

701

Diplomate, American
Board of Psychiatry and Neurology

JOHN R. GILLETTE, M.D.
412 Cedar Street, Suite B
Santa Cruz, CA 95060-4369
(831) 423-8164
FAX (831) 427-3033
Psychiatry

Fellow, American
Psychiatric Association

September 23, 2005

Administrator Mark McClellan
Center for Medicare and Medicaid Services
U.S. Department of Health and Human Services
P.O. Box 8017
Baltimore, MD 21244-8017

Dear Administrator McClellan:

I write to express my very strong support for CMS' proposed revision to the physician payment localities for Santa Cruz and Sonoma counties.

There is currently a large payment discrepancy for physicians in Santa Cruz County due to its being classified as a "rural" county. Counties neighboring Santa Cruz and Sonoma counties have some of the highest payment levels for physicians in the nation, while our cost of housing and living is the same if not higher. The discrepancy is causing some physicians to leave Santa Cruz or not be able to afford to begin practice here, such that quality health care has suffered as a result. This reassignment will help us provide sufficient health care services for our residents.

Physicians here have had a net loss of 19% in real reimbursement since 1991. Our costs have risen 47% and this disparity with our neighboring counties is worsening. The current formula is not working because there is no reassignment as cost of care changes.

I am a senior psychiatrist in our community, essentially the only Medicare Participating Provider with a focus on geriatric psychiatry and now a Medicare beneficiary myself. The other psychiatrists are all hospital or County clinic based and many other private psychiatrists have "opted out" of the Medicare system largely due to reimbursement restrictions. I continue to be frankly worried about the future here as I would like to retire but the high housing prices and business expenses are keeping new physicians from coming here. Many patients are not getting the access to psychiatric care truly needed. And as a Medicare beneficiary, I also want to have access to other physicians!

I commend CMS for acknowledging the discrepancy in payment for physicians, and for proposing this change to correct the situation.

Should you have any questions, please feel free to contact me.

Sincerely,



JG/jg

702
Gordon & Jeannie Potter
1353 Meadow Ct.
Healdsburg, CA, 95448
Sept 22 '05

Centers for Medicare & Medicaid Services
Dept. of Health & Human Services
Attn: CMS-1052-P
P.O. Box 8017
Baltimore, MD, 21244-8017

To Medicare:

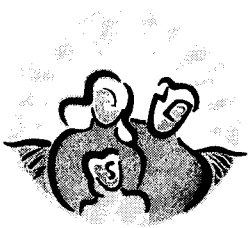
As seniors, both in our mid-seventies, we are very aware of the fact that the high cost of housing together with a "rural" rate of reimbursement has made active practice of medicine unattractive here in Sonoma County. We are losing the doctors we have, and there is no incentive for new ones to come in to take their place. In future we may be forced to go out-of-county for medical care.

Therefore, we urge that the reimbursement rate be raised so that it is at least equal to the rates in other counties in northern California. With respect to the cost of living, there is no place that is "rural" anymore in our area.

Yours truly,

Gordon M. Potter

Jeannie M. Potter



NORTH SONOMA COUNTY
HOSPITAL DISTRICT
Quality, Compassionate Care

SEP 28 2005

703

September 21, 2005

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

Dear GPCIs:

The Healdsburg District Hospital Board of Directors strongly supports your proposal to create a new payment locality for Sonoma County. The new locality would lessen the disparity between practice expenses and Medicare reimbursements.

This disparity has affected our local healthcare system for many years. We have seen many physicians leave Sonoma County to relocate in others areas that have a higher Medicare reimbursement rate. We cannot recruit new doctors because of the high cost of living and low Medicare reimbursement rates. The Hospital has a Physician Referral Program for new residents looking for a doctor, but most local physicians will not accept any new Medicare patients because of the reimbursement rates.

By creating a new payment locality for Sonoma County, you will help ensure the viability of physician's practices in the County and will improve access to care for local Medicare beneficiaries. Your proposal will correct existing payment inequities and will help us achieve your goal of reimbursing physicians based on the cost of practice in their locality.

Thank you for the opportunity to comment on this important issue.

Sincerely,

Herbert Polesky, M.D.
Chairman of the Board

Enclosure – Two copies of letter

SEP 23 1995

704

September 23, 2005

1580 Orchard Street
Santa Rosa, CA. 95404

GPCIs
Centers for Medicare and Medicaid Service
Department of Health and Human Services
Attention DMS-1502-P
P.O. Box 8017
Baltimore, MC 21244-8017

Dear Manager,

I understand that we have a one time opportunity to change federal guidelines for coverage of Medicare and Medical for the population in this area. As a user of Medicare, I am surprised to see that several of the medical groups that formerly accepted payments from Medicare and Medical have gone out of business. They could not afford to receive the low payments for their services. We have a growing elder population and the issue of low pay for the coverage really needs to be adjusted. I am disabled and have had to use Medicare for my primary insurance coverage. Finding someone who will accept Medicare is getting to be harder and harder due to the payment rates.

Our medical costs in Sonoma County have risen faster than other areas and are, on average, 8% higher than similar counties. Santa Rosa, where I reside, is the #6 U.S. city with people 85 and older. We still have the lowest Medicare reimbursement rate in California. At the same time, the number of practicing physicians in Sonoma County has not kept pace with local population growth. The population increased by 13% and primary care physicians only increased by 4%.

More than half of the Sonoma County physicians are not accepting new Medicare patients.

I urge you to consider increasing the payment to physicians in Sonoma County by 8%. This may stem the flow of them leaving our area and bring Sonoma County back in line with current Medicare reimbursement standards to stabilize our medical community.

Thank you for understanding the medical needs of this population and the solution for making the system work better for those of us who rely on Medicare and Medical as our primary insurance coverage.

Regards,



Linda Reitzell

September 18, 2005

705

Dear Medicare :

Are you aware Sonoma County has the lowest Medicare reimbursement rate in California?

Because of this low reimbursement, several medical groups have gone bankrupt and the best one, Health Plan of the Redwoods, had to shut down.

Many doctors have left the county due to low reimbursement; also, most (60%) Sonoma County primary care physicians who are left do not accept new Medicare patients.

Please correct the reimbursement rate in Sonoma County.

Thank you.

Sincerely,
Coleen Johnson
1713 Solano Dr.
Santa Rosa, CA 95404-5330

706

To Medicare:

I would like to call your attention to the increase in population, especially the increase in senior citizens and the increase in immigrants from Mexico that now live and work in Sonoma County. We are 65 miles North of San Francisco. The freeway from there to here and on north is bumper to bumper traffic at commute times.

I moved here in 1958 and the change is unbelievable. Our doctors are responding to this situation by moving elsewhere or refusing to care for patients on Medicare or Medical because of the designation by Medicare of being in a rural county. I would like to ask on the behalf of the patients that live in Sonoma County to have the reimbursement rate changed from rural to urban.

Thankyou,

Shirley Cumming September 21, 1905

SEP 28 2005

707

9/23/2005

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: GPCI

Dear Reader,

This is to convey my support for the proposed rule change that would remove my county from the Rest of California physician payment locality designation. Being a Medicare beneficiary and a patient of a very dedicated physician, I recognize the critical need to align Medicare payments to local doctors with other counties in the San Francisco Bay area.

I'm grateful for your attention to this matter & without any reservations support your proposed changes.

Sincerely,



Dave Mack



Baystate Medical Center/
Tufts University School of Medicine

Department of Anesthesiology

Springfield, MA 01199

Tel: (413) 794-3520

Fax: (413) 794-5349

Prasad R. Kilaru, M.D.
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Alan C. Weintraub, M.D.
Vice Chairman

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Director, Anesthesia Research

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Chief, Pre-Admission Evaluation Clinic

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Chief, Chronic Pain Service

Duane A. Dixon, M.D.
Chief, Acute Pain Service

Ananth Kashikar, M.D.
Chief, Post Anesthesia Care Unit (PACU)

Katharine O. Freeman, M.D.
*Chief, Shriners Hospital,
Department of Anesthesia*

Henry Godek, M.D.
*Chief, Franklin Medical Center,
Department of Anesthesia*

Peter Kaskel, M.D.
*Chief, Mary Lane Hospital,
Department of Anesthesia*

Istvan Pulai, M.D.
*Chief, Maple Surgery Center
Section Chief, Bariatric & Regional Anesthesia*

Jordan L. Blinder, M.D.
Section Chief, Neuroanesthesia

Alan Kulig, M.D.
Section Chief, Vascular Anesthesia

Vijay Gandevis, M.D.
Section Chief, Remote Site Anesthesia

Wagdy Zakhary, M.D.
Section Chief, Orthopedic Anesthesia

Tanya 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. As a physician at a teaching institution, I see the growing concerns within our facility and throughout the state. The impact of inadequate funding on access to necessary medical services by those in need is being felt on every level of patient care.

More specifically, and on a more immediate level, academic anesthesiology departments face severe difficulties with regards to funding. Anesthesiologists are not allowed to receive a full fee for supervision of two cases running simultaneously. The same rule does not apply to surgeons at teaching facilities. Surgeons are allowed to bill Medicare full fees for two overlapping surgeries involving residents, as long as they are present during the critical portions of each procedure involving a resident. Why is there no such flexibility for anesthesiologists? The teaching anesthesiologist is only reimbursed a full fee if he was involved with a single resident on a one-to-one basis.

You can certainly see that providing the same rule for teaching anesthesiologists would enhance the opportunities and allow us to divide our time between two concurrent resident cases allowing full fee reimbursement for each. This simple adjustment would improve the payment structure for our own institution and others like it throughout the State and across the country.

I appreciate your attention to this important issue and hope that you are able to address these concerns. Academic anesthesiology departments would surely benefit from this adjustment and improve the quality of care for patients at all teaching institutions.

Sincerely,



Craig Collins, M.D.
Chief, Outpatient Anesthesia
Department of Anesthesiology
Baystate Medical Center
Assistant Professor of Anesthesiology
Tufts University School of Medicine



Baystate Medical Center

A Member of Baystate Health System



Baystate Medical Center/
Tufts University School of Medicine

Department of Anesthesiology

Springfield, MA 01199

Tel: (413) 794-3520

Fax: (413) 794-5349

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Section Chief, Orthopedic Anesthesia

Tanya 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

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,

Larry Robbins, DO
Staff Anesthesiologist
Department of Anesthesiology
Baystate Medical Center

LR:ab

SEP 28 2005

710

Sept. 22, 2005

Harriet Lewis
887 Sonoma Ave. #10
Santa Rosa, CA 95404
(Sonoma County)

Mark McClellan
Center for Medicare and Medicaid Services
U.S. Department of Health and Human Services
P.O. Box 8017
Baltimore, MD 21244-8017

Dear Mr. McClellan:

I am a resident of Sonoma County in California. We are located 60 miles north of San Francisco and immediately north of Marin County, both urban areas with high costs of living and both with high payment levels for physicians serving Medicare and Medicaid.

Although we are classified as a rural county, we are not. This county also has a very high cost of living; so high that many of our children, including my own, cannot afford to live in here. At the same time that we are becoming increasingly urban, we also have a large population of hispanic and elderly residents who have low or fixed incomes.

I write to express support for CMS' proposed revision to the physician payment localities for Santa Cruz and Sonoma Counties. We are losing doctors and many people find it difficult to find a physician who will accept Medicare. We really need to have the reimbursement rate raised.

Thank you for your attention to this request.

Sincerely,



Harriet K. Lewis
hlewis@sonic.net

GP@1s

9/23/05
711

SEP 28 2005

A Special Note—

In the year 2003, I was forced twice to find new doctors because my doctors had left their practice in Santa Rosa due to the low reimbursement rate.

It is due time that this area, with its high population & high cost of living, be given the increased rate being considered before more & more doctors vacate these premises.

*Sincerely,
Evelyn Beasley*



Ms. Evelyn Beasley
32 Maywood Dr
Santa Rosa, CA 95409

712

SEP 28

Carol Schwartz
3447 Celesta Court
Sebastopol, CA 95472
(707) 829-9352

September 21, 2005

GPCIs
Centers for Medicare & Medicaid Services
Dept. of Health and Human Services
Attn: CMS-1052-P
P.O. Box 8017
Baltimore, MD 21244-8017

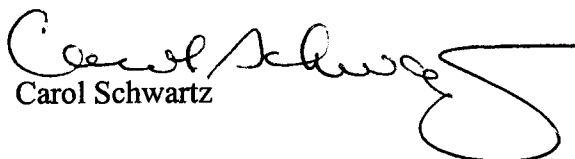
Dear Administrators:

I want to express my strong support for CMS' proposed revision to the physician payment localities for Santa Cruz and Sonoma County. As a long-time resident of Sonoma County I am acutely aware of some of the problems the current system has inflicted upon us all.

The cost of living in Sonoma County is extremely high despite the fact that the county still enjoys a rural ambience. Sonoma County also has a very high percentage of seniors, and elders over 85 years of age. I have elderly relatives that also live in Sonoma County, so I've seen first hand how hard it can be for seniors to get the medical care that they need. The large discrepancy between physician payment rates here and in neighboring counties has exacerbated the flight of doctors from Sonoma County. Many primary care doctors just cannot afford to stay and make their practice survive in the current economic environment. Quality health care is suffering for everyone when the remaining physicians are extremely overworked and underpaid. This federal guideline change will help bring medical costs in line with the actual costs here in Sonoma County and hopefully this will help stem the flow of physicians out and keep the medical services affordable for those of us who are not yet dependent on any federally subsidized program.

This proposed change is long overdue. Please do whatever is necessary to make this change as quickly as possible. Our ability to access healthcare is in your hands.

Sincerely,


Carol Schwartz

SEP 28 2000

713

Margaret (Peggy) Claire Buzanski
424 Newport Place
Santa Rosa, California 95403
707-575-9314

To Whom It May Concern:

This letter is to encourage you to increase the reimbursement rate for Sonoma County Medicare. This would bring Sonoma County in line with current Medicare reimbursement standards in cities of like size and will stabilize our medical community.

Sonoma County is growing rapidly every year. The infrastructure is not keeping up with the growth. The physicians of Sonoma County are living in a very expensive area and being compensated as if we were a rural town. Medical costs have risen in Sonoma County faster than in other areas and are, on the average, 8% higher than similar counties. This is due in part because Santa Rosa with a population of about 100,000 is the sixth in the United States for having the highest percentage of people 85 and older. Seniors (60 years and older) represent 16.6% of the total population. This number will continue to increase at an alarming rate in the next two decades.

Physicians are leaving our county to practice where they can be adequately compensated for treating Medicare patients. Six out of ten physicians in Sonoma County are not accepting new Medicare patients. As a teacher, this is the only medical insurance available to me upon retirement. Please vote to change the reimbursement rate in Sonoma County.

Sincerely,

Peggy C Buzanski

Peggy Buzanski

A8

THE PRESS DEMOCRAT • MONDAY, SEPTEMBER 12, 2005

Paid Advertisement

SEP 28 2005

This says it all - better than any letter I could write

It's your healthcare.

You can make a difference.

M. Montgomery

September 16, 2005

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 11 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. I have personally contacted all of the anesthesiologists with which I completed my fellowship education in Washington D.C. in 1994 to urge them to consider coming to Indianapolis to look at career opportunities. We are increasingly unable to recruit to Riley Hospital for children. In fact all the above mentioned individuals wouldn't think of re-entering academic anesthesia; some of these incredibly skilled educators even considering leaving Pediatric anesthesia altogether because there are so many patients to care for and no reimbursement. Not only here in Indiana, but throughout the country the number of unfilled anesthesia faculty positions at teaching institutions 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

Page 2

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%. *This is unjustifiable. Compared to other specialties in medicine Medicare payment for anesthesia services is much lower (approximately 40% of usual and customary). I wonder why your colleagues would consider not paying respectfully for top quality, expert care. You demand top quality performance from your plumber and your electrician and reimburse them accordingly. Why not do the same for your anesthesiologist? The impact of lower payment is accentuated by 50% reduction for overlapping cases when the anesthesiologist is working with residents. In fact, if you look at the literature published in peer review journals you will find that actual data support the well known belief that patients receive better care, and have fewer morbidity and mortality problems in the peri-operative period when receiving care in the care team mode – especially at high level education institutions. The low reimbursement for anesthesia services and 50% reduction in reimbursement is unfair and unreasonable, and frankly, UNJUSTIFYABLE!*

*The academic anesthesia community has made more strides into patient safety improvement in the past 25 years than all other medical specialties put together. It has been in the realm of the operating room under the direction of academic anesthesiologists that safety monitor research and development as well as use in day to day practice has been implemented for all medical patients not just surgical patients. These monitors include the Oxygen saturation monitor (pulse oximeter), end tidal CO 2 monitor, intra-operative awareness monitor(BIS monitor). I personally wonder whether you yourself or on behalf of a loved one would rather undergo an emergency operative procedure under general anesthesia now or 25 years ago. Consider 25 years from now.....

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

Sincerely,



Leigh B. Latham, M.D.

Clinical Assistant Professor of Anesthesia

Riley Hospital for Children

Indiana University School of Medicine, Indianapolis



COUNTY OF SONOMA
DEPARTMENT OF HEALTH SERVICES

716
Rita Scardaci, MPH – Director
Sharon Aguilera – Assistant Director

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: GPCIs

As the Sonoma County Director of Health Services, I strongly support the proposal to create a new payment locality for Sonoma County. The new locality would lessen the disparity between practice expenses and Medicare reimbursements.

This disparity has adversely affected our local health care system for several years. In many cases, Medicare reimbursements don't cover expenses, and a significant number of local physicians have stopped taking Medicare patients; many specialists have simply left the county. The disparity has also hampered efforts to recruit and retain new physicians to Sonoma County.

By creating a new payment locality for Sonoma County, you will help ensure the viability of physician practices in the county and will improve access to care for local Medicare beneficiaries--the fastest growing population in our county. Your proposal will correct existing payment inequities and will help you achieve your goal of reimbursing physicians based on the cost of practice in their locality.

Thank you for the opportunity to comment on this important issue.

Sincerely,

A handwritten signature in cursive script, reading "Rita Scardaci", is positioned above the typed name.

Rita Scardaci
Director of Health Services
Sonoma County Department of Health Services
3313 Chanate Road
Santa Rosa, CA 95404

cc: Two copies attached.

717

Ann & David Getzoff
7167 East Hurst Avenue
Sebastopol, CA 95472

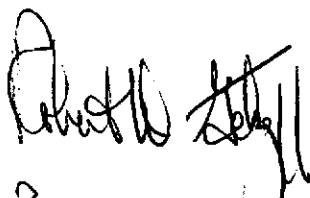
September 9, 2005

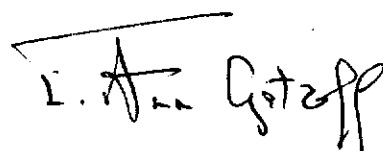
GPCIs
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1052-P
B O Box 8017
Baltimore MD 21244-8017

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.

Sincerely


ROBERT D GETZOFF


E. ANN GETZOFF

Sept 21, 05-

Center for Medicare^{and} Medicaid Services
Dear Sir,

Please raise the Medicare
reimbursement for medical
compensation.

Doroma County is one of the
most expensive places to live
and has a large percent of
Medicare patients.

The counties around this area
have always had a higher
reimbursement rate, we
should be brought up to the
same standard

Thank you

Marian Erickson
14040 Arnold Dr
Glen Ellen
Ca 95442

Jul 28 07

Grace Skidmore Rd
549 Pistachio Pl.
Windsor, CA 95492
Sept 20, 2005

719

Dear Sirs:

I represent nurses at Santa Rosa Memorial Hospital, Sonoma County, Calif. Santa Rosa is 6th in the USA for highest percentage people over 85 yrs. Seniors (over 60) are 16.6% of total population here, up to 19.6% by yr. 2020.

We have lost many Drs. in this county because of inadequate medical compensation for more than 10 yrs. now.

This low reimbursement by Medicare has forced 6 out of 10 primary care physicians to quit accepting new medicare patients.

We support a proposal by Medicare to increase the reimbursement rate for Sonoma County by 8%. This brings Sonoma Cty. back in line with current Medicare reimbursement standards.

We beg you to act now! This is becoming a critical issue here affecting our medicare pts. and future outcome of this county's medical care.

Sincerely, Grace Skidmore
for Nurses at Santa Rosa Memorial Hospital

7777 Bodega Avenue
Sebastopol, CA 95472
September 9, 2005

GPCIs, Center for Medicare and Medicaid Services
Department HHS, atten: CM5-1052-P
PO Box 8017
Baltimore, MD 21244-8017

Dear Gentlemen and Gentlewomen,

Please correct Medicare reimbursement rates for Sonoma County NOW. Increase reimbursement rates by 8%, bringing Sonoma County back in line with current Medicare standards.

In Sonoma County, medical costs have risen faster than in other similar counties; further, among cities with a population over 100,000, Santa Rosa is the 6th in the US for the highest percentage of people 85 and older, high consumers of health care services. As of July 2005, 6 out of 10 Sonoma County primary care physicians were NOT accepting new Medicare patients.

As a senior citizen and registered voter, I request that you increase Medicare reimbursement for Sonoma County by the proposed 8%. Thank you.

Sincerely,

Resident, Burbank Heights and Orchards Senior Housing

Constance W. Mahoney
Edward V. Rungger
Andrew Wickland
John A. McNally
Clyde R. Rungger
John R. Rungger
John M. Rungger
Gladys Derry
Stanley L. Lates
Paul H. Rungger
Guerin Rungger
Laura S. Rungger
Patricia S. O'Fallon
John J. Rungger

SEP 28 2005

Rec'd by TFM
SEP 27 2005

721

Gaia HealthCare Systems, LLC

8125 W. Grand Avenue, Suite LL
Denver, Colorado 80123
(303) 932-9629
(303) 972-9077 fax
thompson@gaiasoftware.us

September 26, 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:

Gaia Healthcare Systems, LLC welcomes the opportunity to offer the following comments on the "Proposed Rule: Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006." We have focused our comments on the "End Stage Renal Disease Relations Provisions" of the propose regulation.

"ESRD-Composite Payment Rate Wage Index"

In analyzing the ESRD-Composite Payment Rate Wage Index, it reveals that the proposed plan of action builds in a favorable economic bias for large urban dialysis facilities and correspondingly puts rural dialysis facilities at an economic disadvantage. In addition, it appears this unfavorable bias towards rural dialysis facilities is so severe that it may lead to the demise of the rural dialysis facility in the economic model that is being constructed by CMS.

In surveying the business operating environments for these two-segmented groups it appears that competitive advantages for success are stacked in favor of the urban facilities. CMS's own analysis states that there are large variations between dialysis facilities for the proposed wage index adjustment. These variations are detailed in Table 37 - - Impact of Proposed Changes in Payments to Hospital Based and Independent ESRD Facilities. This table shows that the net effect of change in the wage index for rural facilities is -0.6 whereas the urban change is +0.2. The table also shows that dialysis facilities with less than 5,000 treatments show a -0.5 change in the wage index whereas dialysis facilities with more than 5,000 treatments all report positive changes in the wage index.

It is known that there is a direct correlation associated with lower treatment volumes for rural dialysis facilities and higher treatment volumes for urban dialysis facilities. Accordingly, these volume discrepancies generally referred to as utilization, causes Medicare Cost Report overhead allocations to be lower on a per treatment basis for higher utilization dialysis facilities. This volume discrepancy also causes higher allocations of overhead cost on a per treatment basis for lower utilization dialysis facilities. In addition, lower utilization facilities generally have higher supply cost because they have less purchasing power in the marketplace. This is because they loose out on volume purchasing discounts, etc. Summarized below are the actual cost and profit profiles for these two-segmented groups:

	<u>Urban</u>	<u>Rural</u>
CMS Core Data Elements		
Treatment Volumes	Higher	Lower
Labor Costs Per Employee	Higher	Lower
Medicare Cost Per Treatment ("Tx") Allocations based on Utilization:		
Labor Cost Per Tx	Lower	Higher
Overhead Cost Per Tx	Lower	Higher
Supply Cost Per Tx	Lower	Higher
Overall Profit	Higher	Lower

The flaw in CMS's reasoning, regarding the proposed wage index, is that CMS is "not" looking at the entire dialysis facility patient delivery system taken as a whole. It is like completing successful heart surgery on a patient and letting the patient die in the recovery room from unrelated complications. The true reason rural dialysis facilities are having difficulties surviving in today's economic environment is that they generally have higher per treatment costs for overhead and supply costs. This is again due to lower utilization. Both the overhead and supply cost are macro economic factors outside the control of the individual facility management teams. Simply stated, these two market factors are aspects of the rural dialysis marketplace that are intrinsic in the individual dialysis delivery system and cannot be controlled on a facility-by-facility basis. This means that the only remaining cost profile item that can be controlled by the rural facility management team is their labor workforce.

The proposed CMS changes to the wage index will eliminate this rural facility competitive advantage of labor cost control. The proposed CMS changes to the wage index will also put rural facilities at an extreme disadvantage for servicing Medicare Beneficiaries. It also appears that with the proposed CMS changes to the wage index, CMS may inadvertently be punishing the rural facilities for having lower labor cost.

By lowering rural facilities reimbursement rates for having low overall labor costs it does not negate the fact that rural dialysis center's labor cost are allocated over a smaller number of treatments due to lower utilization. This makes the rural facilities labor cost higher, on a per treatment basis, than their larger urban dialysis facility counterparts. We make this statement based on the fact that when you factor in the discount for the proposed reduction in the composite reimbursement labor rate, proportionally all three rural dialysis facility cost profiles - labor, supplies, and overhead will now be higher on a per treatment basis.

Under the current composite reimbursement rate structure the only hope rural dialysis facilities have to survive in the market place is to control their overall labor cost on a per employee basis at a level low enough to compensate for low utilization, and high costs per treatment for labor, supplies and overhead. In our opinion, proposed CMS changes to the wage index will eliminate the only competitive advantage for rural facilities, robbing them of their primary way to compete and survive.

In further analyzing the direct patient care labor cost issue for dialysis facilities, we observe higher RN to Non-RN staff ratios in rural facilities versus urban facilities. For example, because dialysis centers, at a minimum, schedule two RN's for staffing to cover daily patient treatment activities and emergencies, rural facilities consequently have higher RN to Non-RN staff ratios. This is because a rural dialysis facility may only have four or five direct patient caregivers on staff at any single time whereas urban dialysis facilities may have ten to twelve patient caregivers working. If both facilities staff two RNs for direct patient care, with the rest of the workforce consisting of Non-RN employees, the rural facilities will have a 20% RN to Non-RN staff ratio. The urban dialysis facility will have a 10% RN to Non-RN staff ratio. It should go without saying that a higher RN to Non-RN staff ratio will result in a higher cost per treatment, even when considering the fact that the RN wage rates are lower for rural dialysis facilities. Again, RN staffing ratios are another built in bias that is outside the control of the rural dialysis facility management team.

In addition to having higher RN staff ratios, rural dialysis facilities cannot manage their workforce as efficiently as urban dialysis facilities simply due to the utilization factor. A large urban dialysis facility running three patient shifts six days a week is inherently more efficient than a rural facility running two patient shifts three days a week. Also, the act of staffing efficiently for two patient shifts three days a week is much more difficult than staffing efficiently for three patient shifts six days a week. Using the same example for the number of employees outlined above, if a rural dialysis facility adds one full time equivalent to a direct patient care staff consisting of five employees they will experience

a 20% increase in their workforce. If an urban facility adds one full time equivalent to a direct patient care staff consisting of ten employees they will experience a 10% increase in their workforce. This fact does not mean that rural facility management teams manage less effectively, but it does mean that there are forces outside of their control that affect their ability to manage. Again, these staffing issues are another built in bias that seem to be penalizing the rural dialysis facility operator.

In summary, urban dialysis facilities have higher treatment volumes that result in inherently lower cost per treatment numbers for all three cost categories - labor, supplies and overhead. Now, CMS is proposing to reward urban dialysis facilities, under the proposed wage index adjustment, with a higher composite reimbursement rate for having higher labor costs per employee. This is coupled with the fact that urban dialysis facilities can generate exponentially more profit because of the combined effect of a lower cost per treatment and higher treatment volume, given a 90% Medicare payer mix. As a result of the proposed wage index changes, it appears that all of the premium money is being allocated to the urban facilities. The fact that rural dialysis facilities are subsidizing urban dialysis facilities is a cause for real concern over whether or not rural dialysis facilities will be able to stay in business. The reality is the rural dialysis facilities employ a cheaper workforce, receive a lower reimbursement rate, and manage to serve Medicare Beneficiaries with a higher RN to Non-RN staff ratio. Where is the justice in that?

In the past, rural facilities were able to compensate for their higher overhead and supply cost by employing a cheaper workforce in order to survive. Without receiving compensation for cheaper labor, the future of the rural dialysis facility is in serious question. This may be a key warning sign of the demise of the rural facility.

In all of the news accounts, we have never heard of an urban dialysis facility going out of business. On the contrary, there are numerous accounts of rural dialysis facilities having gone out of business, for the reasons outlined above. Consequently, this scenario causes extreme hardship to Medicare Beneficiaries. Two years ago the dialysis facility community was told by CMS that it does not guaranty Medicare Beneficiaries that a dialysis facility will be located in their local medical community. CMS also said in such a case the Medicare Beneficiary needs to move to receive treatment. If the master plan for CMS is to put so called high cost rural providers out of business, we believe they will succeed, especially if CMS follows through with the proposed wage index adjustments. It is unfortunate that a person born in rural small town America, that works all their life in that small town where they were born and where they paid their fair share of taxes, cannot receive dialysis treatment and die gracefully in their hometown community. In our opinion, the proposed wage index adjustment is inherently unfair and unjust.

Possible Solutions:

We believe CMS should take into consideration the dialysis delivery system as a whole before making reimbursement policy changes. Our first recommendation is to have one composite rate for the entire dialysis delivery system. Urban dialysis facilities will

continue to benefit from higher volume and lower cost per treatment numbers. This should counterbalance higher labor cost. Rural dialysis facilities will continue to benefit from a cheaper labor force, but they will have to deal with higher cost per treatment numbers and lower utilization issues. The advantage of this proposal is Medicare Beneficiaries should be guaranteed access to care for all dialysis treatment modalities in their local medical community.

Alternately, if CMS has no choice but to move forward with the proposed wage index adjustments, CSM could create a second composite rate adjustment factor that deals with the overhead and supply costs to compensate rural dialysis facilities for lower utilization issues. The spirit and intent of the wage index adjustment is to compensate for unfair costs outside the control of the dialysis provider, such as wages. These being the case, why not compensate rural facilities for utilizations issues outside the control of the dialysis provider? By definition, rural facilities inherently have lower utilization.

Along these lines of discussion, CMS compensates pediatric ESRD facilities through reimbursement exception requests that take into consideration the total costs of the facility, also cost finding and apportionment including its allocated costs. These costs include overhead and other direct and indirect costs to the extent that these costs are directly attributable to the additional facility costs. Accordingly, if increased labor, supply, and overhead costs qualify as reasonable and necessary expenses for pediatric programs under exception requests, why don't they qualify for rural facilities? Also, if labor costs, by definition of the wage index, are outside the control of the dialysis

facilities why not compensate rural dialysis facilities for increased supply and overhead costs outside of their control? We realize the isolated exception request was eliminated for rural facilities, but our argument is that CMS is now micro managing components of the composite rate that are creating negative impacts on whole segments of the dialysis industry. This comes at the expense of the Medicare Beneficiary. Our goal is to guaranty the overall health and welfare for every segment in the dialysis provider community.

The question we are asking ourselves is, by following through on the proposed wage index adjustment, is CSM making a value judgment as to which Medicare Beneficiaries should receive care in their local medical community through reimbursement policy? When in reality rural dialysis facilities are the lower cost provides, considering their total cost profile before any wage adjustments?

Conversely, if CMS sees it's way to protecting and reconciling the inherent biases that we believe are built into the differences between rural and urban dialysis facilities reimbursement rates, to the detriment of the rural facilities, we are recommending that CMS reinstate the floor of 90% and the ceiling of 130%. We believe it is unconscionable to let rural dialysis facilities labor reimbursement rates fall below 90% given their inherent challenges to stay in business. Forget the original reason why the floor and ceiling were put into place. It served a valuable "unintended" purpose in that it limits the downside for the labor adjustment for rural facilities to at least give them a shot at counterbalancing the negative effects generated by lower utilization issues on their cost profile. It also stopped the urban facilities from gaining a windfall in excess profit

through the benefits of high utilization. We believe that the floor and ceiling limits can be adjusted up or down once a proper economic analysis and financial modeling techniques have been completed by CMS regarding the issues outlined in our response.

In this regard, Table 25--Proposed ESRD Composite Rate Labor-Related Share shows a facility labor component percent of 49.538%. In our opinion, the labor related share of capital cost of 4.173% is still capital and is reflected on the Medicare Cost Report as capital related costs. We also believe that since a large part of a dialysis facility's capital related costs are associated with dialysis machines and other types of medical equipment manufactured outside the local medical communities, these hidden labor calculations of 4.173% have nothing to do with the local area wage index and should be eliminated from the calculation.

So if the true labor component for dialysis facilities is 49.538% this means that the overhead and supply components total is 50.462%. We also believe that it is this portion 50.462% of the reimbursement methodology in calculating the composite rate that creates the inherent built in biases, which is fundamentally unfair and eventually may cause the rural facilities to become extinct. Accordingly, once this portion of the cost profile is analyzed for the impact of the forces outside the control of the rural dialysis provider the wage index floor and ceiling can be adjusted to reflect appropriate levels for the dialysis delivery system, taken as a whole.

As it stands right now, we believe that the CMS analysis of the dialysis delivery system is incomplete and the resulting effect on the rural dialysis provider is unknown or unknowable, at this point. The one thing we know for sure is that the urban facilities have survived the current wage index adjustment methodology and will continue to stay in business. In fact, probable most, if not all, of the urban dialysis facilities entered the marketplace knowing the “then” current state of affairs of the composite rate structure. Table 28—Proposed ESRD Wage Index for Rural Areas... shows where twenty-nine states have rural communities wage indexes under the 90% proposed floor. Therefore, it is the rural dialysis facilities future that is in question and yet they are the overall lower cost provider group in the entire delivery system.

