of patients throughout the world.

Novartis supports the comments on the Rule submitted by the Pharmaceutical Research and Manufacturers of America (“PhRMA”) on behalf of the pharmaceutical industry. We write separately, however, to highlight issues that are of particular concern to Novartis. We are extremely concerned that the upcoming changes to the 2005 Medicare payment rates for Part B drugs and biologicals (hereinafter, “drugs”) and the reduced payment rates for administering such drugs will lead to diminished access to critical treatments for Medicare beneficiaries. Moreover, many questions remain unanswered regarding the average sales price (“ASP”) mechanism that will be used to determine the payment rates for drugs in 2005, and we urge the Centers for Medicare & Medicaid Services to provide much needed clarification on the issues discussed below in a timely manner. With regard to drug administration services, we believe that CMS should adopt the recommendations recently made by the American Medical Association (“AMA”) regarding new codes for such services and establish appropriate payment rates for these new codes. Finally, we believe that it is critical for the Centers for Medicare and Medicaid Services (“CMS”) to revise the proposed

pharmacy supply fee paid to entities that provide immunosuppressive agents to ensure that Medicare beneficiaries have continued access to these critical products.¹

I. The Need for Guidance on Average Sales Price

As noted above, Novartis is very concerned that the new method of setting payment rates based on ASP in 2005 will lead to beneficiaries not having the necessary access to Part B drugs through physicians and suppliers to treat their ailments. We encourage CMS to monitor access closely and appreciate the agency's statement recognizing this responsibility. 69 Fed. Reg. at 47573 (discussing plans to study drug utilization patterns). At the same time, we believe that the validity of the ASP-based ratesetting mechanism depends on clear and considered guidance on how to report ASP correctly. Notwithstanding the release of a recent final rule related to ASP reporting, there are a number of other areas for which guidance is needed but has not been provided. We address such issues below.

A. Ensuring the Propriety of ASP Rates

Novartis believes that CMS needs to establish a mechanism that would provide the public with an opportunity to identify errors in the calculation of ASP-based payment rates before the start of the calendar quarter in which the rates are effective. The agency's experience to date indicates that errors in both reporting and computing ASP-based rates may occur. CMS could minimize the impact of such calculation errors by posting the payment rates weeks before they become effective. For example, since the first quarter 2005 rates are based on third quarter 2004 information reported by manufacturers, CMS would obtain that information at the end of October. If CMS were to compute the rates and release them to the public within a few weeks, the public could identify possible mistakes and report them to CMS in time for the agency to make any appropriate changes before the rates go into effect. Novartis urges CMS to take such an approach each calendar quarter beginning with the first quarter 2005 payment rates.

B. Payment for New Drugs

The statute provides for payment for new drugs based on wholesale acquisition cost or methodologies in effect on November 1, 2003, but only for a maximum of a calendar quarter. Social Security Act ("SSA") § 1847A(c)(4). While this provision addresses payment through the first full calendar quarter, it is silent as to the payment rate for a new drug in its second calendar quarter.² Novartis recommends that CMS

¹ All of our comments pertain to "Section 303."

² For example, if a new product is first sold on January 1, 2005, the statute provides a distinct method for establishing payment in the first quarter of 2005 only. The second quarter 2005 rates for most drugs will be based on ASP information reported for the fourth quarter of 2004, but there will be no information to report for the new drug from that time period. The first set of ASP information that could

provide clear guidance on how the payment rate for a new drug in its second calendar quarter will be determined. In our view, given the lack of available ASP information for determining the payment rate, CMS should use the same methodology for the second quarter payment as for the first quarter.

C. Clarification Regarding Reporting

Novartis believes that CMS has failed to provide sufficient guidance to manufacturers regarding certain aspects of the ASP information they must report. For instance, there is a lack of guidance on the duration of the reporting requirement for a National Drug Code (“NDC”) that has been discontinued. Novartis recommends that CMS require manufacturers to report ASP through the shelf life date of the last lot distributed of the discontinued NDC. In addition, we request that CMS identify how a manufacturer is supposed to report ASP information when the calculated ASP is a negative number. Since the next deadline for submitting information is at the end of October, we urge CMS to provide the needed guidance well in advance of that deadline.

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be reported for this new drug would be from the first quarter of 2005, which would be used to establish the payment rate for the third quarter of 2005.

³ 56 Fed. Reg. 35952, 35979 (Jul. 29, 1991).

question 16 that administrative fees should be included in the calculation of ASP if “they ultimately affect the price actually realized by the manufacturer.”⁴ We suggest that CMS clarify that its statement that administrative fees should be included if they affect the price actually realized by the manufacturer was not intended to include all administrative fees, and instead make clear that administrative fees for real services provided by the purchaser for the benefit of the manufacturer would not be included in the ASP calculation. We ask that CMS address this issue before the third quarter 2004 ASP information is due to CMS.

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We appreciate the recent guidance on a revised methodology to handle “lagged” price concessions, 69 Fed. Reg. 55763 (Sept. 16, 2004), and generally believe the revised methodology is an improvement over the prior methodology. However, we believe that there are some ambiguities in the revised methodology that need to be clarified prior to the next deadline for reporting ASP information. In particular, Novartis requests that CMS clarify whether the revised methodology applies to all price concessions or only those price concessions for which data are lagged. In addition, we request that CMS clarify how (if at all) the revised methodology applies to a price concession category (e.g., chargebacks), where some, but not all, of the data to be used in the ASP calculation are available on a lagged basis.

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III. Ensuring Access to Immunosuppressive Agents

After failing to provide for any pharmacy supplying fee for immunosuppressive drugs in 2004 despite a requirement to do so, *see* SSA § 1842(o)(6), Novartis was pleased to see that the agency has proposed such a fee for 2005. 69 Fed. Reg. at 47523. However, we are troubled by the proposed amount for this fee - \$10 per prescription.

⁴ The Q & As are available at http://www.cms.hhs.gov/providers/drugs/aspqa_web_042204.pdf.

