501 - 7,2005 SEP 22 2005 mer Bertie Bourdam I myself sue

JAMES B.WHITNEY P.O. BOX 2414 SANTA ROSA, CA 95405

707 538 4157

9-19-2005

GPCIs

Centers for Medicare & Medicaid Servives Department of Health & Human Services Attention CMS-1502-P P.O. Box 8017 Baltimore, MD 21244-8017

Please increase allowance for Sonoma County California inasmuch as we do have a serious problem here byecause the Doctors do not receive enough money to provide services and therefore go elsewhere or have to decline Medicare recervices.

This is serious!!

James B.. Whitney 273 07 3891 (d/b 11-6-16)

4755 Granada Drive Santa Rosa, CA 95409 September 18, 2005

GPCIs

Centers for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1502-P PO Box 8017 Baltimore MD 212244-8017

For many years, we have felt that the compensation by paid to physicians by Medicare in Sonoma County, California, was grossly unfair. As a consequence, many will not accept Medicare patients, placing an added burden on those who do accept them, and straining the availability of medical care to elderly patients.

The cost of living and the cost of medical care here is no lower than it is in San Francisco and other cities of the Greater Bay Area.

Therefore, we support an increase in the reimbursement rate paid to our physicians, and urge Medicare to provide fair compensation to them.

Thank you.

Robert Overcashier Robert Overcashier Jeanne Overcashier

Jeanne Overcashier

6286 Old Redwood Aug Santa Rosa Ca 95403

Department of Health & Human Service

9/12/2005

attn: CM5-1052P

Sis:

The current Medicor reimburgement standards has
caused severe hardship for my swife and me. as
residents of London county we experienced trouble tree
obtaining medical care because the better physician would
not accept medical patients. There than once a Dr.
would move to another location after looking out for
us - both of us in our seventies. Our age has not
been kind either - we need help with the standards,

Thank You. Jerry Long Sr. James L. Saunders 2022 Turnberry Court Santa Rosa, CA 95403

G.P.C.I. 1/13/00 Jonema Centy's sudail Dernie is excellent! Our dector should not be seralzed financially. Ofhan let Medari to a care the reinfurement sate for our centry by 8% in being with sumanding Cantin rotes.

Jet ---

September 9, 2005

GPCIs
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1052-P
B O Box 8017
Baltimore MD 21244-8017

Sonoma County, California has changed from a rural county to an urban county and I ask that you change the designation of Sonoma County, California to show this heavy population density so that the physicians in Sonoma County can afford to treat we seniors.

60% of the physicians in Sonoma County no longer take new medicare patients.

andrey Eg. Efekenick 479 REASANTHIN AVE N SEBASTOPOL CA. 95472

Sept 15, 2005 Gentlemen We need to correct reinfuscent nto local Doctors and medical groups in Sonoma County. to augt which are reposed to them for medicare patients some leave. Santa Rosa medical costs have sisen faster than in other area. We are 6th in the US for the Account percentage of people 85 or older and growing fast. I want to support Medicaris proposal to increase the reimbursemente rate In So Latte Mesong De 2372 Valley W. De Santa Losa, Ca 95401

To whom it may concern:

Priese accept medicare's proposal to change banta cruz county from a rural to an whan designation for medicare payments to our physicians. This proposal would help keep physicians treating medicare patients in Banta cruz county where the need is abundant.

. ...- .

Banta Cruz, CA 95065

September 12, 2005

GPCIs

Center for Medicare and Medicaid Services Department of Health and Human Services Attention: CMS-1502-P P.O. Box 8017 Baltimore, MD 21244-8017

Dear People,

Santa Cruz County is currently designated as "rural" for payment by Medicare. This designation means that Medicare payments to physicians are 25 percent less in this county compared to our neighboring county, Santa Clara. This disparity in payment coupled with the rising cost of living in Santa Cruz County has caused some physicians to leave the area or, in some cases, to refuse to accept Medicare patients.

Please accept the proposal put forward by Medicare to change the status of Sonoma and Santa Cruz Counties to join the eight other counties in the San Francisco Bay area in an urban designation. The population of Santa Cruz County continues to grow, and we certainly do not meet anyone's definition of "rural". This county contains several large urban cities and towns, and is also one of the most expensive places to live in the State, if not the Country. Most of our citizens work in occupations that are considered urban occupations, or travel to our neighboring high technology areas, such as "Silicon Valley" in Santa Clara, to work.

It is critically important to gain this designation of "urban", both to insure access to medical care for seniors and to insure the ability of our seniors to pay for such care. Your support is sincerely appreciated.

Sincerely,

Larry M. Ernst

Santa Cruz City Resident since 1973

275 Hospital Drive Ukiah, CA 95482

707-462-3111 Fax: 707-463-7384

www.uvmc.org

Ukiah Valley Medical Center

dventist Health

September 13, 2005

Centers for Medicare and Medicaid Services Department of Health and Human Services Attention: CMS-1502-P PO Box 8017 Baltimore, MD 21244-8017

Regarding: GPCIs

Dear Ladies and Gentlemen:

The hospital I am privileged to serve is located in Mendocino County adjacent and immediately north of Sonoma County in California. It is my understanding, accompanied by a well-publicized advertising campaign (including daily full page newspaper ads) and lobbying efforts by the Sonoma County Medical Association, that Medicare has proposed a new rule increasing reimbursement by 8%. While I believe, based on costs to do business in our region, this is well deserved; Mendocino County physicians would forego a 0.4% increase to enable this change. This constitutes a huge economic differential between competing counties.

Ukiah Valley Medical Center is a 78-bed full service hospital providing regional care in a county with 90,000 residents, located 60 miles north of Santa Rosa in Sonoma County. UVMC is the largest private employer in Mendocino County with over 500 employees. In the past year our medical staff has been reduced by 10% of its full time equivalent physicians, and is projected to have a 37% (20 physicians) deficit based on public need by 2007! Costs of living and doing business here are every bit as expensive as Sonoma County and it is exceptionally difficult to recruit physicians and staff to our rural area.

We currently have a deficit of physicians in nearly every specialty on our medical staff, especially primary care. Please analyze our position and move forward with the utmost care to avoid a situation that would certainly evolve into patients inability to access care locally.

I invite someone to call me at 707.463.7360 to discuss this and for further clarification. This action, if passed, will create a disproportionate financial discrepancy that will be practically impossible to overcome and will threaten our existence and the economy of our region. I do not begrudge Sonoma County physicians in advocating for an increase and would support a regional leveling of reimbursement based on actual costs of living and urge CMS to consider this issue most carefully.

Sincerely,

Mark E. LaRose President/CEO

Il Ellow

Cc: Mike Thompson, United States Congressman, First District of California Everett Gooch, Vice President, Governmental Affairs Brian Hanson, M.D., Chief of Staff, Ukiah Valley Medical Center Jarrod McNaughton, Director of Marketing/Development

September 15, 2005

GPCIs Centers for Medicare & Medicaid Services Department of Health and Human Services P.O. Box 8017 Baltimore, MD 21244-8017

Attention: CMS-1052-P

Dear Sir/Ms:

As a senior, registered voter since 1944, and longtime resident of Santa Rosa, I support Medicare's proposed new rule to increase the reimbursement rate for Sonoma County by 8%.

Although I'm a member of Kaiser Permanente and have access to physicians and medical care at an affordable cost, I know that many patients here in Santa Rosa, particularly those without insurance or on Medicare, are having problems in obtaining health care.

I urge you to change the Federal Guidelines to institute a new policy for reimbursement here in Sonoma County.

Respectfully,

Ms. Phyllis A. Terry

1050 3rd Street, #107W

Santa Rosa, CA 95404

September 14, 2005

Re: Increase of 8% in reimbursement rate for Sonoma County physicians

To Whom It May Concern:

Increase the rate! Physicians deserve adequate payment for services rendered!

In the Living Longer, Living Well report, the Sonoma County Area Agency on Aging states that there are 134,975 older adults who are 60+ years of age residing in this county. Since six of ten primary care physicians in this county will no longer accept new Medicare patients because of Medicare's very poor reimbursement policy, this leaves a large portion of Sonoma County elderly struggling to procure medical care.

If Medicare doe not approve a rate increase, even more physicians will leave Sonoma County at a time when its population is aging, The high cost of housing in this county prevents young people from settling here.

Thank you,

Betty Anne Dericco

11721 Old Redwood Highway

Healdsburg, CA 95448-9504

organis ---

September 16, 2005

Centers for Medicare and Medicaid Services Department of Health and Human Services Attention: CMS-1502-P P. O. Box 8017 Baltimore, MD 21244-8017

Re: GPCIs

To Whom It May Concern:

As a resident of Sonoma County, California, and a soon-to-be recipient of Medicare benefits, I strongly support your proposal to create a new payment locality for Sonoma County. I have already experienced cuts in payments from my current insurance carrier, Blue Shield of California, such that my primary care practitioner has declined to participate in the Blue Shield program, and now I understand that 60% of the primary care physicians in my county of Sonoma are no longer accepting Medicare patients due to the low reimbursement rates. Some physicians are retiring early and others are leaving the county due to the low reimbursements, often insufficient to even cover their overhead.

Please create a new payment locality for Sonoma County in keeping with the cost of living that we experience here. Please promote an environment for physicians where we, as citizens of the community, can have access to fine and broad medical services.

Thank you for your attention to this request.

Karen L. Panting 3949 Wallace Road

Santa Rosa, CA 95404

Karen Thanting

707-539-5749



September 15, 2005

Center for Medicare and Medicaid Services Department of Health and Human Services Attention CMS-1502-P PO box 8017 Baltimore, MD 21244-8017

Re: GPCIs

To Whom It May Concern,

MPMG is a large medical group in San Mateo County (locally 06). We are very familiar with the challenges of operating medical practices in the very expensive environment of the San Francisco Bay Area. We strongly support the proposed revision to the physician payment localities in California that you have proposed and published in the reference rule.

You are to be commended for addressing an important issue for physicians and their Medicare beneficiaries in the San Francisco Bay Area. In addressing the two most problematic counties in the state, you have made an important change that will go a long way to ensuring access to care for health care services in our county.

We understand this also to be a fundamental issue of fairness. Our neighboring counties, Santa Cruz and Sonoma have some of the highest payment levels for physician services in the nation. The adjustment that you propose appropriately addresses the current inequitable payment problem.

CMS acknowledges that they have the responsibility to manage physician payment localities. We understand that there have not been revisions to the localities since 1996. You have selected the most important area in our state to begin to correct this problem.

Sincerely,

Brian C. Roach, MD President and CEO

MPMG

577 AIRPORT BLVD., SUITE 300 BURLINGAME, CA 9 4 0 1 0 650/240-8000 FAX 650/240-0900

OEC CO

GPCIs
Centers for Medicare and Medicaid Services
Dept. of Health and Human Services
Attention: CMS-1502-P
P.O. Box 8017
Buttimore MD 21244-8 017

September 16, 2005

I live in Sonoma County and urge you to raise the Medicare reimbursement here.

It's unconscionable that we have among the lowest reimbursement rates in a county where the median home price is more than \$650,000.

I have been reading local newspapers fore twenty years, and have followed this problem as it's developed. I am a public school principal distressed by the impact of this problem, of doctors who cannot afford to accept Medicare patients. A reduced number of doctors in our area can afford to serve our community. All our citizens suffer.

Please raise the Medicare reimbursement in Sonoma County.

Sincerely,

Bethany Wilson

681 Fifth Street East Sonoma, CA 95476



Santa Cruz Women's Health Center, 250 Locust St. Santa Cruz, California 95060 T. 831.427.3500

16 September 2005

Centers for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1502-P P. O. Box 8017 Baltimore, MD 21244-8017

Re. File Code CMS-1502-P

Issue Identifier: GPCI's / Payment Localities

Dear Sirs:

I am writing on behalf of the Santa Cruz Women's Health Center to strongly support your proposed revision to physician payment localities in California recently published in the Federal Register. The Santa Cruz Women's Health Center is a Community Clinic that is one of the Safety Net providers for the un- and under-insured in Santa Cruz County. Because we provide subsidized care to the uninsured poor, our survival depends on adequate reimbursement from those patients who do have health care coverage, including our Medicare patients. We, like others, are also concerned about the viability of the entire health care system which serves our residents. The great difference between the cost of medical practice in Santa Cruz County as measured by GAF cost values and the low rate of reimbursement due to being assigned to Locality 99 has made recruitment and retention of physicians willing to serve Medicare beneficiaries very difficult.

We were pleased to see that your proposed rule would alleviate this problem by removing Santa Cruz and Sonoma Counties from Locality 99 and placing them into unique localities. We laud your efforts to rectify this long-standing inequity. Your proposal will of great help in ensuring access to necessary health care services. The proposed rule is fair. Neighboring counties to Santa Cruz and Sonoma have some of the highest payment levels for physicians in the nation. The adjustment you propose appropriately addresses this payment imbalance. This revision would bring you closer to your goal of reimbursing physicians based on the cost of practice in their locality.

Sincerely,

Kate Hartzell

Kate Hortzell

Chair, Santa Cruz Women's Health Center Board of Directors

GPCI

August 25, 2005

To whom it may concern;

I am writing to urge the change in designation of Santa Cruz County in terms of Medicare reimbursements to, at least, 55 percent. In 1960 Santa Cruz County was considered a rural area but that has changed drastically. Now, though there are some farm producing areas, most of the County is an urban area with manufacturing, national chains, computer industries, etc. as well as small businesses, a community college and a state university, It has become difficult for the average wage earner to live in this County. Home prices have skyrocketed - a 450 square foot home sells for \$500,00 - gas prices are higher than Santa Clara County, as are groceries and household goods.

Doctors have been forced to move out of the area, some will not take patients from some health plans because the reimbursements are too low. Doctors spend many years getting a degree and often have large loans to repay. It is unfair to expect them to live in a 2005 economic area based on 1960 reimbursement scale.

Please make it possible for the citizens of this County to have decent medical coverage. The present reimbursement table is outdated and should be changed. Our lives depend on getting good medical care.

Sincerely,

Barbara J. Symons 225 Mount Hermon Road, Sp 162 Scotts Valley, CA 95066

Teptember 17,2005

Sept. of Medicare + Medicard Ser Dept. of Heath + Herman Ser. Otton.: CMS-1502P F.O. Doy 8017 Daltimore, MD 21244-8017

I am writing in response to Lonoma County that doctors openedical groups receive the propers amount of reimbursement for their services. I am a Senior, have a good Inedical insurance for my physical needs except prescriptions. I desparately need help for them, my income is limited, I may not afford them in time. Please help all of us here in Sonoma County, it will be a great help to stabilize our mediable community.

Thank you for your understanding and

Yours truly of Setty M. Frietan (Elizabeth) 320 | Circulo Japan Rohnert Jack, CA 94928-1927



QUALITY HEALTHCARE CLOSE TO HOME!

HEALTHCARE FOUNDATION 2005 BOARD OF DIRECTORS

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Karen Wallace, Director of Events Lindsay Smith, Admin Assistant

The Healthcare Foundation is a 501 (c) (3) non-profit organization dedicated to raising funds for capital projects in support of healthcare in Northern Sonoma County including funds necessary to the development, implementation and protection of such projects.

Centers for Medicare & Medical Services Dept. of Health & Human Services Attn: CMS-1052-D PO Box 8017 Baltimore, MD 21244-8017

RE: GPCIs Sonoma County, CA

Gentlemen:

The Foundation's mission is stated below. The area we serve has a population of about 60,000. This is more than 10% of Sonoma County. Our population is older than the average of the county. The Foundation has collected funds from over 3,000 households and raised over \$3,000,000. The members of the Foundation, as private citizens, have twice gone to the public to successfully encourage property tax (21,000 parcel) levies to support the community hospital.

The area we serve is short six doctors. We are aware that of the 27 in the area at least 5 doctors will retire in the next few years. We need more doctors to serve our population who will in turn utilize our hospital.

The proposed increase will provide a reasonable reimbursement rate to attract new doctors and provide reasonable compensation for our existing professional staff. This will help us maintain our community hospital and the two non profit health clinics in our агеа.

The positive change is crucial to the healthcare in Sonoma County.

Respectfully,

President

September 14, 2005

Dept of Health & Human Services Attention: CMS-1502-P PO Box 8017 Baltimore, Md. 21244-8017

Re: Increase of Medicare Payments to Sonoma, County, California

Dear Sirs:

Sonoma County doctors have received inadequate Medicare payments for the last 10 years because we have been classified as a "rural" county. Several medical groups here have gone bankrupt, and doctors have even left the county because of low reimbursement. Doctors who remain are reluctant to accept new elderly patients: six out of 10 physicians do not.

Among cities with a population of more than 100,000 Santa Rosa (county seat) ranks 6th in the nation of people 85 years and older. Seniors represent the most rapidly growing segment of the population in the county. Those on Medicare or without insurance have difficulty getting the health care they need.

I urge passage of the proposal that will increase the reimbursement to Sonoma County by 8%. This is urgent to help our seniors. I myself am a senior, thankfully covered by insurance and in good health. I volunteer at Hospice, at church, and support local needy causes. I know first hand the needs of seniors, and increasing the rate for Sonoma County is the right thing to do.

Thank you for your attention and your assistance.

Sincerely,

Jeanine Hillman 501 Firelight Drive

Santa Rosa, Ca. 95403

parine Helins



Klamath Orthopedic Clinic

September 9, 2699 Bryant Williams Drive #1 • Klamath Falls, Oregon 97601 (541) 884-7746 • (541) 884-3677 • (800) 515-1655

www.klamathbones.com

SEP 22 1835

Michael J. Casey, M.D., P.C. Board Certified American Board Orthopaedic Surgery Member American Society for Surgery of the Hand

Karl C. Wenner, M.D., P.C. Board Certified American Board Orthopaedic Surgery North American Spine Society

Miguel Schmitz, M.D., P.C. Board Certified American Board Orthopaedic Surgery Fellowship Sports Medicine & Arthroscopy Member American Orthopaedic Society for Sports Medicine Arthroscopy Association of North America

Kevin T. Heaton, D.O., P.C. Board Certified American Osteopathic Board of Orthopedic Surpeons Fellowship Total Joint Replacement

Edward L. VanTassel, p.o. Board Certified American Osteopathic Board of Orthopedic Surgeons American Osteopathic Academy of Orthopaedics

Jeannette Gansberg Executive Director

Specializing in:
Shoulder
Elbow
Hand
Spine
Total Joint Replacement
Arthritis
Musculoskeletal Trauma
Knee
Foot & Ankle
Sports Medicine
Arthroscopy

Centers for Medicare and Medicaid Services Department of Health and Human Services ATTN: CMS - 1502-P P. O. Box 8017 Baltimore, Maryland 21244-8014

To Whom It May Concern:

This letter is in regards to the recent proposed healthcare cuts for 2006 physician fee schedule. As a practicing orthopedic in rural south-centeral Oregon, this would be quite devastating to not only my practice, but those of my colleagues. Our clinic has made a policy not to limit Medicare patients for over 30 years now, however, with the proposed cuts, it may be necessary to limit our availability to the Medicare population simply for the financial burden that this poses. Our practice currently constitutes nearly 35% Medicare and with ongoing cuts, would be quite difficult to maintain this level of patient care without appropriate reimbursement.

I find it quite concerning that the solution to healthcare costs seems to be cutting reimbursements to the physicians who are providing medical care to Medicare as well as the other population within their respective communities, yet, causes such has malpractice and tort reform continue to rise without any relief in sight.

Particular cuts such as the "Q codes" limiting casting and splinting materials are particularly onerous to an orthopedic practice, which has very high utilization of these products simply due to the nature of our profession. The decrease in reimbursement and joint arthroplasty is also very concerning. This is one of the most difficult procedures that requires a long-term follow up, yet the reimbursement continues to follow. With the aging population, this will become much more necessary for quality of life, which will ultimately lower overall health care costs, simply because people remain more active and healthy, rather than becoming quite sedentary due to extreme joint discomfort.

I do believe that control of health care costs is becoming much more important, however, I do not believe that continued cuts to physicians' health care facilities for reimbursement is the answer. I think other avenues should be entertained such has malpractice and tort reform, controlling equipment and medication costs, as well as controlling the costs of legislation, which ultimately make such recommendations.

In summary, if reimbursements to the medical population continue to increase, myself and my colleagues will be forced to limit the number of Medicare patients that we can treat and ultimately

healthcare costs will rise simply because the only healthcare available will be through the emergency department or other similar facilities. I think controlling healthcare costs is quite important, however, I do not believe the proposed cut backs are the solution.

Sincerely

Kevin Heaton

KH:kd

GPCIs Centers For Medicare & Medicaid Services Attention CMS-1502-P P O Box 8017 Baltimore, Md 21244-8017

Gentlemen:

I strongly support the proposed new rule that is under consideration to increase reimbursement rates for Sonoma County for medical care under Medicare.

I am a medicare recipient who moved to Sonoma County three years ago to be near family. I soon discovered many doctors here do not accept Medicare patients. They tell us they lose money treating these patients.

I am afraid if this funding is not changed, soon there will be no medical care available for us.

Thank you for your support.

Sincerely,

Estes S. yinger Sept 14, 2005

Estes L. Yinger 6467 Meadowridge Drive Santa Rosa, Ca 95409 August 10, 2005

Centers for Medicare & Medicaid Services Department of Health and Human Services ATTN: CMS-1502-P P.O. Box 8017 Baltimore, MD 21244-8017

Dear Colleagues,

It has come to my attention that Medicare is considering changing the teaching physician policy for anesthesiologists. As a member of the American Association of Nurse Anesthetists (AANA), I have significant concerns with any changes that would create further inequities in how the Medicare system treats teaching Certified Registered Nurse Anesthetists (CRNAs) and anesthesiologists, and, more importantly, present possible negative impacts on Medicare beneficiaries' access to safe anesthesia care.

CMS has already twice rejected a proposal to change the anesthesia teaching rules so that teaching anesthesiologists would be paid a full fee for each of two overlapping cases involving medical residents, a manner similar to certain teaching surgeons. Such a proposal provides major new incentives to teach anesthesiology residents, and severe disincentives to teach nurse anesthetists, and is not based on a consensus process that treats both nurse anesthetists and anesthesiologists equally.

I appreciate that Medicare is considering its options on this important policy issue. Nurse anesthesia is a success story. With anesthesia 50 times safer than 20 years ago, CRNAs' patient safety record is shown to be indistinguishable from that of physicians providing anesthesia. CRNAs assure patients access to safe anesthesia care, and predominate in rural and medically underserved America and the Armed Forces. Further, it has been shown CRNAs are educated more cost-effectively than are our colleagues and competitors. Yet, while Medicare Direct GME payments to residents and medical direction payment rules already discriminate against educating CRNAs, the nurse anesthesia profession has been successful at increasing the number of accredited educational programs and graduates to meet growing demand for safe anesthesia care for patients. Thus, changing the anesthesia teaching rules to further dramatically favor one type of anesthesia provider over another creates negative impacts against educating safe anesthesia providers such as CRNAs, harming the healthcare system and patients' access to healthcare services.

So that patients anywhere in the country will continue to have access to the safe anesthesia care that they need, I am requesting that CMS work with both nurse anesthetists and anesthesiologists in developing a consensus proposal to address issues in the anesthesia teaching rules.

Sincerely.

Print name: Jana than R Punn
Street address: 12 17 S. Hawthorne Rd

City/State/Zip: Wiks/m-Sabern NC 27103



TEP 22 7

UNIVERSITY OF MARYLAND SCHOOL OF MEDICINE

August 29, 2005

Centers for Medicare and Medicaid Services Department of Health and Human Services

RE: CMS – 1502 –P TEACHING ANESTHESIOLOGISTS

The current Medicare teaching anesthesiologist payment rule is unfair, unwise and unsustainable. A surgeon may supervise residents in two overlapping operations and collect 100% of the Medicare fees allowed for each case. An internist may supervise residents in four overlapping outpatient visits and collect 100% of the Medicare fees allowed for each patient. However, a teaching anesthesiologist will only collect 50% of the Medicare allowed if he/she supervises residents on two overlapping cases. This is not fair and is not reasonable. Teaching anesthesiologists should be paid on par with their surgical colleagues.

We currently have 32 residents, 3 pain fellows on staff. Four faculty openings exist at the University of Maryland Anesthesiology program. It is difficult for us to retain and recruit faculty due to budget shortfalls and non-competitive salaries which can be directly attributed to the Medicare teaching anesthesiology reimbursement methodology. Our hospital partners subsidize the anesthesiology program with payments of \$6.5 million annually and they cannot sustain this level of support into the future.

Roughly 25% of our current patients are Medicare patients and the increasing elderly population will reduce our ability to be viable unless the arbitrary Medicare reduction is remedied. These reductions do not allow us to cover our costs (currently we lose roughly \$500,000 annually due to this reimbursement methodology) and may lead to reduction in our training programs and our ability to care for Medicare patients.

Sincerely

Douglas G. Martz, Jr., M.I

Acting Chair

University of Maryland Department of Anesthesiology

Sept. 16, 2005 Medicare

Dear Medicare Administrators,

When I moved to Sonoma County over 35 years ago, it was a quiet, slow paced place to live. Since that time however, our county has become highly populated with all the accompanying problems or urban life. While we may have a strong agricultural industry here, we are definitely not a rural community. The cost of living here is now exorbitant with the average house selling for around \$550,000. It is this factor that makes it so hard to live here and is the main reason why we now have difficulty attracting and keeping doctors to our communities. Sonoma County used to have a flourishing medical community but that is no longer the case.

Please re-designate Sonoma County on your Medicare Reimbursements scale. The average doctor, particularly young ones, simply cannot afford to live here and accept Medicare patients. I have just turned 65 and believe me, this is a vital issue for me and most of my friends. Seniors now make up over 16% of our population but that is projected to grow by over 196% by the year 2020.

It is becoming difficult for all of us to live here now but changing your reimbursements for Medicare will make a huge difference in all our lives.

Sincerely,

Sindaward

Linda Ward

149 Sherwood Dr.

Santa Rosa, Ca. 95405

Center for medicar + medicaid Services Dept of Health Human Services

Several medical groups in Sonoma County have gone bankrupt on shut down because of low reimbursements from Medicare.

In July 2015, six out of ten bonome County Primary Care physicians were not accepting medicare patients (nus) and many physicians are leaving bonome Co. to practice where reimburamente are more favoreble. This is not fair to benin litizens on medicare. This leaves many seniors having trouble accessing health cure.

medican per proposed a new rule that would increase the reimbursement rate for foroma lo. by 8 %. This will bring our locally back in line with current medical standards. This will help stabilize our medical community. Please supposed the proposed new rule. and help

Our senior ascers hearthe care

June a Smith Petalumu, Ca 94954 Office of the Chairman Department of Anesthesia

Memorandum

To:

Centers for Medicare and Medicaid Services

CC:

From:

Christine Hunter, M.D.

Chairman, Department of Anesthesia

Robert Wood Johnson Medical School

Date:

September 19, 2005

Re:

TEACHING ANESTHESIOLOGISTS - CMS-1502-P

The proposed rule does not include a correction to the policy of paying teaching anesthesiologists only 50% of the fee for each of two concurrent resident cases. A surgeon may supervise residents in two overlapping operations and collect 100% of the fee for each case. An internist may supervise residents in four overlapping outpatient visits and collect 100% of the fee. But a teaching anesthesiologist will only collect 50% of the Medicare fee if he or she supervises residents in two overlapping cases. This is not fair and it is not reasonable.

Quality medical care, patient safety and an increasingly elderly Medicare population demand that there be a stable and growing pool of physicians trained in anesthesiology. Right now, slots in anesthesiology residency programs are going unfilled because of ill-conceived Medicare policy that shortchanges teaching programs, withholding 50% of their funds for concurrent cases.

In the Northeast there is a shortage of anesthesiologists and the salaries that need to be paid to retain quality physicians are causing us to suffer severe economic losses that cannot be absorbed elsewhere. The CMS anesthesiology teaching rule must be changed to allow academic departments to cover their costs.

Our department's ability to do academic research has been hindered because of the lack of funds. Department budgets are broken by this arbitrary Medicare payment reduction. Medicare must recognize the unique delivery of anesthesiology care and pay Medicare teaching anesthesiologists on par with their surgical colleagues.

The Medicare anesthesia conversion factor is less than 40% of prevailing commercial rates. Reducing that by 50% for teaching anesthesiologists results in revenue grossly inadequate to sustain the service, teaching and research missions of academic anesthesia training programs.

Rosalind Sandler 117A Brooktrail Court Santa Rosa, CA 95409

GPICs
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention CMS-1502-P
P.O. Box 8017
Baltimore, MD 21244-8017

September 17, 2005

To Whom It may Concern:

I am a disabled senior who relies on Medicare as my medical insurance. My doctors all accept Medicare as total payment for services. Three of the six specialists I see on a regular basis are no longer accepting new Medicare patients because of reimbursement rates. I receive excellent care from these doctors and my primary care physician. I don't want them to relocate because of low reimbursement Medicare rates.

I'm writing in support of the Medicare new rule, which would increase the reimbursement rate for Sonoma County, California by 8%.

Let me tell you some documented statistics about where I live in Sonoma County, California:

- > Sonoma County's medical costs have risen much faster than other areas, on average, 8% higher than similar counties.
- > Santa Rosa, the largest city in Sonoma County with a population of 100,000+ is sixth in United States for the highest percentage of people 85 and older.
- > Seniors represent 16.6% of the total population in Sonoma County with a projected rate change of 196% from the year 2000-2020

Amid the astounding growth in elder population, Sonoma County has the lowest Medicare reimbursement rate in California

- > The number of practicing physicians has not kept pace with local population growth
- ➤ In July 2005 six out of ten primary care physicians were NOT accepting new Medicare patients
- > Many physicians are relocating their practices were reimbursement is more favorable

Help me help my home and bring it into line with similar areas in urban areas with like populations.

Sincerely,

Rosalind Sandler
Rosalind Sandler

Saturday, September 17, 2005

Center for Medicine & Medicaid Services Department of Health and Human Services Attention: CMS -1502-P P.O. Box 8017 Baltimore, MD21244-8017

Gentlemen:

I am appalled at the reimbursement that our doctors in Sonoma County receive. I am ninety-one years old and very dependent on Medicare and my additional health insurance.

Last week I called my secondary insurer (CIGNA) because I felt certain they had made a mistake in the reimbursement being paid to my heart doctor. He had billed \$80.00. Medicare only allowed 53.68 for this service then they discounted the bill to \$42.94—my insurance which is 90% coverage is paying \$10.76. This is outrageous. How can we expect to retain good medical personnel in Sonoma County when our doctors are so underpaid in a county where it is so expensive to live?

I would suggest that your staff come to Healdsburg where thirty year old tract houses are selling for over half a million dollars, hotel rooms start at \$300 dollars a night and eating out is pricey. Service people can no longer afford to live here and we certainly are not going to be able to attract new physicians to a locality where the rate of reimbursement means they lose money every time they see a Medicare patient.

Please change the rate of Medicare payments to be more equitable to the cost of living in Sonoma county.

Sincerely Luie D. Jensen

September 19, 2005

GPCIs

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMA-1502-P
PO Box 8017
Baltimore, MD 21244-8017

Sir or Madam:

This is a plea for your support of an increase in reimbursement rate for Sonoma County California for medical services for Medicare and Medicad services providers.

We live in an area that has grown vastly and is also very expensive. In addition to those jarring facts, we have a large population of seniors and the forcast is that the numbers of seniors will continue to grow over the next few years.

Over the past few years our medical support system has suffered and many doctors have been forced to leave our area. We know the system for reimbursement is out of date and urge you to bring Sonoma County into line with other areas of our size.

With Urgent Sincerity, Ervin & Steinhaue,

Ervin R. Steinhauer

3544 Kirkridge St Santa Rosa, Ca. 95403

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9/15/05 Center for Medican Medicais Services hepty Health of Human Services ath: CMS-1502-P P.O. BOX 8017 Bultimore, MD 21244-8017 Re: CMS-1502-P Medicare costs in Soroma County have visen much Jaster than other areas? Jonta A ora with a population of over 100,000 in 6th in the United States Medicare standarde or they are forcing Physicians to leave the sounty to practice where recinturement is more fororable. Therefore, Thousands of Regle especially those on Medicare are having trouble getting health care. reinburement rate for favoura County by 8%. We ned help Now. Sincerely, LOBRAINE GREER Formine Sull Rd Sonta Rosa, la 95-409 CC! GPC1 to melian Medical Service

CITY OF WATSONVILLE

"Opportunity through diversity; unity through cooperation"



ADMINISTRATION BUILDING

215 Union Street Second Floor Fax 831.761.0736

MAYOR & CITY COUNCIL

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PUBLIC WORKS & UTILITIES 831.768.3100 Fax 831.763.4065 PURCHASING

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PARKS & COMMUNITY SERVICES

30 Maple Avenue 831.768.3240 Fax 831.763.4078 September 14, 2005

Centers for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1502-P P. O. Box 8017 Baltimore, MD 21244-8017

Re. File Code CMS-1502-P

Issue Identifier: GPCI's / Payment Localities

Dear Sirs:

I am writing on behalf of the City of Watsonville City Council to strongly support the proposed revision to physician payment localities published in the reference rule. We are very concerned that under-reimbursement of physicians in our county places our residents in jeopardy of experiencing a deterioration of our health care system. We believe that your proposed revision of payment localities would address those concerns and we laud your efforts at rectifying the current damaging situation. Your proposed rule would make an important change that would substantially help in ensuring access to health care services in our city and county.

We understand this to be a fundamental issue of fairness. Neighboring counties to Santa Cruz and Sonoma have some of the highest payment localities in the nation. The adjustment you propose is appropriate and fair in achieving your goal of reimbursing physicians based on the cost of practice in their locality.

Sincerely

Ana Ventura Phares, Mayor

c. Congressman Sam Farr
 Watsonville Community Hospital
 Pajaro Valley Community Health Trust
 Salud Para La Gente

September 17, 2005

Center for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1502-P PO Box 8017 Baltimore, MD 21244-8017

re: GPCI

Geographical Price Cost Index in Santa Cruz County, California

To Whom It May Concern:

As a Medicare recipient and a Santa Cruz County citizen who cares about the thousands of senior citizens and people with disabilities in this county who depend on Medicare for their health care, I am pleased that you intend to raise the reimbursement rate for doctors.

We have been losing experienced doctors in recent years, and recruitment of young doctors to our area has become more and more difficult, in large part because of the enormously high cost of housing in Santa Cruz County. I have had four internists in five vears because the first three all moved out of this county.

Having Medicare coverage doesn't do much good when more local doctors are refusing to take on new Medicare patients because of the low reimbursement rates. So access to health care is shrinking here, and people's fears are increasing.

Please go ahead with your plan to change Santa Cruz County from a rural designation to an urban designation. This will help at least a little to attract and keep doctors in our county who will treat Medicare beneficiaries.

Yours truly,

Elizabeth Sparks

4300 Diamond Street, Apt. 2

Elyabeth Sparler

Capitola, CA 95010-3061

Sep. 16, 2005

GPCIs
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-P
POB 8017
Baltimore, MD 21244-8017

To whom it may concern:

I am writing in support of the proposed increase of 8% to the Medicare reimbursement rate for physicians in Sonoma County California.

This increase is justified and necessary for Medicare recipients and the doctors who treat them. I am a senior citizen and have trouble switching doctors because so many are not accepting Medicare coverage. We need this so better care can be provided and to slow or stop the exodus of physician who leave the county.

I urge all elected officials and government agencies to support this increase.

Thank you.

Mary Romano 729 Barry Ct.

Rohnert Park, CA 94928-4005

(707) 795-5121

September 15, 2005

Centers for Medicare and Medicaid Services Dept of Health and Human Services Attn: CMS-1502-P PO Box 8017 Baltimore MD 21244-8017

To Whom It May Concern:

I am writing in support of changing the designation of Santa Cruz County from "rural" to "urban." This change is warranted by the county's proximity to the Silicon Valley and San Franciso Bay area and the county's extremely high cost of living.

Thank you for your consideration.

Huster of Berjamin

Sincerely,

Kristen K Benjamin 227 Ventana Way Aptos CA 95003

(831) 685-8014





EASTMAN DENTAL CENTER
SCHOOL OF MEDICINE AND DENTISTRY
SCHOOL OF NURSING
STRONG MEMORIAL HOSPITAL
UNIVERSITY MEDICAL FACULTY GROUP

DEPARTMENT OF ANESTHESIOLOGY

September 13, 2005

Centers for Medicare and Medicaid Services Department of Health and Human Services Attn: CMS-1502-P PO Box 8017 Baltimore, MD 21244-8017

Re: CMS-1502-P TEACHING ANESTHESIOLOGISTS

Dear Sir/Madame:

As Program Director for the Residency Program of the Department of Anesthesiology at the University of Rochester in New York, I am writing to request your support of the changes required in the present CMS Medicare Fee Schedule related specifically to TEACHING ANESTHESIOLOGISTS who provide the educational training as models for professional development of young doctors seeking to become academic and private practice anesthesiologists.

I presently have 50 residents in training at the University of Rochester, with 6 fellows, and 42 academic teaching anesthesiologists within the Department of Anesthesiology. At Strong Memorial Hospital we have experienced a 27% growth in surgical volume during the past 4 years, that includes an increasingly aged, acutely ill, and complex number of patients. We have become the only Level 1 Trauma unit in this region. This past year we provided over 27,000 anesthetics. Our commercial reimbursement rates based on productivity per faculty member are some of the lowest in the country making recruitment and retention within the academic milieu a continuously challenging process. Recruitment of recent graduates or experienced anesthesiologists into an academic center is a continuous problem, particularly as recent graduates now have educational debt levels of \$100,000 -300,000, for which private practice offers a considerably higher compensation. Permitting equality in the Medicare Fee Schedule with our surgical colleagues with respect to full payment for each of two patients concurrently cared for following CMS regulations, will substantially augment our ability to provide the academic environment that is needed for the future.

My entire career has been in academic medicine. I have been in academic medicine since graduating from medical school at the University of Rochester in 1988. I have trained in both internal medicine and anesthesiology at Strong Memorial Hospital and have worked here as an academic teaching anesthesiologist throughout my career. My expertise in addition to education, is in pre-operative care and anesthesiology of liver transplantation. I teach residents on a daily basis throughout the year. I thus have experience in a wide variety of areas, and can testify that the serious shortage of academic anesthesiologists

available to: 1) educate; 2) deliver clinical care while supervising residents and medical students; and 3) develop and sustain academic research programs that will attract young physicians into academia that provide the basic and clinical research advances required to continuously improve the quality of health available to our citizens of all ages, is under substantial stress. The United States can not simply rely on, as it has in the past, foreign medical graduates to fill these academic positions and still maintain leadership roles internationally. The loss of academic teaching anesthesiologists is occurring despite the necessity of hospitals on the average needing to support academic anesthesiologists in the amount of approximately \$110,000/year per full time faculty member according to the latest data from the Society of Academic Anesthesiology Chairs.

Redressing the unequal reimbursement for similar care provided by surgeons and anesthesiologists will provide a significant component of the resources required to develop the quality of academic anesthesiology required for the US to advance in this vital field for which most US citizens can expect to undergo surgery at some time during their life. The recognition of the focus on safety and the critical role that anesthesiologists play in allowing interventional and surgical procedures to occur without memory or pain is a fundamental mantra in training anesthesiologists. The combination of education, research, and dedicated models in the field is required for the future.

I urge those making long term decisions in CMS to appreciate the turning point that exists now, no longer with respect to the issue of immediate staffing of private hospitals, but with respect to the present and future training of anesthesiologists by a diminishing number and quality of teaching anesthesiologists.

Thank you for your willingness to seriously consider these issues.

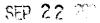
Sincerely yours

Stewart Lustik MD

Residency Program Director Department of Anesthesiology

University of Rochester Medical Center

Rochester, NY 14642



ROCHESTER

MEDICAL CENTER

EASTMAN DENTAL CENTER
SCHOOL OF MEDICINE AND DENTISTRY
SCHOOL OF NURSING
STRONG MEMORIAL HOSPITAL
UNIVERSITY MEDICAL FACULTY GROUP

DEPARTMENT OF ANESTHESIOLOGY

September 13, 2005

Centers for Medicare and Medicaid Services Department of Health and Human Services Attn: CMS-1502-P PO Box 8017 Baltimore, MD 21244-8017

Re: File Code: CMS-1502-P TEACHING ANESTHESIOLOGISTS

Dear Sir/Madame:

As Chairman of the Department of Anesthesiology at the University of Rochester in New York, I am writing to request your support of the changes required in the present CMS Medicare Fee Schedule related specifically to TEACHING ANESTHESIOLOGISTS who provide the educational training as models for professional development of young doctors seeking to become academic and private practice anesthesiologists.

I presently have 50 residents in training at the University of Rochester, with 6 fellows, and 42 academic teaching anesthesiologists within the Department of Anesthesiology. At Strong Memorial Hospital we have experienced a 27% growth in surgical volume during the past 4 years, that includes an increasingly aged, acutely ill, and complex number of patients. We have become the only Level 1 Trauma unit in this region. This past year we provided over 27,000 anesthetics. Our commercial reimbursement rates based on productivity per faculty member are some of the lowest in the country making recruitment and retention within the academic milieu a continuously challenging process. Recruitment of recent graduates or experienced anesthesiologists into an academic center is a continuous problem, particularly as recent graduates now have educational debt levels of \$100,000 -300,000, for which private practice offers a considerably higher compensation. Permitting equality in the Medicare Fee Schedule with our surgical colleagues with respect to full payment for each of two patients concurrently cared for following CMS regulations, will substantially augment our ability to provide the academic environment that is needed for the future.

My entire career has been in academic medicine. I have been in academic medicine since graduating from medical school at Boston University in 1970. I have worked at the best medical centers in this country (Johns Hopkins), Canada (Hospital for Sick Children), and the UK (Hammersmith and St. Mary's). I have been an academic Chairman at Imperial

College in London and presently in the US. I thus have experience in a wide variety of teaching hospitals around the world, and can testify that the serious shortage of academic anesthesiologists available to: 1) educate; 2) deliver clinical care while supervising residents and medical students; and 3) develop and sustain academic research programs that will attract young physicians into academia that provide the basic and clinical research advances required to continuously improve the quality of health available to our citizens of all ages, is under substantial stress around the world. The United States cannot simply rely on, as it has in the past, foreign medical graduates to fill these academic positions and still maintain leadership roles internationally. Most countries within the EU are far more supportive of academic development than the US by virtue of time and compensation provided to academics to teach and participate in clinically related research. It is very clear to me, based on my experiences in multiple countries, that unless we address the issue of compensation for teaching anesthesiologists that the US will continue to fall behind Europe, Japan, and then China in developing the academic leaders in anesthesiology. This is occurring despite the necessity of hospitals on the average needing to support academic anesthesiologists in the amount of approximately \$110,000/year per full time faculty member according to the latest data from the Society of Academic Anesthesiology Chairs.

Redressing the unequal reimbursement for similar care provided by surgeons and anesthesiologists will provide a significant component of the resources required to develop the quality of academic anesthesiology required for the US to advance in this vital field for which most US citizens can expect to undergo surgery at some time during their life. The recognition of the focus on safety and critical role that anesthesiologists play in allowing interventional and surgical procedures to occur without memory or pain is a fundamental mantra in training anesthesiologists. The combination of education, research, and dedicated models in the field is required for the future.

I urge those making long term decisions in CMS to appreciate the turning point that exists now, no longer with respect to the issue of immediate staffing of private hospitals, but with respect to the present and future training of anesthesiologists by a diminishing number and quality of teaching anesthesiologists.

Thank you for your willingness to seriously consider these issues.

Sincerely yours,

James L Robotham, MD, FRCA

Chair, Department of Anesthesiology

University of Rochester Medical Center

In alliance with The University of Vermont

MELINDA L. ESTES, M.D.

President and Chief Executive Officer

September 15, 2005

Centers for Medicare and Medicaid Services Department of Health and Human Services Attn: CMS-1502-P P.O. Box 8017 Baltimore, Maryland 21244-8017

Reference Code: CMS-1502-P

Issue Identifier: Teaching Anesthesiologists

Dear Sir or Madam:

I am writing to you to request a change in your policy on payment for teaching anesthesiologists. This is an important issue for academic medicine and specifically the teaching of Anesthesiology residents in our state.

I have concerns about the current Medicare rule on teaching anesthesiologist payment. The current policy causes a financial burden on both the Anesthesiology Department and this academic medical center. This policy shortchanges teaching programs by withholding 50% of their funds for concurrent cases. Therefore, Anesthesiology teaching programs are suffering severe economic losses that cannot be absorbed elsewhere. Specifically, in our institution, the average reimbursement for all payers is 26 dollars per ASA unit. According to national figures ("MGMA Cost Survey for Anesthesia Practices 2004", the median reimbursement for all payers is over 34 dollars per ASA unit. A good portion of the difference relates directly to the teaching rule. This rule must be changed to allow academic departments to cover their costs.

Academic research in anesthesiology is also suffering as department budgets are tightened to attempt to cover their costs. Anesthesiology is a specialty whose research has had direct benefits in lowering the risk of surgical intervention for the Medicare population.

A surgeon may supervise residents in two overlapping operations and collect 100% of the fee for each case from Medicare. An internist may supervise residents in four overlapping outpatient visits and collect 100% of the fee for each when certain

Teaching Anesthesiologists CMS-1502-P Page 2 of 2

requirements are met. A teaching anesthesiologist will only collect 50% of the Medicare fee if he or she supervises residents in two overlapping cases. This is not fair and it is not reasonable.

Medicare must recognize the unique delivery of anesthesiology care and pay Medicare teaching anesthesiologists on par with their surgical colleagues. The Medicare conversion factor is less than 40% of prevailing commercial rates. Reducing that by 50% for teaching anesthesiologists results in revenue grossly inadequate to sustain the service, teaching and research missions of academic anesthesia training programs. We estimate that the cost to Fletcher Allen Health Care to support the teaching mission of the Anesthesiology department is at least \$2.5 million.

Over the years, many of our graduating residents go on to serve the peri-operative and chronic pain needs of the Medicare population in our rural State. It is important to have a stable and growing pool of physicians trained in anesthesiology so we can continue to provide quality medical care for a growing population of Medicare recipients.

Sincerely,

Melinda L. Estes, M.D.

President and Chief Executive Officer

RL. Colina

cc: Howard Schapiro, M.D., Chair, Department of Anesthesiology

INDIANA UNIVERSITY



September 16, 2005

SCHOOL OF MEDICINE

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1502-P
P.O. Box 8017
Baltimore, MD 21244-8017

RE: CMS-1502-P/TEACHING ANESTHESIOLOGISTS

Dear Dr. McClellan:

I am an anesthesiologist and have served as a fulltime faculty member at Indiana University School of Medicine, Indianapolis, Indiana for the past 31 years. I am writing this letter to urge the Centers for Medicare and Medicaid Services (CMS) to revise the Medicare anesthesiology teaching payment policy.

The current Medicare anesthesiology teaching payment policy (which was instituted in 1995) has been very detrimental to the economic survival of anesthesiology departments in teaching institutions. With decreasing levels of income of anesthesiology faculty, it has become increasingly difficult to retain skilled faculty. The number of unfilled anesthesia faculty positions at teaching institutions across the country has continually increased during the past decade. This has had a serious detrimental impact on the ability of programs to train the future anesthesiologists necessary to help alleviate the widely-acknowledged shortage of anesthesia providers - a shortage that will be exacerbated in coming years by the aging of the baby boom generation and their need for surgical services.

Under current Medicare regulations, teaching surgeons and internists are permitted to work with residents on overlapping cases and receive full payment so long as the teacher is present for critical or key portions of the procedure. Teaching surgeons may bill Medicare for full reimbursement for each of the two procedures in which he or she is involved. An internist may supervise residents in four overlapping office visits and collect 100% of the fee when certain requirements are met.

Academic anesthesiologists similar to surgeons and internists are permitted to work with residents on overlapping cases as long as they are present for critical

DEPARTMENT OF ANESTHESIA

SECTION OF PEDIATRIC ANESTHESIA AND CRITICAL CARE

Riley Hospital for Children Room 2001 702 Barnhill Drive Indianapolis, Indiana 46202-5200

317-274-9981 317-274-8222 Fax: 317-274-0282 or key portions of the procedure. However, unlike teaching surgeons and internists, the reimbursement of teaching anesthesiologists who work with residents on overlapping cases is reduced by 50%. Compared to other specialties in medicine Medicare payment for anesthesia services is much lower (approximately 40% of usual and customary). The impact of lower payment is accentuated by 50% reduction for overlapping cases when the anesthesiologist is working with residents. The low reimbursement for anesthesia services and 50% reduction in reimbursement is unfair and unreasonable.

To ensure the training of much needed future anesthesiologists, I am requesting that CMS review and revise Medicare payment rules for anesthesia services.

Sincerely,

Gopal Krishna, M.D.