In conclusion, we have two observations. First, the data in Table 26--Comparison of the Current and Proposed Labor/Non-Labor Portions of the ESRD Base Composite Rate is reformatted and summarized below for discussion purposes:

	Base Composite Rate	Proposed Composite Rate	% Change Increase (Decrease)
Hospital-Based:			
Labor Share	\$ 48.70	\$ 71.12	46%
Non-Labor Share	\$ 83.71	\$ 61.29	(27%)
Total Costs	\$ 132.41	\$ 132.41	
Independent:			
Labor Share	\$ 52.17	\$ 68.94	32%
Non-Labor Share	\$ 76.18	\$ 59.41	(22%)
Total Costs	\$ 128.35	\$ 128.35	

We believe that CMS did a very good job analyzing the labor component of the composite rate listed in Table 26 and has identified the effective increase in out-of-pocket labor cost, over time between the current composite rate and the proposed composite rate, which is a necessary element in delivering a dialysis treatment to Medicare Beneficiaries. We also believe that the proposed labor component more closely reflects today's true cost of labor for well-run dialysis facilities. We are appreciative of the fact that CMS is finally publishing the true labor component but we are now having difficulty reconciling the stated decrease in the percentage of changes in the Non-Labor component of the composite rate.

It appears to us that the implied statement here is that CMS is operating under the assumption that the true cost for the overhead and supply components for the dialysis composite rate have decreased by 27% and 22% respectively over the same time period. Please see Table 26 listed above. We find it difficult to comprehend and reconcile in our mind the fact that the out-of-pocket cost for overhead and supply components have actually decreased, according to the CMS's analysis. Our belief is that the reality is overhead and supply cost most likely have increased in the same proportionate share as the labor component. By not regularly increasing the composite rate to compensate dialysis facilities for increasing costs, CMS's dialysis reimbursement policies are undermining the ability of dialysis facilities to stay in business, invest in capital, and service Medicare Beneficiaries over the long term.

On the other hand, if CMS truly stands by their analysis, we respectfully request CMS to share their data relating to the overhead and supply components of the composite rate. Table 24--ESRD Composite Rate Market Basket Cost Categories... itemizes the cost categories as percentage of the composite rate. It only seems reasonable to use these same categories to document, according to CMS's analysis, which overhead and supply categories have actually decreased over the same period as outline above. The categories for independent dialysis facilities are as follows:

Cost Category	% Cost Composite Rate	% Change
Total	100.00	No Effect
Wages & Salaries	38.808	+ 32.0
Employee Benefits	8.580	+ 32.0
Professional Fees	0.903	+ 32.0
Electricity	0.818	- (?)
Natural Gas	0.113	- (?)
Water & Sewerage	0.593	- (?)
Pharmaceuticals	0.967	- (?)
Supplies	17.748	- (?)
Labs	0.433	- (?)
Telephone	0.875	- (?)
Housekeeping & Operations	1.247	- (?)
Administrative & Other Costs	14.886	- (?)
Capital Related-Building & Equip	9.071	- (?)
Capital Related-Machinery	4.957	- (?)

Again, it is our contention that the dialysis delivery system must be analyzed in its entirety or we may be simply just move money from one bucket to another to serve specific needs, at any given time. In this case, it appears that CMS is attempting to correct system issues relating to the labor component by discounting real costs associated with the overhead and supply components. Accordingly, our hypothesis is that under the current composite rate structure all three cost categories, labor, supplies and overhead are materially understated and the dialysis composite rate needs to be increased to account for these understatements. Alternately, if CMS can only fix one side of the formula then we should be have full disclosure about the material misstatement of the data on the other side of the equation.

Our second observation is one of CMS's stated goals to identify ways to provide better support for utilization decisions that clearly increase the quality of care while avoiding unnecessary costs for beneficiaries and the Medicare program. Accordingly, another one of our hypothesis is that it would be better to implement the floor and ceiling on the wage index labor component so rural facilities can stay in business. CMS could then encourage all of the urban Medicare Beneficiaries to move to the country so the Medicare program can potential save up to 40% (130% ceiling less the 90% floor) on the labor reimbursement component for dialysis treatments while providing a higher RN patient care ratio.

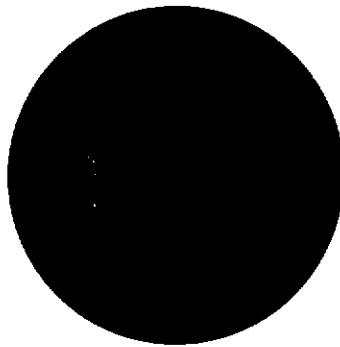
We greatly appreciate this opportunity to comment on the proposed Rule and your review of our concerns. We would be pleased to respond to any questions you may have and look forward to continuing to work with CMS on this matter.

Sincerely,



Bruce J. Thompson, CPA CMA
LLC Manager

COUNTY OF SONOMA
OFFICE OF THE COUNTY ADMINISTRATOR
575 ADMINISTRATION DRIVE – ROOM 104A
SANTA ROSA, CALIFORNIA 95403-2888
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722
BOB DEIS
COUNTY ADMINISTRATOR
JIM ANDERSEN
ASSISTANT COUNTY ADMINISTRATOR
JENNIFER M. MURRAY
DEPUTY COUNTY ADMINISTRATOR
CHRIS THOMAS
DEPUTY COUNTY ADMINISTRATOR

September 20, 2005

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

RE: GPCIs

Dear Mr. Smith:

Sonoma County strongly supports your proposal to create a new Medicare payment locality for Sonoma County, which is currently included in the "Rest of California" payment Locality 99. This has negatively impacted our local health care delivery system and access to care for Medicare patients.

Since the payment localities were created in 1997, medical costs in Sonoma County have risen much faster than in other counties in Locality 99 and are 8% higher than the Locality 99 average, yet providers in Sonoma County are reimbursed at the same low rate as the "Rest of California" Locality. Consequently, many Sonoma County physicians lose money every time they see Medicare patients. The rate has also affected non-Medicare patients whose insurers link their reimbursement rate to Medicare. Several medical groups have gone bankrupt. Many physicians have stopped taking Medicare patients, while others, specifically specialty providers, have left the County to practice elsewhere. Meanwhile, local medical groups are having trouble attracting new physicians to Sonoma County because of the reimbursement rate.

In the proposed new Medicare payment locality, the Medicare reimbursement rate will more closely match expenses of Sonoma County physicians. Creating a new payment locality for Sonoma County will have a minimal effect on other counties in the "Rest of California" locality. Sonoma County's rates will increase by 8%, while rates in the "Rest of California" will stay at the 2005 payment levels – they will not receive the 0.4% increase originally planned for 2006. The proposed new Medicare payment locality for Sonoma County will improve access to care for local Medicare beneficiaries by correcting existing payment inequities and ensuring the viability of physician practices in the County.

September 20, 2005

Sonoma County Board of Supervisors fully supports your proposal to change Sonoma County's payment locality, and appreciates the opportunity to comment on this important issue.

Sincerely,

A handwritten signature in black ink, appearing to read 'Bob Deis', with a long horizontal flourish extending to the right.

Bob Deis
County Administrator

c: Cynthia Melody, Executive Director, Sonoma County Medical Association
Rita Scardaci, Director, Sonoma County Department of Health Services
Mary Maddux-Gonzales, M.D., Sonoma County Public Health Officer

From the Desk of

SEP 28 2015

723

Please pass this proposal
that will bring Sonoma Co.
back in line with current
Medicare reimbursement.

We want our doctor
to stay in Sonoma Co.
Thank you,

Suzanne Leonard

Suzanne Leonard

724

September 26, 2005

Re: GPCIs

Frank Tansey



COUNCIL ON AGING
SERVICES FOR SENIORS

September 22, 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

I understand that Medicare is proposing to create a new payment locality for Sonoma County, California. I would like to address some specific concerns from the perspective of a **Senior Advocate and CEO of the Council on Aging serving this county:**

- Santa Rosa now ranks with retirement destinations such as Clearwater, Florida, St. Petersburg and Miami.
- Among cities with a population of 100,000 or more, Santa Rosa is sixth in the United States for the highest percentage of people 85 and older.
- According to State of California Department of Finance, July 2000 - seniors (60 and older) represent 16.6% of total population in Sonoma County (76259/459258) with a projected rate of change of 196% from the year 2000 to 2020.
- Many of the 1,400 clients we serve daily here at the **Council on Aging** have difficulty seeing a physician in a timely manner as they are on Medicare only with no private insurance. This puts them severely at risk.

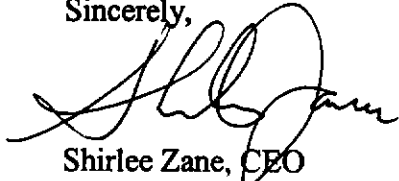
And, amid that astounding growth in elder population, our county is facing strains on the healthcare delivery network that are unacceptable to our Medicare population:

- The number of practicing physicians in Sonoma County has not kept pace with local population growth—over a seven-year period (1995-2002) the population increased 13 percent and the number of physicians practicing increased by only 4 percent.
- In July 2005, 60 percent of Sonoma County primary care physicians were NOT accepting new Medicare patients.
- Many physicians are leaving our county to practice where reimbursement is more favorable resulting in many specialties being under-supplied including: surgery, endocrinology, gastroenterology, hematology, neurology, rheumatology, dermatology and orthopedic surgery. In fact, we have only 2 gerontologists in the County serving more the 76,000 seniors.

It is my understanding that the new locality would increase the Medicare reimbursement rate to more closely match actual practice expenses, helping Sonoma County physicians improve the quantity and quality of care they deliver to Medicare beneficiaries and other patients. The locality change would also aid efforts to recruit and retain physicians in the county, which has a large Medicare population.

I fully support your proposal to change Sonoma County's payment locality, and I appreciate the opportunity to comment on this important issue.

Sincerely,

A handwritten signature in black ink, appearing to read 'Shirlee Zane', written over the printed name.

Shirlee Zane, CEO
Council on Aging of Sonoma County
730 Bennett Valley Road
Santa Rosa, CA 95404
(707) 525-0143

cc: Two copies attached

726

Mark McClellan, MD, PhD
Administrator, Centers for
Medicare and Medicaid Services
Attn: CMS-1502-P/TEACHING ANESTHESIOLOGISTS
P.O. Box 8017
Baltimore, MD 21244-8017

826 NW 165th Place
Shoreline, WA 98177
September 25, 2005

Dear Dr. McClellan,

Academic anesthesiology programs are in trouble, and the CMS policies are partly at fault. The current policy of decreased reimbursement when anesthesiology faculty member supervises more than one resident at a time results in a situation where the department loses money on every case that involves a Medicare patient. Yes, that is correct, the department loses money. The amount received from Medicare when a faculty member supervises two residents is less than what the department has to pay the faculty member based on that faculty member's salary. The pay disparity between private practice anesthesiologists and academic anesthesiologists is already high with the former making 50%-100% more than those in academic departments. In consequence, it is difficult for academic departments to hire and retain good faculty. In my 20 years in academics, I have seen many of my colleagues leave for private practice, in large part or entirely because of the pay differential. Sure, academics may be a calling, but academic anesthesiologists have families, too, and it is hard to deny the appeal of higher pay.

The current CMS policies are particularly disturbing when CMS provides surgeons full payment for concurrent supervision of residents. Certainly faculty presence at all critical events is an important patient safeguard. But this requirement is being accomplished by academic programs now. Not providing full reimbursement for concurrent (resident) supervision for anesthesia care is not equitable.

In short, I support the American Society of Anesthesiology's proposal that would eliminate the disparity in reimbursement policies.

Sincerely,



G. Alec Rooke, MD, PhD

September 25, 2005

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

We are commenting on proposed changes in the 2006 Physician Fee Schedule, specifically related to CPT codes 34101, 34111, 37204, 37205, 37607, 75710, 75827, 75894, 75898, 75960, 75962, 75978, 75827.

Item 1

The proposed 2006 Physician Fee Schedule has removed payment for the following codes in the non-facility setting:

34101	Embolectomy or thrombectomy, with or without catheter; axillary, brachial, innominate, subclavian artery, by arm incision
34111	Embolectomy or thrombectomy, with or without catheter; radial or ulnar artery, by arm incision
37607	Ligation or banding of angioaccess arteriovenous fistula
37204	Transcatheter occlusion or embolization (eg, for tumor destruction, to achieve hemostasis, to occlude a vascular malformation), percutaneous, any method, non-central nervous system, non-head or neck
75894	Transcatheter therapy, embolization, any method, radiological supervision and interpretation.
37205	Transcatheter placement of an intravascular stent(s), (except coronary, carotid, and vertebral vessel), percutaneous; initial vessel
75960	Transcatheter introduction of intravascular stent(s), (except coronary, carotid, and vertebral vessel), percutaneous and/or open, radiological supervision and interpretation, each vessel
75898	Angiography through existing catheter for follow-up study for transcatheter therapy, embolization or infusion

All of these codes have been available for use in the non-facility setting in the past. They have been shown to be effective and safe in the free standing facility. They have been routinely used by Interventional Nephrologists.

If these changes take effect, it will materially interfere with medical care offered by Interventional Nephrologists, most of whom operate in free-standing facilities. It will result in a degradation of the quality of medical care and interfere with the patient's right to choose their medical care provider. Additionally, it will increase the cost of vital

medical services to CMS by requiring fragmentation of bundled procedures, duplication of services and a shift from an out-patient environment to the hospital.

Codes 34101 and 34111 are codes for procedures that are used to treat complications of other vascular access procedures, namely thrombectomy. The major complication of a percutaneous thrombectomy is the migration of an embolus to the feeding artery. When this occurs it blocks blood flow to the hand and to the digits. If not treated in a timely manner, it can have disastrous results. Fortunately, the complication is rare and fortunately, it can be treated in a timely manner resulting in a complete resolution. However, if the code is no longer included, there will be a tendency to delay treatment and refer to the hospital. This will result in increased risk to the patient, prolongation of the accompanying discomfort, duplication of services and a significant increase in cost. In these instances, instead of the patient being returned to the dialysis clinic for their regular dialysis, they will be sitting at the hospital in pain for several hours without dialysis waiting for a treatment at an alternative site.

Codes 37607, 37204, 75894, and 75898 all relate to the treatment of fistula failures by Interventional Nephrologists. The nephrology community and especially those involved with dialysis access intervention have seen the need for increasing the number of functioning fistulas in our dialysis patient community and have made a real commitment to this effort. A significant number of fistulas that are created have early or primary function. This means that they never develop adequately for use. It has been shown through a number of publications that a very large percentage of these failed fistulas can be salvaged. This effort is critical to the development of a fistula based strategy in the US. Interventional Nephrologists have and continue to take the lead in this effort. Since most work in free standing facilities, removing these codes will material affect this effort. Unfortunately, it is at times not obvious until the case is underway that such a procedure will be required. This means that if they are necessary for the success of the case, the procedure will be only partially done. The patient will then be referred to the hospital for a duplication of services and added expense, inconvenience and discomfort with no added benefit as it relates to success or safety.

Codes 37205 and 75898 are codes that relate to a procedure used to treat a complication. The major complication seen with venous angioplasty is rupture of the vein. Fortunately, this is not a common occurrence and fortunately, in the vast majority of cases it is a minor complication requiring no change in medical management. However; occasionally, this complication requires the placement of a stent. This can be easily done at the time and doing so saves a vascular access that would otherwise be lost. If it is not done at the time, a situation which deleting this code would create, then it very likely can not be accomplished. In this instance the patient would lose their access, require a dialysis catheter with all of its complications, be referred to the hospital and require the placement of a new access.

Item 2

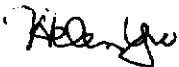
Additionally, the proposed 2006 Physician Fee Schedule has reduced the RVRBS unit value for the following codes in the non-facility setting:

75710 Angiography, extremity, unilateral, radiological supervision and interpretation
75827 Venography, caval, superior, with serialography, radiological supervision and interpretation
75962 Transluminal balloon angioplasty, peripheral artery, radiological supervision and interpretation
75978 Transluminal balloon angioplasty, venous (eg, subclavian stenosis), radiological supervision and interpretation

These are codes that are very commonly used by Interventional Nephrologists. Since most of these practitioners operate in the free standing, non-facility setting, they must support the facilities operation without the benefit of facility charges. This is accomplished through the use of the fees generated by these radiological supervision and interpretation codes. Since the cost of these facilities is continuing to rise, cutting the payment for these commonly used codes will jeopardize their economic viability. Simply stated, they will be required to close. This will result in a degradation of the quality of medical care and interfere with the patient's right to choose their medical care provider. Additionally, it will increase the cost of vital medical services to CMS by requiring a shift from an out-patient environment to the hospital for the patients currently being served and will slow the migration of patients currently locked into a hospital based environment to the out patient setting.

We do not feel that these changes are in the best interest of the patients that we serve.

Sincerely,



Helen Yu, RN
Hemodialysis Nurse
12208 Summer Sky Path
Clarksville, MD 21029

9-19-05

Centers for Medicare & Medicaid Services 728
Dept. of Health and Human Services
Att: CMS-1052-P
P.O. Box 8017
Baltimore, MD 21244-8017

Re: CPEIS

To Whom It may concern:

I am a Senior Citizen relying on Medicare to help pay the medical expenses encountered now that I am in "The Golden Years", which necessary and more frequent trips to my physicians office.

Santa Rosa and other towns in Sonoma County have increased populations of citizens, many of whom commute to work to provide their families with funds to pay ever-increasing mortgage payments and rents, many are patients on Medicare.

Sonoma County is no longer a population of farmers struggling to make ends meet, and still pay for medical care when needed.

Medicare's proposal to create a new payment locality for Sonoma County is long overdue. Our physicians are top quality. Our

physicians hospitals have outstanding specialists who perform surgeries in Sonoma County so we don't have to travel to San Francisco to receive treatment. We need to retain these healers.

The cost of living keeps escalating. Please increase the Medicare reimbursement matched to actual practice expenses so our doctors will be able to live and work in our community, and new physicians will move to our area to treat the increase in population, many of whom are Medicare patients.

Sincerely,

Carol Stratton

911 Boyd St

Santa Rosa, CA 95407

729
SEP 28 2005

September 21, 2005

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

To Whom It May Concern:

I have worked in a medical office for 25 years and seen the patients who are on Medicare and Medicaid being dropped from the practices because of the low reimbursement... It is not the choice of the providers, but the practicality of trying to run a medical office with not enough reimbursement to provide the care needed...

Some of these patients have been in the practice for years and the providers will continue caring for them even though they are losing money and drowning in trying to keep the practice solvent.

We have stopped taking any new Medicare or Medicaid patients because of the lack of adequate reimbursement. We feel badly, but are trying to stay afloat. We are unable to recruit new physicians because the cost of housing and the low reimbursement does not make living here feasible...

We need to bring Sonoma County's Medicare reimbursement rate in line with current Medicare reimbursement standards and help stabilize our medical community.

Sincerely,



Yvonne Martin

730

SEP 28 2005

MARVIN PEDERSON
ATTORNEY AT LAW
815 FIFTH STREET, SUITE 200
SANTA ROSA, CALIFORNIA 95404
(707) 544-9444
FAX (707) 544-5829

September 22, 2005

Administrator Mark McClellan
Center for MediCare and Medicaid
U.S. Department of Health and Human Services
P.O. Box 8017
Baltimore, MD 21244-8017

RE: *CMS Proposed Revision Sonoma County California – Support*

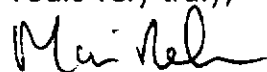
Dear Administrator McClellan

I am a long time resident of Sonoma County California and have practiced law here for 25 years. In my practice I have contact with physicians who I consult for advice. A few physicians have been my clients. I am aware of a few doctors who have left Sonoma County because they simply could not afford to make a living here. I understand that you are considering raising the physician payment rate for Sonoma County and Santa Cruz County and I would emphatically urge you to do this. There are some physicians in Sonoma County who are critical to our health care network. One example is a hand surgeon who gets all of Sonoma County's referrals because he is simply such an excellent specialist in his field. Getting him lined up for a deposition in one case was very difficult for my opposing counsel, and we did it on an evening. If someone like him were to leave Sonoma County, it would compromise the health care of every citizen in our community who suffered a hand injury.

Rents and the cost of medical equipment, staffing, continuing education, and insurance are brutal for local doctors. I know the cost of my overhead is high, but it is dwarfed by what a physician must pay. They should not be required to serve as a charity for our growing elderly population. They must be properly compensated for the life-saving services they provide.

Thank you very much for your consideration and I sincerely hope that you do everything in your power to increase the physician MediCare payment for the doctors in my county.

Yours very truly,



MARVIN PEDERSON

MP/lc

It is extremely important to me -
a senior living on a fixed income -
that Medicare increases the rate
for reimbursement in Sonoma City
in order to strike our medical
community and provide fair and
equal reimbursements for Sonoma
County's senior population.

Thank you for your positive response
to this issue by providing a new
rule for this community.

Joan Talbot

September 20, 2005

732

CPCIS

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

Attention: CMS-1502-P

P.O. Box 8017

Baltimore, MD. 21244-8017

To Whom it may concern:

It has come to my attention that a new rule has been under consideration to increase reimbursement paid by medicare to doctors in Sonoma County (CA) by 8%.

My husband and I, both seniors, look with dismay at the small amount doctors are paid by medicare to cover their services. We think Medicare needs to pay more.

We have lost doctors from this area because they were unable to pay their bills under this system. New doctors are not being attracted here for this reason - low reimbursement.

The majority of physicians will not accept new patients who are covered by medicare. This is a very dangerous situation. Our county has many seniors and more are moving here all the time.

It seems unfair that other areas in California receive more adequate Medicare reimbursement for the physicians.

Our primary care physician is now in his seventies. When he retires, if this situation of inadequate reimbursement is not rectified, I don't know who will be willing to take us as patients.

I encourage you to enact this new rule regarding 8% more reimbursement to Sonoma County's doctors.

Thank you for your consideration.

Arlene Jones

SEP 28 2005

733

ALLAN F. NELSON
3550 Wine Creek Road
Healdsburg, CA 95448-9149

(707) 433-5324 (phone)
(707) 433-6817 (fax)

September 21, 2005

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

Gentlemen:

We are very fortunate here in Sonoma County, California, to have a dedicated team of highly trained doctors backed by outstanding technology at our hospitals and diagnostic centers.

The reimbursement factor from Medicare is an injustice. Quality care is here NOW. Your reimbursement, now 8% less than adjoining counties to the south of us, affects all citizens. Doctors have left the area, retired early, doctor groups have declared bankruptcies. Our population is increasing at a very high rate with seniors accounting for 16% of our population.

Help us stabilize medical care in Sonoma County. Please bring Sonoma County in line with neighboring counties with an 8% increased Medicare reimbursement.

Sincerely,



Claudia Nelson



Human Services Department
County of Sonoma



SONOMA COUNTY AREA AGENCY ON AGING

2250 Northpoint Parkway
Santa Rosa, CA 95402

Dianne M. Edwards
Department Director

Robin Schaefer
AAA Director

September 23, 2005

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

Subject: Medicare Reimbursement Rate

We, the Advisory Council to the Sonoma County Area Agency, strongly support the proposal to create a new payment locality for Sonoma County and increasing the Medicare reimbursement rate for Sonoma County.

Our agency was established in 1980 by the California Department of Aging under the auspices of the Older Americans Act. Our mission is to provide leadership, services, and advocacy to promote the dignity, independence, and quality of life for seniors and adults with disabilities.

The cost of living in Sonoma County is very high—more akin to the San Francisco Bay Area than a small, rural county. The existing rate of reimbursement is insufficient given the cost of providing medical care in Sonoma County.

One of our Advisory Council members, who works in the health care profession, personally knows five physicians who recently left their medical practices due to the low Medicare reimbursement rate.

Additionally, the expected increase in the senior population ("boomer babies") within the next few years has been well publicized, and Sonoma County will be above the state average regarding the percentage of persons 60 and older. Changing Sonoma County's payment locality would provide a more appropriate reimbursement rate.

Sincerely,

Bob Marshall, Chairperson
Advisory Council
Sonoma County Area Agency on Aging

BM:jad

cc: Representative Mike Thompson
Representative Lynn Woolsey



Baystate Medical Center

A Member of Baystate Health System



Baystate Medical Center/
Tufts University School of Medicine

Department of Anesthesiology

Springfield, MA 01199

Tel: (413) 794-3520

Fax: (413) 794-5349

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Chief, Acute Pain Service

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Chief, Post Anesthesia Care Unit (PACU)

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Chief, Shriners Hospital,
Department of Anesthesia

Henry Godek, M.D.
Chief, Franklin Medical Center,
Department of Anesthesia

Peter Kaskel, M.D.
Chief, Mary Lane Hospital,
Department of Anesthesia

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Vijay Gandevis, M.D.
Section Chief, Remote Site Anesthesia

Wagdy Zakhary, M.D.
Section Chief, Orthopedic Anesthesia

Tanya 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 anesthesiology 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,

Jordan Blinder, M.D.
Department of Anesthesiology
Baystate Medical Center
Assistant Professor of Anesthesiology
Tufts University School of Medicine

SEP 18

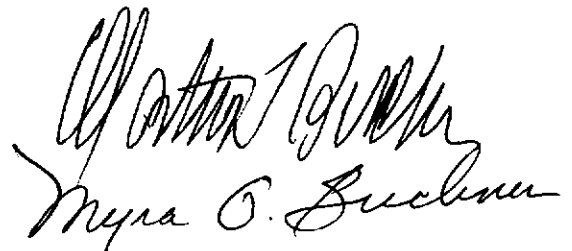
735

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.



**MYRA O. BUCHNER
MARTIN S. BUCHNER
776 PINE CREST AVE.
SEBASTOPOL, CA 95472**



University of Pittsburgh Physicians
Department of Anesthesiology

SEP 29 2005

September 27, 2005

Kaufmann Medical Building
Suite 910
3471 Fifth Avenue
Pittsburgh, PA 15213
412-692-4500
Fax: 412-692-4515

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

Rita M. Patel, MD
Associate Professor
Vice Chair for Education

Dear Dr. McClellan:

Re: CMS-1502-P - TEACHING ANESTHESIOLOGISTS

Charles D. Boucek, MD
Associate Professor
Director
Grand Rounds

I am writing as a practicing anesthesiologist, the Residency Program Director in Anesthesiology, and Assistant Dean for Graduate Medical Education at the University of Pittsburgh, to urge the Centers for Medicare and Medicaid Services (CMS) to change the Medicare anesthesiology teaching payment policy.

Terry L. Edwards, MD
Assistant Professor
Chair
REC Evaluation and Competence
Committee

It is unclear to me what the rationale is for Medicare's discriminatory payment arrangement, which applies only to anesthesiology teaching programs. 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. Any anesthesiologist following the American Society of Anesthesiology and the American Medical Association's professional/ethical guidelines/codes is ALWAYS present for critical or key portions of the procedure. In order to provide excellent patient care and teach, the presence of the attending teaching anesthesiologist generally extends beyond that requirement. The penalty for overlapping cases is a 50% reduction in medicare reimbursement for each. WHY? There is no logic to this; the penalty is unfair and unreasonable.

Theresa A. Gelzlnis, MD
Assistant Professor
Co-Chair
REC Curriculum Committee

Michael P. Mangione, MD
Associate Professor
Director
Medical Student Programs

In the University of Pittsburgh anesthesiology residency program, our residents/fellows work under the supervision of our teaching faculty. The faculty are personally involved and dedicated to excellent patient care and teaching our next generation of anesthesiologists. We urge CMS to apply teaching payment rules consistently across medical specialties and assure that anesthesiology teaching is reimbursed on par with other teaching physicians.

David G. Metro, MD
Assistant Professor
Associate Program Director

Ryan C. Romeo, MD
Assistant Professor
Director
Clinical Procedures Course

Please end the anesthesiology teaching payment penalty. Support our academic anesthesiology programs. They are teaching those who will take care of you when you most need it.

Erin A. Sullivan, MD
Associate Professor
Chair
REC Curriculum Committee

Helen R. Westman, MD
Associate Professor
Director
Educational Program Development

Sincerely,

Rita M. Patel MD

Rita M. Patel, MD

Peter M. Winter, MD
Professor and Chairman Emeritus
Director
Faculty Development

cc: Carol Rose, MD
Ronald Szabat, JD, LLM



738
SEP 29 2005

MOHAMMAD H. CHAUDHRY, M.D.

CARDIOVASCULAR MEDICINE

September 27, 2005

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

Re: CMS-1502-P

Dear Sir/Madam:

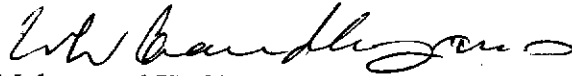
Please accept the following comments on the above referenced rule. Specifically, I wish to express my concern and disappointment with the proposed reduction of the conversion factor and practice expense for Thoracic Electrical Bioimpedance (CPT 93801). Under this proposal, it will be challenging, if not impossible, to continue to offer the same level of service as we do today.

As I understand it, the practice expense component of the reimbursement is based on the costs of staff time, equipment and disposables. A decrease in practice expense, therefore, implies that these costs have somehow decreased compared to prior levels. That is not the case. In December 2003, the cost of equipment was listed at \$22,790 resulting in a PE value of 1.14. In 2004, the equipment cost was left at \$22,790 although the cost had increased to an average of \$34,211. Moreover, the practice expense was reduced from 1.14 to 1.02. In 2005, Addendum D for practice expense equipment was increased to \$28,265 and again PE value was reduced – this time to 0.98. In addition, it is undeniable that staffing costs have increased since 2003, as have the cost of the disposable sensors used for each TEB procedure. On top of the decrease in PE, the reduction in the conversion factor will result in an additional fall in reimbursement that is unfair and inappropriate.

I strongly urge you to reconsider the reduction of the conversion factor and the impact it would have on all services currently provided to your beneficiaries. In addition, I ask that you increase the PE value for TEB to the 2003 level of 1.14.

My Medicare patients deserve access to the same technological advances and innovations as my non-Medicare patients.

Sincerely,

A handwritten signature in black ink, appearing to read 'Mohammad H. Chaudhry', with a stylized flourish at the end.

Mohammad H. Chaudhry, M.D.

Enclosure: Original letter
2 copies original letter

 American College of
Emergency Physicians®

Rec'd 9/28/05
L.A.W. 739

SEP 29 2005

September 23, 2005

Attention: CMS-1502-P

Washington, D.C. Office

2121 K Street, N.W.
Suite 325
Washington, D.C. 20037

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

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

Dear Dr. McClellan:

On behalf of the American College of Emergency Physicians (ACEP), I am pleased to submit comments on the proposed rule: "Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006," published in the Federal Register on August 8, 2005. ACEP is a national medical specialty society with more than 23,000 members, dedicated to improving the quality of emergency care through continuing education, research, and public education. We appreciate the opportunity to provide the Centers for Medicare & Medicaid Services (CMS) with our comments on fee schedule payment policy and its effects on the practice of emergency medicine.

The 4.3 percent cut in the physician fee schedule for 2006, along with additional cuts over the next five years, comes on the heels of updates that were significantly less than medical inflation costs. The cut will negatively affect emergency physicians disproportionately. While physicians in other types of practice can limit their financial losses in ways much more subtle than dropping out of the Medicare program, emergency physicians will continue to see everyone who comes to the emergency department, regardless of payment.

Emergency physicians provide care 24 hours per day, 7 days a week to an ever-growing population demanding their services. Emergency departments provided 114 million visits in 2003, according to the CDC's latest survey data, representing an increase of 26 percent in the past 10 years. Over 18 million visits represented Medicare patients and half of those visits were classified emergent or urgent. As payment for Medicare beneficiary visits decreases, the number of uninsured (45.8 million according to the Census Bureau) and the underinsured (Medicaid and some private plans) who seek care in the ED continues to grow.

In the wake of Hurricane Katrina, emergency physicians and other health care practitioners all over the South have struggled valiantly to respond to the unprecedented surge in patients from ravaged areas along the Gulf Coast. The price tag for all this additional uncompensated care will be staggering, and the cost to emergency physicians must be recognized as a legitimate component of practice expenses.

SGR

The Sustainable Growth Rate (SGR) formula is itself truly unsustainable. This fact has now been expressed repeatedly by MedPAC, the majority of Congress, and even the CMS Administrator in the Press Release accompanying this draft rule. ACEP, along with the

entire house of medicine, has consistently urged CMS to remove drugs from the SGR pool retroactive to 1996. Another year has passed, and the Agency continues to "explore its authority" to make this change. This "paralysis by analysis," rather than use of clear administrative authority will greatly affect the ability of Congress, particularly through such proposals as H.R. 3617, to rescind the SGR in favor of the same type of market basket indices used by CMS for all the other Medicare health providers.

In addition, ACEP continues to question whether CMS has under-estimated the costs of new benefits and we urge you to provide more detail on actual costs of benefits, whether legislated or through national coverage decisions, as claims data become available. We urge you to reevaluate costs of such benefits as the "Welcome to Medicare" physical added by the MMA 2003. These physicals may be straightforward for some beneficiaries, but may uncover a need for more extensive testing/screening in others. The physicals will undoubtedly uncover chronic conditions in some proportion of elderly patients, and the need for ongoing treatment of these conditions will drive up volume of physician services, which, in turn will make it even more likely that the target will be exceeded.

Additionally, early users of electronic health records enhanced with decision support tools have reported prompts for performance of additional diagnostic tests/screenings, which could offset CMS' initial forecasts that EHRs will save billions of dollars. Again, we urge you to work with physician groups to develop methodologies to more accurately forecast costs of new coverage benefits along with new technologies to diagnose and treat newly covered benefits, as well as costs in implementing EHRs.

Practice Expenses

After years of supporting and justifying the "top-down" methodology for setting practice expense relative values, CMS is now embracing the "bottom-up" approach for determining the practice expense RVUs associated with the direct costs of clinical labor, supplies and equipment. We have carefully reviewed the description of the new PE RVU methodology in the proposed rule. We do not believe sufficient details have been provided for us to make meaningful comments. It would have been helpful if the proposed rule had provided service-specific examples of how PE RVUs would be calculated using the current and the proposed methodologies.