While the agency reports that it was presented with a variety of information and suggested fees, CMS provides no explanation as to why it chose the lowest of any of the figures that it was provided. *See* 69 Fed. Reg. at 47523. Given the critical nature of these products to Medicare beneficiaries receiving them, it is imperative that beneficiaries have access to them. With the change in the methodology for determining payment rates for these products in 2005 and the possibility of reduced rates, ensuring a proper supplying fee is especially important. We encourage CMS to consider additional information provided regarding an appropriate supplying fee and to finalize a rate that will ensure that beneficiaries continue to have access to immunosuppressive drugs.

IV. Conclusion

For the reasons discussed above, Novartis urges CMS to be vigilant about ensuring beneficiary access to drugs as the new ASP payment mechanism is implemented. While monitoring access is important in this regard, CMS also should ensure that the determined payment rates are accurate by establishing a process that it will follow in each calendar quarter to provide the public with sufficient opportunity to review the rates and raise issues to CMS before the rates go into effect. Novartis also recommends that CMS adopt the AMA's suggested coding changes for drug administration services and fully implement these changes effective January 1, 2005. Finally, we urge the agency to establish an appropriate pharmacy supplying fee for immunosuppressive products in the final rule.

We thank CMS in advance for its serious consideration of these comments, as well of those submitted by PhRMA, as the new payment methodology for Part B drugs continues to take shape.

Sincerely,

Jim Elkin
Vice President
Federal Government Relations
Novartis Corporation
701 Pennsylvania Ave. NW, Suite 725
Washington, D.C. 20004
Phone 202 638 7429

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 10-19

SECTION 952

I would like CMS to clarify if the phrase "(with the exception of licensure)" can be read or interpreted to include chiropractors in the states where state laws and a chiropractor's license permits him/her to perform and practice physical therapy.

If in the states where a chiropractor is not permitted to practice physical therapy, the answer would be "No".

Based on the the following sentence, one can conclude that a chiropractor fits the same discriptions:

"Some States permit licensed physicians, physician assistants, clinical nurse specialists, and nurse practitioners to furnish PT, OT, [[Page 47551]] and SLP services also. "

[[Page 47537]]

Regulations in 42 CFR 485.705 specify that, We are proposing to amend the regulations to include the statutory requirement that only individuals meeting the existing qualification and training standards for therapists (with the exception of licensure) consistent with Sec. 484.4 qualify to provide therapy services incident to physicians' services.

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

We beg you to NOT pass this policy whereby a physician can only refer "incident to" services to physical therapists. All qualified health care providers should be allowed to provide services to patients with a physicians prescription or under their supervision.

Submitter : Mrs. Melissa Fahrney Date & Time: 09/25/2004 04:09:38

Organization : Mrs. Melissa Fahrney

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I've been informed that this proposed change will limit available therapy to allow physical therapists only to be able to bill medicare and have patients. If this is true, it is a sad statement. The importance of medical based massage therapy, performed by professional and licensed massage therapists, to the healing of so many individuals will be lost if ONLY physical therapists are allowed to function. Massage therapists provide not only physical healing but add a much needed dimension to medicare patients of spiritual and mental well-being. Please do not take this HIGHLY IMPORTANT service away from the people who need it most and can afford it the least. I'm not talking about "spa massages"...I'm talking about those techniques that are designed and used specifically for medical and mental health use (i.e., neuromuscular therapy, somatic massage, etc.) Research and physicians are now realizing the usefulness, practicality and professionalism of medical massage therapy. To take it away will also mean a decrease in those who are highly trained to work alongside physicians and healthcare professionals. MTs are getting specialized training to do this job and to limit their presence will also impact the profession as a whole. Please heed mine and others' petitions to stop the ridiculous notion that physical therapists should be the only ones to be able to help patients via this medicare system. Thank you kindly, Melissa

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

GENERAL

GENERAL

This proposed policy revision whereby a physician can only refer "incident to" services to physical therapists would be a disservice to all Americans who pay for health care insurance and all Americans needing the services of qualified health care providers.

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 10-19

SECTION 952

to further clarify the following:

"existing Medicare policy concerning which professionals may provide a given service."

If the above captioned refers to that a chiropractor may perform "incident to" PT under "existing Medicare policy" and such policy is not amended and is still "the exception of licensure" under section 952?

<http://frwebgate2.access.gpo.gov/cgi-bin/waisgate.cgi?WAISdocID=46319546935+23+0+0&WAISaction=retrieve>

"Physician means a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, or a chiropractor, as defined in section 1861(r) of the Act."

"As noted in the preamble to Phase I final rule (66 FR 926), some physical therapy services can be performed by physicians, and we defer in this rule to existing Medicare policy concerning which professionals may provide a given service."

<http://frwebgate2.access.gpo.gov/cgi-bin/waisgate.cgi?WAISdocID=46319546935+23+0+0&WAISaction=retrieve>

[Federal Register: March 26, 2004 (Volume 69, Number 59)]

[Rules and Regulations]

[Page 16053-16146]

From the Federal Register Online via GPO Access [wais.access.gpo.gov]

[DOCID:fr26mr04-27]

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

We beg you to NOT pass this policy whereby a physician can only refer "incident to" services to physical therapists. All qualified health care providers should be allowed to provide services to patients with a physicians prescription or under their supervision.

Thanks for your help!

Sincerely and best wishes in all of your endeavors to help others

Submitter : Mrs. Tracy Warner Date & Time: 09/24/2004 12:09:00

Organization : Iowa Hospital Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Comment letter from the Iowa Hospital Association attached.



Attachment #4138

September 24, 2004

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, S.W.
Room 445-G
Washington, DC 20201

Ref: CMS-1429-P – Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2005; Proposed Rule (69 *Federal Register* 47488), August 5, 2004.

Dear Dr. McClellan:

On behalf Iowa's 116 hospitals, the Iowa Hospital Association (IHA) appreciates the opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS) on the proposed revisions to the Medicare physician fee schedule for calendar year (CY) 2005. Approximately 60% of the family practice physicians in the state of Iowa are employed by hospitals so the importance of adequate Medicare reimbursement is as important to our members as it is to physicians. IHA's comments on this rule revolve around a key payment policy change that should apply to critical access hospitals (CAHs) in the same manner as physicians billing to the Medicare carrier in order to help improve beneficiary access to care in physician shortage areas.