Professor of Anesthesia

912 Humboldt Street Santa Rosa, CA 95404 September 15, 2005

GPCIs
Centers for Medicare & Medicaid Services
Attention: CMS-1052-P
P.O.Box 8017
Baltimore, MD 21244-8017

Greetings from Sonoma County, California:
Our once-rural and farming county is now a vital part of the commerce of the greater San Francisco Bay Area. Santa Rosa, our county seat, is the largest city between San Francisco and Portland. As a member of the Sonoma County Economic Development Board I participate in reccommendations and decisions affecting our 19 Billion dollar economy. One of these important engines is health and medical care and its future where 1 out of 6 are seniors over 60 years old yet a majority of our primary care physicians are not accepting new patients under Medicare.

As one of 58 California counties, Sonoma County has experienced more rapid rise in overall healthcare costs than similar size counties and our longtime HMO was forced to close is doors.

Medicare reimbursement is such a significant benchmark that your proposed % increase will serve as a tremendous fulfillment and stimulus to the medical and heathcare community. Yes, "8 is Great!". I appreciate and welcome the support by the Centers for Medicare & Medicaid Services for an increase of 8% reimbursement in Medicare for the people and healthcare providers of Sonoma County.

Sincerely

Donald & Tee

RECEIVED

SEP 1 2 2005

SONOMA COUNTY
MEDICAL ASSOCIATION

Janta Rosa, CA 9 9 Struprom St. 25409

59pt, 5, 2005 542

To: Centres for Medicare Services Re: Increasing Reinbursements for Sonoma Country Physicians.

The Enclosed thank showing the murase in Median home prices during the past year here illustrated the problem we are having attracting and Kerping physicians of any age. In ou area like ous, with its higher than average percentage of prople over 65, there is a dire need for now physicians and to propody comprisate the ones we have. We serious should not have to add working about whether our doctor can continue to care for us to all the ofther workies that are part of ogeing. Please increase the Reinburguent Rate 8%. Sincerely, Carolyn L. Perry

SEP 22 ARE 543

RECEIVED
SEP 12 2005

SONONG COUNTY MEDICAL ASSOCIATION

September 7, 2005

Center for Medicare and Medicaid Services:

We are writing to request an increase in Medicare reimbursements to our Sonoma County physicians.

Sonoma County is not a rural area. Santa Rosa provides access to very sophisticated medical treatments for the entire area north of San Francisco. Home purchases are unbelievably high as well as rentals. New physicians are locating elsewhere and many of our established physicians are either retiring, going into research or in some other way no longer providing medical service to our communities. Please consider the seriousness of this problem and increase reimbursements to the physicians. It is vital.

Marjone Nash Marjone Nash

6455 Stone Bridge Road

Santa Rosa, CA 95409

Howard Nash

6455 Stone Bridge Road Santa Rosa CA 95409 September 17, 2005

To whom it may concern:

I am a registered nurse. I have been a provider and educator of health care in Sonoma County for thirty years. I have had a severe pulmonary disease since 1996 and have been retired since 1999.

Over the years I have been appalled at the steady decline in the quality of health care in Sonoma County. If I was not knowledgeable about the provision of health care, I would have been lost in the system years previously.

Sonoma County is a "non" system of care. Patients clamor for care only to be turned away by another over worked and under paid provider. Doctors have been fleeing the area for years and we are under-staffed with primary providers and specialty area doctors. I have seen and heard of patients dying early because of the lack and shortage of good health care.

I have another home on the Oregon Coast and I am very impressed with health care health care in that state. Oregonians have other problems, like a lack of health care coverage but the service is outstanding.

I am a resident of Sonoma County and I support the new medicare proposal. Medicare must correct reimbursement rates in Sonoma County, NOW!

Respectfully submitted,

daurel Freed

Laurel Freed

457 Woodley Place

Santa Rosa, CA 95409

9th Floor - TUCMC 3509 North Broad Street Philadelphia, PA 19140 Tel: (215) 707-5776 Fax: (215) 707-1585

September 18, 2005

Mark B. McClellan, M.D., Ph.D.
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re:

TEACHING ANESTHESIOLOGISTS

CMS-1502-P

Dear Dr. McClellan:

On behalf of the Temple University Hospital, I appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule covering Revisions to Payment Policies under the Medicare Physician Fee Schedule (PFS) for Calendar Year 2006.

With respect to proposed payments for teaching anesthesiologists, we request that the final rule revise the current Medicare PFS by allowing full payment for the services they provide when directing two overlapping procedures administered by an anesthesiology resident, when the teaching anesthesiologist is present during the critical or key portions of both procedures.

Under current payment policy, CMS treats anesthesia services under the PFS differently than it treats other physician services. With respect to teaching surgeons, for example, CMS allows full payment for surgeons who direct two overlapping surgeries as long as the surgeon is present during the key or critical portions of the surgery.

In contrast, CMS bases payments for anesthesia services on the sum of the "base unit" (reflecting pre-and post-operative care) plus the anesthesia time units (actual time performing procedure). The anesthesiologist may personally perform the service or may direct the performance by residents. When the anesthesiologist directs the anesthesia case, however, the payment for that direction is at 50% of the allowance otherwise recognized if the anesthesiologist personally performed the service.

We believe that the current policy unfairly discriminates against teaching anesthesiology programs by imposing an arbitrary 50% payment reduction for this critical service. Furthermore, because the Medicare conversion factor is approximately 40% less than prevailing commercial rates, this revenue reduction results in payment well below the cost of delivering care and providing the medical education service. Consequently, Temple University Hospital's Anesthesiology program has suffered significant economic loss and has struggled in recent years to achieve market-competitive salaries and a fully staffed department.

In its proposed rule, CMS states,

...The American Society of Anesthesiologists suggests that the teaching physician regulations for teaching anesthesiologists should be similar to those for teaching surgeons for overlapping complex surgery in terms of critical periods, overlap, and availability of teaching physicians. However, the critical portions of the teaching anesthesia service and the critical portions of the teaching surgeon service are not the same (emphasis added).

We disagree with CMS's assessment that the critical portions of teaching anesthesiology and teaching surgeon services are not comparable. To the contrary, it is required in all cases that the attending physician, regardless of whether the physician is a surgeon or anesthesiologist, be present during the critical or key portions of the procedure. The physical presence of these attending physicians allows them to directly supervise the residents, and personally take over patient care as necessary.

For the above reasons, we urge the Centers for Medicare and Medicaid Services to revise the current Medicare PFS by allowing full payment for the services of a teaching anesthesiologist for directing two overlapping procedures when the teaching anesthesiologist is with the resident during the critical or key portions of both procedures.

Robert E. Pezzoli

President and Chief Operating Officer Temple University Health System 9/20/05

Centers for Medicare and Medicaid Services

Dept. of Health and Human Services

Attn: CMS-1502-P Mailstop: C4-26-05 7500 Security Blvd.

Baltimore, Md. 21244-1850

Re: CMS-1502-P Addendum C

This is a response or comment on behalf of the American Academy of Maxillofacial Prosthetics (AAMP), to the Proposed Rule CMS-1502-P, with specific reference to Addendum C.

The American Academy of Maxillofacial Prosthetics has previously submitted additional data regarding practice expense values for CPT codes 21076-21087. Enclosed in this package in response to CMS-1502-P are (3) CD copies of the spreadsheet data outlining the detail of practice expenses which accurately reflect the multiple visit scenario inherent in the practice parameters for each of these codes. In addition, data is included which accounts for the costs associated with outside dental laboratory support necessary for many of these codes (*see metal alloy frameworks via the spreadsheet). The AAMP has worked with Carolyn Mullen of CMS throughout this process; this same data was submitted in March of 2005 as well.

In addition, the August 8, 2005 CMS update contained a request for information regarding pricing of SL203 – Tissue Conditioner, Coe Soft. This material is used in many of the applications for 21076-21087 and I have enclosed pricing and unit information for review.

Hopefully, the data enclosed will complete the process for review and update of the PE component of our codes.

Sincerely

Terry M. Kelly D.M.D.

Vice President Elect
American Academy of Maxillofacial Prosthetics

H. Lee Moffitt Cancer Center 12902 Magnolia Drive Tampa, FL. 33612

e-mail: <u>kellyT@moffitt.usf.edu</u> phone: 813-979-3968

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Includes: 6oz powder, 6oz liquid, accessories and patient brochures. Each...... 204-7397

Powder 602 204-8866	1® \$80.50 4© \$78.95
Liquid Soz204-7884	1@\$54.25

KOOLINEFT

'GC',',

- GC America, inc.

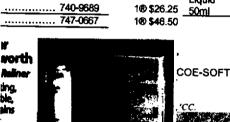
Professional Package

Hard Chairside Denture Reliner

includes: Soz powder, 2oz liquid and accessories.

Cures in the patient's mouth.

Kooliner*



Soft

Liquid

50ml

18 \$105.50 Extra Soft

i Soz powder and 6oz liquid. 743-2749 1@\$79.75 143-2772

..... 743-2806

: Soz powder and 6oz liquid.

.....743-6534

.....743-6567

I Package

J6ml

Coe-Soft"" - GC America, Inc. Resilient Soft Denture Reline Material

For chairside use. A soft reline material for upper and lower dentures.

Professional Package

Includes: 6oz powder, Soz liquid, lubricant and accessories.

Each 206-3584 1@ \$102.50 Powder 6oz 206-4566

1@\$82.95

1@\$54.25

Liquid 206-5050 Soz

COE-RECT

Coe-Rect™-GC America, Inc.

Hard Denture Reline and Repair Material

For chairside use. Cures in 7 minutes with low exothermic heat.

Standard Package

Includes: Soz powder, Soz liquid, 5/8oz repair

liquid and accessories.

1@ \$96.50



Super-Soft™ - GC America, Inc.

Denture Reliner

A heat-processed permanent liner.

Professional Package

Includes: Soz powder and 6oz liquid.

Each......206-6033 1@ \$82.95



..754-5920

1@\$21.25

1@\$79.75

There ere (12) units per professional package.

Unit cost = 8.54 565

TO CMJ. Before I become a declying Stayish look, A couldn't lat, Atoob 80 M.G. wolfell 6 to 8 teues a day + still letes below up, Lene & been on dealysis for 4 merether. In down to my people enlight + latery agreen + & down to no water pille, I feel better & hopens to get Place do not best book spending Su dealisis. thise geger at Di Vitto Shila. The every life + they to Cool ' your trus Hory Clear

TO: CMS

FROM: BETTY MCDOWELL

SEPTEMBER 19, 2005

Please be advised that I am dialysis patient. I would like my providers to be able to continue to improve the quality of care they give. PLEASE DO NOT CUT PAYMENTS FOR DIALYSIS. Dialysis is my life-line.

Thank you,

Betty V. Mc Jowelle Betty McDowell

9/20/2005

Center for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1502-P Baltimore, MD. 21244-8017

Re: Film Code CMS1502-P

Issue Identifier: GPCI's Payment localities

Dear CMS Staff:

I am writing to strongly support the proposed revision to physician payment localities in California that you published earlier this month. I hope that you adopt this rule as final in November. As a Dominican Hospital Foundation Board member, I am very concerned that as our physicians age and retire, we as a community are able to attract new physicians to take their place. I have followed the issue s surrounding the inclusion of Santa Cruz County within locality 99 for California and welcome the opportunity to support your proposed solution to the current inequitable payment policy. I believe adoption of your proposed rules will go along way to ensure ongoing access to high quality care for community residents.

As you know, physicians in Santa Cruz receive reimbursement at levels 25% less than physicians in two of our neighboring counties. Current payments are about 10% less than they should be, given the county's current GAF. They do not reflect the high cost of practice in our community.

You are to be commended for proposing a rule that would address this problem for physicians in Santa Cruz and Sonoma Counties, the two most problematic counties in California. I believe this to be fair and appropriate. Thank you for considering my comments.

Sincerely

Carlos Arcangeli M.D. 1595 Soquel Dr. Ste 110 Santa Cruz, Ca. 95065



H U M A N R E S O U R C E S D E P A R T M E N T 809 Center Street, Room 6, Santa Cruz, CA 95060 • 831 420-5040 • Fax: 831 420-5041 • www.ci.santa-cruz.ca.us

September 19, 2005

Center for Medicare and Medicaid Services Department of Health and Human Services Attn: CMS-1502-P P.O. Box 8017 Baltimore, MD 21244-8017

To Whom It May Concern:

On behalf of the employees of the City of Santa Cruz, I am requesting your support for an increase in the Medicare reimbursement rate for Santa Cruz County, California, physicians.

Santa Cruz County is a beautiful place to live, rich with culture, excellent schools and unparalleled natural beauty. It is also one of the most expensive places to live in the country. The median price of a single family dwelling in Santa Cruz County is over \$750,000, which makes it difficult to recruit young doctors to the area. Many of the doctors currently practicing in Santa Cruz County are approaching retirement and in order to maintain quality healthcare in this area, we must be able to attract physicians and other healthcare providers and compensate them fairly.

In order to continue to offer quality healthcare to the employees of the City of Santa Cruz and to the constituents of Santa Cruz County, I ask that you consider supporting the increase in the Medicare reimbursement rate for Santa Cruz County physicians.

Thank you for your attention to this matter.

Sincerely,

Dee Schabot

Acting Assistant Director of Human Resources

Cc: Richard Wilson, City Manager

nabod

Kelly Menehan, Acting Director of Human Resources

September 19, 2005

GPCIs Centers for Medicare & Medicaid Services Department of Health and Human Services Attention CMS-1052-P PO Box 8017 Baltimore, MD 21244-8017

RE: Medicare Reimbursement Guidelines for Sonoma County California

Gentlemen:

We in Sonoma County need you to adjust the cost of medical services for Medicare recipients to reflect the true cost of doing business. Sonoma County is no longer "rural." Santa Rosa, the county seat, has a population of well over 100,000 people with 16.6% of the residents 60 years and older. The County is considered a part of the San Francisco Bay Area, one of the most expensive places to live in the entire country. The median cost of housing in Sonoma County is now over \$600,000.

We are loosing doctors at an alarming rate. Six out of ten doctors are not accepting Medicare patients. While the focus of this letter is on Medicare, I can tell you as a Human Services Department employee that it is next to impossible for a Medi-Cal (Medicaid) patient to find a doctor. Even those of us with good HMO coverage have difficulty finding a doctor due to the lack of physicians and low reimbursement rates. Increasing the amount of reimbursement to our doctors will help to attract more practitioners to our area.

Thank you for your consideration to this request.

Sincerely,

Alix Ann Shor

1730 St. Francis Rd. Santa Rosa, CA 95409

(707) 538-0708

FELLOW, AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS
FELLOW, AMERICAN COLLEGE OF SURGEONS
FELLOW, AMERICAN ASSOCIATION OF HIP AND KNEE SURGEONS

BOARD CERTIFIED

AMERICAN BOARD OF ORTHOPAEDIC SURGERY

JOHN A. BRADFORD, M.D., P.A.

ORTHOPAEDIC SURGEON

151 BROADWAY

BANGOR, MAINE 04401

TELEPHONE (207) 945-9461

FAX (207) 945-3241

September 13, 2005

Centers for Medicare and Medicaid Services Department of Human Services Attn. CMS-1502-P PO Box 8017 Baltimore, Maryland 21244-8017

RE: Bundling codes for treatment of fracture care

Dear Sir or Madam:

As an orthopedic surgeon, I am writing with regard to the proposal that Medicare and Medicaid bundled cast and splint costs into the fracture code. I trust that you are aware that the materials are indeed quite expensive, in fact more so than ever, and this constitutes a significant burden to orthopedic surgeons especially.

Unfortunately, many of us refuse to see Medicaid patients for just this reason with remuneration being so paltry that it is very difficult indeed. I choose not to do this and have done a fair amount of charity care and pro-bono work as well. I am happy to continue this but hope that the government agencies understand that this represents yet another setback in our attempt to treat people who are often the most needy. I would be grateful if you would kindly reverse this decision to consider bundling codes for treatment of fracture care. Thank you for your attention to this.

Most sincerely,

John A. Bradford, M.D.

JAB/dhpwr

GPC1s.

attention; CMS-1502-P

agree that medicare should propose a

new-rule that would increase the reinstancement

rate to the Somoma County Poetors by 8% or more.

This proposal well bring the Sonoma Countyrates

back in lines with the other counties in California,

Thank you for your imediate cansideration

Charles Btwichelfer.

C.B. TWICHELL, SR. 519 COLONIAL PARK DR. SANTA ROSA, CA 95403-1147

September 20, 2105 -

Smanue County is an expension area to live in, yet the Medicare reimbursement to physicians is the lowest in Colifornia. The sesuet is a lessening of some for we serious, with many doctors repring new Medicare patients.

We understand you are lousidering a charge in upone rules which much spronde greater which much spronde greater reimhursed rates - a charge that we agree seems reasonable.

I fil

Garaldine Morton

8424 Cypius Voy Serte Rose, CA. 95405

MEDICARE - 555 9-17-05 I support your proposal to increase the reinbusment Nate for Sonoma Co. by 8% In cities with a population of Over 100,000 people, Santa Rosa is one, it's the sixth highest Percentage of people 85 and older. Deniors 60 and older make up 16.6% of the total population in Soroma County. You are not paying / reinbusing our doctors enough right now you have us as a rual Community. We are no longer We are a thriving city: Some of my doctors will not take medicare patients as They don't get enough reinbursmost From you. Mary a Twichell

September 19, 2005

CPCIs Centers for Medicare & Medicaid Services Department of Health and Human Services Attn.: CMS-1502-P Post Office Box 8017 Baltimore, MD 21244-8017

The doctors in Sonoma County California have been delivering health services to my wife and me for 20 yr. under Medicare. They have done a good job of doing so at a reimbursement level equivalent to a rural area even though we are now a county of almost a half million people, suburban to the City and County of San Francisco, and an integral part of the Bay Area of 6, 000 000 inhabitants. Our living costs are equivalent to all parts of this urban region.

Because of the lower level of reimbursement, many doctors are not accepting new Medicare patients, and some have even canceled existing clients. The older population is growing in Sonoma County and we do need Doctors to participate in the Medicare system. We ask that you adjust the reimbursement level of our Sonoma County Physicians commensurate with the other urban counties of the San Francisco Bay area.

Thank you for giving our request your thorough consideration.

ams Obword - Charlyn a. Board James O. and Charlyn A. Boord

8831 Oakmont Drive

Santa Rosa, Ca. 95409

Seatlemen: you to increase your accepting Medicare gatieste so rectify this by Sixenely, Glady Sequist

September 19, '05

GPCIS

Centers for Medicare and Medicaid Services
Dept. of Health and Human Services
Attn: CMS-1502-P
P.O. Box 8017
Baltimore. MD 21244-8017

Dear Sirs/Mmmes:

Sonoma County in California has a huge percentage of older citizens who need health care regularly and need to have dependable, readily available services to maintain quality life.

Please increase the reimbursement rate for Sonoma County by at least 8% to bring it more in line with current reimbursement standards elsewhere. The population growth in this county has increased enormously over the past 7 years, but the numbers of practicing physicians have increased only 4%. Many doctors are moving to other places where they can make more money, so that now thousands of our older residents, especially those on Medicare or without any medical insurance at all, are have a great deal of difficulty finding a doctor to help them. This means that their medical problems worsen without care and many will die.

In July this year, 3/5ths of our county's primary care physicians were NOT accepting new Medicare patients because their reimbursements didn't compensate enough for their expenses.

It is important that the doctors receive adequate compensation for their many hours of hard work and dedication to the health of our communities. Please increase the rate by at least the proposed 8%--more if possible!

The Lucy Welson

Thank you for your attention to the above.

Sincerely,

Ms. Lucy Nelson 54 Ellie Drive Santa Rosa, CA 95403

September 19, 2005

GPCIs Centers for Medicare and Medicaid Services Department of Health and Human Services Attention : CMS-1502-P

Gentlemen:

We join with others in our community to express our concern over the Medicare reimbursement rates for Sonoma County, California. This area has long been established as a Standard Metropolitan Statistical Area and yet is being treated for Medicare reimbursement as a rural area. There is no logic or fairness to that designation when other nearby rural counties are reimbursed at higher rates. The effect of this lower rate on our medical community has been a persistent and drastic reduction in the retention of well qualified physicians and other practitioners to care for this growing area. Some of our best family physicians are now reluctantly refusing to accept patients who are covered by Medicare because of the inability to recover the cost of treatment. The problem will only worsen if measures to remedy this unfair designation of Sonoma County as a rural area are not taken quickly.

Respectfully,

William C. Hart

Jean W. Hart

Jean H. Hart

Sept 20,05 500

GPC15,

Please hear me!

Tell medicare to Correct reimbursment in Sonoma Co, Now!

> Yours, Shirley Hataury Petaluna, Ca 94952

Blease Rolf the pool Glease gay Dr. mne. It's very hand to And a Dr. because it Costs Mem to ser Medicale Patients Hank you Wester
101 Enterprise Dr.
Smite 140
Rohnert Park, CA 94928

Center for Medicare and Medicaid Services Department of Health and Human Services Attention CMS-1502-P PO Box 8017 Baltimore, MD 21244-8017

Re: GPCIs

To Whom It May Concern:

I am a member of the Monterey Bay Psychological Association (MBPA) and am writing to lend my support for the proposed revision of the physician payment localities in California recently published in the reference rule. With no revisions since 1996 I am pleased that you have selected two of the most highly impacted areas in our state, Santa Cruz and Sonoma Counties, to begin correcting the problems of payment inequities. I understand that the proposed revisions represent a fundamental issue of fairness – neighboring counties to Santa Cruz and Sonoma have some of the highest payment levels for provider services in the nation. The adjustment that you propose appropriately addresses the long-standing reimbursement inequities in these two counties.

I understand that the CMS is interested in the opinion of the California Medical Association regarding this proposed rule change. As a psychologist and allied professional, I have observed the negative impact of the present rules on providers and patients alike. Santa Cruz County is one of the highest cost-of-living areas in the country, yet we have one of the lowest reimbursement rates in the state.

Though I strongly support the proposed changes for Sonoma and Santa Cruz Counties, it is important to note that we in Santa Cruz County are concerned that the current changes will not solve the problem for Monterey County, which MBPA also represents. Yet, like Santa Cruz County, Monterey County has grown significantly in the last 10 years and has been facing the same payment discrepancies between the neighboring counties that we have. As a result, Medicare recipients in Monterey County have also experienced difficulty in finding physicians, psychologists and other service providers. I ask that you seriously consider including Monterey County in future revisions.

Once again, I strongly support your proposed revision to the physician payment localities in California.

Respectfully yours,

With w Juston Dla)

California Licansed Paychelpist

California Licansed Paychelpist

Second policy. New dodos
aren't coming into the county
because they cannot
afford to live here.

HMO's are failing-hospitals
are closing, many are
Left without adequate
case.

50-please vote to correct the reconsument rate! Montha Popue For voting to increase the reimbursement note to Sonoma County doctors.

My doctor of over twenty years closed his practice is joined traiser because he was actually being money. I had an actually being difficult time finding any doctor who would accept Medicare patients even though I carried a

Dick Linebarger P.O. Box 1470 Felton CA 95018

CENTER FOR MEDICARE SERVICES

P.O. BOY 107

BALTIMORE :M:D 21244

9, 18, 05

Dear CENTER FOR MEDICARE SERVICES.

I am a 69 1/2 year old guy that receives MEDICARE services.

I do not think that MEDICARE pays enough to Doctors in Santa Cruz County. When I went to have some tests made in my Cardiologists office and when I saw from the copy of services that you paid for for that visit and tests I was very upset. I asked Dr. O'GRADY how his office could do such a complex and time consuming test at the price you paid for it. He told me that he lost money whenever he provided services with a medicare payment plan. Whenever I, or my wife, are in need of some medical specialist we have to do a lot of looking to find one that will accept either of us as a patient. You pay way to little for doctors in a county where the median value of owner occupied houses is \$377.500.

I understand that you are looking at the possibility of raising the amount you pay to doctors in Santa Cruz County.

Please do so.

Satyagraha July

Dick Linebarger



Human Resources Agency

Adult & Long Term Care Division
Administrative Division
Don Allegri, Division Director
Mailing Address: PO Box 1320, Santa Cruz, CA 95061
1400 Emeline Ave, Santa Cruz, CA 95060
Phone (831) 454-4391 Fax (831) 454-4290
www.hra.co.santa-cruz.ca.us

9/16/05

Centers for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1502-P P. O. Box 8017 Baltimore, MD 21244-8017

Re. File Code CMS-1502-P

Issue Identifier: GPCI's / Payment Localities

Dear Sirs:

I am writing as the Director of Adult & Long Term Care Services, a division of the Human Resources Agency in the County of Santa Cruz, California. This letter is sent to strongly support your proposed revision to physician payment localities in California recently published in the reference rule. The great difference between the cost of medical practice in Santa Cruz County as measured by GAF cost values and the low rate of reimbursement due to being assigned to Locality 99 has made recruitment and retention of physicians willing to serve Medicare beneficiaries very difficult. This further compromises the medical treatment options for the clients served in our programs.

We were pleased to see that your proposed rule would alleviate this problem by removing Santa Cruz and Sonoma Counties from Locality 99 and placing them into unique localities. We commend your efforts to rectify this long-standing inequity. Your proposal will help to ensure access to necessary health care services. The proposed rule is fair. Neighboring counties to Santa Cruz and Sonoma have some of the highest payment levels for physicians in the nation. The adjustment you propose appropriately addresses this payment imbalance. This revision would bring you closer to your goal of reimbursing physicians based on the cost of practice in their locality.

Sincerely,

Don Allegri

Director of Adult & Long Term Care Services

Human Resources Agency County of Santa Cruz

4453 La Paz Lane Santa Rosa, CA 95404 September 20, 2005

Centers for Medicare & Medicaid Services Department of Health and Human Services PO Box 8017 Baltimore, MD 21244-8017

Dear Sir or Madam:

I am a resident of Sonoma County, California. I am a licensed Marriage Family Therapist, a Registered Nurse, and a Public Health Nurse. I am also the mother of a child with severe special needs.

I know how important adequate reimbursement is for health care providers so that they can continue to serve the poor, elderly, and disabled. In some areas of medicine there are only one or two providers who will take new Medicare patients. This impacts all of our society: families, schools, businesses, and the legal system, as individuals who need treatment are unable to receive it. People who are unable to obtain treatment for psychiatric illness may require more intensive treatment at greater cost and further suffering. Those with chronic medical conditions need ongoing care so that they can prevent more costly hospitalizations or worsening of their chronic illness.

It is important for Sonoma County health care providers to be reimbursed for their services so that people who need their services have access to them. When health care providers leave because they can not afford to live here they are no longer available to provide care to any of the other citizens of the county.

My son has private insurance that covers many of his needs. Some of his peers do not. They all deserve good care and those who provide treatment deserve to be reimbursed in a manner that encourages them to continue to care for those on Medicare and to remain in our community.

Please increase the rate of reimbursement by 8% for the healthcare providers in our county.

Sincerely,

Carol L. Hasenick, RN, PHN, MFT

Carl Glasenes RAPHN MITI

September 19, 2005

Centers for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1502-P PO Box 8017 Baltimore, MD 21244-8017

Re: GPCIs

We are writing with regard to the possible Medicare proposal to create a new payment locality for Sonoma County. We strongly support this action. The regrettable fact is that Sonoma County has become a very expensive place to live and work. Our understanding is that in a new locality, the reimbursement rates used by Medicare would conform more closely to the actual expenses incurred by physicians and other health service providers than is currently the case.

This is important because established doctors are leaving the area due to financial pressures and both the quantity and quality of care for both Medicare beneficiaries and other patients are being jeopardized. There is a substantial Medicare population in this county, and absent a realistic payment schedule, the ability to attract and retain physicians locally is being compromised.

We strongly urge you to implement the proposed change Sonoma County's payment locality in the interest of fairness and our communities continued access to high quality medical care.

Respectfully, MMas G. abrams

Thomas G. Abrams Anne M. Abrams 1702 Barlow Ln.

Sebastopol, CA 95472

cc: Enclosed two copies

33 35 C

Larry E. Mitchell 901 Russell Avenue # 131 Santa Rosa, Ca 95403 (707) 544-5498

GPCIS

CENTER FOR MEDICARE & MEDICAID SERVICES DEPARTMENT OF HEALTH AND HUMAN SERVICES ATTENTION CMS-1502-P P.O. BOY 8017

BALTIMORE, MD. 21244-8017

DEAR SIRS,

PLEASE HELP STABILLIZE OOR MEDICAL COMMUNITY BY INCREASING THE REIMBURSEMENT RATE FOR SONOMA COUNTY BY ELOSHT PERCENT. THANK YOU FOR YOU GOOD WORK.

SINCERELY, Janmy Mustdeam

September 10, 2005 To Medicare - all y you who have the power to Change for the letter the payment locality" of Soroma County. Our doctors now receive less reinbursament for sirvices rendered to their patients thou doctors in our neighboring Counter of Marin and Napal Danta Rosa itself is a real-live City of over 180,000 persons. The Citizens of Sonoma County are not all spridd - out on large ranches or forms! We need our doctors and Our doctors need four rein -burgament for their services.

Blease use your vote to bring
"payment locality" up to date
in line with our neighbors
in Marin and Napa!

Thank you

Marjorie Greefhend
Registered Voter Home Commer
3121 Hartley Strine
Santo Rassel, CA 95405

P.O. Box 1205 Guerneville CA 95446

September 20, 2005

To: GPCIs

From: JoAnn Cipra

RE: Medicare reimbursement in Sonoma County California

I want my voice to be heard! I am requesting that Medicare increase the reimbursement rate in Sonoma County California by at least 8% to bring our County back in line with current Medicare reimbursement standards.

At this time, I have very few choices of medical doctors who are accepting Medicare insurance in Sonoma County. The reimbursement fees simply do not cover the doctor's expenses. What this means to me as a senior citizen, I cannot get the medical treatment that I need. I pay the Medicare fee each month, plus \$150 a month for a Blue Cross Insurance supplement. I have NO coverage for dental, prescriptions, eye glasses, hearing aid. It takes nearly all my income just to cover my health expenses. This is NO way to live in my retirement years.

Please increase the reimbursement to Sonoma County doctors so I can at least see the professionals I need to.

I think it is very disheartening the manner in which many of us senior citizens are forced to live under the current administration. It is a disgrace to this country that it more and more life is only for the rich.

Sincerely,

JoAnn Cipra

JoAnn Cog

RENAL LEADERSHIP COUNCIL

Providers of Quality Care for the Nation's Dialysis Patients

September 20, 2005

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

Re: CMS-1502-P: Preliminary Comments of the Renal Leadership Council on the Physician Fee Schedule Proposed Rule

Dear Administrator McClellan:

I am writing on behalf of the Renal Leadership Council (RLC) to present our members' preliminary views about the Proposed Rule for Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year [CY] 2006 (Proposed Rule). 70 Fed. Reg. 45764. The RLC is a coalition representing the four largest entities providing dialysis care and services to Medicare beneficiaries: DaVita, Inc.; Fresenius Medical Care North America; Gambro Healthcare/USA; and Renal Care Group. Collectively, these suppliers operate more than 2,700 dialysis facilities in 42 states that provide dialysis care to approximately 200,000 patients. In addition to this letter, the RLC plans to submit more detailed comments on the Proposed Rule.

The RLC is pleased that CMS published a correction to the proposed End Stage Renal Disease (ESRD) drug add-on adjustment. As the Agency has recognized, the Proposed Rule did not account for three "J"-code changes implemented in 2003 and incorrectly calculated the weight for EPO by including expenditures for hospital-based facilities. Without this correction, the drug add-on adjustment would have inappropriately taken dollars out of the ESRD program in contrast to congressional intent that the changes be budget neutral. The RLC appreciates the opportunity members had to raise our concerns with the Agency so early in the comment period and the Agency's prompt review and response to them.

As noted in our discussions with CMS, our members are also concerned about several critical issues related to the calculation of the drug add-on payment that are not addressed in the correction notice. Specifically, the RLC urges CMS to:

• Fix the drug add-on adjustment by (1) adjusting the trend factor used to calculate the add-on to reflect the historical trend for ESRD drugs; (2) estimating appropriately the 2006 ASP+6 percent for calculation of the add-on; (3) ensuring that the Agency

has correctly estimated the amount of spending on syringes used to administer EPO, which is directly related to the actual number of EPO administrations; and (4) calculating separate add-on adjustments for hospital-based and independent facilities to reflect the intent of Congress.

• Provide an appropriate, stable methodology for the reimbursement of ESRD drugs by (1) ensuring the timeliness of updates; (2) protecting small independent facilities that are disadvantaged by a methodology that relies upon averages rather than on the most current data; and (3) recognizing the impact a single, dominant product – EPO – has on prices.

I. Calculating the drug add-on adjustment

A. Calculating the correct growth factor

CMS should correct its calculation of the trend factor used to determine the drug add-on adjustment to reflect the historical growth rate of ESRD drugs. CMS has proposed to use an EPObased growth estimation of 9 percent to determine the amount at which total ESRD drug expenditures will grow in CY 2006. This percentage does not reflect the historical trend factor. MedPAC has consistently indicated an historical trend factor significantly higher than 9 percent. For example, in the March 2005 report, MedPAC calculated the increase in spending for separately billed drugs other than EPO as 17 percent per year between 1996 and 2003 and 14 percent per year for EPO alone during the same period. In a report commissioned by the Kidney Care Partners (KCP), The Moran Company (TMC) also indicated that CMS's proposed estimate is "materially lower than the drug trend observed in the last few years for which ESRD drug claims data are publicly available."2 TMC's analysis of the publicly available 5 percent sample data indicates a growth trend of approximately 11.2 percent from 2001-2003.3 Although it may be true that there is no clear and consistent pattern of year-to-year changes in drug spending, using the aggregate trend rather than an artificial annual trend will produce meaningful differences in the drug add-on adjustment.4 When comparing these different approaches, TMC calculated that within 3 years, the use of a 9 percent growth rate rather than an 11.2 percent growth rate would result in a 6.18 percent difference,

3Id.

4*Id*.

¹MedPAC, "Report to the Congress: Medicare Payment Policy," 123 (March 2005).

²The Moran Company, "Analysis of the Proposed 2006 Update to the ESRD Prospective Payment System" 6 (September 2005).

assuming a stable base.⁵ Because the calculation of the growth factor significantly affects the overall add-on percentage, it is critical that CMS use the more accurate historical trend data.

In addition, the RLC disagrees with the Agency's assessment that it is "reasonable to correlate the growth of Epogen and separately billable drugs in an independent facility, since Epogen constitute[s] the largest amount of drugs dispensed in an independent facility." 70 Fed. Reg. at 45791. Even though it is true that independent facilities dispense more EPO than the other separately billable drugs, there is no evidence that this fact necessarily leads to the conclusion that the growth rate for other separately billable drugs matches that of EPO. The RLC members' experience indicates that the growth of several of the other separately billable drugs historically has exceeded the growth rate of EPO. As already noted, MedPAC also recognizes this difference in trends. In its March 2005 report and contrary to the assumption in the Proposed Rule, MedPAC estimated a difference three-percentage points in the growth trends of EPO and the other separately billable drugs.⁶

Given the calculations of significantly higher percentage increases in the growth trend by MedPAC and TMC, as well as MedPAC's ability to estimate different growth rates for EPO and other separately billable drugs, it seems clear that CMS has miscalculated the trend factor and applied an incorrect assumption. Thus, the RLC urges CMS to develop separate trend factors for EPO and other separately billable drugs and to use historical data that are also available to the public for verification.

B. Estimating the 2006 ASP+6 percent

The RLC is concerned that the proposed methodology for calculating the 2006 ASP+6 percent for purposes of determining the drug add-on adjustment will result in an understatement of reimbursement and will not be budget neutral. Any methodology adopted should be based upon the most recent manufacturer pricing data available – rather than a four-quarters average – to more accurately reflect price changes in the payments.

CMS should include an inflation factor that represents historical trends of ESRD drugs only, not all drugs in the aggregate. The proposed inflation factor of 5.7 percent, which is the forecast of the Producer Price Index (PPI) for all prescription drugs, does not reflect the actual ESRD drug trends. The table below shows the recent ASP+6 percent trends for ESRD drugs, the actual trend shows declining prices of 1.2 percent overall and 6.3 percent for the non-EPO drugs.

⁵*Id*.

⁶See supra, note 1.

Dr. Mark McClellan September 21, 2005 Page 4

Drug	Jan'05 Payme Limit	nt	Apr'05 Paymer Limit	nt	Jul'05 Payme: Limit	nt	Jul'05 vs. Jan'05
Epogen	\$9.317		\$9.250		\$9.307		(0.1%)
Zemplar	\$4.017		\$3 .971		\$3.871		(3.6%)
Venofer	\$0.362		\$0.365		\$ 0.365		0.8%
Hectorol	\$2.797		\$2.784		\$ 1.501		(46.3%)
Ferrlecit	\$4.829		\$4.726		\$ 4.713		(2.4%)
Infed	\$11.060		\$11.218		\$11.223		1.5%
Carnitor	\$14.649		\$11.122		\$12.174		(16.9%)
Alteplase	\$30.152		\$30.089		\$30.772		2.1%
Calcitriol	\$0.710		\$ 0.859		\$0.623		(12.3%)
Vancomycin	\$ 2.419		\$3.188		\$2.983		23.3%
Weighted Avg ASP+6%							
Total	\$	7.69	\$	7.58	\$	7.60	(1.2%)
Non-Epogen	\$	4.27	\$	4.06	\$	4.00	(6.3%)

A broad industry update trend of 5.7 percent is not an appropriate estimate for ESRD.

C. Estimating of the number of EPO administrations

Additionally, the RLC is concerned that CMS has overstated the number of administrations of EPO in its calculation of the drug add-on adjustment. In the Proposed Rule, CMS estimates the number of administrations of EPO to deduct the 50 cents included in EPO payments for syringes from the total 2005 spending for this drug. CMS calculated the aggregate syringe value to be \$1.6 million for hospital-based facilities and \$26.8 million for independent facilities. 70 Fed. Reg. at 45791. According to TMC analysis, even if facilities administered EPO in conjunction with each of the 34.5 million projected dialysis treatments, the total amount of payments attributable to syringes would be \$0.50 * 34.5 million = \$17.25 million in the aggregate. Because not all patients receive EPO during each treatment, that estimate also overstates the true cost of syringes. It is more likely that the amount would be \$15 - 16 million. The RLC strongly encourages CMS to modify its estimation of the amount attributable to syringes for purposes of calculating the drug add-on adjustment.

⁷See supra, note 2 at 8.

D. Establishing two drug add-on adjustments

If CMS maintains distinct drug reimbursement methodologies for hospital-based and independent facilities, it should establish distinct drug add-on adjustments. CMS has incorrectly interpreted Section 623(d) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) to require it to adopt a single add-on adjustment for both hospital-based and independent facilities. This interpretation ignores statutory rules of construction and the legislative history. It is also inconsistent with CMS precedent and public policy. Therefore, the RLC urges CMS to revise its interpretation of this section and to implement two separate drug add-on adjustments.⁸

The plain language and legislative history of Section 623 requires the creation of separate add-on adjustments because both demonstrate that Congress did not seek to upset the existing balance between hospital-based and independent facilities. Congress did not require CMS to adopt a single reimbursement methodology for separately billable drugs. See 42 U.S.C. § 1395rr(b)(13)(A); H. Rep. No. 108-391 at 683-87. The text and Conference Report indicate that Congress intended to modify only the payments for erythropoietin and drugs billed separately by independent facilities. If Congress had intended to establish a single reimbursement methodology for all drugs billed separately by hospital-based and independent facilities, it would have expressly eliminated the authority upon which CMS relies to use a cost-based methodology to reimburse hospital-based facilities for separately billable drugs. It did not. See Social Security Act § 1861(v). The only changes Congress made were to the methodology the Agency employs to reimburse independent facilities for all separately billable drugs and hospital-based facilities for EPO.

Because Congress maintained the distinction in the reimbursement methodology, it would be inconsistent for the Agency to adopt a single drug add-on adjustment to apply across the different methodologies. The clear intent of Congress was for the Agency to establish separate drug add-on adjustments. In addition to the text and legislative history, the bill's managers – Sens. Grassley, Baucus, Santorum, and Conrad – have indicated in a letter to CMS that they envisioned two distinct add-on adjustments as well. Other agencies also support this interpretation. For example, when the Office of the Inspector General (OIG) conducted its congressionally mandated study to determine the cost of separately billable drugs, it expressly excluded the hospital-based facilities from its analysis, consistent with the mandates of the MMA.

⁸In addition to this brief analysis, the RLC has prepared a detailed legal analysis to present to the CMS Office of the General Counsel in the coming days.

⁹OIG, "Medicare Reimbursement for Existing End Stage Renal Disease Drugs" (May 2004).

CMS incorrectly asserted in the CY 2005 Final Rule that the use of the word "difference" in the singular form requires the Agency to establish a single, integrated add-on percentage. In addition to being inconsistent with the Agency's initial interpretation of the statute, it also fails to comply with the statutory rule that states that legislative terms that are singular in form may apply to multiple subjects or objects. See Smith v. Zachary, 255 F.3d 446 (7th Cir. 2001); Johnson v. Penrod Drilling Co., 803 F.2d 867 (5th Cir. 1986); see also, 1 U.S.C. § 1 ("[i]n determining the meaning of any Act of Congress ... words importing the singular number include and apply to several persons, parties, or things). Thus, CMS's assertion that it must interpret the term "difference" as requiring only one add-on adjustment is incorrect. 10

A single drug add-on adjustment also thwarts Congressional intent by providing a windfall to hospital-based facilities and reducing the overall reimbursement amount independent facilities receive. According to TMC's analysis, the windfall problem would continue under the Proposed Rule if adopted by increasing hospital-based facility reimbursement approximately \$54 million and lowering the reimbursement to independent facilities by the same amount in 2006 alone. The two-year combined effect would result in a decrease of \$82 million to independent facilities. The single add-on adjustment would lead to a loss of approximately \$2.00 per treatment for independent facilities, while hospital-based facilities will receive a windfall of approximately \$11 per treatment in addition to their profits on separately billable drugs. Independent facilities provide the majority of care to individual with kidney failure. The continued extraction of funding from their reimbursement will negatively affect access to care and drive patients to higher cost settings. Allowing this windfall inappropriately rewards hospital-based facilities for providing the same care that independent facilities do. In addition to being bad policy and inconsistent with Congress's

¹⁰In addition, CMS incorrectly asserts that 42 U.S.C. § 1395rr(b)(7) requires it to adopt a single add-on adjustment to allow it to maintain higher payments to hospital-based facilities. 69 Fed. Reg. at 66320. This interpretation is incorrect because 42 U.S.C. § 1395rr(b)(7) requires only that the rates between the types of facilities be different; the statute does not specify that the hospital-based rate must be higher. 42 U.S.C. § 1395rr(b)(7).

CMS also incorrectly implies that it must adopt a single add-on adjustment because to do otherwise would require different calculations for budget neutrality and the case-mix adjustors based upon facility type. Nothing in the statute requires the calculation of the add-on adjustment to be implemented in the same manner as the case-mix adjustors or the budget neutrality requirement. In addition, it is not appropriate to compare the case-mix adjustors to the drug payment add-on because they are based on different underlying payment methodologies. Providing separate add-on adjustments would result in different payment rates to independent and hospital-based facilities, but would not run afoul of the budget neutrality requirement, as CMS itself implied in the preamble to last year's Notice of Proposed Rulemaking for CY 2005 by stating that providing separate add-on adjustments was a legitimate alternative to a single add-on adjustment.

¹¹ See supra, note 2 at 9.

mandate, it also contradicts the statutory requirement to establish payment methodologies that encourage efficient care. See 42 U.S.C. § 1395rr(b)(7).

To comply with Congressional intent, CMS should ensure that the drug add-on adjustment provides an appropriate offset to the legislated changes in the drug reimbursement methodology. This means that hospital-based facilities must have an add-on adjustment that accounts for changes in EPO payments and that independent facilities must receive an add-on adjustment that accounts for changes in the reimbursement for <u>all</u> separately billed drugs, including EPO.

II. Determining the appropriate methodology for reimbursing separately billable drugs

Establishing a new methodology for reimbursing all separately billable drugs provided by independent facilities and EPO provided by hospital-based facilities will dramatically affect the overall reimbursement to dialysis facilities, as well as the ability of these facilities to provide high quality care to patients. The RLC strongly urges CMS to consider the economic hardship inherent in a system in which reimbursement lags real provider payments particularly in an environment where drugs are a major component of the therapy provided, and a single, dominant product (EPO) can materially impact this equation.

The ESRD program presents unique challenges when establishing a reimbursement methodology for drugs. More than in any other aspect of outpatient care, drug therapy is a significant component of the life-sustaining services delivered to dialysis patients. Patients receive one or more of these drugs during each of their thrice-weekly dialysis sessions. Drugs account for approximately 40 percent of revenues, with EPO accounting for 70 percent of this amount. Another challenge is that the drug that has had the greatest impact on improving patient care and quality of life and is administered to most patients – EPO – is provided by a single manufacturer. This manufacturer dominates the market.

Because of these factors, facilities are particularly sensitive to the lag time between a manufacturer's increase in price and its inclusion in the reimbursement rate. Using a system that relies upon annual averages rather than the most current data means that facilities will receive payments that do not cover the current cost of the drugs they provide. Given the already negative Medicare margins, as recognized by MedPAC, ¹³ and the lack of an annual update mechanism, facilities simply do not have the financial flexibility to make up such differences.

¹³ See supra, note 1 at 129.

In addition to being disadvantaged by a methodology with a lag time between payment rates and actual costs, small, independent facilities would also suffer under a system that relies upon industry averages. These facilities are most often located in underserved, low-population, rural areas. They do not have the same buying power or economies of scale that larger facilities do. This difference usually results in such facilities paying higher prices for drugs. If they are reimbursed at an average amount that includes the significantly lower prices negotiated by large dialysis organizations, it is unlikely that they could cover the true cost of their drugs with Medicare payments.

In addition to these comments, the RLC may respond more extensively under separate cover to the proposal to shift to an Average Sales Price methodology. The RLC is currently working with TMC to evaluate the effect of this change and will provide CMS with comments based upon this work before the end of the comment period. Consistent with recommendations from CMS personnel during a recent meeting, the RLC is scheduling a meeting with Liz Richter and Amy Bassano to discuss alternatives and develop a workable solution to this issue.

V. Conclusion

The RLC members sincerely appreciate your review of our concerns and look forward to working with the Agency to resolve them. Again, the RLC is extremely pleased that the Agency issued a correction acknowledging the errors related to the "J"-codes and the resultant weighting changes for the top ten ESRD drugs, including EPO. We look forward to having the opportunity to discuss these, as well as our subsequent, comments with you in person. In the meantime, please do not hesitate to contact Kathy Means at 202-457-6328 if you have questions regarding these comments.

Sincerely,

Executive Director

Analysis of the Proposed 2006 Update to the ESRD Prospective Payment System

September, 2005

THE MORAN COMPANY

Analysis of the Proposed 2006 Update to the ESRD Prospective Payment System

On Monday, August 8, 2005, the Centers for Medicare and Medicaid Services (CMS) published a proposed rule setting forth policy and methodology changes for 2006 in the prospective payment system for End Stage Renal Disease (ESRD) services under Medicare. On August 26, CMS posted a correction notice on its Web site revising some of the data used to calculate the 2006 payment amounts, and providing corrected update adjustment factors. The Moran Company was commissioned by Kidney Care Partners (KCP) to conduct an analysis of the data and methodology used by CMS to determine its proposed payment policy, in order to identify methodology and data issues that might warrant comments on the proposed rule. This report presents our findings regarding issues of potential technical concern that KCP may wish to address in communications with the agency going forward. Our analysis is directed toward the CMS data and methodology as amended by the correction notice.

Policy Summary

In the Medicare Modernization Act (MMA), Congress mandated a number of important policy changes to reimbursement for treatment of dialysis patients. Prior to 2005, Medicare made two types of payments to ESRD providers:

- They were paid a flat dollar "composite rate" payment per dialysis treatment.
- They were separately reimbursed for drugs under the then-prevailing payment methodology under §1842(o) of the Social Security Act¹, which provided for reimbursement of drugs at Average Wholesale Price (AWP) minus 5% (although erythropoietin (EPO) for ESRD use was reimbursed at a separate statutory rate of \$10.00 per 1,000 units.)

In the MMA:

- The Congress provided a uniform 1.6% update to the base composite rate for both hospitals and free-standing facilities.
- The Congress directed that, in lieu of prior payment methodologies, ESRD providers would be reimbursed for the actual acquisition cost of drugs.
- The statute provided a prospective adjustment to the basic composite rate, commonly called the "drug spread add-on", to reflect compensation to ESRD providers for the loss of the "spread" between prior payments and acquisition cost.

¹ Statutory references in this paper, unless otherwise noted, are to the Social Security Act, as amended by MMA.

 The statute authorized the Secretary to make case mix adjustments for ESRD patients, and to adjust the wage indexing methodology applied to ESRD payments.