In addition, ACEP is very concerned that those specialty societies that submitted their own survey data are winners under the revised methodology, which appears to be a troubling path to "the rich get richer" as those who can afford extensive studies will be rewarded. At some point in time, CMS must make arrangements to update practice expenses costs across all specialties in an equitable manner, using a similar approach to the AMA's discontinued Socioeconomic Monitoring Survey. 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 that the increases observed in supplemental practice expense data "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."

We urge a delay in the implementation of the proposed PE/HR figures until such time as a multi-specialty practice expense survey can be conducted. This survey would need to be revised to explicitly address the question of uncompensated care. We acknowledge that such a survey could be expensive and suggest that CMS consider applying some of the funds that will not be used to extend the oncology demonstration to this purpose.

In previous comments, ACEP has commented extensively about the inadequacy of the rates in the practice expense portion of the fee schedule in recognizing the increasing amounts of uncompensated care provided by emergency physicians. However, unlike hospitals, physicians cannot offset losses with Medicare funding for bad debt claims or disproportionate share payments. Emergency physicians are mandated by federal law to provide care to all comers. This requirement, along with the increase in the number of uninsured has resulted in more uncompensated care and ED closures. The current reduction in the update factor and the proposed changes in the practice expense methodology further reduce resources to emergency medicine. Therefore, ACEP urges CMS to delay the implementation of the proposed PE/HR figures until a uniform practice expense survey across all specialties that explicitly addresses uncompensated care can be conducted. This survey should be completed as soon as possible so that fair and equitable practice expense RVUs can be implemented.

Telehealth: Modification of the Definition of an Interactive Telecommunications System for Purposes of Furnishing a Telehealth Service

ACEP appreciates CMS' concern with the clinical adequacy of one-way video (two way audio) for patient evaluation. In considering the request described in the NPRM submitted by The Medical College of Georgia (MCG), the question is whether the benefit of getting timely and appropriate treatment to a stroke patient in a rural hospital emergency department merits a limited modification in the current definition of interactive telecommunications system for purposes of furnishing a telehealth consultation. In this circumstance, we urge you to support the MCG's request for a modification and continue to allow billing of one-way video under limited, fact-based circumstances.

As noted in the draft, the MCG uses an interactive audio and one-way, real-time video telecommunications system, over an internet-based protocol, to furnish consultations for acute ischemic stroke patients. The physician at the distant site (typically a neurologist) can see the patient; however, the patient and physician (or practitioner) in the emergency room who is with the patient cannot see the neurologist. Under this model, the neurologist at the distant site examines the stroke patient in real-time video and reviews CT scans and other critical laboratory data to assess the stroke patient's suitability for tissue-type plasminogen activator (tPA) treatment. As the use of tPA treatment is restricted to 3 hours after onset of stroke, rapid evaluation by a neurologist for stroke patients located in outlying rural hospitals is crucial. MCG believes that the use of an interactive two-way video system does not provide added benefit to the consulting neurologist, would be unnecessarily cumbersome, but the use of one-way video currently cannot be billed as a telehealth consultation.

Mark B. McClellan
September 23, 2005
4

ACEP appreciates the opportunity to offer these comments and looks forward to continuing to work cooperatively with CMS in order to address these important issues. Please do not hesitate to contact Barbara Marone, ACEP's Federal Affairs Director at (202) 728-0610 ext. 3017 if you have any questions about our comments and recommendations.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Robert E. S.", written in a cursive style.

Robert E. S

September 26, 2005

Lana Price
Attention: CMS-1502-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Dear Lana Price:

My name is Sean Schloss. I am a hemodialysis patient at Davita Port Charlotte, Florida. I am sending to you this letter to appeal to Medicare about payment rates to dialysis providers.

It is very vital to my life and to other dialysis patients' lives that no further reduction of payments to the dialysis provider is made. Without a steady increase in the payment rates, the dialysis patients can look forward to reduced quality of care at dialysis facilities, as well as reduced access to care. Dialysis providers will not be able to hire and train highly qualified candidates. Also, the reduction in payment rates may lead to the closing of dialysis facilities.

I have been a dialysis patient for over 15 years. The dialysis facilities I have had the good fortune to participate in, have been excellent facilities. I would like to see them continue their excellence and continue to improve and be able to obtain and maintain exceptional caregivers, salaries for staff, equipment, supplies, and new technologies.

Once again, I ask you to please review your policy/rules on reimbursement to dialysis facilities and take into consideration the "human side" of this issue.

Thank you for your considerations and your attention to our concerns.

Respectfully,

Sean A. Schloss.

(Ms) Sean A. Schloss
23281 Nancy Avenue
Port Charlotte, Florida 33952



SEP 29 2005

741

Excel Diagnostic Imaging Clinics
September 19, 2005

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

Re: Comments of August 8, 2005 Proposed Rule - CMS - 1502-P

Gentlemen and/or Ladies

Excel Diagnostic, Ltd. ("Excel") would like to take this opportunity to comment on the proposed Centers for Medicare & Medicaid Services' ("CMS") rule in the August 8, 2005 Federal Register, 70 Fed. Reg. 45764. Excel is a Texas limited partnership that operates an independent diagnostic testing facility in Houston, Texas. As Excel provides a full range of nuclear medical procedures, we are greatly concerned regarding the proposed rule and its direct negative effect on our operations.

NUCLEAR MEDICINE SERVICES

We strongly oppose the inclusion of both diagnostic and therapeutic nuclear medicine in the definition of designated health services ("DHS") under section 1861(s)(4) of the Social Security Act, commonly referred to as the "Stark" provisions, and raise the following points in support of our opposition.

1. CMS has previously determined that nuclear medicine services are *not* DHS.

The January 4, 2001 final regulations clearly and permanently established the principle that nuclear medicine services are not DHS. The language is clear and precise, "radiology . . . does not include nuclear medicine procedures." 42 C.F.R. 411.351. The preamble confirms this determination wherein it states, "[w]e are excluding nuclear medicine, since those services are not commonly considered to be radiology." Note that the language of the January 2001 regulation did not merely fail to include nuclear medicine in its listing of radiology services, but specifically excluded it.

The January 2001 regulation fairly interprets the law, and the language of that law has not changed; nor has the regulation been held by any court not to be a fair interpretation of the law. Accordingly, it is inappropriate to change that regulation without specific direction from Congress in the form of a statutory change.

Committed to Excellence

Texas Medical Center:
Texas Nuclear Imaging, Inc.
1213 Hermann Drive Ste. 885
Houston, Texas 77004
Phone: 713-523-6700
Fax: 713-523-2626

Southwest:
Excel Diagnostics, LTD.
9701 Richmond Ave. Ste. 124
Houston, Texas 77042
Phone: 713-781-6200
Fax: 713-781-6206
Houston • New York • Washington DC • Austin • Dallas • Los Angeles • Minneapolis • San Antonio • Hong Kong • London • Munich

Southwest:
Westchase Imaging, LTD.
9701 Richmond Ave. Ste. 124
Houston, Texas 77042
Phone: 713-781-0800
Fax: 713-781-6206

CMS has consistently taken the position that interpretative regulations, properly promulgated, cannot be rescinded absent a change in the underlying law itself. It would be inappropriate to change that policy now.

2. The underlying rationale for excluding nuclear medicine has not changed.

Nuclear medicine services are clearly different from radiology services, at least as different as the other services that the January 4, 2001, final rule excluded and which continue to be excluded from the definition of radiology services.¹ In fact, these types of “interventional radiology” procedures are closer to radiology procedures than nuclear medicine by any interpretation.

It must be recognized that the support for CMS’ apparent rationale for proposing to extend the application of the Stark provisions to nuclear medicine because nuclear services have become more widely used and offer similar diagnostic results to traditional radiology procedures is largely founded upon arguments with an ulterior motive—specifically, the fight for control over who can bill for and perform these procedures. In the case of nuclear services, radiologists want to vest control from those who have legitimately secured it and developed considerable expertise (at significant costs no less). Put simply, this is an interdisciplinary fight over involvement in patient care and the related financial issues in which CMS should not become entangled.²

Finally, note that it is a basic principle of regulatory interpretation that if the regulation language itself is clear and precise, the Preamble language should not be used to try to interpret (or in this case, to reinterpret the language). Accordingly, there is no basis to change the regulation on the grounds that the rationale previously considered has changed.

3. There is no basis to include nuclear medicine as a DHS because of the risk of abuse.

The proposal to add nuclear medicine as a DHS relies to a great degree on the need to regulate the type of abuses that the Stark provisions are intended to combat. Yet, there are no actual studies or data that have been published or made available by CMS to show that the exclusion of nuclear medicine as a DHS service since 2001 has, in fact, resulted in abuses. There is no comparison in the little data shown between radiologist owned and operated nuclear medicine facilities and non-radiologist owned facilities. The large growth in the use of these

¹ (1) “X-ray, fluoroscopy, or ultrasound procedures that require the insertion of a needle, catheter, tube, or probe through the skin or into a body orifice; (2) [r]adiology procedures that are integral to the performance of a nonradiological medical procedure and performed – (i) [d]uring the nonradiological medical procedure; or (ii) [i]mmediately following the nonradiological medical procedure when necessary to confirm placement of an item placed during the nonradiological medical procedure” 42 C.F.R. § 411.351; 66 Fed. Reg. 856, 956 (Jan. 4, 2001).

² See section 1801 of the Social Security Act, which prohibits the Secretary of the U.S. Health & Human Services from interfering in the legitimate practice of medicine.

services shows the advancement and expanded coverage of these services, and is no indication of abuse. CMS' reliance on complaints from radiologists who seek a stronger foothold on this new technology is, therefore, misfounded.

Similarly, the risk of anti-competitive behavior would increase by limiting the parties that may provide nuclear medicine services, which is contrary to the CMS rationale of protecting against abuse and ensuring quality patient care. This Administration has consistently supported pro-competitive behavior. Accordingly, only if Congress determines that nuclear medicine should be included as one of the DHS and amends the law should the regulation be changed.

4. Patient care will be affected.

Nuclear medicine is a developing field that is leading to significant advancements in diagnostic medicine. The new technology results in better patient care through earlier and more efficient detection of disease. Nuclear medicine is used to (a) determine the presence or spread of cancer; (b) analyze kidney function; (c) view blood flow, heart functions and respiratory issues; (d) identify bleeding or blockages in the bowel or gallbladder; (e) locate infections; and (f) evaluate the thyroid. By being able to provide these important services more directly, through shared ventures that spread the cost of the expensive equipment involved, physicians (internists, cardiologists, urologists, etc.) are able to more directly and efficiently diagnose and treat their patients. Early detection resulting from this care not only saves patients' lives, but saves federal programs from more costly care incurred when no diagnosis is made timely.

5. Many physicians put substantial capital and devote a substantial portion of their practices to establishing qualified nuclear medicine arrangements.

Arrangements to foster the provision of nuclear medicine were established in good faith, with the reasonable understanding that CMS would stand by its legally promulgated interpretations. Nuclear equipment is very expensive, and significant resources have been put into ventures to make this technology available to patients. Requiring physicians to divest their interests in these ventures would have detrimental financial impact on them and would be tantamount to an illegal taking without just compensation—a violation of the Constitution of the United States.

6. Should the Secretary decide to include nuclear medicine services in the definition of DSH, relief should be provided to pre-existing arrangements that met the January 4, 2001 standards.

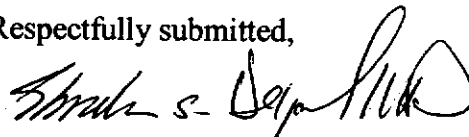
For the above-stated reasons, we believe that CMS should retract its proposal to add nuclear medicine services as DHS. If CMS refuses to retract this proposal, we believe that the Agency should protect those arrangements that were in place prior to the proposed rule. There is much precedent under the Medicare program to "grandfather" arrangements legitimately entered into prior to CMS reversing or altering its position on a regulatory interpretation. Even with

regard to other provisions of the Stark Law (e.g., the specialty hospital ownership), CMS grandfathered arrangements that were operational prior to the change.

A less equitable, but nonetheless minimally restitutive action, would be to give such pre-existing arrangements a substantive delay in effectuating compliance with another exception, for example by allowing such arrangements to be divested or physician ownership over a period of at least five years. This would be the minimum period for physicians to recover a fair share of their capital investments and dispose of their assets without having to resort to "bargain basement" sales.

Thank you for the opportunity to comment on this proposal.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Ebrahim S. Delpassand", written over a horizontal line.

Ebrahim S. Delpassand, M.D.
Chairman & Medical Director
Excel Diagnostics, LTD

Richard L. Wallingford, O.D.
President



SEP 29 2005

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American Optometric Association
243 N. Lindbergh Blvd. • St. Louis, MO 63141 • (314) 991-4100
FAX: (314) 991-4101

September 28, 2005

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

Dear Dr. McClellan:

On behalf of its more than 35,000 members, the American Optometric Association (AOA) is pleased to submit these comments related to the August 8, 2005 *Federal Register* publication of the *Proposed Rule for Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006*.

Resource-Based Practice Expense (PE) RVUs

CMS is proposing a new "bottom-up" methodology for calculating PE RVUs to replace the current "top-down" approach. CMS also proposes to use the current indirect practice expense costs except for services affected by supplementary survey data submitted by several physician specialties, which CMS is now proposing to accept. Further, CMS proposes to transition to the new PE values over a four-year period. Impact tables accompanying the proposed rule indicate that the new "bottom up" PE RVU methodology and other proposed changes in the PE RVU calculations (when fully implemented in 2009) would reduce Medicare payments for optometrists by 3.1 percent. The redistributive effect of the proposed changes would be even greater for other physician specialties, ranging from -4.4 percent for ophthalmology to +17.5 percent for dermatology.

Recently posted tables listing the fully implemented, new PE values also reveal troublesome changes in PE values for CPT codes that Medicare treats as a bundled service, does not cover at all, or does not consider valid for Medicare purposes. Other eye care service codes show huge reductions in PE values. Several examples are provided in the table on the following page.

Code	Status	Description	2005 Non-Facility PE	Proposed 2009 Non-Facility PE	Percent Change
92015	N	Refraction	1.49	0.38	-74.5%
92354	B	Special spectacles fitting	8.86	1.87	-78.9%
92355	B	Special spectacles fitting	4.33	1.09	-74.8%
92358	B	Eye prosthesis service	0.97	0.32	-67.0%

To say the least, we do not understand all of these changes and we are concerned that these new Medicare-published PE values will produce significant reductions in payments for the affected services to the extent that private or non-Medicare public payers rely upon them. As noted in the table, Medicare either considers these services bundled (B) or non-covered (N). AOA considers that new PE values like these are flawed and we urge CMS not to adopt them in the final rule.

In addition, AOA has carefully reviewed the language in the proposed rule relating to the new PE RVU methodology. Unfortunately, our assessment of this methodology has been hampered by the fact that so little information was provided in the proposed rule about exactly how the new PE RVUs were calculated and how various decisions made by CMS along the way affected these calculations. This becomes particularly apparent when one compares the amount of space devoted in the preamble to a detailed description of the current "top down" methodology with the relatively small amount of text devoted to a description of the new "bottom up" alternative. In this regard, we find it regretful that the proposed rule does not provide service-specific examples of how PE RVUs would be calculated using the current and the proposed methodologies. We believe this would have made it much easier for stakeholders to understand—and comment upon—what is being proposed.

In calculating the new PE RVUs, CMS is apparently proposing to use new direct expense calculations, while retaining the current indirect practice expense costs (except for those services affected by CMS-accepted supplemental survey data). However, since indirect expenses were originally allocated based on the direct expenses for each CPT code, incorporating new direct expense costs, while retaining the original indirect expenses for most codes, may create inequities or have other unintended consequences. In any case, once again, the relative paucity of information provided in the proposed rule regarding the various facets of the new PE RVU methodology makes it hard for us to assess the proposal.

In sum, the lack of specificity and information makes it difficult at this time to provide more detailed comments or advice regarding the proposed PE RVU methodology. However, if CMS decides to proceed with the proposed change in

methodology, AOA certainly agrees that a four-year transition period would be prudent to minimize the immediate impact of the resulting redistributive effect and to provide additional time to assess the need for refinements or adjustments in the PE RVUs. AOA anticipates that the final rule will provide more detailed information about the new PE methodology, and we urge CMS to provide stakeholders a further opportunity to submit comments based on this additional detail by issuing a final rule with comment period.

Supply Items Needing Specialty Input for Pricing

The proposed rule requested specialty input related to the pricing of certain supply and equipment items. These included four items relevant to optometrists: (1) SJ073, DMV remover; (2) SJ074, Lens cleaner; (3) SJ076, Nose pads; and (4) EQ271, Radiuscope. AOA is pleased to be able to provide information regarding each of these items.

EQ271 Radiuscope – \$1,595, MARCO, Lombart Part #5005, Lombart Instruments, 800 443-0120; 5358 Robin Hood Road, Norfolk, VA 23513

SJ073 DMV Remover – \$19.95 (box of 10), Ultra I, www.bernell.com; 4016 N. Home Street, Mishawaka, IN 46545; 800 348-2225

SJ076 Nose Pads – Silicone Nose Pads, 25 pair - \$16.90 for Flex D; 25 pair - \$19.95 for Symmetrical; 25 pair - \$47.25 for Strap Bridge; Supplyeyes, Inc. Cumming, GA, 800-727-3725

SJ074 Lens Cleaner – one ounce \$.69; Hilco, 33 West Bacon Street, Plainville, MA 02762; 800-955-6544

Malpractice RVUs

CMS proposes several changes in methodology related to malpractice RVUs. One of these directly impacts the practice of optometry. Specifically, in determining malpractice RVUs, CMS proposes to crosswalk the specialty of optometry to the Insurance Services Office (ISO) non-surgical risk factor for the specialty of allergy and immunology, rather than to the higher risk factors for ophthalmology used in 2005. This change would produce a reduction in payments for services provided to Medicare beneficiaries by optometrists. This proposed change is based on recommendations from the Professional Liability Workgroup of the AMA/Specialty Society RVS Update Committee (RUC). It is unclear to us what the basis was for the RUC recommendation. The proposed crosswalk recommendation was not based on an examination of professional liability insurance premium data or other objective evidence.

As you are aware, prior to 2005 CMS had crosswalked optometry to the even higher risk factors for the “all physicians” category.

Coverage of Screening-Glaucoma

CMS proposes to expand the list of individuals eligible for coverage of glaucoma screening services to include Hispanic American Medicare beneficiaries age 65 and over. AOA heartily endorses this improvement in Medicare policy.

Sustainable Growth Rate (SGR)

The proposed rule forecasts a Medicare fee schedule update of -4.3 percent for 2006 and indicates that a complete discussion of the methodology for calculating the SGR will be provided in the final rule. The proposed rule also observes that it has been suggested that CMS has the authority to make "certain administrative adjustments in the SGR methodology, such as removing Part B drug payments from the calculation of both projected and actual expenditures (retroactively to 1996) that are used to set the spending target."

AOA joins Members of Congress and other physician organizations in continuing to urge CMS to take administrative steps to improve the SGR and fee schedule update calculations. First, we believe that CMS should remove Medicare-covered, physician-administered drugs and biologics from the physician payment formula, retroactive to 1996. These drugs and biologics are not paid under the Medicare physician fee schedule and their inclusion in the SGR calculation simply does not make sense. Second, we urge CMS to ensure that increases in spending on physicians' services that arise from government-mandated improvements in Medicare benefits for such things as preventive and screening services are appropriately treated in the SGR calculation. Finally, AOA believes that CMS should ensure that the SGR fully reflects the impact on physician spending stemming from national coverage decisions, such as those relating to implantable cardiac defibrillators, PET scans, and macular degeneration treatment. Such coverage decisions can have a significant impact on Medicare expenditures for physicians' services, and physicians should not be penalized for this. If adopted, all of the above recommendations would make the SGR and physician fee schedule update calculations fairer and more accurate. Equally important, AOA believes they would also facilitate the adoption of more permanent improvements in the fee schedule update formula currently being contemplated by the Congress.

We hope the preceding comments are helpful as CMS proceeds to develop a final rule. If you or your staff have any questions about the comments or would like AOA to be of additional assistance, please contact Ms. Kelly Hipp, Director of Professional Relations. Ms. Hipp can be reached at 703 739-9200 or email at KHipp@aoa.org.

Sincerely yours,



Richard L. Wallingford, Jr., OD

SEP 29

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Robert F. Sauter, M.D. (1951-1999)
Alan D. Platin, M.D. (1937-2003)
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G. Huff Peeler, M.D.
Carol I. Lynn, M.D.
Laura J. Bishop, M.D.
Heather P. Chauhan, M.D.

Robert M. Ruch, M.D., Emeritus
Walter A. Ruch, Jr., M.D., Emeritus
Walter A. Ruch, M.D., (1894-1958)
Bradford W. Kincheloe, M.D., (1944-1996)

Nina F. Wolfe
Executive Director

September 27, 2005

Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244-1850

Re: Proposed Reimbursement Decrease in 2006

To Whom It May Concern:

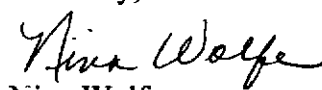
I am writing on behalf of our physicians in response to the proposed decrease in Medicare Fee Reimbursement that will take effect January 1, 2006. We are an obstetrical/gynecological practice that has accepted Medicare patients on an on-going basis in order to provide accessible healthcare to our senior citizens. We have adhered to the concept that our elderly, more than any other segment of our society, needs convenient, caring, uncomplicated medical care. And, yet, they are the patients whose care has become the most complicated and inconvenient. Filing regulations related to Medicare claims and services have reduced access to healthcare for these individuals as more and more physicians find they are unable to bear the cost of trying to keep up with the ever-changing requirements made by Medicare while reimbursements continue to shrink.

As you know, the cost of everything has increased and, with the rate of malpractice insurance premiums increasing by double digits, and our legislators unwilling to commit to tort reform, we will no longer be able to accept falling reimbursements.

I hope that you will think about the fact that you, like I, will someday depend upon Medicare physicians for healthcare. It is my fervent hope and prayer that there will be quality, caring physicians left who will accept me (and you) as a patient.

Please reconsider your decision to reduce physician reimbursement.

Sincerely,


Nina Wolfe
Executive Director



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SEP 29
elerhythmics, LLC

Monitoring Service

"Monitoring the Rhythm of Life"

September 28, 2005

Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244-1850

To Whom It May Concern:

As a small independent diagnostic testing facility that performs 30-day cardiac event monitoring, holter monitoring, and pacemaker follow-up services, the proposed 27% reimbursement decrease in cardiac event monitoring and 15% for holter monitoring and pacemaker follow-up services beginning in 2006 will be the first step in putting us out of business. There is just no way we can continue to give employees an annual 2 – 3 percent raise, address increase in overhead, increased insurance premiums, (last year 47% increase for BCBS of TN for approximately 50 employees), purchase and repair monitors and equipment, provide indigent care, cover malpractice cost, phone cost, computer – IS personnel cost etc. How can CMS expect anyone to even want to work in the medical field?

Cuts in this area will increase cost to the emergency rooms and result in numerous physician office visits for transient and infrequent symptoms. The diagnostic yield for these services has been proven to be extremely cost effective. It just makes absolutely no financial sense at all.

Please, I respectfully ask your reconsideration in this matter. I would welcome you to do an on-site visit and give me any input at all on how you think we can survive and what else we can cut to adjust to this proposed decrease in reimbursement. I would appreciate hearing from someone as soon as possible.

Sincerely,

Jan M. Callaway
CMO

JMC:ss

745
STANLEY L. SMITH JR., M.D., F.A.C.S.

SURGERY

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PHONE (901) 761-1155 FAX (901) 761-1240

BAPTIST HOSPITAL MEMPHIS
METHODIST HOSPITAL GERMANTOWN

September 27, 2005

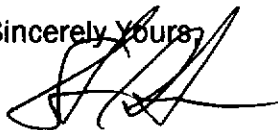
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244-1850

To Whom It May Concern:

I am writing you this letter to express my sincere concern over the proposed Medicare fee reimbursement cuts that will take affect January 1 2006. It is already extremely difficult for surgeons to take care of Medicare patients. They represent some of the oldest, sickest patients that we are asked to see and their operations are often complex, very detailed and associated with many co-morbidities. We get paid less for caring for this population than we do anyone else in the medical field. As our reimbursement rates decline, office expenses, malpractice expenses, and cost of running a medical office continue to climb.

I fear that if this decline in Medicare rates is not stopped and reversed there will be a hard time finding surgeons to take care of Medicare age patients. In Memphis, TN I already have a hard time finding internists who will accept new Medicare patients into their practices because of the poor reimbursement rate. We in the medical field are not in this field to make a "financial killing" but we do expect to be able to make a living and be reimbursed adequately for our services. I strongly encourage you to reconsider lowering the Medicare rate any further as I believe this will make it more and more difficult for Medicare aged patients to obtain healthcare.

Sincerely Yours,



Stanley L. Smith, Jr., M.D.

SLS; au

SEP 29

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JEROME S. SIEGEL, M.D., F.A.C.P.

INTERNAL MEDICINE - CARDIOLOGY

A. GRAHAM WARR, M.D.

INTERNAL MEDICINE - ADOLESCENT MEDICINE

6025 Walnut Grove Rd - Suite 607 - Plaza #1 Memphis TN 38120

901-683-2161 fax# 901-681-0768

September 27, 2005

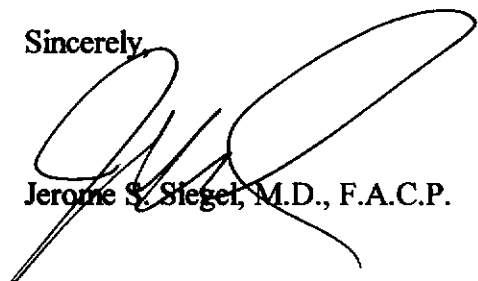
Centers for Medicare and Medicaid Services
7500 Security Blvd
Baltimore, MD 21244-1850

TO WHOM IT MAY CONCERN:

This letter is to express my outrage over the proposed Medicare payments to physicians for 2006. I find it absurd that my rent goes up, my payroll goes up, my insurance goes up, and all other expenses of remaining in practice continue to climb while you choose to cut my fees which are already rock bottom.

It should be noted that if this outrageous proposal goes in to affect, I will have to stop seeing new Medicare patients.

Sincerely,



Jerome S. Siegel, M.D., F.A.C.P.

L. K. McCOWN, M.D.
Internal Medicine
JOHN R. AUSTIN, M.D., F.A.C.P.
Internal Medicine

9-27-05

JOSEPH E. ALLEN, II, M.D.
Internal Medicine
JEFFERY N. HOOVER, M.D.
Internal Medicine

Dear CMS :

I am writing to comment on the present proposal to decrease Medicare payments to physicians that is set to go into effect on 1-1-2006.

Malpractice insurance premiums are rising seriously. Insurance companies are requiring more & more from us, and paying less & less. Proposed cuts in Medicare payments for physician services will reduce ALL payments (from every source).

These financial pressures are forcing the doctors in this group (and most others that I know) to re-evaluate whether we should limit the number of Medicare-covered patients we see (or stop seeing them altogether). Patients covered by Medicare are usually more complicated & require more time to manage than patients with private insurance (younger & healthier, on average).

Please, reconsider your plans to cut payments to doctors. The payments are already too low !!!

Sincerely
Dr. Joseph E. Allen II, M.D.
Joe E. Allen II



Nuclear Cardiology

HeartSafe®



SEP 29 2005

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Board Certified in
Cardiovascular Diseases

H. Manning Curtis, M.D., FACC, FCCP
Lin Miao, M.D., FACC
Melissa J. Tracy, M.D.

September 28, 2005

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:

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%. 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 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.

I am an invasive noninterventionalist practitioner boarded in nuclear cardiology as well as medicine and cardiovascular diseases. My stress laboratory is certified by the Intersocietal Commission for the Accreditation of Nuclear Medicine Laboratories. We have been performing gated SPECT tomographic imaging and one of the primary lacks of this equipment is that the post-stress gated SPECT ejection fraction does not reflect ischemia during exercise, and the most telling of diagnostic criteria of ischemia and outcomes is ejection fraction during exercise and the first-pass imaging is the best quantitative way of getting that information. Even in patients who have coronary artery disease, if they increase their quantitative ejection fraction during exercise and their ejection fraction augments and does not drop during stress, they are at marked decreased risk to patients who have coronary disease who drop their ejection fraction during exercise. SPECT tomographic gated imaging does not give us this information and with this in mind we have added first-pass imaging and we believe that first-pass imaging is a method of decreasing unnecessary cardiac catheterizations. For example, a patient with a SPECT imaging demonstrating ischemia who augments his ejection fraction during exercise on first-pass is not likely to have a cardiac event in the next year versus a person who drops his ejection fraction and may actually have more extensive coronary disease than is suspected on nuclear SPECT imaging. In addition, there are some patients who have balanced ischemia and those patients with left main disease will drop their ejection fractions during stress indicating the presence of disease that is not noted on the SPECT tomographic images and not reflected in the ejection fraction done after stress in many cases.

September 28, 2005

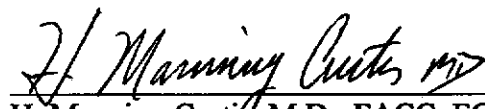
Page -2-

As you can see, there are, in fact, equipment costs that I and my colleagues 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. We have already placed this equipment in our practice at cost to our lab in order to provide first-pass imaging and this cost was incurred in order to improve the quality of our diagnostic studies. It should be noted that the performance of first-pass service requires additional staff time and physician time in order to bring this excellent technology to the patient. Installation and running of the equipment has added additional cost to the practice. We also incur leasing cost on this equipment and in private practice these additional costs are affected by decisions by CMS in terms of our financial liability. The consequences of failure to change the payment rate on first-pass are as follows: The private laboratories which are attempting to offer the very best service to patients will not be able to provide that service. I believe that the rate of false information garnered from SPECT tomographic imaging will lead to unnecessary cardiac catheterizations when a SPECT image indicates ischemia and we do not have a first-pass quantitative ejection fraction during peak exercise to determine the risk of this ischemia. In other words, a drop in ejection fraction which cannot be given to us by SPECT gated imaging is very indicative of increased risk to the patient. It is my opinion that to drive this reimbursement cost down in this case is actually compromising the very best clinical practice and will subsequently increase cost on the other end. As an example, CT angiography may be pushed in the near future and yet a CT angiography does not give quantitation of the obstruction even with 64-slice CTA. The physiology and the effects on wall motion and ejection fraction during exercise give physiologic and hemodynamic significance to obstructions found by SPECT tomographic imaging which cannot be derived by CTA or by gated SPECT ejection fraction post-exercise. There will be in the near future a push towards CTA for the diagnosis of coronary disease and yet the diagnosis could likely lead to increasing cardiac catheterization rates. This information from first-pass precludes a necessity of cardiac catheterization if there is augmentation of exercise first-pass EF in single-vessel disease and also picks up falsely normal SPECT tomographic imaging by demonstrating a drop in ejection fraction which would lead to appropriate and timely catheterization.

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 978-688-2206

Sincerely,


H. Manning Curtis, M.D., FACC, FCCP



SEP 19

749

**Joint Council
of Allergy,
Asthma and
Immunology**

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Suite 3-3
Palatine, IL 60067
Voice: 847-934-1918
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E-Mail: info@jcaai.org

September 28, 2005

FEDERAL EXPRESS

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

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

Dear Dr. McClellan:

The Joint Council of Allergy, Asthma and Immunology (JCAAI) is pleased to have this opportunity to comment on the Revisions to Payment Policies under the Physician Fee Schedule for 2005 as published in the August 8, 2005 Federal Register.

JCAAI is an organization sponsored by the American Academy of Allergy, Asthma and Immunology and the American College of Allergy, Asthma and Immunology. It represents the interests of over 4,500 physicians board-certified in allergy and immunology.

Use of JCAAI survey data

We are pleased that CMS is proposing to accept the practice expense survey of allergists conducted by JCAAI and submitted to CMS earlier this year. That survey was conducted in accordance with CMS criteria, was based on the AMA SMS survey, and met CMS precision criteria. We believe the new data, which is based on a much larger sample of allergists than all three years of the SMS data together, is much more accurate than existing data.

We are concerned, however, that the RVUs based on the new data will be phased in over four years. In the past, when CMS has accepted specialty survey data, it became effective in that calendar year. CMS has not provided any rationale for why it is breaking with past

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policy or why it has decided to phase-in the specialty survey data. We ask that CMS follow its previous policy and implement changes resulting from the new data all at once. In particular, we are concerned about the continued applicability of the old and incorrect scaling factors. Supply costs and indirect costs make up an inordinately high proportion of allergy practice costs. The scaling factors applicable to these cost categories have, in the past, resulted in significant discounting of those costs. The survey data accepted by CMS is a much more accurate picture of the true costs of allergy practices and shows that allergy practices have been significantly underpaid in the past, particularly for indirect costs, as a result of scaling factors developed from poor data. We believe it is inequitable for these erroneous scaling factors to have continued effect, and ask that CMS calculate new RVUs for allergy services based on the new survey data, and that these new RVUs be used during the phase in.

Change to Bottom-Up Methodology

We support CMS' proposal to change to a bottom-up methodology for determining practice expense values. We believe this is a more rational approach. We are concerned, however, that there be an ongoing mechanism for updating direct practice expense costs. The cost of equipment and supplies change frequently. New technology can result in higher costs; at the same time the cost of new technology frequently decreases as the equipment becomes more established. Further, sometimes federal regulatory requirements impose new requirements on physicians which result in increased costs. An example of this is the OSHA requirement of two to three years ago that physicians implement the use of the more costly safety needles. Through the work of the PEAC, codes which included safety needles as a supply item were reviewed and supply costs were adjusted as appropriate.

With the role of the RUC/PERC being phased out, we are concerned that there will be no adequate mechanism for addressing changes in practice expenses. We believe CMS must ensure that such a mechanism exists, and we ask that this be addressed in the final rule.

Phase-In of New Methodology

Except as noted above, with respect to the phase-in of specialty survey data, we generally support CMS' proposal to phase-in the elimination of the non-physician work pool and the bottom up methodology.

Allocation of Indirect Costs

CMS has asked for recommendations for further refinement of the indirect practice expense methodology. It is difficult to come up with specific proposals in this

regard, because it is impossible, given the complexity of the fee schedule calculations, to determine the effect a different methodology might have on our specialty. However, we do have concerns that the indirect costs of an allergy practice are not properly accounted for in the current methodology.