Section 413. Physician Scarcity Areas (PSAs) and Health Professional Shortage Area (HPSA) Incentive Payments

Thirty seven of Iowa's fifty four CAHs have elected to be paid under an optional method for outpatient services, frequently referred to as "Method II," that allows the hospital to receive payment equal to 101 percent of cost for facility services plus 115 percent of the physician fee schedule for professional services rendered. Most of Iowa's CAHs that elected this option began the process of billing professional physician services on the UB-92 hospital claim form to the Medicare fiscal intermediary (FI) as of July 1, 2004. Section 413(a) of the Medicare Prescription Drug, Improvement and Modernization Act (MMA) provides a five percent bonus for professional services rendered in either primary care or specialty care PSAs. In providing this additional payment, Congress was attempting to incent physicians to serve Medicare beneficiaries in areas with a shortage of physicians, and to make it easier to recruit and retain physicians to these areas.

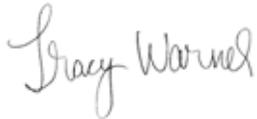
IHA is concerned that CMS has not addressed how PSAs will apply to CAHs that bill for physicians under method II. The proposed rule is unclear on whether or not CAHs that have elected Method II billing are eligible for these bonuses just as they are eligible for HPSA bonuses. IHA recommends CMS provide clear direction in the final rule that would allow a maximum payment that could be made to a CAH for both technical and professional services would be the 101 percent base rate for CAHs, plus 115 percent of the physician fee schedule amount for professional services under Method II bill, plus ten percent for the HPSA bonus, plus five percent for the PSA bonus.

Building a healthier Iowa for 75 years!

Further, IHA is concerned that the Medicare FI systems will be unable to process UB-92 claims that include physician services that are provided in areas that make them eligible for the enhanced PSA bonus, just as these systems struggled with processing claims for the HPSA bonus. IHA recommends CMS work diligently to ensure that its claims systems, and those of its intermediaries and carriers, are ready to process enhanced payments beginning January 1 to ensure a smooth implementation of this provision. In addition, IHA recommends CMS keep CAHs **and** the fiscal intermediaries informed of physician billing changes. **It should be a routine matter for CMS to consider how CAHs will be impacted by all policies and instructions the agency issues and IHA encourages CMS to specifically address this fact in all its communications.**

Thank you for your review and consideration of these comments. If you have any questions please contact me at 515/288-1955.

Sincerely,

A handwritten signature in cursive script that reads "Tracy Warner".

Tracy Warner
Vice President, Finance Policy

cc: Iowa Congressional Delegation

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

GENERAL

GENERAL

regarding:1429-p. As a massage therapist i beleive it would be detrimental to my clients not to be able to continue receiving assistance in payments for my services in relation to the chiropractor that i work with, Dr. Tom West. These clinets benefit greatly from my services and would not be able to receive treatments of this type from any other professional. ie. physical therapists.

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

GENERAL

GENERAL

Issues 20-29, THERAPY-INCIDENT TO

I demand you to NOT pass this policy whereby a physician can only refer "incident to" services to physical therapists. All qualified health care providers should be allowed to provide services to patients with a physicians prescription or under their supervision. All physical therapists are not created equal, nor are patients needing just their services.

Phil Bertrand, ABMP Certified member in good standing.

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

GENERAL

GENERAL

ASP estimates bear no resemblance to the prices we pay for chemotherapy drugs. There are a number of drugs that we buy that will cost more than we are reimbursed by Medicare.

ASP does not fully fund the cost of procuring chemotherapy drugs. There are storage costs, handling costs and acquisition costs.

After studying the impact of ASP+6% my figures show that Medical Specialists of Fairfield will lose approximately 17.5% of its revenue from Medicare. This is a far cry from the 2%-8% reduction the government says we will lose. This reduction will impact the medical group tremendously. Layoffs will occur as well as patients being sent to the hospital for treatment.

I do not dispute the fact that the system needs to be worked on but before we implement any drastic changes we must study the problem closer. Keep the payment schedule as it is, for 2005, and run the new system at the same time. If we rush into this change for 2005 I feel Cancer patients will be the ones who suffer.

Thank you .

Submitter : Mrs. Margaret Zappolo Date & Time: 09/24/2004 12:09:00

Organization : Danbury Office of Physician Services

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Please support Mr. Norwood's bill to preserve access to cancer care under the medicare program. The cuts scheduled for 2005 will make it impossible to provide cancer care on an outpatient basis. As both the Nurse manager for an outpatient cancer center and having had family members going under chemotherapy treatments, now and 20 years ago, I can personally attest to the strides that have been made in this arena. We all know the payment system was flawed, but remember, it was not the physicians who developed this system but the government. Overpayments in drug reimbursement allowed us to develop high quality care for these patients and many if not most services available to patients are NOT reimbursed by Medicare. Some example's of these services include dietary consults, social work services and nursing provided by highly qualified nurses who often have advanced degrees as giving chemotherapy is NOT like giving antibiotic. (Some medicines can actually eat away a persons skin if not given appropriately) MMA driven reductions WILL endanger patient access to community cancer care. The payment rates for drug administration services DO NOT reflect the actual costs of providing care in the community offices. Continuation of underpayments on the professional side coupled with errors in the perception of the magnitude of the underpayments on the drug side creates a situation of unsustainable losses for many community cancer care givers. I would be happy to discuss this at length with anyone who does not fully understand the devastating impact of this bill.

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

GENERAL

GENERAL

The Hailey Medical clinic has supported massage therapy as an adjunct to the physicians care for the past 5 years. The massage therapists on staff are a valuable asset to preventative care , education and pain management for the patients. Do not omit massage therapy from the provider list for medicare.

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

GENERAL

GENERAL

See attached document.