CMS implemented these payment changes for 2005 by rulemaking in calendar year 2004. In that process, CMS made a number of significant policy choices:

- It elected to use pricing information collected by the Health and Human Services
 Office of Inspector General (OIG) to set "average acquisition cost" payments for
 ESRD drugs.
- It elected to implement the drug spread add-on as a percentage adjustment (8.7% in the Final Rule) applied uniformly to both the hospital and free-standing facility rates.
- It implemented a limited system of case mix adjustment.
- It deferred implementation of wage index adjustments.

For 2006, CMS is proposing to revisit some, but not all, of these policy choices. Highlights of the proposed rule include the following:

- For 2006 and later years, CMS proposes to move ESRD drug reimbursement from the current schedule based on acquisition costs to payment under §1847A, which provides for reimbursement of all ESRD drugs at average sales price (ASP) plus 6%. Beginning 1/1/06, these payment rates will be updated quarterly.
- CMS will update the drug spread add-on required by the statute in 2006 to reflect this change, and to incorporate later data.
- CMS will implement a transition to a new wage index policy based on the recently-revised structure for wage area classification implemented for other payment systems.
- CMS is proposing no changes in the case mix adjustment system implemented in the 2005 Final Rule.

Based on our review of these policy changes, and the data and methodological issues that underlie them, we believe that the primary issues of concern to the KCP members are likely to flow from the way in which CMS elected to update the drug spread add-on adjustment, which it is proposing to increase from the 8.7% adjustment provided in the 2005 rates to an 11.3% adjustment for 2006.²

The Drug Spread Add-On Methodology

While CMS draws on data from a variety of sources to determine the amount it proposes for the drug spread add-on adjustment, the critical variables are presented in Figure One.

² This amount was corrected, in the Web site notice, from the published value of 8.9%.

Figure One

% ADD-ON = <u>WTD % CHANGE * PRIOR LAW DRUG \$\$\$</u> TREATMENTS * WTD COMPOSITE RATE

As indicated in that figure, there are four key variables that drive calculation of the adjustment:

- The percentage change in payment rates for ESRD drugs between prior policy and the proposed payment methodology, weighted by volume across the drugs actually used by ESRD providers.
- CMS's estimate of the volume of drug spending that would have occurred under prior law.

These two values are multiplied together to obtain an estimate of the aggregate dollar value of the difference between prior payment policy and the proposed policy. This value is then related to the composite rate via two additional variables.

- The estimated number of dialysis treatments to be performed in the adjustment year; and
- The weighted average value of the composite rate (which we estimate, using CMS data, to be \$128.81 in 2005 and later years).

First, the estimated dollar difference between prior and proposed drug payment policy is divided by the estimated treatments to convert it into a per treatment value. This value is than divided by the \$128.81/treatment weighted composite rate to determine the add-on percentage.

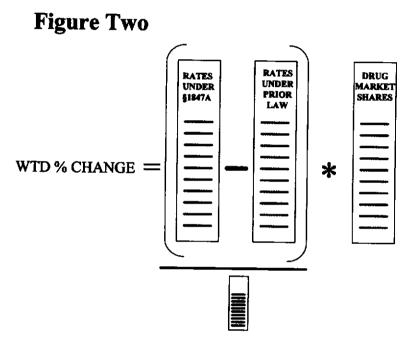
As indicated in Figure One, this methodology creates a linear relationship between the estimate of the add-on percentage, and changes in any of these four variables. Holding the other three variables constant, a ten percent increase in the value of a variable in the numerator will increase the add-on percentage by ten percent, e.g., from 11.3% to 12.4%. Conversely, a ten percent increase in the estimated number of treatments would reduce the value of the add-on percentage by a factor of 1/1.1, or by 9.09% percent.

Based on our analysis, we do not believe that the variables in the denominator of this calculation have a meaningful effect on the accuracy of the CMS add-on estimate. With respect to the composite rate, this is true tautologically, since the composite rate values are fixed in statute and hence invariant. While CMS slightly reduced the estimate of treatments from the 35.8 million estimate in the 2005 Final Rule to the 35.4 million value used in the proposed rule, this change of slightly more than 1% in the numerator would cause only a comparably small change in the add-on percentage.

Variations in the data CMS uses in the numerator of this calculation, however, could have a more material effect, since our analysis suggests the potential for greater uncertainty over the appropriate values to use for each of these variables. In the sections that follow, we discuss each of these values in turn.

The Weighted Percentage Change Calculation

The methodology CMS has employed in all three rulemakings related to the ESRD prospective payment system is summarized in the graphic in Figure Two.



Under this methodology, CMS determines three sets of values for each of the top ten (volume) ESRD drugs:

- The dollar per unit value of the post-MMA drug payment policy (in this case, ASP + 6%) for each drug.
- The dollar per unit value of the pre-MMA drug payment policy (\$10/1,000 for EPO, AWP-5% for the others); and
- The respective market share of the drug among the top ten, weighted by payment volume.

Using these variables, CMS calculates a percentage change from pre- to post-policy prices for each of the ten drugs, and then produces a composite percentage change weighted by payment market share. Table One shows the data CMS is using in this proposed rule as amended by the correction notice, to make this calculation.

Table One

Calculation of Weighted Percentage Change Due to Payment Policy Change

	Ta	ble 20	Ta	ble 21	Table 22	Table 23	
Drugs	ASF	P+6 2Q 05	AW	/P 2Q 05	% of Top Ten	% Change	Weighted Impact
EPO	\$	9.25	\$	10.00	69.33%	7.50%	-5.20%
Calcitriol	\$	0.86	\$	1.40	0.84%	38.70%	-0.33%
Doxecalciferol	\$	2.78	\$	3.11	1.48%	10.60%	-0.16%
Iron dextran	\$	11.22	\$	18.04	0.23%	37.80%	-0.09%
lron sucrose	\$	0.37	\$	0.66	7.03%	45.10%	-3.17%
Levocarnitine	\$	11.12	\$	36.75	0.77%	69.70%	-0.54%
Paracalcitol	\$	3.97	\$	5.37	14.61%	26.00%	-3.80%
Sodium ferric glut	\$	4.73	\$	8.23	4.96%	42.60%	-2.11%
Alteplase, recomb	\$	30.09	\$	38.82	0.56%	22.50%	-0.13%
Vancomycin	\$	3.19	\$	5.55	0.19%	42.60%	-0.08%
							-15.59%

The data values for the pre- and post-policy prices are based on administrative data. The ASP-based payment values are derived from manufacturer ASP reports for the second calendar quarter of 2005; the values published track to the values presently reported for this period on the CMS Web site. The prior law payment values are derived from published AWP prices for the first quarter of 2005; these have been updated to the second quarter using an increase percentage that annualizes to 3.0%.

As the data suggest, the percentage change calculated using this methodology is highly sensitive to the market share assumptions, particularly that for EPO. In contrast to all other drugs, the pre- to post-policy payment change for EPO is only 7.5%, in comparison to the 10-70% changes for the other products. Since EPO is the dominant product, relatively small changes in the market share attributed to EPO can produce large changes in the reported composite percentage change — which as noted above produces a proportional increase (or decrease) in the add-on percentage.

- CMS indicates in the proposed rule that the market share values it is using are derived from 2004 claims data. Since these data were not available in time for this analysis, it is impossible, at this point, to verify this calculation.
- These data, however, were completely revised by the correction notice.
- In the proposed rule, CMS indicated that it would use full year market share data from 2004 a period prior to the change in payment methodology to weight this calculation. We believe that this is the correct methodology choice.
- Absent evidence that the revised data reflect errors, we believe that this
 calculation, as corrected, has been properly done.

Estimating Pre-Policy ESRD Drug Spending

As suggested above, the other major determinant of the accuracy of the drug spread addon adjustment percentage is the accuracy of CMS's estimates of pre-policy drug spending. A formal statement of CMS's approach to estimate these values would be the following:

Figure Three

PRIOR LAW DRUG $$$_{YEAR} = ACTUAL $$_{2003} * (1 + TREND)^{(YEAR-2003)}$

In its methodology description, CMS indicates that it bases its projections on actual claims data for drugs billed by ESRD providers in 2003. After conversations with CMS analysts involved in generating these estimates, we have checked their 2003 EPO spending estimates against publicly-available data from the 2003 5% Outpatient Standard Analytical File (SAF), and believe that the base values they are using are consistent with the data we see in the SAF.

To index these values forward to 2005 (and subsequently to 2006), CMS indicates that it performed an analysis involving 2005 claims data, in which they derived a year over year growth trend of 9% for EPO, and then applied that trend to update both EPO and non-EPO drug spending to 2005 (and then to 2006).

Since the 2005 claims data CMS employed in this analysis are not available to the public, we cannot verify the accuracy of this estimate, or test the applicability of this EPO-based trend to other products.

This value, however, is materially lower than the drug trend observed in the last few years for which ESRD drug claims data are publicly available. As CMS indicates in its discussion of this issue in the preamble to the proposed rule, there is no clear and consistent pattern of year-to-year changes in drug spending. In the aggregate, however, the trend is clearly upward: the 2003 drug spending totals for all ESRD drugs reflect an 11.2% compound annual increase over the level of ESRD drug spending in 2001.

Since, as noted above, the drug spread add-on percentage varies in direct proportion to changes in estimated prior law drug spending, even relatively small differences in assumed growth rates, when compounded over a 2-3 period, can produce meaningful differences in the drug spread add-on percentage. This reality is demonstrated in Table Two.

Table Two

Effect of Alternative Drug Spending Growth Assumptions

	9% Growth Rate	11.2% Growth Rate
2003 Base	100.00	100.00
2006 Estimate	129.50	137.50
% Difference		6.18%

As shown in this table, a 2.2% difference in the annual trend assumption employed in the CMS methodology would, compounded over the three year period between 2003 and 2006, result in a 6.18% difference in the value of prior law ESRD drug spending 2006, which, holding everything else constant, could increase the calculated drug spread add-on percentage from 11.3% to 12.0%%.

The exact effect of disparities in trend assumptions, over time, will depend on whether and how CMS makes future adjustments to reflect variance between forecast trends and actual changes in ESRD drug spending. The presentation in the proposed rule suggests that CMS intends to anchor its future calculations in historical drug spending data for CY 2004, and then to continually rebase the calculation to historical actuals before estimating a new prospective adjustment.

If this methodology is followed, the impact will depend on whether the variance between projected trends and actuals is random over time. If CMS overestimates trend in some years while under-estimating trend in other years, the cumulative effect of prospective adjustments would be neutral relative to the statutory intent to make budget-neutral adjustments to the drug spread add-on adjustment going forward.

If, however, there is a bias (even if inadvertent) in the relationship between forecast trends and subsequent actuals, errors relative to pure budget neutrality could accumulate over time. Table Three shows the potential magnitude of such effects.

Table Three

Effects of Lags in Adjustments to Drug Spread Add-On Calculations

	Base Year 2005	Year 1	Year 2	Year 3
Hypothetical CMS Projected Trend Hypothetical "Actual" Trend Drug Spend Add-On Units	100.00	9% 12%	9% 12%	9% 12%
Contemporaneous Estimates w. Retro Adjustment Actual Drug Spend Disparity		109.00 112.00 (3.00)	122.08 125.44 (3.36)	136.73 140.49 (3.76)

In this table, we have applied the stated CMS estimating methodology in a scenario in which drug trend was consistently estimated at 9%, but actual trend was retrospectively determined to be 12%. In each year, we have retrospectively adjusted the prior year's drug trend to the actual before applying the 9% forecast trend off that adjusted base. As the data presented in the table indicate, a consistent downward bias in the prospective estimate would mean that, even after reconciliation to known actuals, the drug spread add-on percentage calculation would accumulate errors. Since payments to providers would not be retrospectively adjusted to offset the prior underestimate, there would be a widening disparity between actual payments and true budget neutrality.

The Adjustment for EPO Syringes

In its projections of pre-policy drug spending, CMS correctly adjusts the values used to reflect the fact that, beginning in 2005, Medicare makes separate payment at \$0.50 per unit for syringes used to administer EPO for ESRD use. In the proposed rule, CMS indicates that the amounts of the adjustments made were \$1.6 million for hospital-based facilities and \$26.8 million for free-standing facilities. While claims data for 2005 are not yet available to directly check these values, there is reason to believe that these amounts may be overstated, resulting in a corresponding understatement of pre-policy drug spending in 2005 and 2006. The reason for this conclusion is that, even were it assumed that Medicare would pay for an EPO syringe in 100% of the estimated 34.5 million dialysis treatments, total spending on syringes would be only \$17.25 million across both settings of care. It is our understanding that intermediaries will reimburse only one syringe per dialysis treatment. We believe, therefore, that CMS should recheck the source of the data being used to make these adjustments.

Measuring the Effects of Uniform Adjustments on Free-standing Providers

Whatever judgment KCP members may reach about the accuracy of the drug spread addon adjustment percentage, CMS's decision to continue to make uniform adjustments to

³ If the prospective trend estimate reflected a consistent over-estimate, of course, the bias would work in the opposite direction.

both the hospital and free-standing rates means that a proportionate share of the adjustment will be paid to hospital-based providers in 2006, even though they will continue to be paid on a cost basis for drugs other than EPO. KCP members requested that we update our prior estimates of the magnitude of this effect to be consistent with the CMS proposed add-on percentage of 11.3%. Our findings from this analysis are presented in Table Four.

Table Four
Impact of Uniform Adjustment Policy on Free-Standing Providers

Estimates of Dollar Value of Reimbursement Policy Change

	2005 Base	2006 Increment (millions of dolla	2006 Implied urs)	Treatments	Base Rate	Adjustment Value (millions of	
Hospital EPO Freestanding Total	\$18 \$445 \$463	\$2 \$50 \$52	\$20 \$495 \$516	4,946,302 30,453,698 35,400,000	\$132.41 \$128.35	\$74 \$442 \$516	+\$54 -\$54

As these data indicate, the corrected CMS add-on percentage is consistent with an estimate that the MMA reimbursement policy change will lower EPO reimbursements to hospitals by approximately \$20 million in 2006, while drug reimbursements to free-standing providers would be lower by \$495 million. By applying a uniform percentage adjustment to both the hospital and free-standing rates, however, the CMS methodology weights the value of the adjustment toward hospital providers. We estimate that an 11.3% adjustment would increase hospital reimbursements by approximately \$54 million in 2006. This \$54 million gain relative to CMS's estimates of the reimbursement policy shortfall would be offset, however, by lowering reimbursements to freestanding providers by the same amount, or \$1.53 per treatment (\$54 million divided by 35.4 million projected treatments). If a uniform add-on policy is implemented in the Final Rule for 2006, the cumulative effect of this reallocation of the drug spread add-on would reduce payments to free-standing providers in 2005-2006 by \$82 million.

In evaluating the appropriateness of the uniform adjustment policy, KCP members asked us to evaluate how cost-based reimbursement for non-EPO drugs in the hospital setting affects the economics of dialysis treatment by hospital-based providers. To evaluate this question, we tabulated payments to hospital-based ESRD providers for non-EPO drugs as reported in the 2003 5% Sample Outpatient Standard Analytical File. Our findings are as follows:

Table Five
Non-EPO Drug Reimbursements by Provider Type

Drug	Average Payme				
	Free-Standing	Hospi	ital-Based	Hospital/Free-Standing	
Alteplase	\$	27.39	\$	52.03	190%
Calcitriol	\$	1.20	\$	4.62	384%
Doxercalciferol	\$	4.14	\$	9.50	229%
Iron Dextran	\$	13.98	\$	30.46	218%
Iron Sucrose	\$	0.58	\$	1.19	206%
Levocarnitine	\$	26.66	\$	28.72	108%
Paricalcitol	\$	4.34	\$	11.70	270%
Sodium ferric glut	\$	7.08	\$	18.26	258%
Vancomycin HCL	\$	5.45	\$	13.28	243%

These data are preliminary, and should be interpreted with considerable caution. This table reports the payment values, recorded at the level of individual claims, for dialysis provider bill types presented by both hospitals and free-standing providers. It is our understanding that, in paying ESRD claims from hospital-based providers, fiscal intermediaries annually establish prospective payment rates for ESRD drugs other than EPO based on hospital billed charge amounts for each drug, and the cost-to-charge ratio information presented on cost reports. This practice is consistent with the statutory payment policy of cost-based reimbursement for these drugs. We have confirmed that, in the underlying data, the drug-specific payment amounts do vary by hospital. Absent far more detailed analysis of these data, however, we cannot tell whether the significant observed disparities in reimbursement for these drugs between hospital-based and free-standing providers reflect actual reimbursement differences, rather than being artifacts of anomalies in unit coding of these drugs by hospital-based providers.

Summary Conclusions

As the discussion in the preceding sections makes clear, our analysis suggests that CMS's calculation of an 11.3% drug spread add-on, while materially corrected from the calculations presented in the proposed rule, may still be subject to some degree of uncertainty. Although CMS's estimate of dialysis treatments in either 2005 or 2006 could be a potential source of error, we do not believe such an error, if any, is likely to be material. By contrast, potential errors in either the policy change percentage, or the

⁴ In prior work, we have noted that unit coding errors in hospital outpatient departments for separately-reimbursed prescription drugs can be frequent. In the bospital OPPS, errors in coding translate directly into errors in payment, since the payment methodology works on a per-unit basis. In the instant case, however, if intermediaries are paying for drugs based on charge information rather than the unit count, payments for the drugs could accurately reflect the Medicare concept of reasonable cost even if the cost per observed unit appear inflated relative to the AWP-based payment policy applicable to freestanding centers in 2003.

estimate of prior law drug spending in 2005 and 2006, could be material. Though CMS has made a substantial effort to correct its calculation of the weighted change in payment rates between prior policy and current law, subsequent experience may show that CMS's estimate of a 9% drug growth trend may be understated. As noted above, consistent underestimates, if accumulated over time, could lower payments to ESRD providers relative to budget neutrality.⁵

⁵ In evaluating the accuracy of compensation for policy changes in drug reimbursement, it is also important to understand that, under the ESRD prospective payment methodology CMS has implemented, the portion of the payment intended to compensate providers for changes in drug reimbursement is subject to wage indexation. While this payment policy is clearly implied by the language of §623 of MMA, it has the effect redistributing the add-on value relative to the drug costs experienced by providers, which are generally based on uniform national market prices.



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American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN-

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September 22, 2005

Mark B. McClellan, MD, PhD Administrator Centers for Medicare and Medicaid Services Department of Health and Human 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 2006; Proposed Rule; CMS-1502-P

Dear Dr McClellan:

The American Academy of Pediatrics (AAP) appreciates the opportunity to provide comments on the August 8th Notice of Proposed Rulemaking entitled Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006. Although very few pediatric services are included in the Medicare program, payment policies introduced in Medicare are frequently adopted by the Medicaid program and eventually by private payors. Therefore, the Academy offers these comments on the proposed rule to ensure that new policies appropriately accommodate the unique aspects of health care services delivered by primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists.

Oral/Intranasal Immunization Administration Codes (90467-90468 and 90473-90474)

The Academy strongly applauds CMS for publishing the RUC-recommended relative value units (RVUs) for the oral/intranasal immunization administration codes (90467-90468 and 90473-90474). By virtue of this action, CMS has measurably reduced financial impediments to appropriate and timely immunizations, the full impact of which is magnified by the significant influence that Medicare payment policy has on the Medicaid program and the private sector.

Relative Value Units for Non-Covered Services

There remain two "N" (noncovered) status codes for which CMS has not yet published RUC-recommended RVUs:

- 1. Code 99173 (screening test of visual acuity, quantitative, bilateral) and
- 2. Code 92551 (screening test, pure tone, air only)

Codes 99173 and 92551 have been through the RUC, where direct practice expense inputs were approved and recommended for inclusion in RBRVS. However, vision and hearing screening are Medicare non-covered services. CMS' refusal to publish RVUs for such pediatric services even though the codes have gone through the same validated valuation process as active Medicare codes distinctly disadvantages children, their providers, and children's preventive health services. Based on our aforementioned arguments, we reiterate that CMS has a responsibility to publish RVUs for codes even when such services may not be covered under the Medicare program.

On page 66245 of the 2005 final rule (Vol. 69, No. 219, November 15, 2004), CMS noted, "because we have not yet established a consistent policy regarding the publication of RVUs for noncovered services, we will need to examine this issue further to carefully weigh the pros and cons of publishing these RVUs for noncovered services." The AAP believes that CMS already has a policy on noncovered services; it was established when CMS published RVUs for the preventive medicine services codes (99381-99397). Other than logistical considerations in the final rule document, we can see no "cons" in following such a precedent. In fact, as more non-Medicare payors adopt RBRVS, it becomes increasingly important to include noncovered services and their RUC-recommended RVUs on the Medicare physician fee schedule. While CMS does note that it has included practice expense RVUs for a small number of noncovered services on the CMS Web site, such a supplement will not have the same effect as will the inclusion of the RVUs on the actual Medicare physician fee schedule.

Considerations for the Final Rule: New CPT Codes

Neonatal Continuing Intensive Care Services (99300)

While the new CPT code (99300) for continuing intensive care services provided to neonates with present body weight of 2501-5000 grams is not included in the proposed rule, the Academy expects that in its final rule, CMS will accept the RUC's recommended work value for the code of 2.40. This relative value was recommended by the RUC during its April 2005 meeting, where results of a survey were analyzed to ensure that the recommended work value accurately accounts for physician resources expended with the typical patient.

Care Plan Oversight Services (99339 and 99340)

While the new CPT codes (99339 and 99340) for care plan oversight provided to patients not under the care of a home health agency, hospice program, or nursing facility are not included in the proposed rule, the Academy expects that in its final rule, CMS will accept the RUC's recommended work values for the codes of 1.25 (99339) and 1.80 (99340). These relative values were recommended by the RUC during its April 2005 meeting, where results of surveys were analyzed to ensure that the recommended work values accurately account for physician resources expended with the typical patient.

Moderate (Conscious) Sedation (99143, 99144, 99145, 99148, 99149, and 99150)

CPT 2006 will include a complete revision of the moderate (conscious) sedation codes, namely six new codes that allow differential reporting based on patient age and model of administration. The new codes represent five years of multispecialty facilitation with the ultimate outcome being the development of codes that eliminate double counting of the service of moderate sedation.

Given CMS' direct involvement in the development of these codes, it follows that the status indicator for the new codes should be changed from "B" (Bundled code. Payment for covered services is always bundled into payment for other services not specified. If RVUs are shown, they are not used for Medicare payment. If these services are covered, payment for them is subsumed by the payment for the services to which they are incident.) to "A" (Active code. These codes are separately payable under the fee schedule if covered. There will be RVUs for codes with this status. The presence of an "A" indicator does not mean that Medicare has made a national coverage determination regarding the coverage of the service. Carriers remain responsible for coverage decisions in the absence of a national Medicare policy.). Furthermore, it is expected that CMS will accept the April 2005 RUC recommendations for the new moderate sedation codes and include them in the 2006 RBRVS final rule.

Pulse Oximetry

The Academy would like to reiterate its objection to CMS' practice of not allowing separate payments for pulse oximetry (CPT codes 94760 and 94761) when the procedure is provided along with any other service(s) payable under the physician fee schedule.

Presently, CMS assigns codes 94760 (noninvasive ear or pulse oximetry for oxygen saturation; single determination) and 94761 (noninvasive ear or pulse oximetry for oxygen saturation; multiple determinations) status indicator "T" (Injections. There are RVUs for these services, but they are only paid if there are no other services payable under the physician fee schedule billed on the same date by the same provider. If any other services payable under the physician fee schedule are billed on the same date by the same provider, these services are bundled into the service(s) for which payment is made.). We suggest that a reasonable alternative would be for CMS to change the status indicator to "N" (Noncovered service. These codes are noncovered services. Medicare payment may not be made for these codes. If RVUs are shown, they are not used for Medicare payment.) or "R" (Restricted coverage. Special coverage instructions apply. If the service is covered and no RVUs are shown, it is carrier-priced.) in order to allow non-Medicare payors to utilize the RVUs to determine their fee schedules independent of Medicare payment policy.

Since pulse oximetry is not included in any of the office evaluation and management survey vignettes, the procedure should not be considered "bundled" into the office evaluation and management codes. Additionally, with the increase in the incidence of childhood asthma, pulse oximetry has become a standard of care for children presenting with respiratory distress symptoms. The procedure requires resources beyond those required for the evaluation and management of the patient in the office setting. For these reasons, the Academy feels strongly

that pulse oximetry should be considered a separate procedure and that payment should not be bundled into the office evaluation and management codes.

The Academy appreciates the opportunity to provide comments on the August 8th proposed rule and looks forward to working with CMS to ensure that the physician fee schedule accurately reflects the work value of physician practice and pediatric care.

Sincerely,

Carl D. Berkow & M.

Carol D. Berkowitz, MD, FAAP

President

CDB/ljw



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> Henry VanBrocklin, Ph.D. Lawrence Berkeley National Laboratory

September 7, 2005

NOT OPPS

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

Re:

File Code CMS-1502-P

Proposed rule for the Medicare Program regarding Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006 -- <u>NUCLEAR</u> <u>MEDICINE SERVICES</u>

Dear Administrator McClellan:

The Academy of Molecular Imaging (AMI)¹ appreciates the opportunity to comment on the proposed Physician Fee Schedule rule, as published in the Federal Register on August 8, 2005 by the Centers for Medicare and Medicaid Services (CMS). AMI comments specifically on the provision relating to physician referrals for nuclear medicine services with which they have financial relationships. Under the proposed rule, CMS would reclassify nuclear medicine services as Designated Health Services (DHS), thereby bringing them within the category of services covered by the physician self-referral law. AMI believes that this change would significantly limit beneficiary access to nuclear medicine services. Of special concern is its potential impact on the availability of positron emission tomography (PET) scans, which constitute an important share of Medicare-covered nuclear imaging. AMI respectfully requests that this proposed change not be included in the final rule for two reasons. First, Congress did not intend for the physician self-referral law to apply to nuclear medicine services because it recognized, as has CMS, that nuclear medicine is a distinct medical specialty from radiology. Second, nuclear medicine services are not at risk for the kind of over-utilization that the physician self-referral rules are designed to prevent.

Execution Line ALMI is a professional organization committed to advancing the field of molecular imaging. In addition to its annual conference, the AMI holds programs designed to educate clinicians, government agencies and the public about molecular imaging, and publishes a journal, Molecular Imaging and Biology.

However, in the event that CMS disagrees with AMI's recommendations and does reclassify nuclear medicine services as DHS, AMI requests that the final rule exempt from the prohibition on self-referrals physician ownership arrangements that have been formed in good-faith reliance on the existing regulations.

I. Nuclear Medicine Services are not DHS Under the Physician Self-Referral Statute

The statutory text, legislative history, and CMS's own long-standing interpretation of the physician self-referral law clearly support the exclusion of nuclear medicine from the definition of DHS. Congress specifically elected not to classify nuclear medicine services as DHS. Under Section 1877(h)(6) of the Social Security Act, DHS encompass only certain enumerated services, which do not include nuclear medicine. The statute specifically lists the following services:

clinical laboratory services; physical therapy services; occupational therapy services; radiology services, including magnetic resonance imaging, computerized axial tomography, and ultrasound services; radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment, and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health services; outpatient prescription drugs; and inpatient and outpatient hospital services.²

The proposed rule acknowledges that the statute does not mention nuclear medicine. In order to bring nuclear medicine within the scope of the statutory limitations on physician self-referral, the proposed rule must therefore argue somehow that nuclear medicine is encompassed in one of the congressionally enumerated categories. CMS proposes to accomplish this by re-designating nuclear medicine procedures under what it calls "radiology and certain other imaging services." However, this phrase is not included in the applicable statutory provision and is clearly beyond the scope of the statutory language.

Specifically, the words "certain other imaging services" do not even appear in Section 1877(h)(6). In fact, Congress has expressly rejected virtually identical statutory phrasing. The original provision included the extremely broad category "radiology, and other diagnostic services" as DHS in Section 1877(h)(6)(D) of the Omnibus Budget Reconciliation Act of 1993. The following year, however, in the Social Security Act Amendments of 1994, Congress narrowed that broad language by striking the phrase "other diagnostic services," and replacing it with a far more precise description of the covered services. The new, narrowly drawn category of DHS consisted of "radiology services, including magnetic resonance imaging, computerized axial tomography, and ultrasound services." This provision does not mention nuclear medicine or particular nuclear medicine technologies, such as PET.

The proposed rule now seeks to rely on language that Congress has previously rejected. If Congress had intended to broaden the scope of the statute to include nuclear medicine services it would have retained the earlier, broadly drawn category. Alternatively, Congress could have listed nuclear medicine services, such as PET, alongside of MRI, CT, and ultrasound. Instead, when Congress amended the statute, it affirmatively defined the scope of radiology services to omit nuclear medicine.

² 42 U.S.C. § 1395nn(h)(6) (2005).

³ 70 Fed. Reg. 151 (Aug. 8, 2005).

⁴ Public Law 103-66, Sec. 13,562 (Aug. 10, 1993).

⁵ Public Law 103-432, Sec. 152 (Oct. 31, 1994).

Moreover, this interpretation of Section 1877(h)(6)(D) conforms to CMS's own long-standing and well-considered view that nuclear medicine is not a radiology service for the purpose of the physician self-referral law. After carefully considering the statutory text and legislative record, CMS concluded in its January 4, 2001 final rule to "exclude[] nuclear medicine [from DHS] because those services are not commonly considered to be radiology." It bears emphasis that this judgment was based on a specific factual finding with respect to the proper classification of nuclear medicine.

As will be discussed below, the proposed rule offers no evidence to support reversing the factual and regulatory conclusion that it reached less than five years ago. As the Supreme Court has observed, a "settled course of behavior embodies [an] agency's informed judgment that, by pursuing that course, it will carry out the policies committed to it by Congress." Because agencies and reviewing courts alike operate under "a presumption that those policies will be carried out best if the settled rule is adhered to," an agency that departs from such a rule "is obligated to supply a reasoned analysis for the change beyond that which may be required when an agency does not act in the first instance." The proposed rule does not satisfy this obligation. For CMS to reclassify nuclear medicine in the manner indicated would be to allow its preferred regulatory application to dictate its factual findings, rather than the reverse.

II. Nuclear Medicine Is a Distinct Medical Specialty from Radiology

Nuclear medicine services are clinically and technically distinct from the services that Congress enumerated when it defined the scope of "radiology services" in Section 1877(h) (6) (D). The American Board of Nuclear Medicine (ABNM), the primary certifying organization for the practice of nuclear medicine in the United States, defines nuclear medicine as "the medical specialty that employs radionuclides to evaluate metabolic, physiologic and pathologic conditions of the body for the purposes of diagnosis, therapy and research." In a typical procedure, a physician trained as a nuclear medicine specialist supervises the administration of a radioactive material into a patient. The subsequent distribution of this material within the body is then determined by a special device that detects the radioactivity coming from the patient. The nuclear medicine physician makes a diagnosis based on that distribution.

The introduction of radiolabeled, biologically active compounds into patients distinguishes nuclear medicine from radiology. Although radiologists sometimes do administer "contrast agents," such as barium sulfate or iodine (X-ray), or gadolinium (MRI), these agents are biologically inert, and their function is entirely different from that of radioisotopes in a nuclear

⁶ 66 Fed. Reg. 927 (Jan. 4, 2001). More recently, CMS confirmed its practice of construing the scope of "radiology services" narrowly with respect to other (non-nuclear) procedures, finding that "angiographies, angiograms, cardiac catheterizations, and endoscopies . . . are not fundamentally radiological in nature because they do not involve an imaging service that is described in 1877(h)(6)(D) of the Act." 69 Fed. Reg. 16,104 (Mar. 26, 2004).

⁷ Motor Vehicle Manufacturers Ass'n of the U.S., Inc. v. State Farm Mutual Automobile Ins. Co., 463 U.S. 29, 42-43 (1983) (quoting Atchison, Topeka & Santa Fe Ry. v. Wichita Bd. of Trade, 412 U.S. 800, 807 (1973) (internal citations omitted)).

http://www.abnm.org/index.html (accessed June 28, 2005).

⁹ See, e.g., http://www.radiochemistry.org/nuclearmedicine/definition.htm. Through PET, for example, the molecular errors that cause disease can be accurately identified and understood in terms of the specific nature of the disease. This separates PET from conventional anatomic imaging modalities such as X-ray films, CT and MRI. By assisting physicians in the diagnosis and management of tumors, cardiac disorders and neurological disorders, PET can eliminate unnecessary surgeries, reduce the number of diagnostic procedures, and otherwise help physicians to determine the best, most effective mode of treatment for a patient.

medicine procedure. Additionally, some of the procedures performed in nuclear medicine are for therapeutic purposes, and specialized training, such as that obtained in programs leading to certification by the ABNM, is a prerequisite for clinically appropriate use.

The proposed rule provides little in the way of independent authority to controvert its earlier position that nuclear medicine services "are not commonly considered to be radiology." The proposed rule relies, first, on an excerpt from Dorland's Illustrated Medical Dictionary and a statement by the Society for Nuclear Medicine, confirming that nuclear medicine procedures involve the introduction into the body of tracers that emit small amounts of radiation. The proposed rule appears to imply that because nuclear medicine employs radioactive material, logically it must be a subspecialty of diagnostic radiology. This implication is not warranted. Radioactive materials are used in many other areas of clinical practice--for example, the performance of radioimmunoassays and irradiation of blood products. Importantly, these procedures are not considered radiological services merely because they involve radioactive material. ¹⁰

The proposed rule also relies on a letter from the American College of Radiology (ACR). claiming that nuclear medicine is "a part of the specialty of radiology" and noting that the American Board of Radiology's (ABR) process of certifying diagnostic radiologists includes examination in nuclear medicine. This position is directly contradicted by the American Board of Medical Specialties (ABMS), the body that officially sanctions all medical residency training programs in the United States. It is physicians trained in ABMS-approved programs, rather than the ABR, that define the specialty of nuclear medicine. According the ABMS, Nuclear Medicine and Radiology each posses "primary" (that is, fundamental and independent) board status as medical specialties. Nuclear Medicine, like Radiology, is one of only 26 distinct medical disciplines subject to Primary Board Certification. Services such as CT and MRI, by contrast, have "affiliate" status, and are among the many subspecialty groups within radiology. Moreover, the ABMS oversees separate specialty training programs in both diagnostic radiology and nuclear medicine. Although some nuclear medicine training is incorporated into the diagnostic radiology training program, and the ABR does include questions on nuclear medicine in its certification examination, physicians become eligible to take the ABNM examination only after successfully completing a nuclear medicine residency program. 11

The proposed rule further attempts to bolster its assertion that nuclear medicine is a subcategory of radiology by citing the fact that the Social Security Act "places nuclear medicine in the same category as diagnostic radiology for coverage and payment purposes." CMS points to Section 1833(t), providing payment for "outpatient hospital radiology services (including diagnostic and therapeutic radiology, nuclear medicine, CAT scan procedures, magnetic resonance imaging, and ultrasound and other imaging services, but excluding mammography)," as described in Section 1833(a)(2)(E)(i). CMS interprets this provision to mean that Congress considers nuclear medicine to be a subcategory of radiology services. In fact, Section 1833(t) is strictly a payment provision, and refers to the grouping of technologies in Section 1833(a)(2)(E)(i) exclusively for

¹⁰ In addition, hospitals and clinics frequently house nuclear medicine departments that are separate from their radiology departments, whereas ultrasound, MRI and CT are virtually always performed in radiology departments.
¹¹ In addition, for a physician to be eligible for a dual certification in nuclear medicine and radiology under the ABNM program, she must first obtain separate approval for her proposed training program from both the ABNM and the ABR. After completing her training, she must then pass a certifying examination in radiology and a certifying examination in nuclear medicine, each administered by its respective certifying board.

the administrative purposes of providing for Medicare reimbursement. ¹² Further, 1833(a) (2) (E) predates the enactment Section 1877, limiting physician self-referrals, by several years. If Congress had considered Section 1833(a) (2) (E) an authoritative description of the scope of radiology services, it could have imported that language directly into Section 1877(h) (6) when it amended the self-referral law in 1993 and 1994. The fact that Congress did not do so lends further support to the position that Congress has never considered nuclear medicine a subcategory of radiology for the purpose of Section 1877(h) (6).

Finally, the proposed rule suggests that the fact that nuclear medicine and radiological services are both paid under Section 1861(s)(3) evidences their clinical similarity. Again, the proposed rule supplies no basis for concluding that their common classification in this narrow context bears on the question of whether nuclear medicine is a subspecialty of radiology, or whether that classification represents anything more than administrative convenience. In fact, Section 1861(s)(3) applies to all diagnostic tests regardless of their clinical properties, and includes not only MRI, CT, and PET, but also diagnostic clinical laboratory tests.¹³

III. Nuclear Medicine Services are not Subject to Over-Utilization

The proposed rule offers no evidence that nuclear medicine services are abused or over-utilized. CMS maintains that any lingering doubt about whether "nuclear medicine services are radiology...within the meaning of section 1877(h)(6)" should be resolved in favor of the proposed rule, because such services "pose the same risk of abuse that the Congress intended to eliminate for other types of radiology, imaging, and radiation therapy services and supplies." 14

The empirical support cited for this claim is particularly misleading and unreliable. The proposed rule relies on a number of studies of diagnostic imaging, but none that have reviewed the utilization of any nuclear medicine service, including PET. Although the proposed rule acknowledges that the principal study on which it relies excluded nuclear imaging, it insists that there is "[no] basis for assuming that physician behavior would be different for nuclear imaging than it is for other imaging services." Imaging services encompass an extremely wide variety of technologies and clinical uses, and it is not easy to extrapolate data from one service and apply it to another. Unlike most radiology services, nuclear medicine imaging introduces radioactive material directly into the body. This is an important factor in limiting clinical use of nuclear medicine imaging to medically useful and appropriate circumstances. Second, as is discussed below, limitations on Medicare coverage for PET likewise significantly constrain its use. Unlike CT and MRI, PET is subject to numerous national coverage determinations limiting coverage to certain tumor types and indications. ¹⁵

¹² Under CMS's reading of Section 1833(t), Congress' inclusion of the catch-all category of "other imaging services" in the parenthesis following "radiology services" would make *any* imaging service a subcategory of radiology.

¹³ The Section covers "diagnostic X-ray tests (including tests under the supervision of a physician, furnished in a place of residence used as the patient's home, if the performance of such tests meets such conditions relating to health and safety as the Secretary may find necessary and including diagnostic mammography if conducted by a facility that has a certificate (or provisional certificate) issued under Section 354 of the Public Health Service Act), diagnostic laboratory tests, and other diagnostic tests."

^{14 70} Fed. Reg. 151 (Aug. 8, 2005).

¹⁵ See, e.g., Medicare National Coverage Determinations Manual § 220.6 (Rev 35, May 6, 2005).

The proposed rule also relies on the fact that since the publication of the Phase I final rule excluding nuclear medicine services from DHS, "many more nuclear medicine procedures have been performed in physician offices or in physician-owned freestanding facilities." The proposed rule reports that while physician services in general increased by 22 percent between 1999 and 2003, imaging services increased by 45 percent, and nuclear medicine services increased by 85 percent. The implication appears to be that the absence of self-referral restrictions on nuclear medicine services has made such services increasingly, perhaps even especially, subject to over-utilization. This implication is unwarranted. Two particular considerations account for the relative growth of nuclear imaging services. First, nuclear medicine imaging still represents only a very small fraction of all diagnostic imaging. For this reason, even modest numerical growth can appear dramatic when it is presented in the form of a percentage increase. Despite PET's recent increase in utilization the total number of PET scans performed is dwarfed by the number of other imaging procedures performed, such as MRI and CT. In 2004, PET still accounted for less than one percent of Medicare reimbursement for diagnostic imaging.

Second, as the proposed rule notes, Medicare coverage of PET scans has expanded since December 2001, a change that reflects CMS's recognition of PET's utility in diagnosing and treating an increasing variety of cancers. In fact, expansion of coverage by Medicare, and not inappropriate referral, is likely the most important factor in increased utilization of PET scans. Unlike Medicare coverage of MRI and CT, coverage of PET initially was extremely limited and only applied to a handful of cancer indications and qualifying uses, such as staging. Although CMS has gradually extended PET coverage for cancer over the past four years, at present Medicare still only covers the 8 to 10 leading tumor types. Coverage also remains limited to certain functions, such as diagnosis and staging, and does not apply to the monitoring of therapeutic response. Further, many common cancers, such as prostrate, ovarian, and testicular remain ineligible, while others, such as breast and cervical, are covered but reimbursement is confined to clinically appropriate referrals. CMS has proposed to expand coverage to all cancers, but the decision has not yet been implemented. These tight coverage policies function as an intrinsic check on the risk of exactly the kinds of over-utilization and abuse that that the self-referral prohibitions are designed to prevent. In summary, the very specific criteria enumerated in the expansion of Medicare coverage for PET scans created a scenario where the increase in utilization, sanctioned by Medicare, is highly unlikely to include clinically unnecessary or inappropriate PET scans.

As part of its proposed expansion of PET coverage, CMS is working with AMI to establish a national data registry, which will be one of the first new coverage policies instituted under Coverage with Evidence Development (CED). Any new coverage of PET would require the referring physician to submit a case report form to a data registry. The data registry will provide CMS with accurate information on how PET impacts patient management and improves health outcomes. Such information will afford CMS an invaluable tool with which to evaluate PET's utility in improving the management of oncology patients.

The proposed rule further states that the "risk of abuse and anti-competitiveness" that exists with physician self-referrals in general "is exacerbated by the greater affordability of nuclear medicine equipment." This statement misapprehends both the importance of many physician-owned nuclear medicine services to patient access, and the nature of most current physician ownership

¹⁶ 70 Fed. Reg. 151 (Aug. 8, 2005).

interests. Because the equipment in physician-owned PET centers is expensive, typically an individual physician owns only a small percentage interest, and, as a result, has a very modest stake in the center's profitability. These small stakeholders do not have a substantial incentive to over-utilize PET scans. By including nuclear medicine as a DHS, however, the proposed rule would encourage many individual and group physician-owners to acquire expensive PET equipment to operate in their own private offices, under the in-office ancillary service exception to the self-referral rule. The proposed rule would thus result in many physicians acquiring a more substantial ownership interest in PET scanners than they now possess, and for that reason could exacerbate, rather than mitigate, the potential for over-utilization.

IV. Should CMS Reclassify Nuclear Medicine Services as DHS, Existing Physician Ownership Interests Should be Exempted from the Prohibition on Self-Referrals

If CMS does reclassify nuclear medicine as a DHS, contrary to the statutory language, it should take strong measures to protect current physician-stakeholders. CMS rightly acknowledges that the guidance it offered in the Phase I final rule has "encouraged physician investment in nuclear medicine equipment and ventures, particularly PET scanners, which are very expensive and often require a substantial financial investment on the part of physician-owners." Many physicians have entered into ownership arrangements in good-faith reliance on the existing regulations, not least CMS's express exclusion of nuclear imaging from DHS. Accordingly, the proposed rule recognizes that it may be necessary to extend special consideration to physicians who have pre-existing ownership interests. The rule specifically requests comments on whether to delay the new rule's effective date or to "grandfather" certain arrangements. As set out below, AMI respectfully requests that CMS minimize the impact of any change to the physician self-referral requirements on both beneficiary access and physician-investors by exempting existing physician-owned nuclear medicine services from reclassification as DHS.

When Congress established, in the Medicare Modernization Act, an 18-month moratorium on physician self-referrals to specialty hospitals, it concluded that as a matter of basic fairness it would be inappropriate to apply the new prohibition to physicians who had already made substantial investments in such hospitals. Accordingly, Congress provided for the grandfathering of existing facilities and those under development as of the date that the specialty hospital bill was passed by both houses. The case for grandfathering is even more compelling with respect to nuclear medicine services, because physicians have relied on CMS's express declaration that nuclear medicine is not a subspecialty of radiology. AMI urges that a similar grandfathering exemption be adopted for physician-owned nuclear medicine services, and proposes the following language:

Any nuclear medicine service provided at a facility in operation or under development on the effective date of the final rule, and for which

(i) the number of physician investors has not increased since that date;

¹⁷ 70 Fed. Reg. 151 (Aug. 8, 2005).

¹⁸ See CMS Transmittal No. 62, March 19, 2004, available at http://www.cms.hhs.gov/manuals/pm_trans/R62OTN.pdf.

- (ii) the specialized services furnished by the facility have not expanded beyond imaging since that date; and
- (iii) there has not been a substantial increase in the capacity of the facility due to the addition of capital equipment, except for capital equipment acquired for the purpose of replacing or upgrading existing equipment, is not a Designated Health Service.

Conclusion

AMI believes that compelling evidence of congressional intent, the clinical distinctiveness of nuclear medicine from radiology, strong inherent checks against over-utilization, and the specific structure of physician ownership interests all counsel strongly against subjecting nuclear medicine services to the prohibition against physician self-referral. For these reasons, AMI respectfully requests that CMS maintain its present policy that nuclear medicine services are not DHS. AMI would welcome the opportunity to meet with agency staff during the comment period in order to discuss these issues in more detail.

Very truly yours,

R Edward Coleman

R. Ed Coleman, M.D.



American Academy of Family Physicians

11400 Tomahawk Creek Parkway, Leawood, KS 66211-2672

September 6, 2005

Mark B. McClellan, M.D., Ph.D.
Administrator, Centers for Medicare and Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS-1502-P
P.O. Box 8017
Baltimore, MD 21244-8017

Dear Dr. McClellan:

I am writing on behalf of the American Academy of Family Physicians, which represents more than 94,000 family physicians and medical students nationwide. Specifically, I am writing to offer our comments on the proposed rule regarding "Medicare Program: Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006," as published in the *Federal Register* on August 8, 2005. We especially draw your attention to our comments on the Sustainable Growth Rate and payment reforms that promote higher quality ambulatory care.

Resource-Based Practice Expense Relative Value Units (RVUs)

Changes in Practice Expense Methodology

CMS proposes the following changes to its practice expense methodology:

- Use a bottom-up methodology to calculate direct practice expense costs
- Eliminate the non-physician work pool
- Use the current indirect practice expense RVUs, except for those services affected by supplementary survey data accepted by CMS
- Transition the resulting revised practice expense RVUs over a four-year period

The Academy has historically supported a bottom-up approach to the calculation of direct practice expenses and elimination of the non-physician work pool. As such, we support CMS's proposals in this regard and believe they are long overdue, even though family physicians will benefit only marginally from the proposed changes (i.e., CMS estimates allowed charges by family physicians will only be 0.2% greater after the proposed changes are fully implemented in 2009).

We agree with CMS that these changes will produce a more accurate, more intuitive, and more stable practice expense methodology. The methodology will be more accurate, because, as CMS notes, the practice expense inputs are better refined and more current than those historically used by CMS. Also as CMS notes, we believe it will be more accurate because the bottom-up methodology assumes that the costs of the clinical staff, supplies and equipment are the same for a given service, regardless of the specialty that is performing it. This assumption does not hold true under the top-down direct cost methodology, where the specialty-specific scaling factors create widely differing costs for the same service.

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The bottom-up methodology has always been more intuitive to us than the top-down method employed by CMS, and the elimination of the non-physician work pool will make it even more intuitive. As noted in the proposed rule, under the proposed changes, any revisions made to the direct inputs would now have predictable results, since changes in the direct practice inputs for a service would proportionately change the practice expense RVUs for that service without significantly affecting the practice expense RVUs for unrelated services. Finally, stability should be improved, because direct practice expenses should only change for a service if it is further refined or when prices are updated, while indirect practice expenses should change only when there are changes in the mix of specialties performing the service or with the use of any future new survey data for indirect costs.

With respect to the indirect practice expenses, we continue to question why CMS uses physician work RVUs, rather than physician time, in its formula for allocating indirect expenses. We continue to believe physician time makes more sense than physician work in this regard. By definition, physician work is a product of time and intensity. We would contend that physician time is more likely than physician work to drive indirect expenses since we are not convinced such expenses vary with physician intensity. For example, consider two physician services, done in an office, that involve the same amount of time but different levels of intensity. Does it make sense to say that the cost of the utilities varies with the intensity of the service when, for example, the cost of the electricity is, in fact, a function of the time the lights are on while the services are being done? We do not think so. Therefore, as we did when CMS first proposed its formula for indirect practice expense RVUs, we would recommend that CMS use physician time rather than physician work in the allocation of indirect expenses.

Lastly, as concerns the four-year transition for these changes, we understand CMS's desire to ameliorate the impact of the other proposed changes, especially for those specialties that will be significantly, negatively impacted by the changes. We also appreciate CMS's desire to give everyone affected ample opportunity to identify any anomalies in the practice expense data, to make any further appropriate revisions, and to collect additional data, as needed prior to the full implementation of the proposed changes. However, we would note that Congress enacted the original legislation mandating resource-based practice expenses in 1994 and that CMS delayed its initial implementation by a year before entering a four-year transition to resource-based practice expenses under its current methodology. Thus, it has already been a decade of delays and transitions since Congress directed CMS to implement resource-based practice expenses, and we find it ironic that CMS proposes to further draw out that transition. We would encourage CMS to shorten or eliminate the transition and finally complete the process of implementing resource-based practice expenses.