Indirect costs for codes with work values are currently allocated based on physician work and direct costs. The proposed rule does not explain how CMS allocates indirects for codes without work values; nor have we been able to find an explanation of this in other Federal Register fee schedule notices. Although it is not possible to determine, from the information provided, exactly what percentage of total practice expense RVUs for a given code reflect direct costs and what percentage reflect indirect costs, we believe the current use of physician work and direct costs to allocate indirect costs likely results in an undervaluing of indirect costs for allergy services.

One reason for this is that many allergy codes have either no work RVUs or very low work RVUs in relation to PE RVUs. CMS states that an overall 41% of RVUs represent physician work; 45% represent practice expense, and 5% represent malpractice. However, this is not true for a number of allergy codes. Of most concern is the code which describes preparation of allergy immunotherapy vials (CPT Code 95165). For that code, physician work represents only 22% of the total RVUs. Nevertheless, indirect costs associated with this service are substantial. They include communications with primary care physicians' offices with respect to patients for whom the allergist prepares allergy immunotherapy vials for outside administration related to reactions, lapses in immunotherapy administration schedules, vaccine spoilage or loss as well as a variety of other problems. These problems are typically dealt with by administrative and clinical staff as well as the physician. Other costs include maintenance of the allergy immunotherapy laboratory where immunotherapy vials are prepared under sterile conditions, and maintenance and restocking of allergenic extract inventories. None of these costs meet the definition of direct costs used by the CPEP/PEAC, and hence fall into the indirect category.

Because of the low or non-existent physician work values, the current methodology for allocation of indirect costs, which uses physician work and direct costs to allocate indirect costs, results in a significant under-allocation of indirect costs for this code compared to other codes.

We realize this service may be somewhat unusual and that use of physician work and direct costs as allocators of indirect cost results may yield reasonable results for many codes. However, for allergy immunotherapy services, the result is not fair and the implications of this are significant for the specialty since this code, alone, accounts for anywhere from 10%-20% of revenue in the typical allergy practice.

Consequently, we request that CMS establish a process for reviewing those codes for which the direct cost/physician work allocation methodology does not yield fair results such as those codes with significant service related indirect costs and disproportionately low work RVUs (WRVUS). We believe there must be a mechanism for allowing adjustments to be made in cases where there is compelling evidence that the existing formula for allocating indirect costs yields an inequitable result.

Alternatively, CMS should revise the process for determining direct costs to allow costs which are specific to a service or family of services to be included in the direct cost category. Under the current definition of direct costs, all administrative time is considered indirect. We suggest that administrative and clinical staff time that clearly relates to specific procedures or categories be treated as direct time. Moving some of these costs from the indirect to the direct category would, we believe, result in a more equitable reimbursement.

If CMS does not establish an exception mechanism, as outlined above, or does not permit a more expansive definition of direct costs, we request that the agency address, in the final rule, other ways in which specialties could seek to have these inequities corrected.

CPT Code 95015

We are pleased to see that CMS is proposing to adopt our recommendation to change the supply input for CPT Code 95015 to include .3 ml of venom instead of .1 ml of antigen.

CPT Code 95070

This code, which describes a challenge test using drugs or biologicals, would decrease by 64% by the end of the phase-in period. We are concerned with this precipitous drop and believe this is another reason why it is important that there be an ongoing process in place to review practice expense inputs.

CPT Codes 95115/95117 – Allergy Injections

JCAAI, together with a number of other specialties, have requested, by separate comment letter, that the zero-day global status of these codes be changed to XXX. This would make them consistent with other injection codes. These codes currently have no physician work. We do not believe the zero-day global status, which is designed to ensure that all the physician work associated with a procedure (including the evaluation of the patient the day prior and the day of the procedure) is included in a single payment.

Where a code does not have any physician work to begin with, the zero-day global status is not appropriate.

Coding for Administration of IVIG

We are concerned that currently, physicians are unable to bill for IVIG administration in the office using the higher complexity infusion code applicable to chemotherapy and biological response modifiers. CMS currently gives carriers the discretion to designate those biological response modifiers which can be billed using the chemotherapy administration code. However, we are not aware that any Medicare carriers have permitted physicians to bill IVIG using the higher complexity code. We believe CMS should issue a national policy instructing carriers to pay for IVIG administration under the higher complexity code. We believe such a policy is appropriate for the following reasons:

- Administering IVIG to patients with primary immune deficiency disease is a complex undertaking which typically takes between three to eight hours and requires careful monitoring by a trained infusion nurse. In primary immune deficiencies and in other indications, IVIG modifies aberrant immune response to protect, maintain and restore normal physiology to prevent disease. As is commonplace with this type of therapy, adverse events (AE) occur frequently, and the risk of severe adverse effects (AEs) is real. For example, the FDA licensing studies of IVIG for patients with primary immune deficiency disease include an occurrence of AEs as high as in 72% of patients. There are many acute AEs, including thromboembolism, hypotension, seizures, aseptic meningitis syndrome, anaphylaxis, acute respiratory distress syndrome, and transfusion associated lung injury. All IVIG products also include a black box warning regarding acute renal failure. The proper diagnosis of acute AEs in the context of IVIG infusions requires expert supervision and skilled intervention. This is necessary to minimize the impact of the AEs to the patient receiving treatment and in some cases, it can be life-saving.
- Given the gravity and acuity of risks in administering IVIG, special precautions are required. These include careful monitoring of the entire infusion process, which can be as short as three to four hours, but as long as eight hours. Expert nursing care by registered nurses skilled in the administration and risks of IVIG is essential. Nurse to patient ratios of 1:1 and never less than 1:2 are essential to allow frequent clinical assessment (including neurological checks), measurement of vital signs every 15 minutes (including temperature, respirations, heart rate and blood pressure) and comprehensive documentation. Physician and nurse

assessment of a patient to determine suitability for the infusion is also necessary as certain comorbidities of the primary diagnoses can preclude, or alter, the administration of IVIG. The immediate availability of the physician to evaluate the patient at any point during the infusion for assessment of potential complications is also critical. Finally, preparedness for a number of interventions to manage common infusion-related complications, including adjustment of the infusion rate, supplementation with physiological fluids, and provision of analgesics, non-steroidal anti-inflammatories, bronchodilators, antihistamines, steroidal anti-inflammatories, or occasionally systemic sympathomimetics is also required. Clearly, the safe and effective prescription and administration of IVIG requires a highly skilled and coordinated effort from both nurse and physician.

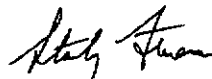
In this regard, we note that the nurse time necessary for the typical IVIG administration is just as much, if not more, than that required for a chemotherapy infusion. In fact, while the nurse-to-patient ratio for IVIG is typically one-to-one, generally a single nurse can monitor two or more chemotherapy infusions.

For these reasons, we believe CMS should issue specific instructions stating that IVIG administration should be billed using the higher complexity HCPCS code that applies to administration of chemotherapy, biological response modifiers, and other complex infusions.

* * *

We thank you for your consideration of these comments. If you have any questions, please contact our Washington counsel, Rebecca Burke, at 202-872-6751.

Sincerely,

A handwritten signature in black ink, appearing to read "Stanley Fineman".

Stanley Fineman, M.D.
President



SEP 29 2005

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GE Healthcare

101 Carnegie Center
Princeton, New Jersey 08540
USA

September 28, 2005

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

Re: Comments on proposed Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006

Dear Dr. McClellan:

GE Healthcare is a unit of General Electric Company that is headquartered in the United Kingdom with expertise in medical imaging and information technologies, medical diagnostics, patient monitoring systems, disease research, drug discovery and biopharmaceuticals. Worldwide, GE Healthcare employs more than 42,000 people committed to service healthcare professionals and their patients in more than 100 countries.

We appreciate the opportunity to submit comments on the proposed Revisions to Medicare Payment Policies Under the Physician Fee Schedule for Calendar Year 2006, published in the August 8, 2005 Federal Register (Vol. 70, No. 151).

ASP Issues

I. Price Concessions: Wholesaler Chargebacks

CMS proposes an estimation ratio methodology that would require manufacturers to calculate separately a weighted average of lagged price concessions related to direct sales and lagged price concessions related to indirect sales, and then combine the calculations to determine the weighted average of all lagged price concessions that a manufacturer would include in their ASP calculations.

We recommend that CMS not adopt this requirement and instead maintain the current ASP calculation. The proposed calculation would require significant modifications to our accounting and reporting systems if we had to segregate the price concessions for direct and indirect sales. We believe that such an expense would be unjustified because manufacturers' direct and indirect sales are stable and therefore the concessions are stable. A further breakdown of sales would not have a significant impact on the ASP calculation.

Moreover, the definitions in the rule for direct and indirect sales seem contradictory. The explanation of the calculation of lagged price concessions to sales on page 45843 contains definitions of direct and indirect sales that differ from the definitions on page 45844. The definitions do not seem to consider the fact that a manufacturer can be either a wholesaler or supplier. Should CMS choose to adopt the revised ratio methodology, we request that the definitions be clarified further.

II. Revised Format for Submitting ASP Data

In a separate information collection notice published subsequent to the proposed rule, CMS proposed to revise the ASP reporting format to accommodate the submission of both the ASP and the WAC. In addition, CMS also proposed to collect supplementary data, some of which we believe is irrelevant to the calculation of reimbursement rates. We seek clarification on the following required information:

Package Size (Volume per item)

Does this mean volume per unit (NDC level) or volume per item (bottle/vial, etc) in each unit?

Expiration date for the last lot manufactured

We recommend that CMS require this information only for reports submitted after the date that the last lot was manufactured. The requirement should end when all lot sales made before the expiration date have been reported.

Clarification is needed as to whether the manufacturer needs to provide the expiration dates only for discontinued products or for every product that is reported on the spreadsheet?

Date the NDC was first marketed (for products first marketed on or after October 1, 2005)

We recommend that CMS require this information on the first date of marketing or that the first date of sales would be submitted "once with the first submission for new NDCs." This limitation is clearly provided in the Information Collection Notice but omitted in the proposed rule.

We also recommend that the date refer to the FDA approval date rather than the market entry date.

Date of first sale for products first sold on or after October 1, 2005

We recommend that the date of the first sale be considered the date of the first invoice for the new product.

Lastly, the proposed regulation did not clearly specify the timing in which we have to start submitting the additional data elements. Please clarify whether this requirement is effective for the forth quarter 2005 ASP submission which is due on January 30, 2006, or would it be effective for the first quarter 2006 ASP data due on April 30, 2006? We recommend that CMS require the latter.

Thank you for the opportunity to comment on this important rule. Should you have any questions on the ASP calculation, please contact Agnes Goins at 609-514-6740 or at agnes.goins@ge.com. For any other questions, please do not hesitate to contact Jane Majcher at 609-514-6701 or at jane.majcher@ge.com.

Sincerely,



Jane Majcher
Director, Reimbursement Strategy
Medical Diagnostics



Agnes Goins
Manager, Government Operations
Medical Diagnostics

29 751

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September 28, 2005

VIA FEDERAL EXPRESS

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

**Re: Comments to “Proposed Rule: Medicare Program; Revisions
to Payment Policies under the Physician Fee Schedule for
Calendar Year 2006”
CMS-1502-P – “NUCLEAR MEDICINE SERVICES”**

Dear Sir/Madam:

This letter sets forth comments to the Proposed Rule: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006 – “NUCLEAR MEDICINE SERVICES” (hereinafter the “Proposed Rule”), which proposes to include nuclear medicine services as “designated health services” (DHS) under Section 1877 of the Social Security Act (42 U.S.C. § 1395nn), commonly referred to as the “Stark Law”.

For the reasons set forth below, the Proposed Rule should be amended to include an exception permitting physician investment, made prior to the effective date of the Proposed Rule, in healthcare entities which provide nuclear medicine services and supplies. In the alternative, there should be an exception which would permit physician investment in a healthcare entity which provides nuclear medicine services and supplies if the physician who refers patients for nuclear medicine services, is on-site and directly supervises the technician performing the nuclear medicine procedure on patients referred by that physician.

According to the Proposed Rule, CMS has reconsidered the question of whether nuclear medicine services and supplies should be considered DHS under the Stark Law. The Proposed Rule would amend 42 C.F.R. §411.351 (Definitions) to delete from the definition of:

(i) "radiation therapy services and supplies" language that excluded therapeutic nuclear medicine services and supplies, and (ii) "radiology and certain other imaging services" language that specifically excluded diagnostic nuclear medicine services.

The Proposed Rule is grossly unfair because it does not contain an exception for situations in which physicians, in reliance on CMS' promulgation of Phase I (66 Fed. Reg. 856) and Phase II (69 Fed. Reg. 16054) final rules of the Stark Law, expended substantial financial and other resources to invest in healthcare entities that provide nuclear medicine services and supplies. In both the Phase I and Phase II final rules, CMS specifically declined to include nuclear medicine services and supplies within the definition of DHS. Thus, in reliance on such previous guidance from CMS, particularly that provided in the Phase I final rule, many physicians invested in healthcare entities providing nuclear medicine services. This included committing extensive financial resources to purchase or lease equipment (e.g., nuclear cameras, treadmills, etc.) and space, hire technicians and other employees and enroll in various third-party payor plans and the Medicare program.

If the Proposed Rule were enacted in the form proposed by CMS, many physicians who, in reliance on CMS' prior guidance, invested in these existing nuclear medicine services would be required to divest their ownership or investment interest in the healthcare entity providing these services. In many cases, these health care entities, would have to be dissolved and/or liquidated; various leases and contracts would have to be terminated and many employees would have to be terminated. Needless to say, the impact of some or all these actions could be devastating on the financial resources of the physician investors and would otherwise be grossly inequitable.

Accordingly in order to prevent such manifest injustice, we urge CMS to amend the Proposed Rule by adding provisions to specifically exclude from the Stark Law a physician's ownership or investment interest in a healthcare entity which provides nuclear medicine services and supplies, if such relationship was established prior to the effective date of the Proposed Rule.

In the alternative, we ask that CMS create a new exception under the Stark Law for a physician's investment or ownership interest in a healthcare entity which provides nuclear medicine services and supplies, if the physician who refers patients to such entity directly supervises (on-site) the technicians or other personnel performing the nuclear medicine procedures on patients referred by that physician.

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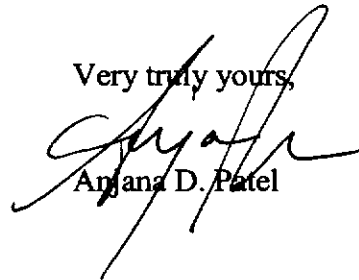
Centers for Medicare and Medicaid Services

September 28, 2005

Page 3

CMS certainly has discretion to adopt one or both of the exceptions to the Stark Law described above to remedy a grossly unjust result. We urge CMS to consider this comment letter and to accordingly propose an exception to the Stark Law as described above.

Very truly yours,

A handwritten signature in black ink, appearing to read 'Arjana D. Patel', is written over the typed name. The signature is fluid and cursive, with a large initial 'A'.

Arjana D. Patel

SEP 29 2005

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LINCARE
19387 U.S. 19 NORTH
CLEARWATER, FLORIDA 33764

TEL: 727, 530-7700
800, 284-2006
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VIA Overnight Mail

September 28, 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: Comments Submitted Regarding Proposed Rule Entitled:
Medicare Program Revisions to Payment Policies Under the
Physician Fee Schedule (FY 2006).**

Section: Inhalation Drugs and Dispensing Fee

File Code CMS-1502-P

Dear Administrator McClellan:

Lincare Holdings Inc. ("Lincare") is writing to submit comments to Proposed Rule CMS-1502-P, "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006" (the "Proposed Rule"). Unless otherwise indicated, our comments are directed at those provisions of the Proposed Rule affecting payment for respiratory medications administered through a nebulizer ("inhalation drugs") and the corresponding dispensing fee.

Lincare is one of the nation's largest providers of home respiratory equipment and related services to patients in the home setting. Our customers typically suffer from chronic obstructive pulmonary disease, commonly referred to as COPD, such as emphysema, chronic bronchitis or asthma, and require supplemental oxygen, inhalation drugs or other respiratory therapy services in order to alleviate the symptoms of respiratory disease. We currently serve over 600,000 customers throughout the United States through nearly 900 local operating centers and 22 respiratory and infusion pharmacies.

In short, we believe that CMS has an obligation to ensure that the dispensing fee paid to inhalation drug suppliers, including Lincare, adequately covers the necessary costs of supplying inhalation drugs to Medicare beneficiaries. We believe that the dispensing fees established for the 2005 calendar year do not cover the full range of costs incurred by inhalation drug suppliers and, while the changes to a number of longstanding Medicare shipping policies have provided new options to beneficiaries and the inhalation drug suppliers that serve them, these policies have not reduced suppliers' costs. Indeed, with the pending increase in fuel costs generally, and more recently stemming from the devastation caused by Hurricane Katrina and Rita, Lincare expects transportation and other related costs that depend upon transportation to *increase* in 2006.

While the Proposed Rule predicts that the coverage of metered dose inhalers under the Part D Program will shift a number of beneficiaries away from traditional nebulizer-based medications, there is simply no data available at the present time to support this assertion with an as-of-yet untested Part D program. At a minimum, until additional data is collected by CMS with regard to the conversion of beneficiaries' longstanding medication needs, Lincare believes it is unwise to gamble with Medicare beneficiaries' care by adjusting downward the dispensing fee paid to inhalation pharmacy suppliers.

A more detailed summary of our comments follows below.

Background on COPD and Treatments for this Disease

COPD is the fourth leading cause of death in the United States, following heart disease, cancer and stroke. COPD affects approximately 16 million people, causing significant morbidity from time of onset. Furthermore, it is the only major chronic disease currently increasing in prevalence and mortality. Financially, COPD patients engender a total estimated annual health care cost of more than \$40 billion in the United States alone. Sixty percent of these costs are related to direct medical expenditures (hospital services, emergency department visits, primary care visits, and medication) with the balance being indirect costs associated with morbidity and premature death. Of the total direct medical costs, pharmaceuticals average approximately 10% (\$2.3 billion). Respiratory conditions are attributed with the most frequent reason for hospitalizations, accounting for an estimated 17% of all occurrences.

Inhaled bronchodilators (such as albuterol and ipratropium) are the cornerstone of pharmacological therapy for patients with COPD. The proper use of these respiratory medications can decrease airway resistance and dynamic hyperinflation of the lungs, thereby alleviating the most disabling symptom of COPD, dyspnea, or shortness of breath. Reduction of dyspnea in COPD is the primary goal of respiratory medication therapy, and prudent use of respiratory medications can serve to improve the long-term outcome of the disease in a manner that is both cost effective and minimizes adverse effects.

Costs Incurred by Inhalation Drug Suppliers

First and foremost, we are writing to provide CMS with information on the various services that inhalation drug suppliers currently furnish Medicare beneficiaries and the associated costs of these services. In addition, we are writing to address whether any of the services being provided by inhalation drug suppliers may be covered through another part of the Medicare program, such as the physician fee schedule or the DME benefit.

To that end, specialty inhalation drug suppliers such as Lincare incur a myriad of costs that should be considered by CMS when establishing or adjusting the dispensing fee to be paid. Inhalation drug suppliers are not typical "retail" or big box pharmacy stores. While some inhalation drugs are relatively common (e.g., albuterol sulfate), other inhalation drugs must be compounded by the supplier based upon specific physician orders. Also, inhalation drug suppliers, such as Lincare, maintain professional staff including pharmacists and respiratory therapists to provide telephonic or in-person patient education and consultative services.

Services furnished by suppliers of inhalation drugs fall within seven broad categories. Those categories, and the percentage of Lincare's total costs of dispensing inhalation drugs associated with each category, are as follows: 1.) Patient Intake (17.8% of costs); 2.) Compounding, Dispensing and Pharmacy Assessment (19.0%); 3.) Delivery, Set-up and Patient Education (27.3%); 4.) Follow-up and Compliance Monitoring (11.6%); 5.) Quality Assurance, Accreditation, Licensing and Regulatory Compliance (11.0%); 6.) Medicare Billing and Compliance Requirements (9.1%); and 7.) Other Direct and Indirect Costs and Expenses (4.2%). Functionally, the majority of these costs are associated with salaries and related expenses of professional employees, including pharmacists, pharmacy technicians and respiratory therapists, non-professional customer service, support and administrative staff, facility and related expenses (centralized pharmacies and local branch locations), freight and other delivery charges, and business infrastructure costs necessary to operate as a pharmacy and support high quality patient care (MIS and communication systems, licensing and regulatory compliance, accreditation, professional liability insurance).

A more detailed summary of the components of these seven broad categories are set forth below:

Patient Intake

Local service center

- Receipt of patient demographics from ordering physicians
- Receipt of medical information from ordering physicians, including qualifying diagnoses
- Notification of central pharmacy re: medication order
- Verification of patient demographic information
- Verification of beneficiary Medicare coverage and secondary insurer information
- Verification of patient caregiver and/or next of kin information
- Establishment of patient health record in computerized MIS
- Patient assessment by respiratory therapist of clinical condition and assessment of home environment

Pharmacy

- Receipt of verbal or written order for inhalation medications
- Physician contacted to confirm medication order
- Independent database searched to verify physician UPIN number
- Patient pharmacy profile established in computerized MIS

Compounding, Dispensing and Pharmacy Assessment

Compounding

- Specialized facilities (separate from drug storage and dispensing area) and equipment required for de novo pharmacy compounding operations
- Validation and regular review of the compounding process to assure sterility and potency to beyond-use-date of the compounded inhalation medication
- Sterility and dose potency testing of compounded doses
- Specialized training and testing of pharmacists and pharmacy technicians
- Staff competency evaluation and testing
- Environmental monitoring and testing

Dispensing

- Verification of patient demographic information
- Prescription review and verification, including qualifying diagnosis for the ordered medication, dose size and strength, daily dosing frequency ("SIG") and length of therapy
- Preparation of dispensing label
- Counting and packaging unit doses of medication
- Pharmacist final verification prior to dispensing (correct patient, drug, dose, frequency (SIG), route of administration)
- Pharmacist verification and "wet ink" initialing of prescription label

Pharmacy assessment

- Obtaining information on other medications that the patient may be self-administering
- Assurance that inhalation medications are compatible with other drugs the patient is taking
- Determining other diagnoses and co-morbidities that the patient may be subject to
- Assuring that the inhalation medications are not contraindicated for those secondary diagnoses
- Making patient aware that pharmacy consulting services are available
- Providing a secure, physical space in the pharmacy for "walk in" consulting upon patient request
- Assessing side effects from the prescribed medication

Delivery, Set-up and Patient Education

Delivery

- Packaging and handling of medications for delivery
- Coordinating express and ground delivery services
- Delivery costs: third-party express and ground delivery services, including fuel surcharges
- Obtaining and documenting proof of delivery
- Arrangements for first-dose medication services

Set-up

- Completion of patient documentation including medical information release forms, HIPAA instruction and compliance forms, certification of patient and/or caregiver training and instruction
- After hours/on-call technical and clinical support

Patient education

- Instruction of patient and/or caregiver on implementation of drug treatment regimen, anticipated therapeutic outcome and potential side-effects
- Instruction of patient and/or caregiver on proper infection control in the home, safe handling and storage of medications, and emergency preparedness
- After hours/on-call capabilities for home visits for patient set-up, education or troubleshooting

Follow-up and Compliance Monitoring

Follow-up

- Assessment of patient's retained knowledge of equipment use and purpose of therapy, safety and infection control procedures
- Handling of changes in patient circumstances, including beneficiary change of address, disconnected telephone, change of secondary insurer, illness requiring hospitalization
- Handling and processing changes in physician orders and new prescriptions
- Identifying through patient interaction changes in clinical conditions and reporting same to treating physician
- Providing periodic feedback to the physician on patient compliance and progress

Compliance Monitoring

- Monthly call to verify patient's ongoing medical status and determine if any changes have occurred in medical condition and/or other medication regimen
- Verification of number of doses consumed since last dispensing and number of doses remaining
- In-home visits to patients as required or as established in plan of care

Quality Assurance, Accreditation, Licensing and Regulatory Compliance

Quality Assurance

- Employee training and periodic validation of competency
- Periodic validation of all service delivery documentation and record keeping systems
- Compliant investigation and resolution
- Compliance monitoring and auditing of company service and support systems
- Customer satisfaction evaluation and follow-up
- Facility and operating equipment maintenance
- Process improvement programs
- Medical waste management and removal

Accreditation

- Accreditation agency oversight and compliance
- Demonstration of adherence to pharmacy operations, compounding guidelines promulgated by the United States Pharmacopoeia

Licensing

- Separate pharmacy licensing and renewal for all states into which inhalation medications are dispensed
- Separate pharmacist licensing and renewal for certain states into which medications are dispensed, as required by state pharmacy regulations
- Special local water and sewage disposal licensing and permitting
- DME distributor licensing

Medicare Billing and Compliance

- Collection and verification of all required documentation

(Verbal and written order documentation, patient demographic and insurance information, physician demographics and license information, delivery tickets and proof of delivery, proof of initial and ongoing

medical necessity, medical information releases, proof of receipt of information privacy notices, proper HCPCS coding of all items dispensed and delivered)

- Invoice preparation and claim submission to Medicare, secondary insurer and the patient (co-payment and/or deductible)
- Computer systems for electronic batching and transmission of invoices
- Personal financial assessment in the event waiver of co-payment is requested or required
- Collection follow-up procedures
- Posting of payments to individual patient accounts
- After appropriate appeals and collection efforts, write off of unpaid bills as bad debt

Other Direct and Indirect Costs and Expenses

- Corporate oversight of quality and regulatory systems
- Employee benefits management
- Professional and business liability insurance
- Management information and records management systems
- Communications and networking expenses
- Facility and equipment operating costs, rent, repairs and maintenance
- Mileage/fuel reimbursement for field staff making home visits

At Lincare, we provide these services to facilitate a high level of patient care and, importantly, to manage a patient's COPD or other related illness. At Lincare, and other similarly situated inhalation drug suppliers, we are not merely filling and dispensing drugs to a patient. At Lincare, we offer critical components of the total respiratory services required by patients which go far beyond mere drug dispensing.

We would note that CMS is bound to make payment for Medicare covered items and services in a manner that approximates the costs of the supplier's furnishing of such items and services or be comparable to charges of similarly situated suppliers. Specifically, Section 1842(b)(3) of the Act requires that CMS pay a reasonable cost or charge for any item or service covered under Part B of the Medicare Program. While no "specific" statutory formula has been established regarding the "dispensing fee" calculation, the general statutory payment provisions which mandate that Medicare payments for Part B items and services be "reasonable" should be considered by CMS when calculating a dispensing fee paid to licensed pharmacies furnishing inhalation drugs.

CMS' regulations implementing the statutory mandate of Section 1842(b)(3) also make clear that Medicare must pay a reasonable charge for any covered Medicare Part B item or service and clarify that the Act affords CMS flexibility in determining what is reasonable. See, 42 C.F.R. § 405.500 et. seq. Specifically, the regulations provide that "the law allows for flexibility in the determination of reasonable charges to accommodate reimbursement to the various ways in which health services are furnished and charged for." 42 C.F.R. § 405.502(a). The regulations include certain criteria to assist CMS in determining reasonable charges.

CMS has a longstanding history of recognizing services as "related to patient care" and reimbursing providers for these services. Accordingly, CMS should consider all reasonable costs when establishing the costs of the dispensing fee to be paid to inhalation pharmacies that furnish inhalation drugs. Reimbursable patient costs can and should include, among other things, patient set-up, delivery, pharmacy staff, patient refill and related compliance activities, regulatory compliance and risk management, patient/caregiver education and training, facility costs, billing, quality assurance and drug utilization review, and accreditation and licensing activities.

Lincare further believes that the agency has failed to undertake any meaningful study of the costs associated with inhalation drug dispensing services in direct contrast to its prior commitment to the industry. Of note, the final 2005 Physician Fee Schedule expressly states that CMS is "continuing to study these services and associated cost categories as the new payment systems are implemented and we gain experience with them. We intend to revisit this issue and proceed through notice and comment rulemaking in order to establish an appropriate dispensing fee for 2006." 66 Fed. Reg. 66236, 66339 (November 15,

2004). To our knowledge, and notwithstanding the agency's express commitment to study this issue before establishing a dispensing fee in 2006, it has not done so. Instead, the Proposed Rule suggests, without a single published agency study to date that the fee is too high and simply requests that the industry supply CMS with data by September 30, 2005.

We believe that the agency has failed to fulfill its prior commitment to the industry to study this issue in depth and, more importantly, has shirked its APA notice and comment rulemaking obligations to collect meaningful data for a service that could have adverse consequences to Medicare beneficiaries. We strongly encourage CMS to collect and publish the available data in a subsequent rulemaking notice, giving all interested parties an opportunity to comment on the data before establishing a final dispensing number for 2006. This is the standard rulemaking process that CMS follows for other all other Part B RVU adjustments as well as the process employed by CMS throughout the entire Part A program.

As CMS is aware, in October, 2004, CMS released a copy of its letter to the Department of Health and Human Services commenting on a draft report by the Government Accountability Office (GAO) entitled "Medicare: Appropriate Dispensing Fee Needed for Suppliers of Inhalation Therapy Drugs." CMS noted the extreme variation that the GAO found in the costs of dispensing inhalation drugs to Medicare beneficiaries. GAO found that 2003 per patient monthly costs of dispensing these medications ranged from a low of \$7 to a high of \$204.

Further, CMS has considered an industry-sponsored study prepared by Muse & Associates entitled, "The Costs of Delivering Inhalation Drug Services to Medicare Beneficiaries." The Muse study was based on a survey of 109 pharmacies representing 2,448 branch locations and providing services to 337,348 Medicare beneficiaries (estimated by Muse to represent 61% of all Medicare inhalation drug therapy patients in the first quarter of 2004). The Muse study concluded that a dispensing fee of \$68.10 would be necessary to maintain existing levels of service to Medicare beneficiaries and provide an average operating margin of 7% to inhalation drug pharmacies. Muse also estimated that a \$68.10 dispensing fee, in combination with federally-mandated reductions in Medicare payment amounts for inhalation drugs, would result in \$4.0 billion to \$7.0 billion in program savings over a 10-year period. After reviewing the information from the GAO survey, the Muse study and other comments, CMS indicated that it believed that \$55.00 to \$64.00 per month is a reasonable range for a 2005 dispensing fee. CMS ultimately set the dispensing fee at \$57.00 in its 2005 final rule, CMS-1429-FC.

In short, the only studies that have been conducted (both GAO and industry supplied) more than support the current dispensing fee established in 2005 and, further, both suggest that there is ample data to support a *higher*, not *lower*, dispensing fee in 2006.

Of significance, Lincare estimates that the combined drug payment reductions will produce \$10.5 billion of federal budget savings over 10 years, in contrast to the initial CBO estimates of only \$4.2 billion. Accordingly, Lincare believes that the payment reductions will have a far greater adverse impact on DMEPOS suppliers than predicted by CBO or CMS—further warranting extreme caution when considering any modifications to the dispensing fee to be paid to DMEPOS suppliers. Since CMS now is approaching one years' worth of claims data under the new ASP + 6% drug payment methodology, Lincare respectfully requests that CMS re-examine the total impact of the inhalation drug cuts in comparison to original estimates and, further, that this study be performed before adjusting the dispensing fee.

Inhalation pharmacy supplier costs have not gone down in 2005, as CMS appears to suggest in its Proposed Rule. To the contrary, inhalation pharmacy suppliers have seen their dispensing costs rise in the past year, as increases in gasoline prices have adversely affected shipping costs through higher fuel surcharges by common carriers and pharmacy wage inflation has added to direct labor costs. Muse & Associates issued a memorandum to the American Association for Homecare in May, 2005, presenting a method for calculating a justifiable annual update in the dispensing fee for home respiratory services. Muse proposes the creation of a Market Basket Index (MBI) that reflects the year-to-year cost increases associated with providing dispensing services to patients. Muse constructed a customized index based on government published inflation statistics for a compilation of goods and services applied to actual industry data. Using this approach, Muse estimates that costs to provide services covered by the dispensing fee increased by

3.2% from calendar year 2003 to calendar year 2004 and suggests that this percentage be used as the increase from 2005 to 2006 as in other areas of the Medicare program that use the MBI approach for annual updates. This would result in a 2006 dispensing fee of \$58.82, *an increase of \$1.82 over the current fee level*. As a point of reference, CMS notes in the Proposed Rule that the percent change in the CPI for medical care for the 12-month period ending June 2004 was 5.1%.

We also point out that the devastation in the Gulf States as a result of Hurricanes Katrina and Rita have significantly impacted business throughout America that depend upon interstate transport to move goods, services and people back and forth. Among others, UPS has notified customers of an increase in fuel surcharge caps to 12.5% effective October 3, 2005, which when implemented will push up the average delivery cost per package by an additional 4% over increases already established for 2005. In the past year, the IRS has increased the deduction for mileage reimbursement for business travel from \$0.375 to \$0.405, an increase of 8%, and has implemented an additional 20% increase to \$0.485 per mile through the end of this year, reflecting the heavy burden of rising fuel costs on businesses. Likewise, the increase in fuel costs is widely noted as the "straw that broke the camels back" for both Delta Airlines and Northwestern Airlines—both of whom have filed for bankruptcy. While the full economic impact of Hurricanes Katrina and Rita may not be known for some time, we believe it is inappropriate at this point in time for CMS to further reduce payments to inhalation drug suppliers.

Lincare also reminds CMS that it is expected to implement additional quality standards pursuant to Section 302(a) of the Medicare Modernization Act of 2003 (MMA) which requires that the Secretary develop and implement such standards that will be applied by a recognized independent accreditation organization. CMS has just recently published for comment the proposed supplier quality guidelines pursuant to public rulemaking. The 104-page document sets forth proposed supplier business quality standards and supplier product-specific service requirements. We understand that CMS has indicated that these new quality standards will be implemented as early as April of 2006, which will further impact the costs incurred by all DMEPOS suppliers, including inhalation drug suppliers.