Attachment #4144

Community Oncology Alliance

DEDICATED TO EXCELLENCE IN CANCER CARE IN THE UNITED STATES

September 24, 2004

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1429-P
PO Box 8010
Baltimore, MD 21244-8012

Dear Dr. McClellan:

Pursuant to the instructions posted in the Federal Unique/Vol. 69, No. 150/Thursday, August 5, 2004/Proposed Rules, what follows are comments regarding CMS-1429-P, *Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005*. This letter is written on behalf of the Community Oncology Alliance (COA), which represents the interests of community cancer clinics across the United States.

I will come right to the point. The Medicare reimbursement changes scheduled for implementation on 1/1/05 will devastate cancer care in this country. Although the new reimbursement system may be ready for implementation, it has fundamental flaws and it will be untested and not properly analyzed. Unfortunately, this last fact is uncontestable. We are experimenting on and risking the health of the cancer care delivery system in this country.

Let me once again reiterate — as I know our representatives have done in personally meeting with you — that COA strongly supports balanced Medicare reform that addresses the appropriate payment for both cancer drugs and essential medical services required by Americans battling cancer. As such, COA supports the concept of balanced Medicare reform as contemplated by the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). There are many Members of Congress who have visited community cancer clinics in their districts/states over the past two years and who have come to understand and appreciate the realities of delivering quality cancer care in the outpatient, community setting. We especially appreciate the tireless efforts of many Members of Congress in ensuring that in 2004 community cancer clinics are still able to deliver quality, accessible cancer care to all Americans.

Unfortunately, Medicare reimbursement changes scheduled for 2005 will result in devastating, historic cuts in Medicare cancer care funding. CMS estimates that these cuts will amount to \$530 million, over an 8% decrease. Unfortunately, our analysis, based on real market pricing data, is that this estimate is unrealistically low. COA estimates that these cuts will amount to \$969 million, or a 17.8% decrease. Independent analyses performed by over 200 community oncology clinics estimated an average clinic reimbursement decrease of over 16%. Unfortunately, the real impact of these cuts will be in the range of 40-50% of a cancer clinic's working capital, which funds their operations.

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The overall problem with aspects of this rule, and the general approach to Medicare reform for payment of cancer care in 2005, is that we are rushing to implement a totally new, untested, and unproven reimbursement system that only exists now as a concept. Frankly, it is mind boggling that the government is risking the future of cancer care in this country on an untested system. It is simply reckless to be implementing this new system without the proper analyses.

The following facts relating to the calculation of Average Selling Price (ASP) — the new Medicare drug reimbursement system to be implemented on 1/1/05 — are especially disconcerting and underscore one of the fundamental problems with the conceptual ASP system: in no way will it be properly tested and analyzed by 1/1/05.

To date, CMS has been able to produce preliminary estimated reimbursement rates on about 7% of the drugs we use in cancer care. These estimates were based on 1st quarter ASP data submitted by pharmaceutical manufacturers. CMS is now not releasing any 2nd quarter ASP data. Instead, CMS is changing the ASP calculation methodology for ASP data submitted by pharmaceutical manufacturers for 3rd quarter.

Unfortunately, this 3rd quarter data will form the Medicare reimbursement rates for 1/1/05 when the new Medicare changes go into effect. There is no guarantee that CMS will get it right with this new methodology and that the reimbursement rates will be ready in time. Certainly, there will be no data or time to analyze this new methodology. We are especially concerned that the new methodology will allow for gaming of the reimbursement system.

As we have pointed out, the ASP-based drug reimbursement system has obvious flaws that have not been addressed. Although CMS has attempted to address in its most recent rule the problem of ASP/reimbursement variability, it has ignored the problem that there will be a 3-6 month time lag in updating the reimbursement rates. Drug price increases during this time period will not be reflected in the reimbursement rates even though cancer clinics will be paying more for drugs.

As you know, the transitional 32% increase in services reimbursement is scheduled to decrease to 3% in 2005 for no rational reason and with no modifications to any codes to date. Although we understand that this issue is being looked at, we have received no feedback even though we have produced a comprehensive report on this that took 18 experienced practice administrators 4 months to complete.

COA was created to bring the voice of community oncology to Washington, DC. We have educated many Members of Congress, both in our practices and in DC. This year alone, we have produced more data on community oncology operations than ever provided. We have committed to working with the Congress and the Administration in achieving balanced, equitable Medicare reform. Once more, and for the record, I would personally like to underscore that we in community oncology did not create this Medicare reimbursement system that some like to vilify us about — the government created it. It is offensive to every community oncologist, nurse, administrator, and staff person to be accused of taxing cancer patients.

These looming Medicare cancer care reimbursement cuts have also emboldened private insurers around the country to arbitrarily cut their reimbursement for cancer care.

The net impact of this is that we are heading to disaster. There will be patient access problems next year. I say this with confidence because the changes already being made are impacting cancer care in this country. This is not about crying wolf. It is all too real.

The only rational course of action is to make 2005 a transition year during which the current and new systems can be run in parallel, with a floor based on 2004 rates. During the year additional data from MedPAC, OIG, and the cancer community will be provided and CMS will have the time to properly analyze the new system. We pledge the support of community cancer care.

I do not envy the Herculean task CMS has of implementing the cancer care reimbursement changes, let alone the entire Medicare prescription drug bill. Although the Medicare reimbursement changes to cancer care may be ready for implementation by 1/1/05, what is uncontested a fact is that there will be little to no analyses regarding the ASP system.

Please understand that those of us on the front lines of treating people with cancer cannot sit by and let this experiment on cancer care take place. We would no more use an untested, untried drug on a patient to gauge its effectiveness than idly sit back and watch a new reimbursement system be implemented in order to gauge its impact on the cancer care delivery system.

I appreciate the concern you have expressed about the importance of this issue and your attention to it. We realize that CMS is simply changed with implementing the provisions of the Medicare bill. However, as a physician, you can appreciate our duty to protect our patients and not let reimbursement changes get in the way of caring for them.