Payment for Splint and Cast Supplies

Since 2000, CMS has excluded cast and splint supplies from the practice expense database for the Current Procedural Terminology (CPT) codes for fracture management and cast/strapping application procedures, since these supplies could otherwise be separately billed using Healthcare Common Procedure Coding System (HCPCS) codes Q4001 through Q4051. CMS now proposes to eliminate the separate HCPCS codes for these casting supplies and to again include these supplies in the practice expense database. By bundling the cost of the cast and splint supplies into the practice expense component of the applicable procedure codes under the fee schedule, physicians will no longer need to bill Q-codes in addition to the procedure codes to be paid for

these materials. This change would affect the practice expense RVUs for the following CPT codes: 23500 through 23680, 24500 through 24685, 25500 through 25695, 26600 through 26785, 27500 through 27566, 27750 through 27848, 28400 through 28675, and 29000 through 29750.

We appreciate that this proposal makes coding and billing for fracture management and casting/strapping easier by reducing the number of codes that physicians must submit in such situations. We also appreciate that CMS has invited the relevant medical specialties to review direct practice expense inputs for the codes in question and provide CMS with feedback regarding the appropriateness of the type and amount of casting and splinting supplies and about the amount of casting supplies needed for the 10-day and 90-day global procedures. We would encourage CMS to vet the feedback it receives with the Practice Expense Review Committee of the American Medical Association/Specialty Society Relative Value Scale Update Committee, so the resulting inputs enjoy the same level of scrutiny and cross-specialty refinement that all of the other direct practice expense inputs have.

Pricing of Hyperbaric Chamber

In Table 19 of the proposed rule, "Equipment Items Needing Specialty Input for Pricing and Proposed Deletions," CMS indicates that it is seeking pricing information on hyperbaric chambers from family medicine, internal medicine, and emergency medicine, based on the fact that these three specialties are the primary providers of CPT code 99183, "Physician attendance and supervision of hyperbaric oxygen therapy, per session." CMS currently assigns a price of \$125,000 to this equipment.

While family physicians may be a common provider of this service according to Medicare data, we do not believe that they are common purchasers of such equipment. According to Medicare data, over 90% of hyperbaric oxygen therapy is done in the hospital setting, and only 8% occurs in the physician office setting. We believe that very few, if any, family physicians own a hyperbaric chamber. Accordingly, CMS may want to consult with the hospital community about the cost of this equipment. Alternatively, CMS may want to contact the American College of Hyperbaric Medicine (ACHM) for any information it has in this regard. CMS can access contact and other information about the ACHM on-line at www.hyperbaricmedicine.org

Malpractice RVUs

In the proposed rule, CMS proposes to make some adjustments to its malpractice RVU methodology. These adjustments include excluding data for any specialty that performs less than five percent of a particular service or procedure from the malpractice RVU calculation for that service or procedure. The purpose of applying the minimum threshold was to identify and remove from the data specialties listed infrequently as performing a certain procedure, under the assumption that the infrequent instances of these specialties in CMS's data represent aberrant occurrences and that removing the associated risk factor from the malpractice RVU calculation would improve accuracy and stability of the RVUs.

We have reviewed the proposed adjustments and have no objections as a result. As noted in the proposed rule, for the most part, they have little or no affect, either on individual codes or on specialties. For instance, the overall impact of removing the risk factor for specialties that occur less than five percent of the time in the CMS data yields no impact on the malpractice RVUs for over 5,280 codes, and there is an impact of less than 1 percent on the malpractice RVUs for over

1,300 additional codes. Only 16 codes decrease by at least 0.1 RVUs, with the biggest decrease being a negative 0.28 impact on the malpractice RVU for CPT code 17108, "Destruction of skin lesions, from a current RVU of 0.82 to a proposed RVU of 0.54." Conversely, there are only 219 codes for which RVUs increase by at least 0.1, the largest increase being a positive 0.81 RVU increase for CPT code 61583, "Craniofacial approach, skull," from a current RVU of 8.32 to a proposed RVU of 9.13. Among codes whose malpractice RVUs would increase under CMS's proposal, 646 have increases of less than 1 percent. The impact by specialty also appears minimal. For family medicine, there would be no impact on allowed charges. For all other physician specialties, the impact ranges from -0.1% to +0.2%.

One adjustment that we did not note in the proposed rule was the use of more current and more accurate premium data. We continue to have concerns that CMS's use of "actual" premium data is progressively less comprehensive over time. As we understand it, CMS is using actual data for 2001 and 2002 and projected data for 2003. The actual data for 2001 represents 46 states plus Washington, DC, and Puerto Rico. The data for 2002 represents only 33 states. And, the 2003 data was projected because none of the State Departments of Insurance had market share information at the time the premium data was collected and because private insurers were not amenable to releasing premium data to CMS. Thus, out of three years of data for 50 states plus DC and Puerto Rico, CMS is using "actual" data for only about half the combination of time and states.

We continue to find this paucity of actual premium data troubling. We find it hard to fathom why CMS, working, for example, with the National Association of Insurance Commissioners, can't obtain market share data for 2003 now that we are over halfway through 2005. The reluctance of liability insurers to disclose premium data to CMS is understandable. However, the insurers are not the only ones with such information. The physicians who pay those premiums also know what they are, and we understand that the RUC has offered to work with CMS to collect premium data from physicians in an effort to get more current data. We would continue to encourage CMS to pursue this offer and other avenues for collecting more current actual data, rather than relying, as it apparently does, on an amalgam of actual and projected data.

Telehealth

Medicare regulations at 42 CFR 410.78 currently require the use of an interactive two-way audio and video telecommunications system to furnish a telehealth consultation. In response to a request from the Medical College of Georgia (MCG), CMS is considering whether or not to modify its definition of an interactive telecommunications system to permit one-way video in place of an interactive two-way video system. In this case, the one-way video permits the consulting physician at the distant site to see the patient, but the patient and presenting physician or practitioner cannot see the consultant.

The use of an interactive audio and video telecommunications system permitting two-way real-time interaction between the physician or practitioner at the distant site and the beneficiary and tele-presenter (if necessary) at the originating site is a substitute for the face-to-face examination requirements of a consultation under Medicare, according to CMS. CMS is concerned that the use of one-way video may not be clinically adequate for the evaluation of certain types of patients. Since telehealth services are intended as a substitute for services that traditionally require a face-to-face interaction between a physician (or practitioner) and a patient, CMS believes that the use of a two-way video communication is much less of a departure from this

standard than a one-way video communication, because the face-to-face interaction between a physician and a patient allows two-way interactive communication, both verbally and physically. CMS is concerned that, without two-way video, communication of many subtle but important nuances of the interaction between the physician at the distant site and patient or clinical staff at the originating site would be lost, leading to reduced diagnostic accuracy and the possibility of unfavorable medical outcomes.

However, CMS recognizes that in some situations, such as the one described by the MCG (i.e., a timely neurological evaluation for determining suitability for tPA treatment in acute ischemic stroke patients), the benefit of using available one-way video in a timely fashion may outweigh the benefits otherwise attributed to two-way video. Therefore, CMS is reviewing its definition of an interactive telecommunications system and requests specific public comments regarding the added clinical value of two-way interactive video as compared to one-way video for the purpose of furnishing telehealth services. CMS is also interested in receiving comments as to whether an interactive audio and one-way video telecommunications system that permits the physician at the distant site to examine the patient in real-time is clinically adequate for a broad range of specialty consultations.

From an AAFP perspective, telemedicine is the integration of information technology and telecommunication to enhance healthcare delivery. We believe that telemedicine can enrich the delivery of medical care at remote sites such as rural areas and, by creating ready access to information, can provide rural physicians with current medical information that may not be available in an isolated setting. We believe that reimbursement should be made for physician services that are reasonable and necessary, safe and effective, medically appropriate and provided in accordance with accepted standards of medical practice. The technology used to deliver the services should not be the primary consideration; the critical test is whether the service is medically reasonable and necessary.

From our perspective, two-way video may add value to the telehealth consultation by allowing the patient and presenting physician or practitioner to see the body language and non-verbal communication presented by the consulting physician. However, we would not advocate for denial of telehealth services provided using interactive audio and one-way video telecommunication equipment.

In fact, an interactive audio and one-way video telecommunications system that permits the physician at the distant site to examine the patient in real-time is clinically adequate for a broad range of specialty consultations. As noted above, we believe it is the nature of the service, not the nature of the technology that is paramount. Using the analogy of a face-to-face examination put forth by CMS, we would note that a telehealth consultation using interactive audio and one-way video telecommunication equipment is comparable to a physician treating a blind patient. CMS would not deny a face-to-face consultation on the basis that the patient could not see the consulting physician; we fail to see why it would deny a telehealth consultation on the same basis. Accordingly, we would encourage CMS to revise its definition of an interactive telecommunications system to include interactive audio and one-way video telecommunication equipment.

Multiple Procedure Reduction

Medicare has a longstanding policy of reducing payment for multiple surgical procedures performed on the same patient, by the same physician, on the same day. In those cases, full payment is made for the highest priced procedure and each subsequent procedure is paid at 50 percent. Effective January 1, 1995, the multiple procedure policy, with the same reductions, was extended to nuclear medicine diagnostic procedures (CPT codes 78306, 78320, 78802, 78803, 78806 and 78807).

In the current proposed rule, CMS proposes to extend the multiple procedure payment reduction to technical component (TC) only imaging services and the TC portion of global imaging services for certain imaging modalities (i.e., ultrasound, computed tomography (CT), computed tomographic angiography, magnetic resonance imaging (MRI), and magnetic resonance angiography) that involve contiguous body parts within a family of codes. For example, the reduction would apply to an MRI of the abdomen done on the same date as an MRI of the pelvis but would not apply to a CT of the chest done on the same date as a CT of the head. From CMS's perspective, when multiple images are acquired in a single session, most of the clinical labor activities (e.g., greeting, positioning, and escorting the patient, providing education and obtaining consent, retrieving prior exams, setting up the IV, and preparing and cleaning the room) and most supplies (except film) are not performed or furnished twice. Thus, CMS believes it is making duplicate payments for TC of multiple diagnostic imaging services, particularly when contiguous body parts are viewed in a single session. The discount would not apply to the professional component (i.e., the physician interpretation and report) of such procedures.

We concur with CMS's proposal and encourage its adoption. We agree that CMS is making duplicate payments for certain practice expenses when multiple images are acquired in a single session, especially when contiguous body areas are involved. As the Medicare Payment Advisory Commission (MedPAC) noted in its March 2005 Report to Congress, in which it made a similar recommendation, Medicare's payment rates are based on each service being provided independently. When that is not the case, certain efficiencies may accrue of which CMS should take advantage. This proposal attempts to do just that.

We would also urge CMS to consider applying a reduction to the professional component in such situations as well. Just as with the technical component, there are certain efficiencies when a physician is reading images of contiguous areas of the same patient on the date. For instance, the interpreting physician only has to review the patient's history once to know what he or she is seeking, and often, some portion of the scan is an overlap (i.e., a scan of the pelvis often includes a portion of an abdominal scan). Also, usually there is only one dictation for the multiple scans. Accordingly, there is less physician work involved than would be the case if the scans were interpreted independently at different points in time, and CMS should consider applying the multiple procedure reduction to the professional component, too.

Coverage of Screening Glaucoma

Currently, Medicare regulations at 42 CFR 410.23(a)(2), which govern conditions for and limitations on coverage of screening for glaucoma, define the term ``eligible beneficiary" to include individuals in the following high risk categories:

Individual with diabetes mellitus;

- Individual with a family history of glaucoma; or
- African-Americans age 50 and over.

Based on its review of the current medical literature, CMS believes that the evidence is adequate to conclude that Hispanic persons age 65 and older are at high risk and could benefit from glaucoma screening. Therefore CMS proposes to revise the definition of an eligible beneficiary to include Hispanic Americans age 65 and over. In view of the possibility that it may be appropriate to include other individuals in the statutory definition of those at "high risk" for glaucoma, CMS is requesting comments on this issue and is specifically requesting that anyone providing it with specific recommendations on this issue also provide documentation in support of them from the peer-reviewed medical literature.

Like CMS, we have reviewed the current medical literature on this subject. Unlike CMS, we found insufficient evidence to recommend for or against screening adults for glaucoma. We also note that the U.S. Preventive Services Task Force (USPSTF) found insufficient evidence to recommend for or against screening adults for glaucoma. The USPSTF's recommendation, including clinical considerations and references from the peer-reviewed literature can be found on-line at http://www.ahrq.gov/clinic/uspstf05/glaucoma/glaucrs.htm#clinical The clinical considerations note that increased intraocular pressure, family history, older age, and being of African American descent place an individual at increased risk for glaucoma. However, there is no reference to Hispanic persons age 65 and over being at high risk. Based on this information, we would not support CMS's proposal to extend its definition of eligible beneficiary to include Hispanic persons age 65 and over or any other category of individual not already covered by the current definition.

Sustainable Growth Rate (SGR)

In the proposed rule, CMS notes that it is currently forecasting an update of -4.3% for 2006, and it attributes much of the blame for this reduction to substantial growth in Medicare spending, especially:

- An increase in spending for office visits, with a shift toward longer and more intense visits.
- Greater utilization of minor procedures, including physical therapy and drug administration.
- More patients receiving more frequent and more complex imaging services, such as MRIs and echocardiograms.
- More laboratory and other physician-ordered tests.
- Higher utilization of physician-administered prescription drugs.

CMS encourages comments regarding possible changes to the SGR methodology, including the legal theories that support them. CMS is particularly interested in:

- comments on steps to promote physician payment adequacy without increasing overall Medicare costs,
- particularly interested in comments that build on recent progress on payment reforms to promote higher quality and avoid unnecessary costs, and
- ways to promote higher-quality ambulatory care that can achieve offsetting savings by avoiding complications or unnecessary services.

As regards the SGR, we oppose expenditure targets, including the SGR, which are linked to the Gross Domestic Product, in favor of a system based on a fair representation of physicians' costs of delivering care. The cuts in physician payment projected by CMS result from the inherently flawed SGR payment update formula. The SGR, which is linked to the Gross Domestic Product, penalizes physicians and other practitioners by failing to accurately reflect volume increases resulting from new coverage decisions and initiatives promoted by the Federal government. Only physicians are subject to arbitrary cuts due to factors beyond their control. Every other category of health care provider receives positive updates, based on a measure of inflation in their practice costs. That is why we and other physicians are working to enact a bill to replace the SGR with a new payment system that reflects increases in medical practice costs. We note that MedPAC also calls for repealing the SGR formula and basing the conversion factor on the Medicare Economic Index (MEI).

Until a complete revision of the reimbursement formula is accomplished, there is an administrative adjustment that CMS can make immediately. Specifically, CMS should immediately remove, retroactive to the inception of the SGR, the physician-administered drugs from the SGR. These in-office medications are not reimbursed under the Medicare physician fee schedule and should never have been part of the formula used to calculate the conversion factor for physician services. Moreover, the Medicare Modernization Act restructured how these medications are paid for. CMS's continued inaction, in the face of a growing Medicare ambulatory care reimbursement crisis, is of great concern.

Indeed, we fail to see how CMS can include such drugs in the SGR calculation, given the statutory language surrounding SGR. Specifically, section 1848(f)(2) of the Social Security Act specifies that the SGR for all physicians' services shall be equal to the product of:

- (A) 1 plus the Secretary's estimate of the weighted average percentage increase (divided by 100) in the fees for all physicians' services in the applicable period involved,
- (B) 1 plus the Secretary's estimate of the percentage change (divided by 100) in the average number of individuals enrolled under this part (other than Medicare+Choice plan enrollees) from the previous fiscal year to the applicable period involved,
- (C) 1 plus the Secretary's estimate of the projected percentage growth in real gross domestic product per capita (divided by 100) from the previous applicable period to the applicable period involved, and
- (D) 1 plus the Secretary's estimate of the percentage change (divided by 100) in expenditures for all physicians' services in the fiscal year (compared with the previous fiscal year) which will result from changes in law and regulations, determined without taking into account estimated changes in expenditures resulting from the update adjustment factor determined under subsection (d)(3)(B) or (d)(4)(B), as the case may be,

minus 1 and multiplied by 100.

As far as we can see, there is no reference to drugs administered incident to a physician's service anywhere in this formula. There is a reference to "physicians' services," but section 1861(q) defines those as "professional services performed by physicians, including surgery, consultation, and home, office, and institutional calls (but not including services described in subsection (b)(6) [i.e., services of interns or residents in training under an approved teaching program])." Further, section 1861(s) of the Social Security Act, which defines "medical and other health services," draws a distinction between "physicians' services" (1861(s)(1)) and "services and supplies"

(including drugs and biologicals which are not usually self-administered by the patient) 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" (1861(s)(2)(A)).

Since the statute states that "physicians' services," not "medical and other health services," should be included in the SGR computation, we believe that CMS cannot consider drugs furnished in a physician's office that are not usually self-administered in the SGR. Not only does CMS have the obvious statutory authority and guidance to not include these inoffice drugs in the SGR, but they have the obligation to remove them from the SGR. That being the case, and since they have been erroneously included in the SGR since the inception of the formula, these drugs should be removed retroactive to the first use of the formula, and CMS should adjust its calculations accordingly.

With respect to payment reforms that promote higher quality ambulatory care, we support Congressional actions to achieve the following regarding physician reimbursement in federally-funded health care programs:

- Incorporate the features of the AAFP's care coordination model for Medicare beneficiaries. The physician designated to be the patient's overall health care manager ("personal medical home") shall receive a per-member, per-month stipend in addition to fee-for-service payments.
- Ensure that pay-for-performance programs occur in the context of a positive annual
 update; that they reward physicians for reporting the "starter set" of performance
 measures being developed by a consortium of payers and physicians; and that such
 programs do not force physicians to compete for limited withholds.

Care Management Stipend

Having a usual source of care is extremely influential in the care people receive. For instance, People who have a usual source of care are also more likely to receive preventive care services, independent of having insurance. (DeVoe JE, Fryer GE, Phillips RL, Green LA. Comparing receipt of preventive care among adults based on insurance status and/or a usual source of care. Am J Public Health 2003; 93(5)). Likewise, we know that for people with chronic health conditions, there are reductions in expenditures with no significant differences in self-rated health status when people have a family physician as their usual source of care (2000 Medical Expenditure Panel Survey). Finally, several studies have confirmed improved coordination of care and reduced expenditures by providing people with a primary care physician as a usual source of care. In fact, Bodenheimer et al. found that 18 of 27 studies concerning just three chronic conditions (congestive heart failure, asthma and diabetes) demonstrated reduced costs or lower use of health care services when the chronic care model was fully implemented, almost exclusively in primary care settings (Bodenheimer T, Wagner EH, Grumbach K., Improving primary care for patients with chronic illness: The chronic care model, part 2. JAMA 2002; 288(15):1909-1914).

Yet, there is no direct compensation to family physicians and other primary care physicians for the considerable time and effort of assuring that each patient's care is organized correctly and is integrated in a way that makes sense to the patient, while remaining cost-effective to the Medicare program. As noted, such coordination and management ensure that patients' health is

stabilized and that expensive progression of their illness and costly hospitalizations are minimized. A blended model of payment combining fee-for-service reimbursements plus a perbeneficiary, per-month stipend for care management, paid directly to each patient's designated physician ("personal medical home"), is a promising option that would enable family physicians to redesign their offices to deliver high quality preventive and chronic care with improved outcomes for Medicare beneficiaries.

Pay-for-Performance

MedPAC recommended in its March 2005 report that Congress create Medicare pay-forperformance programs for physician services. The Academy would support a Medicare pay-forperformance program for physicians that:

- occurred within the context of a positive annual update in Medicare;
- rewarded physicians who were reporting performance measures as chosen by the
 collaborative efforts of the AAFP, American College of Physicians (ACP), Agency for
 Healthcare Research and Quality (AHRQ), and America's Health Insurance Plans
 (AHIP); and
- did not force physicians to compete for mandatory withholds.

AAFP currently has over 57,000 members in active practice, the vast majority of whom are in small and medium size practices, not large groups. We anticipate that this will be the typical construct of family medicine well into the future. Most people in this country receive the majority of their care from physicians in small and medium size ambulatory care settings. Currently about a quarter of all office visits in the U.S are to family physicians, and the average family practice has about a quarter of patients who are Medicare beneficiaries. Implementing value based purchasing or pay-for-performance in the Medicare program has tremendous implications for millions of patients and for the specialty of family medicine, and AAFP is therefore committed to involvement in the design of a new pay-for-performance program that meets the needs of patients and physicians.

Physicians and Pay-for-Performance

The AAFP supports moving to pay-for-performance in the Medicare program with the goal of continuously improving care of patients. As we recently stated in a joint letter to Congress with our colleague organizations ACP, the American Academy of Pediatrics, and the American College of Obstetricians and Gynecologists, "we believe that the medical profession has a professional and ethical responsibility to engage in activities to continuously improve the quality of care provided to patients... Our organizations accept this challenge." We have committed to work toward transformation of medical practice, to strengthen the infrastructure of medical practice to support pay-for-performance, and to engage in development and validation of performance measures. While several specific issues remain that must be addressed in implementing pay-for-performance in Medicare, AAFP has a framework for a phased in approach for Medicare.

AAFP is involved in several efforts that are fundamental to moving toward a pay-for-performance system.

First of all, we know that the development of valid, evidence-based performance measures is imperative for a successful program to improve health quality. The AAFP participates actively in the development of performance measures through the Physician Consortium for Performance Improvement. We believe that multi-specialty collaboration in the development of evidence-based performance measures through the consortium has yielded and will continue to yield valid measures for quality improvement and ultimately pay-for-performance.

The AAFP was the first medical specialty society to join the National Quality Forum (NQF). And along with ACP, AHIP and AHRQ, the AAFP is a founding organization of the Ambulatory care Quality Alliance (AQA). However, it is important to distinguish between the role of the NQF and that of AQA. With its multi-stakeholder involvement and its explicit consensus process, the NQF provides essential credibility to the measures that it approves – measures developed by the Physician Consortium, NCQA and others. The AQA's purpose is to determine which of the measures approved through the NQF consensus process should be implemented initially (the starter set), and which should then be added so that there is a complete set of measures, including those relating to efficiency, sub-specialty performance, and patient experience. Having a single set of measures that can be reported by a practice to different health plans with which the practice is contracted is critical to reducing the reporting costs borne by medical practices. Measures that ultimately are utilized in a Medicare pay-for-performance program should follow this path.

Information Technology in the Office Setting

Health information technology effectively utilized in the physician's office is necessary to the success of quality improvement and pay-for-performance programs. We have learned from the Integrated Healthcare Association's (IHA) experience in California that physicians and practices that invested in EHRs and other electronic tools to automate data reporting were both more efficient and achieved better quality results, and did so at a more rapid pace than those that lacked advanced HIT capacity. The AAFP created the Center for Health Information Technology (CHiT) in 2003 to facilitate adoption and optimal use of health information technology by family physicians with the goal of improving the quality and safety of medical care and increasing the efficiency of medical practice. We now estimate that over 20 percent of family physicians are utilizing EHRs in their practices, which is twice the number from this time last year. Through a practice assessment tool on the CHiT web site, physicians can assess their readiness for EHRs. We know from the HHS-supported EHR Pilot Project conducted by the AAFP that practices that had a well defined implementation plan and analysis of workflow and processes had greater success in implementing an EHR.

We also know that cost can be a barrier to IT adoption and have worked aggressively with the vendor community through our Partners for Patients Program to lower the price point. The AAFP's Executive Vice President serves on the Certification Commission for Health Information Technology (CCHIT) which certifies EHRs. The AAFP sponsored the development of the Continuity of Care Record standard, now successfully balloted through the American Society for Testing and Materials (ASTM). We initiated the Physician EHR Coalition, now jointly chaired by ACP and AAFP, to engage a broad base of medical specialties to advance EHR adoption in small and medium size ambulatory care practices.

The AAFP quality initiatives span efforts to emphasize measures like quality improvement, office redesign, and integration of the chronic care model. For example, through our Practice Enhancement Program, teams of physicians and their office staff participate in an intense

educational experience accompanied with pre and post course work to acquire the practical tools, skills and knowledge to implement the planned care model into their everyday practices. In another example, through the web-based METRIC (Measuring, Evaluating and Translating Research into Care) program, family physicians assess their systems in practice, review charts and enter patient data, receive feedback on their performance, implement a quality improvement plan, re-measure and reassess. Two module topics currently are available: diabetes and coronary artery disease. The AAFP takes seriously the responsibility to work with our members to continuously improve their clinical care and office infrastructure to better meet the needs of their patients.

Current Payment Environment

While these innovations are exciting and hold great promise, the environment in which physicians practice is challenging at best. And it will come as no surprise that family physicians, while they enjoy caring for their patients, are not enthusiastic about the Medicare program. This program has a history of disproportionately low payments to family physicians, largely because it is based on a reimbursement scheme that is designed to reward volume and to discourage innovations in the provision of care. In general, the prospect of annual cuts in payment is discouraging. The regulatory approach is punitive, and physicians live in fear of violating rules they don't even know about. In the current environment, physicians know that they will face a 4.3-percent cut in January 2006, and that without Congressional action to repeal the Sustainable Growth Rate formula and create a structure for sustainable financing, they face steadily declining payments into the foreseeable future, even while their practice costs are increasing. To overlay a pay-for-performance program in Medicare, therefore, poses a unique set of challenges and it must be done thoughtfully and carefully because of its size and complexity.

Our consistent message is that if it is not done well, a value-based purchasing or pay-for-performance program will not only fail to improve health care quality but could unravel the preparation and progress that medical specialty societies have carefully undertaken.

"Doing it well" means phasing in a value-based purchasing program that provides incentives for structural and system changes, that encourages reporting of data on performance measures and ultimately rewards continual improvements in clinical performance. Yet, moving the Medicare program in this direction cannot be accomplished in an environment of declining physician payment; Congress and CMS must take steps to stabilize physician payment through positive updates, as proposed by MedPAC. Furthermore, because of its financing structure with Part A and Part B, we believe it is important that CMS report on Medicare program savings, whether they be in Part A or Part B, resulting from Part B quality improvement efforts so that physicians are not penalized into the future.

A Framework for Pay-for-Performance

The following is a proposed framework for phasing in a Medicare pay-for-performance program for physicians that is designed to improve the quality and safety of medical care for patients and to increase the efficiency of medical practice.

<u>Phase 1</u>: All physicians would receive a positive update in 2006, based on recommendations of MedPAC, reversing the projected 4.3-percent reduction. Congress should establish a floor for such updates in subsequent years.

<u>Phase 2</u>: Following completion of development of reporting mechanisms and specifications, Medicare would encourage structural and system changes in practice, such as electronic health records and registries, through a "pay-for-reporting" incentive system such that physicians could improve their capacity to deliver quality care. The update floor would apply to all physicians.

<u>Phase 3</u>: Assuming that physicians have the ability to do so, Medicare would encourage reporting of data on evidence-based performance measures that have been appropriately vetted through mechanisms such as the National Quality Forum and the Ambulatory Care Quality Alliance. During this phase, physicians would receive "pay-for-reporting" incentives; these would be based on the reporting of data, not on the outcomes achieved. The update floor would apply to all physicians.

<u>Phase 4</u>: Contingent on repeal of the SGR formula and development of a long term solution allowing for annual payment updates linked to inflation plus funds to provide incentives through pay-for-performance programs, Medicare would encourage continuous improvement in the quality of care through incentive payments to physicians for demonstrated improvements in outcomes and processes, using evidence-based measures such as the provision of preventive services, performing HbA1c screening and control, prescribing aspirin to diabetics, etc. The update floor would apply to all physicians.

This sort of phased-in approach is crucial for appropriate implementation. While there is general agreement that initial incentives should foster structural and system improvements in practice, decisions about such structural measures, their reporting, threshold for rewards, etc. remain to be determined. The issues surrounding collection and reporting of data on clinical measures are also complex. For example, do incentives accrue to the individual physician or to the entire practice, regardless of size? In a health care system where patients see multiple physicians, to which physician are improvements attributed?

The program must provide incentives – not punishment – to encourage continuous quality improvement. For example, physicians are being asked to bear the costs of acquiring and using health information technology in their offices, with benefits accruing across the health care system – to patients, payers, insurance plans, etc. Appropriate incentives must be explicitly integrated into a Medicare pay-for-performance program if we are to achieve the level of infrastructure at the medical practice to support collection and reporting of data.

The AAFP appreciates the opportunity to share our enthusiasm for, yet caution about, a Medicare pay-for-performance program. We also appreciate this opportunity to comment on matters related to the Medicare Fee Schedule. As always, the American Academy of Family Physicians looks forward to working with CMS in its continued efforts to ensure access to appropriate physician services.

Sincerely,

Michael Fleming, M.D.

licent Kenym

Board Chair

September 23, 2005

FEDERAL EXPRESS

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Attn: CMS-1502-P
7500 Security Boulevard - Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-8017

Re: Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006; CMS-1502-P

Dear Dr. McClellan:

The medical specialties listed below are writing to request that CMS make a change in the status of allergy injection codes (CPT Codes 95115 and 95117) from the current zero day global "000" status to "XXX" status. We are making this request based on the advice of the RUC Workgroup which was assigned to review these codes as part of the five-year review process. The Workgroup did not support the request for work RVUs for these codes, which currently have no work values, and the specialties who presented these codes subsequently withdrew them from the 5-year review process. During the Workgroup's consideration of these codes, the Workgroup stated its belief that the "000" status assigned to these codes by CMS was incorrect and should be changed. They recommended that we seek such a change from CMS. A CMS physician, Dr. Edith Hambrick, attended the session and suggested we submit our request as comments on the 2006 proposed fee schedule notice.

In support of this request, we note that the following other injection codes, all of which describe similar services, have an "XXX" status:

 90471 – immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections) Mark McClellan, M.D., Ph.D. September 23, 2005 Page 2

- 90465 immunization administration under 8 years of age when physician counsels the patient/family (includes percutaneous, intradermal, subcutaneous, or intramuscular injections)
- 90782 therapeutic, prophylactic or diagnostic injection subcutaneous or intramuscular
- 90783 intra-arterial
- 90784 intravenous
- 90788 intramuscular injection of antibiotic
- G0351 therapeutic or diagnostic injection

Therefore, this request would make treatment of the allergy injection codes consistent with other similar codes. We would also note that "000" status applies to minor surgical procedures and is not appropriate for allergy immunotherapy injections. The work value assigned to "000" procedures include pre- and post-service work, including evaluation of the patient the day prior and the day of the procedure. It is for this reason that an E/M service can be billed on the same day as a "000" procedure only if it represents a separate and distinct service and is billed with a 25 modifier. There is no physician evaluation activity or, for that matter, any physician work built into the payment for allergy injections, which is a further reason why the global period status is inappropriate.

If you have any questions concerning this request, please contact Rebecca Burke, Washington counsel to the Joint Council of Allergy, Asthma and Immunology, at 202-466-6550.

Respectfully submitted by:

The American Academy of Pediatrics
The American College of Physicians
The American Academy of Family Practice
The Joint Council of Allergy, Asthma and
Immunology
The American Academy of Otolaryngic
Allergy

Cc: Edith Hambrick, M.D. (via Federal Express) Robert Zwolak, Chair, RUC Workgroup 4 \widehat{Da} vita.

SEP 5 576

West Georgia
1216 Stark Avenue
Columbus, GA 31906
Tel: (706) 320-0103 | Fax: (706) 320-1906
www.davita.com

9-19-05

Dear Mrs. Lana Price,

I am a relative y a dialysis patient, and I am writing about the article that she brought home about that new rule that has been proposed about the Medicare Program for the ESRD. When she found out that she had this problem of Kidney Yaclase, she just new it was her time. But when those ductors came to her and told her about that dealysis and the treatments that she would have to go through, she was so scared, and when she went to the store dince and say cow how she was Treated by the nurses, techs, and even the ague staff. They treated her like she was family. We prayed for her sa, because She was so spraid of needles, but the way they talk and treated heret was a Lad sende to place ask CM3 not to cut payments for Sincerely yours dialysis.

Sincerely Jones My fir In Bide \widehat{Da} vita.

Dear Mrs. Lan Anie,

My name is Liggy Mc Brile, Jama dealysis patient I am writing you about the article that I read in our monthly paper. Called the Life Line. The article's heading was Um Can Help knowe Quality Care, and under that it was the Problem I don't know what the Problem is, but I thank Docker everyday that there are is a program for dialysis patients. I am hoping that the Medicare Modernization actobes not change. There is a great need for all the nurses, technicisms, and of course the oppin staff of the Olinia Every clinica I have been in, the staff was very caring and patient to everyone I the patients, we don't want to it to be interpered with the quality of our care and may be even enew technologies would be discoursed So please ask CMS not to eat payments for dealysis.

Stark for So Yery Much, Propy McBall



Tulare County Medical Society. Inc.

3333 SOUTH FAIRWAY VISALIA, CA 93277 (559) 627-2262 Fax (559) 734-0431

September 15, 2005

Mark B. McClellan, MD, PhD Administrator Centers for Medicare & Medicaid Services Department of Health & Human Services 7500 Security Boulevard Baltimore, MD 21244-1850

Subject: August 8, 2005 Proposed Rule: CMS-1502-P

Dear Doctor McClellan:

The Tulare County Medical Society wishes to comment on the proposed removal of two California counties (Santa Cruz and Sonoma) from payment locality 99, Rest of California. The proposed removal will result in a .4% reduction in the reimbursement to the remaining Area 99 counties to fund the increased payment for Santa Cruz and Sonoma Counties.

The Tulare County Medical Society represent over 200 practicing physicians in Tulare County exceeding 70% of the actively practicing physicians in our county. Physicians in our county are already suffering from the shortage of an adequate supply of physicians to treat the population of our area. The .4% reduction will add additional burdens to the already nearly impossible situation of retaining and attracting competent medical professionals to Tulare County.

It is obvious that Santa Cruz and Sonoma County physicians have effectively lobbied for the proposed removal of their counties from Area 99. However, this piece meal action to a very complex health care delivery system will provide more complications than solutions. The California Medical Association debated this matter at significant length over the past year. CMA submitted a proposal to remove the two counties and several others and the cost of such a proposal was to be shared by all physicians in California. This was a remarkable proposal that was presented by a coalition of all of organized medicine in California.

The Tulare County Medical Society supports the California Medical Association's recommendation that Congressman Thomas and the Centers for Medicare and Medicaid Services work together to devise a nationwide fix to the GPCI problem. The proposed rule to extract Sonoma and Santa Cruz counties from California's area 99 is an illogical step to take at this time. It hurts many physicians and their patients while failing to solve many very serious local and nationwide problems.

Sincerely

Lonnie R. Smith, M.D.

President

Tulare County Medical Society

Mark B. McClellan, M.D., PhD, Administrator Centers for Medicare & Medicaid Services Department of Health & Human Services 7500 Security Boulevard Baltimore, MD 21244-1850

Subject: August 8, 2005 Proposed Rule: CMS-1502-P

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As a practicing physician in Tulare County it seem fundamentally wrong to lower payments to physicians in our county to pay physicians in another county. I can tell you first hand that there is a woeful shortage of physicians in Tulare County and virtually no access for Medicare and Medi-Cal patients because of reimbursements that make a medical practice financially unviable. This is especially troublesome for a doctors considering relocation to Tulare County compounding the already severe shortage of physicians.

It is obvious that Santa Cruz and Sonoma County providers have effectively lobbied for the proposed removal of their counties from Area 99. However, this piece meal action to a very complex health care delivery system will provide more complications and problems than solutions. I urge you to consider a comprehensive review of the RBRVS payment system that adequately compensates all providers.

Sincerely,

Godofredo Celis, M.D.

Mark B. McClellan, M.D., PhD, Administrator Centers for Medicare & Medicaid Services Department of Health & Human Services 7500 Security Boulevard Baltimore, MD 21244-1850

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Sincerely, Lillson

Gary Gibbs, M.D.

Mark B. McClellan, M.D., PhD, Administrator Centers for Medicare & Medicaid Services Department of Health & Human Services 7500 Security Boulevard Baltimore, MD 21244-1850

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Sincerely:

Lonnie R. Smith, M.D.

Mark B. McClellan, M.D., PhD, Administrator Centers for Medicare & Medicaid Services Department of Health & Human Services 7500 Security Boulevard Baltimore, MD 21244-1850

Subject: August 8, 2005 Proposed Rule: CMS-1502-P

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Sincerely.

Ralph Kingsford, M.D.

Mark B. McClellan, M.D., PhD, Administrator Centers for Medicare & Medicaid Services Department of Health & Human Services 7500 Security Boulevard Baltimore, MD 21244-1850

Subject: August 8, 2005 Proposed Rule: CMS-1502-P

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Sincerely.

Robert Allen, M.D.

I. W. When Me

RALPH LARSEN

405 Crestridge Pl.
Santa Rosa, CA 95409
Ph- 707-538-4900 Fax 538-5912
lars747@sonic.net
9/13/2005

GPCIs
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1502-P
Box 8097
Baltimore, MD 21244-8017

Dear Sirs:

I am 85 years old, and completely dependent on my doctors and their re-imbursement from Medicare.

I have already lost my cardiologist -moved to Texas because of the situation here. Other doctors are very unhappy, and rightly so, that their Medicare compensation is well below that of the surrounding area.

I strongly urge that this be corrected, and that their compensation be leveled with that of our adjacent areas.

Sincerely,

Raiph Larsen

Ralph Larsen



NATIONAL RENAL ADMINISTRATORS ASSOCIATION

RECEIVED - CMS

2005 SEP 23 A 11: 24

September 23, 2005

The Honorable Mark McClellan
Administrator
Attention: CMS-1502-P
Centers for Medicare and Medicaid Services
U. S. Department of health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Ave., S.W.
Washington, D. C. 20201

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006

Dear Dr. McClellan:

The National Renal Administrators Association (NRAA) welcomes the opportunity to comment on the "Proposed Rule: Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006." We will focus our comments on the "End Stage Renal Disease Related Provisions" of the proposed regulation.

The NRAA is a voluntary organization representing professional managers of dialysis facilities and centers throughout the United States. Our Association represents free-standing and hospital-based facilities, which are for-profit and non-profit providers located in urban, rural, and suburban areas serving dialysis patients in all settings. While the proposed Rule affects our entire membership, we will focus many of our comments on the impact of the regulation on small independent facilities, primarily in rural and inner-city America.

While we have significant concerns with a number of key provisions in the proposed Rule, we appreciate the many hours of work that you and your staff devoted to developing the regulations and the open dialogue that has taken place this past year with the dialysis community. As you know, the Medicare Modernization and Improvement Act of 2003 (MMA) brought dramatic changes to the reimbursement structure for ESRD providers and our industry has faced a difficult year of transition for facilities and patients across the country.

Though the MMA required the implementation of case mix adjusters and a new methodology for determining reimbursement for drugs and an add-on to the composite rate, it still did not provide our industry with an annual market basket update. As you know, the Medicare program accounts for over 80 percent of the revenue for most dialysis facilities and yet our members are the only providers under Medicare that are not statutorily entitled to an annual adjustment in the composite rate and do not receive cost or bad debt payment for erythropoietin and non-routine drugs. Our membership, particularly the independent free-standing facilities and small hospital-based units, are required to absorb cost increases, shifting reimbursement policies, budget neutrality requirements and the prospects of a value-based performance system without any additional Medicare funds and nowhere to look for new revenue. For many, the only choice will be to lower labor costs by replacing licensed personnel with technicians, sending patients to hospitals for high cost medication infusion, or to close their doors.

We believe that it is incumbent upon the Centers for Medicare and Medicaid Services (CMS) to recognize this reality in fashioning the final regulations. We also urge the Administration to join with our industry and patients in requesting that Congress treat dialysis providers as all others under the Medicare program and enact into law an annual market basket update in the composite rate equivalent to the Medicare Payment Advisory Commission (MedPAC) recommendations of 2.5 percent in 2006.

With regard to the Proposed Rule, we will focus most of our comments on the sections relating to "Revised Pricing Methodology for Separately Billable Drugs and Biologicals Furnished by ESRD Facilities" and "Proposed Revisions to Geographic Designations and Wage Indexes Applied to the ESRD Composite Rate Payment." We are generally supportive of the provisions captioned the "Proposed Revisions to the Composite Rate Exceptions Process" and "Telehealth." We will also raise two areas of concern with the existing case mix adjustment system.

Telehealth

The NRAA fully supports including dialysis facilities as an approved place of service. In so doing, it is important that CMS clearly articulate that the place of service refers to the clinic or facility as a whole as the originating site. We support adding physicians, nurse practitioners, physician assistants and non-group medical nutritional therapy to the available telehealth services and allowing certified registered dietitians, registered dietitians, and nutritional professionals to bill for their services.

ESRD - Pricing Methodology & Drugs and Biologicals

We greatly appreciate CMS' quick recognition and resolution of errors in the initial proposed Rule relating to the calculation of the add-on adjustment. The September 1 correction notice resolves our concerns with regard to the exclusion of three "J" codes and the inclusion of hospital-based facility data in the calculation of the weight to be given erythropoietin.

We remain concerned, however, that CMS has not corrected the calculation of the trend factor, the estimation of the cost of syringes for administering erythropoietin, and the calculation of the update factor for Average Sales Price (ASP).

With regard to the trend factor, we must take issue with the reliance on an erythropoietin-based growth factor of 9 percent as the basis for calculating the trend factor for determining the drug add-on adjustment. It is imperative that CMS use a growth factor that truly reflects the historical growth rate of all types of ESRD drugs.

In its March 2005 report, MedPAC determined that the spending for non-erythropoietin separately billable drugs was 17 percent per year between 1996 and 2003. It also determined that the historical trend for erythropoietin was 14 percent per year for the same period. By so substantially underestimating the growth factor (9 percent estimated vs. 14 percent actual for erythropoietin and 9 percent vs. 17 percent for non-erythropoietin medications) dialysis facilities will lose hundreds of millions of dollars. Not only does this defy congressional intent that the add-on adjustment should not result in lower payments, it will cause severe financial harm to small independent and hospital based dialysis facilities who are struggling to remain in business. This could result in a decrease in the access to care and adversely impact the quality of care provided to patients.

The proposed Rule also assumes that the growth rate of erythropoietin can be applied to separately billable drugs and, thereby, CMS can avoid a separate calculation for these drugs. MedPAC has recognized the inadequacy of this approach and in its March 2005 report estimated a significant difference in the growth rate of erythropoietin and other drugs. CMS should undertake a similar analysis and recalculate the growth factor using separate estimates for erythropoietin and separately billable drugs.

We are also concerned that CMS miscalculated the amount or cost of syringes used to administer erythropoietin. It appears that CMS, estimated the value of syringes, at \$1.00 versus the allowed \$.50 and, as a result, has significantly overestimated the total amount of payments attributable to syringes. This has a substantial impact on the calculation of the drug add-on adjustment. We would urge CMS to re-examine its assumptions and correct the amount of payment based upon the use of syringes and then re-calculate the drug add-on adjustment.

With regard to the determination that the price of drugs will be based upon ASP+6 percent, we are gravely concerned with the methodology employed by CMS and the ultimate impact on our members. In our comments last year, we urged CMS to rely upon an inflation factor that reflects historical trends of ESRD drugs rather than all drugs as a more accurate reflection of the costs of drugs actually used by dialysis facilities. Unfortunately, our recommendation was ignored last year and seems to be ignored again in the proposed Rule. The inflation factor of 5.7 percent is the forecast for all prescription drugs, not injectable medications. This does not reflect the actual ESRD drug trends as determined by CMS' own analysis. We would again urge CMS to base the inflation factor only on the actual drugs used in dialysis facilities.

In determining the appropriate basis for establishing drug reimbursement, it is also important to recognize that, in providing quality care to patients, dialysis providers are much more reliant on pharmaceuticals than other providers. A disproportionate share of our costs relates to injectables and other medications that are necessary in treating our patients. With the costs of pharmaceuticals increasing significantly (e.g. Amgen raised the price of Erythropoietin this past quarter by 4.9 percent for most independent facilities) and the fact that these increases occur at various times throughout the year, we are very concerned with the inherent time lag in reimbursement for these products in any of the proposed systems. This again will more severely impact small independent providers more adversely as they cannot, despite purchasing through GPO's, purchase medications at the lowest price.

Whether CMS bases reimbursement on ASP, Average Manufacturers Price (AMP), Average Acquisition Cost (AAC), or Average Wholesale Price (AWP), there is still a substantial period of time in which our members must absorb the cost increases before the reimbursement rates are adjusted. For the smaller facilities, particularly in rural and inner-city areas, the additional costs are extremely problematic, forcing them to look for savings in other areas that may impact patient care or creating an insurmountable barrier to their remaining in business. We urge CMS to recognize these difficulties and adjust the reimbursement rate to compensate for the time lag.

We are also concerned that neither the ASP nor other methodologies compensate for wastage, spoilage or the costs of handling pharmaceuticals. Nor are these costs reflected in the composite rate. In this regard, I am enclosing as Attachment 1 to our comments an article entitled "Analyzing the True Cost of Delivering Medications" by John A. Sargent and William W. Kingston that appeared in a recent issue of the American Journal of Kidney Diseases. As the article emphasizes, it is incumbent upon CMS to understand the full costs to providers of purchasing and providing the necessary drugs and biologicals to dialysis patients and to make certain that facilities are fairly reimbursed for all of these costs.

Hospital Reimbursement

NRAA believes all providers, both freestanding and hospital based, should be reimbursed fairly for drugs based on a cost plus system. Money should not be shifted from one type of provider to another when both are administering the same drugs. The add-on percentage should include an amount to compensate for the lag in drug reimbursement when there are price changes.

ESRD - Composite Payment Rate Wage Index

For many years the NRAA has urged CMS to update the labor component of the ESRD market basket to reflect current costs. We are pleased that CMS has recognized the importance of revising the wage index, rather than relying upon data which is more than

20 years old. In reviewing the methodology set forth in the proposed Rule, however, we are extremely concerned with the immediate impact on dialysis facilities in many states. We are mystified by the negative affect on the composite rate when labor costs have increased in all areas of the country over the past two decades and question whether CMS is basing its calculations on 40 percent or 100 percent of the wage adjustment that took place in the 1990's.

As an example, if CMS uses the wage amount as if it represented 100 percent of the wage adjustment, rather than 40 percent, the difference between the 1990 wage index and the current wage index will result in an overstated adjustment. For example, the "old rate" for Orlando, Florida is 1.0009 and the "new" rate is .9677, a difference of .0332. However, Orlando's wages only reflect 40 percent of the delta between the wage index prior to 1990 and the new one. Not knowing what the wage index for Orlando was prior to 1990, we will assume it was .9600 and was going to 1.009. The total difference for the five-year phase in was 1.009 minus .9600 which equals .0409. Only 40 percent of that difference was applied before the phase-in was terminated by congressional action. Therefore, the wage index since 1990 would be .9600 plus 40 percent of the difference, equaling .9796. To bring it to the "new" wage index, the difference would be .9796 minus .9677, equaling .0119. This is a significant difference from the adjustment proposed by CMS.

Furthermore, we are extremely concerned with the impact of the revised wage index on dialysis facilities in rural areas and in certain states. Implementation of the "new" index in Ohio, for example, will result in the composite rate for numerous facilities being reduced by more than \$14.00 for each treatment. Obviously, facilities cannot suffer such a large loss in revenue and continue to serve patients. We are most concerned with the impact in states such as Ohio and in other states with a large rural population.

Compounding this problem is the fact that dialysis facilities are not entitled to an annual update in the composite rate and have no means of gaining additional revenue. We fear that in those areas that will incur a dramatic loss in reimbursement the provider will have no choice but to discontinue treatments and no other provider will be interested in assuming responsibility for these patients. It is imperative that CMS and Congress act on the MedPAC recommendations of increasing the composite rate by the 2.5 percent for 2006.

Given our limited access to data and the underlying assumptions used in calculating the "new" indices, the NRAA encourages CMS to develop a state specific impact analysis and share this information with the dialysis community. Once this data is available then, working with the community, CMS would be better able to make adjustments in the current floor and ceiling and to fashion a transition period that will not destabilize dialysis services in critical areas of the country. It is clear that the current proposal is disruptive and that the transition period is inadequate. We would urge CMS to delay implementation for a six month period, engage the community in discussions, and then determine appropriate adjustments in the floor and a transition period that may need to exceed two years.

ESRD - Exceptions Process

The NRAA supports the provisions in the proposed Rule concerning the exceptions process. It appears, however, that the language on pages 45873-74 eliminates the current provisions implementing the congressional requirement allowing facilities to maintain their existing exception status. Given the clear intent of this section of the proposed Rule, we do not believe that this was intended by CMS. Simply re-instating the language that is currently in 42 CFR 413.180 (e) and clarifying the language in the preamble would eliminate this concern.

Case Mix Adjustment

We appreciate this opportunity to raise two concerns with the current case mix adjusters. Our first concern relates to the current reimbursement for patients who are double amputees. Reimbursement for these individuals is reduced by an average \$20 per treatment following the second leg amputation because of the adjusters relating to height and body mass. Yet, these patients still require the same or additional treatment time (as demonstrated in Attachment 2) and, since they are wheelchair or stretcher bound, they need additional staff assistance for transport upon arrival and within the facility.