Lastly, we note that CMS seeks input regarding whether any of these additional services are reimbursed through any other code (or combination of codes). While the supplier standards (42 C.F.R. 424.57(c)) require that inhalation pharmacies provide these services, CMS does not, to our knowledge, separately reimburse pharmacy monitoring and compliance, delivery or quality assurance of any of the services listed above. Lincare, like other high quality inhalation suppliers, provides these services to facilitate the provision of medical care for patients with complex medical needs. Given that drugs are reimbursed at ASP + 6%, the dispensing fee is effectively the only way in which these important services will be captured and reimbursed.

In short, at a time where costs of inhalation drug suppliers are *increasing* due to a combination of unforeseen natural disasters, general increases in the CPI, and new regulatory requirements imposed by Congress, Lincare strongly opposes any efforts to decrease the current dispensing fee paid to inhalation drug suppliers. In our view, as reflected in the data listed above, we believe the current 2005 dispensing fee is too low and does not adequately cover the costs incurred by a specialty inhalation drug supplier.¹

¹ CMS reports in the Proposed Rule that at least one major chain drug store suggested that a \$25 dispensing fee would be an adequate amount in its submitted comments to last year's NPRM. We point out that CMS implemented the dispensing fee on the basis of one fee per customer per 30 or 90-day supply, not on the basis of a separate fee *with each dispense* as suggested by the commenter, which makes a comparison to the \$25 figure tenuous at best. The commenter also pointed out that the ASP methodology was not an appropriate model for reimbursement. In light of the fact that CMS proceeded to implement the ASP model, any references to comments submitted before the ASP system took effect can not be relied upon today. CMS reports in the Proposed Rule that another retail pharmacy indicated that "a dispensing fee of five to six times the prior \$5 dispensing fee was necessary to cover costs." We believe that statement to be inaccurate. Lincare believes that the referenced retail pharmacy comments suggested a fee of "5-6 times the current supplying fee" in order to cover costs. We believe the commenter was referring to the \$10 supplying fee proposed by CMS in last year's NPRM, *indicating a required dispensing fee of \$50*

Impact on 90-Day Supply Provisions

For calendar year 2005, CMS introduced a 90-day supply option for dispensing inhalation drugs—the Proposed Rule seeks comments on the impact of this new option. The 90-day supply schedule has not been widely chosen by Medicare beneficiaries or their prescribing physicians due to a number of clinical, practical and economic considerations. Monthly shipments foster more frequent patient contact and correspond better with patient compliance protocols. Frequent contact with the patient provides opportunities for ongoing education regarding their lung disease and the importance of adhering to the physician prescribed drug regimen to produce a positive health outcome. Even with frequent contact, prescription compliance is challenging among our patients, with compliance rates, as measured by monthly reorders, of approximately 50% for all active patients and 74% for long-term patients on therapy for more than a year.

In addition, there is reluctance on the part of patients to receive a 90-day supply of drugs at one time, not only due to the sheer number of medication vials that need to be stored and refrigerated, but for economic reasons as patients receive larger, quarterly invoices for co-payments due in the month of shipment as opposed to a more manageable monthly payment cycle. As CMS is well aware, many seniors are on a fixed and sometimes limited budget. While 90-day drug supply arrangements are prevalent in the private sector, patients are frequently encouraged to use such programs for maintenance medications by reduced and/or waived copayments offered by the applicable commercial payor. Medicare does not offer such a discount and, indeed, waiver of any coinsurance amounts otherwise due a provider or supplier may subject that provider to fines or penalties.

Provision of 90-day drug supplies also work better for maintenance medications with a stable and managed medical condition such as certain types of heart disease (e.g., cholesterol medications) and/or diabetes. In the COPD population, patient prescriptions (type of drug, dosage, frequency of administration) often change within a 90-day period due to side effects, dosage efficacy or other factors. These changes can occur frequently at the start of therapy as the physician adjusts treatment in accordance with the patient's pulmonary response to the therapy. Additional changes occur over time due to the progressive nature of chronic lung disease, as the patient's lung capacity diminishes.

Our experience with inhalation drug therapy patients indicates an average of 5.1 prescription changes in the initial year of drug therapy, with 32% of active patients with one to three prescription changes and 68% with four or more changes per year. Shipping on a 90-day supply schedule would likely result in an excessive supply of unused medications. Additionally, patients may terminate therapy due to death or other circumstances within a 90-day period with unused supplies of drugs on hand. CMS has not addressed how a supplier should handle drugs not used by beneficiaries who may die before running out of drugs and, at least in other areas of the Part B program, suppliers have been found at fault for items and supplies not used by beneficiaries prior to the date of death.

Lastly, the 90-day dispensing fee established in 2005 is inadequate to cover the costs of dispensing a 90-day supply. In our view, CMS' presumption that a 90-day drug quantity significantly reduces a supplier's costs is flawed. In 2005, CMS established a dispensing fee amount of \$80.00 for a 90-day supply in

to \$60. In any event, Lincare does not believe that the costs incurred by chain drug stores are comparable to those incurred by specialty inhalation pharmacy suppliers. Chain drug stores do not, typically, provide in-home delivery services, respiratory therapy support services, and/or patient education and patient compliance monitoring services (just to name a few). While chain drug stores maintain some inhalation drugs, they do not typically offer the full range of inhalation drugs, including specialty compounded drugs that are requested by many physicians on a per-patient basis. Chain drug stores typically do not employ respiratory therapists who are available to assist patients when drug complications or nebulizer questions arise. Most do not provide billing services to Medicare Part B on behalf of beneficiaries, and require payment of the 20% co-payment in cash at the point of sale.

comparison to a \$57.00 fee for a 30-day supply. Supplying larger dose quantities with less frequency would reduce certain variable costs associated with providing inhalation drug therapy, primarily in the areas of freight costs (modestly offset by larger package size and weight) and opportunities for certain staff reductions due to lower dispensing volumes and less frequent claim submission; however, a majority of the fixed costs remain the same. At a minimum, we estimate that the 90-day dispensing fee should be approximately \$130 in order to encourage pharmacies to shift to a 90-day supply. However, even at that fee, we believe that the clinical and practical considerations of shifting to a 90-day supply would limit the adoption of the practice by inhalation drug suppliers for the reasons outlined above.

Revised Time Frame for Delivery Refills

CMS seeks information on how revised guidelines regarding the time frame for delivery of refills has affected the need for overnight delivery services and the extent to which suppliers have shifted their shipping to ground services. Our mix of ground and express shipments has changed only slightly in 2005 versus a year ago. In calendar year 2004, we shipped 58.2% of our volume overnight or express and 41.8% ground. This year, our overnight and express shipments account for 57.7% of volume, with ground comprising 42.3%. One of the challenges with moving more volume to ground is the irregular ordering patterns of many patients. Many patients simply wait until they are out (or virtually out) of medication before authorizing a refill, precipitating the need for overnight delivery. Medicare rules require that the DMEPOS pharmacy not allow more than a 30-day supply of drugs on hand (assuming a 30-day supply schedule). While CMS has attempted to mitigate the impact of this by allowing shipments to occur on the 25th day of a 30-day shipment cycle thereby allowing overlapping claims for drug payments, we have experienced numerous problems with claims processing by the DMERCs for the associated dispensing fee (HCPCS code G0371). The DMERC claim processing systems were set up to process G0371 as "one unit per 30-day period." We have received tens of thousands of dispensing fee claim denials as a result, with DMERC systems unable to reconcile dispensing fees that may occur within 25 to 29 days of each other. While Lincare is pursuing an adjustment of these claims through the appeal processes, this has resulted in additional costs being incurred by Lincare personnel, considerable frustration when dealing with the DMERCs and, most importantly, a significant delay in receiving proper payment. While we are aware that CMS has instructed the DMERCs to rectify this claims processing problem, we have not seen a complete resolution of the issue.

Impact of Metered Dose Inhalers Under Part D

The Proposed Rule appears to suggest that the availability of metered dose inhalers (MDIs) under Medicare Part D will impact the need for traditional inhalation drugs furnished in connection with nebulizer devices which are currently covered under Part B. We disagree with this presumption. Over the past decade, MDIs have become the first line of therapy for the vast majority of patients with airway disease. Most clinicians with whom we work agree that nebulizers are prescribed for administering bronchodilator medications to patients with severe disease at risk for hospitalization and those incapable of using MDIs for a variety of reasons, including inadequate manual dexterity, poor inspiratory effort and mental impairment. In considering this particular aspect of respiratory medication delivery, there can be no doubt that a certain percentage of the patient population does and always will have difficulty performing effective MDI technique. For this portion of the population, of which the elderly Medicare beneficiary is likely to be a significant component, available medical literature may even suggest a contraindication for MDI delivery. It is our belief that the vast majority of physicians are aware of the potential difficulties of MDI delivery and do exercise appropriate judgment on a patient-by-patient basis. Once the need for inhalation therapy is established, the choice of delivery system should, and for all practical purposes does, reside exclusively with the prescribing physician.

Importantly, the push to "switch" beneficiaries from nebulizer-based medications to MDIs may have a significant adverse financial impact on such beneficiaries. By our estimates, beneficiary out of pocket costs in 2006 for MDIs covered under Medicare Part D *will substantially exceed the costs* for inhalation drugs already covered under Part B. Consider the following analysis of projected annual costs for a standard MDI regimen under Medicare Part D for the most commonly prescribed respiratory medications:

<u>MDI</u>	<u>Annual Drug Costs (*)</u>	<u>Patient Deductible</u>	<u>Patient Co-Payment</u>	<u>Part D Premium</u>	<u>Total Patient Cost/Yr</u>
Combivent	\$1,828.71	\$250.00	\$394.68	\$386.40	\$1,031.08
Generic Albuterol	\$83.65	\$83.65	\$0.00	\$386.40	\$470.05
Proventil	\$496.73	\$250.00	\$61.68	\$386.40	\$698.08
Atrovent	\$1,656.83	\$250.00	\$351.71	\$386.40	\$988.11
Advair 250/50	\$1,521.29	\$250.00	\$317.82	\$386.40	\$954.22

(*) *derived from sample of mail order pricing for retail pharmacies in Florida, New York and California markets as published on www.medicare.gov website under Medicare-Approved Drug Discount Cards*

() Part D Assumptions:**

Monthly premium of \$32.20

Yearly deductible of \$250.00

25% coinsurance up to \$2,250

100% coinsurance up to \$3,600

5% coinsurance beyond \$3,600

Beneficiaries under Part B Medicare enjoy the benefit of coverage for inhalation drugs delivered via a nebulizer. The annual patient out-of-pocket costs for a standard regimen of inhalation drug therapy ranges between \$273.30 and \$586.06, including co-payments and annual patient deductibles. In the absence of other considerations, Medicare beneficiaries will experience a *financial loss* in most instances if they were to abandon inhalation drug therapy under Part B in favor of MDI therapy under Part D. In addition, with the announcement by the FDA that MDIs using chlorofluorocarbon (CFC) propellants must no longer be produced, marketed or sold in the United States after December 31, 2008, it is expected that new CFC-free MDIs may be more expensive than the CFC-containing products they replace. In short, MDIs are not a fungible substitute for traditional inhalation medications and, indeed, beneficiaries' costs and consequently, the Medicare Program's costs, may actually increase with the availability of MDIs under Part D.

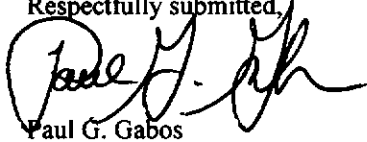
Conclusion

As CMS is well aware, the availability of inhalation medications to patients in the home setting is met by a relatively small number of niche pharmacies that are able to meet the unique distribution and patient care needs of these Medicare beneficiaries. Changes in reimbursement for inhalation drugs, first taking effect in 2004 with a reduction in the AWP-based payment rates for inhalation drugs, and in 2005 with the implementation of the ASP-based reimbursement system with dispensing fee, have had a *significant economic impact on Lincare* and other home respiratory therapy providers. We have witnessed both local and national inhalation pharmacies withdraw from the provision of inhalation drug therapy and expect continued consolidation in the market.

At Lincare alone, we estimate that there was a *\$54 million reduction* to our revenues in 2004 and project an additional reduction of approximately *\$140 million in 2005* as a result of these reimbursement changes. Lincare has worked hard to preserve a consistent level of high quality care for the home respiratory patient. Over the past year, we have found ways to become more efficient in the delivery of care to our patients through process improvements, improved productivity and, where possible, modest staff reductions. We remain concerned that CMS continues to discount the nature and type of services that an inhalation pharmacy supplier offers to Medicare beneficiaries. We are concerned that CMS' apparent efforts to reduce the dispensing fee to some arbitrary amount, perhaps as suggested by a national chain drug store (in comments submitted over a year ago, prior to the implementation of the ASP reimbursement system, and which may have been misconstrued), would significantly disrupt access to these inhalation drugs by Medicare patients suffering from COPD and other pulmonary diseases. Certainly, this was not the intent of Congress in passing legislation in 2003 to expand coverage for prescription drugs for Medicare beneficiaries.

Lincare wishes to thank CMS for the opportunity to comment on the Proposed Rule. We support CMS in its efforts to validate the payment mechanism for inhalation drugs and recognize that balancing the fiscal realities of the Medicare program against maintaining quality health care and access to needed drugs are the primary objectives of sound administration of the program. We believe that access to these critical medications and related therapies can only be preserved by maintaining the current \$57.00 dispensing fee and, indeed, we believe that the data actually supports an *increase* rather than a *decrease* to the current dispensing fee. We encourage CMS to carefully consider the data submitted by all suppliers and, if necessary, to propose a supplemental rulemaking that will outline the process to collect this data and/or we encourage CMS to engage appropriate experts to fully and finally evaluate the necessary services and costs associated with the dispensing of inhalation drugs to Medicare beneficiaries.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Paul G. Gabos", written over a circular stamp or seal.

Paul G. Gabos

SEP 29 2005

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THE AMERICAN GERIATRICS SOCIETY

THE EMPIRE STATE BUILDING, 350 FIFTH AVENUE, SUITE 801, NEW YORK, NY 10118 TEL: (212) 308-1414 FAX: (212) 832-8646

LINDA HIDDEMAN BARONDESS
Executive Vice President

September 26, 2005

The Honorable Mark McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8012
Baltimore, MD 21244-8012

Attention: CMS-1502-P

Dear Dr. McClellan:

The American Geriatrics Society (AGS), an organization of nearly 6,800 geriatrics' healthcare professionals who are specially trained in the management of care for frail, chronically ill older patients, appreciates the opportunity to provide comments on the proposed physician fee schedule for calendar year 2006.

Background

Geriatricians are physicians who are initially board certified in family practice or internal medicine; since 1994 all geriatricians have been required to complete fellowship training in geriatrics beyond their residencies. Geriatricians serve as both primary care providers and consultants to other primary care providers on the sickest patients in Medicare, serving these patients across the full care continuum. The patients of geriatricians are often medically complex, chronically ill, and frail because of a combination of physical, mental and social ailments. Geriatric medicine promotes wellness and preventive care in older persons, with emphasis on care management and coordination, frequently involving a team of health care professionals. The care management and coordination helps patients maintain functional independence in some cases and decrease the rate of decline in others, thus improving their overall quality of life.

As the percentage of the elderly population continues to grow, the demand for geriatric care continues to increase. Unfortunately, there is a severe shortage of geriatricians. Today, there are approximately 6,800 certified geriatricians in the United States. This number is expected to decline substantially as the present initial cadre of geriatricians retires just as the baby boom generation attains Medicare eligibility.

Geriatricians typically see patients with multiple chronic conditions, such as cognitive impairment, functional status limitations, diabetes and heart disease. These patients require longer visits than average Medicare patients because of their care management needs, additional frequent telephone management of chronic problems, ongoing interactions with family and other non-face to face service demands. Furthermore, the overhead expenses for some geriatric practices managing these complex patients are higher because of the need to use an interdisciplinary team (e.g., social workers, psychologists, registered dietitians), many of whom are not statutorily eligible to bill Medicare for the services they provide to the frail elderly. The need for some offices to use highly skilled staff to assist with care management between visits and to be available in the office for patient visits dramatically increases geriatricians practice expenses.

At the same time, one key reason for the low numbers of geriatricians practicing in the United States is inadequate reimbursement. Unlike most other physician specialties, geriatricians are almost entirely dependent on Medicare revenues. However, Medicare does not reimburse geriatricians adequately for services furnished to the complex frail elderly. For example, in addition to extensive pre and post visit care (e.g., telephone management, email exchange, care coordination), the work and overhead expense of which is not captured using existing office visit HCPCS codes, many patients require long office visits where they are evaluated by a physician based team. Due to the limitations of the Medicare benefit structure, many of the services provided by non-physicians (e. g., family counseling performed by a social worker) are not billable to Medicare and their expense must be borne by the practice. Furthermore, long patient visits do not allow geriatricians to increase patient volume, as many other specialties do, to offset low reimbursement.

In summary, there are no financial incentives for providers to take the time necessary to provide services to medically complex, chronically ill or frail older adults. It is often financially impossible to maintain a practice under the current system. These problems need to be addressed to effectively deal with our growing aged population. In fact, low reimbursement may result in non-geriatric primary care providers dropping the care of complex Medicare patients thereby further increasing the burden on geriatricians to provide these services. Considering the resource utilization of the frail elderly, CMS should be implementing strategies to encourage entrance into the field of geriatrics, rather than the opposite.

Neither the current nor the proposed fee schedule payment methodology addresses the items mentioned above nor does it consider the higher costs of geriatricians' practices in assigning the practice expense RVUs.

Specific Comments:

The AGS has the following specific comments on the proposed fee schedule rule for 2006.

Sustainable Growth Rate Issues.

CMS asked for specific feedback regarding the Sustainable Growth Rate (SGR) projections of a negative update for 2006 of minus 4.3 percent. Specifically, CMS highlighted several areas of increased spending growth that are largely responsible for the proposed reductions. These cuts, when considered in the context of the long-term payment inequities for geriatrics discussed above, could drive geriatrics professionals from Medicare participation and discourage medical students from entering this critically important specialty. The AGS has the following response to CMS's questions.

Sustainable Growth Rate/Part B Drugs. In the 2006 rule, CMS notes the possibility of making certain administrative adjustments in the SGR methodology, such as removing Part B drug payments from the calculation of projected and actual expenditures that is used to set spending targets. The AGS urges CMS to consider taking immediate administrative action in this area, such as removing Part B drug payments from the formula, to decrease the negative update. We believe that CMS has the statutory authority to take this action.

Sustainable Growth Rate/Care Management Fees. The AGS has long sought Medicare coverage of a care management fee for providers that see medically complex Medicare beneficiaries. We strongly believe a care management fee targeted to the care of complex elderly patients, or related payment restructuring, that encourages and compensates care coordination would ultimately eliminate fragmentation and duplication of care. For example, such a fee would enable physicians to create the infrastructure (e.g., hiring of clinical staff, use of electronic health records) needed to deliver more cost effective care. A care management fee would allow physicians to communicate more effectively, and rapidly, with other care providers, thereby minimizing duplicative care (e.g., multiple providers ordering the same diagnostic tests) and reducing unnecessary office and hospital visits.

There is a growing body of evidence that care coordination decreases the number of provider visits, hospitalizations, and nursing home placements, as well as the number of unnecessary tests, ultimately decreasing costs to Medicare.

Consistent with CMS's ongoing efforts to improve care to the frail elderly, we ask CMS to consider a physician-based demonstration project for care management services or other payment changes that looks at the creation of care management fees with the goal of improving the quality of care provided to the sickest Medicare patients while reducing costs. Such a demonstration project could be implemented in 2006 across the entire country, much as the Oncology demonstration project was implemented last year. Data

from this demonstration would be available for analysis prior to 2007 and could be used to improve the program.

Practice Expense Issues.

Practice Expense: Bottom Up Method. Instead of using the top-down approach to calculate the direct practice expense (PE) RVUs, where the aggregate costs for each specialty are scaled to match the aggregate SMS costs, CMS proposes to adopt a bottom-up method of determining the direct costs for each service. Under the proposed method, the direct costs would be determined by summing the costs of the resources - the clinical staff, equipment and supplies - typically required to provide the service. These costs would be calculated from the refined CPEP/RUC inputs in the existing PE database.

CMS expresses concern that shifts in some of the PE RVUs resulting from their proposals, when combined with an expected negative update factor for CY 2006, could cause "some measure of financial stress on medical practices." Therefore, they propose to transition the proposed PE changes over a 4-year period. The PE RVUs will be calculated on the basis of a blend of RVUs calculated using the proposed methodology described above (weighted by 25 percent during CY 2006, 50 percent during CY 2007, 75 percent during CY 2008, and 100 percent thereafter), and the current CY 2005 PE RVUs for each existing code.

The AGS supports a bottom-up approach to the calculation of direct practice expenses. We believe these changes will produce a more accurate and stable practice expense methodology for the long term. However, we are concerned that geriatrics will experience a 1% reduction under the new methodology.

Unlike other specialties, many geriatric professionals receive all or a majority of their reimbursement from Medicare, as their practice is comprised of solely Medicare beneficiaries. Thus, while we agree technically with these changes, we object in principle to a new payment methodology that penalizes geriatrics. We would like to work with CMS to alleviate the geriatrics' reduction under the new bottom up methodology, perhaps with some of the care management demonstration approaches discussed above. Furthermore, we believe the four-year transition period is a critical component of the change, as it will lessen the impact of the proposed reductions. We hope that CMS will develop a process to educate and work with interested stakeholders during the transition period to understand the new payment methodology, identify areas where the methodology causes non-intuitive decreases in payment, and work with stakeholders to identify better ways to pay for the indirect practice expenses so that inappropriate payment reductions are avoided.

Practice Expense: Eliminate the Nonphysician Work Pool: Using new survey data for the major specialties that comprise the nonphysician work pool, CMS proposes to eliminate the pool and calculate the PE RVUs for the services currently in the pool by the same methodology used for all other services. The AGS supports this change.

Contractor Pricing of Unlisted Therapy Modalities and Procedures. Currently, there are two unlisted CPT codes with assigned RVUs, CPT 97039 *Unlisted modality* and 97139 *Unlisted therapeutic procedure*. To make the pricing methodology consistent with the policy for other unlisted services, and to more appropriately match payments with the actual resources expended to deliver the services provided, CMS proposes to have the contractors value CPT codes 97039 and 97139.

The AGS is concerned about this proposed change for several reasons. First, this action may create increased administrative burdens, such as manual claim review or the need to submit documentation. Second, it is unknown whether the revaluation will achieve savings and whether any such savings could be the result of contractors setting arbitrarily low payments for these codes no matter what service is being provided. This could be the unintended result of a contractor attempting to minimize its own burden of having to review hundreds of claims manually. A third result could be slowed payments or lower payments from contractors that cause some providers to no longer provide these services at all.

For these reasons, we urge CMS to re-evaluate this change. CMS should delay this change and work with interested specialties to better understand what services are billed under these codes, whether there really is a payment or coding problem, and, if so, how to best solve the problem (e.g., by creating new codes for services billed under 97039 and 97139).

Therapy Cap. The statutory moratorium on imposition of a cap on outpatient physical therapy and speech-language pathology services, and a separate cap on occupational therapy services will expire on December 31, 2005. In this regard, the proposed rule estimates the value of the therapy caps for 2006 would be \$1,750.

The AGS has long supported the permanent repeal of a cap on outpatient physical therapy and speech-language pathology services. The imposition of the cap would deny access to needed services for needy Medicare beneficiaries. We realize this is a statutory issue. Thus, we ask that CMS work with the Congress to permanently repeal the cap on outpatient physical therapy and speech-language pathology services.

Chemotherapy Demonstration. CMS has conducted a \$300 million demonstration to improve the quality of chemotherapy services. Under this rule, CMS invited specific input on the merits of the program, asking four questions. Responses to these questions are below.

First, are there more effective measures related to quality of care, for example, measures related to the use of evidence-based guidelines? One appropriate measure in this area would address the needs of patients at the end of life. The AGS has proposed such a measure to CMS as part of our ongoing collaboration around quality indicators. The proposed measure is based on field-testing done by a joint Rand/Pfizer project entitled Assessing Care for Vulnerable Elderly Persons or ACOVE. Under the measure, all persons age 75 or older should have in their outpatient charts (1) an advance directive

indicating the patient's surrogate decision maker/life-sustaining treatment preferences, or (2) documentation of a discussion about who would be a surrogate decision maker or a search for a surrogate/preferences, or (3) indication that there is no identified surrogate/preference. We believe such a measure more effectively addresses quality of life issues in this arena.

Second, CMS asks how the experience of the oncology demonstration program be considered in the context of physician payments? The AGS found it interesting that CMS acknowledged, through this demonstration, the unique care management needs of a subset (i. e., cancer patients) of medically complex patients. We have long worked for similar recognition about the larger frail elderly patient base served by geriatricians and other primary care providers. In the future, as discussed above in the context of a care management fee targeted to the complex, frail elderly, CMS might consider addressing this significant need as a whole, rather than in a disease specific manner. Another means of accomplishing this goal would be through pay for performance measures, which if constructed properly might account for some of the care management needs of frail, elderly patients.

General Policy Comments:

The AGS has several longstanding policy concerns regarding the Medicare fee schedule; these are provided below.

The practice expense RVU undervalues the costs of providing care outside the office setting, such as the pre and post care involved in home health, hospice and nursing home visits. Many geriatricians encounter substantial costs because they provide a large portion of their care outside the office, typically in nursing home and other non-office settings. Despite the fact that such care occurs in a non-office setting, a significant amount of office expense relates to such care. For instance, hidden office costs for care provided before and after a nursing home visit include numerous follow-up phone calls with families and nursing home staff, signing certifications, travel time, and reviewing faxed information regarding the patient's health care status. The cost of providing such care is expensive and, unfortunately, these costs are not captured in either the work or practice expense RVUs for the current codes for reporting nursing home and domiciliary visits. In short, geriatricians must maintain their offices and hire staff to provide a number of care management services from their offices, despite the fact that they spend a large portion of their practice in other settings.

Typically, geriatricians experience higher office-related costs than other physicians do. As we discussed above, geriatricians incur greater overhead costs to care for their patients when compared to other physicians. For example, on average, the frail elderly need more time to dress and undress, requiring more staff and more exam rooms. Furthermore, it takes office staff considerably longer to take vital signs, counsel, and process the frail elderly. These patients also need more time to perform visit-related tasks, such as walking into or sitting down in an exam room. Due to the high incidence

of dementia and the large number of medical conditions afflicting each patient, staff spends much more time questioning patients, their family, or caregivers, as well as understanding and responding to their questions. In order to provide high quality care, geriatricians must use a larger than average number of other health care professionals.

Geriatric providers typically see fewer patients than other physicians, because of the complex nature of their patient base. The appointment slots assigned to physicians in geriatric practice are longer than that provided by other physicians. New patient appointment slots are longer than a typical internal medicine practice visit as are follow up visits. Thus, practice expenses for geriatricians are spread over a smaller number of patients.

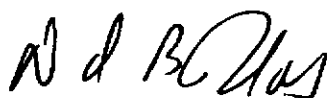
We have found that not only does low volume create reimbursement problems (as outlined above), it also places geriatricians at higher risk of being incorrectly profiled by Carriers (through comparison to an inappropriate peer group), determined to be billing outliers, and then inappropriately punished by Carriers for appropriate coding and billing for the care of complex patients.

One solution to these problems is the development of an add-on code or modifier to use for certain complex patients with selected diseases who require extra post service care. In this situation, the physician would document the care and report the add-on code or modifier for the visit. CMS would associate a specific payment with the code or modifier. The AGS requests that CMS work with it and other interested specialties to develop coding mechanisms for complex patients.

Conclusion

We hope to work with CMS on the development of the final rule. If you should have questions or comments on this letter, please contact Susan Emmer in our Washington office at (301) 320-3873.

Sincerely,

A handwritten signature in black ink, appearing to read "D. Reuben".

David Reuben, MD

President

American Geriatrics Society

SEP 29 2005

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Office of the Executive Vice President

Ralph W. Hale, MD, FACOG
Telephone: 202/863-2525
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September 27, 2005

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

Re: Medicare Program; Revision to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006; Proposed Rule (CMS-1502-P)

Dear Dr. McClellan:

The American College of Obstetricians and Gynecologists (ACOG), representing more than 49,000 physicians and partners dedicated to improving women's health, appreciates the opportunity to comment on the "Medicare Program; Revision to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006; Proposed Rule" published in the **Federal Register**, August 8, 2005. Our primary concern in reviewing any proposal for new reimbursement policies is the potential impact these policies may have on access to and quality of health care for women.

Professional Liability Insurance (PLI) Relative Value Units

This year the AMA/Specialty Society Relative Value Scale Update Committee (RUC) Professional Liability Insurance (PLI) workgroup concluded that the PLI factor for gynecologic oncologists (currently 5.63 RVUs) should be crosswalked to surgical oncology (currently 6.13 RVUs). We concur with the RUC's recommendation, since gyn-oncologists pay similar PLI premiums to other oncologists and incur similar risk. We ask that CMS reconsider the decision to reject the RUC's recommendation.

The resource-based methodology continues to underestimate the cost of PLI for physicians who perform obstetric and gynecologic services. While CMS refers to "Malpractice" RVUs, this component of the RBRVS is, in fact, based on the cost of professional liability insurance. This cost is incurred by ob/gyns whether providing obstetric services or non-surgical gynecologic services. Basing PLI RVUs on premiums paid by physicians who offer only non-surgical gynecologic care results in grossly inadequate PLI relative value units for services provided by ob-gyns. For instance, in Missouri, the average PLI premium for ob/gyns was \$103,000 in 2004 (*Medical Liability Monitor*, October 2004, Vol.29, No. 10). The PLI portion of code 59400, global obstetric care with vaginal delivery, is 4.47 RVUs. At \$38 per RVU, the PLI portion of each delivery is \$170. A physician would need to deliver over 600 babies for the PLI portion of Medicare fee schedule to cover the obstetric PLI premium in Missouri. The national average is 140 deliveries per year.

Practice Expense

ACOG commends CMS's goal of using a method of establishing indirect practice expense (PE) that is accurate and consistent across specialties.

In looking at the effect of the proposed revised "bottom up" methodology, we see that the non-facility practice expense component of obstetric and gynecologic services is consistently and significantly reduced under the proposed methodology. For instance, for CPT code 57460, biopsy of cervix w/scope, the proposed methodology will result in a non-facility PE RVU of 4.74 RVUs, down from the 5.57 PE RVU value that is listed in the proposed rule for 2006. This is a 9% reduction in PE RVU value. On the other hand, the services for which CMS is accepting supplemental surveys seem to be consistently higher. We question whether using multiple methods and sources will result in the desired accuracy and consistency.

We appreciate that CMS is attempting to make the payment system for PE more understandable and intuitive, but the explanation that is given in the proposed rule is difficult to understand. We suggest that CMS offer two or more examples of how practice expense is calculated, starting with the inputs that are used and moving through the process of developing the final PE RVUs for those CPT codes.

ACOG believes that the non-facility PE RVUs for three codes have mistakenly been removed. CPT code 59812, treatment of incomplete abortion, any trimester, completed surgically, 59840, induced abortion, by dilation and curettage, and 58841, induced abortion, by dilation and evacuation, all included non-facility RVUs in 2003. These codes went through the RUC's Practice Expense Advisory Committee (PEAC) in January 2003. ACOG submitted non-facility practice expense for these codes at that time since these procedures are often done in the office setting. We ask that CMS include the appropriate non-facility RVUs for these codes in the final rule.

The non-facility practice expense for 58356, endometrial cryoablation is listed as 6.85 RVUs in the proposed rule. CMS Manual System Pub. 100-04, Transmittal 475, Change Request 3726, February 11, 2005, amended the physician fee schedule and corrected this non-facility PE to 61.43 RVUs. We ask that the final 2006 fee schedule reflect this change.

Additionally, 57558, hysteroscopy, biopsy, is frequently performed in the office, so it should include non-facility PE RVUs reflecting the cost of the endoscopy equipment.

Additional pricing information has been requested for the following items, either in the proposed rule or in discussions with CMS staff:

A4562: Medicare payment for pessaries, HCPC code A4562, is consistently less than the cost incurred by the practice, and there are large disparities in the amount that Medicare fiscal intermediaries pay for pessaries across the country. We have included an invoice from a practice in Washington state for \$50.00 plus \$10.69 shipping, plus \$4.40 sales tax, for a total of \$65.09. Medicare reimbursement for this pessary was \$18.63. We ask that CMS address this problem to ensure that all providers are adequately reimbursed for the cost of pessaries.

EQ253: Ultrasound, echocardiography digital acquisition should be eliminated from CPT codes 76825-76828. EQ254 is the more accurate code for the equipment used.

EQ122: Fetal monitor software should be removed from 76818 and 76819. EQ249 adequately describes the equipment that is used.

SD217: Diaphragm fitting set. We have attached a quote from CooperSurgical of \$75 for a set.

Mark McClellan, MD, PhD

September 27, 2005

Page 3

SA090: Kit, moulage is used for CPT code 19396, preparation of moulage for custom breast implant, a service that is usually provided by plastic surgeons, not by ob-gyns.

SG092: A quote for 5 yds of sterile packing gauze is attached. The quotes we got were \$5.33 and \$7.00 plus shipping and tax.

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

SGR

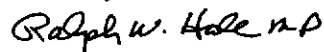
ACOG is working collaboratively with our surgical, primary care and specialty care colleagues, Congress and CMS in discussions of establishing a system that rewards quality in Medicare. However, some performance measures may involve additional office visits, lab tests, imaging exams or other physician interventions that would only exacerbate problems with the current volume formula. Because of this incompatibility, and other problems inherent in the current formula, we believe that performance based purchasing should only be instituted when the SGR formula is replaced with a formula that adequately accounts for physician costs, such as the Medicare Economic Index.

Until the SGR can be replaced, ACOG recommends that CMS remove drugs from the physician spending pool, retroactive back to the base period. CMS can then recalculate actual expenditures using the revised definition of physicians' services. Recalculating the base period actual expenditures will also, by definition, recalculate the base period allowed expenditures. We believe that revising calculations for the purpose of setting future payment amounts is permissible and appropriate.