Sincerely,

Kurt Tauer, MD
Practicing Medical Oncologist
President, Community Oncology Alliance

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

GENERAL

GENERAL

PhRMA comments regarding Medicare: Physician Fee Schedule (FY 2005), File Code: CMS-1429-P

Submitter : Date & Time:

Organization :

Category :

Issue Areas/Comments

GENERAL

GENERAL

PhRMA comments regarding Medicare: Physician Fee Schedule (FY 2005), File Code: CMS-1429-P

CMS-1429-P-4146-Attach-1.pdf



September 24, 2004

VIA MESSENGER

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Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
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Washington, D.C. 20201

File Code: CMS-1429-P

Dear Administrator McClellan:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to submit these comments in response to the proposed rule issued by the Centers for Medicare and Medicaid Services (CMS) on 2005 payments for Medicare Part B drugs and revisions to the physician fee schedule.¹ PhRMA is a voluntary, nonprofit organization representing the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow Medicare beneficiaries to lead longer, healthier, and more productive lives. PhRMA companies are leading the way in the search for cures.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("the MMA") includes several provisions that change the payment methodology for Part B drugs and other aspects of the physician fee schedule. Several of these provisions took effect as early as January 1, 2004. Since that time, CMS has continued to implement a number of wide-sweeping changes to the Medicare Part B program in relatively short time frames and we applaud CMS for its efforts. We also appreciate the opportunity to comment on the proposed rule. PhRMA believes that a broad range of information and perspectives will lead to successful implementation of the Medicare Part B reforms. Accordingly, we ask CMS to consider the principles and comments set forth below as it finalizes the proposed rule.

¹ Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005, proposed rule, 69 Fed. Reg. 47488 (August 5, 2004).

PhRMA Principles

1. **Patient access to care should be protected.** The new payment methodologies should maximize beneficiaries' access to innovative and clinically appropriate therapies in accessible settings.
2. **Providers' independent clinical decisions and choice of medicines must be preserved.** The new payment system should preserve the independence of providers' clinical decisions and minimize inappropriate payment barriers to choice of medicines. Moreover, CMS should not create financial incentives that encourage under- or over- utilization of services.
3. **Manufacturers should have adequate notice of reporting obligations and an opportunity to comment.** Manufacturers should be afforded meaningful notice, specific guidance, and the opportunity to comment on implementation of the new reporting obligations under the Act.
4. **Manufacturers' reporting obligations should be clear, transparent, and explicit.** The reporting requirements for pharmaceutical manufacturers should be easily understood, feasible, practicable, and not overly burdensome.
5. **Manufacturer-submitted sales, price, and commercial information should remain confidential.** Because of its proprietary and sensitive nature, CMS should recognize and maintain the confidentiality of sales, pricing, and other commercial information submitted to the Agency under the Medicare Part B program.

Our comments are set forth in detail below.

I. Beneficiary Access

PhRMA appreciates CMS' continued efforts to monitor potential access problems that could result from implementation of the Part B reforms that were mandated by the MMA. As you know, beneficiary access to clinically appropriate medicines and services is essential to Medicare patients. Accordingly, PhRMA reiterates its request that CMS develop a thorough and systematic plan to capture, evaluate, and respond to emerging access problems. It is essential that CMS solicit input and suggestions from beneficiaries, providers, and other stakeholders to maximize the effectiveness of its monitoring efforts and to minimize the potentially adverse effects on patient access. In the six months

following implementation of the initial Part B reforms, a number of providers have expressed concern that reductions in drug and drug administration reimbursements will adversely affect patient access. CMS has acknowledged these concerns and stated that it intends to monitor potential access problems.² However, CMS has not articulated specific details regarding how it will monitor and respond to these issues. Thus, we urge CMS to establish a systematic mechanism that allows beneficiaries, providers, and other parties to report potential access problems or concerns electronically or by telephone.³

II. Methodology for ASP-Based Payments and Reductions Triggered by OIG Findings

Timely clarification of several Average Sale Price (ASP) provisions is also needed. Under the MMA, reimbursement for a number of Part B drugs will be calculated using manufacturers' submitted ASP information. To date, CMS has issued two rules on ASP submission requirements.⁴ Both clarify some ongoing issues regarding the ASP-reporting requirement. Most recently, for example, CMS adopted several changes to address ongoing concerns about the methodology for estimating price concessions associated with the ASP-reporting requirements. PhRMA believes that these modifications will reduce volatility in the ASP-based payment rates; thus, we are pleased that CMS implemented them. Nevertheless, we remain concerned that CMS has not addressed many other critical questions about ASP. For example, CMS has not yet clarified which drugs and biologicals are subject to the ASP-reporting requirements or which sales are exempt from ASP-calculations. Nor has CMS specified whether a

² In the proposed rule, CMS states "not believe the payment changes for drugs . . . will result in access problems" but will "continue studying this issue," acknowledging "a concern among physicians and others that the large changes in Medicare's payments may affect their ability or willingness to continue making drugs and related services available." Elsewhere in the preamble, CMS noted that some physicians have concerns about their ability to purchase drugs at 106% of ASP.

³ Although the MMA requires MedPAC and the General Accounting Office (GAO) to submit several reports regarding patient access issues, many of the reports will not be completed or released until 2007. Given the potentially immediate effects of these reforms on patient access, it is essential that CMS adopt appropriate measures immediately to ensure that it has adequate information and the ability to respond quickly in the interim.

⁴ Medicare Program; Manufacturer Submission of Average Sales Price (ASP) Data for Medicare Part B Drugs and Biologicals, Interim Final Rule, 69 Fed. Reg. 17935 (April 6, 2004). PhRMA submitted comments to the interim final rule on June 7, 2004; Medicare Program: Manufacturer Submission of Manufacturer's Average Sales Price (ASP) Data for Medicare Part B Drugs and Biologicals, Final Rule (CMS-138-F, available at <http://www.cms.hhs.gov/providers/drugs/cms1380f.pdf>).

divesting manufacturer may transfer ASP-reporting responsibilities to an acquiring manufacturer before transfer of the NDC is complete. With the October 30th deadline for the second submission of ASP-reporting data fast approaching, it is critical that CMS issue further instruction regarding these issues as soon as possible.