To adequately reimburse facilities for the costs of treating these patients, the NRAA recommends that CMS base the reimbursement for these individuals on their full estimated height. Current policy for nutritional instruction and weight management for Registered Dietitians states: "Each new or transfer patient will be measured....either by standing with a stadiometer......or estimation of height from arm span." It would be consistent with this policy to base reimbursement on determining an individual's height by using the outstretched arm as an estimate of full height. Such a modification in current practice would more truly reflect the costs of treating these individuals.

We remain concerned with the disparity in the case mix adjusters assigned to the young adults and oldest patients under the case mix criteria implemented in April. While some statisticians believe that the cost of treatment for young adult patients exceeds the cost for our most senior patients, the experience in many facilities is quite the opposite. Given the numerous chronic conditions suffered by the more aged and the fact that many of them are not ambulatory, we find that the cost of treatment for these aged individuals exceeds that of young adult patients. We would encourage CMS to engage in a study focusing specifically on the cost of treatment of these two age groups and then, if appropriate, adjust the current weights assigned to them. Our members would be pleased to assist in the development and implementation of such a study.

The NRAA greatly appreciates this opportunity to comment on the proposed Rule and your review of our concerns. We would be pleased to respond to any questions you may have and look forward to continuing to work with CMS on all matters affecting the dialysis community.

Sincerely,

Maureen Michael

Manuen michael

President

NRAA



Reprinted from:

VOL 45, NO 5, MAY 2005

American Journal of Kidney Diseases

Analyzing the True Cost of Delivering Medications

John A. Sargent, PhD, and William W. Kingston, MEng



Analyzing the True Cost of Delivering Medications

John A. Sargent, PhD, and William W. Kingston, MEng

e Reimbursement to providers for delivering medications in the dialysis field is a subject of current concern, with some payors limiting payment to an amount equaling the provider's acquisition cost. At the same time, some providers arbitrarily mark up medications by a large factor. For dialysis, as well as for the general medical field, an objective approach is required for both providers and payors to fairly set prices and reimbursement levels. This analysis evaluated all cost elements involved in the delivery of medications and determined that an incresse over the acquisition cost is appropriate for pricing and reimbursement. The incresse has 2 parts: a fixed cost associated with resources required for a medication irrespective of its cost and a markup on the acquisition price. The conclusion of this analysis is that an incresse over acquisition cost in reimbursement of providers for delivering medications is required to fairly compensate them for their actual costs and avoid compelling them to either incur a loss or cost shift by overcharging some payors to compensate for underpayment by others. Planned adjustments in Medicare reimbursement for dialysis may not recognize this reality. Am J Kidney Dis 45:817-925.

INDEX WORDS: Costs; delivery; dialysis; drug; medication; reimbursement.

LL PAYORS FOR health services are interested in avoiding overpayment for covered services, including medications. Correspondingly, providers want to be adequately compensated for providing health services, including delivering medications. Apparently, many providers use pricing formulae for drugs, as well as services, as a means of increasing revenue to cover losses elsewhere in their businesses. I In such cases, the charge for a medication may have little bearing on the actual cost of the drug, but will reflect some "standard markup formula" of the provider.1 Compensation for delivering medications has been a particular issue in governmentfunded programs, specifically, with Medicare funding for nonroutine medications in the endstage renal disease (ESRD) program, and has changed during the years. More than a decade ago, the practice of payment for ESRD medications by using a formula based on the amount charged was changed, and compensation was instead based on the average wholesale price, with Medicare paying a percentage of that value.2 Recently, the approach has changed to conform to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003,3 and a method based on acquisition cost plus a flat fee based on the volume of treatments performed has been proposed.4 This approach appears to address paying for other delivery costs; however, the method used to develop the add-on fee simply attempts to maintain the status quo and does not consider the adequacy of the reimbursement.5

The general attitude that drug reimbursement should be based on the drug purchase price is

widely shared, even outside the medical field. In the early 1990s, there was concern about reimbursement for erythropoietin for the treatment of anemia in patients with ESRD, which was being reimbursed at that time at a flat rate of \$40 for treatments that included crythropoietin for up to 7,000 U/dose. It was discovered that the average administered dose was 2,700 units (priced at \$10/1,000 units by Amgen, its manufacturer [Thousand Oaks, CA]), and there was some outrage over the perception of profiteering, a view reflected in an article in the Wall Street Journal. 6 Regardless of whether this allegation was correct, the view that formed the basis of the article was that a provider should not be paid more for a medication than its purchase price. This perception ignores the actual cost of administering a medication, perhaps through a superficial understanding of the costs involved.

The goal of this article is to provide a framework for discussing appropriate pricing and payment for medications between providers and payors, using the dialysis setting as a specific case, rather than address a specific method of

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reimbursement. It provides a method to develop the general components of cost and mutually establish a fair level of reimbursement.

The method defines relationships that address the total cost of delivering medications to patients. These relationships contain coefficients that need to be quantified for the specific provider's business. We indicate how these coefficients can be calculated and also provide an example. We do not propose universal values because values would be expected to be different for each provider. Even so, the provider-specific values would be expected to be in the same range because of the commonality of activities involved in the administration of a given drug. This expectation is in contrast to the vast differences among similar medical providers for the same medications that have been reported recently (eg, a more than 5-fold price difference among California hospitals for Percocet [Endo Pharmaceuticals, Chadds Ford, PA]).

These factors also will vary based on the type of drug, although certain classes of drugs may have similar coefficients based on the similarity of their administration. For example, delivery of an antibiotic would differ from the use of paricalcitrol or intravenous iron in terms of supplies, monitoring, and so on required. Also, supply costs may differ based on the size of the provider and ability to negotiate the price of supplies; overhead costs may differ; receivables and collections costs may vary; and salary and benefit levels certainly will vary.

Drugs are not an isolated aspect of the dialysis treatment, and a payor might contend that they are already paying some of these costs as part of other payments. It is true that if staff is underutilized, staff requirements may not incrementally increase, but it should be an essential part of discussions with payors regarding a fair rate of reimbursement that there are costs other than the purchase price of the drug involved in its delivery, and it is essential to determine how these costs are covered. For example, it is not uncommon for some dialysis providers that use a combination of treatment nurses and technicians to have at least I nurse whose sole duty is to administer medications (as required by many state statutes). That is, if no medications were administered, this nursing position might be eliminated. Likewise, supplies required for other

aspects of drug delivery, such as needles, alcohol wipes, and so on, would not be required. The overall thrust of the article is that there are costs associated with medications in addition to the purchase price, and part of the reimbursement discussion should be where those costs are covered.

The following analysis provides a generalized description of cost elements involved in providing medications and is intended as a deliberate approach for both providers and payors in the dialysis field, but also in other areas of medicine. For providers, it should give some insights about what this part of their treatment obligations costs them and help establish reasonable formulary prices for objective discussion with payors. For payors, this analysis should assist them in recognizing the true cost of medications for their clients and beneficiaries. The elements of cost are general so that the individual provider can determine the actual values for their specific situation, although an illustrative example is included to show the nature of the computations. It also is hoped that the practice, where it exists, of simply "marking up" medications1 will yield to a more structured and deliberate approach to the pricing and reimbursement of medications.

ANALYZING THE COST OF A MEDICATION

The basic cost of delivering a medication consists of 4 components: (1) purchase price of the drug, (2) cost of supplies necessary to deliver it, (3) cost of labor to deliver it, and (4) overhead costs necessary for the medication to be available to clinical staff.

The basic cost of the drug delivery is the sum of these components. Detailed relationships for these components are developed next. To obtain the overall cost, relationships also include coefficients to account for factors that increase the cost relative to the basic calculation. For example, the cost of purchasing the medication must be adjusted to reflect the frequent situation in which more medication must be purchased than is actually delivered to the patient. These coefficients are discussed. In addition to explaining how this analysis can be used to yield the actual cost of delivering a medication, factors and coefficients are developed for the specific case of the delivery of vancomycin in the dialysis setting.

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Specifically, we consider the example of a 1,000-mg dose of vancomycin, which the provider purchases by the box (containing ten 500-mg vials) at a purchase price of \$30.00 (or \$3.00/vial). The dose is prepared by dissolving the contents of each of 2 vials of vancomycin in 10 mL of sterile water, which will require two 10-mL sterile water vials, along with 2 needlesyringe barrel combinations and associated alcohol wipes. After the 2 vials of vancomycin are reconstituted, they are introduced into a 100-mL bag of sterile saline, which is connected through a tubing set to an infusion pump. The 1,000 mg of antibiotic then is administered over the course of an hour, with nursing staff periodically checking the process and the patient. The calculations described are listed in Table 1, which also shows data to be entered and calculations, performed (as described next) to yield the specific parame-

The generalized cost of administering a medication can be represented as:

$$C_{\rm M} = (C_{\rm P} + C_{\rm S} + C_{\rm T} + C_{\rm DVHD})a*b*c$$
 (1)

where C_M is the true cost, or fair charge, for the medication; C_P is the purchase cost of the medication; C_S is the cost of supplies required to administer the drug; C_T is the labor cost required to administer the drug; C_{OVMD} is the overhead cost of providing the medication; and a, b, and c are coefficients that adjust the medication cost based on facility financial experience and requirements (defined next). Each of the terms in equation I is developed in turn.

Purchase Cost of a Medication, C_P
C_P can be represented as:

$$C_p = d * e(Pm/M)$$
 (2a)

where P is the purchase price of a given quantity of the medication, M is the amount purchased for P, and m is the net amount of the medication the patient receives (presumably the amount ordered and the basis for filing a payment claim). For the example of vancomycin, the cost of 1,000 mg of vancomycin is the cost of two 500-mg vials (P, the cost of I vial, is \$3.00; M is 500 mg; and m is 1,000 mg): Pm/M = (\$3.00)(1,000 mg)/500 mg = \$6.00.

The coefficient d is a usage coefficient that accounts for less than the full delivery of the purchased amount (M/m * number of administrations from a single purchased amount - M, which for a medication in which less than the full purchased amount is used will yield d > 1.0). In the vancomycin example, all contents of the 2 vials are used, and d = 1.0 (M is 500 mg; m is 1,000 mg; the number of administrations from a single vial is 0.5, and d = 500/(1000 * 0.5) =1.0.). The coefficient e is a breakage, spillage, and/or spoilage coefficient (e > 1.0). This coefficient considers that in addition to the difference between the discrete dose and the purchased quantity of medication addressed by coefficient d, there will be spillage, breakage, spoilage, and so on in the process of administering medications to patients. There will be a practical upper limit on this coefficient (ie, it is unlikely that a large fraction will be lost or spilled). Our available information for the vancomycin example did not include accurate data for breakage, spillage, and spoilage, and an assumption was made that of 20 boxes purchased (200 vials), 1 vial would be discarded for this reason: c = (1/(1 -1/base for 1 spoiled unit) = 1/(1 - 1/200) = 1/1 -0.005) = 1/0.9950 = 1.005.

Using these values for the vancomycin example, $C_P \approx 1.0 * 1.005(\$6.00) = \$6.03$.

Cost of Supplies, C_S
C_S is defined as:

$$C_3 = Cost_{\text{disposables}} + Cost_{\text{admin soles}} + Cost_{\text{admin soles}}$$

Costaliposobles. Disposables consist of needles, syringes, intravenous administration sets, alcohol wipes, and so on. For the vancomycin example, disposables consist of an intravenous set (\$1.17 each), 2 needles (\$0.08 each), 2 syringe barrels (\$0.18 each), and 4 alcohol wipes (\$1.67/box of 200: \$0.03), for a total Cost_{disposables} of \$1.72.

Cost administration solutions for this case are the sterile saline or sterile water used to dissolve lyophilized medications; they also include saline used to administer the drug to the patient (eg. 150 to 250 mL for intravenous administration of this antibiotic). The cost of solutions will be 2 vials of sterile water (\$0.22

8ymbal	Variable/Coefficient	Source	Calculation Formula - Explanation	Value
alculation of C _p				
Р	Price of a unit of drug	Entered	\$30/box of ten 500-mg vinis	\$3,00
M	Purchased amount	Entered	500-mg viel	500 mg
m	Administered amount	Entered	1.000 mg	1,000 mg
***	No. administration from vial	--	M/m	0.5
d	Usage coefficient	Calculated	M/(m * no. administrations from visi)	1.00
•	Base amount for 1 unit	Entered	Assumes for 20 boxes, 1 vial is not	· 200 vials for 1
	sociad	•	tised	discarded
A	Breukugu, spillage, spollage	Calculated	1/(1 - 1/base for 1 spoiled unit)	1.005
•	Purchase cost of drug	Calculated	D*e(Pm/M)	\$6.03
C _P valculation of C _P	Lifteliate control mag	Cerculated		42.00
	Manadan mataga barrata R/	Entered	IV tubing, 2 needles & syringe	\$1.72
Cost _{olepowelian}	Needles, syringe barrels, IV		barreis	41=
	sets	Catanad		\$1,36
Cost _{raterio} sotra	Sterile water, eddlum	Entered	Two 10-mL water, 100 mL aodium	4120
	chloride, wipes		chioride, 4 alcohol wipes	64 500 ample
	Purchase cost of equipment	Entered	From provider purchase data	\$1,500 each
	No. of Items	Entered	Extra needed on spare	2
	No. of uses/mo	Entered	Table 2 adjusted for all pump	24
			delivered drugs (Table 2)	
Costodario marije	Cost per use of equipment.	Calculated	(5-y cost of pumps)/(monthly usage	\$2.06
,	(over 5 y)		* 60 mo)	
Cs	Cost of supplies	Calculated	Cost _{deposition} + Cost _{adente} acine + Cost _{adene spip}	\$5.16
Calcutation of C _T				
Tadministrativa	Check orders, chart, make chart entries	Entered	Time motion evaluation by experienced staff	4 min
Tours	Drewing, dispolving, pump	Entered	Time motion evaluation by	8 min
· Garrery	set up. & etair		experienced staff	•
Treesland	Monitoring patient & delivery	Entered	Time motion availation by	5 min
- maraomy			experienced staff	
t	Basis of staff compensation	Entered	1h	60 min
1	Salary	Entered	\$24.95 for southeast US; \$30 for CA	\$24.85
	Fringes	Entered	23.7% of salary in southeast	23.7%
_	Hourly cost of staff	Calculated	Salery * (1 + Fringes)	\$30,74/h
q		Calcutated	CT = Q* (Teamhington + Tablesy +	\$7.69
G	Cost of labor			41.04
			T _{ermina} VI.	
Calculation of Cover	A		Day tour an auditory himself and	\$0.41
COVHO	Overhead costs	Calculated	See last, eg, paris are lumped and	₩W-T I
			entered	
Calculation of a				****
	Base revenus expected	Entered	Reimburgement data from provider	\$100.00
	Amount of expected	Entered	Reimburgement data from provider	\$96.65
	revenue collected			
8	Collection coefficient	Calculated	Expected revenue/actual collection	1,033
Calculation of b				
Tpermany	Time for payment from	Entered	From provider financial-collection	72 d
- best/Tt.	primary payor		data	
т.	Time for payment from	Entered	From provider firenciel-collection	99 d
Termindary	secondary	1001 64	data	-
	Value of money	Entered	From investment experience of a	10%
r	Affirm of mouses.	Cillaien	dalysis provider	1474
_	Barataskia a albertask	Caladabad		1.0212
D	Receivables coefficient	Calculated	b = 1 + (8T _{pdropy} + .2(T _{moundary} -	1.0212
			T°0′365	
Calculation of c			Consequently level of a soft for	0 P
	Desked profit	Entered	Ressonable level of profit for	8%
			cialysis enterprise	4.00
۵	Profit factor	Calculated	1 + desired profit	1.08
Calculation of C _M				A
C _M	True cost/leir charge for	Calculated	$C_{M} = (C_{p} + C_{p} + C_{T} + C_{OVHD})$	\$21,98
- M	medication	_	*a*b*c	
Factors in the cost				
relationship				
· desirent son sub-	Intercept of cost vorice	Calculated	$a^b^c (C_m + C_T + C_{OVHD})$	\$15,10
	curve	American	= > - (-B10100)	+
		Calculated	a-b-c-d-a	1,145
	Stope of cost v price curve			

Table 2. Calculation of Medication Doses per Treatment for 1 Hospital and 2 Free Standing Officers

HCPO	Drug	HCPC-Dose	Old Price	New Price			riding Clini Clinic B	
90732 90747	· I I A SELECTION OF A SECURITY OF THE PERSON OF THE PERSO	1,000 U 0.5 mL	\$10.00 \$23.28	\$9.76 \$23.26	822	1,010	1,628	748
J0636 J0690 J0713	Hepatits B vaccine Calcitriol Cefazolin sodium injection Cefazoline	40 μg 0.1 μg 500 mg	\$110.92 \$1.38 \$1.78	\$57.27 [°] \$0.96 \$0.28	7	1 17 9 1	3	6
J1270 J1580 J1750	Doxercalciferol, Injection Gontamyoin Iron dextran	500 mg 1 μg 80 mg	\$6.75 \$5.50 \$1.95	\$3.74 \$2.60 \$1.44	520 1	142 9	4 904	
J1756 J1955 J2501	Iron sucrese Injection Levocamitine	50 mg 1 mg 1 g	\$17,91 \$0.66 \$34,20	\$11.06 \$0.37 \$13.63	276	6 95	340	2
J2550 J2550 J2816	Paricalcitol Promethazine HCl injection Sodium famic gluconate complex	1 μg 50 mg 12.5 m g	\$5.33 \$2.67 \$8.17	\$4.00 \$2.15 \$4.95		310	25	12 83 16 268
12997 13370 17130	Alteplace recombinant Vancomycin HCl injection Hyperionic saline solution Medicare composite rate	1 mg 500 mg 20 mL	\$36.70 \$7.03 \$3.16	\$31.74 \$2.98 \$1.25	5	15	9 14	1 9 11
	Total non-erythropoietin medications given				817	\$142,74 758	\$132.03 1,299	\$125.73 408
	Treatments Erythropoletin administered/ treatment				1,053 0.78	1,406 0.72	1,711 0.95	965 0.79
	Medications administered/ treatment				0.78	0.54	0.76	0.42

Abbreviation: HCPC, Healthcare Common Procedure Code.

each) and a 100-mL bag of sterile saline (at \$0.92), for a total Cost_{admin solus} of \$1.36.

Costadmin equip. This term reflects the cost of specialized equipment for the administration of a drug; specifically, when a continuous infusion device is used, such as is the case for this example, and part of its cost must be allocated to the delivery of that drug. (This will be the cost per use of this equipment over its expected life, or, in some cases, the pump must be rented, which reflects the same cost factor.) For vancomycin, an infusion pump is needed, and this must be accounted for as Cost admin equip. The provider that is the source of data for this example has 2 pumps available (a second as a backup or in the case in which 2 are needed simultaneously). The pumps cost \$1,500 cach, and we assume that they have a 5-year life (60 months). As listed in Table 2, clinic A performs approximately 15 treatments per month in which vancomycin is administered. Considering that other medications may require a pump, we assumed there may be 24 pump uses per month, or 1,440 uses over

the life of the pumps. The cost of administration equipment would then be \$2.08 per use ($Cost_{ndmin}$ equip = 2 * \$1,500/1,440 uses). Using these values for the vancomycin example:

$$C_8 = $1.72 + $1.36 + $2.08 = $5.16$$

Cost of Labor for Delivery of the Medication, C_T C_T can be represented as:

$$C_{\rm r} = q * (T_{\rm administrative} + T_{\rm delivery} + T_{\rm monitoring})/t$$
(2c)

In equation 2c, the 3 terms "administrative," "delivery," and "monitoring" refer to the time allocated to the separate tasks required of clinical nursing staff in the administration of a drug.

Administrative tasks are common to all medications and reflect the time required to check physicians' orders, check the patient's chart for information that might suggest a contraindication for administration, and make appropriate entries in the medical record.

Delivery of the drug involves the time needed to draw and administer it. For some drugs, this may amount to delivery of a pill or a simple injection. For others, it may require drug preparation (eg, vancomycin) and assembly of delivery means (eg, saline drip or infusion pump).

Monitoring is necessary for some drugs. For such medications as intravenous antibiotics, the patient must be monitored as the medication is being administered, requiring extra nursing time.

Total time required, T, will be some fraction of a unit of time, t, on which staff cost, q, is hased. Administrative, delivery, and monitoring tasks are estimated to take 4, 5, and 6 minutes, respectively, for a total effort of 15 minutes. The labor rate varies in various parts of the country (a sampling of the southeast, \$24.85/h, and California, \$30.00/h). We chose the lower value of \$24.85/h and a provider rate of 23.7% in fringes, which results in a labor cost of \$30.74/h.

The cost of labor associated with administering 1,000 mg of vancomycin is $C_T = $30.74(15 \text{ minutes/60 minutes}) = 7.69 .

Overhead Cost, COVID

This is the cost of making the drug available, which is defined as:

$$C_{OVHD} \approx C_{ocderleg} + C_{delivery} + C_{recviewesvillep} + C_{AP} + C_{AR}$$
 (2d)

The 5 cost terms in equation 2d are activities required to have the medication available for clinical staff. Cordering is the cost of locating the supplier, requesting and receiving quotes, negotiating the price, and placing the order. Cablivery reflects the shipping cost (generally the responsibility of the purchaser). In addition, some medications ordered by a physician may not be kept in stock by the facility and must be purchased from a commercial pharmacy, and such drugs must be delivered by the pharmacy or picked up by facility staff. Crecylavest/disp is the cost of receiving medication deliveries; storage and special conditions (temperature and security), and breakout of the quantities needed by clinical staff. CAF (accounts payable) and CAR (accounts receivable) reflect administrative resources to process invoices and make payments, as well as generate claims and collect for services.

These costs are difficult to determine for each separate item used in dialysis, such as for an individual administration of the antibiotic of our example, and an approach that considers total costs in these categories divided by the quantity of medications processed may be appropriate.

A typical value for these efforts applicable to the vancomycin example, provided by a 4-clinic dialysis program, was approximately \$0.41.

Adjustment Coefficients a, b, and c

The sum of these cost factors (equations 2a to 2d) represents the cost of providing the medication. This sum must be further adjusted for 3 factors: a, collection coefficient; b, receivables coefficient; and c, profit factor.

Collection coefficient (a) - (a ≥ 1.0) addresses the situation in which all costs of the medications cannot be collected and will include "bad debt." A value of 1 indicates complete collection of expected payment for a claim, or a = (amount expected)/amount collected). For example, if a Medicare patient has secondary insurance, which pays 80% of an outstanding balance, Medicare pays 80% of the claim, the secondary payor pays 80% of the balance, leaving 4% of the claim as the patient's responsibility, and if the patient cannot pay this amount (which can be the case for impoverished patients), the remaining 4% is uncollectible. In this case, a = 1.0/0.96 = 1.042. This coefficient should be based on facility experience, and analysis of billing and receivables for the 4-clinic provider mentioned resulted in a yield of \$96.85 for each \$100.00 expected. That is, there was \$3.15 of had debt for each \$100 that would legitimately be expected to be collected. This yields a collection coefficient a of \$100.00/ \$96.85 = 1.033.

Receivables coefficient (b) -(1.0 < b < 1.1) recognizes that the clinical facility must carry the cost of drug administration as part of its working capital until it gets reimbursed by payors. In current medical reimbursement, it is virtually certain that the facility must pay vendors, suppliers, and staff (ie, all costs described in equations 2a to 2d) before payment is received.

The coefficient can then be defined as:

$$b = 1 + (0.8T_{\text{primery}} + 0.2T_{\text{accordery}}) * r/365$$

where r is the value of money (0.05 < r < 0.2),

T_{primery} is the lag between delivery of services and payment by the primary carrier, and T_{accondary} is the lag between delivery of services and payment by the secondary carrier. Note that only in the event full payment is received simultaneously with delivery of services will b equal 1.0.

Our representative provider collects payment from primary insurance plans in 72 days from date of service ($T_{poisson} = 72$ days) and from secondary payors in 99 days ($T_{secondary} = 99$ days). With the value of money at 10%, these data yield:

$$b = 1 + (0.8 * 72 + .2 * 99) * r/365 = 1.0212$$

Profit factor (c) is the final coefficient in equation 1 (1.0 < c < 1.2). The cost terms in equation 1, together with adjustments for receivables cost and collection efficiency, capture the costs involved in delivering the medication. Therefore, at a value of 1.0 for c. the provider would "break even" on the delivery of medications. However, for providers to operate as successful businesses, they must receive returns on financial investments similar to what could be carned by investing elsewhere. The terms in equation 1 require capital investments proportional to the costs, either in working capital to fund costs until they are reimbursed or for investments in equipment. and have been normalized to values per administration. Selecting a value for c greater than 1.0 then provides an easy method of incorporating a return on invested capital adequate to compensate the provider for assuming the risks involved in the business and competitive with alternate investments. When reimbursement rates are subject to negotiation, using this term also provides a clear understanding of the proposed return on investment for both parties in the negotiation.

Actual profit in the dialysis field varies. Some of the larger corporate providers that have the advantages of volume purchasing contracts and centralized administrative functions can realize profits greater than 10%. Many smaller providers have profits considerably less than this figure. For the purpose of this example, we assumed a profit of 8%, for which the profit factor is: c = 1 + profit = 1.08.

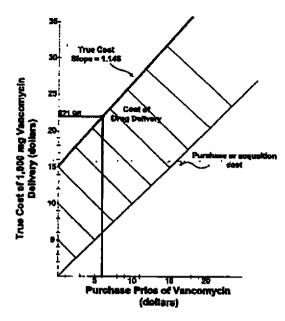


Fig 1. Cost of delivering 1,000 mg of vancomycin as a function of its price; see example in text.

Combining All Factors to Compute the Actual Cost of Drug Delivery

 C_M is described in equation 1 as: $C_M = (C_P + C_S + C_T + C_{OVHD})a * b * c$. Substituting equation 2a for C_P , equation 1 becomes:

$$C_{M} = \left[(C_{3} + C_{T} + C_{OVED}) + d * c(Pm/M) \right] a * b * c \quad (3)$$

From our vancomycin example:

$$C_M = (\$5.16 + \$7.69 + \$0.41 + \$6.03) * 1.033 * 1.0212 * 1.08 = \$21.98$$

Note that if equation 3 is expanded:

$$C_M = a * b * c * (C_S + C_T + C_{OVMD})$$

+ $a * b * c * d * e(Pm/M)$ (3a)

it will be in the form y = A + Bx (ic, a straight line with alope B and intercept A), with Pm/M, the price of the administered quantity of the medication, as the independent variable (Fig 1).

Specifically for equation 3a, the intercept will be:

$$a*b*c*(C_S+C_T+C_{OVHD})$$
 (3b)

and represents the fixed cost of giving the medication (ie, if the purchase price of the medication

were zero, it would still cost this amount to deliver it).

The slope:

is the required markup on purchase price of the delivered dose of the medication (Pm/M).

For our example, equation 3a becomes:

$$C_M = 1.033 * 1.0212 * 1.08 * ($5.16 + $7.69 + $0.41) + 1.033 * 1.0212 * 1.08 * 1.0 * 1.005(Pm/M)$$

$$C_M = 1.139(\$13.26) + 1.145(Pm/M)$$

= \$15.10 + 1.145(Pm/M)

ANALYSIS OF MEDICATION PRICING

If medication prices charged by the provider are plotted as a function of the purchase price per dose, a straight line should result with a positive slope (slope > 1.0) for medications that have the same administration route and so on (ie, when Cs and C_T are the same), as shown in Fig 1. This relationship also will apply when there is a price increase for the same drug or a different amount of the same medication is used as long as there are no changes in supply requirements. For example, if the ordered amount of vancomycin were reduced to 500 mg (1 vial), 1 needlesyringe barrel and 1 vial of sterile water would not be needed. However, all other cost factors would remain the same and the cost of administrating 500 mg would be:

$$C_M = 1.139(\$12.78) + 1.145(\$Pm/M) = \$14.56 + 1.144(\$3.00 * 500/500) = \$18.00$$

The relationship developed for the case of administering 1,000 mg of vancomycin is shown in Fig 1. In this case, the main costs are associated with labor and supplies, with only a small markup on the actual purchase price of the delivered medication. Accordingly, if the dose were reduced from 1,000 to 500 mg, the reduction in cost would be only \$3.98 for a \$3.00 reduction in purchase price, and the total cost would be \$18.00, consisting of \$0.54 of fewer supplies and \$3.44 less because of less vancomycin purchased.

: : :

In this example, a fair price for the delivery of vancomycin purchased at \$6.00 for a 1,000-mg

dose would be \$21.98, or 3.66 times the purchase price of the antibiotic; the cost of 500 mg would be 6.00 times the \$3.00 purchase price. That is, 27% of the total cost in the 1,000-mg case and 17% of the total cost in the 500-mg case are represented by what the drug cost to purchase.

It should be noted that different drugs may have a different graphical relationship, such as Fig 1. Examination of equation 3b indicates that the intercept for differing drugs will be different based on the supplies needed (C₅) and labor required (C_T). Coefficients b, c, and C_{OVID} would be expected to be the same irrespective of the medication for a specific provider. The slope (see equation 3c) also may vary, basically because d and e, the usage and breakage/spillage/ spoilage coefficients, will vary based on the drug. Coefficients a, b, and c most likely will be a function of the provider business model. Several medications may follow a curve similar to that in Fig 1 as long as they have similar methods of delivery and similar d/e values. Nonetheless, one would expect several relationships like Fig 1 that can describe the wide range of medications used by a specific provider.

DISCUSSION

In the illustrative calculation of the cost of administering vancomycin, one would calculate a markup of 366% for a 1,000-mg dose and 600% for a 500-mg dosc. On the face of it (ie, without analysis of the resources necessary to deliver this medication), these levels of costs might seem excessive. However, from the analysis, we contend that this is fair payment for this antibiotic. Nonetheless, it would be a gross misreading of this analysis to say that markups of this magnitude are justified for all medications, although on the basis of a recent report, this value may seem modest.1 It may be because of such examples (markups of 1,350% for medications that cost less than \$40.00 were cited for 1 large provider) that payors believe this is an area of proven abuse. The thrust of this analysis is that the concept of a standard markup is ill conceived. However, as recently reported, the process of pricing medications using markup formulae is very common, and we believe it is justifiably criticized. We contend that providers should adopt a pricing model more closely following this analysis because it reflects the impact on

their business and addresses common perceptions of fairness.

Given analyses similar to the one discussed as the basis for this article, payors should be willing to accept the resulting costs as legitimate amounts for payment. When such analyses are not available, they should be requested. The range of prices for the medical facilities that were the subject of a recent report indicates that this type of analysis probably was not used in developing their pricing models. Also, such analyses can be extended easily to other aspects of medical charges, much as for nonmedical businesses.

In January 2005, the Centers for Medicare and Medicaid Services instituted a new reimbursement process for the ESRD program that would, on the surface, seem to address some of the issues discussed in this article. This new policy decreases the amount that the Centers for Medicare and Medicaid Services will authorize for medications, in line with their determination of the drug acquisition cost (Table 2), which for 500 mg of vancomycin is \$2.98 (\$0.02 less than the purchase price by many dialysis providers, as discussed). Concomitantly, there will be an additional payment of 8.7% of the composite rate as a "drug add-on adjustment," seemingly accounting for the nonacquisition costs discussed in this article and addressing the actual costs of drug administration. However, the apparent intent of the method used to determine the add-on is to preserve the reimbursement status quo without addressing the adequacy of previous levels of reimbursement.5 Moreover, in the second quarter of 2005, concurrently with introducing a casemix adjustment, the composite rate will be reduced by 8.84% as a "budget neutrality" change. The budget neutrality adjustment appears to be intended to offset a presumed increase in reimbursement resulting from the introduction of the case-mix formula. However, depending on the true impact of the case-mix changes, it seems possible that the reduction may effectively take away some or all of the drug add-on adjustment, leaving the provider with overall reduced reimbursement for medications.

SUMMARY AND CONCLUSIONS

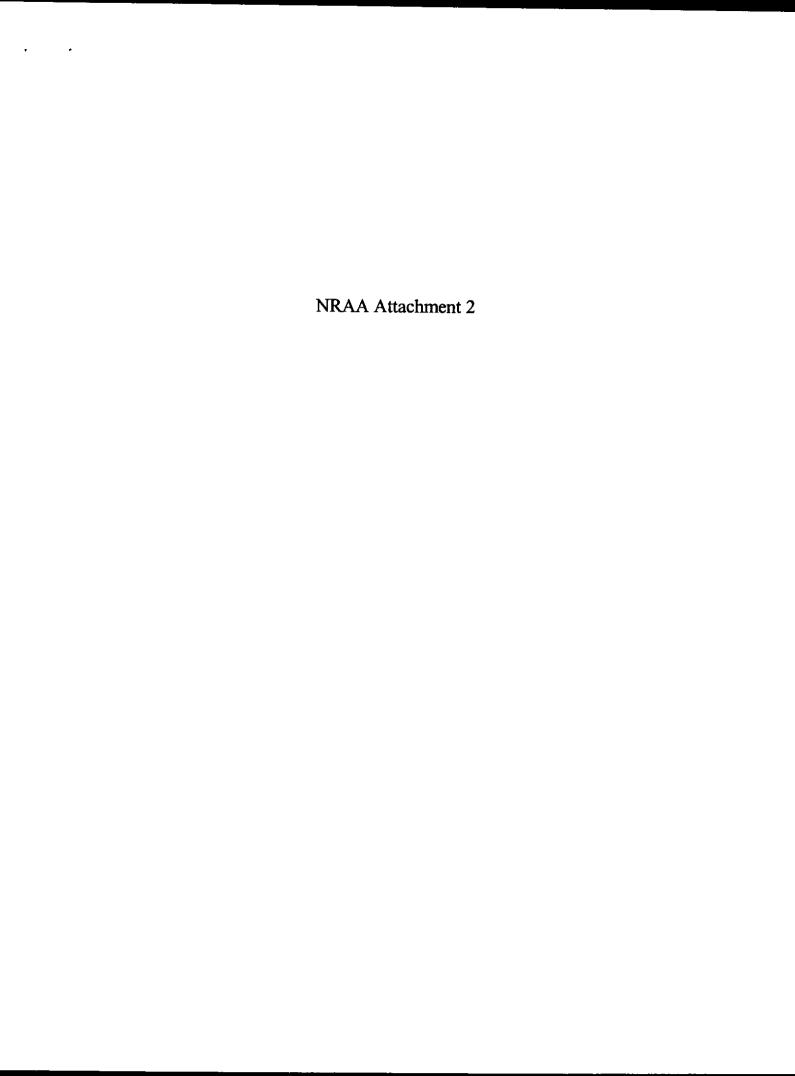
It is in the interest of everyone involved in the delivery of medical care to understand its true costs, and this certainly applies to the cost of

delivering medications. It often has appeared to be the practice to adopt a seemingly arbitrary approach to this subject, on the part of the provider and payor. The markup method of wellrecognized medical providers, as recently reported,1 supports the need for the methods discussed to provide a defensible rationale for pricing in medical care. It also shows the challenges that confront this effort. The payors may be inclined to base payment solely on the price the provider pays its supplier. Conversely, the provider may apply a "standard" markup or even come up with a charge based on what it believes someone will pay. The reported practices may be a product of inadequate payment for services to which the providers respond by marking up prices when they can, followed by other restrictions in payment, and the process goes on.

In either case, there is an issue of fairness: reimbursing on the basis of the price to the provider forces the provider to either lose money or overcharge someone else. Conversely, arbitrarily setting a price based on what a payor will pay can result in overcharging the payor. It may be naive to think that this process can be arrested by analyzing the elements of cost and engaging in objective discussions, but to break the cycle, this approach may have merit and will help the industry move toward a greater degree of fairness in drug pricing and reimbursement. Failure to do so hurts everyone associated with delivering medical care and ultimately hurts the patient.

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Facility Oriando Florida	Date of Birth	Treatment time pre double amputee	Treatment time post amputee	Height Pre doub. Amputee cm	Height Post double amputee cm	Weight pre double amputee kg	Weight TX rate post double Pre amputee amputer kg	TX rate Pre amputee	TX rate Post amputee	ate utee
pt 1 No change in t	pt 1 No change in treatment hours	•	•	175.26	139.7	79.54	59.5	132.58		117.01
pt 2 Treatment hou post amputee	ot 2 Rreatment hours INCREASED post amputee	9.	•	158.1	114.3	89	8	133.58		109.16
pt 3 227/: Treatment hours decreased decreased post amputee	2/27/1965 urs decreased st amputee	e ri	•	165.1	134.6	60.4	56.5	146.98		13.1.85 1.85
pt 4 No change in t	pt 4 7/16/2027 No change in treatment hours	•	•	187.96	147.32	8	14	160.14		132.22
pt 5 No change in t	10/20/1936 treatment hours	u) u)	8.6	157.48	150.88	59.4	ଜ	118.46		108.86
pt 6 No change in t	pt 6 5/21/1950 No change in treatment hours	•	•	170.18	140.97	110	126	152.58		143.72
pt 7 No change in t	pt 7 7/29/2019 No change in treatment hours	10 10	50	162.6	110.5	76.1	59.9	148.06		128,09
pt 8 No change in t	pt 8 7/23/1949 No change in treatment hours	•	•	170.2	141	112.5	88.6	163.86		129,78
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yet we get paid an average of \$20.00 per treatment less even though we dialyze the same amount of time and patients are more difficult Summary 8 out of 9 patients treatment time remained the same or increased with double amputee to move in and out of dialysis chairs and scale pre and post treatme Takes two staff versus one.

Only one patient decreased dialysis time post amputee.

123.47

Title of Policy/Procedure: Height Measurement Policy and Procedure_______

Issued/Revised Date: _8/30/05
Approved By: Clinical Manager/

General Information:

Medicare method of "height as patient presents" is used for billing and reimbursement. Medicare method of height is different from the standard method. Such is the case for patients with lower limb amputation. For the purpose of kinetics, the use of height before amputations for a person missing both lower limbs would be appropriate. For Medicare billing, the "height as patient presents" means actual bottom of longest limb to top of head. The Registered Dietitians will be measuring patients both ways to support both reasons.

Medicare requires that heights be measured on a regular basis. The Registered Dietitians will do this annually. This information will be given to the Billing Secretary and changes made in the patient records computer. Nursing will work with the Dietitians to communicate any new lower limb amputations that need a re-measure.

1. FOR THE LAB COMPUTER AND NUTRITIONAL ASSESSMENT:

Each new or transfer patient will be measured by the Registered Dietitian either by standing with a stadiometer, by estimating stature from knee-height caliper, or estimation of height from arm span. This information will be given to the medical secretary to enter into the laboratory computer for kinetic calculations. This method of measurement is the standard of care by the Nutritional Assessment anthropometry. This type of measurement is also used by the Registered Dietitians for Nutritional Assessments

2. FOR THE MEDICARE BILLING AND 2728 FORM:

The second method of measurement meets Medicare requirements for billing, and is referred to in Medicare language as "height as patient presents". Those patients with bilateral amputations will be measured from the top of the head to the tip of the longest lower limb stump. This information needs to be given to the Head Nurse and the Billing /Accounts Receivable Secretary for recording on Medicare Form 2728 and entered into the Patient records computer (QCS). Anytime a patient's height is shortened by new or progressive amputation of a lower limb, they will need to be remeasured upon return to the outpatient dialysis center. This new information also needs to be updated in QCS by the RD.

Example: A person with one full leg still has full height. Once the person becomes a bilateral amputee, they become shorter "height as patient presents", and Medicare reimbursement changes. So they are remeasured and the height in the QCS system gets changed.

MIDTOWN NUTRITION CARE 119 WEST 57TH STREET—SUITE 1414 NEW YORK, NY 10019 (212) 333-4243

September 22, 2005

Centers for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1502-P Mail Stop C4-26-05 7500 Security Boulevard Baltimore, MD 21244-1850

Re: Proposed Rule, Medicare Program: Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006

Specific Re: Impact of Proposed Elimination of Nonphysician Work Pool on Medical Nutrition Therapy Services (CPT 97802-4)

Specific CMS Language: "We recognize that there are still some outstanding issues that need further consideration, as well as input from the medical community. For example, although we believe that the elimination of the nonphysician work pool would be, on the whole, a positive step, some practitioner services, such as audiology and medical nutrition therapy, would be significantly impacted by the proposed change....We, therefore, welcome all comments on these proposed changes..." Federal Register, August 8, 2005, p. 45777

Dear Sir or Madam:

Midtown Nutrition Care respectfully submits the following comments that will show how CMS may not only avoid any negative impact on medical nutrition therapy services, but also increase access to these important preventive medicine services.

History of Medical Nutrition Therapy Reimbursement

- 1. August 4, 1995, 104th Congress, 1st Session, Representative Serrano introduced the first medical nutrition therapy bill, HR 2247, "Medical Nutrition Therapy Act of 1995". Relevant reimbursement language was "...the amount paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by a fee schedule established by the Secretary for the purposes of this subparagraph." [emphasis supplied]
- 2. July 17, 1996, 104th Congress, 2nd Session, Senator Bingaman introduced S 1964, "Medical Nutrition Therapy Act of 1996". Relevant reimbursement language was "...the amount paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by a fee schedule established by the Secretary for the purposes of this subparagraph." [emphasis supplied]

- 3. January 7, 1997, 105th Congress, 1st Session, Representative Serrano introduced HR 288, "Medical Nutrition Therapy Act of 1997". Relevant reimbursement language was "...the amount paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by a fee schedule established by the Secretary for the purposes of this subparagraph." [emphasis supplied]
- 4. June 24, 1997, 105th Congress, 1st Session, Senators Craig and Bingaman introduced S Amdt 454, which became Section 5105 of PL 105-33, "Study on Medical Nutrition Therapy Services." It provides "(a) Study: The Secretary of Health and Human Services shall request the National Academy of Sciences, in conjunction with the United States Preventive Services Task Force, to analyze the expansion or modification of preventive benefits provided to medicare beneficiaries under title XVIII of the Social Security Act to include medical nutrition therapy services by a registered dietitian. (b) Report: (1) Initial report: Not later than 2 years after the date of the enactment of this Act, the Secretary shall submit a report on the findings of the analysis conducted under subsection (a) to the Committee on Ways and Means and the Committee on Commerce of the House of Representatives and the Committee on Finance of the Senate. (2) Contents: Such report shall include specific findings with respect to the expansion or modification of coverage of medical nutrition therapy services by a registered dietitian for medicare beneficiaries regarding—(A) cost to the medicare system; (B) savings to the medicare system; (C) clinical outcomes; and (D) short and long term benefits to the medicare system. (3) Funding: From funds appropriated to the Department of Heath and Human Services for fiscal years 1998 and 1999, the Secretary shall provide such funding as may be necessary for the conduct of the analysis by the National Academy of Sciences under this section."
- 5. March 18, 1999, 106th Congress, 1st Session, Representative Johnson, on behalf of herself, Representative Serrano, and numerous others, introduced HR 1187, "Medical Nutrition Therapy Act of 1999". Relevant reimbursement language was "...the amount paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined under the fee schedule established under section 1848(b) [the physician fee schedule] for the same services if furnished by a physician." [emphasis supplied]
- 6. December 15, 1999, the Institute of Medicine of the National Academy of Sciences issued its report, "The Role of Nutrition in Maintaining Health in the Nation's Elderly, Evaluating Coverage of Nutrition Services for the Medicare Population," National Academy Press, Washington, DC, 2000, ISBN 0-309-06846-0. Among its findings was: "The registered dietitian is currently the single identifiable group of health professionals qualified to provide nutrition therapy. It is recognized that other health care professionals in particular fields may be qualified to provide nutrition therapy and should be considered on an individual basis as a reimbursable provider." (Page 272 of published report)
- 7. December 2000, 106th Congress, 2nd Session, Congress enacted PL 106-554, which contains Section 105, "Coverage of Medical Nutrition Therapy Services for Beneficiaries with Diabetes and Renal Disease." Relevant reimbursement language is "...the amount paid shall be 80 percent of the lesser of the actual charge for the services or 85 percent of the amount determined under the fee schedule established under section 1848(b) [the

physician fee schedule) for the same services if furnished by a physician." [emphasis supplied] Other relevant language is: "The term 'medical nutrition therapy services' means nutritional diagnostic, therapy, and counseling services for the purpose of disease management which are furnished by a registered dietitian or nutrition professional."