The Medicare Fee Schedule and Resource Based Relative Value System are used not only by CMS, but are also used as benchmarks by many insurers. Declining reimbursement in the face of rising costs, especially the cost of professional liability insurance, is already forcing some physicians to stop accepting new Medicare and Medicaid patients, and will soon have serious adverse effects on women's access to care. We are hopeful that CMS will act to prevent the projected reductions in payments to physicians.

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

Sincerely,



Ralph W. Hale, MD, FACOG
Executive Vice President



Sutter Health
With You. For Life.

SEP 29 2005

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September 26, 2005

Honorable Mark B. McClellan, M.D., Ph.D.
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, D.C. 20201

REF: CMS-1502-P

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

Dear Dr. McClellan:

Sutter Health is pleased to submit the following comments on the notice of proposed rulemaking (NPRM) on the Medicare Program: Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006 (*Federal Register*, Volume 70, Number 151, Page 45764, published August 8, 2005).

Sutter Health, one of the country's leading not-for-profit networks of community health care services, serves more than twenty Northern California counties. Sutter Health provides care for more inpatients than any other network in Northern California, and is the region's largest provider of maternity services; orthopedics, pediatrics and cancer care services. Sutter Health has care centers in more than 100 Northern California communities; more than two dozen acute care hospitals; graduate medical education programs, medical research facilities, region-wide home health, hospice and occupational health networks, and long term care centers. This experience provides us with unique insights into the practical impact of Medicare's physician fee schedule.

We want to focus on your invitation for comments regarding the proposal that Santa Cruz and Sonoma Counties be removed from the Rest of California payment locality and that each would become its own payment locality.

Geographic Practice Cost Indices (GPCIs)

Sutter Health strongly supports and endorses the proposal to remove Santa Cruz and Sonoma Counties from the Rest of California payment locality and that each would be its own payment locality.

Sutter Health commends CMS for this proposal. The proposed removal of Santa Cruz and Sonoma Counties from the Rest of California payment locality effectively addresses the two largest inequities of the current payment locality policies. As Sutter Health has consistently raised in correspondence and meetings with CMS officials, these two counties have county-specific geographic adjustment factors (GAFs) that are substantially above the GAF for the Rest of California payment locality. As noted by CMS, "the county-specific GAF of Santa Cruz County is 10 percent higher than the Rest of California locality GAF. . . [and] . . . the county-specific GAF of Sonoma is 8 percent [greater]."

We are mindful that this proposal, if adopted in the final rule, while providing a higher GAF for Santa Cruz and Sonoma counties, will, as required by current law, result in a 0.1 percent (one tenth of one percentage point) reduction in the GAF for the Rest of California payment locality for 2006 compared to 2005. That is, in 2005 the Rest of California GAF is 1.012. If the proposal is adopted in the 2006 final rule, the Rest of California GAF would be 1.011. And while Santa Cruz and Sonoma counties are in Sutter Health's service areas, the Rest of California locality, as revised, will still include many counties also in Sutter Health's service area that will have inadequate and inequitable reimbursement. Nonetheless, given the gross disparities under existing policies and the very minimal adverse impact of this proposal, we feel that the proposed approach for Santa Cruz and Sonoma counties is clearly warranted and appropriate.

We applaud CMS for taking this unprecedented action in addressing California's locality problem without forcing payment reductions. We strongly recommend support of the proposal and continued cooperation for a complete resolution to the payment inequities within the GPCI. Towards that end, while we understand and appreciate the consequences, we would encourage CMS to consider the California Medical Association proposal that would more broadly address locality revision and bring more equitable payments to all counties adversely impacted in the future.

In closing, we want to again commend CMS for its sensitivity to this issue and the reasonableness of its proposal. If this proposal is adopted in the final rule it should arrest any diminution in the availability and accessibility of physicians services to Medicare beneficiaries.

Sincerely,



Patrick E. Fry
President and CEO

**Schering-Plough**

Thomas J. Sabatino, Jr.
Executive Vice President
and General Counsel

Schering-Plough Corporation
2000 Galloping Hill Road
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Telephone (908) 298-7367
Fax (908) 298-7555

September 22, 2005

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

Re: Comments on CMS-1502-9 – Payment for Covered Outpatient Drugs and Biologicals: ASP Issues

Schering-Plough Corporation appreciates the opportunity to provide comments on the proposed changes to average sales price (ASP) methodology for Medicare Part B Drugs in the Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006; Proposed Rule (42 CFR Part 414) issued August 8, 2005. Schering-Plough is a global science-based health care company with leading prescription, consumer and animal health products headquartered in Kenilworth, N.J. Through internal research and collaborations with partners, Schering-Plough's 30,000 employees discover, develop, manufacture and market advanced drug therapies to meet important medical needs.

b. Price Concessions: Wholesaler Chargebacks

CMS is proposing to change the methodology for calculating ASP under §414.804 to smooth variations in the ASP that would result from quarterly fluctuations in reporting of wholesaler chargebacks. CMS proposes to calculate the ASP as a weighted average of a "direct sales ASP" and an "indirect sales ASP." CMS has asked for comments on requiring manufacturers to calculate separate ASPs for direct and indirect sales and then calculate a total ASP as a weighted average of the two. CMS is also seeking comments on the potential effects of this approach on the ASP, as well as comments on the definitions of direct and indirect sales.

Separating "Direct" and "Indirect" Sales

Schering-Plough's preliminary calculations indicate that there would be very little difference in the ASPs for its reported products between those calculated under the existing methodology and those calculated under the proposed methodology separating direct and indirect sales. We are concerned that there would be substantial added expense and complexity involved in the proposed calculation to achieve only a small result. We believe this particular modification in the ASP calculation would be unnecessary and potentially harmful, since it would increase the potential for

unintentional calculation error and related corporate liability, and should, therefore, not be included in the final regulation.

If CMS decides to include the division of direct and indirect sales in the ASP methodology in the final rule, it should make the use of this modified calculation voluntary, so that manufacturers would only need to bear the expense of preparing the additional ASPs if they believed it would materially affect the final ASP amount. Since the purpose of the revised calculation seems to be to smooth out the effect on ASP of quarter-to-quarter fluctuations in chargebacks, manufacturers whose ASPs are not affected by these fluctuations should be free to continue using the original ASP methodology.

The small effect of the proposed methodology change for our products can be seen in the following table of sample ASPs, calculated with and without the separate calculation of indirect and direct sales ASPs.

Table 1: Effect on Schering-Plough's ASP Calculation of Separating ASP Calculations of "Indirect" and "Direct" Sales.

NDC	Product Description	ASP		Difference	
		(Filed 7/30/05)	(Ind/Dir Sales ¹)	\$	%
00085053901	Intron A Powder For	\$ 620.94	\$ 620.98	0.04	0.01
00085117701	Integrilin 2mg/ml 10	\$ 55.82	\$ 55.82	0.00	0.00
59930151701	Albuterol Sulfate In	\$ 2.07	\$ 2.10	0.03	1.41

1. Assumes that sales to suppliers are included in Direct Sales.

If CMS decides to include the division of direct and indirect sales in the ASP methodology in the final rule, it should provide greater clarity with regard to which sales are considered "direct" and which are considered "indirect." First, the proposed rule and the preamble provide different descriptions of direct and indirect sales that need to be reconciled. §414.802 of the proposed rule defines direct sales as "...sales directly from the manufacturer to the provider (for example, physician or other health care provider) or *supplier* [emphasis added]." However, the preamble to this section (b. Price Concessions: Wholesaler Chargebacks [70FR45843]) states that direct sales are "...sales directly from manufacturer to providers, such as hospitals or HMOs," while indirect sales are "sales to wholesalers and distributors and *other similar entities that sells* [sic] *to others in the distribution chain* [emphasis added]." This inconsistency raises questions about whether sales to group purchasing organizations and other entities that sell to physicians are included in direct sales (as they are "suppliers") or indirect sales (as they are resellers in the distribution chain).

Second, different ways of grouping various types of sales in the definitions will affect the final combined calculation of ASP. Limiting the definition of "direct sales" to sales to the end user results in an "indirect sales" category that includes nearly all of our business. Nearly all sales of our products covered under Medicare Part B are sales to wholesalers, group purchasing organizations and other intermediaries who resell. We have practically no sales directly to the end user (e.g. physician, hospital, or patient). Although our price concessions may be passed through to the end users, we would not

know that and would report the concessions in connection with the intermediate purchaser. Separating the two categories using these definitions would be the easiest approach for us to implement, though it would have little effect on the outcome.

Including sales to “suppliers” in direct sales, and distinguishing them from sales to other resellers would be more complicated to implement. It will also require that CMS develop more specific criteria for distinguishing “suppliers” from other entities in the supply change.

If the intent of the division of direct and indirect sales is to smooth the impact of chargebacks on ASP, then it would seem more appropriate to separately calculate ASPs for sales associated with a chargeback and those that have no chargeback. If only chargeback sales are included in the definition of “indirect sales,” a much larger proportion of our Part B drug sales would be considered “direct,” resulting in a more substantial effect on the combined ASP. Even under this definition, however, there would be only a small difference between the ASP without the division and the combined ASP with the division.

Table 2: Effect of Different Definitions of “Direct” Sales on Schering-Plough’s Recalculation of ASP.

NDC	Product Description	ASP (Filed 7/30/05)	Recalculated ASP		
			Phys/Hosp Only ¹	Phys/Hosp/ Supplier ²	Non- Charge- back Only ³
00085053901	Intron A Powder For	\$ 620.94	\$ 620.73	\$ 620.98	\$ 619.94
00085117701	Integrilin 2mg/ml 10	\$ 55.82	\$ 55.82	\$ 55.82	\$ 56.88
59930151701	Albuterol Sulfate In	\$ 2.07	\$ 2.10	\$ 2.10	\$ 2.16

1. Only sales directly to end users (e.g. physicians, hospitals) are included in Direct Sales.

2. Sales to end users plus sales to “suppliers” to end users are included in Direct Sales.

3. Only non-chargeback sales are Direct Sales. All sales with chargebacks are considered Indirect Sales.

Addressing Timing Issues with Excluded Sales

If CMS is exploring changes to the ASP methodology to reduce quarter-to-quarter variability in ASP, then Schering-Plough proposes that CMS modify the ASP calculation to adjust for timing problems related to sales to the government excluded class of trade. This is our most significant source of variability and a matter that we have raised with CMS in all of our ASP submissions and on which we continue to seek guidance.

Schering-Plough adopts the ratio methodology for lagged price concessions as proposed by PhRMA to CMS in comments to the CMS interim final rule on June 7, 2004, and as subsequently adopted by CMS. The ratio method smoothes ASP results by comparing the average ratio between historical price concessions and historical sales revenue, rather than simply using a 12-month average to estimate price concessions.

The ratio methodology addresses price concessions, but it does not solve problems with timing of chargebacks on excluded and non-excluded sales that create variability in the ASP. The problem is that sales to wholesalers may result in a later resale to an excluded government class of trade, and a chargeback from that sale. The sale to the wholesaler cannot be identified as an excluded government sale until the manufacturer receives the chargeback request in a later quarter. Since government sales are uneven from quarter-to-quarter, the volume of "excluded" chargebacks in a subsequent quarter may not match the volume of "excluded" sales in that quarter. As a result, a manufacturer backs out the government sale from the total sales number from one quarter, but the true sale that the manufacturer should back out is the original sale to the wholesaler in a different quarter. Subtracting these sales from a quarter in which no corresponding sale to a wholesaler occurred will automatically result in fluctuations in ASP, either positively or negatively. This timing issue will always result in fluctuations in ASP from quarter-to-quarter.

This issue may result in unforeseen results when an NDC has lower gross sales but very high indirect government exclusions in one quarter. This may occur, for instance, in quarters when the VA or DOD is purchasing product in large quantities at the beginning of a new contract. If the ratio methodology for price concessions is used as currently written, but the timing of government exclusions is not addressed, then a negative ASP sales number will result. We suggest, therefore, that CMS modify the ratio method to account for the timing of government exclusions.

Conclusion

In conclusion, Schering-Plough is successfully implementing its ASP reporting responsibilities without significant difficulty. CMS's proposal to modify the ASP methodology to separately calculate ASPs for "direct" and "indirect" sales would add substantial cost and complexity to Schering-Plough's calculations. It would increase the potential for calculation error and, thus, the liability for filing false reports. This change would be meaningless for Schering-Plough, since nearly all of its sales for Part B drugs would be considered "indirect" sales under most definitions.

If CMS proceeds to make the division of "direct" and "indirect" sales final, Schering-Plough requests that it provide much greater clarification on the how price concessions are allocated to these two categories.

Schering-Plough would prefer to receive guidance from CMS on how to resolve timing problems related to backing excluded government sales out of total sales.

Sincerely,



Thomas J. Sabatino, Jr.



AMERICAN
PSYCHOLOGICAL
ASSOCIATION

Practice Directorate

September 28, 2005

Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
200 Independence Ave. SW
Washington, DC 20201

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

Dear Dr. McClellan:

The American Psychological Association (APA) is pleased to offer comments on the proposed Medicare Fee Schedule for 2006. APA is the professional organization representing more than 150,000 members and associates engaged in the practice, research and teaching of psychology.

APA commends CMS for its continuing efforts to refine the resource-based relative value scale (RBRVS), and for its history of working with the health care community through each step of the refinement process. CMS' participation with the health care community through the RVS Update Committee (RUC) and the Practice Expense Advisory Committee (PEAC), along with its on-going efforts to gather data on the actual cost of liability insurance, have greatly benefited the Medicare program.

Practice Expense

In the past few years, CMS has worked closely with the specialty societies on nearly all aspects of the practice expense portion of the fee schedule. APA has worked with the Practice Expense Advisory Committee (PEAC) to refine each mental health CPT code's direct practice costs. We believe that the PEAC has done outstanding work and that the refinements approved by the PEAC may allow CMS to utilize a more simplified practice expense methodology. We think that simplifying the methodology will make practice expense a more understandable factor of the RBRVS.

We have one primary concern with the new methodology. That is the NPRM's lack of clarity regarding the impacts that the change in methodology will have on each health care specialty. Specifically, CMS did not publish comprehensive impact tables showing the affect that this will have during each year of the phase-in and the cumulative effect on

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payments to each specialty. As explained below, this information is needed because it would assist our members in planning the future costs of maintaining a practice.

Since 2000, CMS has been reliable in its efforts to craft short and long-term impact tables per specialty. Oftentimes, CMS has provided impact tables related to each proposed shift in methodology, and then one comprehensive table showing all the effects of the combined changes. This data was crucial in our being able to identify errors in CMS assumptions. In addition, we could assist our membership as they planned for the moderate-term effects of CMS payment policies on their practice finances.

Because we cannot thoroughly assess the efficacy of the new practice expense methodology without this data, we request that CMS delay implementing this policy change for one year to allow us to work with CMS in evaluating the new approach.

Zero Work-Pool

We understand that CMS accepted surveys from the major specialties affected by the zero-work value practice expense pool. The surveys showed that the practice expense/hour rates for those specialties are higher than the rates that were provided in the original data. We assume that applying the new practice expense values that result from removing the remaining codes from the zero-work value and incorporating the increased practice expense per hour will cause a shift in the total pool of practice expense relative values (PERVUs). As with the proposed change to the practice expense methodology, CMS did not publish in the proposed rule a table showing the impact that the elimination of the zero-work value pool of PERVUs will have across all specialties.

Recommendations concerning impact tables

We strongly recommend that CMS publish impact tables across specialties in the final rule of the 2006 Medicare Fee Schedule so that health care professionals can anticipate the future costs of providing services to Medicare beneficiaries. The impact tables should show the following payment changes:

Payment change incorporating only the shift in PERVUs resulting from the elimination of the zero-work value pool;

Payment changes over 4 years, incorporating the proposed practice methodology and using 2005 conversion factor;

Payment changes over 4 years incorporating the proposed practice expense methodology and using the proposed conversion factor for 2006 (or an alternative conversion factor should one be crafted between the date of this letter and the publication of the final rule);

Payment changes over 4 years incorporating all of the proposed revisions.

The Tobacco Cessation Counseling Benefit

Included in the proposed rule on the 2006 Medicare Fee Schedule are the values for the new tobacco cessation counseling benefit. We commend CMS for recognizing the importance of helping beneficiaries to eliminate the use of tobacco products. However, as currently designed the benefit is severely lacking and may not accomplish its goal of reducing tobacco use among the elderly and disabled.

The benefit allows for sessions with one of two durations: brief (3 to 10 minutes) and intensive (longer than 10 minutes). Payment for the brief session is set at \$12.89 while payment for the intensive session is \$25.39, regardless of how long the intensive session lasts. There is no indication how CMS came up with these reimbursement rates.

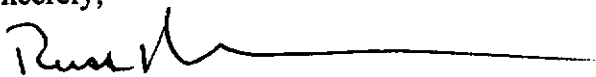
We believe the decision by CMS not to designate extended sessions (e.g., 30 or 60 minutes) at a higher reimbursement rate fails to take into account the need many beneficiaries have for more in-depth counseling to increase their chances of quitting such a life-threatening habit. It was noted in the CMS decision memorandum on the smoking and tobacco use cessation counseling benefit (CAG-00241N) that the Public Health Service 2000 Guideline showed an abstinence rate of 26.5% for 31 to 90 minutes cessation counseling sessions. This is considerably more than the 14.4% abstinence rate for 1 to 3 minute sessions and the 18.8% rate for 4 to 30 minute sessions. We are puzzled why CMS did not allow for the option of longer sessions given the increased potential of achieving the goal of tobacco cessation that longer counseling sessions afford.

Recommendations regarding the tobacco cessation counseling benefit

We recommend that CMS expand the tobacco cessation counseling benefit to allow for 30-minute and 60-minute sessions. While some beneficiaries may only need brief counseling, for others 10 minutes or less will not be enough. Providing in-depth interventions should result in more beneficiaries ceasing to use tobacco, thus improving their current health and reducing the odds of incurring tobacco-related health problems in the future. Because tobacco cessation counseling utilizes behavioral interventions to address a physical health problem, we believe the reimbursement rate for the extended sessions should equal the amount paid for a health and behavior intervention of similar duration under CPT code 96152. At that rate a 30-minute tobacco cessation counseling session should be valued at \$47.75 and a 60-minute session valued at \$95.50.

We thank you for this opportunity to provide comments on the proposed 2006 Medicare fee schedule. For additional information or assistance, please contact our Federal Regulatory Affairs Officer, Kimberley Moore, at 202-336-5889.

Sincerely,



Russ Newman, Ph.D., J.D.
Executive Director for Professional Practice



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September 28, 2005

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

**RE: CMS-1502-P – Revisions to Payment Policies under the
Physician Fee Schedule for Calendar Year 2006**

Dear Dr. McClellan:

On behalf of the American Association for Respiratory Care (AARC), I am pleased to submit comments on the proposed rule published in the *Federal Register* on August 8, 2005, to revise payment policies under the Physician Fee Schedule for Calendar Year (CY) 2006. The AARC is the national professional association representing over 37,000 respiratory therapists who treat high-risk patients with chronic conditions such as asthma and chronic obstructive pulmonary disease (COPD), including emphysema and chronic bronchitis. Our comments are outlined below.

Inhalation Drugs and Dispensing Fees

Metered-Dose Inhalers (MDIs) and Dry Powder Inhalers (DPIs)

- **CMS must recognize the importance of patient education and training in the effective use of Metered-Dose Inhalers (MDIs) and Dry Powder Inhalers (DPIs) in managing the costs of aerosol drug therapies as part of the new Medicare Part D coverage.**

When the new Medicare Part D benefit becomes effective January 1, 2006, coverage will be available for the first time for both inhalation drugs administered via nebulizers, as well as aerosol drug therapies such as Metered-Dose Inhalers (MDIs) and Dry Powder Inhalers (DPIs). CMS expects both drug delivery systems will play an important role in the Medicare program for years to come. The AARC is concerned, however, that too much focus on the appropriate dispensing fee for inhalation drugs could ignore critical

patient training and assessment components essential to effective aerosol therapy once MDIs and DPIs are covered by Medicare.

The importance of patient education and training was recognized as a cost effective measure in treating patients with diabetes when Section 4105 of the Balanced Budget Act of 1997 required Medicare to cover diabetes self-management training services (DSMT) furnished by a certified provider who met certain quality standards. The Act also included coverage of follow-up training under the DSMT program subsequent to the initial training after a certain time period. While we recognize that patient education and training in this instance is not the same as the DSMT program established for diabetics, the AARC believes a compelling argument can be made that patient education and training is equally important in the proper use of MDIs and DPIs and that an analogy can be drawn between the two.

Metered-dose inhalers (MDIs) are the most common devices worldwide for therapeutic aerosol delivery and are the most common form of medication next to the pill or tablet.¹ However, it is important for CMS to realize that a prescription for MDI/DPI use is not as simple as a prescription for a pill or tablet.

Unlike most forms of drug therapy, the success of aerosol therapy requires that the patient master a complex technique to inhale the drug deeply into the airways. Misuse of an MDI/DPI can severely compromise a patient's health and physical condition. Not only can a lack of instruction or even poor instruction compromise the patient's health, but also improperly administered MDIs/DPIs can waste medication, which can prove costly to the Medicare program.

Since elderly Medicare patients may have cognitive or physical constraints that may limit their ability to properly use the MDI/DPI, special training or education and follow-up in a physician's office, clinic, or other outpatient setting is essential to ensure that the patient is using the MDI/DPI properly.

The importance of patient education cannot be stressed enough given the warning issued by the Food and Drug Administration (FDA) in April 2005 about the incorrect use and inadvertent oral administration of two asthma drugs, Foradil Aerolizer and Spiriva HandiHaler. These two drugs are capsules that resemble those typically taken orally, although they are to be administered only via an inhaler. The packages, supplied in unit dose form, did not prominently display "NOT FOR ORAL USE" and the FDA received as many as 30 cases concerning the inadvertent oral administration of these drugs. While most cases did not result in adverse events, one case report described difficulty breathing after injecting the drug orally, and another indicated hospitalization was necessary due to a chronic obstructive pulmonary disease exacerbation. The FDA is working with the manufacturers on labeling and packaging changes to minimize misuse, but the FDA has also issued suggestions that healthcare providers who administer and dispense these drugs should be counseled on the potential for confusion with oral products, and that patients should also be counseled about the potential confusion and ways to avoid it.

¹ Fink JB. Metered-Dose Inhalers, Dry Powder Inhalers, and Transitions. *Respiratory Care* 2000;45(6):623

- **Effective techniques differ between MDIs and DPIs**

The techniques used to administer MDIs and DPIs effectively differ between the two types of devices. An MDI is most effective when it is shaken before use and the patient uses a slow inspiratory flow rate for expiratory reserve volume, a breath hold, and a spacing device.² If an MDI is not used for more than a week, the inhaler should be primed before use to ensure that the dosing chamber is full.³

To administer a DPI, the patient must first activate the device to load the dose of medication. In order to prevent losing the medication, the DPI should be held level and the patient should not exhale into the device.⁴ A spacing device is not required because there is no need for coordination between actuation and inhalation. The patient then rapidly inhales. DPIs rely on the inspiratory flow rate to disperse the powder. A faster rate will generate an aerosol with finer particles, resulting in improved lung deposition.⁵

Patients need to know (and be able to demonstrate) the proper use of each MDI and DPI prescribed.⁶ While MDIs and DPIs are simple to operate, each has technical limitations that can limit effectiveness. Fink et al.,⁷ note that common problems with MDIs include improperly coordinating actuation with the beginning of inspiration thereby reducing the amount of medication inhaled; the occurrence of actuation near end-inspiration can reduce the inhaled dose, failure to shake prior to the first actuation after a period of hours or days may increase dose variability and consistency across the life of the MDI, and reducing the canister temperature to below 15°C substantially reduces the emitted dose.

The Fink et al.⁸ study also identifies some common problems associated with DPI use. For example, when using a DPI, the patient's inspiratory effort is key to the mechanical energy that releases the drug from the inhaler. Failure to produce the minimum inspiratory flow for a specific DPI substantially reduces the inhaled dose, as does exhalation into a DPI. Also, shaking a DPI can shake the dose out of the inhalation flow path, drastically reducing the inhaled dose. Failure to keep the flow path open eliminates the ability to inhale through the device.⁹

- **Clinical studies and scientific literature focus on common errors in MDI/DPI use and stress the importance of patient education and training in proper techniques to obtain optimal drug delivery.**

² Shangle, et al. Aerosol Delivery Devices: New Ways to Deliver Inhaled Medications. AARC Times 1999:17-22

³ Ibid.

⁴ Ibid.

⁵ Pauwels, R, et al. Airway deposition and airway effects of anti-asthma drugs delivered from metered-dose inhalers. European Respiratory Journal 1997;10(9):2127-2138.

⁶ Fink, JB, Rubin MEng, BK. Problem With Inhaler Use: A Call for Improved Clinician and Patient Education. Respiratory Care 2005;50(10):1360-1375.

⁷ Ibid.

⁸ Ibid.

⁹ Ibid.

There are numerous clinical studies and scientific literature that stress the importance of patient education in learning the proper techniques of MDIs/DPIs. Good patient instruction can take between 10-30 minutes and should include demonstration, practice, and confirmation of patient performance.¹⁰ It has been shown that repeated instruction improves performance¹¹ and follow-up instruction is a necessary element to ensure that patients continue to practice proper techniques. Although previous studies suggested that verbal instruction is insufficient and mechanical aids may be necessary, a controlled, randomized trial of two instruction methods conducted by De Blaquiére, et al, indicated that verbal instruction alone is as effective as verbal instruction supplemented with a visual aid in teaching the correct use of MDIs.¹²

In a study of 101 elderly patients,¹³ it was noted that common errors in using MDIs included:

- Not starting inhalation from functional residual capacity
- Not activating inhaler at the start of inspiration
- Not inhaling slowly
- Not holding breath after inhalation
- Actuating canister twice during same inhalation

The study reported that of the 101 elderly patients, 45% actuated the MDI after the end of inspiration, and 41% had breath-hold less than 5 seconds. Also, 30% had too rapid an inspiration, and 25% actuated the canister before inspiration.¹⁴

In another smaller study, observation of 12 elderly patients with poor MDI technique revealed that 100% made no attempt at breath-hold, and 58% did not continue inhalation after actuation of the canister.¹⁵

Important factors to be considered in the proper use of MDIs was outlined in a June 2000 Consensus Statement on Aerosols and Delivery Devices.¹⁶

"Patient and health care worker education on proper use of delivery systems is important. Aerosol therapy should not be initiated without instructing the patient in the proper use of the device, proper handling, cleaning/disinfection, the expected effects and potential adverse effects of the drug, and the importance of patient adherence to a therapeutic regimen. Pressurized Metered-Dose Inhaler (pMDI) efficacy is particularly user-dependent and thus these educational issues

¹⁰ Fink, JB. Metered-Dose Inhalers, Dry Powder Inhalers, and Transitions. *Respiratory Care* 2000;45(6):623-635

¹¹ De Blaquiére P, et al. Use and misuse of metered-dose inhalers by patients with chronic lung disease: a controlled randomized trial of two instruction methods. *Am Rev Respir Dis* 1989;140(4):910-916.

¹² Ibid.

¹³ Daniels S, Meuleman J. Importance of Assessment of Metered-Dose Inhaler Technique in the Elderly. *JAGS* 1994;42(1):82-84.

¹⁴ Ibid.

¹⁵ Allen SC, Prior A. What determines whether an elderly patient can use a metered dose inhaler correctly? *Br J Dis Chest* 1986;80:45-49.

¹⁶ "Consensus Statement: Aerosols and Delivery Devices." June 2000. Vol.45. No.6. Special Issue Consensus Conference on Aerosols and Delivery Devices Conference.

are particularly important with these devices (Table 2). Because patient education is so critical to achieving the goals of aerosol therapy, it should be properly reimbursed."

Table 2. Factors Important in Patient Instruction in the Use of pMDIs	
pMDI issues	Shaking canister Priming new or infrequently used inhaler Removal of cap before treatment Holding canister upright Assessing when inhaler is empty
Holding chamber issues	Preparation of device (remove cap, attach inhaler) Single actuation into chamber Priming/cleaning issues Immediate inhalation after loading device
Patient issues	Breathing pattern (inspiratory flow, breath- hold) Time between each actuation Use only as prescribed
pMDI = pressurized metered-dose inhaler	

- **Health care professionals providing patient training and education in the use of nebulizers, MDIs and DPIs must be qualified by virtue of their education, training and competency testing.**

The AARC believes that individuals permitted to provide patient training and education in the use of nebulizers, MDIs and DPIs must be qualified by virtue of their education, training and competency testing. Without properly trained personnel to correctly train patients, Medicare will continue to experience larger expenditures for pulmonary patients because of higher consumption of health resources than is necessary.

Lack of proper techniques by health care professionals as well as patients has also been well documented. Kelling et al¹⁷ showed that only 40 percent of physicians correctly performed four or more of seven steps comprising a recommended inhalation maneuver. However, it is often not the physician who instructs the patient, but respiratory therapists and nurses who are involved in inpatient and outpatient education programs.

Guidry, et al¹⁸ conducted a study designed to compare the knowledge of MDI use among hospital personnel involved in treating and educating patients with obstructive airways disease. Of the findings, 95 percent of the respiratory therapists performed at least four of seven steps correctly, compared with 65 percent of house staff physicians, 57 percent of nurses, and 50 percent of non-pulmonary faculty. Most participants followed package insert instructions, while only 18 percent followed recent recommendations for proper

¹⁷ Kelling JS, Smith RL, Altone MD. Physician knowledge in the use of canister nebulizers. Chest 1987;91(suppl):58S-64S.

¹⁸ Guidry, GG, et al. Incorrect Use of Metered Dose Inhalers by Medical Personnel. Chest 1992;101:31-33.

MDI use. The study concluded that 1) medical personnel should have additional instructions in proper MDI usage, and 2) respiratory therapists and nurses can play a prominent role in instructing patients in their proper use. Because of the time required for initial instruction and repeated reinforcement, it is likely that personnel other than physicians often instruct patients in the outpatient setting.¹⁹ The Guidry, et al²⁰ study found that “respiratory therapists and nurses are at least as qualified as physicians to perform the important task of patient education in proper MDI use.”

The Consensus Statement on Aerosols and Delivery Devices²¹ also noted that, “The available evidence suggests that respiratory therapists can provide value in this area [patient education]. Respiratory therapists can also implement protocols to increase the conversion of nebulizers to pMDI and DPI delivery systems and to reduce the misallocation of aerosol therapy.”

It is certainly desirable for health care professionals to invest in the time and expense to acquire the knowledge and skills necessary to evaluate the patient, determine the therapy modality, and select the most effective drug delivery system. According to published, peer-reviewed scientific evidence, however, this has not happened to the extent that all patients requiring aerosol therapy have access to appropriate training in order to gain optimum benefit from these drugs.

Respiratory therapists are trained to assess the patient's condition. In addition to a defined scope of practice, respiratory therapists utilize clinical protocols or practice guidelines that improve the quality of care and significantly reduce the misallocation of respiratory therapy services.

The AARC's Clinical Practice Guidelines for Selection of Aerosol Delivery Devices include the following requirements for appropriate personnel:

- 10.2 Personnel;
- 10.2.1 Knowledge and skills at several levels are required to fully utilize and apply these devices;
- 10.2.1.1. Level II personnel provide initial assessments and care of the unstable patient;
- 10.2.1.1.1. Utilizing proper technique for administration of MDI, accessory device, dry power inhaler, SVN, LVN, USN; and SVN via IPPB;
- 10.2.1.1.2 Practicing proper use, maintenance, and cleaning of equipment
- 10.2.1.1.3 Encouraging effective breathing patterns and coughing techniques;
- 10.2.1.1.4 Modifying technique in response to adverse reactions;
- 10.2.1.1.5 Modifying dosages and/or frequency as prescribed in response to severity of symptoms;

¹⁹ Daniels S, Meuleman J. Importance of Assessment of Metered-Dose Inhaler Technique in the Elderly. JAGS 1994;42(1):82-84.

²⁰ Guidry, GG, et al. Incorrect Use of Metered Dose Inhalers by Medical Personnel. Chest 1992;101:31-33.

²¹ “Consensus Statement: Aerosols and Delivery Devices.” June 2000. Vol.45. No.6. Special Issue Consensus Conference on Aerosols and Delivery Devices Conference.

- 102.1.1.6 Assessing patient condition and response to therapy;
- 102.1.1.7 Performing auscultation and inspection and taking vital signs;
- 102.1.1.8 Performing peak expiratory flow rate, spirometry, or ventilatory mechanics;
- 102.1.1.9 Recognizing and responding to therapeutic and adverse responses and complications of medication and/or procedure;
- 102.1.1.10 Understanding and complying with Universal Precautions.

Effective techniques are critical to the proper use of aerosol drug therapies. The AARC would be glad to work with CMS to develop proper training protocols for educating patients in correct MDI and DPI use.

- **The AARC recommends that CMS include, as a separate payment, an education component paid to the physician when Metered Dose Inhalers (MDIs) and Dry Powdered Inhalers (DPIs) are prescribed.**

The AARC recommends that CMS include, as a separate payment, an education component paid to the physician when MDIs and DPIs are prescribed. Educating patients on the proper use of these devices and the precautions required for the various medications used in them are essential to insure the efficacy of the therapy and the safety of the patient. The clinicians' role in patient education extends beyond device selection to include teaching with demonstration and evaluation of patient's return demonstration, to following patient's skill at subsequent visits.²²

The AARC believes there are two billing alternatives for the education and training of the patient service. A separate HCPCS code (in the "G" series) defining the education and training of the patient for the use of a MDI or DPI would be one alternative. This code could be defined with the time generally spent with the typical patient in education and training. A second alternative, and one that would be the easiest to implement, would be to suggest the use of an evaluation and management code representing the time spent on education and training for the typical patient.

Given the range of time it takes for proper instruction as indicated elsewhere in our comments, the AARC believes an evaluation and management code 99213, which physicians typically spend 15 minutes on face-to-face contact with the patient and/or family, would be an appropriate code for physicians to bill their services when prescribing MDIs and DPIs. Since repeated follow-up is necessary to insure continued proper use of these medications, we believe the evaluation and management code 99211 would be appropriate for follow-up visits, where the presence of a physician may not be required and the time spent performing or supervising the services is typically 5 minutes.