Additionally, CMS should further describe how it will translate manufacturer-submitted ASPs into ASPs that correspond with HCPCS codes in order to set payment rates.⁵ In the proposed 2005 physician fee schedule rule, CMS describes its proposed methodology for using ASP data to develop ASP-based payment rates. As instructed, manufacturers are to report ASP by 11-digit NDC codes even though Medicare payments are based on HCPCS codes that often encompass multiple NDC codes. Thus, CMS must translate the manufacturer-submitted ASPs into ASPs that correspond to HCPCS codes in order to set payment rates.

Under the MMA, the payment methodology differs slightly for “single source” and “multiple source” drugs. The payment for multiple source drugs generally equals 106% of ASP, while the payment for single source drugs generally equals the lesser of 106% of ASP or 106% of wholesale acquisition cost. A multiple source drug is a drug for which there are two or more drug products marketed in the U.S. that are rated by FDA as therapeutically equivalent and pharmaceutically equivalent and bioequivalent; single source drugs that were included in the same HCPCS code as of October 1, 2003 are treated as multiple source drugs.⁶ A single source drug is a biological, or a drug marketed under an NDA that is not a multiple source drug (including a drug marketed by cross-licensed producers or distributors operating under the NDA).⁷

The ASP used for payment purposes (for both multiple source and single source drugs) is a volume-weighted figure calculated by CMS from the manufacturer-submitted ASPs. For multiple source drugs, “the [ASP] for all drug products included within the same [HCPCS] code is the weighted average of the manufacturers’ [ASPs] for those drug products”; this ASP is calculated by “[c]omputing the sum of the products (for each [NDC] assigned to the drug products) of the manufacturers’ [ASPs] and the total number of units sold,” and then “[d]ividing that sum by the sum of the total number of units sold for all NDCs assigned to the drug products.”⁸ For single source drugs, the ASP “is the volume-weighted average of the manufacturers’ [ASPs] for all [NDCs] assigned

⁵ Manufacturers’ ASPs will affect Medicare payments with a two-quarter lag (e.g., payment rates for the first quarter of 2005 will be based on manufacturers’ ASP submissions from the third quarter of 2004).

⁶ Social Security Act (SSA) § 1847A(c)(6)(C).

⁷ SSA § 1847A(c)(6)(D).

⁸ Proposed 42 CFR § 414.904(b).

to the drug or biological product”; this ASP is calculated by computing “[t]he sum of the products (for each [NDC] assigned to the drug product) of the manufacturer’s [ASP] and the total number of units sold,” and then “[d]ividing that sum by the sum of the total number of units sold for all NDCs assigned to the drug product.”⁹

CMS does not specifically discuss the “units” that will be used in its ASP-calculation procedure. Presumably this should be a measure that correlates with the units referenced in the HCPCS code descriptor (e.g., milligrams, milliliters, etc.). However, for ASP-reporting purposes CMS has instructed manufacturers that “number of units” means the number of that 11-digit NDC code sold during the quarter in U.S. non-exempt sales¹⁰; thus, the reported “number of units” does not take account of different NDC codes having different package sizes or strengths. PhRMA is concerned that this “unit” concept would not produce sensible results if carried over to the CMS ASP calculations.¹¹ Incorrectly calculated ASP-based payments could have an adverse effect on patient access and the Medicare Part B program. Consequently, CMS should clarify the description of ASP calculations.

Moreover, detailed instruction regarding how the OIG will calculate the Widely Available Market Price (WAMP) or conduct comparisons between WAMP, the Average Manufacturer Price (AMP), and ASP for Medicare Part B is needed. The MMA specifies that the otherwise-applicable ASP-based payment will be reduced if the HHS Office of Inspector General (OIG) finds that the ASP exceeds WAMP by a specified percentage (5% in 2005) or exceeds the Average Manufacturer Price (AMP) by 3%; this specification applies to both single source and multiple source drugs. In such an event, “the payment in the quarter following the transmittal of this information [by the OIG to CMS] is the lesser of the [WAMP] or 103 percent of the [AMP].”¹² The proposed rule does not discuss how the OIG will calculate WAMP¹³ or conduct these comparisons. For example,

⁹ Proposed 42 CFR § 414.904(c).

¹⁰ Similarly, proposed 42 CFR § 404.902 cross-references the definition of “unit” in 42 CFR part 414 subpart J, which defines unit as “the product represented by the 11-digit National Drug Code.” See 42 CFR § 414.802.

¹¹ For example, assume a drug has two NDCs, one corresponding to 1 mg tablets in a 10-tablet bottle and one corresponding to 1 mg tablets in a 100-tablet bottle. Assume that in a particular quarter the manufacturer sells 100 units of each NDC, the 10-tablet NDC has an ASP of \$10, and the 100-tablet NDC has an ASP of \$100. The numerator of the volume-weighted ASP used to calculate the payment rate would be \$10 x 100 + \$100 x 100, or \$11,000. If the denominator were the sum of the total manufacturer-reported “number of units” for each NDC (200, 100 for each NDC), the volume-weighted ASP would be \$55, even though the average per-milligram sales price for both NDCs was \$1.

¹² Proposed 42 CFR § 414.904(d)(3).

¹³ WAMP is defined in the MMA as “the price that a prudent physician or supplier would pay for the drug,” taking into account “the discounts, rebates, and other price concessions routinely made

it is not clear whether the OIG would conclude that the ASP exceeded the WAMP or the AMP by the relevant percentages if this only occurred in one quarter, or whether the OIG would use some type of volume-weighted ASPs, AMPs, and WAMPs in making these comparisons. Nor does the proposed rule explain how a drug could qualify for the normal payment rate again once its payment was reduced to the lesser of WAMP or 103% of AMP. Because these WAMP, AMP and ASP calculations and comparisons can affect payment rates and therefore beneficiary access, CMS should further define the circumstances that can lead to such reductions. Furthermore, CMS should specify how a drug can qualify for the normal payment rate once a reduction has occurred.