- 8. August 2, 2001, CMS published in the Federal Register its proposed rule for the medical nutrition therapy benefit which was to become available on January 1, 2002. Part of the proposed rule was "Payment for Medical Nutrition Therapy (§414.64)." It states, in relevant part: "The statute specifically provides that medical nutrition therapy services may only be provided by registered dietitians or nutrition professionals. We do not believe that physicians will be able to satisfy the qualification requirements and therefore will not be able to provide this service themselves. Therefore, we are not establishing physician work RVUs for this service. We interpret section 105(c)(2) of BIPA to mean that if a physician were to furnish this service, that the service was performed 'incident to' the physicians treatment plan and provided by a registered dietitian or nutrition professional." [emphasis supplied]
- 9. November 1, 2001, CMS published in the Federal Register its final rule. Among the responses to the comments received was: "While medical nutrition therapy may be performed by a physician who is also a registered dietitian, this does not make it a physician's service that requires a work RVU. Physicians may occasionally perform other services that have no physician work, such as chemotherapy administration or the technical component of a diagnostic x-ray test. When such services with no physician work are performed by a physician, we do not establish a physician work RVU just because the service was performed by a physician in that instance. Physicians will occasionally meet the statutory qualifications to be considered a registered dietitian or nutrition professional who can bill Medicare for medical nutrition therapy service. In these circumstances, we will pay the physician 80 percent of 100 percent of the physician fee schedule amount.... We initially anticipated that physicians would never bill Medicare for medical nutrition therapy services because they generally would never meet the statutory requirements to be considered dietitians or nutrition professionals. In this circumstance, we agree that it seems unusual to apply a reduction for a service that seldom would be furnished by a physician. However, we believe that the statute requires that Medicare payment be based on the 85 percent level. We understand that, although not common, there are physicians who do meet the statutory requirements to be considered registered dietitians or nutrition professionals. In these circumstances, our payment the physician will be based on 100 percent of the physician fee schedule amount, not the 85 percent that we will pay to a registered dietitian or nutrition professional." [emphasis supplied] (Page 55279 of 2001 Federal Register)
- 10. Earlier in the final rule CMS states: "The American Dietetic Association (ADA) and many individuals submitted comments concerning the proposed reimbursement rate for medical nutrition therapy services. They stated that the proposed reimbursement rate for these services is too low and would result in limited beneficiary access to these services since private practice dietitians will chose not to participate....They believe that the proposed rate for Medicare is far short of what was envisioned by the Congress....The commentators also stated that any refinement of medical nutrition therapy values should

be based on the underlying E/M codes that they believe are the statutory basis for medical nutrition therapy payment. While commentators acknowledge that physicians may perform other tasks besides nutrition assessment, therapy and counseling during an office visit, they believe those additional services are the basis for the Congress' instruction to reimburse non-physician providers of medical nutrition therapy at 85 percent of the amount physicians receive. The AMA's Health Care Professionals Advisory Committee (HCPAC) submitted a comment that suggested there should be physician work for medical nutrition therapy. This group provides recommendations on valuing services for codes used by non-physician providers....We have reviewed the statute and legislative history. There is no indication that Congress envisioned a particular payment amount or expected us to use an E/M service to determine the value of medical nutrition therapy." [emphasis supplied] (Page 55278 of 2001 Federal Register)

Using a Reimbursement Methodology That Includes a Physician Work Value Will Not Only Avoid Any Negative Impact On Medical Nutrition Therapy Services From the Elimination of the Nonphysician Work Pool, But Will Also Increase Access To These Preventive Medicine Services

- 11. We agree that Congress probably did not envision a particular amount or particular E/M service, but did Congress intend to pay nutritionists 85% of what a physician is paid for administering chemotherapy or performing the technical component of a diagnostic x-ray? Or did Congress intend to pay dietitians 85% of what it costs a physician to employ a dietitian to provide the services? If Congress had intended to focus on a dietitian's work value, then why didn't the law establish a separate fee schedule for dietitians (as Medicare has for psychologists and as the 1995, 1996 and 1997 bills had envisioned)?
- 12. After the 1995, 1996 and 1997 bills by Representative Serrano and Senator Bingaman that would have established a separate dietitian fee schedule, and after the 1997 Craig and Bingaman amendment established a study to be made of "medical nutrition therapy services by a registered dietitian", what did Representatives Johnson, Serrano and others intend when they introduced in March 1999 a bill that would have paid dietitians the amount determined under the physician fee schedule for the same services if furnished by a physician instead of pursuant to a separate dietitian fee schedule? And after the December 1999 report by the National Academy of Sciences found the registered dietitian to be the single identifiable group qualified to provide medical nutrition therapy (although others may be qualified), what did Congress intend when they passed in December 2000 a law that continued to determine payment not pursuant to a separate dietitian fee schedule but by paying 85% (instead of 100% as in the Johnson bill) of the amount determined under the physician fee schedule for the same services if performed by a physician, and also defined the providers to be registered dietitians or other nutrition professionals?
- 13. Could it possibly be that Congress intended by not having a separate dietitian fee schedule that Congress meant to exclude physician work value? Or, is it at least as likely that Congress intended to pay 85% of what a physician would be paid, including physician work value, so as to insure that reimbursement would be fixed at a level that would enable a sufficient number of dietitians to participate so that Medicare

beneficiaries would have access to this preventive benefit (and preventive benefits are what Congress want all entitled beneficiaries to get so as to hold down costs over the long term). The original sponsor of the medical nutrition therapy benefit and cosponsor of the bill that eventually became the law has asked CMS to "...please be aware of Congress' intent that payment be sufficient to provide access to care for the beneficiaries of the service. Establishing a zero work value for nutrition therapy severely limits access to these services and thus subverts the intent of the law." (See copy of September 22, 2005 letter to CMS from Representative Serrano, attached as Exhibit "A")

- 14. That the envisioned access has not been provided can be seen from the fact that prior to passage the CBO estimated the annual cost of medical nutrition therapy services to be \$60 million, whereas only about \$1 million per year has been spent annually since the benefit became available in 2002. This represents visits by only about 250,000 beneficiaries out of an estimated 8 million plus beneficiaries with diabetes and renal disease (the two conditions for which Medicare currently provides medical nutrition therapy benefits). Only about 10% of dietitians (7,000 out of 65,000 nationwide) have become Medicare providers, compared with over 90% of physicians. Journal of the American Dietetic Association, June 2005, p. 990 (copy, along with p.995, footnote references, attached as Exhibit "B").
- 15. There is a lengthy discussion in the November 1, 2001 final rule (Pages 55278-80 of 2001 Federal Register) stating that work value should not be included because medical nutrition therapy services do not involve medical histories, physical examinations or medical decisions, or the use of medical equipment and supplies and clinical personnel involved in most evaluation and management services by physicians. However, the evaluation and management code to which the medical nutrition therapy codes was compared for the basis of valuation is Preventive Medicine Service Counseling and/or Risk Factor Reduction Intervention (CPT Code 99401) which, unlike most evaluation and management codes, does not generally involve medical histories, physical examinations or medical decisions, or the use of medical equipment and supplies and clinical personnel! (A copy of the CPT's entire Preventive Medicine Services section, 2 pages, is attached as Exhibit "C".)
- 16. We think the reason CMS did not notice that CPT Code 99401 does not generally involve these components is because 2 interrelated points had been raised in comments to the proposed rule. First that CMS should compare the 15-minute medical nutrition therapy code CPT 97802 to the 15-minute office visit code CPT 99213, rather than to the 15-minute preventive medicine counseling code CPT 99401; and second that a physician's work value should be included in valuing medical nutrition therapy services. Therefore, it was natural for CMS to look at the medical history, physical examination, medical decision, medical equipment, medical supplies and clinical personnel components of CPT Code 99213, and not notice that these components are generally lacking in CPT Code 99401. (Attached as Exhibit "D" is a copy of the entire final rule "Payment for Medical Nutrition Therapy" discussion, pp. 55278-55281.)
- 17. Because CPT Code 99401 does not generally involve medical histories, physical examinations or medical decisions, or the use of medical equipment and supplies and

clinical personnel, the valuation of CPT Code 99401 is already significantly lower than other 15-minute evaluation and management service codes that involve these components, see 2005 Relative Value Units for the following codes (Pages 66666, 66668 and 66671 of 2004 Federal Register):

15-minute Code	Work RVU	Non-facility Practice Expense RVU	Malpractice RVU	Non-facility Total
99213 (Office Visit)	0.67	0.69	0.03	1.39
99241 (Office Consultation)	0.64	0.64	0.05	1.33
99401 (Prev Medicin Counseling)	0.48 ne	0.62	0.01	1.11
97802 (Med Nutrition Therapy)	0.00 on	0.47	0.01	0.48

- 18. The discussion by CMS that stated that work value should not be included because medical nutrition therapy services do not involve medical histories, physical examinations or medical decisions, or the use of medical equipment and supplies and clinical personnel was set forth for the first time in the final 2001 rule, and not in the proposed 2001 rule. Therefore, CMS was unable to receive comments that might have pointed out that CPT Code 99401 also does not generally involve medical histories, physical examinations or medical decisions, or the use of medical equipment and supplies and clinical personnel (so while the lack of these components may be a good reason for cross walking the medical nutrition therapy codes to CPT Code 99401, rather than to CPT Code 99213, it is not a good reason to disregard physician work value).
- 19. However at this time CMS can take notice that CPT Code 99401 does not generally involve medical histories, physical examinations or medical decisions, or the use of medical equipment and supplies and clinical personnel, and therefore could (and should) continue the comparison to CPT Code 99401, but utilize the CPT Code 99401 work value, plus the CPT Code 99401 practice and malpractice expense RVUs for valuing the medical nutrition therapy codes (and then paying a physician 80% of 100%, and a dietitian 80% of 85%, of the total of these 3 values). This would be analogous to the payment of physician assistants and nurse practitioners 80% of 85% of CPT Code 99213 or other evaluation and management services that, as appropriate for their practice, contain medical history, physical examination, medical decision, medical equipment, medical supplies and clinical personnel components. And this would allow a physician who is also a dietitian to be paid appropriately (80% of 100%) for medical nutrition

therapy services since a physician cannot otherwise use CPT Code 99401 because while it has been valued, CPT Code 99401 is a noncovered service for which Medicare payment may not be made. (Page 66671 of 2004 Federal Register; Page 45999 of 2005 Federal Register)

- 20. As in the 2001 final rule, the valuation of the 15-minute individual medical nutrition therapy Code 97803 should continue to be the same as the valuation of the 15-minute individual medical nutrition therapy Code 97802; and the valuation of the 30-minute group medical nutrition therapy Code 97804 should continue to approximate the hourly valuation of the individual medical nutrition therapy codes based on an assumption of an average of 5 patients in a group (that is, each RVU value for the 30-minute group increment should be determined by multiplying the corresponding RVU value for the individual 15-minute increment by 2, then dividing by 5).
- 21. Unlike the issue of medical history, physical examination, medical decision, medical equipment, medical supplies and clinical personnel components, which was raised for the first time in the 2001 final rule, the issue of whether the two individual 15-minute codes would be valued the same or differently was fully discussed in the 2001 proposed rule, in comments thereto, and in the final rule, which stated as follows: "We have reviewed the payments for CPT codes 97802 and 97803 and agree with the commentator that these two codes should have the same values. The essential difference between an initial and follow up medical nutrition therapy service is the time spent performing the service. Initial visits will be longer than follow-up visits and will likely involve Medicare payment for more increments of service. We will pay less for follow up visits because they will typically involve fewer 15 minute increments of time than an initial visit. The payment rate we are establishing in this final rule for CPT code 97803 will be the same as the proposed rate for CPT code 97802. We have also changed the payment rate for CPT code 97804 assuming that the code will normally be billed for 4 to 6 patients with the average of 5. Using the revised values, the payment rate for group medical nutrition therapy would approximate the hourly rate paid for other medical nutrition therapy services." (Page 55281 of 2001 Federal Register)
- 22. That reasoning was sound in 2001 and remains sound, and should continue to be followed, rather than create a 0.01 less RVU for CPT code 97803 as proposed at Page 45997 of the August 8, 2005 Federal Register.

Our Practice

- 23. Our group practice, Midtown Nutrition Care, has seven full-time Registered Dietitians who see approximately 700 patients per month, about 1/3 of which have diabetes or kidney disease.
- 24. We are providers for all the major commercial insurance companies in our area. These currently pay an average of \$42.53 per 15-minute increment for CPT Codes 97802 and 97803 (which codes are valued equally by the commercial insurers we bill these codes). Copies of explanations of benefits (with patient identifiers deleted), which show

these amounts to be \$50, \$44.80, \$40.32 and \$35 per 15-minute increment, are attached as Exhibit "E".

- 25. Because Medicare currently pays only about \$18 per 15-minute increment for our geographical area, which is one of the highest in the nation (and would be reduced an additional 10% under the proposed 2006 physician fee schedule) we cannot afford to see Medicare patients and none of us has become a Medicare provider. We therefore turn away a couple of Medicare patients per day and most of these patients are unable to obtain medical nutrition therapy services because virtually none of the private practice nutritionists in our area accept Medicare.
- 26. If payment for the 15-minute increment were to a little more than double as proposed above it would roughly equal the <u>average</u> we are receiving from commercial insurance companies in our area and we would all become providers and accept Medicare. Based on my experience as co-reimbursement chair for the New York State Dietetic Association I also believe that the vast majority of private practice nutritionists in my area and nationwide would do likewise. Therefore, if the above proposal is followed it will not only avoid any negative impact from the elimination of the nonphysician work pool, it will also provide appropriate access to care for all Medicare beneficiaries entitled to these services.

Sincerely yours,

Robert Howard, RD, JD Managing Partner JOSÉ E. SERRANO 16TH DISTRICT, NEW YORK

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www.house.gov/serrano

Congress of the United States House of Representatives

Washington, DC 20515-3216

COMMITTEE: APPROPRIATIONS

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HOMELAND SECURITY

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MEMBER, CONGRESSIONAL BLACK CAUCUS

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DEMOCRATIC STEERING
COMMITTEE

September 22, 2005

Dr. Mark B. McClellan Centers for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1502-P P.O. Box 8017 Baltimore, MD 21244-8017

Dear Dr. McClellan:

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

As you review the rule pertaining to medical nutrition therapy benefits, please be aware of Congress' intent that payment be sufficient to provide access to care for the beneficiaries of the service. Establishing a zero work value for nutrition therapy severely limits access to these services and thus subverts the intent of the law.

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

Mose E. Serrano

Member of Congress

EXHIBIT "A"

mation packets, meetings and conference calls, and support developing language that describe MNT services provided by RDs as a component of the CCI program.

MEDICARE ADVANTAGE

Medicare+Choice will be replaced with Medicare Advantage effective January, 2006. CMS announced on December 6, 2004 that there will be 26 Medicare Advantage regions established across the nation for health insurance plans wishing to participate in the new program. Participating health insurance plans will be required to service the entire region. Each Medicare Advantage regional plan will have a network of providers who agree to contractually specified reimbursement levels for covered benefits.

The intent of this new provision is to have traditional fee-for-service Medicare compete head to head on prices with private insurance companies. In order to gain sufficient support to pass the bill, this new provision is a 6-year demonstration program in up to six standard metropolitan statistical areas (SMSAs). Private insurers will be able to begin bidding to serve Medicare beneficiaries in regions beginning in 2006. Payment rates would be based on a blended average of the bids. The traditional Medicare system will compete with private plans in selected SMSAs beginning in 2010. There are significant incentives in the new law to encourage private insurance companies to participate in this program.

How the Medicare Advantage program affects utilization of the Medicare MNT coverage, and the two new programs that include MNT benefits, remains to be seen. There is the potential for significant growth in MNT services. According to the proposed rules released by CMS, beginning in 2006, the Medicare Advantage program will have to "enrich the range of benefit choices available to enrollees, including not only improved prescription drug benefits, but also other benefits not covered by traditional Medicare, and the opportunity to share in savings where plans can deliver benefits at lower costs" (78).

MEDICARE MNT'S IMPACT ON PRIVATE INSURANCE PLANS' COVERAGE

ADA researchers conducted an environmental scan in 2002 to determine if the MNT benefit (which went into effect January 1, 2002) had increased the coverage of nutrition services provided by RDs within private insurance or health care plans. While the scan is not representative of all managed care organizations or the health care marketplace, a positive change in coverage was noted since 1999, when a benchmark was set (79). The growth in coverage of dietetic services are attributable to a number of factors: costs, consumer demand, and recognition of MNT, the availability of data on the effectiveness of nutrition interventions, and new tools such as codes that allow direct reimbursement to dietetic professionals. Dietetics professionals may find an increasingly receptive environment for their knowledge and skills, and involvement in disease management services, as more private sector plans reported contracting with RDs for nutrition services. Additionally, several plans in the 2002 scan indicated they follow Medicare's lead in adopting CPT codes.

MEDICARE MNT UTILIZATION RATES

During the first year of Medicare MNT coverage under Medicare, 4,125 individuals enrolled as MNT providers and billed approximately \$800,000 for individual and group MNT services (80). (When Congress was considering the MNT bill in 2000, it was estimated that a scaled-down MNT bill establishing coverage to beneficiaries with diabetes, cardiovascular disease, and/or renal disease, would cost a little less than \$1 billion per year [81].) Recent CMS data indicates nearly 7,000 registered dietitians or licensed nutrition professionals have enrolled as providers of MNT (82). Only 211,000 Medicare beneficiaries received MNT services since the benefit's inception, yielding approximately \$3.3 million of new revenue for RDs.

Those are disappointing statistics inasmuch that they indicate an underutilization of the MNT benefit. Based on estimates from the National Diabetes Information Clearinghouse and United States Renal Data System, approximately 8.6 million indi-

viduals (or 18.3%) at least 60 years old are diagnosed with diabetes or acute renal failure, making most of them eligible for MNT Medicare services (83). In terms of income potential to RDs, the CBO-projected \$60 million annual outlays for Medicare MNT for diabetes and kidney disease are far higher than the actual \$1 million annual average. Data provided by CMS indicate a small but growing demand for Medicare MNT for diabetes and kidney disease when beneficiaries obtain a referral by their physicians.

How the Medicare
Advantage program
affects utilization of
the Medicare MNT
coverage, and the
two new programs
that include MNT
benefits, remains to
be seen.

There are a number of reasons to expect greater demand for Medicare MNT services. First of all, the Medicare Modernization Act includes two MNT components, one of which is the Initial Preventive Physical Examination, which went into effect January 1. 2005. The American Diabetes Association estimates that more than onethird of Americans with diabetes do not know they have the disease (84). If the "Welcome to Medicare" physical is successful in identifying people who have diabetes but did not know it, the utilization rate for MNT should show a significant increase.

The chronic care provisions of the Medicare Modernization Act also provide an opportunity for significant growth in MNT utilization, because MNT also is a component of that provision. Currently, 78% of the Medicare population has one or more chronic conditions that require ongoing medical management (85). Almost two thirds (63%) have two or more chronic conditions, and 20% of Medicare beneficiaries have five or more chronic conditions (86). Therefore, participating in Medicare's new chronic care disease management

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99373

complex or lengthy (eg., lengthy counseling session with anxious or distraught patient, detailed or prolonged discussion with family members regarding seriously ill patient, lengthy communication necessary to coordinate complex services of several different health professionals working on different aspects of the total patient care plan)

Care Plan Oversight Services

Care Plan Oversight Services are reported separately from codes for office/outpatient, hospital, home, nursing facility or domiciliary services. The complexity and approximate physician time of the care plan oversight services provided within a 30-day period determine code selection. Only one physician may report services for a given period of time, to reflect that physician's sole or predominant supervisory role with a particular patient. These codes should not be reported for supervision of patients in nursing facilities or under the care of home health agencies unless they require recurrent supervision of therapy.

The work involved in providing very low intensity or infrequent supervision services is included in the pre- and post-encounter work for home, office/outpatient and nursing facility or domiciliary visit codes.

99374

Physician supervision of a patient under care of home health agency (patient not present) in home, domiciliary or equivalent environment (eg. Alzheimer's facility) requiring complex and multidisciplinary care modalities involving regular physician development and/or revision of care plans, review of subsequent reports of patient status, review of related laboratory and other studies, communication (including telephone calls) for purposes of assessment or care decisions with health care professional(s), family member(s), surrogate decision maker(s) (eg, legal quardian) and/or key caregiver(s) involved in patient's care, integration of new information into the medical treatment plan and/or adjustment of medical therapy, within a calendar month; 15-29 minutes

99375

30 minutes or more

99377

Physician supervision of a hospice patient (patient not present) requiring complex and multidisciplinary care modalities involving regular physician development and/or revision of care plans, review of subsequent reports of patient status, review of related laboratory and other studies, communication (including telephone calls) for purposes of assessment or care decisions with health care professional(s), family member(s), surrogate decision maker(s) (eg, legal guardian) and/or key caregiver(s) involved in patient's care, integration of new information into the medical treatment plan and/or adjustment of medical therapy, within a calendar month; 15-29 minutes

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99379

Physician supervision of a nursing facility patient (patient not present) requiring complex and multidisciplinary care modalities involving regular physician development and/or revision of care plans. review of subsequent reports of patient status, review of related laboratory and other studies, communication (including telephone calls) for purposes of assessment or care decisions with health care professional(s), family member(s), surrogate decision maker(s) (eg, legal guardian) and/or key caregiver(s) involved in patient's care, integration of new information into the medical treatment plan and/or adjustment of medical therapy, within a calendar month; 15-29 minutes

99380

30 minutes or more

Preventive Medicine Services

The following codes are used to report the preventive medicine evaluation and management of infants, children, adolescents and adults.

The extent and focus of the services will largely depend on the age of the patient.

If an abnormality/ies is encountered or a preexisting problem is addressed in the process of performing this preventive medicine evaluation and management service, and if the problem/abnormality is significant enough to require additional work to perform the key components of a problem-oriented E/M service, then the appropriate Office/Outpatient code 99201-99215 should also be reported. Modifier '-25' should be added to the Office/Outpatient code to indicate that a significant, separately identifiable Evaluation and Management service was provided by the same physician on the same day as the preventive medicine service. The appropriate preventive medicine service is additionally reported.

An insignificant or trivial problem/abnormality that is encountered in the process of performing the preventive medicine evaluation and management service and which does not require additional work and the performance of the key components of a problem-oriented E/M service should not be reported.

The "comprehensive" nature of the Preventive Medicine Services codes 99381-99397 reflects an age and gender appropriate history/exam and is NOT synonymous with the "comprehensive" examination required in Evaluation and Management codes 99201-99350.

Codes 99381-99397 include counseling/anticipatory guidance/risk factor reduction interventions which are provided at the time of the initial or periodic comprehensive preventive medicine examination. (Refer to codes 99401-99412 for reporting those counseling/anticipatory guidance/risk factor reduction interventions that are provided at an encounter separate from the preventive medicine examination.)

Immunizations and ancillary studies involving laboratory, radiology, other procedures, or screening tests identified with a specific CPT code are reported separately. For immunizations, see 90471-90474 and 90476-90749.

New Patient

99381 Initial comprehensive preventive medicine

evaluation and management of an individual including an age and gender appropriate history, examination, counseling/anticipatory guidance/risk factor reduction interventions, and the ordering of appropriate immunization(s), laboratory/diagnostic procedures, new patient; infant (age under 1 year)

99382

early childhood (age 1 through 4 years)

99383

late childhood (age 5 through 11 years)

99384

adolescent (age 12 through 17 years)

99385

18-39 years

99386

40-64 years

99387

65 years and over

Established Patient

99391 Periodic comprehensive preventive medicine

reevaluation and management of an individual including an age and gender appropriate history, examination, counseling/anticipatory guidance/risk factor reduction interventions, and the ordering of appropriate immunization(s), laboratory/diagnostic procedures, established patient; infant (age under 1 year)

99392

early childhood (age 1 through 4 years)

99393

late childhood (age 5 through 11 years)

99394

adolescent (age 12 through 17 years)

99395

18-39 years

99396

40-64 years

99397

65 years and over

Counseling and/or Risk Factor Reduction Intervention

New or Established Patient

These codes are used to report services provided to individuals at a separate encounter for the purpose of promoting health and preventing illness or injury.

Preventive medicine counseling and risk factor reduction interventions provided as a separate encounter will vary with age and should address such issues as family problems, diet and exercise, substance abuse, sexual practices, injury prevention, dental health, and diagnostic and laboratory test results available at the time of the encounter.

These codes are not to be used to report counseling and risk factor reduction interventions provided to patients with symptoms or established illness. For counseling individual

patients with symptoms or established illness, use the appropriate office, hospital or consultation or other evaluation and management codes. For counseling groups of patients with symptoms or established illness, use 99078.

Preventive Medicine, Individual Counseling

99401

Preventive medicine counseling and/or risk factor reduction intervention(s) provided to an individual (separate procedure); approximately 15 minutes

99402

approximately 30 minutes

99403

approximately 45 minutes

99404

approximately 60 minutes

Preventive Medicine, Group Counseling

99411

Preventive medicine counseling and/or risk factor reduction intervention(s) provided to individuals in a group setting (separate procedure); approximately 30 minutes

99412

approximately 60 minutes

Other Preventive Medicine Services

99420

Administration and interpretation of health risk assessment instrument (eg. health hazard appraisal)

99429

Unlisted preventive medicine service

Newborn Care

The following codes are used to report the services provided to newborns in several different settings.

For newborn hospital discharge services provided on a date subsequent to the admission date of the newborn, use 99238.

For discharge services provided to newborns admitted and discharged on the same date, use 99435.

99431

History and examination of the normal newborn infant, initiation of diagnostic and treatment programs and preparation of hospital records. (This code should also be used for birthing room deliveries.)

99432

Normal newborn care in other than hospital or birthing room setting, including physical examination of baby and conference(s) with parent(s)

99433

Subsequent hospital care, for the evaluation and management of a normal newborn, per day

99435

History and examination of the normal newborn infant, including the preparation of medical records. (This code should only be used for newborns assessed and discharged from the hospital or birthing room on the same date.)

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55278 Federal Register/Vol. 66, No. 212/Thursday, November 1, 2001/Rules and Regulations

Payment for Medical Nutrition Therapy (§ 414.64)

Section 105(c) of the BIPA requires that we pay for medical nutrition therapy services at 80 percent of the lesser of the actual charge for the services or 85 percent of the smount determined under the physician fee schedule for the same services if the schedule for the same services if the services had been furnished by a physician. Based upon consultation with the American Dietetic Association (ADA) to assess the types of resource inputs used to furnish a 15-minute medical nutrition therapy session by a registered dietitian or professional nutritionist, we proposed the following-

For CPT code 87802—Medical nutrition therapy; initial assessment and intervention, individual, face-to-face with the patient, each 15 minutes, we did not propose physician work RVUs for this service, based on the statutory provision that specifically provides that medical nutrition therapy services may only be furnished by registered dietitians or nutrition professionals. For practice expense, we proposed 0.47 RVUs and, for malpractice, we proposed 0.01 RVUs for a total of 0.48 RVUs.

For CPT code 97803—Reassessments and intervention, individual, face-to-face with the patient, each 15 minutes, we proposed 0.0 work RVUs, 0.34 practice expense RVUs and 0.01 malpractice RVUs for a total of 0.85 RVUs.

For CPT code 97804—Croup, 2 or more individuals, each 30 minutes, we proposed 0.0 work RVUs, 0.14 practice expense RVUs and 0.01 malpractice RVUs for a total of 0.15 RVUs. To determine payment, the RVUs shown above would need to be multiplied by the physician fee schedule conversion factor and 0.85 (to reflect the statutory requirement that payment be 85 percent of the amount determined under the physician fee schedule).

We also stated that, consistent with the definition in the CPT's Physical Medicine Rehabilitation codes, a group is considered to be 2 or more individuals and that Medicare copayments and deductibles would apply for medical nutritional therapy services.

Comment: The American Dietetic
Association (ADA) and many
individuals submitted comments
concerning the proposed reimbursement
rate for medical nutrition therapy
services. They stated that the proposed
reimbursement rate for these services is
too low and would result in limited
beneficiary access to these services
since private practice dietitians will
choose not to participate. Some
commenters referenced reimbursement

rates currently paid by private insurers of \$85 to \$125 for 1 to 1½ hours for an initial visit and \$85 per hour for followup. They believe that the proposed rate for Medicare is far short of what was envisioned by the Congress. Commenters indicated that the statute clearly states that medical nutrition therapy payment should be 80 percent of the lesser of the actual charge or 85 percent of the amount determined under the physician fee schedule for the same service, provided by a physician. According to commenters, physicians who are also registered distitions, use E/ M codes 99213 through 99215 and 99244 when providing medical nutrition therapy services. The commenters stated that E/M codes 99203 through 99205 are appropriate reference points for determining medical nutrition therapy payment. The commenters also stated that any refinement of medical nutrition therapy values should be based on the underlying E/M codes that they believe are the statutory basis for medical nutrition therapy payment. While commenters acknowledge that physicians may perform other tasks besides nutritional assessment, therapy and counseling during an office visit, they believe those additional services are the basis for the Congress' instruction to reimburse non-physician providers of medical nutrition therapy at 85 percent of the amount physicians receive. The AMA's Health Care Professionals Advisory Committee (HCPAC) submitted a commant that suggested there should be physician work for medical nutrition therapy. This group provides recommendations on valuing services for codes used by nonphysician providers. The HCPAC indicated that it evaluated each of the medical nutrition therapy codes and compared them to services that are available to other providers but not nutritionists (for example, physical therapy services). The comment further stated that the 15 percent reduction should not apply because the HCPAC took this into account when developing the recommendations. The HCPAC further added that there should be work values for medical nutrition therapy just as there are for physical and occupational therapy.

Response. We have reviewed the statute and legislative history. There is no indication that Congress envisioned a particular payment amount or expected us to use an E/M service to determine the value of medical nutrition therapy. Section 105(c) of the BIPA states that "the amount paid shall be 80 percent of the lesser of the actual charge

for the services or 85 percent of the amount determined under the fee schedule established under section 1848(b) of the Act for the same services if furnished by a physician." The BIPA Conference Report indicates that payment will equal "the lesser of the actual charge for the service or 85 percent of the amount that would be paid under the physician fee schedule if such services were provided by a physician." The statute and Conference Report direct us to establish the physician fee schedule amount for nutrition therapy services. The Medicare allowed charge would equal 100 percent of the physician fee schedule amount if the services are performed by a physician and 85 percent of the physician fee schedule amount if the services are performed by a registered distition or nutrition professional. The commenters suggest that physicians currently bill for an E/ M service when they provide nutrition services. We do not believe that it is appropriate to compare medical nutrition therapy provided by a registered distribution an RM service provided by a physician. Registered distribution and RM service provided by a physician. Registered distribution and take medical histories. they are not trained to and do not perform physical examinations, nor do they make medical decisions. Furthermore, when physicians use an E/ M code to report the provision of counseling or coordination of care, they typically have also performed a medical history, physical examination, and engaged in medical decision making as part of that service. If such an individual performed a service that met the requirements of an E/M service, then it would be be appropriate for him or her to report an B/M service. Further, we note that the E/M services include not only an amount attributable to physician work, but also payment for physician practice expenses. For instance, a level 3 new patient office visit (CPT code 99203) includes payment for 50 minutes of nurse time. A level 3 established patient office visit (CPT code 09213) includes 35 minutes of nurse time. Both of these codes include additional compensation for medical equipment and supplies that are typically used in an office visit but are not used as part of a medical nutrition therapy service. If we were to adopt the commenters' view and crosswalk values for medical nutrition therapy to an E/M service, we would be including payment not only for the counseling service of the practitioner. but also, inappropriately for the costs of clinical personnel that are not involved in the nutrition therapy service.

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Commenters indicated that the statute established the 85 percent adjustment to account for activities that are typically performed by a physician during an E/ M service are not performed by a nutritionist. The statute and legislative history do not indicate that the 85 percent adjustment is intended to serve this purpose. In fact, the commenters themselves note that "consistent with other non-physicien providers, reimburgement is set at a percentage of the physicien's fee schedule." Under the physician fee schedule, we will pay a physician 80 percent of 100 percent of the physician fee schedule amount, and, if a non-physician practitioner provides an identical service. Medicere pays 80 percent of 85 percent of the physician tes schedule amount. For instance, under CPT code 89213, a level 3 established patient office visit is one of the most common services provided by physicians, physician assistants and nurse practitioners. Even though the service is considered to be identical, we can by law pay a physician assistant and nurse practitioner only 85 percent of what we pay a physician to do the same service. Thus, in the case of other practitioners, the percentage does not reflect that a non-physician practitioner provides fewer services than a physician. Because there is no indication in the statute that the 85 percent adjustment should apply differently in the context of medical nutrition therapy than for other services performed by non-physician practitioners, we believe it is appropriate to pay 80 percent of 100 percent of the physician fee schedule amount when medical nutrition therapy is provided by a physician end 80 percent of 85 percent of the physician fee schedule amount when the service is provided by a registered dictition or nutrition professional.

In response to the comment about payment rates of private insurers for medical nutrition therapy, we cannot use such information in a relative value system to establish payment. Section 1848(c) of the Act requires us to establish RVUs that recognize the relative resources involved in furnishing different physician fee schedule services. Thus, our role is to establish the appropriate relative payment emounts. The total payment amount is determined under a formula prescribed in section 1848(d) of the Act. We have no authority to change the formula.

In response to the HCPAC recommendation, we reiterate that it is inappropriate to compare medical nutrition therapy services to E/M services performed by physicians, While medical nutrition therapy may be

performed by a physician who is also a registered dietitian, this does not make it a physician's service that requires a work RVU. Physicians may occasionally perform other services that have no physician work, such as chemotherapy administration or the technical component of a diagnostic x-ray test. When such services with no physician work are performed by a physician, we do not establish a physician work RVU just because the service was performed by a physician in that instance. Physicians will occasionally meet the statutory qualifications to be considered a registered distitian or nutrition professional who can bill Medicare for medical nutrition therapy services. In these circumstances, we will pay the physician 80 percent of 100 percent of the physician fee schedule amount. In this unusual circumstance, we are paying for a medical nutrition therapy service provided by a physician under section 1861(s)(2)(V) and not a physician's service under section 1861(s)(1) of the Act.

Comment: One comment indicated that the 85 percent adjustment should not apply because the RVUs we used are not based on physician work or physician practice expenses to deliver the service. This commenter indicated that we proposed an inadequate payment by not following the statutory scheme and proceeded to apply a 15 percent discount that is neither fair nor

reasonable.

Response. The statute requires us to establish a physician fee schedule amount for the service and pay 80 percent of 100 percent of the amount if the service is provided by a physician and 80 percent of 85 percent if the service is provided by a registered distitian or nutrition professional. We initially anticipated that physicians would never bill Medicare for medical nutrition therapy services because they generally would not meet the statutory requirements to be considered registered dietitians or nutrition professionals. In this circumstance, we agree that it seems unusual to apply a reduction for a service that seldom would be furnished by a physician. However, we believe that the statute requires that Medicare payment be based on the 85 percent level. We understand that, although not common, there are physicians who do meet the statutory requirements to be considered registered distitians or nutrition professionals. In these circumstances, our payment to the physician will be based on 100 percent of the physician fee schedule amount, not the 85 percent that we will pay to a registered dietitian or nutrition professional. We believe the statute

would not allow a physician who does not meet the statutory requirements for a registered distitian or nutrition professional to be paid for a medical nutrition therapy service. If a physician provides medical nutrition counseling as part of a patient encounter that meets the requirements for an E/M service, the physician can bill Medicare for a physician's service.

Comment: We received one comment requesting that we clarify that Medicare will pay qualified providers in private practice settings or physician offices where they may be independent contractors. The commenter also asked how we intend to pay for medical nutrition therapy in the hospital outpatient department. The commenter also asked for clarification on reassignment of payment if a registered dictitian is an employee of physicians or hospital outpatient facilities.

hospital outpatient facilities.
Response: Medicare will pay qualified distitians and nutrition professionals who enroll in the Medicare program regardless of whether they provide medical nutrition therapy services in an independent practice setting, hospital outpatient department or any other setting, with the exception of services provided to patients in an inputient stay in a hospital or skilled nursing facility. In these circumstances, our payment to the hospital or skilled nursing facility includes payment for medical nutrition therapy. If a qualified practitioner provides medical nutrition therapy in any other setting, including a private practice setting, section 1833(a)(1)(T) of the Act requires that Medicare payment equal 80 percent of the lesser of actual charges or 80 percent of 85 percent of the amount determined under the physician fee schedule. Payment in the hospital outpatient department will be made under the physician fee schedule. not under the hospital outpatient prospective payment system.
Current rules regarding reassignment

Current rules regarding reassignment of benefits would apply to medical nutrition therapy. We want to emphasize that medical nutrition therapy cannot be provided incident to a physician's service unless the physician also meets the qualifications to bill Medicare as a registered dictitian or nutrition professional.

or nutrition professional.

Comment: Commenters objected to the methodology used to establish the proposed RVUs for this service. They believe it is inappropriate to use the top-down or no-work pool methodology to determine medical nutrition therapy payment, They believe that medical nutrition therapy payment should not be based on comparison to a preventive medicine code (CPT code 99401) in the zero-work pool methodology. The

EX HIBIT "D" PAGE 2 OF 4 commenters indicated that preventive medicine services omit the problemoriented components of the comprehensive history, as well as other essential assessment points, such as the patient's chief complaint and history of present illness. They disagree with our assertion in the proposed rule that physicians do not perform nutrition services and essert that it is inappropriate to use the top-down or zero-work methodology to establish the RVU for medical nutrition therapy.

Response: We use the top-down methodology or no-work pool methodology to price the practice expense RVUs for all services priced under the Medicare physician fee schedule. Given that the statute indicates that medical nutrition therapy should be paid using the physician fee schedule, we believe it is reasonable and appropriate to use the same methodologies that we use to develop RVUs for other physician fee schedule services. With respect to use of the preventive medicine service, we used a service that we felt had similar practice expenses to medical nutrition therapy, It is not clear why practice expenses for a counseling service would differ based on the health status of the patient.

Comment: A commenter representing distitions asked us to review the relativity of payment across the three medical nutrition CPT codes. The commenter indicated that payment for CPT code 97803 was set at 72.9 percent of proposed RVUs for CPT code 97802 and 97804 was set at 31 percent of CPT code 97802. The commenter argues that, because reassessments are shorter than initial assessments, the proposed RVUs are actually discounted twice (that is, less payment per 15 minutes of time as well as less total time). They believe that the value of CPT codes 97802 and 97803 should be identical. The commenters indicated that E/M services provided by physicians do not receive the same discount. The commenter also stated that the payment for CPT code 97804 was less than for other group services and gave the example of a nurse or pharmacist providing nutrition instruction under the diabetes selfmanagement training benefit.

Response: We have reviewed the payments for CPT codes 97802 and 97803 and agree with the commenter that these two codes should have the same values. The essential difference between an initial and follow up medical nutrition therapy service is the time spent performing the service. Initial visits will be longer than follow-up visits and will likely involve Medicare payment for more increments of service. We will pay less for follow

up visits because they will typically involve fewer 15 minute increments of time than an initial visit. The payment rate we are establishing in this final rule for CPT code 97803 will be the same as the proposed rate for GPT code 97802. We have also changed the payment rate for CPT code 97804 assuming that the code will normally be billed for 4 to 6 patients with the average of 5. Using the revised values, the payment rate for group medical nutrition therapy would approximate the hourly rate paid for other medical nutrition therapy services. (We note that the RVU units between the proposed and final rule show some marginal change because of changes made in the practice expense methodology that affect all physician fee schedule services). We do not agree with the comment that "evaluation and management services provided by physicians do not receive the same discount." B/M service are not time based services and, as stated above, for many reasons are inappropriate comparisons to medical nutrition therapy service codes.

Comment: Many commenters stated that co-payments must be structured so that they are not barriers to the medical nutrition the next beauty.

nutrition therapy benefit.

Assponse: Section 105(c) of the BIPA modifies section 1833(a)(1) of the Act to add subparagraph (T) that requires that Medicare payment equal 80 percent of the lesser of the actual charge for the services or 85 percent of the amount determined under physician fee schedule. The statute requires the same coinsurance for medical nutrition therapy services that applies to other Part B services.

Comment: Commenters suggested that initial medical nutrition therapy sessions for treatment of diabetes or renal disease should be billed under CPT code 97802 and subsequent medical nutrition therapy sessions should be billed under CPT code 97803. New diagnoses due to a change in medical condition or unanticipated complications should be billed under CPT code 97802 and subsequent medical nutrition therapy sessions should be billed under CPT code 97803.

Response: At the present time, we are requiring that medical nutrition therapy be reported by using CPT codes 97802, 97803, and 97804. We will revisit our coding requirements when we publish the NCD for medical nutrition therapy. The NCD will set forth the structure of the medical nutrition therapy benefit in detail. We will make a decision concerning creation or modification of codes and creation of modifiers for reporting medical nutrition therapy once the NCD has been published. Until

the NCD is published, creation or modification of codes and creation of modifiers would be premature. Therefore, we are requiring that the initial individual medical nutrition tharapy visit be reported as CPT code 97802 and all follow up visits (for interventions and reassessments) for individual medical nutrition therapy be reported as CPT code 97803. All group medical nutrition therapy visits should be reported as CPT code 97804 whether they are initial or follow up visits.

Comment Commenters urged us to define medical nutrition therapy descriptors consistently. They stated that the descriptors in Table 5 of the proposed rule should agree with the descriptors in \$444.125.

descriptors in § 414.132.

Response: We agree. We will make the descriptors for medical nutrition therapy consistent with the nomenclature in CPT and our regulations.

Comment We received a comment that recommended that we consider including additional items in the practice expense inputs for medical nutrition therapy. The commenter indicated that inputs should include steff costs for training on billing procedures, Health Insurance Portability and Accountability Act training, audit expenses, and other costs resulting from Medicare policies and procedures. The commenter indicated that expenses of registered distiflans in private practice differ little from other practitioners.

Response: There are two major data

sources used in the practice expense methodology—estimates of direct inputs and aggregate practice expense per hour information from the AMA's Socioeconomic Monitoring Survey. At this time, we are using the practice expense per hour for all physicians to establish the prectice expense RVUs for medical nutrition therapy. We are not currently using the estimates of direct expanses for medical nutrition therapy because the services are valued in the no-work pool. However, we are researching alternatives to the no-work pool that would allow all no-work services to be priced under the topdown methodology. If we develop such an alternative, the estimates of direct expenses will be important in determining the RVUs for medical nutrition therapy. Indirect expenses are based on physician work and direct inputs. We believe that many of the costs identified by this commenter are induct costs that would likely be included in practice expenses reported through the SMS survey. Since the commenter has suggested that practice expenses for private practice registered distitians differ little from other

EXHIBIT "O"
CAGS 3 OF 4

practitioners, we believe the average practice expense per hour for all physicians is sufficient to use in the practice expense methodology.

Result of Evaluation of Comments

The payment rate we are establishing in this final rule for CPT code 97803 will be the same as the rate for CPT code 97802. We are also changing the payment rate for CPT code 97804 using the essumption that the code will normally be billed for 4 to 5 patients with the average of 5. Using these revised values, the payment rate for group medical nutrition therapy will approximate the hourly rate paid for other medical nutrition therapy SETVICES.

F. Telehealth Services

Beginning October 1, 2001, the BIPA amended section 1834 of the Act to specify that we pay a physician (as defined in section 1861(r) of the Act) or a practitioner (described in section 1842(b)(18)(C) of the Act) for telehealth services that are furnished via a telecommunications system to an

eligible telehealth individual.
The BIPA defined Medicare telehealth services as professional consultations. office or other outpatient visits, and office psychiatry services identified as of July 1, 2000, by CPT codes 99241 through 99275; 99201 through 99215. 90804 through 90809 and 90862 (and as we may subsequently modify) and any additional service we specify. The BIPA defines an eligible telehealth individual as an individual enrolled under Part H who receives a telehealth service furnished at an originating site.

Section 1834(m) of the Act, as added by the BIPA, limited an originating site to a physician's or practitioner's office. hospital, critical access hospital, rural health clinic, or Federally qualified health center. Additionally, the BIPA specified that the originating site must be located in one of the following

geographic areas:

 In an area that is designated as a rural health professional shortage area (HPSA) under section 332(a)(1)(A) of the

Public Health Service Act. In a county that is not included in a Metropolitan Statistical Area (MSA).

However, an entity participating in a Federal telemedicine demonstration project that has been approved by, or receives funding from us as of December 31, 2000 would not be required to be in a rural HPSA or non-MSA

The BIPA also required that we pay a physician or practitioner located at a distant site that furnishes a telehealth service to an eligible telehealth beneficiary an amount equal to the

amount that the physician or practitioner would have been paid under Medicare had the service been furnished without the use of a telecommunications system

This section also provided for a facility fee payment for the period beginning October 1, 2001 through December 31, 2002, to the originating site of \$20. For each subsequent year, the facility fee for the preceding year is increased by the percentage increase in the MEI as defined in section 1842(1)(3) of the Act. The BIPA also amended section 1833(a)(1) of the Act to specify that the amount paid must be 60 percent of the lesser of the actual charge or the amounts specified in new section 1834(m)(2) of the Act.

In order for us to have this benefit expansion implemented timely, we have used a program memorandum. The program memorandum was effective October 1, 2001. This final rule will be

effective January 1, 2002.

The rule published on August 2, 2001 proposed to establish policies for implementing the provisions of section 1834(m) of the Act, as added by the BIPA, that change Medicare payment for

telehealth services.

We proposed to revise § 410.78 to specify that Medicare beneficiaries are eligible for telehealth services only if they receive services from an originating site located in either a rural HPSA as defined by section 332(a)(1)(A) of the Public Health Services Act or in a county outside of a MSA as defined by section 1885(d)(2)(D) of the Act.

1. Definitions

Section 1834(m)(4)(F) of the Act, which was added by the BIPA and became effective for services beginning October 1, 2001, defined telehealth services as professional consultations, office and other outpatient visits. individual psychotherapy, pharmacologic management, and any additional service we specify. Additionally, this provision identified covered services by HCPCS codes identified as of July 1, 2000. We proposed to revise § 410.78 to implement this coverage expansion to include the following services (and corresponding CPT codes):

. Consultations (codes 99241 through 99275

 Office and other outpatient visits (codes 99201 through 89215).

 Individual psychotherapy (codes 90804 through 90809).

 Pharmacologic management (code 80862).

We solicited comments regarding the guidelines that we should use to make additions or deletions of services. We

also solicited comments about specific services that may be appropriate to be covered under the Medicare telehealth benefit.

In this final rule, we are specifying at § 410.78 that, except for the use of store and forward technology in the demonstration programs conducted in Alaska or Hawaii, an interactive telecommunications system must be used and the medical examination of the patient must be at the control of the physician or practitioner at the distant site. We are defining interactive telecommunications system as multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and physician or practitioner at the distant site. We are also specifying that telephones, facsimile machines, and electronic mail systems do not meet the definition of an interactive telecommunications system.

A patient need not be present for a Federal telemedicine demonstration program conducted in Alaska or Hawaii. We are specifying that for Federal telemedicine demonstration programs conducted in Alaska or Hawaii Medicare payment is permitted for telehealth when asynchronous store and forward technologies, in single or multimedia formats, are used as a substitute for an interactive telecommunications system Additionally, we are specifying that the physician or practitioner at the distant site must be affiliated with the

demonstration program We are defining asynchronous, store and forward technologies, as the transmission of the patient's medical information from an originating site to the physician or practitioner at the distant site. The physician or practitioner at the distant site can review the medical case without the patient being present. An asynchronous telecommunications system in single media format does not include telephone calls, images transmitted via facsimile machines, and text messages without visualization of the patient (electronic mail). Photographs must be specific to the patient's medical condition and adequate for rendering or confirming a diagnosis or treatment plan. Finally, we are defining the originating site as the location of an eligible telehesith individual at the time the service being furnished via a telecommunications system occurs.

Conditions of Payment

The BIPA changed the telepresenter requirements. In accordance with section 1834(m)(2)(C) of the Act, a

EXHIBIT "D PAGE 4 OF 4

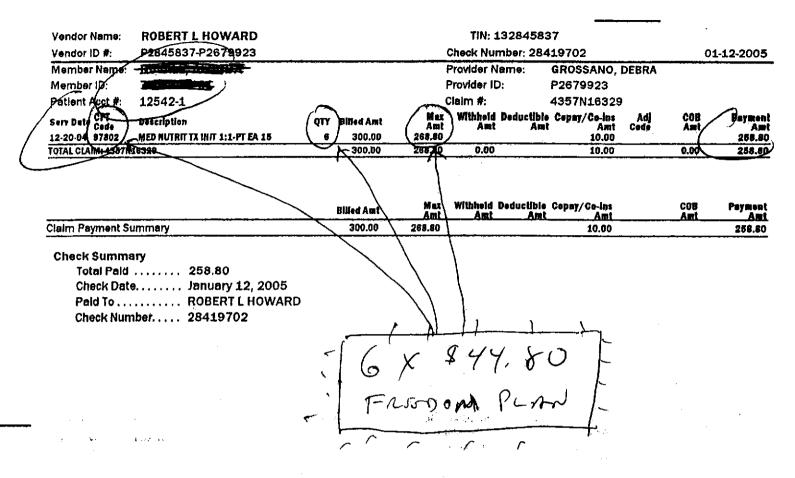
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EXHIBIT "E" PAGE 1 OF 4

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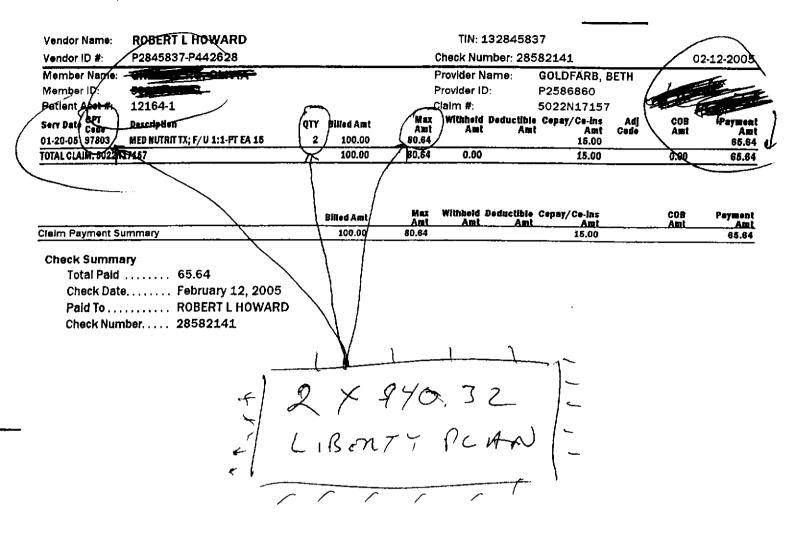
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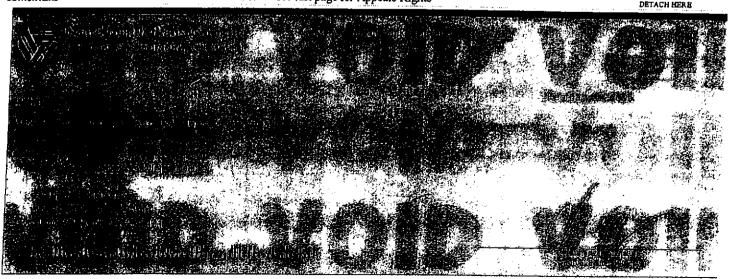
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28582141# #:031100267#: 6301446914 509# EXHIBIT "5" - PAGE 3 OF 4 GROUP HEALTHUNG DRPORATED RO. 802 2814 NEW YORK NY 10110-2814

Y PAY TO THE ORDER OF

MIDTOWN NUTRITION CARE 119 WEST 57TH ST.

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NEW YORK , NY

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GROUP HEALTH INCORPORATED PO BOX 2814. NEW YORK NY 10116-2814 DETACH BEFORE CASHING

EXPLANATION OF BENEFITS

CHECK NUMBER

Check Date: 08/13/04 9582195

Provider: GOLDFARB BETH R RD

The information below summarizes GHI's claim settlement(s) for the service(s) and patient(s) listed.

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To report suspected fraud, call GHI's Fraud Hotline at 1-888-4-KO-FRAUD (1-888-456-3728) or e-mail kofraud@ghi.com

EXHIBIT "E"
PAGE 4 OF 4



Center for Medicare & Medicaid Services
Department of Health and Human Services
ATTN: CMS-1502-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

September 22, 2005

Re: Federal Register/Volume 70, No. 151/Monday, August 8, 2005/Proposed Rules Department of Health and Human Services 42 CFR, Parts 504, 410, 411, 413, 414, and 426

Satellite Healthcare, Inc. operates dialysis centers in Northern California and would like to commend CMS for your proposals regarding dialysis reimbursement outlined in the August 8, 2005 proposed rule.

Referencing: ESRD Drugs and Biologicals

We support your calculations of the drug add-on using the ASP+6% and strongly agree with the proposal to update the payments on a quarterly basis.

Referencing: ESRD-Composite Payment Rate Wage Index

We are especially pleased with CMS recognizing the importance of "modernizing the current ESRD wage index". Your proposed changes to the geographical wage index and revisions to geographic designations are welcomed and begin addressing a major issues felt by dialysis providers, especially in California, where the cost of providing dialysis services are among the highest in the country.

Satellite Healthcare, Inc. fully supports the following proposals and applauds your efforts on modernizing ESRD in the United States.

Implementing Revised Geographic Wage Indexes

- 1. Revising the ESRD composite payment system labor market areas based on Core-Based Statistical Areas (CBSA) developed by the Office of Management and Budget (OMB).
- 2. Increasing the labor component of the composite rate to 53.7% and monitoring and adjusting labor/non-labor costs on an annual basis using.