Patients trained and educated on the correct treatment regimen using the appropriate drug delivery system with the correct technique can improve the cost effectiveness of aerosol and inhalation drug therapies overall. A reasonable education fee will reduce costs in the

²² Fink, JB, Rubin MEngr, BK. Problem With Inhaler Use: A Call for Improved Clinician and Patient Education. Respiratory Care 2005;50(10):1360-1375.

long run if family practice physicians are able to utilize the expertise of respiratory therapists to assist in the evaluation and training of their patients.

Dispensing Fee

- **The AARC recommends that CMS set the CY 2006 monthly dispensing fee amount for inhalation drug therapy services at \$68.10, adjusted for inflation.**

In its proposed rule, CMS is seeking comments on the costs and services that fall appropriately within the scope of providing inhalation drug therapy services to Medicare beneficiaries in order to establish a dispensing fee amount for CY 2006. CMS notes that the new amount is likely to be less than the current \$57 per month transitional fee in CY 2005. This presumed reduction is based in part on a study provided by GAO that reported a wide range of services and costs provided by inhalation drug suppliers and two retail pharmacies that indicated a fee of \$25 was adequate to cover costs.

The AARC opposes any reduction to the respiratory medication dispensing fee. As stated in previous AARC comments on Medicare respiratory drug payments, there are numerous costs associated with the dispensing and management of Medicare patients receiving respiratory medications from Part B pharmacy providers. Common operational expenses include but are not limited to pharmacy general and administrative costs, dispensing, patient-management, compounding and delivery. Despite the drastic reduction in drug payment, the cost of doing business has at best remained the same, but most likely has increased with inflation. Without an appropriate dispensing fee, the current ASP payment methodology falls dramatically short of covering the cost of dispensing and managing Medicare patients.

The AARC is not unaware that physicians may have been inclined to prescribe inhalation drugs for their patients via the nebulizer rather than an MDI, because respiratory therapy drugs delivered via a nebulizer were covered and MDIs were not. Because there are unspecified numbers of pulmonary patients who cannot adequately use an MDI, or are too ill to do so, there are sound clinical reasons for Medicare to continue covering adequately the use of the nebulizer. Elderly patients may have physical conditions, such as arthritis, or peripheral neuropathy as a result of diabetes, or a B12 deficiency that would preclude them using an MDI.

As we stated in our comments last year, the use of nebulizers is medically necessary in a significant number of Medicare patients for many reasons including:

- Frailty
- Arthritis
- Sight impairment
- Compromised mental capacity
- Exacerbation of a chronic condition such as Chronic Obstructive Pulmonary Disease (COPD)

- Inability to understand how to effectively use MDIs
- Inadequate hand/breath coordination
- Inadequate inspiratory force and volume

While inhalation therapy patients may use MDIs at the outset of their treatment during mild stages of COPD, most available studies conclude that patients whose conditions worsen over time do not receive the symptomatic relief from MDIs that is provided through nebulized medications. Further, current clinical practice and previous Medicare policy require physicians to attest to the medical necessity for a nebulizer versus an MDI.

We cannot emphasize strongly enough that an adequate dispensing fee is critical so that physicians will not feel pressured to prescribe an MDI when a nebulizer is clinically more appropriate. The AARC believes this situation could happen if homecare pharmacies drop out of the inhalation drug business because the dispensing fee has been cut so significantly that they will no longer be able to sustain that end of the business.

The 2004 study conducted for the American Association of Homecare (AAH) on "The Costs of Delivering Inhalation Drug Services to Medicare Beneficiaries,"²³ upon which CMS based its current dispensing fee amount, emphasized that the 2005 Medicare reimbursement formula based on average sale price (ASP) would under-reimburse the actual cost of providing two common respiratory medications by \$68.10 per monthly supply. The study surveyed 109 pharmacies in the homecare pharmacy industry and involved inhalation drug therapy services to 337,348 Medicare beneficiaries per month, who were estimated to be 61 percent of all Medicare inhalation drug therapy patients in the first quarter of 2004. This study is the most comprehensive study to date of the types of services and associated costs that are required to treat Medicare beneficiaries who require nebulizer medications and is representative of the standard of care in home inhalation therapy today.

GAO surveyed 12 inhalation therapy companies, which CMS notes represents 42 percent of the market. While the results may indicate a variation in costs, a number of pharmacies estimated that costs could exceed \$100 per month. Last, the amount of time it takes a homecare pharmacy each month to support Medicare beneficiaries on inhalation drug therapy in their homes is vastly different than the services provided by a typical retail pharmacy. For CMS to compare retail pharmacies' costs and services to those provided by homecare pharmacies lacks a full understanding of the current community standard and should not be the basis to lower the dispensing fee amount for CY 2006.

To date, no new studies have been published regarding medication dispensing fees, nor has any new financial data been presented that would displace the findings presented by the AAH study. Reducing the fee in the absence of data seems arbitrary and inappropriate at this time. Therefore, the AARC recommends that CMS continue to use the AAH findings as the standard of care and establish a monthly CY 2006 dispensing fee amount of \$68.10, adjusted for inflation.

²³ "The Costs of Delivering Inhalation Drug Services to Medicare Beneficiaries." August 2005. Muse & Associates, Washington, DC.

The AARC appreciates the opportunity to comment on CMS' revisions to the Physician's Fee Schedule for CY 2006. If we can provide additional information or assistance, please contact Cheryl West, Director of State Government Affairs at 972-243-2272, or at west@aarcc.org.

Sincerely,

A handwritten signature in black ink, appearing to read "John D. Hiser", with a long horizontal flourish extending to the right.

John D. Hiser, MEd, RRT, FAARC
President

SEP 29 2005

Mission •
to prevent and cure diabetes
and to improve the lives of all
people affected by diabetes.

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Cure • Care • Commitment.

September 27, 2005

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

Comment Regarding Proposed Rule CMS-1502-P:

This letter is in comment to the CMS Proposed Rule, Regulation CMS-1502-P, Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006. Specifically, the American Diabetes Association disputes the rationale used to exclude diabetes self-management training (DSMT) (as described by HCPCS codes G0108 and G0109) from the list of Medicare telehealth services. As one of the two deemed certifying bodies of DSMT by CMS, the Association urges that DSMT be reimbursable as a telehealth service.

There are currently over 1900 DSMT programs (delivering services at over 2800 sites) recognized by the Association as meeting the National Standards for Diabetes Self-Management Education. These programs are required to deliver a curriculum with 9 content areas, with a 10th area as an option:

1. Diabetes disease process
2. Nutritional management
3. Physical activity
4. Medications
5. Monitoring
6. Prevent, detect, and treat acute complications
7. Prevent, detect, and treat chronic complications through risk reduction
8. Goal setting and problem solving
9. Psychological adjustment
10. Preconception care, management during pregnancy, and gestational management

Within the entirety of the nine required curriculum content areas (areas 1 – 9), there are only two portions which are best accomplished through face-to-face interaction: insulin injection technique, part of the “Medications” curriculum content area (#4); and blood glucose monitoring technique on a specific meter, part of the “Monitoring” curriculum content (#5).

The remainder of the curriculum can easily and effectively be done via a telehealth setting. Furthermore, the two areas mentioned above (insulin injection technique and blood glucose monitoring) do not necessitate in-person delivery but can be readily accomplished in real time with via interactive cameras on the educator and on the patient. As such, even these two portions

which are best done in an interactive face-to-face setting can be properly accomplished via a specific form of telehealth.

Given that the majority of the curriculum for an American Diabetes Association Recognized DSMT program can be done via telehealth, the Association urges that telehealth DSMT service to be reimbursed by CMS as well as other payers of DSMT.

It is critically important to note that there is substantial evidence regarding the success of using a telehealth approach to DSMT. Please see the attachments for documentation of this success.

It is the opinion of the Association that CMS should be seeking ways broaden DSMT services to Medicare beneficiaries with diabetes. Furthermore, given the growing prevalence of diabetes in all age ranges, steps taken now will not only address current diabetes issues but will also better prepare CMS for the future influx of beneficiaries with this disease. Including DSMT as a reimbursable telehealth service is consistent with the new Medicare approach to focus more on preventive medicine, as evidenced by a number of newly reimbursable items (Welcome to Medicare physical, diabetes screening, etc.). The Association strongly believes that telehealth for DSMT is the logical next step to reach an even greater number of Medicare beneficiaries with diabetes.

Please feel free to contact me for any additional information at (703) 549-1500 x2540.

Sincerely,

A handwritten signature in cursive script, appearing to read "Blanche Bronzini".

Blanche Bronzini, RN, MPH, CDE
National Director, Recognition Programs

The Role of the Certified Diabetes Educator in Telephone Counseling

Joy T. Hayes
MS, RD, LD, CDE

Jackie L. Boucher
MS, RD, LD, CDE

Nicolaas P. Fronk
PhD

Eve Gehring
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Mary Spencer
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From the Center for Health Promotion,
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The Diabetes Educator, 367 West Chicago
Avenue, Chicago, IL 60610-3025.

PURPOSE

This paper describes a telephone-based, outcomes-focused approach to diabetes education provided by certified diabetes educators (CDEs).

METHODS

Random chart audits were conducted to evaluate the scope of practice and effectiveness of telephone-based interventions provided by CDEs to people with diabetes. Four case studies and a sample prevention case are used to illustrate the role of telephone-based CDEs in providing diabetes education.

RESULTS

Counseling provided by CDEs helped to identify potential barriers and strategies for making lifestyle behavioral changes.

CONCLUSIONS

Telephone-based counseling is a brief, effective, ongoing intervention that gives patients with diabetes immediate access to CDEs who provide education to support lifestyle behavioral changes.

The AADE guidelines, "The 1999 Scope of Practice for Diabetes Educators and the Standards of Practice for Diabetes Educators"¹ provides a framework for health professionals to teach self-management skills to people with diabetes. Although diabetes education can occur successfully in a wide variety of settings and formats, a multidisciplinary team approach is the preferred method for providing comprehensive diabetes education.¹ The purpose of this article is to demonstrate how certified diabetes educators (CDEs) can provide telephone-based, ongoing, outcomes-focused diabetes care and education using the "Scope of Practice and Standards of Practice for Diabetes Educators." Also discussed in this article is how telephone-based CDEs are part of an integrated care delivery system that uses a systems approach to population health.²

SYSTEMS APPROACH TO POPULATION HEALTH

At HealthPartners, a not-for-profit, community-governed managed-care organization (MCO) located in the midwestern United States, a systems approach is used to target and tailor interventions to the diabetes population served.² The idea is that all key stakeholders must work together systematically to provide the patient with appropriate diabetes care as recommended by the American Diabetes Association (ADA) "Standards of Medical Care"³ and the "National Standards for Diabetes Self-Management Education."⁴ The key stakeholders include the patient and family, physician, nurse, dietitian, pharmacist, telephone counselors (including CDEs), employer, and MCO. To be most effective, the diabetes team members are part of an integrated care delivery system.

An integrated delivery system has the capacity to systematically identify individuals with diabetes, create targeted interventions, and tailor treatments to the individual patient. Communication between all team members is vital for coordinated care. The medical information system provides the needed information linkages and is designed as a closed-loop system that allows for both input and feedback.⁵ As a team member in an integrated diabetes care delivery system, the CDE on the Partners for Better Health (PBH) Phone Line reinforces clinic-based education and provides ongoing lifestyle behavior change counseling that enhances and reinforces diabetes self-management skills.

How Patients Access CDEs on the PBH Phone Line

The PBH Phone Line is staffed with approximately 12 full-time equivalents of lifestyle behavior change counselors who have varied degrees and health expertise. The staff is divided into 3 main groups: registered dietitians (RDs), health educators, and pharmacists. Many of the counselors have expertise in specialty areas such as nutrition, exercise physiology, community health, behavioral health, alternative health, and physical therapy. Some of the RDs are also CDEs.

There are 3 ways that a patient with diabetes can access a CDE on the PBH Phone Line: through self-referral, healthcare provider referral, and proactive follow-up received after completion of a health risk appraisal (HRA). The referral system is an important component of the integrated diabetes care delivery system and gives patients access to diabetes resources, education, and support.

Self-Referral

A patient may learn about the PBH Phone Line through member direct mailings, television, radio and newspaper advertisements, health-education classes, and worksite or clinic promotions. When a patient initiates a call to the PBH Phone Line, a telephone counselor completes a brief health assessment to identify the patient's needs and then triages the patient to appropriate resources within the MCO delivery system and/or the community.

Healthcare Provider Referral

At a clinic visit, healthcare providers may determine that the patient would benefit from lifestyle behavior change counseling and make a referral to the PBH Phone Line for ongoing follow-up between clinic visits. Providers may proactively refer patients to a PBH Phone Line CDE after reviewing glycosylated hemoglobin (HbA_{1c}) levels on an at-risk list. Healthcare providers receive a list of their diabetes patients that is stratified by risk^{6,7} into 3 categories of HbA_{1c} levels: >10%, 8% to 10%, and <8%. Those with elevated HbA_{1c} levels may be contacted and scheduled for a clinic visit and/or referred to the PBH Phone Line CDE for ongoing education and support.

Health Risk Appraisal

The third way a patient with diabetes gets referred to the PBH Phone Line is through a health risk appraisal (HRA). Patients with diabetes who complete a HRA and indicate they are willing to be contacted are proactively called to discuss behavioral health risks that have been identified through this appraisal.

How the Diabetes Education Process is Applied by Telephone-Based CDEs

As an extension of the care delivery system, PBH Phone Line CDEs receive patient referrals for diabetes education and lifestyle behavior change counseling.⁸ According to the "Scope of Practice for Diabetes Educators,"¹ *diabetes education* is defined as an interactive, collaborative, ongoing process involving the person with diabetes and the educator. This process includes (1) assessment of the patient's needs, (2) planning and implementation of an action plan, (3) documentation, and (4) evaluation. A flow diagram that outlines how the PBH Phone Line manages the special needs of people with diabetes is shown in Figure 1.

Assessment of Patient's Needs

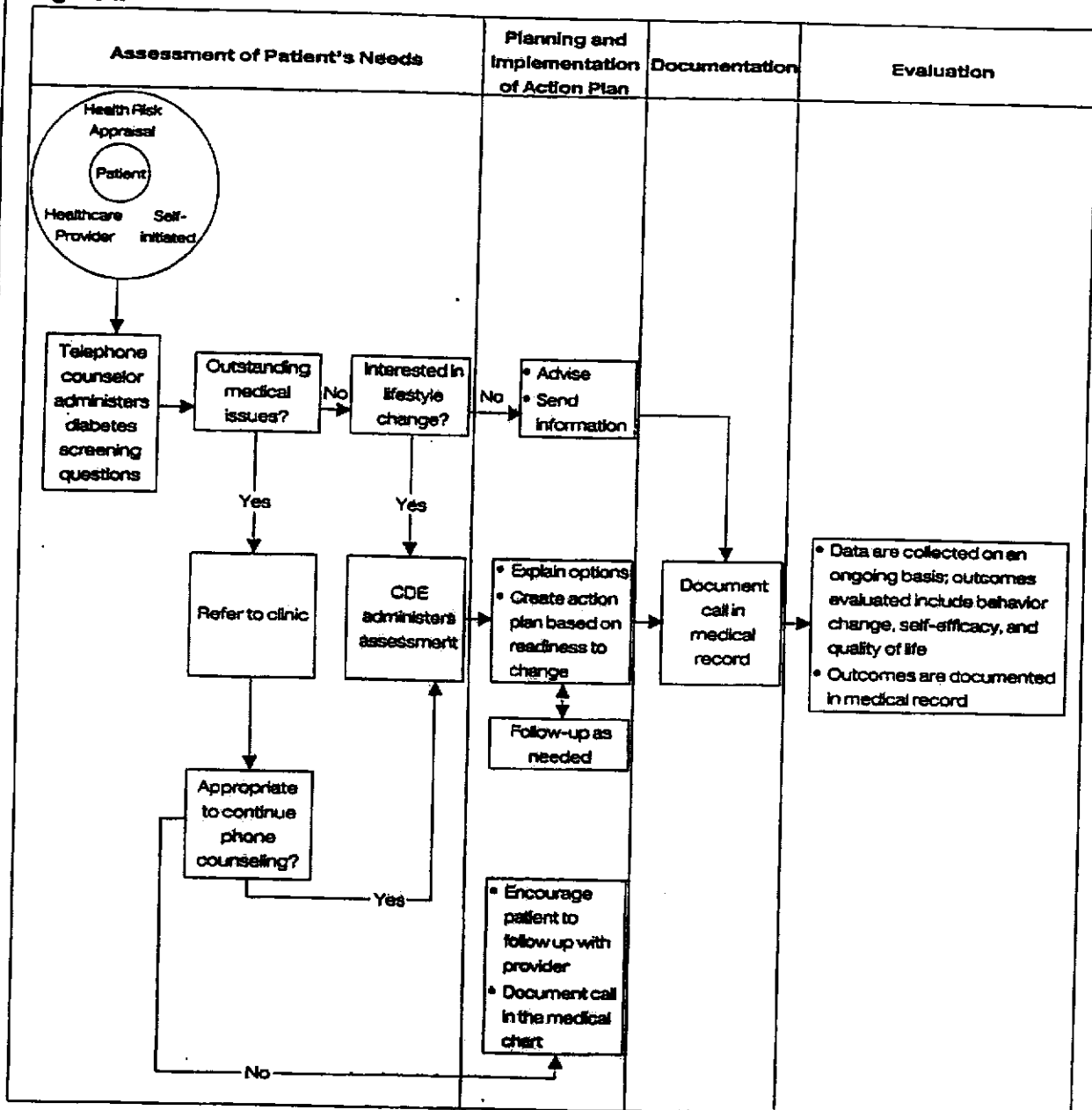
To assess a patient's health education needs, the PBH Phone Line counselor, who may or may not be a CDE, administers a set of diabetes screening questions to determine which intervention is appropriate for the patient. Patients who have medical issues are referred back to their clinic for medical management. Through the triage process (Fig 1), the telephone counselor assesses whether patients are ready to make lifestyle behavior changes that can help improve their diabetes control. Patients who are not ready to make any changes are reminded of the importance of good blood glucose control for preventing diabetes complications, offered health information, and invited to call back when they are ready to make some changes. If they are ready to change and feel support would be helpful, resource and support options are discussed. Resources include telephone courses and counseling, classes, one-to-one clinic-based counseling, or self-study options. A PBH Phone Line counselor who is not a CDE may choose to refer patients to a CDE for a more in-depth assessment. A referral is made to a CDE if the patient has poor diabetes control, a poor understanding of diabetes, multiple medical concerns, or questions about diabetes self-management.

PRACTICAL APPLICATION

Effective diabetes education requires an active teaching/learning process between the person with diabetes and the educator. Various educational models have been proposed in the literature, most incorporating the following basic steps: (1) assessing the learning needs of the person with diabetes, (2) identifying appropriate behavioral goals and objectives, (3) planning behavioral strategies for promoting behavioral change, and (4) evaluating patient outcomes. Each step is critical given that time constraints are often cited as a major obstacle to effective teaching. Hayes and colleagues have conducted a study evaluating the effectiveness of how certified diabetes educators (CDEs) provide telephone-based counseling using the "Scope of Practice and Standards of Practice" for Diabetes Educators. Using Prochaska's Theoretical Model of Health Behavior Change, CDEs assessed readiness to change in persons with diabetes and applied stage-matched counseling via the telephone to help successfully change behaviors. As an alternative to delivering diabetes care and education in a clinic setting, telephone-based counseling was successful in providing education to persons with diabetes who might not otherwise have come to the clinic to receive care. Telephone-based counseling is one approach to consider when determining how to deliver immediate diabetes education. Further studies need to be conducted in the area of telephone-based counseling, evaluating the documentation of educational assessment, the actual education provided, and follow-up care.

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Figure 1.



Diabetes standards of education applied through telephone triage.

Planning and Implementing an Action Plan

Patients have the opportunity to talk with PBH Phone Line counselors repeatedly at no cost. If the patient is interested in working with a PBH Phone Line CDE to make lifestyle behavior changes, individualized lifestyle behavior change counseling is initiated. Initial goals are set as part of an individualized action plan, educational materials tailored to the stage of readiness of the individual are sent, and a follow-up telephone appointment is made. A patient's readiness to change, based on the transtheoretical model of behavior change,^{9,10} is assessed at each call. For example, if the patient chooses to participate in the *Beyond the Basics*⁴ diabetes education class (an American Diabetes Association "Recognized" diabetes education program), a class flyer is sent with enrollment instructions. Patients who choose a telephone-based course are enrolled in the course by the CDE, who then mails them a course manual and schedules the first course. Telephone courses include weight management, stress management, heart health, back health, and smoking cessation. Each course can be tailored to the individual needs of the patient with diabetes by providing information on how to eat healthier, be more physically active, and promote positive self-care measures. Patients who want to learn about diabetes in a self-directed manner can set up an individualized plan with the CDE to discuss specific health topics and educational concerns. They may also request patient education materials or book and video loans from the PBH Resource Library. In addition, Internet addresses for credible online health resources are available that can be accessed directly by patients.

Documentation

Calls are documented in the patient's medical record in both an electronic and paper format. This is a critical component of the closed-loop system that makes it possible for all diabetes team members to communicate education plans between each other and stay informed of the patient's health status and goals.

Evaluation

Telephone-based courses and ongoing counseling sessions are evaluated by outcome criteria including a patient satisfaction questionnaire and a behavior change questionnaire.

These questionnaires are administered at the beginning and end of the course and at 6 months after completion of the course. This evaluation allows for course enhancements based on patient feedback. Course effectiveness is evaluated based on health behavior change, patient self-efficacy, and quality of life.¹¹

DIMENSIONS OF PRACTICE AND TELEPHONE RESPONSIBILITIES OF THE CDE

According to the "Scope of Practice for Diabetes Educators,"¹¹ the primary responsibility of the CDE is to educate people with diabetes, their families, and appropriate support systems about diabetes self-management. The educational topics should include, but not be limited to, the disease process, treatment options, nutrition, physical activity, medications, blood glucose monitoring, acute and chronic complications, and coping skills.

A synopsis of 5 case studies and outcomes is shown in Table 1. These case studies demonstrate how PBH Phone Line CDEs assess, plan, document, and evaluate outcomes of patients with diabetes using the telephone triage process (Fig 1). The educational content areas addressed in each case study are listed in Table 2. Together, these tables and figure show how CDEs provide diabetes education over the telephone and are in a unique position to supply ongoing follow-up in a cost-effective way. They also demonstrate how CDEs provide immediate feedback on behavior changes as patients use problem solving for high-risk situations that could impact their ability to maintain lifestyle behaviors.

Establishing and maintaining healthy lifestyle behaviors involve multifaceted processes that last a lifetime. PBH Phone Line CDEs use the transtheoretical model of behavior change^{9,10} in their counseling to help patients successfully change lifestyle behaviors. Because change is not linear or a single event, CDEs expect patients to experience lapses or have extended relapses as they proceed toward establishing new eating, activity, and self-care behaviors. Through stage-matched counseling, CDEs help patients understand the impact of acute and chronic problems on health behaviors, lifestyle, and the learning process. The CDEs also help patients identify potential barriers and strategies for making permanent health behavior changes.

Table 1.

Diabetes Case Studies and Outcomes Following Telephone-Based Intervention With a CDE

Case Study	Brief Synopsis	Outcomes
1	Referral source: diabetes resource nurse Medical history: 66-year-old female with newly diagnosed type 2 diabetes; history of hypertension, dyslipidemia; diet and exercise recommended as part of diabetes treatment plan; physician recommended low-sodium diet as part of hypertension treatment plan Lifestyle history: low exercise level (walked infrequently); preferred vegetarian diet; did not like taste of food cooked without salt Intervention: participated in 7 follow-up calls, 15 to 20 minutes each, with PBH Phone Line CDE over 8-month period	Clinical: postintervention HbA_{1c} 6.1%; fasting blood glucose decreased from 157 mg/dL to 96 mg/dL; body weight decreased 25 pounds; blood cholesterol dropped from 257 mg/dL to 221 mg/dL Behavioral: increased exercise level by walking 45 minutes daily, increased stamina
2	Referral source: clinic-based RD Medical history: 81-year-old male with history of type 2 diabetes, hypertension, congestive heart failure; taking insulin to manage diabetes Lifestyle history: physician reported patient didn't know how to eat healthy or plan appropriate menus given his medical problems/lifestyle; patient indicated a desire to take better care of himself so he could continue living independently and maintain health Intervention: participated in 8 counseling calls, 15 to 20 minutes each, with a PBH Phone Line CDE over 5-month period	Clinical: after 1 year of follow-up, providing self-management education/support, HbA_{1c} decreased from 7.8% to 6.1%; body weight decreased 14 pounds Behavioral: monitored portions, decreased salt intake when eating out; followed simple meal plan, used <i>Month of Meals</i> book by ADA (loaned from the PBH Resource Library)
3	Referral source: clinic-based RD Medical history: 66-year-old female with 5-year history of type 2 diabetes, hypertension, dyslipidemia; taking oral agents glipizide and metformin Lifestyle history: reported struggling with obesity all her life, tried numerous low-calorie diets; lived with/cared for 91-year-old mother with Alzheimer's; reported overeating in evenings due to stress of caring for mother Intervention: completed 10-session course, <i>A Call to Change . . . Healthy Lifestyles, Healthy Weight</i> (telephone based); continues monthly follow-up with PBH Phone Line CDE for ongoing support to manage stress	Clinical: HbA_{1c} decreased from 7.3% to 5.0%; body weight decreased 41 pounds after 1 year of telephone follow-up; blood pressure decreased from 142/80 mm Hg to 116/68 mm Hg; total cholesterol decreased from 238 mg/dL to 135 mg/dL, triglycerides decreased from 507 mg/dL to 133 mg/dL in 1 year; oral agent dose was reduced, glipizide discontinued, continued to take metformin Behavioral: exercised daily by swimming or walking; made low-fat food choices; managed stress by attending support group and being more assertive
4	Referral source: diabetes resource nurse Medical history: 50-year-old female with 15-year history of type 2 diabetes; taking insulin and metformin; history of dyslipidemia, hypertension, retinopathy Lifestyle history: reported history of compulsive eating Intervention: completed 10-session course, <i>A Call to Change . . . Healthy Lifestyles, Healthy Weight</i> (telephone based); referred back to diabetes resource nurse/physician for medication questions/adjustments	Clinical: HbA_{1c} decreased from 8.3% to 6.8% while participating in telephone-based weight management course; weight remained stable throughout course Behavioral: set realistic goals for exercise; addressed barriers to chronic disease management and their affect on compulsive eating behaviors
5*	Referral source: clinic-based RD Medical history: 27-year-old female assessed at high risk for developing diabetes due to risk factors of gestational diabetes, dyslipidemia, obesity Intervention: completed 4-session course, <i>A Call to Change . . . Reducing Your Risk for Diabetes</i> (telephone based); continues monthly follow-up with PBH Phone Line CDE for ongoing support for weight management, risk reduction	Clinical: participant lost 24 pounds in 10 weeks Behavioral: established normalized eating pattern (3 meals, healthy snacks); brought low-fat foods to work for breakfast, dinner; switched from regular to diet pop; started walking program; reduced stress by planning ahead and taking time for self-care activities twice a week

*Case 5 is a diabetes prevention case.

Table 2.

Diabetes Self-Management Education Content Areas Addressed by Telephone-Based CDEs

Content Areas	Case Study 1	Case Study 2	Case Study 3	Case Study 4	Case Study 5*
Reinforce general diabetes information by reviewing the diabetes disease process and treatment options	✓				
Incorporate appropriate nutrition management					
• Dyslipidemia counseling	✓		✓	✓	✓
• Hypertension counseling	✓	✓	✓	✓	
• Weight-management counseling	✓	✓	✓	✓	✓
• Menu planning		✓			
• Dining out			✓	✓	
• Label reading	✓		✓	✓	
• Healthy normalized eating			✓	✓	✓
Incorporate physical activity into lifestyle	✓		✓	✓	✓
Reinforce blood glucose monitoring and using results to improve control	✓	✓	✓	✓	
Review prevention and treatment of hypoglycemia and hyperglycemia				✓	
Reinforce prevention of diabetes or complications through risk reduction behaviors				✓	✓
Assist in goal setting to promote health and problem solving for daily living	✓	✓	✓	✓	✓
Help with integrating psychosocial adjustment to daily life (includes stress management).	✓		✓	✓	
Promote preconception care					✓
Provide and encourage social support	✓	✓	✓	✓	✓
Provide diabetes education and support for family	✓				
Address high-risk situations such as travel, diabetes emergencies, and sick days	✓	✓	✓	✓	

*Case Study 5 is a diabetes prevention case.

Random Chart Audit Data

As part of the closed-loop medical information system, the PBH Phone Line staff documents all incoming and outgoing calls in a database to track demographic information, types of calls, and outcomes. In the year 2000, the PBH Phone Line had 260 000 contacts/encounters with patients. Of those, 234 contacts and 794 encounters were with patients with diabetes. *Contacts* are defined as a service or interaction between a telephone counselor or administrative staff person and a patient that may or may not be education based. An *encounter* is defined as an educational interaction between a telephone counselor and a patient.

A chart audit was conducted to assess behavioral outcomes for diabetes patients who received 2 or more calls from a PBH Phone Line CDE. Patients selected for the chart audit were identified randomly from the PBH Phone Line database. Data collected from the chart audit included type of diabetes, how the patient heard about the PBH Phone Line, medications, height, weight, HbA_{1c}, start and end date of counseling, number of calls, and stage of change for 4 different lifestyle behaviors (aerobic exercise, physical activity, normalized eating, and low-fat eating). Definitions of the lifestyle behaviors are shown in Table 3. Lifestyle behaviors were coded during the chart audit as follows: 1=precontemplation, 3=contemplation, 5=preparation, 7=action, and 9=maintenance. Statistics for behavioral and clinical outcomes were analyzed using paired and

Table 3.

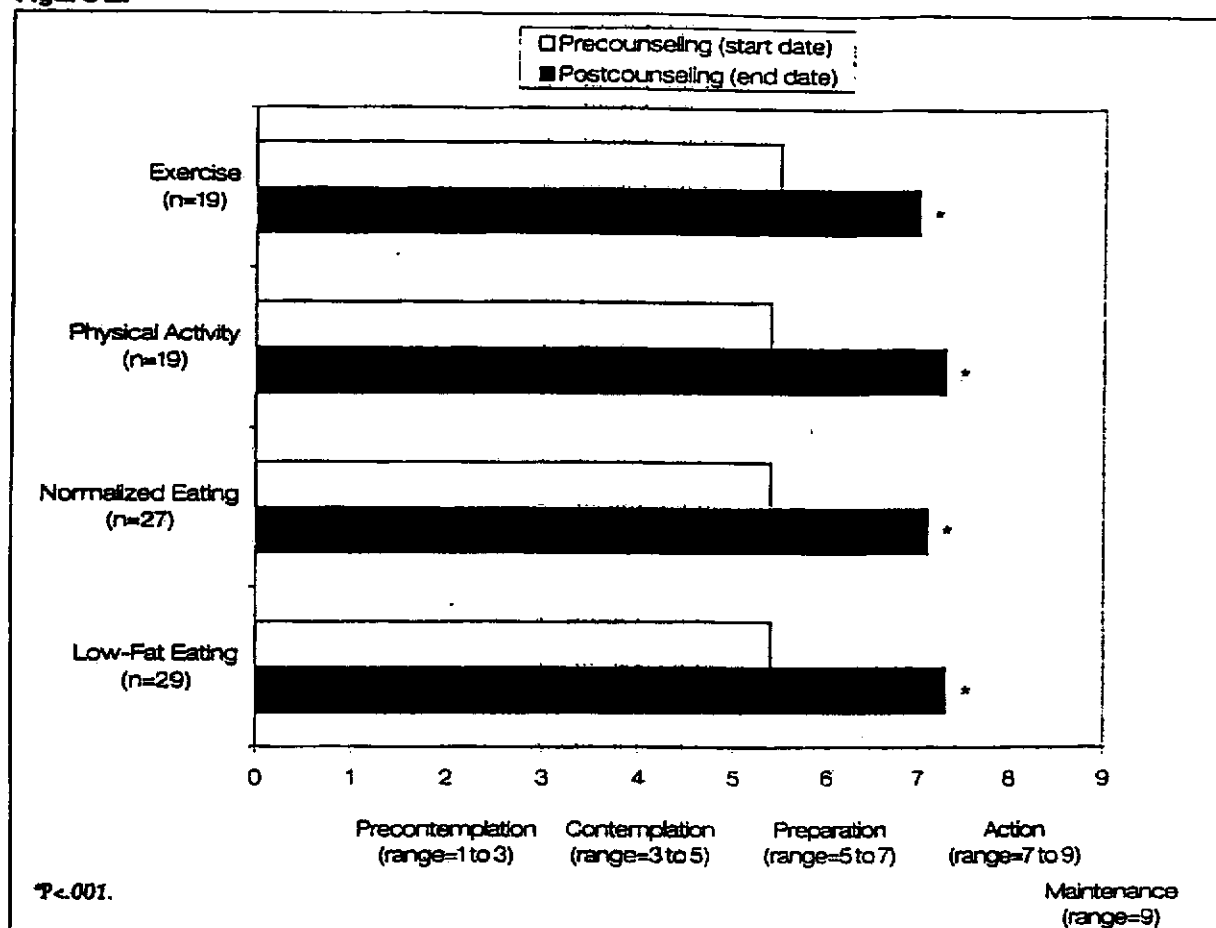
Stages of Change Definitions for Lifestyle Behaviors

Behavior	Precontemplation	Contemplation	Preparation	Action	Maintenance
Exercise	Person is doing aerobic exercise 0-2 days per week and is not interested in making changes in the next 6 months.	Person is doing aerobic exercise 0-2 days per week and is thinking about increasing the number of days in the next 6 months.	Person is doing aerobic exercise 0-2 days per week and is planning to increase the number of days in the next 30 days.	Person is doing aerobic exercise ≥ 3 days per week for ≤ 6 months.	Person is doing aerobic exercise ≥ 3 days per week and has maintained this behavior for ≥ 6 months.
Physical Activity	Person is physically active 0-3 days per week and is not interested in making changes in the next 6 months.	Person is physically active 0-3 days per week and is thinking about increasing the number of days in the next 6 months.	Person is physically active 0-3 days per week and is planning to increase the number of days in the next 30 days.	Person is physically active ≥ 4 days per week for ≤ 6 months.	Person is physically active ≥ 4 days per week and has maintained this behavior for ≥ 6 months.
Normalized Eating	Person is eating 3 meals per day, 0-3 days per week, and is not interested in making changes in the next 6 months.	Person is eating 3 meals per day, 0-3 days per week, and is thinking about increasing the number of days in the next 6 months.	Person is eating 3 meals per day, 0-3 days per week, and is planning to increase the number of days in the next 30 days.	Person is eating 3 meals per day, ≥ 4 days per week, for ≤ 6 months.	Person is eating 3 meals per day, ≥ 4 days per week, and has maintained this behavior for ≥ 6 months.
Low-Fat Eating	Person is not interested in making changes to lower dietary fat in the next 6 months.	Person is thinking about lowering dietary fat in the next 6 months.	Person plans to lower dietary fat in the next 30 days.	Person reports making food choices necessary to lower dietary fat for < 6 months.	Person reports making food choices necessary to lower dietary fat and has maintained the behaviors for ≥ 6 months.

unpaired *t*-tests. Means and standard deviations were used to describe the population. Data for statistics were limited to patients who had data available at both the start and end dates of counseling, and those who had a body mass index (BMI) > 25 kg/m². Thus, data for all 40 patients are not included in all statistical analyses.