III. Payment Methodology for Separately Billable Drugs Furnished in Association with End Stage Renal Disease Services

PhRMA also strongly urges CMS to reconsider its proposal to pay for separately billable drugs used by dialysis facilities at 97% of ASP because it conflicts with the MMA and congressional intent. Moreover, it could threaten patient access to needed therapies, particularly for patients that receive care through independent dialysis facilities.

The MMA requires CMS to set 2005 payment rates for separately billed drugs at the acquisition cost for the particular drug, as determined by the OIG.¹⁴ Insofar as the OIG has not determined the acquisition cost for a particular drug, the Secretary may determine the appropriate payment. In May 2004, the OIG completed a study on the acquisition costs of ten drugs based on analysis of 2003 costs for the four largest dialysis chains and a sample of 122 independent

available to such prudent physicians or suppliers.” SSA § 1847A(d)(5). The term is not defined in the proposed rule.

¹⁴ Section 623(d)(1) amends §1881(b) of the Social Security Act (SSA) in part by adding new subsection 13(A). The new sections set forth the payments amounts for separately billed drugs and biologicals furnished in 2005 and 2006 as follows:

(ii) For such drugs and biologicals (including erythropoietin) furnished in 2005, the acquisition cost of the drug or biological, as determined by the Inspector General reports to the Secretary as required by section 623(c) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Insofar as the Inspector General has not determined the acquisition cost with respect to a drug or biological, the Secretary shall determine the payment amount for such drug or biological;

(iii) For such drugs and biologicals (including erythropoietin) furnished in 2006, such acquisition cost or the amount determined under section 1847A for the drug or biologicals, as the Secretary may specify.

(Emphasis added).

dialysis facilities.¹⁵ But instead of basing 2005 payment for dialysis drugs on acquisitions costs, CMS proposed to set the payment rate at 97% of ASP, reasoning that:

[T]he IG found that, on average, in 2003 the four largest chains had drug acquisition costs that were 6 percent lower than the ASP of 10 of the top drugs A sample of the remaining independent facilities had acquisition costs that were 4 percent above the ASP. Based on this information, the overall weighted average drug acquisition cost for renal dialysis facilities is 3 percent lower than the ASP. Therefore, payment for a drug . . . furnished during 2005 in connection with renal dialysis services and separately billed by renal dialysis facilities will be based on the ASP of the drug minus 3 percent.¹⁶

CMS' proposal, however, fails to comply with the statute. Given the methodology set forth by the statute, CMS should use a blend of the acquisition costs determined by the OIG for the four largest providers¹⁷ and for independent dialysis facilities for each product, adjusted for inflation and other legitimate acquisition costs, to establish payment rates in 2005 for OIG-studied drugs. Specifically, CMS could calculate a weighted average acquisition cost for each drug for the four largest providers and the independent dialysis facilities, then update that figure for 2005 using the 3.39 inflationary factor cited by CMS (compounded for 2004 and 2005). Moreover, CMS should make a separate adjustment to reflect additional acquisition costs that the OIG indicated it did not consider such as inventory costs, working capital costs, and spoilage/waste costs, along with such considerations as bad debt.

¹⁵ HHS Office of Inspector General, OEI-03-04-00120, Medicare Reimbursement for Existing End-Stage Renal Disease Drugs (May 2004). Figures cited in the OIG's report indicated that the four largest dialysis chains accounted for approximately 73% of Medicare's dialysis expenditures, and that Medicare reimburses about 1142 independent dialysis facilities. See id. at ii, 4.

¹⁶ 69 Fed. Reg. at 47,522. CMS apparently developed the 97 percent of ASP "overall weighted average drug acquisition cost" based on information in the OIG's report stating that (as of 2002) the four largest dialysis chains accounted for 73% of Medicare reimbursement. That is, the 97% of ASP figure can be derived by weighting the average acquisition cost of the four largest dialysis chains (94% of ASP) at 73% and weighting the average acquisition cost of the independent dialysis facilities sampled by the OIG (104% of ASP) at 27%.

¹⁷ Acquisition costs for the 4 largest dialysis providers are set forth in Table 1 of the OIG Report. HHS Office of Inspector General, OEI-03-04-00120, Medicare Reimbursement for Existing End-Stage Renal Disease Drugs (May 2004) at ii, 8. Acquisition costs for Independent dialysis facilities are set forth in Table 2 of the OIG Report. See id.

IV. Initial Preventive Physical Exam and Screening Tests

A. Initial Preventive Physical Exam, Diabetes Screening Test, and Mammography Services

PhRMA commends CMS for the proposed implementation plan for the MMA-mandated initial preventive physical examination and other screenings. Under section 611 of the MMA, subject to certain eligibility and other limitations, new Medicare beneficiaries will be eligible for an initial preventive physical exam on or after January 1, 2005. Under sections 613 and 614 of the MMA, coverage of diabetes screening test and improved payments for select mammography services also is provided. As CMS noted, it was the intent of Congress to offer a broad benefit that would provide “baseline information on the health status of [beneficiaries], allow early detection and treatment of disease states, and provide opportunity for the physician to refer beneficiaries to other Medicare covered services.”¹⁸ To optimize these benefits, CMS should include a broad array of services, including calculation of body mass index and ankle brachial index tests in the examination, and other useful diagnostic tests.

B. Cardiovascular Screening

The MMA provides for Part B coverage of cardiovascular screening blood tests.¹⁹ Specifically, the statute (1) requires that Medicare cover tests for cholesterol and other lipid or triglyceride levels, and (2) authorizes CMS to approve additional cardiovascular disease screening tests that have been recommended by the United States Preventive Services Task Force (USPSTF). In the Proposed Rule, CMS identifies three tests that will be covered initially under the cardiovascular screening benefit: (1) a total cholesterol test; (2) a cholesterol test for high density lipoproteins; and (3) a triglycerides test.²⁰ CMS states that other tests will be eligible for coverage if determined to be appropriate “through a National Coverage Determination (NCD).”

The Medicare system will be best served by providing for the broadest possible access to the cardiovascular screening benefit. This will maximize the potential for early detection and treatment of cardiovascular disease, and thus will produce improvements in beneficiary quality of life, as well as more appropriate care in Medicare. Accordingly, we recommend that CMS avoid placing undue restrictions on the scope of tests covered by this benefit.