¹ Federal Register/Volume 70, No. 151/Monday, August 8, 2005/Proposed Rules Department of Health and Human Services 42 CFR, Parts 504, 410, 411, 413, 414, and 426 (p.45793)

3. Annual Update of the Geographic Wage Index by using the most updated Medicare hospital cost reports.

Market Basket: Although the commentary states that data from 1996 through 1999 showed "little difference" in cost weights, there have been some significant changes since then. In our view, using CY 1997 as the base year for the market basket may not sufficiently represent the current economic realities experienced over the last 8 years. Given the rapid increase in direct labor and benefit cost it would be prudent to evaluate more current cost report data.

We strongly support your proposal to establish a single labor-related share applicable to all ESRD facilities based on labor-related categories included in the ESRD composite rate market basket.

Recommendation: Annual review of Medicare Cost Reports to assure that the most updated data is being reviewed.

<u>Transition Period</u>: With regard to the timing and phase in of the changes we strongly support the two-year transition period, which would allow facilities to be paid the higher of the new wage adjusted composite rate immediately, or a 50-50 blend of the current and new wage adjusted composite rate.

Wage Index Cap: We agree that the wage index cap should be eliminated. The basis for the wage index cap was important prior to composite payment rate and is no longer valid.

Wage Index Floor: We support reducing the wage index floor to 0.85 in 2006, further reduction to 0.8 in 2007, and re-evaluating the need for continuing the floor in 2008 with the goal of eliminating the floor.

We understand the importance and constraints of having any changes to the ESRD wage index remain budget neutral by Section 623(d) of MMA amended section 1881(b)(12)(E)(i) of the Act and commend your efforts with creating legislation that shows your continued commitment with updating and modernizing the ESRD system in the Unites States. Lastly, we strongly support and urge you to update the geographic wage index on an annual basis, as part of the overall ESRD payment update.

Sincerely,

Mark Burke

Chief Executive Officer Satellite Healthcare, Inc.

al Bullo

RITA ROVER, MA, MS, RD

MEDICAL NUTRITION THERAPY

168 LAUREL AVENUE NORTHPORT, NY 11768 Phone: 631-261-8386

September 26, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Impact of Proposed Elimination of Nonphysician Work Pool on Medical Nutrition Therapy Services (CPT Codes 97802-4)

I join in the attached comments of Midtown Nutrition Care. What appears to have happened is that Congress in its final legislative version discounted medical nutrition therapy services by 15% if performed by a dietitian who is not also a physician. Then CMS compared the medical nutrition therapy codes to a physician's preventive medicine counseling code that is discounted about 20% from other evaluation and management codes because that physician's code does not generally involve medical histories, physical examinations or medical decisions, or the use of medical equipment and supplies and clinical personnel. Then since medical nutrition therapy services do not generally involve medical histories, physical examinations or medical decisions, or the use of medical equipment and supplies and clinical personnel, CMS again discounted the value of the medical nutrition therapy codes by about 50% by dropping the physician's work value from the already discounted physician's preventive medicine counseling code.

Referring to Congress's 15% discount, CMS said at page 55279 of the November 1, 2001 Federal Register (quoted in paragraph 9 of Midtown Nutrition Care's comments) that "it seems unusual to apply a reduction for a service that seldom would be furnished by a physician." But it is not unusual because so long as an appropriately discounted code like the physician's preventive medicine counseling code is used, with its work value, the 15% discount creates for dietitians a payment structure with a 35% total discount from other evaluation and management codes (and for the few qualified physicians, a 20% total discount from other evaluation and management codes). This payment structure would therefore be sufficient, but not overgenerous, and assure access for the beneficiaries of the service (see September 22, 2005 letter of Representative Jose Serrano attached as Exhibit "A" to Midtown Nutrition Care's comments).

Using an already discounted code because of the lack of medical history, physical examination, medical decision, medical equipment, medical supplies and clinical personnel components, then dropping work value because of the lack of these components, creates a <u>double</u> discount, which causes the payment structure to be less than half of what I typically receive from commercial health plans, and is much too low, so I cannot afford to participate in Medicare.

I have been a private practice dietitian for 18 years in Long Island, New York, and have seen over 5,000 patients in that time, many with diabetes or kidney disease. I now regularly refuse to see Medicare beneficiaries, but if an appropriate payment structure were established I would become a Medicare provider and start seeing these beneficiaries.

Sincerely, Reta Roser, RS

Rita Rover, RD

MIDTOWN NUTRITION CARE 119 WEST 57TH STREET—SUITE 1414 NEW YORK, NY 10019 (212) 333-4243

September 22, 2005

Centers for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1502-P Mail Stop C4-26-05 7500 Security Boulevard Baltimore, MD 21244-1850

Re: Proposed Rule, Medicare Program: Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006

Specific Re: Impact of Proposed Elimination of Nonphysician Work Pool on Medical Nutrition Therapy Services (CPT 97802-4)

Specific CMS Language: "We recognize that there are still some outstanding issues that need further consideration, as well as input from the medical community. For example, although we believe that the elimination of the nonphysician work pool would be, on the whole, a positive step, some practitioner services, such as audiology and medical nutrition therapy, would be significantly impacted by the proposed change....We, therefore, welcome all comments on these proposed changes..." Federal Register, August 8, 2005, p. 45777

Dear Sir or Madam:

Midtown Nutrition Care respectfully submits the following comments that will show how CMS may not only avoid any negative impact on medical nutrition therapy services, but also increase access to these important preventive medicine services.

History of Medical Nutrition Therapy Reimbursement

- 1. August 4, 1995, 104th Congress, 1st Session, Representative Serrano introduced the first medical nutrition therapy bill, HR 2247, "Medical Nutrition Therapy Act of 1995". Relevant reimbursement language was "...the amount paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by a fee schedule established by the Secretary for the purposes of this subparagraph." [emphasis supplied]
- 2. July 17, 1996, 104th Congress, 2nd Session, Senator Bingaman introduced S 1964, "Medical Nutrition Therapy Act of 1996". Relevant reimbursement language was "...the amount paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by a fee schedule established by the Secretary for the purposes of this subparagraph." [emphasis supplied]

- 3. January 7, 1997, 105th Congress, 1st Session, Representative Serrano introduced HR 288, "Medical Nutrition Therapy Act of 1997". Relevant reimbursement language was "...the amount paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by a fee schedule established by the Secretary for the purposes of this subparagraph." [emphasis supplied]
- 4. June 24, 1997, 105th Congress, 1st Session, Senators Craig and Bingaman introduced S Amdt 454, which became Section 5105 of PL 105-33, "Study on Medical Nutrition Therapy Services." It provides "(a) Study: The Secretary of Health and Human Services shall request the National Academy of Sciences, in conjunction with the United States Preventive Services Task Force, to analyze the expansion or modification of preventive benefits provided to medicare beneficiaries under title XVIII of the Social Security Act to include medical nutrition therapy services by a registered dietitian. (b) Report: (1) Initial report: Not later than 2 years after the date of the enactment of this Act, the Secretary shall submit a report on the findings of the analysis conducted under subsection (a) to the Committee on Ways and Means and the Committee on Commerce of the House of Representatives and the Committee on Finance of the Senate. (2) Contents: Such report shall include specific findings with respect to the expansion or modification of coverage of medical nutrition therapy services by a registered dietitian for medicare beneficiaries regarding—(A) cost to the medicare system; (B) savings to the medicare system; (C) clinical outcomes; and (D) short and long term benefits to the medicare system. (3) Funding: From funds appropriated to the Department of Heath and Human Services for fiscal years 1998 and 1999, the Secretary shall provide such funding as may be necessary for the conduct of the analysis by the National Academy of Sciences under this section."
- 5. March 18, 1999, 106th Congress, 1st Session, Representative Johnson, on behalf of herself, Representative Serrano, and numerous others, introduced HR 1187, "Medical Nutrition Therapy Act of 1999". Relevant reimbursement language was "...the amount paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined under the fee schedule established under section 1848(b) [the physician fee schedule] for the same services if furnished by a physician." [emphasis supplied]
- 6. December 15, 1999, the Institute of Medicine of the National Academy of Sciences issued its report, "The Role of Nutrition in Maintaining Health in the Nation's Elderly, Evaluating Coverage of Nutrition Services for the Medicare Population," National Academy Press, Washington, DC, 2000, ISBN 0-309-06846-0. Among its findings was: "The registered dietitian is currently the single identifiable group of health professionals qualified to provide nutrition therapy. It is recognized that other health care professionals in particular fields may be qualified to provide nutrition therapy and should be considered on an individual basis as a reimbursable provider." (Page 272 of published report)
- 7. December 2000, 106th Congress, 2nd Session, Congress enacted PL 106-554, which contains Section 105, "Coverage of Medical Nutrition Therapy Services for Beneficiaries with Diabetes and Renal Disease." Relevant reimbursement language is "...the amount paid shall be 80 percent of the lesser of the actual charge for the services or 85 percent of the amount determined under the fee schedule established under section 1848(b) [the

physician fee schedule] for the same services if furnished by a physician." [emphasis supplied] Other relevant language is: "The term 'medical nutrition therapy services' means nutritional diagnostic, therapy, and counseling services for the purpose of disease management which are furnished by a registered dietitian or nutrition professional."

- 8. August 2, 2001, CMS published in the Federal Register its proposed rule for the medical nutrition therapy benefit which was to become available on January 1, 2002. Part of the proposed rule was "Payment for Medical Nutrition Therapy (§414.64)." It states, in relevant part: "The statute specifically provides that medical nutrition therapy services may only be provided by registered dietitians or nutrition professionals. We do not believe that physicians will be able to satisfy the qualification requirements and therefore will not be able to provide this service themselves. Therefore, we are not establishing physician work RVUs for this service. We interpret section 105(c)(2) of BIPA to mean that if a physician were to furnish this service, that the service was performed 'incident to' the physicians treatment plan and provided by a registered dietitian or nutrition professional." [emphasis supplied]
- 9. November 1, 2001, CMS published in the Federal Register its final rule. Among the responses to the comments received was: "While medical nutrition therapy may be performed by a physician who is also a registered dietitian, this does not make it a physician's service that requires a work RVU. Physicians may occasionally perform other services that have no physician work, such as chemotherapy administration or the technical component of a diagnostic x-ray test. When such services with no physician work are performed by a physician, we do not establish a physician work RVU just because the service was performed by a physician in that instance. Physicians will occasionally meet the statutory qualifications to be considered a registered dietitian or nutrition professional who can bill Medicare for medical nutrition therapy service. In these circumstances, we will pay the physician 80 percent of 100 percent of the physician fee schedule amount.... We initially anticipated that physicians would never bill Medicare for medical nutrition therapy services because they generally would never meet the statutory requirements to be considered dietitians or nutrition professionals. In this circumstance, we agree that it seems unusual to apply a reduction for a service that seldom would be furnished by a physician. However, we believe that the statute requires that Medicare payment be based on the 85 percent level. We understand that, although not common, there are physicians who do meet the statutory requirements to be considered registered dietitians or nutrition professionals. In these circumstances, our payment the physician will be based on 100 percent of the physician fee schedule amount, not the 85 percent that we will pay to a registered dietitian or nutrition professional." [emphasis supplied] (Page 55279 of 2001 Federal Register)
- 10. Earlier in the final rule CMS states: "The American Dietetic Association (ADA) and many individuals submitted comments concerning the proposed reimbursement rate for medical nutrition therapy services. They stated that the proposed reimbursement rate for these services is too low and would result in limited beneficiary access to these services since private practice dietitians will chose not to participate....They believe that the proposed rate for Medicare is far short of what was envisioned by the Congress....The commentators also stated that any refinement of medical nutrition therapy values should

be based on the underlying E/M codes that they believe are the statutory basis for medical nutrition therapy payment. While commentators acknowledge that physicians may perform other tasks besides nutrition assessment, therapy and counseling during an office visit, they believe those additional services are the basis for the Congress' instruction to reimburse non-physician providers of medical nutrition therapy at 85 percent of the amount physicians receive. The AMA's Health Care Professionals Advisory Committee (HCPAC) submitted a comment that suggested there should be physician work for medical nutrition therapy. This group provides recommendations on valuing services for codes used by non-physician providers....We have reviewed the statute and legislative history. There is no indication that Congress envisioned a particular payment amount or expected us to use an E/M service to determine the value of medical nutrition therapy." [emphasis supplied] (Page 55278 of 2001 Federal Register)

Using a Reimbursement Methodology That Includes a Physician Work Value Will Not Only Avoid Any Negative Impact On Medical Nutrition Therapy Services From the Elimination of the Nonphysician Work Pool, But Will Also Increase Access To These Preventive Medicine Services

- 11. We agree that Congress probably did not envision a particular amount or particular E/M service, but did Congress intend to pay nutritionists 85% of what a physician is paid for administering chemotherapy or performing the technical component of a diagnostic x-ray? Or did Congress intend to pay dietitians 85% of what it costs a physician to employ a dietitian to provide the services? If Congress had intended to focus on a dietitian's work value, then why didn't the law establish a separate fee schedule for dietitians (as Medicare has for psychologists and as the 1995, 1996 and 1997 bills had envisioned)?
- 12. After the 1995, 1996 and 1997 bills by Representative Serrano and Senator Bingaman that would have established a separate dietitian fee schedule, and after the 1997 Craig and Bingaman amendment established a study to be made of "medical nutrition therapy services by a registered dietitian", what did Representatives Johnson, Serrano and others intend when they introduced in March 1999 a bill that would have paid dietitians the amount determined under the physician fee schedule for the same services if furnished by a physician instead of pursuant to a separate dietitian fee schedule? And after the December 1999 report by the National Academy of Sciences found the registered dietitian to be the single identifiable group qualified to provide medical nutrition therapy (although others may be qualified), what did Congress intend when they passed in December 2000 a law that continued to determine payment not pursuant to a separate dietitian fee schedule but by paying 85% (instead of 100% as in the Johnson bill) of the amount determined under the physician fee schedule for the same services if performed by a physician, and also defined the providers to be registered dietitians or other nutrition professionals?
- 13. Could it possibly be that Congress intended by not having a separate dietitian fee schedule that Congress meant to exclude physician work value? Or, is it at least as likely that Congress intended to pay 85% of what a physician would be paid, including physician work value, so as to insure that reimbursement would be fixed at a level that would enable a sufficient number of dietitians to participate so that Medicare

beneficiaries would have access to this preventive benefit (and preventive benefits are what Congress want all entitled beneficiaries to get so as to hold down costs over the long term). The original sponsor of the medical nutrition therapy benefit and cosponsor of the bill that eventually became the law has asked CMS to "...please be aware of Congress' intent that payment be sufficient to provide access to care for the beneficiaries of the service. Establishing a zero work value for nutrition therapy severely limits access to these services and thus subverts the intent of the law." (See copy of September 22, 2005 letter to CMS from Representative Serrano, attached as Exhibit "A")

- 14. That the envisioned access has not been provided can be seen from the fact that prior to passage the CBO estimated the annual cost of medical nutrition therapy services to be \$60 million, whereas only about \$1 million per year has been spent annually since the benefit became available in 2002. This represents visits by only about 250,000 beneficiaries out of an estimated 8 million plus beneficiaries with diabetes and renal disease (the two conditions for which Medicare currently provides medical nutrition therapy benefits). Only about 10% of dietitians (7,000 out of 65,000 nationwide) have become Medicare providers, compared with over 90% of physicians. Journal of the American Dietetic Association, June 2005, p. 990 (copy, along with p.995, footnote references, attached as Exhibit "B").
- 15. There is a lengthy discussion in the November 1, 2001 final rule (Pages 55278-80 of 2001 Federal Register) stating that work value should not be included because medical nutrition therapy services do not involve medical histories, physical examinations or medical decisions, or the use of medical equipment and supplies and clinical personnel involved in most evaluation and management services by physicians. However, the evaluation and management code to which the medical nutrition therapy codes was compared for the basis of valuation is Preventive Medicine Service Counseling and/or Risk Factor Reduction Intervention (CPT Code 99401) which, unlike most evaluation and management codes, does not generally involve medical histories, physical examinations or medical decisions, or the use of medical equipment and supplies and clinical personnel! (A copy of the CPT's entire Preventive Medicine Services section, 2 pages, is attached as Exhibit "C".)
- 16. We think the reason CMS did not notice that CPT Code 99401 does not generally involve these components is because 2 interrelated points had been raised in comments to the proposed rule. First that CMS should compare the 15-minute medical nutrition therapy code CPT 97802 to the 15-minute office visit code CPT 99213, rather than to the 15-minute preventive medicine counseling code CPT 99401; and second that a physician's work value should be included in valuing medical nutrition therapy services. Therefore, it was natural for CMS to look at the medical history, physical examination, medical decision, medical equipment, medical supplies and clinical personnel components of CPT Code 99213, and not notice that these components are generally lacking in CPT Code 99401. (Attached as Exhibit "D" is a copy of the entire final rule "Payment for Medical Nutrition Therapy" discussion, pp. 55278-55281.)
- 17. Because CPT Code 99401 does not generally involve medical histories, physical examinations or medical decisions, or the use of medical equipment and supplies and

clinical personnel, the valuation of CPT Code 99401 is already significantly lower than other 15-minute evaluation and management service codes that involve these components, see 2005 Relative Value Units for the following codes (Pages 66666, 66668 and 66671 of 2004 Federal Register):

15-minute Code	Work RVU	Non-facility Practice Expense RVU	Malpractice RVU	Non-facility Total
99213 (Office Visit)	0.67	0.69	0.03	1.39
99241 (Office Consultation)	0.64	0.64	0.05	1.33
99401 (Prev Medicin Counseling)	0.48 ne	0.62	0.01	1.11
97802 (Med Nutritio Therapy)	0.00 n	0.47	0.01	0.48

- 18. The discussion by CMS that stated that work value should not be included because medical nutrition therapy services do not involve medical histories, physical examinations or medical decisions, or the use of medical equipment and supplies and clinical personnel was set forth for the first time in the final 2001 rule, and not in the proposed 2001 rule. Therefore, CMS was unable to receive comments that might have pointed out that CPT Code 99401 also does not generally involve medical histories, physical examinations or medical decisions, or the use of medical equipment and supplies and clinical personnel (so while the lack of these components may be a good reason for cross walking the medical nutrition therapy codes to CPT Code 99401, rather than to CPT Code 99213, it is not a good reason to disregard physician work value).
- 19. However at this time CMS can take notice that CPT Code 99401 does not generally involve medical histories, physical examinations or medical decisions, or the use of medical equipment and supplies and clinical personnel, and therefore could (and should) continue the comparison to CPT Code 99401, but utilize the CPT Code 99401 work value, plus the CPT Code 99401 practice and malpractice expense RVUs for valuing the medical nutrition therapy codes (and then paying a physician 80% of 100%, and a dietitian 80% of 85%, of the total of these 3 values). This would be analogous to the payment of physician assistants and nurse practitioners 80% of 85% of CPT Code 99213 or other evaluation and management services that, as appropriate for their practice, contain medical history, physical examination, medical decision, medical equipment, medical supplies and clinical personnel components. And this would allow a physician who is also a dietitian to be paid appropriately (80% of 100%) for medical nutrition

therapy services since a physician cannot otherwise use CPT Code 99401 because while it has been valued, CPT Code 99401 is a noncovered service for which Medicare payment may not be made. (Page 66671 of 2004 Federal Register; Page 45999 of 2005 Federal Register)

- 20. As in the 2001 final rule, the valuation of the 15-minute individual medical nutrition therapy Code 97803 should continue to be the same as the valuation of the 15-minute individual medical nutrition therapy Code 97802; and the valuation of the 30-minute group medical nutrition therapy Code 97804 should continue to approximate the hourly valuation of the individual medical nutrition therapy codes based on an assumption of an average of 5 patients in a group (that is, each RVU value for the 30-minute group increment should be determined by multiplying the corresponding RVU value for the individual 15-minute increment by 2, then dividing by 5).
- 21. Unlike the issue of medical history, physical examination, medical decision, medical equipment, medical supplies and clinical personnel components, which was raised for the first time in the 2001 final rule, the issue of whether the two individual 15-minute codes would be valued the same or differently was fully discussed in the 2001 proposed rule, in comments thereto, and in the final rule, which stated as follows: "We have reviewed the payments for CPT codes 97802 and 97803 and agree with the commentator that these two codes should have the same values. The essential difference between an initial and follow up medical nutrition therapy service is the time spent performing the service. Initial visits will be longer than follow-up visits and will likely involve Medicare payment for more increments of service. We will pay less for follow up visits because they will typically involve fewer 15 minute increments of time than an initial visit. The payment rate we are establishing in this final rule for CPT code 97803 will be the same as the proposed rate for CPT code 97802. We have also changed the payment rate for CPT code 97804 assuming that the code will normally be billed for 4 to 6 patients with the average of 5. Using the revised values, the payment rate for group medical nutrition therapy would approximate the hourly rate paid for other medical nutrition therapy services." (Page 55281 of 2001 Federal Register)
- 22. That reasoning was sound in 2001 and remains sound, and should continue to be followed, rather than create a 0.01 less RVU for CPT code 97803 as proposed at Page 45997 of the August 8, 2005 Federal Register.

Our Practice

- 23. Our group practice, Midtown Nutrition Care, has seven full-time Registered Dietitians who see approximately 700 patients per month, about 1/3 of which have diabetes or kidney disease.
- 24. We are providers for all the major commercial insurance companies in our area. These currently pay an average of \$42.53 per 15-minute increment for CPT Codes 97802 and 97803 (which codes are valued equally by the commercial insurers we bill these codes). Copies of explanations of benefits (with patient identifiers deleted), which show

these amounts to be \$50, \$44.80, \$40.32 and \$35 per 15-minute increment, are attached as Exhibit "E".

- 25. Because Medicare currently pays only about \$18 per 15-minute increment for our geographical area, which is one of the highest in the nation (and would be reduced an additional 10% under the proposed 2006 physician fee schedule) we cannot afford to see Medicare patients and none of us has become a Medicare provider. We therefore turn away a couple of Medicare patients per day and most of these patients are unable to obtain medical nutrition therapy services because virtually none of the private practice nutritionists in our area accept Medicare.
- 26. If payment for the 15-minute increment were to a little more than double as proposed above it would roughly equal the <u>average</u> we are receiving from commercial insurance companies in our area and we would all become providers and accept Medicare. Based on my experience as co-reimbursement chair for the New York State Dietetic Association I also believe that the vast majority of private practice nutritionists in my area and nationwide would do likewise. Therefore, if the above proposal is followed it will not only avoid any negative impact from the elimination of the nonphysician work pool, it will also provide appropriate access to care for all Medicare beneficiaries entitled to these services.

Sincerely yours,

Robert Howard, RD, JD Managing Partner JOSÉ E. SERRANO 16TH DISTRICT, NEW YORK

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September 22, 2005

Dr. Mark B. McClellan
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-P
P.O. Box 8017
Baltimore, MD 21244-8017

Dear Dr. McClellan:

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

As you review the rule pertaining to medical nutrition therapy benefits, please be aware of Congress' intent that payment be sufficient to provide access to care for the beneficiaries of the service. Establishing a zero work value for nutrition therapy severely limits access to these services and thus subverts the intent of the law.

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

Vose E. Serrano

Member of Congress

EXHIBIT "A"

mation packets, meetings and conference calls, and support developing language that describe MNT services provided by RDs as a component of the CCI program.

MEDICARE ADVANTAGE

Medicare+Choice will be replaced with Medicare Advantage effective January, 2006. CMS announced on December 6, 2004 that there will be 26 Medicare Advantage regions established across the nation for health insurance plans wishing to participate in the new program. Participating health insurance plans will be required to service the entire region. Each Medicare Advantage regional plan will have a network of providers who agree to contractually specified reimbursement levels for covered benefits.

The intent of this new provision is to have traditional fee-for-service Medicare compete head to head on prices with private insurance companies. In order to gain sufficient support to pass the bill, this new provision is a 6-year demonstration program in up to six standard metropolitan statistical areas (SMSAs). Private insurers will be able to begin bidding to serve Medicare beneficiaries in regions beginning in 2006. Payment rates would be based on a blended average of the bids. The traditional Medicare system will compete with private plans in selected SMSAs beginning in 2010. There are significant incentives in the new law to encourage private insurance companies to participate in this program.

How the Medicare Advantage program affects utilization of the Medicare MNT coverage, and the two new programs that include MNT benefits. remains to be seen. There is the potential for significant growth in MNT services. According to the proposed rules released by CMS, beginning in 2006, the Medicare Advantage program will have to "enrich the range of benefit choices available to enrollees, including not only improved prescription drug benefits, but also other benefits not covered by traditional Medicare, and the opportunity to share in savings where plans can deliver benefits at lower costs" (78).

MEDICARE MNT'S IMPACT ON PRIVATE INSURANCE PLANS' COVERAGE

ADA researchers conducted an environmental scan in 2002 to determine if the MNT benefit (which went into effect January 1, 2002) had increased the coverage of nutrition services provided by RDs within private insurance or health care plans. While the scan is not representative of all managed care organizations or the health care marketplace, a positive change in coverage was noted since 1999, when a benchmark was set (79). The growth in coverage of dietetic services are attributable to a number of factors: costs, consumer demand, and recognition of MNT, the availability of data on the effectiveness of nutrition interventions, and new tools such as codes that allow direct reimbursement to dietetic professionals. Dietetics professionals may find an increasingly receptive environment for their knowledge and skills, and involvement in disease management services, as more private sector plans reported contracting with RDs for nutrition services. Additionally, several plans in the 2002 scan indicated they follow Medicare's lead in adopting CPT codes.

MEDICARE MNT UTILIZATION RATES

During the first year of Medicare MNT coverage under Medicare, 4,125 individuals enrolled as MNT providers and billed approximately \$800,000 for individual and group MNT services (80). (When Congress was considering the MNT bill in 2000. it was estimated that a scaled-down MNT bill establishing coverage to beneficiaries with diabetes, cardiovascular disease, and/or renal disease, would cost a little less than \$1 billion per year [81].) Recent CMS data indicates nearly 7,000 registered dietitians or licensed nutrition professionals have enrolled as providers of MNT (82). Only 211,000 Medicare beneficiaries received MNT services since the benefit's inception, yielding approximately \$3.3 million of new revenue for RDs.

Those are disappointing statistics inasmuch that they indicate an underutilization of the MNT benefit. Based on estimates from the National Diabetes Information Clearinghouse and United States Renal Data System, approximately 8.6 million indi-

viduals (or 18.3%) at least 60 years old are diagnosed with diabetes or acute renal failure, making most of them eligible for MNT Medicare services (83). In terms of income potential to RDs, the CBO-projected \$60 million annual outlays for Medicare MNT for diabetes and kidney disease are far higher than the actual \$1 million annual average. Data provided by CMS indicate a small but growing demand for Medicare MNT for diabetes and kidney disease when beneficiaries obtain a referral by their physicians.

How the Medicare
Advantage program
affects utilization of
the Medicare MNT
coverage, and the
two new programs
that include MNT
benefits, remains to
be seen.

There are a number of reasons to expect greater demand for Medicare MNT services. First of all, the Medicare Modernization Act includes two MNT components, one of which is the Initial Preventive Physical Examination, which went into effect January 1, 2005. The American Diabetes Association estimates that more than onethird of Americans with diabetes do not know they have the disease (84). If the "Welcome to Medicare" physical is successful in identifying people who have diabetes but did not know it, the utilization rate for MNT should show a significant increase.

The chronic care provisions of the Medicare Modernization Act also provide an opportunity for significant growth in MNT utilization, because MNT also is a component of that provision. Currently, 78% of the Medicare population has one or more chronic conditions that require ongoing medical management (85). Almost two thirds (63%) have two or more chronic conditions, and 20% of Medicare beneficiaries have five or more chronic conditions (86). Therefore, participating in Medicare's new chronic care disease management

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99373

complex or lengthy (eg. lengthy counseling session with anxious or distraught patient, detailed or prolonged discussion with family members regarding seriously ill patient, lengthy communication necessary to coordinate complex services of several different health professionals working on different aspects of the total patient care plan)

Care Plan Oversight Services

Care Plan Oversight Services are reported separately from codes for office/outpatient, hospital, home, nursing facility or domiciliary services. The complexity and approximate physician time of the care plan oversight services provided within a 30-day period determine code selection. Only one physician may report services for a given period of time, to reflect that physician's sole or predominant supervisory role with a particular patient. These codes should not be reported for supervision of patients in nursing facilities or under the care of home health agencies unless they require recurrent supervision of therapy.

The work involved in providing very low intensity or infrequent supervision services is included in the pre- and post-encounter work for home, office/outpatient and nursing facility or domiciliary visit codes.

99374

Physician supervision of a patient under care of home health agency (patient not present) in home, domiciliary or equivalent environment (eg. Alzheimer's facility) requiring complex and multidisciplinary care modalities involving regular physician development and/or revision of care plans, review of subsequent reports of patient status, review of related laboratory and other studies, communication (including telephone calls) for purposes of assessment or care decisions with health care professional(s), family member(s), surrogate decision maker(s) (eg., legal guardian) and/or key caregiver(s) involved in patient's care, integration of new information into the medical treatment plan and/or adjustment of medical therapy, within a calendar month; 15-29 minutes

99375

30 minutes or more

99377

Physician supervision of a hospice patient (patient not present) requiring complex and multidisciplinary care modalities involving regular physician development and/or revision of care plans, review of subsequent reports of patient status, review of related laboratory and other studies, communication (including telephone calls) for purposes of assessment or care decisions with health care professional(s), family member(s), surrogate decision maker(s) (eg. legal guardian) and/or key caregiver(s) involved in patient's care, integration of new information into the medical treatment plan and/or adjustment of medical therapy, within a calendar month; 15-29 minutes

99378

30 minutes or more

EXHIBIT "C" PAGE 1 OF Z 99379

Physician supervision of a nursing facility patient (patient not present) requiring complex and multidisciplinary care modalities involving regular physician development and/or revision of care plans, review of subsequent reports of patient status, review of related laboratory and other studies, communication (including telephone calls) for purposes of assessment or care decisions with health care professional(s), family member(s), surrogate decision maker(s) (eg, legal guardian) and/or key caregiver(s) involved in patient's care, integration of new information into the medical treatment plan and/or adjustment of medical therapy, within a calendar month; 15-29 minutes

99380

30 minutes or more

Preventive Medicine Services

The following codes are used to report the preventive medicine evaluation and management of infants, children, adolescents and adults.

The extent and focus of the services will largely depend on the age of the patient.

If an abnormality/ies is encountered or a preexisting problem is addressed in the process of performing this preventive medicine evaluation and management service, and if the problem/abnormality is significant enough to require additional work to perform the key components of a problem-oriented E/M service, then the appropriate Office/Outpatient code 99201-99215 should also be reported. Modifier '-25' should be added to the Office/Outpatient code to indicate that a significant, separately identifiable Evaluation and Management service was provided by the same physician on the same day as the preventive medicine service. The appropriate preventive medicine service is additionally reported.

An insignificant or trivial problem/abnormality that is encountered in the process of performing the preventive medicine evaluation and management service and which does not require additional work and the performance of the key components of a problem-oriented E/M service should not be reported.

The "comprehensive" nature of the Preventive Medicine Services codes 99381-99397 reflects an age and gender appropriate history/exam and is NOT synonymous with the "comprehensive" examination required in Evaluation and Management codes 99201-99350.

Codes 99381-99397 include counseling/anticipatory guidance/risk factor reduction interventions which are provided at the time of the initial or periodic comprehensive preventive medicine examination. (Refer to codes 99401-99412 for reporting those counseling/anticipatory guidance/risk factor reduction interventions that are provided at an encounter separate from the preventive medicine examination.)

Immunizations and ancillary studies involving laboratory, radiology, other procedures, or screening tests identified with a specific CPT code are reported separately. For immunizations, see 90471-90474 and 90476-90749.

New Patient

Initial comprehensive preventive medicine 99381

evaluation and management of an individual including an age and gender appropriate history, examination, counseling/anticipatory guidance/risk factor reduction interventions, and the ordering of appropriate immunization(s), laboratory/diagnostic procedures, new patient; infant (age under 1 year)

early childhood (age 1 through 4 years) 99382

late childhood (age 5 through 11 years) 99383 adolescent (age 12 through 17 years) 99384

99385 18-39 years

40-64 years

65 years and over 99387

99386

99394

Established Patient

Periodic comprehensive preventive medicine 99391

reevaluation and management of an individual including an age and gender appropriate history, examination, counseling/anticipatory guidance/risk factor reduction interventions, and the ordering of appropriate immunization(s), laboratory/diagnostic procedures. established patient; infant (age under 1 year)

early childhood (age 1 through 4 years) 99392

late childhood (age 5 through 11 years) 99393

adolescent (age 12 through 17 years)

18-39 years 99395 99396 40-64 years

65 years and over 99397

Counseling and/or Risk Factor **Reduction Intervention**

New or Established Patient

These codes are used to report services provided to individuals at a separate encounter for the purpose of promoting health and preventing illness or injury.

Preventive medicine counseling and risk factor reduction interventions provided as a separate encounter will vary with age and should address such issues as family problems, diet and exercise, substance abuse, sexual practices, injury prevention, dental health, and diagnostic and laboratory test results available at the time of the encounter.

These codes are not to be used to report counseling and risk factor reduction interventions provided to patients with symptoms or established illness. For counseling individual

patients with symptoms or established illness, use the appropriate office, hospital or consultation or other evaluation and management codes. For counseling groups of patients with symptoms or established illness, use 99078.

Preventive Medicine, Individual Counseling

Preventive medicine counseling and/or risk factor 99401 reduction intervention(s) provided to an individual (separate procedure); approximately 15 minutes

approximately 30 minutes 99402 approximately 45 minutes

approximately 60 minutes 99404

99403

Preventive Medicine, Group Counseling

Preventive medicine counseling and/or risk factor 99411 reduction intervention(s) provided to individuals in a group setting (separate procedure); approximately 30

approximately 60 minutes 99412

Other Preventive Medicine Services

Administration and interpretation of health risk assessment instrument (eg, health hazard appraisal)

Unlisted preventive medicine service 99429

Newborn Care

The following codes are used to report the services provided to newborns in several different settings.

For newborn hospital discharge services provided on a date subsequent to the admission date of the newborn, use 99238.

For discharge services provided to newborns admitted and discharged on the same date, use 99435.

History and examination of the normal newborn 99431 infant, initiation of diagnostic and treatment programs and preparation of hospital records. (This code should also be used for birthing room deliveries.)

Normal newborn care in other than hospital or birthing 99432 room setting, including physical examination of baby and conference(s) with parent(s)

Subsequent hospital care, for the evaluation and 99433 management of a normal newborn, per day

History and examination of the normal newborn 99435 infant, including the preparation of medical records. (This code should only be used for newborns assessed and discharged from the hospital or birthing room on the same date.)

EXHIBIT "C" PAGE 2 OF 2 Paymant for Medical Nutrition Therapy (§ 114.64)

Section 105(c) of the BIPA requires that we pay for medical nutrition therapy services at 80 percent of the lesser of the actual charge for the services or 85 percent of the amount determined under the physician fee schedule for the same services if the services had been furnished by a physician. Based upon consultation with the American Distetic Association (ADA) to assess the types of resource inputs used to furnish a 15-minute medical nutrition therapy session by a registered dictitian or professional nutritionist, we proposed the following

For CPT code 97802—Medical nutrition therapy; initial assessment and intervention, individual, face-to-face with the patient, each 15 minutes, we did not propose physician work RVUs for this service, based on the statutory provision that specifically provides that medical nutrition therapy services may only be furnished by registered dietitians or nutrition professionals. For practice expense, we proposed 0.47 RVUs and, for malpractice, we proposed 0.01 RVUs for a total of 0.48 RVUs.

For CPT code 97803—Reassassments and intervention, individual, face-to-face with the patient, each 15 minutes, we proposed 0.0 work RVUs, 0.34 practice expense RVUs and 0.01 malpractice RVUs for a total of 0.85 RVUs.

For CPT code 97804—Group. 2 or more individuals, each 30 minutes, we proposed 0.0 work RVUs, 0 14 practice expense RVUs and 0.01 malpractice RVUs for a total of 0.15 RVUs. To determine payment, the RVUs shown above would need to be multiplied by the physician fee schedule conversion factor and 0.85 (to reflect the statutory requirement that payment be 85 percent of the amount determined under the physician fee schedule).

We also stated that, consistent with the definition in the CPT's Physical Medicine Rehabilitation codes, a group is considered to be 2 or more individuals and that Medicare copayments and deductibles would apply for medical nutritional therapy services.

Comment: The American Dietetic
Association (ADA) and many
individuals submitted comments
concerning the proposed reimbursement
rate for medical nutrition therapy
services. They stated that the proposed
reimbursement rate for these services is
too low and would result in limited
beneficiary access to these services
since private practice dietitians will
choose not to participate. Some
commenters referenced reimbursement

rates currently paid by private insurers of \$85 to \$125 for 1 to 1½ hours for an initial visit and \$85 per hour for followup. They believe that the proposed rate for Medicare is far short of what was envisioned by the Congress. Commenters indicated that the statute clearly states that medical nutrition therapy payment should be 80 percent of the lesser of the actual charge or 85 percent of the amount determined under the physician fee schedule for the same service, provided by a physician. According to commenters, physicians who are also registered distitions, use E/ M codes 99213 through 99215 and 99244 when providing medical nutrition therapy services. The commenters stated that E/M codes 99203 through 99205 are appropriate reference points for determining medical nutrition therapy payment. The commenters also stated that any refinement of medical nutrition therapy values should be based on the underlying E/M codes that they believe are the statutory basis for medical nutrition therapy payment. While commenters acknowledge that physicians may perform other tasks besides nutritional assessment, therapy and counseling during an office visit, they believe those additional services are the basis for the Congress' instruction to reimburse non-physician providers of medical nutrition therapy at 85 percent of the amount physicians receive. The AMA's Health Care Professionals Advisory Committee (HCPAC) submitted a commant that suggested there should be physician work for medical nutrition therapy. This group provides recommendations on valuing services for codes used by nonphysician providers. The HCPA(indicated that it evaluated each of the medical nutrition therapy codes and compared them to services that are available to other providers but not nutritionists (for example, physical therapy services). The comment further stated that the 15 percent reduction should not apply because the HCPAC took this into account when developing the recommendations. The HCPAC further added that there should be work values for medical autrition therapy just as there are for physical and occupational therapy.

Response. We have reviewed the statute and legislative history. There is no indication that Congress envisioned a particular payment amount or expected us to use an E/M service to determine the value of medical nutrition therapy. Section 105(c) of the BIPA states that "the amount paid shall be 80 percent of the lesser of the actual charge

for the services or 85 percent of the amount determined under the fee schedule established under section 1848(b) of the Act for the same services if furnished by a physician," The BIPA Conference Report indicates that payment will equal "the lesser of the actual charge for the service or 85 percent of the amount that would be paid under the physician fee schedule if such services were provided by a physician." The statute and Conference Report direct us to establish the physician fee schedule amount for nutrition therapy services. The Medicare allowed charge would equal 100 percent of the physician fee schedule amount if the services are performed by a physician and 85 percent of the physician fee schedule amount if the services are performed by a registered distition or nutrition professional. The commenters suggest that physicians currently bill for an E/ M service when they provide nutrition services. We do not believe that it is services. We go not believe that it is appropriate to compare medical nutrition therapy provided by a registered distitlan to an R/M service provided by a physician. Registered distitlans do not take medical histories, they are not trained to and do not perform physical examinations, nor do they make medical decisions. Furthermore, when physicians use an E/ M code to report the provision of counseling or coordination of care, they typically have also performed a medical history, physical examination, and engaged in medical decision making as part of that service, If such an individual performed a service that met the requirements of an E/M service, then it would be be appropriate for him or her to report an B/M service. Further, we note that the E/M services include not only an amount attributable to physician work, but also payment for physician practice expenses. For instance, a level 3 new patient office visit (CPT code 99203) includes payment for 50 minutes of nurse time. A level 3 established patient office visit (CPT code 99213) includes 35 minutes of nurse time. Both of these codes include additional compensation for medical equipment and supplies that are typically used in an office visit but are not used as part of a medical nutrition therapy service. If we were to adopt the commenters' view and crosswalk values for medical nutrition therapy to an E/M service, we would be including payment not only for the counseling service of the practitioner, but also, inappropriately for the costs of clinical personnel that are not involved in the nutrition therapy service.

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Commenters indicated that the statute established the 85 percent adjustment to account for activities that are typically performed by a physician during an E/ M service are not performed by a nutritionist. The statute and legislative history do not indicate that the 85 percent adjustment is intended to serve this purpose. In fact, the commenters themselves note that "consistent with other non-physician providers, reimbursement is set at a percentage of the physicien's fee schedule." Under the physician fee schedule, we will pay a physician 80 percent of 100 percent of the physician fee schedule amount, and, if a non-physician practitioner provides an identical service. Modicare pays 80 percent of 85 percent of the physician fee schedule amount. For instance, under CPT code 99213, a level 3 established patient office visit is one of the most common services provided by physicians, physician assistants and nurse practitioners. Even though the service is considered to be identical, we can by law pay a physician assistant and nurse practitioner only 85 percent of what we pay a physician to do the same service. Thus, in the case of other practitioners, the percentage does not reflect that a non-physician practitioner provides fewer services than a physician. Because there is no indication in the statute that the 85 percent adjustment should apply differently in the context of medical nutrition therapy than for other services performed by non-physician practitioners, we believe it is appropriate to pay 80 percent of 100 percent of the physician fee schedule amount when medical nutrition therapy is provided by a physician and 80 percent of 85 percent of the physician fee schedule amount when the service is provided by a registered distition or nutrition professional.

In response to the comment about payment rates of private insurers for medical nutrition therapy, we cannot use such information in a relative value system to establish payment. Section 1848(c) of the Act requires us to establish RVUs that recognize the relative rosources involved in furnishing different physician fee schedule services. Thus, our role is to establish the appropriate relative payment amounts. The total payment amount is determined under a formula prescribed in section 1848(d) of the Act. We have no authority to change the formula.

In response to the HCPAC recommendation, we reiterate that it is inappropriate to compare medical nutrition therapy services to E/M services performed by physicians, While medical nutrition therapy may be

performed by a physician who is also a registered dieutian, this does not make it a physician's service that requires a work RVU. Physicians may occasionally perform other services that have no physician work, such as chemotherapy administration or the technical component of a diagnostic x-ray test. When such services with no physician work are performed by a physician, we do not establish a physician work RVU just because the service was performed by a physician in that instance. Physicians will occasionally meet the statutory qualifications to be considered a registered dietitian or nutrition professional who can bill Medicare for medical nutrition therapy services. In these circumstances, we will pay the physician 80 percent of 100 percent of the physician fee schedule amount. In this unusual circumstance, we are paying for a medical nutrition therapy service provided by a physician under section 1861(s)(2)(V) and not a physician's service under section 1861(s)(1) of the Act,

Comment: One comment indicated that the 85 percent adjustment should not apply because the RVUs we used are not based on physician work or physician practice expenses to deliver the service. This commenter indicated that we proposed an inadequate payment by not following the statutory scheme and proceeded to apply a 15 percent discount that is neither fair nor

reasonable. Response. The statute requires us to establish a physician fee schedule emount for the service and pay 80 percent of 100 percent of the amount if the service is provided by a physician and 80 percent of 85 percent if the service is provided by a registered distitian or nutrition professional. We initially anticipated that physicians would never bill Medicare for medical nutrition therapy services because they generally would not meet the statutory requirements to be considered registered dietitians or nutrition professionals. In this circumstance, we agree that it seems unusual to apply a reduction for a service that seldom would be furnished by a physician. However, we believe that the statute requires that Medicare payment be based on the 85 percent level. We understand that, although not common, there are physicians who do meet the statutory requirements to be considered registered distitians or nutrition professionals. In these circumstances, our payment to the physician will be based on 100 percent of the physician fee schedule amount, not the 85 percent that we will pay to a registered dictitian or nutrition professional. We believe the statute

would not allow a physician who does not meet the statutory requirements for a registered distitian or nutrition professional to be paid for a medical nutrition therapy service. If a physician provides medical nutrition counseling as part of a patient encounter that meets the requirements for an E/M service, the physician can bill Medicare for a physician's service.

Comment: We received one comment requesting that we clarify that Medicare will pay qualified providers in private practice settings or physician offices where they may be independent contractors. The commenter also asked how we intend to pay for medical nutrition therapy in the hospital outpatient department. The commenter also asked for clarification on reassignment of payment if a registered distitution is an employee of physicians or hospital outpaties and employee of physicians or

hospital outpatient facilities. Response: Medicare will pay qualified distitians and nutrition professionals who enroll in the Medicare program regardless of whether they provide medical nutrition therapy services in an independent practice setting, hospital outpatient department or any other setting, with the exception of services provided to patients in an inpatient stay in a hospital or skilled nursing facility. In these circumstances, our payment to the hospital or skilled nursing facility includes payment for medical nutrition therapy. If a qualified practitioner provides medical nutrition therapy in any other setting, including a private practice setting, section 1833(a)(1)(T) of the Act requires that Medicare payment equal 80 percent of the lesser of actual charges or 80 percent of 85 percent of the amount determined under the physician fee schedule. Payment in the hospital outpatient department will be made under the physician fee schedule, not under the hospital outpatient

prospective payment system.
Current rules regarding reassignment of benefits would apply to medical nutrition therapy. We want to emphasize that medical nutrition therapy cannot be provided incident to a physician also meets the qualifications to bill Medicare as a registered dictitian or nutrition professional.

Comment: Commenters objected to the methodology used to establish the proposed RVUs for this service. They believe it is inappropriate to use the top-down or no-work pool methodology to determine medical nutrition therapy payment. They believe that medical nutrition therapy payment should not be based on comparison to a preventive medicine code (CPT code 89401) in the zero-work pool methodology. The

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commenters indicated that preventive medicine services omit the problem-oriented components of the comprehensive history, as well as other essential assessment points, such as the patient's chief complaint and history of present illness. They disagree with our assertion in the proposed rule that physicians do not perform nutrition services and assert that it is inappropriate to use the top-down or zero-work methodology to establish the RVU for medical nutrition therapy.

Response: We use the top-down methodology or no-work pool methodology to price the practice expense RVUs for all services priced under the Medicare physician fee schedule. Given that the statute indicates that medical nutrition therapy should be paid using the physician fea schedule, we believe it is reasonable and appropriate to use the same methodologies that we use to develop RVUs for other physician fee schedule services. With respect to use of the preventive medicine service, we used a service that we felt had similar practice expenses to medical nutrition therapy. It is not clear why practice expenses for a counseling service would differ based on the health status of the patient.

Comment: A commenter representing distitians asked us to review the relativity of payment across the three medical nutrition CPT codes. The commenter indicated that payment for CPT code 97863 was set at 72,9 percent of proposed RVUs for CPT code 97802 and 97804 was set at 31 percent of CPT code 97802. The commenter argues that, because reassessments are shorter than initial assessments, the proposed RVUs are actually discounted twice (that is, less payment per 15 minutes of time as well as less total time). They believe that the value of CPT codes 97802 and 97803 should be identical. The commenters indicated that E/M services provided by physicians do not receive the same discount. The commenter also stated that the payment for CPT code 97804 was less than for other group services and gave the example of a nurse or pharmacist providing nutrition instruction under the diabetes selfmanagement training benefit.

Response: We have reviewed the payments for CPT codes 97802 and 97803 and agree with the commenter that these two codes should have the same values. The essential difference between an initial and follow up medical nutrition therapy service is the time spent performing the service, initial visits will be longer than follow-up visits and will likely involve Medicare payment for more increments of service. We will pay less for follow

up visits because they will typically involve fewer 15 minute increments of time than an initial visit. The payment rate we are establishing in this final rule for CPT code 67803 will be the same as the proposed rate for GPT code 97802. We have also changed the payment rate for CPT code 97804 assuming that the code will normally be billed for 4 to 6 patients with the average of 5. Using the revised values, the payment rate for group medical nutrition therapy would approximate the hourly rate paid for other medical nutrition therap services. (We note that the RVU units between the proposed and final rule show some marginal change because of changes made in the practice expense methodology that affect all physician fee schedule services). We do not agree with the comment that "evaluation and management services provided by physicians do not receive the same discount." B/M service are not time based services and, as stated above, for many reasons are inappropriate comparisons to medical nutrition therapy service codes.

Comment: Many commenters stated that co-payments must be structured so that they are not barriers to the medical nutrition therapy benefit.

Response: Section 105(c) of the BIPA modifies section 1833(a)(1) of the Act to add subparagraph (T) that requires that Medicare payment equal 80 percent of the lesser of the actual charge for the services or 86 percent of the amount determined under physician fee schedule. The statute requires the same coinsurance for medical nutrition therapy services that applies to other Part B services.

Comment: Commenters suggested that initial medical nutrition therapy sessions for treatment of diabetes or renal disease should be billed under CPT code 97802 and subsequent medical nutrition therapy sessions should be billed under CPT code 97803. New diagnoses due to a change in medical condition or unanticipated complications should be billed under CPT code 97802 and subsequent medical nutrition therapy sessions should be billed under CPT code 97803.

Response: At the present time, we are requiring that medical nutrition therapy be reported by using CPT codes 97802, 97803, and 97804. We will revisit our coding requirements when we publish the NCD for medical nutrition therapy. The NCD will set forth the structure of the medical nutrition therapy benefit in detail. We will make a decision concerning creation or modification of codes and creation of modifiers for reporting medical nutrition therapy once the NCD has been published. Until

the NCD is published, creation or modification of codes and creation of modification of codes and creation of modifiers would be premature.

Therefore, we are requiring that the initial individual medical nutrition therapy visit be reported as CPT code 97802 and all follow up visits (for interventions and reassessments) for individual medical nutrition therapy be reported as CPT code 97893. All group medical nutrition therapy visits should be reported as CPT code 97804 whether they are initial or follow up visits.

Comment Commenters urged us to

Comment Commenters urged us to define medical nutrition therapy descriptors consistently. They stated that the descriptors in Table 5 of the proposed rule should agree with the descriptors in § 414.132.

Response: We agree. We will make the descriptors for medical nutrition therepy consistent with the nomenclature in CPT and our regulations.

Comment We received a comment that recommended that we consider including additional items in the practice expense inputs for medical nutrition therapy. The commenter indicated that inputs should include staff costs for training on billing procedures, Health Insurance Portability and Accountability Act training, audit expenses, and other costs resulting from Medicare policies and procedures. The commenter indicated that expenses of registered distitians in private practice differ little from other practitioners.

Response: There are two major data sources used in the practice expense methodology—estimates of direct inputs and aggregate practice expense per hour information from the AMA's Socioeconomic Monitoring Survey. At this time, we are using the practice expense per hour for all physicians to establish the practice expense RVUs for medical nutrition therapy. We are not currently using the estimates of direct expanses for medical nutrition therapy because the services are valued in the no-work pool. However, we are researching alternatives to the no-work pool that would allow all no-work services to be priced under the topdown methodology. If we develop such an alternative, the estimates of direct expenses will be important in determining the RVUs for medical nutrition therapy. Indirect expenses are based on physician work and direct inputs. We believe that many of the costs identified by this commenter are indirect costs that would likely be included in practice expenses reported through the SMS survey. Since the commenter has suggested that practice expenses for private practice registered distitians differ little from other

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practitioners, we believe the average practice expanse per hour for all physicians is sufficient to use in the practice expense methodology.

Result of Evaluation of Comments

The payment rate we are establishing in this final rule for CPT code 97803 will be the same as the rate for CPT code 97802. We are also changing the payment rate for CPT code 97804 using the easumption that the code will normally be billed for 4 to 6 patients with the average of 5. Using these revised values, the payment rate for group medical nutrition therapy will approximate the hourly rate paid for other medical nutrition therapy services.

F. Telehealth Services

Beginning October 1, 2001, the BIPA amended section 1834 of the Act to specify that we pay a physician (as defined in section 1861(r) of the Act) or a practitioner (described in section 1842(b)(18)(C) of the Act) for telehealth services that are furnished via a telecommunications system to an

eligible telehealth individual. The BIPA defined Medicare telehealth services as professional consultations, office or other outpatient visits, and office psychiatry services identified as of July 1, 2000, by CPT codes 99241 through 99275; 99201 through 99215, 90804 through 90809 and 90862 (and as we may subsequently modify) and any additional service we specify. The BIPA defines an eligible telcheelth individual as an individual enrolled under Part B who receives a telehealth service furnished at an originating site.

Section 1834(m) of the Act, as added by the BIPA, limited an originating site to a physician's or practitioner's office, hospital, critical access hospital, rural health clinic, or Federally qualified health center. Additionally, the BIPA specified that the originating site must be located in one of the following

geographic areas:

· In an area that is designated as a rural health professional shortage area (HPSA) under section 332(a)(1)(A) of the

Public Health Service Act.

 In a county that is not included in a Metropolitan Statistical Area (MSA), However, an entity participating in a Federal telemedicine demonstration project that has been approved by, or receives funding from us as of December 31, 2000 would not be required to be in a rural HPSA or non-MSA.

The BIPA also required that we pay a physician or practitioner located at a distant site that furnishes a telehealth service to an eligible telehealth beneficiary an amount equal to the

amount that the physician or practitioner would have been paid under Medicare had the service been furnished without the use of a telecommunications system

This section also provided for a facility fee payment for the period beginning October 1, 2001 through December 31, 2002, to the originating site of \$20. For each subsequent year, the facility fee for the preceding year is increased by the percentage increase in the MEI as defined in section 1842(I)(3) of the Act. The BIPA also amended section 1833(a)(1) of the Act to specify that the amount paid must be 80 percent of the lesser of the actual charge or the amounts specified in new section 1834(m)(2) of the Act.

In order for us to have this benefit expansion implemented timely, we have used a program memorandum. The program memorandum was effective October 1, 2001. This final rule will be

offective January 1, 2002. The rule published on August 2, 2001 proposed to establish policies for implementing the provisions of section 1834(m) of the Act, as added by the BIPA, that change Medicare payment for telehealth services.

We proposed to revise § 410.78 to specify that Medicare beneficiaries are eligible for telehealth services only if they receive services from an originating site located in either a rural HPSA as defined by section 832(a)(1)(A) of the Public Health Services Act or in a county outside of a MSA as defined by section 1886(d)(2)(D) of the Act.

Definitions

Section 1834(m)(4)(F) of the Act. which was added by the BIPA and became effective for services beginning October 1, 2001, defined telebealth services as professional consultations, office and other outpatient visits. individual psychotherapy, pharmacologic management, and any additional service we specify. Additionally, this provision identified covered services by HCPCS codes identified as of July 1, 2000. We proposed to revise § 410.78 to implement this coverage expansion to include the following services (and corresponding CPT codes);

 Consultations (codes 99241 through 99275)

 Office and other outpatient visits (codes 99201 through 99215).

 Individual psychotherapy (codes 90804 through 90809).

 Pharmacologic management (code 90862).

We solicited comments regarding the guidelines that we should use to make additions or deletions of services. We

also solicited comments about specific services that may be appropriate to be covered under the Medicare telehealth benefit

In this final rule, we are specifying at § 410.78 that, except for the use of store and forward technology in the demonstration programs conducted in Alaska or Hawaii, an interactive telecommunications system must be used and the medical examination of the patient must be at the control of the physician or practitioner at the distant site. We are defining interactive telecommunications system as multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the petient and physician or practitioner at the distant site. We are also specifying that telephones. facsimile machines, and electronic mail systems do not meet the definition of an interactive telecommunications system.

A patient need not be present for a Federal telemedicine demonstration program conducted in Alaska or Hawaii. We are specifying that for Federal telemedicine demonstration programs conducted in Alaska or Hawaii, Medicare payment is permitted for telehealth when asynchronous store and forward technologies, in single or multimedia formats, are used as a substitute for an interactive telecommunications system Additionally, we are specifying that the physician or practitioner at the distant site must be affiliated with the

demonstration program We are defining asynchronous, store and forward technologies, as the transmission of the patient's medical information from an originating site to the physician or practitioner at the distant site. The physician or practitioner at the distant site can review the medical case without the patient being present. An asynchronous telecommunications system in single media format does not include telephone calls, images transmitted via facsimile machines, and text messages without visualization of the patient (electronic mail). Photographs must be specific to the patient's medical condition and adequate for rendering or confirming a diagnosis or treatment plan. Finally, we are defining the originating site as the location of an eligible telehealth individual at the time the service being furnished via a telecommunications system occurs.

Conditions of Payment

The BIPA changed the telepresenter requirements. In accordance with section 1834(m)(2)(C) of the Act, a

EXHIBIT "D PAGE 4 OF 4

Page 3 of 3 PROVIDER NAME PROVIDER NUMBER STATEMENT DATE TAX ID MIDTOWN NUTRITION CARE 9203E 03/10/05 132845837 SITE NUMBER CHECK NUMBER 100 0000026514400 **Detail of Claims** PATIENT NAME PATIENT ACCOUNT NUMBER MEMBER ID CLAIG NUMBER CONTRACT TYPE 132171 50610214700 PSU CODE 15 Allowed Charges Charges Not Allowe Procedure Code: 97802 Service Date(s): 02/25/05 - 02/25/05 \$300.00 \$0.00 \$300.00 No. of Units: 6 Payment Allowed Amount \$300.00 Calculation Copayment 5.00 Plan Payment for this Service: \$295.00 Total Patient Responsibility: \$5:00 Total Payment for this Claim: \$295.00 CHECK NEWDER 6000026514400 ioviderinumber 92016 <u>64-975</u>

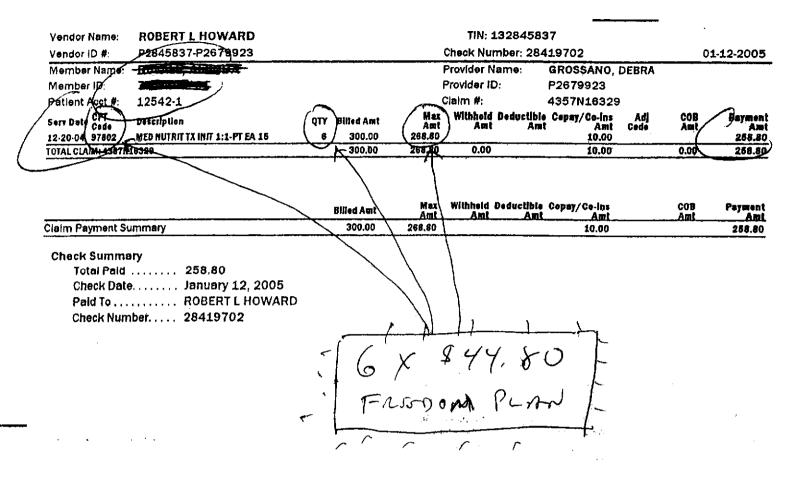
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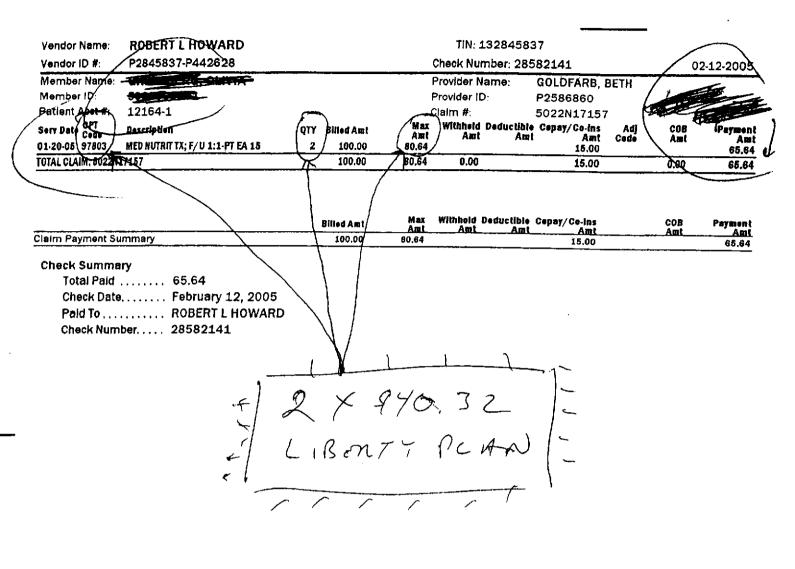
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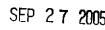
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EXHIBIT "E"
PAGE 4 OF 4

Note(s):



The Heart Group

A steady pulse of excellence.

September 26, 2005

BY OVERNIGHT DELIVERY

Mark McClellan, M.D., Ph.D.
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-P
Mail Stop C4-26-05
Baltimore, MD 21244-8150

Re: Comments on 2006 Physician Fee Schedule Proposed Rule (CMS-1502-P)

Dear Dr. McClellan:

On behalf of the 24 cardiologists at The Heart Group and our 100,000 patients in Akron Ohio, I am writing to you to express my strong concerns with the proposed payment rates under the physician fee schedule for certain codes for First Pass imaging services — Current Procedural Terminology (CPT) codes 78481 and 78483. With the proposed change in practice expense methodology, I understand that when the change is fully implemented, the practice expensive values for these codes will decrease by as much as 60%. We understand that much of this decrease is the result of the data the Centers for Medicare and Medicaid Services (CMS) will use to set the rates, which reflect that there are no equipment costs for these services. We use these codes at The Heart Group and I know that equipment is used in furnishing the services billed under 78481 and 78483 because I incur the cost of the dedicated camera used to conduct the First Pass imaging service. I urge CMS to consider the equipment costs when determining the practice expense relative value units (RVUs) used to set the 2006 payment rates for these codes.

We have found that First Pass imaging adds additional diagnostic information on the function of the heart at peak stress which adds incrementally to the SPECT data. Furthermore, the RV function derived from First Pass imaging allows for a more complete assessment of overall cardiac function. We believe the First Pass image data; which requires additional equipment, processing time and interpretation, is a distinct and beneficial service to our patients. The additional First Pass data, combined with SPECT reduces the number tests with equivocal or sub-diagnostic results obtained with SPECT alone. Also, these images are obtained without the administration of additional isotope to the patient or increased patient acquisition time. Therefore, the additional data from First Pass is obtained without further risk or inconvenience to the patient.

The First Pass camera is a separate and distinct expense from our SPECT camera with distinct acquisition investment, maintenance fees and staff training required. The Heart Group lease for the First Pass camera is with the CDL corporation and our SPECT camera is leased for an additional expense from the Digirad corporation. The First Pass report is read and interpreted distinct from the SPECT imaging report and the two independent report results are then considered by the cardiologist for a complete picture of cardiac function. We also incur distinct digital storage expenses for the First Pass image data.

As you can see, there are, in fact, equipment costs that The Heart Group incur when performing First Pass imaging tests. It is surprising that the data you are using to set the payment rates for these codes contain no costs for equipment. I respectfully ask the agency to fix this when finalizing the 2006 payment rates. Current reimbursement for First Pass is not sufficient to sustain the investment in equipment and staffing. Consequently, any further reduction will require discontinuation of this service with resultant deterioration of the quality of care to our patients. The quality provided with First Pass imaging, in combination with traditional SPECT imaging, cannot be replaced by other imaging modalities.

Mark McClellan, M.D., Ph.D. Administrator, Centers for Medicare & Medicaid Services September 26, 2005 Page Two

For these reasons, I ask that CMS reassess the equipment costs for CPT codes 78481 and 78483. At the very least, CMS can use the equipment costs for other codes, such as 78465, to quantify the equipment costs used in these procedures and to then compute the 2006 payment rates for the codes utilizing this information.

Thank you for your consideration of this matter. I look forward to a favorable resolution to the payment rates in the final rule. If you have questions, please do not hesitate to contact me at 330-255-3405.

Sincerely,

Richard W. Davenport CMPE Chief Administrative Officer



American Academy of Otolaryngology—Head and Neck Surgery Working for the Best Ear. Nose, and Throat Care

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Mark McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1502-P
PO Box 8017
Baltimore, MD 21244-8017

Re: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2006

Dear Dr. McClellan:

On behalf of the American Academy of Otolaryngology—Head and Neck Surgery (AAO-HNS), I am pleased to submit the following comments on the proposed rule, published in the *Federal Register* on August 5, 2005, relating to revised payment policies under the physician fee schedule for Calendar Year 2006. Our comments focus on the proposed revisions to the practice expense (PE) methodology and the negative update factor for the physician fee schedule, including problems with the calculation of the Sustainable Growth Rate (SGR).

Practice Expense (PE) Proposals for CY 2006

AAO-HNS recommends a delay in the implementation of the practice expense proposal in 2006 until additional information about the methodology is provided, appropriate practice expense surveys are conducted and appropriate payments for services in the non-physician work pool (e.g., audiology) are established. Our comments on specific proposals are provided below.

1. Supplemental PE Surveys

In accordance with section 212 of the BBRA, CMS established criteria to evaluate survey data collected by organizations to supplement the SMS survey data normally used in the calculation of the PE component of the PFS. To continue to ensure the maximum opportunity for specialties to submit supplemental PE data, CMS extended until 2005 the period that they would accept survey data that meet the criteria set forth in the November 2000 PFS final rule.

For the current 2005 fee schedule, CMS received surveys from the American College of Cardiology (ACC), the American College of Radiology (ACR), and the American Society for Therapeutic Radiation Oncology (ASTRO). At the request of ACC and the ACR, CMS deferred using their data until issues related to the nonphysician work pool could be addressed. The ASTRO survey was rejected for failure to meet data precision requirements.

For 2006, CMS proposes to use the previously submitted ACC, ACR and ASTRO survey data in the calculation of PE RVUs. For 2006, also CMS proposes to use surveys from the Association of Freestanding Radiation Oncology Centers (AFROC), the American Urological Association (AUA), the American Academy of Dermatology Association (AADA), the Joint Council of Allergy, Asthma, and Immunology (JCAAI), and a joint survey from the American Gastroenterological Association (AGA), the American Society of Gastrointestinal Endoscopy (ASGE) and the American College of Gastroenterology (ACG).

The following table compares the PE/HR figures that were in place at the time the resource based practice expense methodology was implemented in 1999 to the proposed PE/HR figures listed in a September 1, 2005 Federal Register correction notice.

Specialty	Initial PE/HR (1999)	Proposed PE/HR (Initial)	Proposed PE/HR (Corrected)	Percent Change
Radiology	\$58.2	\$96.30	\$136.70	135%
Cardiology	\$82.9	\$156.30	\$184.30	122%
Radiation Oncology	\$58.2	\$128.30	\$138.00	137%
Urology	\$94.6	\$121.70	\$163.20	73%
Dermatology	\$115.0	\$152.10	\$212.50	85%
Allergy/Immunology	\$126.4	\$179.60	\$233.70	85%
Gastroenterology	\$56.6	\$85.00	\$133.20	135%

This table shows the dramatic changes in PE/HR that have been associated with recent supplemental surveys. In addition to these surveys, we note that for the 2004 fee schedule, CMS increased the PE/HR for hematology/oncology - that had been \$93.4 in 1999 - to \$189.0. PE/HR figures in excess of \$200/HR are so much higher than other specialty's that they raise questions about the validity of the results. Given the importance of these data in the calculation of practice expense RVUs, we believe CMS should consider referring all survey results to the RUC/PEAC for peer-review.

In the proposed rule, CMS explicitly states that they are not proposing to extend the deadline for submitting supplemental survey data at this time. However, they invite comment on the most appropriate way to ensure the PE/HR figures are accurate and consistent across specialties.

AAO-HNS is deeply concerned that the PE/HR figures that are proposed for use in 2006 will create a two-tiered system with specialties that have recently submitted supplemental surveys having PE/HR figures that are significantly higher than all other specialties. As such, we view the proposed system as inequitable with a high probability that significant distortions in the relativity of practice expense payments across specialties will be created.

We note that our concerns are shared by the CMS contractor responsible for evaluating the supplemental survey data. In its June 8, 2005 report titled "Recommendations Regarding Supplemental Practice Expense Data Submitted for 2006", the Lewin Group stated:



"As we discuss elsewhere in this paper, the increase in total practice expense per hour value for urology is consistent with increases observed in other supplemental practice expense data. This suggests a broad trend in rising physician practice expenses and suggests the need for a multi-specialty practice expense survey, similar to the AMA's SMS survey." (page 10)

"The increase in total practice expense per hour value for allergy and immunology is consistent with increases for other supplemental practice expense data. This may suggest a secular trend in rising physician practice expenses and the need for a multi-specialty practice expense survey, similar to the AMA's SMS survey so that all specialty groups can be equally compared." (page 31)

We urge a delay in the implementation of the proposed PE/HR figures until such time as a multi-specialty practice expense survey, similar to the AMA's SMS survey, can be conducted. We acknowledge that a broad multi-specialty survey could be expensive. We suggest that CMS explore the possibility of sharing the cost with all the specialties affected by the practice expense methodology. Alternatively, the necessary funds could be obtained through a reallocation of the demonstration funds associated with the oncology demonstration project that pays physicians who administer chemotherapy in their office an additional \$130 per encounter to assess selected patient comfort factors (nausea and/or vomiting; pain; and fatigue). We note that this \$130 payment exceeds the payment made for a level 3 office consultation (CPT code 99243).

Based on information in the 2005 final rule published on November 15, 2004, we estimate the cost of this demonstration in 2005 to be more than \$260 million. We question the value of the data that is being collected and the appropriateness of targeting additional funds to a single specialty. Much more useful information could be obtained from a multi-specialty survey of practice expenses. For the physician fee schedule to be widely accepted, it is essential that it be widely viewed as fair and equitable. An important step toward assuring fairness and equity would be to conduct a uniform survey of practice expenses of all specialties that are paid under the physician fee schedule.

At a minimum, CMS must re-open the process for submitting supplemental surveys so that other specialties can determine the extent to which their practice expenses have changed since 1999. Clearly, this option is not preferred since it disadvantages those smaller specialties for which the cost of an appropriately conducted survey is simply prohibitive.

2. Revisions to the PE Methodology

Consistent with the agency's goals of using the most appropriate data, simplifying the methodology, and increasing the stability of the payment system, CMS also proposes to:

- use a bottom-up methodology to calculate direct PE costs;
- eliminate the nonphysician work pool;
- utilize the current indirect PE RVUs, except for those services affected by the accepted supplementary survey data; and,
- transition the resulting revised PE RVUs over a four-year period.



Mark McClellan, MD, PhD September 23, 2005 Page 4 of 6

The proposed rule includes a very detailed description of the current "top-down" methodology but a very sketchy description of the proposed methodology. Although CMS describes the new methodology as "simple" we find it quite difficult to understand. Before the new methodology is implemented, we believe it is incumbent on CMS to provide sufficient details so that the medical community can understand the system and provide the agency meaningful and constructive comments. This cannot be done in the short period of time between now and January 1, 2006. Therefore, we recommend that CMS withdraw the proposal for this year and re-publish it in the future in a Federal Register notice that includes a description of the methodology that is at least as detailed as the description of the current methodology provided in this proposed rule.

In this proposed rule, CMS also identifies several outstanding issues that need further consideration. For example, CMS is proposing to exempt certain services from the calculation of PE RVUs under the proposed methodology and to use the current RVUs in their place. These services include audiology, medical nutrition therapy, ESRD visit codes and the new drug administration codes. CMS notes that the proposed transition period would give them the opportunity to work with the affected specialties to collect the needed survey or other data or to determine whether further revisions to the PE methodology are needed.

We appreciate the opportunity to offer comments on this issue since audiology services are an important component of many of our members' practices. However, we are opposed to the approach proposed by CMS. We do not believe the transition period should be used to identify a solution to the problems associated with these services. Rather, we believe CMS should work with AAO-HNS and other affected physician specialty societies to develop and evaluate appropriate changes to the methodology before the methodology is put into effect. As noted earlier, an important step would be the collection of practice expense data by CMS across all specialties. Alternatively, CMS should re-open the process for submitting supplemental surveys so that AAO-HNS and other specialties can determine the extent to which their practice expenses have changed since 1999. In any event, the recent supplemental practice expense surveys should not be incorporated into the methodology until all other specialties have either conducted a survey or stated that they so not wish to do so.

Sustainable Growth Rate (SGR)

Updates to Medicare physician payments are made each year based on a statutory formula established in section 1848(d) of the Social Security Act. The calculation of the Medicare physician fee schedule update utilizes a comparison between target spending for Medicare physicians' services and actual spending. The update is based on both cumulative comparisons of target and actual spending from 1996 to the current year, known as the Sustainable Growth Rate (SGR), as well as year-to-year changes in target and actual spending. The use of SGR targets is intended to control the growth in aggregate Medicare expenditures for physicians' services. In the proposed rule, CMS projects a negative 4.3 percent update to physician payment rates for 2006.

Flaws in the SGR formula led to a 5.4% payment cut in 2002, and additional cuts in 2003 through 2005 were averted only after Congress intervened. The Medicare Trustees project that physicians and other health professionals face steep pay cuts (about 26%) from 2006 through 2011. If these cuts begin, on January 1, 2006, average physician payment rates will be less in 2006 than they were in 2001, despite substantial practice cost inflation. These reductions are not cuts in the rate of increase, but are actual cuts in the amount paid for each service. Our members simply cannot absorb these severe payment cuts and, unless CMS or Congress acts, some of them may be forced to avoid, discontinue or limit the provision of services to Medicare patients.

The American Medical Association (AMA) has identified administrative steps that CMS should take that would significantly reduce the costs associated with a permanent legislative fix to the Sustainable Growth Rate (SGR) formula. We support the AMA's efforts to persuade CMS of the appropriateness and necessity of the administrative actions that are described below.

1. CMS must remove Medicare-covered, physician-administered drugs and biologics from the physician payment formula, retroactive to 1996.

When CMS calculates actual Medicare spending on "physicians' services," it includes the costs of Medicare-covered prescription drugs administered in physicians' offices. CMS has excluded drugs from "physicians' services" for purposes of administering other Medicare physician payment provisions. Thus, removing drugs from the definition of "physicians' services" for purposes of calculating the SGR is a consistent reading of the Medicare statute. Further, drugs are not paid under the Medicare physician fee schedule, and it is illogical to include them in calculating the SGR.

2. <u>CMS must ensure that government-induced increases in spending on physicians' services are accurately reflected in the SGR target</u>

The Federal government encourages greater use of physician services through legislative actions, as well as a host of other regulatory decisions. These initiatives clearly are good for patients and, in theory, their impact on physician spending is recognized in the SGR target. In practice, however, many have either been ignored or undercounted in the target. Since the SGR is a cumulative system, erroneous estimates compound each year and create further deficits in Medicare spending on physicians' services.

As a result of implementing a new Medicare benefit (e.g., preventive services and screening services) or expanding access to existing Medicare services, Medicare spending on physicians' services will increase. Such increased spending will occur due to the fact that new or increased benefits will trigger physician office visits, which, in turn, may trigger an array of other medically necessary services, including laboratory tests, to monitor or treat chronic conditions that might have otherwise gone undetected and untreated, including surgery for acute conditions. This increased spending should be factored into the calculation of the SGR so that physicians are not penalized for providing these important services.

Mark McClellan, MD, PhD September 23, 2005 Page 6 of 6

CMS should also seek to identify other spending increases attributable to quality improvement programs and ensure that they, too, are reflected in the SGR law and regulation factor. For example, Medicare's Quality Improvement Organizations (QIO) have encouraged physicians to determine the left ventricular function of all patients with congestive heart failure, measured using a nuclear medicine test or an echocardiogram.

3. CMS must ensure that the SGR fully reflects the impact on physician spending due to national coverage decisions

When establishing the SGR spending target for physicians' services, the law requires that impact on spending, due to changes in laws and regulations, be taken into account. The AMA believes that any changes in national Medicare coverage policy that are adopted by CMS pursuant to a formal or informal rulemaking, such as Program Memorandums or national coverage decisions, constitute a regulatory change as contemplated by the SGR law, and must also be taken into account for purposes of the spending target.

CMS has expanded covered benefits through the adoption of more than 80 national coverage decisions (NCDs), including implantable cardioverter defibrillators, diagnostic tests and chemotherapy for cancer patients, carotid artery stents, cochlear implants, PET scans, and macular degeneration treatment. While every NCD does not significantly increase Medicare spending, taken together, even those with marginal impact contribute to rising utilization.

AAO-HNS strongly supports Medicare beneficiary access to these important services. However, physicians should not have to finance the costs resulting from the attendant increased utilization. Accordingly, CMS should ensure that the impact on utilization and spending resulting from all national coverage decisions is taken into account for purposes of the SGR spending target.

Conclusion

Our major concerns relate to the proposed practice expense proposals for 2006 and the proposed reduction in the conversion factor for 2006. We have recommended a delay in the implementation of the proposed practice expense changes and provided specific recommendations for changes in the SGR methodology.

The American Academy of Otolaryngology—Head and Neck Surgery appreciates the opportunity to provide these comments and recommendations on behalf of behalf of our members. We trust you will find our comments compelling and that necessary and appropriate changes will be made in the final rule. If you require further information, please contact Linda Taliaferro, MHCM, Director of Socioeconomic Affairs at (703) 684-4286 or Ltaliaferro@entnet.org.

Sincerely,

David R. Nielsen, MD

Executive Vice President and CEO



9/22/2005

Center for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1502-P
PO Box 8017
Baltimore MD 21244-8017

File Code: CMS-1502-P

Issue Identifier: TEACHING ANESTHESIOLOGISTS

As a teaching anesthesiologist in an accredited university residency program and assigned to oversee our day to day business office, I am concerned about the lack of a correction in the discriminatory policy of paying teaching anesthesiologists only 50% of the fee for each of two concurrent resident cases. The gap between reimbursement in the private sector and university setting is widening and creating a situation in which it is becoming impossible to attract anesthesiologists into the academic setting. This will not allow the continued flow of qualified anesthesiologists to take care of Medicare patients and educate qualified residents for quality anesthesia care in the future. You have invited comments suggesting improvements to the current policy "that would allow it to be more flexible for teaching anesthesia programs". The proposed rule acknowledges that revisions are necessary.

- 1. The current Medicare teaching anesthesiologist payment rule is unwise, unfair and unsustainable.
- 2. Quality medical care, patient safety and an increasingly elderly Medicare population demand that the United States have a stable and growing pool of physicians trained in anesthesiology.
- 3. Right now, slots in anesthesiology residency programs are going unfilled because of ill-conceived Medicare policy that shortchanges teaching programs, withholding 50% of their funds for concurrent cases.
- 4. Anesthesiology teaching programs, caught in the snare of this trap, are suffering severe economic losses that cannot be absorbed elsewhere.
- 5. The CMS anesthesiology teaching rule must be changed to allow academic departments

to cover their costs.

- 6. Academic research in anesthesiology is also drying up as department budgets are broken by this arbitrary Medicare payment reduction.
- 7. Medicare must recognize the unique delivery of anesthesiology care and pay Medicare teaching anesthesiologists on par with their surgical colleagues.
- 8. A surgeon may supervise residents in two overlapping operations and collect 100% of the fee for each case from Medicare. An internist may supervise residents in four overlapping outpatient visits and collect 100% of the fee for each when certain requirements are met. A teaching anesthesiologist will only collect 50% of the Medicare fee if he or she supervises residents in two overlapping cases.
- 9. The Medicare anesthesia conversion factor is less than 40% of prevailing commercial rates. Revenue is grossly inadequate to sustain the service, teaching and research missions of academic anesthesia programs.

Thank you for your attention to this matter. Training residents by qualified teaching attending anesthesiologist is the only way to insure the continued level of medical care for Medicare patients.

Sincerely,

Dr. Stephen K. Patteson, MD

1905 Hickory Glen Rd

Knoxville, TN 37932



Community Hospital of the Monterey Peninsula®

September 22, 2005

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

RE: CMS-1502-P

To Whom It May Concern:

On August 3, 2005, Centers for Medicare & Medicaid Services ("CMS") unveiled its physician payment rules for 2006 and proposed moving two California counties (Santa Cruz and Sonoma) out of Payment Area 99, "Rest of California," at the cost of reducing reimbursement to the remaining Area 99 counties, including those already adversely impacted by averaging with lower-cost counties. Monterey County would continue to reside in Area 99 and the proposed rule would result in an additional 0.4% cut in physician reimbursement for Monterey County physicians.

Community Hospital of the Monterey Peninsula, representing more than 2100 employees and in excess of 300 active, practicing physicians on our medical staff, objects to the proposed rule because it fails to correct proven inadequacies in physician reimbursement to all counties in Area 99 that exceed a 5% threshold (the so-called "105% Rule") over the national 1.000 average. Specifically, by extracting Santa Cruz and Sonoma counties from Area 99, CMS is exacerbating reimbursement deficiencies for the California counties of Monterey, San Diego, Sacramento, Santa Barbara, and El Dorado.

Is there a more equitable solution? Yes.

Community Hospital of the Monterey Peninsula supports the proposal drafted by the California Medical Association for and at the recommendation of CMS. The proposal included a formula to determine which counties qualified for their own payment regions. In 1996 CMS began an attempt to decrease the number of payment localities for Medicare Part B providers. In determining which counties belonged where, CMS determined that a 5% or greater differential in practice costs from other California counties qualify an individual county for its own payment region. Given that Monterey County has one of the highest costs of living (and, indeed, practice costs) in the country, it is unfathomable why Monterey County would not qualify for its own payment region. For the past several years, as practice costs in Monterey County have increased at the same rate as those in San Francisco County, physicians have become more and more disillusioned with the Medicare system. It is indeed a sad state when many physicians practicing in our community have had to make the regrettable decision to stop seeing Medicare patients.

Hopes were high when the California Medical Association was able to secure consensus on a formula that would allow, with CMS's regular updates, for counties demonstrating 5% or greater differential from the "rest of California" to be removed into their own payment locality with the offsetting financial burden being spread throughout the entire state. Unfortunately, this rational and equitable solution is not reflected in CMS-1502-P.

In summary, Community Hospital of the Monterey Peninsula supports the California Medical Association's recommendation that Congressman Thomas and CMS work together to devise a nationwide fix to the GPCI problem. The current proposed rule (CMS-1502-P) to extract Santa Cruz and Sonoma counties from California's Area 99 is not, in our opinion, a viable step toward that goal. As one of the leading hospitals in our region, we cannot afford to lose any more physicians to continued inequitable cuts in Medicare reimbursement.

Respectfully,

COMMUNITY HOSPITAL OF THE MONTEREY PENINSULA

Steven Packer, M. D.

President/CEO

The Honorable Sam Farr Dr. Scott H. Schneiderman

cc:



David S. Abrams, M.D. William H. Bailey, M.D. Scott Blois, M.D. W. Richard Cashion, Jr., M.D. Paul R. Coffeen, M.D. Robert F. Denver, D.O. Parul M. Desai, M.D. Deborah L. Ekery, M.D. Roger S. Gammon, M.D. Stephen H. Garland, M.D. Jerry H. Gilbert, M.D. Boguslaw Godlewski, M.D. lames P. Goolsby, M.D. Ronald R. Hall, M.D. Mell C. Jackson, Jr., M.D. David J. Kessler, M.D. George W. Lowe, M.D. Henry S. Lucid, M.D. Adolph Mares, Jr., M.D. William E. McCarron, M.D. Thomas R. McMinn, M.D. Steven T. Minor, M.D. David L. Morris, M.D. Sam Narra, M.D. Paul R. Pagley, M.D. Robert W. Pederson, M.D. Matthew Phillips, M.D. Mark F. Picone, D.O. Wm. A. Robinson, M.D. George P. Rodgers, M.D. Eric F. Roehm, M.D. Neil Sawhney, M.D. Arthur M. Smith, M.D. David D. Swett, M.D. Russell S. Whitaker, M.D. leffrey N. Whitehill, M.D. Frank J. Zidar, M.D.

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BY OVERNIGHT DELIVERY

Mark McClellan, M.D., Ph.D.
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-P
Mail Stop C4-26-05
Baltimore, MD 21244-8150

Re: Comments on 2006 Physician Fee Schedule Proposed Rule (CMS-1502-P)

Dear Dr. McClellan:

As a physician, I am writing to you to express my strong concerns with the proposed payment rates under the physician fee schedule for certain codes for First Pass imaging services – Current Procedural Terminology (CPT) codes 78481 and 78483. With the proposed change in practice expense methodology, I understand that when the change is fully implemented, the practice expense values for these codes will decrease by as much as 60%. I also understand that much of this decrease is the result of the data the Centers for Medicare and Medicaid Services (CMS) will use to set the rates, which reflect that there are no equipment costs for these services.

I use these codes in my practice and I know that additional equipment is used in furnishing the services billed under 78481 and 78483 because I incur the cost of the dedicated camera used to conduct the First Pass imaging service. I urge CMS to consider the equipment costs when determining the practice expense relative value units (RVUs) used to set the 2006 payment rates for these codes.

Austin Heart is a 41 physician single specialty cardiology group associated with the Heart Hospital of Austin. The practice services central Texas in a 80 mile radius from the city of Austin. We have a fully integrated EMR system, in office QA and peer review procedures, research department and we are the only private practice group in the state that is an independent accredited provider of CME. This year will have over 120,000 patient encounters. Our ability to offer first pass imaging is important in delivering quality patient care.

We evaluated a first pass system prior to its implementation. The physicians read the perfusion studies and noted whether the first pass information added independent clinical value. They identified many cases in which the perfusion imaging suggested a mild amount of disease, but the first pass independently identified those patients as being at high risk. Subsequent cardiac catheterizations confirmed the first pass data. In addition, the first pass was helpful in clarifying mildly positive perfusion studies as in fact being low risk, and thus obviated the need for further testing.

We are currently performing close to 9,000 nuclear studies per year and have found the first pass system is adding significant clinical information and it is done with no additional risk to the patient. It does come with incremental cost as it is a separate camera system, requires separate processing and analysis and of course has to be maintained.

This clinical procedure has been a major advance in the perfusion studies as it combines the best of two possible situations. We now can assess the perfusion of the myocardium, as well as the peak exercise ejection fraction. This combination of data will lead to more accurate diagnosis, improved patient care and lower overall costs as we will define the patients at increased risk more selectively. At the proposed reimbursement, it would be impossible to continue to provide this service.

For these reasons, I ask that CMS reassess the equipment costs for CPT codes 78481 and 78483. At the very least, CMS can use the equipment costs for other codes, such as 78465, to quantify the equipment costs used in these procedures and to then compute the 2006 payment rates for the codes utilizing this information.

Thank you for your consideration of this matter. I look forward to a favorable resolution to the payment rates in the final rule. If you have questions, please do not hesitate to contact me at 512-206-3662.

Sincerely,

Matt Phillips, M.D.

Ellea Pul

President

Austin Heart, PA



September 13, 2005

SEP 27 2005

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1502-P/TEACHING ANESTHESIOLOGISTS
P.O. Box 8017
Baltimore, MD 21244-8017

Dear Dr. McClellan:

I am writing as an Academic Anesthesiologist at the H. Lee Moffitt Cancer Center in Tampa, Florida to urge the Centers for Medicare and Medicaid Services (CMS) to change the Medicare anesthesiology teaching payment policy.

Our institution, trains both Anesthesiology Residents and Certified Registered Nurse Anesthetist (CRNA) students and we therefore are fully aware of the economic impact of Medicare's discriminatory payment arrangement. It applies only to anesthesiology teaching programs, and has had a serious detriniental impact on the ability of our anesthesiology residency program to retain skilled faculty and to train the new anesthesiologists necessary to help alleviate the widely-acknowledged shortage of anesthesia providers -- a shortage that will be exacerbated in coming years by the aging of the baby boom generation and their need for surgical services.

The proposed policy revision will not affect in any way the education of Certified Registered Nurse Anesthetist (CRNA) students or the number of CRNA students trained at our institution.

Under current Medicare regulations, teaching surgeons and even internists are permitted to work with residents on overlapping cases and receive full payment so long as the teacher is present for critical or key portions of the procedure. Teaching surgeons may bill Medicare for full reimbursement for each of the two procedures in which he or she is involved. An internist may supervise residents in four overlapping office visits and collect 100% of the fee when certain requirements are met.

Teaching anesthesiologists are also permitted to work with residents on overlapping cases so long as they are present for critical or key portions of the procedure. However, unlike teaching surgeons and internists, since 1995 the

teaching anesthesiologists who work with residents on overlapping cases face a discriminatory payment penalty for each case. The Medicare payment for each case is reduced 50%. This penalty is not fair, and it is not reasonable.

Correcting this inequity will go a long way toward assuring the application of Medicare's teaching payment rules consistently across medical specialties and toward assuring that anesthesiology teaching is reimbursed on par with other teaching physicians.

Please end the anesthesiology teaching payment penalty.

Sincerely yours,

Jose Sarria, M.D.

Date: September 20, 2005

Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS-1502-P
P.O. Box 8017
Baltimore MD 21244-8017

Re: File Code CMS1502-P

Issue Identifier: GPCI's / Payment Localities

Dear CMS Staff:

I am writing to strongly support the proposed revision to physician payment localities in California that you published earlier this month. I hope that you adopt this rule as final in November. As an employee of Dominican Hospital, I am very concerned that as our physicians age and retire, we as a community are able to attract new physicians to take their place. I have followed the issues surrounding the inclusion of Santa Cruz County within Locality 99 for California and welcome the opportunity to support your proposed solution to the current inequitable payment policy. I believe adoption of your proposed rule will go a long way to ensuring ongoing access to high quality care for community residents.

As you know, physicians in Santa Cruz receive reimbursement at levels 25% less than physicians in two of our neighboring counties. Current payments are about 10% less than they should be, given the county's current GAF. They do not reflect the high cost of practice in our community.

You are to be commended for proposing a rule that would address this problem for physicians in Santa Cruz and Sonoma Counties, the two most problematic counties in California. I believe this to be fair and appropriate. Thank you for considering my comments.

Soudle M. Cornicle, CLS

Sincerely,

Name:

Saralee McCormick

Address: 145 Seaborg Place

Santa Cruz, CA 95060

Strong Memorial Hospital • Golisano Children's Hospital at Strong • Highland Hospital
The Highlands • Eastman Dental Center • Visiting Nurse Service

SEP 27 2005

Steven I. Goldstein General Director and Chief Executive Officer

Strong Memorial Hospital

September 16, 2005

Centers for Medicare and Medicaid Services Department of Health and Human Services Attn: CMS-1502-P PO Box 8017 Baltimore, MD 21244-8017

Re: CMS-1502-P TEACHING ANESTHESIOLOGISTS

Dear Sir/Madame,

As the CEO of Strong Memorial Hospital at the University of Rochester in New York, I am writing to request your support of the changes required in the present CMS Medicare Fee Schedule related specifically to TEACHING ANESTHESIOLOGISTS who provide the educational training as models for professional development of young doctors seeking to become academic and private practice anesthesiologists.

We presently have 50 residents in anesthesiology training at the University of Rochester, being trained by 42 academic teaching anesthesiologists within the Department of Anesthesiology. At Strong Memorial Hospital we have experienced a 27% growth in surgical volume during the past 4 years, that includes an increasingly aged, acutely ill, and complex number of patients. We have become the only Level 1 Trauma unit in this region. This past year we provided over 27,000 anesthetics. Our commercial reimbursement rates based on productivity per faculty member are some of the lowest in the country making recruitment and retention within the academic milieu a continuously challenging process. Recruitment of recent graduates or experienced anesthesiologists into an academic center is a continuous problem, particularly as recent graduates now have educational debt levels of \$100,000 -300,000, for which private practice offers a considerably higher compensation. Permitting equality in the Medicare Fee Schedule with their surgical colleagues with respect to full payment for each of two patients concurrently cared for following CMS regulations, will substantially augment our ability to provide the academic environment that is needed for the future.

Centers for Medicare and Medicaid Services 916/05 Page Two

Redressing the unequal reimbursement for similar care provided by surgeons and anesthesiologists will provide a significant component of the resources required to develop the quality of academic anesthesiology required for the US to advance in this vital field for which most US citizens can expect to undergo surgery at some time during their life. The recognition of the focus on safety and the critical role that anesthesiologists play in allowing interventional and surgical procedures to occur without memory or pain is a fundamental mantra in training anesthesiologists. The combination of education, research, and dedicated models in the field is required for the future.

I urge those making long term decisions in CMS to appreciate the turning point that exists now with respect the present and future training of anesthesiologists.

Thank you for your willingness to seriously consider these issues.

Sincerely,

Steven I. Goldstein President & CEO

Strong Memorial Hospital

Electronic comments: http://www.cms.hhs.gov/regulations/ecomments

Copies to mail@asawash.org

To send to members of congress requesting that they communicate with CMS in support of this regulatory change:

www.capwiz.com/asa/home/





Baystate Medical Center/
Tufts University School of Medicine

Department of Anesthesiology

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Tel: (413) 794-3520 Fax: (413) 794-5349

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Duane A. Dixon, M.D. Chief, Acute Pain Service

Ananth Kashikar, M.D. Chief, Post Anesthesia Care Unit (PACU)

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Alan Kulig, M.D. Section Chief, Vascular Anesthesia

Vijay Gandevia, M.D. Section Chief, Remote Site Anesthesia

Wagdy Zakhary, M.D. Section Chief, Orthopedic Anesthesia

Tanys Lucas, M.D. Section Chief, Obstetrical Anesthesia Section Chief, Student Affairs September 15, 2005

Centers for Medicare and Medicaid Services Department of Health and Human Services Attn: CMS-1502-P P.O. Box 8017 Baltimore, MD 21244-8017

Re: TEACHING ANESTHESIOLOGISTS

Throughout the State of Massachusetts, there are continuing concerns about the adequacy of federal support for teaching institutions. The current Medicare teaching anesthesiologist payment rule is unwise, unfair and unsustainable. Quality medical care, patient safety and an increasingly elder population demand that the United States have a stable and growing pool of physicians trained in anesthesiology.

Right now, slots in anesthesiology residency programs are going unfilled because of Medicare policy that shortchanges teaching programs by withholding 50% of funds for concurrent cases. Anesthesiology teaching programs are suffering severe economic losses that cannot be absorbed elsewhere. The CMS anesthesiology teaching rule must be changed to allow academic departments to cover their costs. Academic research in anesthesiology is also at a loss as there are limited funds available because of this arbitrary Medicare payment reduction.

Why is it that surgeons may supervise residents in two overlapping operations and collect 100% of the fee for each case from Medicare and an anesthesiologist on the same case can only collect 50% of the Medicare fee if he or she is supervising two residents on overlapping cases? In addition, internists are allowed to supervise four residents for outpatient visits and are reimbursed at 100% of the fee if certain requirements are met. This is not fair and it is not reasonable.

Medicare must recognize the unique delivery of anosthesiology care and pay Medicare teaching anesthesiologists on par with their surgical colleagues. The Medicare anesthesia conversion rate is less than 40% of prevailing commercial rates. Reducing the fees by another 50% for teaching anesthesiologists results in revenue grossly inadequate to sustain our programs. The service, teaching and research missions of academic anesthesia training programs in our country will surely suffer from this course of action.

I appreciate your attention to this important issue and hope that you are able to address these concerns. Academic anesthesiology departments are depending on changes to this rule in order to improve the quality of care for patients at all teaching institutions.

Sincerely,

Stephen V. Hall, M.D. Staff Anesthesiologist

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Robert Parker, DO

Sincerely

Director, OB Anesthesia **Baystate Medical Center**

Associate Professor of Anesthesiology **Tufts University School of Medicine**





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Centers for Medicare and Medicaid Services Department of Health and Human Services Attn: CMS-1502-P P.O. Box 8017 Baltimore, MD 21244-8017

Re: TEACHING ANESTHESIOLOGISTS

Teaching institutions across the country urge your support to increase federal funding for academic anesthesiology departments. Current CMS rules make it difficult for departments like ours to survive.

Under current guidelines, cases involving residents can only be reimbursed a full fee if they are supervised on a one-to-one basis. It does not allow for overlapping cases to each realize a full fee for services. Surgeons at teaching institutions are not restricted by the same rules. They collect the full fee as long as they are present for the key portions of the procedures. This puts academic anesthesiology departments such as ours at a disadvantage as we cannot collect the full fees for reimbursement of similar cases. Patients, especially those covered by Medicare and Medicaid will potentially have difficulty accessing adequate patient care if this practice is allowed to continue.

The more flexible rule allowed for surgeons, if applied to anesthesiologists in teaching institutions, would go a long way toward improving funding for our programs and increase patient satisfaction. I urge you to consider recommending this change for the enhancement of teaching facilities and improvement of quality patient care.

Sincerely,

Neil R. Connelly, M.D.

Director, Anesthesia Research

Baystate Medical Center

Associate Professor of Anesthesiology Tufts University School of Medicine





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Re: TEACHING ANESTHESIOLOGISTS

An important concern is facing academic anesthesiology departments throughout the country. Teaching institutions are facing severe shortages in federal funding. If allowed to continue, this may potentially cause inadequate access to services by patients in need.

Speaking as a physician in a teaching institution, one cause for this problem can be attributed to the CMS rules for Part B reimbursement in that reimbursement for anesthesia residents is not cover by a full fee unless supervised on a one-to-one basis. This same rule does not apply to our colleagues performing surgery. They are allowed full payment for supervision of overlapping cases as long as they are present for a critical portion of the procedure. This rule, along with the cuts to teaching institutions in the Balanced Budget Act of 1997, have made it difficult to fund our academic environment and provide adequate services to all patients. Medicare and Medicaid patients are hit the hardest by this rule as the inadequate funding makes it difficult for them to access quality patient care.

Anesthesiologists at teaching institutions should be allowed to supervise overlapping cases involving residents and receive a full fee for each case. The current CMS rule is discriminatory and does not allow teaching programs adequate federal support. Please consider improvements to the Medicare reimbursement structure by allowing this rule change. Future anesthesiologists and patients can only benefit in the long run. Thank you for your considered support.

Sincerely.

Ananth Kashikar MD

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