¹⁸ CMS Press Release, Medicare Proposes Payment Rates and Policy Changes for Hospital Outpatient Services, Aug. 9, 2004, available at <http://www.cms.hhs.gov/media/press/release.asp?Counter=1155>

¹⁹ MMA § 612.

²⁰ 69 Fed. Reg. at 47,517.

Specifically, we recommend that, rather than initiating a coverage determination for each screening test, CMS should consider as presumptively covered every cardiovascular screening test that is recommended by USPSTF. This approach would avoid duplication of effort and unnecessary delays in providing access to appropriate screening tests by relying on the recognized expertise of the USPSTF in evaluating the appropriateness of cardiovascular screening methods.

V. Payments to Physicians for Drug Administration Services

The MMA directs CMS to establish appropriate coding and reimbursement for drug administration services. Accurate reporting and billing for drug administration that takes into account the complexity of the services and resource consumption is critical to ensure beneficiary access to needed drug therapies. As CMS notes in the proposed rule, a work group of the AMA's CPT Editorial Panel has reviewed all drug administration codes to determine whether revision or additional codes are needed.²¹ CMS should implement the Panel's recommendations effective January 1, 2005 to ensure continuity and improved patient access to needed medicines.

VI. Separate Payments For Clotting Factors

The MMA requires CMS to establish a separate payment beginning in 2005 for items and services associated with furnishing clotting factors to hemophilia patients.²² CMS has proposed to establish a separate payment of \$0.05 per unit for the items and services associated with furnishing clotting factors, based on a January 2003 GAO report estimating the costs of these items and services. A number of providers (including hemophilia treatment centers and specialty pharmacies) that supply clotting factors have expressed concern that a \$0.05 per unit payment, combined with cuts in clotting factor payments, would jeopardize their ability to supply clotting factor. Given these concerns, we urge CMS to evaluate whether a different rate is more appropriate based on the information the agency receives in response to its request for "updated data and comments on the GAO report [and] information on the fixed and variable costs of furnishing clotting factor."²³

²¹ Two of the specific issues under review are: (1) whether the current coding distinction between chemotherapy and nonchemotherapy infusions allows for recognition of the resources needed to administer non-cancer drugs with high toxicity or potential for serious side effects; and (2) whether the current coding for chemotherapy administration captures all the support services provided by oncology practices for chemotherapy patients.

²² The separate payment (combined with clotting factor payments) may not produce total payments exceeding the amount Medicare would have paid for the clotting factors alone under the pre-MMA (95% of AWP) payment methodology.

²³ 69 Fed. Reg. at 47,523.

VII. Supplying Fees for Immunosuppressive, Oral Anti-Cancer Drugs, and Oral Anti-Emetics

Under the MMA, CMS must pay an appropriate “supplying fee” to pharmacies that dispense certain oral drugs covered by Medicare Part B (*i.e.*, certain immunosuppressive drugs, oral anti-cancer drugs, and oral anti-emetics). CMS proposes to establish a separate supplying fee of \$10 per prescription effective in 2005.²⁴ We urge CMS to recognize the additional services that many pharmacies provide in dispensing these oral drugs, especially in rural areas, such as compliance monitoring, education regarding potential side effects, counseling, etc., so that an appropriate supply fee is paid that adequately compensates pharmacies for these overhead costs. As CMS noted, retail chain pharmacies have suggested a fee of \$12 - \$15 per prescription, while specialty pharmacies supplying mainly immunosuppressive drugs had suggested a fee of \$44 - \$56 per prescription.

Given the wide discrepancy between the proposed rate and provider reports, CMS should carefully consider additional information on the appropriateness of the proposed \$10 fee. This should include information concerning whether a higher fee is appropriate for immunosuppressives supplied during the initial month following a beneficiary’s organ transplant, due to extra resources associated with frequent changes in prescriptions during this initial period.

VIII. Dispensing Fees for DME Inhalation Drugs

CMS should thoroughly review updated information concerning the appropriate payment rate for Medicare Part B inhalation therapy such as nebulizers, maintenance and servicing of nebulizers, inhalation drugs administered through nebulizers, dispensing fees, and beneficiary training on use of nebulizers and certain other equipment. DME inhalation drugs will be paid under the 106% of ASP methodology in 2005, which will result in large payment reductions for a number of high-volume inhalation drugs.²⁵

Recognizing concerns about the effect of the reduced DME inhalation drug payments on beneficiary access, CMS proposed to continue paying a dispensing fee for these drugs in 2005, but it did not propose a specific amount for the dispensing fee. As with the “supplying fee” for oral drugs, CMS requested

²⁴ 69 Fed. Reg. at 47,523.

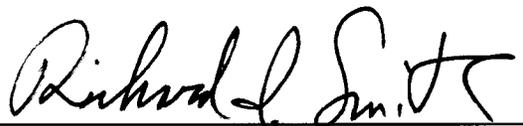
²⁵ CMS noted that the estimated payments listed in the proposed rule are not necessarily the actual payment amounts for the first quarter of 2005; actual payments for the first quarter of 2005 will be based on the ASPs submitted by manufacturers for the third quarter of 2004.

information on "the additional services these pharmacies [supplying inhalation drugs] provide to Medicare beneficiaries, the extent to which inhalation drugs can be furnished without these additional services and the extent to which such services are covered under Medicare."²⁶ To minimize disruption to patient access, PhRMA strongly urges CMS to consider establishing dispensing fees that include an appropriate transitional payment, given the significant payment reductions scheduled to begin in 2005.

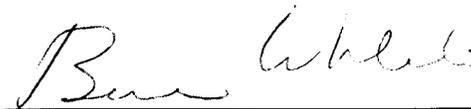
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PhRMA hopes that these comments are useful. We look forward to working with CMS and trust that the Agency will not hesitate to contact us with questions, comments, or requests for additional information.

Sincerely,



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



Bruce N. Kuhlik
Senior Vice President and General
Counsel

²⁶ 69 Fed. Reg. 47,549.