Patients were referred by healthcare providers ($n=30$), representatives in the Member Services department ($n=2$), employer promotions ($n=2$), or self-referred ($n=6$) after reading a health plan publication. Thirty-seven had type 2 diabetes and 3 had type 1 diabetes. Twelve were controlling their diabetes with exercise and nutrition only, 18 were taking oral medications, 7 were taking insulin, and 3 were using combination therapy.

Figure 2.



Stage of change movement.

On average, patients had 8.3 contacts (SD=8) with the PBH Phone Line CDE. The contacts were made over an average of 172 days (SD=217), or about 5.5 months. Precounseling (start date) and postcounseling (end date) assessment of stage of change for each of the 4 lifestyle behaviors (aerobic exercise, physical activity, normalized eating, and low-fat eating) suggests that stage-matched telephone counseling effectively moves individuals into action and maintenance stages for 4 effective diabetes lifestyle management strategies (Figure 2). All stage movements were statistically significant ($P<.001$).

Chart audits to review clinical data demonstrated that these behavioral changes impacted clinical outcomes. HbA_{1c} and weight were recorded if labs and weight were measured within 3 months of the telephone precounseling and postcounseling. HbA_{1c} (n=14) decreased from 8.8% to 7.6% (n=14, $\Delta=1.2\%$) and weight decreased from 253 pounds to 241 pounds (n=22, $\Delta=12$ pounds). While none of these changes were statistically significant, they are clinically meaningful. Epidemiological data from the United Kingdom Prospective Diabetes Study¹² demonstrated that for every 1.0% decrease in HbA_{1c} there was a 35% reduction in the risk of microvascular complications. While other factors, such as medication adjustment, may have contributed to the improvements in HbA_{1c}, interventions provided by Phone Line CDEs did result in measurable lifestyle behavior changes.

CONCLUSION

Telephone-based counseling is a brief, ongoing intervention that gives patients with diabetes immediate access to CDEs who can provide continued contact and education to support lifestyle behavior change. This counseling approach allows a large population to be reached. Integrating telephone-based counseling in a managed-care setting

meets provider and patient needs by reinforcing clinic-based education, being available to patients at teachable moments, and providing ongoing support to make lifestyle behavior changes. Thus, the CDE providing the telephone-based counseling can act as an extension of the clinic-based care delivery team, ensuring continuity of care.

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Telephone-Based Interventions For Diabetes Care

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ABSTRACT

Telephone-based interventions (TBIs) are one form of telemedicine that has been used for many years to provide certain services to patients. TBIs have been used for providing acute medical management, directing access to care, delivering and reinforcing education, and promoting self-care behaviors. Three types of TBIs with varying levels of intensity and educational components have been evaluated with diabetes patients. The purpose of this article is to review TBIs used to enhance diabetes care and promote diabetes self-management behaviors. Benefits of TBIs, specific types of interventions, outcomes, and scope of practice of diabetes educators providing TBIs as well as legal and reimbursement issues will also be addressed.

The Institute of Medicine has defined telemedicine—also called telehealth—as “the use of electronic information and communications technologies to provide and support health care when distance separates the participants (1).” This definition has since expanded and now includes all types of telecommunication and informatics technology used to deliver health care services and disseminate educational information to patients and populations. Some of the technologies used in telemedicine include telephones (all forms), computers, interactive video transmissions, direct links to health care instruments, transmission of images, and teleconferencing by telephone or video (2,3).

Telephone-based interventions, one of the most studied telemedicine technologies, have been used for many years to provide a variety of services. Over the past decade, the technology for using the telephone to deliver interventions to improve health behavior and health care has expanded (4). Interventions using telephone technology have been used to promote rehabilitative behavior, prevent

pre-term and low-birth weight infants, increase mammography rates, improve medication compliance, promote smoking cessation, and support overweight individuals in their weight-management efforts (4–6). Health maintenance organizations also use TBIs to improve access to care for their members and to provide acute care interventions (7,8).

While traditional counseling interventions for diabetes care and education have been face-to-face in individual or group settings, TBIs have become an attractive alternative.

Evaluation surveys developed and administered by a managed care organization (MCO) to its providers and members indicate that telephone counseling is a desirable service.

BENEFITS OF TBIs FOR PATIENTS

Ninety-five percent of households have a telephone which means TBIs have the potential to reach a large number of patients (9). Patients can use these services without leaving their homes, making the services desirable to patients with limited mobility, those living in remote areas, or even those with hectic schedules who are less apt to schedule appointments. Because of the anonymity of TBIs, individuals who are reluctant to seek face-to-face counseling may be more willing to participate in TBIs. Interventions using the telephone may also be more attractive to ethnic minorities who have language barriers (eg, no bilingual clinic staff may exist to provide them with the health and self-care information they need), to those who have access barriers, or to those who fail to meet appointments (6,10,11).

Another key benefit of TBIs is that patients want them. Evaluation surveys developed and administered by a managed care organization (MCO) to its

providers and members indicate that telephone counseling is a desirable service (5). In a survey of 5,099 MCO members, 75 percent indicated they would like health improvement communication by telephone. In a different survey targeted at providers, physicians (n=100) rated telephone-based counseling as one of the highest education strategies for effectiveness. Interventions using the telephone have the potential to improve patient-provider communication between clinic visits, to improve the patient's ability to manage her/his diabetes, and to enhance the link between diabetes educators and patients. Telephone-based interventions also have the potential to increase patient satisfaction with care provided (5).

TBIs FOR DIABETES CARE AND SELF-MANAGEMENT EDUCATION

Three types of TBIs with varying levels of intensity and educational components have been evaluated with diabetes patients (see Table 1). The first intervention uses TBIs as an adjunct to an educational program. Diabetes educators make telephone calls to reinforce knowledge and skills previously learned by diabetes patients (12). The use of TBIs as the primary intervention for diabetes patients is the second type. Telephone calls provide education, reinforce compliance, identify and correct medical management problems, and improve access to care (13). The third type of intervention is automated telephone disease management (ATDM) calls (10,11,14,15).

ATDM consists of hierarchical, branching components using statements and questions recorded in human voice. Diabetes patients listen to messages and respond to questions using their touch-tone telephone keypads. ATDM calls can be used to gather medical management information and/or provide educational messages. Medical management information captured can be reviewed by a health professional to identify patients who need additional follow-up. These patients can subsequently be contacted and managed via telephone or scheduled for follow-up clinic appointments.

Interventions using the telephone—either telephone counseling or ATDM calls—can be initiated reactively, through call-in services or help lines, or proactively, via outreach services that are initiated by health care providers. Most TBIs in diabetes care have relied on proactive telephone calls. The number, length, and timing of calls varies from single contacts to up to 17 calls over a 12-month time frame (see Table 1). Of the few studies completed using TBIs, most rely on brief calls, 12 minutes or less. TBIs have been used as a main intervention or as an adjunct to multicomponent interventions that could include a combination of group classes, individual face-to-face counseling, written self-help materials and/or telephone contacts (see Table 1). The diversity of components allows greater flexibility and potentially improved cost-effectiveness in providing individual patient services. Both Spanish- and English-speaking patients are receptive to TBIs to access patient education (10).

Outcomes of TBIs, when used as an adjunct to usual care, include improvements in hemoglobin A1c (HbA1c), fewer symptoms of depression, greater self-efficacy to perform self-care activities, and fewer days in bed because of illness in the prior week (see Table 1). Patients also have reported greater satisfaction with care, including the technical quality of the services they received, their choice of providers, continuity of care, communication with providers, and the quality of their health outcomes (15).

SCOPE OF PRACTICE

While there are no specific standards of practice for nurses and registered dietitians providing TBIs, most TBIs are consistent with face-to-face interventions and do comply with the definition of diabetes education as defined in the Scope of Practice for Diabetes Educators (16). "Diabetes education is defined as an interactive, collaborative, ongoing process involving the person with diabetes and the educator." In the Scope of Practice, it is noted that the diabetes educator should perform the following:

- Assess educational needs
- Plan the teaching-learning and

behavioral change process

- Implement the educational plan
- Document the process, including followup with the primary-care provider
- Evaluate based on outcome criteria

Providing all or some of the aspects of diabetes education via the telephone is common. Diabetes nurse educators report using the telephone to provide medical management, and ongoing support, to reinforce education, and to provide additional education to patients (17). Nurses feel telephone calls give patients emotional support, provide opportunities for assessing patient progress, reinforce education, and increase knowledge. Topics reportedly discussed over the telephone include self-monitoring of blood glucose (SMBG), hyperglycemia, insulin use, nutrition, and psychosocial issues. During these discussions, educators are able to provide acute medical management for hypoglycemia and hyperglycemia by working with physicians to adjust medications or recommend additional lifestyle behavior changes (17).

Telephone communications also allow diabetes educators to assess/reassess the individual's educational needs, identify goals and appropriate interventions to meet goals, and evaluate the individual's achievement of those goals on an ongoing basis. The content of telephone calls can be similar to face-to-face interventions. While some education may be limited by TBIs, such as teaching SMBG and insulin injections, most content areas for diabetes education can be taught over the telephone. However, health professionals providing TBIs should follow their professional scope of practice and the scope of practice for diabetes educators and be familiar with the core principles of telemedicine issues by the Interdisciplinary Telehealth Standards Working Group (see Table 2) (3).

TBIs: LICENSURE AND REGULATION CONCERNS

Health professionals who provide telephone counseling across state lines need to be aware of interstate practice and licensure issues. Since many states require licensure for different health care professionals, there are concerns about whether a health care provider in

one state can provide TBIs to a patient in another state. The Center for Telemedicine Law Licensure Task Force has previously reported that practitioners may need to retake licensing exams or undergo procedural requirements to practice telemedicine (18). Most of the laws, however, relate to physicians and nurses. Very little information is available on licensure issues for RDs who provide services across state lines. Some states have recognized that medical consultation by a health care provider (eg, physician) who is licensed by another state occurs and note that it is permissible (18). However, consultation is different from regular or frequent contact which could occur with TBIs.

Besides state licensure laws, there is the consideration of where the individual's health care is provided and where the individual's health plan is located. With some health plans having patients in multiple states, there are questions as to whether licensure in the state in which the health plan originates is adequate.

At this time, with the growth of technology in health care, there may be more questions than answers. The current approach to reducing liability and avoiding licensure issues across state lines is to provide a disclaimer declaring that the advice being supplied is not to be used without referring to the patient's own physician or health care provider (2).

TBI: REIMBURSEMENT

Most of the cost of a TBI is for personnel and/or for the technology (ie, the hardware and software used to implement ATDM). While telephone contact has been excluded from reimbursement for government-supported programs, there is reimbursement from various employers and managed care organizations for services from health call centers on a per-member-per-month basis (2). Some states also have individual laws. California law allows videotelemedicine but excludes reimbursement for telephone calls (19). The California Medicaid Program (MediCal) adds restrictions on reimbursement for telemedicine, which includes TBIs. For example, payment for telemedicine services must be supported by published, peer-reviewed scientific studies concluding

Table 1: Telephone Interventions Used For Diabetes Care

Ref.	Intervention Components	Target Population	Type of Telephone Counselor	Number and Timing of Calls	Outcomes
11	All study patients received automated telephone disease management (ATDM) calls to provide health status information for 12 months and responded to queries using their touch-tone telephones. The purpose of the study was to determine whether low-income diabetes patients were able and willing to use ATDM calls to provide health information.	Low-income adult patients ($n=272$) with a diagnosis of diabetes or a prescription for a hypoglycemic agent. 20 patients spoke Spanish as primary language.	ATDM messages and queries written by physicians.	Attempts to collect ATDM assessment data were made every 2 weeks. Patients received up to a maximum of six calls over three consecutive days and were contacted again the following week if they were not reached.	Patients successfully completed 4,141 of 5,967 ATDM assessments. Compared with patients completing less than 50% of their assessments, more frequent respondents reported fewer symptoms of poor diabetes control, had lower BMIs and had better quality of life scores.
12	Three-day multidisciplinary team-taught patient education program, including a brief review session one month after the program and individual appointments with the dietitian and nurse educator. The intervention group also received 4 telephone calls over 10 weeks following the program and an additional 1-hour nurse visit.	Adult patients with type 2 diabetes receiving primary care from a general medical clinic. Participants randomly assigned to intervention ($n=28$) or control ($n=25$) group.	Nurse educator	Four calls over 10 weeks; average call length was 6 minutes.	Intervention group performed self-monitoring of blood glucose monitoring more frequently than control group ($p<0.0001$). No differences in the posttest HbA _{1c} values or weight change.
13	The control group received usual care; physician visits every three to four months. The intervention group received nurse-initiated telephone contacts between physician visits to provide education, reinforce compliance, monitor health status, resolve clinical issues, and facilitate access to care.	Adult patients with type 2 diabetes receiving primary care from a general medical clinic. Participants randomly assigned to intervention ($n=275$) or control ($n=71$) group.	Nurse	Monthly calls; mean=13 contacts/patient; each contact ranged from 1 to 70 minutes with mean of 12 minutes/contact.	At one year, between-group differences favored intervention patients: Fasting plasma glucose (174.1 vs. 193.1, $p=0.01$) and HbA _{1c} (10.5% vs. 11.1%, $p=0.046$). Significant differences were not observed for quality of life or diabetes-related symptoms.
14-15	Intervention patients received ATDM calls to provide systematic monitoring and patient education and to support the targeted telephone nurse follow-up for 12 months. Patients randomized to the control group received their usual care; they had no ATDM calls (thus, no additional clinical assessments, patient education, appointment reminders, or follow-up data collection).	Low-income adult patients ($n=280$ initially; $n=248$ at 12 months) with a diagnosis of diabetes or a prescription for a hypoglycemic agent were randomized into usual care or intervention group.	ATDM messages and queries written by physicians. RN provided follow-up calls.	Intervention patients received biweekly ATDM assessment calls with optional health tips and dietary education module. Calls lasted 5-8 minutes. Patients had periodic contact with RN to address ATDM reported problems. On average, patients completed 17.1 ATDM calls over the year, including 13.1 biweekly assessments and 4.0 self-care education calls. On average, patients had 5.6 contacts with RN; average call was 12.4 minutes.	Intervention patients reported an average of 9.2 SMBG readings during ATDM assessments, listened to 6.4 health tips, and completed 4.9 dietary education modules. Compared with patients receiving usual care, patients in the intervention group at follow-up reported fewer symptoms of depression ($p=0.023$), greater self-efficacy to perform self-care activities ($p=0.006$) and fewer days in bed because of illness in the prior week ($p=0.026$). There were no intervention effects on diabetes-specific quality-of-life scales. Patients receiving the intervention were also more satisfied with the quality of their care and continuity/access to care.

ing that those services are equal to or better than face-to-face interactions between clinicians and patients (19).

The Benefit Improvement Protection Act (BIPA) of 2000, section 223 included revisions to telehealth services for Medicare beneficiaries. Previously, the Balanced Budget Act of 1997 limited reimbursement to patients living in areas with a health professional shortage and the consultation had to be provided via an interactive audio-video telecommunication system. BIPA now broadens the previous stipulation, indicating that patients just can't be at the same location as the individual physician or practitioner providing the telehealth service. BIPA also included the following changes: (1) Facilities providing a telehealth service can charge a facility fee. (2) A physician or practitioner can now get paid the same amount as a face-to-face visit. (3) Fees no longer need to be split between the referring site and the distant site. (4) In order for individuals to receive a telehealth service, it must be furnished at a site that originates in either a rural health professional shortage area, a county that is not included in a Metropolitan Statistical Area, or from an entity that participates in a Federal telemedicine demonstration project that has been approved (or receives funding from) the Secretary of Health and Human Services as of December 31, 2000.

However, only physicians or practitioners described in section 1842(b) (18) (C) of the Social Security Act may provide teleconsultations. This is a key limitation, as registered dietitians are not recognized practitioners under this section of the Medicare statute. However, BIPA does stipulate that The Secretary of Health and Human Services will conduct a study to identify practitioners that may be reimbursed for telehealth services. This report shall be submitted to Congress not later than 2 years after the date of the enactment of this Act with recommendations. Additionally, within Medicare, the Health Care Financing Administrations is conducting research demonstrations projects with diabetes patients to explore whether the use of advanced telemedicine technology improves clinical outcomes for patients with diabetes (20). So opportunities are available for reimbursement

Table 2: Summary of the Core Principles of Telemedicine

- *The basic standards of professional conduct must not be altered by the use of telemedicine technologies to deliver health care, conduct research, or provide education.*
- *Health care systems and health care professionals must not use telemedicine to provide services that are not legally or professionally authorized.*
- *Professional and clinical standards must be reviewed to determine if modifications are necessary when changes in patterns or delivery of care are made to maintain quality of care.*
- *The use of telemedicine technologies must not require extra licenses.*
- *Each health care profession must develop its own methods of ensuring the competency of its practitioners in telemedicine.*
- *Telemedicine practice guidelines should be based on empirical evidence first, then professional consensus among all involved health care disciplines if the data are lacking.*
- *The integrity and therapeutic value of the client-practitioner relationship must be maintained.*
- *Confidentiality and integrity of all records are vital.*
- *Documentation must be clear, complete, and protect patient confidentiality.*
- *Informed consent for participation in telemedicine must be obtained.*
- *The safety of clients and practitioners must be ensured.*
- *There must be commitment to a systematic and comprehensive research agenda by government agencies and health care professions.*

See reference 3

of telehealth services provided by dietitians in the future.

FUTURE DIRECTION

Interventions using the telephone can provide quick, inexpensive, and time-saving access to care for both patients and health care providers. TBIs can be used to improve self-management practices of patients with diabetes and to evaluate patient's diabetes management. One of the greatest challenges to the health care system includes the integration of TBIs with face-to-face interventions in a coordinated approach that will not only improve health-related and quality-of-life outcomes, but enhance the provider-patient relationship. Communication via a computerized medical record will be a

critical component in enhancing provider-to-provider communication and the provider-patient relationship. Additional studies are needed to determine the appropriate number of TBI calls needed as well the ideal mix of intervention components required to support the individual with diabetes.

Registered dietitians can have a key role, not only in TBIs, but also in all types of telemedicine interventions provided to patients. However, with the advanced pace of technology, RDs need to position themselves now. Start by getting involved in research projects, home care, or other areas of your organization or other agencies that are using technology to provide care to patients. Opportunities avail; start by finding them.

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An Example Of RDs Implementing A Telephone Intervention

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RD/CDE's role in diabetes care.

CASE STUDY

7/21/00-Clinic Visit

A 73-year-old woman has complained of urinary frequency, urgency, and lower abdominal discomfort for the past 2-3 months; excessive thirst, increased fatigue and an 8-lb. weight loss since January. She reports she has had type 2 diabetes for about 4 years. She states that her morning blood glucose (BG) levels are typically 100-140 mg/dl and her last HbA1c was 10%. Urinalysis is markedly abnormal with glucose greater than 1000 mg/dl. Physician and patient agree she needs to start insulin. Patient will continue on both Glucophage and glyburide while titrating insulin. Insulin

therapy was initiated. She has appointment scheduled with the Diabetes Resource Nurse (DRN) on 7/22/00 for education on insulin use.

Five days later

Patient contacts DRN reporting BG levels for past few days have been over 400 mg/dl; DRN advises that she contact PBH Phone Line to review life-style choices.

Same day

Assessment. Patient contacts PBH Phone Line and RD completes diabetes patient profile screen and assessment; reports BG levels for past 2 days have been over 400 mg/dl; states BG was 200 mg/dl at 8:30 AM, 400 mg/dl before lunch, 421 mg/dl before dinner; patient going out of town

HealthPartners, a not-for profit community-governed managed-care organization located in the Midwest of the United States, uses a telephone-based intervention for diabetes education—the Partners for Better Health (PBH) Phone Line—as one component of the diabetes education program. Telephone-based Registered Dietitians (RD)/Certified Diabetes Educators (CDE) participate as members of a multidisciplinary diabetes care team in an integrated delivery system. The roles of the telephone-based RD/CDEs are varied and unique. Below is a case study that demonstrates the PBH Phone Line

and concerned about what to eat; PBH Phone Line RD advises patient to speak with Phone Line RD/CDE for further diabetes assessment and nutrition instruction.

Same day

Assessment/Education/Goal Setting. PBH Phone Line RD/CDE contacts patient for more in-depth diabetes assessment. RD/CDE completes detailed initial assessment identifying individual's specific educational and self-management needs; patient reports that her physician increased NPH insulin from 8 to 12 units at bedtime; discusses basic diabetes survival skills and develops meal plan for next two days focusing on three regular meals, consistent portion sizes, carbohydrate distribution and monitoring BG levels 3-4x/day; short-term goals were agreed upon and follow-up appointment with RD/CDE scheduled.

Three days later

Education/Goal Setting/Evaluation. PBH Phone Line RD/CDE contacts patient for follow-up goals. Patient reports meeting short-term goals of eating three regular meals with consistent portions and monitoring BG levels 3x/day. Her morning BG levels are 80-100 mg/dl; noon and PM BG levels run in range of 200-300 mg/dl. RD describes in more detail the nutritional management of diabetes with focus on carbohydrates and how they affect BG levels. Short-term goals are set by patient and a follow-up is scheduled in two weeks with RD/CDE.

Two weeks later

Assessment. PBH Phone Line RD/CDE contacts patient for follow-up call; patient reports BG levels have significantly increased since discontinuing glyburide; morning BG levels are 200 mg/dl, noon BG levels are 250-300 mg/dl; states she feels better since insulin initiation and thinks that her overall BG levels have decreased. She is advised to schedule appointment with physician for follow-up on medical management of diabetes. The follow-up appointment with RD/CDE is scheduled for 2 weeks. Patient is advised to complete 3-day food diary and doctor

recommends she see RD/CDE in clinic for face-to-face encounter; she is given a completed written referral for clinic-based RD/CDE appointment.

Two weeks later

RD makes three attempts to reach patient for scheduled appointment and leaves message for patient to call and schedule appointment. RD sends unable-to-reach letter to encourage her to call and reschedule appointment.

8/29/00-Clinic visit

Follow-up with physician. Patient reports she is trying faithfully to follow her diet and is walking on a regular basis. She has not had any low blood glucose reactions; insulin therapy continues. Physician restarts 5 mg glyburide b.i.d. with goal for patient to continue to monitor BG levels 4 times/day and phone them in weekly.

Two weeks later

Assessment/Evaluation. Patient recontacts PBH Phone Line RD/CDE. She states her BG levels have been ranging between 112-142 mg/dl. She has been very active with housework and walking, eating more fresh fruit and vegetables, and is aware of portions and carbohydrate-containing foods because she now understands how they affect her BG levels. She schedules an appointment to see clinic-based RD/CDE on 9/29/00 and a follow-up with PBH Phone Line RD/CDE after face-to-face RD/CDE consult at clinic.

Two weeks later

Clinic-based RD/CDE Nutrition Consult for Diabetes. Clinical RD/CDE is very impressed with patient's knowledge of carbohydrate-containing foods as well as portion sizes. She reinforces meal plan that was set by PBH Phone Line RD/CDE and congratulates her on her efforts to manage her diabetes.

Two weeks later

Goal Setting/Evaluation. At follow-up appointment with PBH Phone Line RD/CDE patient reports "taking care of her diabetes is a lot of work but feels much better with BG levels under control": morning BG levels 70-110 mg/dl,

noon 200-270 mg/dl, dinner 120-222 mg/dl; RD/CDE commends patient on diabetes management and reinforces previous goals. Follow-up appointment scheduled in three weeks.

Future calls

PBH Phone Line RD/CDE will continue to follow patient every 3 weeks to review goals, monitor outcomes of medical nutrition therapy and revise therapy, as needed. Follow-up phone calls will continue until member is comfortable with diabetes self-management skills.

ROLES OF THE PBH PHONE LINE RD/CDE

This case study is only one example of a telephone-based intervention. The following list was adapted from the Scope of Practice for Qualified Dietetics Professionals in Diabetes Care and Education and summarizes the many roles of the PBH phone line RD/CDE (2).

- Complete a patient profile and assessment screen for diabetes and an in-depth diabetes assessment, including readiness to change. If medical issues are identified, the patient is referred back to her/his health care provider.
- Interpret appropriate laboratory results from the electronic medical record.
- Reinforce general diabetes information by reviewing the diabetes disease process and treatment options. If the patient has not attended an American Diabetes Association-recognized diabetes education program, they are advised to do so and are provided with enrollment information.
- Provide individualized nutrition prescription using the appropriate meal-planning approaches, while reinforcing blood glucose monitoring to improve control. Coordinate exercise strategies and make referral to exercise specialist as needed.
- Assist in problem-solving for daily living, including high-risk situations such as hyperglycemia, hypoglycemia, travel, and sick days.
- Document outcomes in both the paper and electronic medical record to communicate with all diabetes team members.
- Collect satisfaction and behavior change data and evaluate telephone-based courses and counseling using out-

come criteria. Use the data to develop and revise telephone protocols, courses, and educational materials to ensure quality diabetes care.

■ Provide professional diabetes expertise to other health professionals on the PBH Phone Line.

The general scope of practice of a diabetes educator has changing dimensions because of the health care professionals who provide it and the changing health-

care system. The primary role of a diabetes educator is to provide an "accessible therapeutic experience for people with diabetes, their families, and appropriate support systems that enhance effective self-care management and improve health outcomes and quality of life (1)." Telephone-based diabetes interventions, such as the PBH Phone Line, can meet this primary role and be a valuable resource for patients with diabetes.

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Growing Options For The Treatment Of Diabetes

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ABSTRACT

Over the past five years, major advances in the treatment of diabetes have occurred. Forms of insulin and means of delivery have improved control of glucose following meals and overnight and have offered newer, non-injection options of administration. Oral medicine classes have grown from two to six in the past five years and improve glycemic control as well as blood lipids, blood pressure, clotting, endothelial dysfunction, and preserve beta-cell function.

INSULIN OPTIONS

Waiting to Inhale . . .

Patient barriers to insulin therapy range from the standard fear of needles to the misconception that insulin means "the diabetes is now bad," or that insulin is the "last phase of diabetes" before complications and death. These and many other hurdles to insulin therapy have led researchers to explore alternative routes of insulin administration.

Inhaled insulin (insulin inhaled into the lungs via oral administration) is the newest avenue for mealtime insulin administration. Taken from the field of pulmonary medication delivery systems commonly used to deliver asthma medications, this method may be commercially available some time in 2001. Packets of dry regular insulin are placed in a flashlight-size container. The patient

then breathes insulin into the bronchial linings where it is absorbed through the respiratory mucosa. Surprisingly, the insulin is absorbed (about 15 percent of an inhalation-administered dose is bioavailable compared to about 45 percent of a subcutaneously injected dose) more quickly than the very rapid insulin analogues such as insulin lispro.

The major problems currently associated with the use of inhaled insulin are the large size of the delivery container and the cost of the insulin since significantly more insulin must be administered to achieve therapeutic goals when compared to subcutaneous injections. In addition, because of the short duration of the insulin, there is a need to frequently administer the inhaled insulin and to continue basal insulin injections. As with nasal delivery of insulin, the presence of respiratory infections or disease hampers the effectiveness of inhalation treatment (1). Despite these drawbacks, inhaled insulin may find a role when combined with basal insulin injections or in patients with type 2 diabetes who have adequate basal insulin secretion. With the prospect of fewer or no injections, its approval is eagerly awaited by many.

SLOW, BUT STEADY, MAY WIN THIS RACE

When replacing insulin, it is necessary to give both basal insulin (to suppress hepatic glycogenolysis and gluconeogenesis) and bolus insulin (to meet short-term requirements, such as glycemia following a meal). NPH, lente, and ultralente have been used as basal insulin options for many years. Unfortunately, all these insulins have a peak action, which is often

unpredictable, and they either don't last a full 24 hours or last for more than 24 hours. Insulin analogs that address these issues are in production with release planned in the next year.

Insulin glargine (Lantus, Aventis Pharmaceuticals) was approved by the U.S. Food and Drug Administration in April 2000 and was still awaiting release as of the preparation of this paper. This insulin relies on insolubility at the body's pH of 7 for its prolonged absorption. It does not appear to have a peak and it lasts for 24 hours. To achieve its slow absorption from the injection site, insulin glargine is constituted at a pH of 4, causing it to burn or be irritating upon injection. This very acidic pH precludes the mixing of insulin glargine with other insulins, but this fact is of limited interest in view of the manufacturer's recommendation that glargine be dosed once daily, at bedtime. Another basal insulin currently in trials is NN304 (Detemir, Novo Nordisk Pharmaceuticals) which creates its 24-hour action by combining insulin with a fatty acid molecule. Similar to glargine, it appears to last 24 hours and has no significant peak action.

Unfortunately, as with any insulin, these basal insulins do not "read" the insulin sensitivity changes of the body and adjust with changing needs. But, these new insulins may offer some advantages over NPH and lente for certain patients, reducing the risks of hypoglycemia, especially in the early morning hours. Another potential use will be in the patient who is frequently in diabetic ketoacidosis (DKA) because of skipped injections secondary to emotional or situational difficulties. A single injection each day will provide 24-

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Diabetes Care 24: 202-208.
- JD Piette, SJ McPhee, M Weinberger, CA Mah, and FB Kraemer
Use of automated telephone disease management calls in an ethnically diverse sample of low-income patients with diabetes
Diabetes Care 22: 1302-1309.
- JD Piette, and CA Mah
The feasibility of automated voice messaging as an adjunct to diabetes outpatient care
Diabetes Care 20: 15-21.

Abstract 1 of 3 ■ *Diabetes Care* 24:202-208, 2001
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Clinical Care/Education/Nutrition Original Article

Impact of Automated Calls With Nurse Follow-Up on Diabetes Treatment Outcomes in a Department of Veterans Affairs Health Care System

A randomized controlled trial

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OBJECTIVE— We evaluated automated telephone disease management (ATDM) with telephone nurse follow-up as a strategy for improving diabetes treatment processes and outcomes in Department of Veterans Affairs (VA) clinics. We also compared the results with those of a prior ATDM trial conducted in a county health care system.

RESEARCH DESIGN AND METHODS— A total of 272 VA patients with diabetes using hypoglycemic medications were randomized. During the 1-year study period, intervention patients received biweekly ATDM health assessment and self-care education calls, and a nurse educator followed up with patients based on their ATDM assessment reports. Telephone surveys were used to measure patients' self-care, symptoms, and satisfaction with care. Outpatient service use was evaluated using electronic databases and self-reports, and glycemic control was measured by HbA_{1c} and serum glucose testing.

RESULTS— At 12 months, intervention patients reported more frequent glucose self-monitoring and foot inspections than patients receiving usual care and were more likely to be seen in podiatry and diabetes specialty clinics. Intervention patients also were more likely than control patients to have had a cholesterol test. Among patients with baseline HbA_{1c} levels $\geq 8\%$, mean end-point values were lower among intervention patients than control patients (8.7 vs. 9.2%, respectively; $P = 0.04$). Among intervention and control patients with baseline values $\geq 9\%$, mean end-point values were 9.1 and 10.2%, respectively ($P = 0.04$). At follow-up, intervention patients reported fewer symptoms of poor glycemic control than control patients and greater satisfaction with their health care.

CONCLUSIONS— This intervention improved the quality of VA diabetes care. Intervention effects for most end points replicated findings from the prior county clinic trial, although intervention—control differences in the current study were smaller because of the relatively good self-care and health status among the current study's enrollees.

[[Full Text of Piette et al.](#)] [[Reprint \(PDF\) Version of Piette et al.](#)]

Abstract 2 of 3 ■

Diabetes Care, Vol 22, Issue 8 1302-1309, Copyright © 1999 by American Diabetes Association

ARTICLES

Use of automated telephone disease management calls in an ethnically diverse sample of low-income patients with diabetes

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OBJECTIVE: We examined whether low-income patients with diabetes were able and willing to use automated telephone disease management (ATDM) calls to provide health status information that could improve the quality of their care. **RESEARCH DESIGN AND METHODS:** A total of 252 adults with diabetes, 30 of whom spoke Spanish as their primary language, were enrolled at the time of clinic visits in a Department of Veterans Affairs health care system ($n = 132$) or a county health care system ($n = 120$). Patients received ATDM calls for 12 months and responded to queries using their touch-tone telephones. We examined 1) whether patients completed ATDM assessments consistently over the year and used the calls to report their self-monitored blood glucose (SMBG) levels, 2) the characteristics of patients most likely to use the system frequently, 3) whether patients responded consistently within ATDM assessments, and 4) whether ATDM assessments differentiated among groups of patients with different clinical profiles at baseline. **RESULTS:** Half of all patients completed at least 77% of their attempted assessments, and one-fourth completed at least 91%. Half of all patients reported SMBG levels during at least 86% of their assessments. Patients completed assessments and reported glucose levels consistently over the year. Health status indicators were the most important determinants of assessment completion rates, while socioeconomic factors were more strongly associated with patients' likelihood of reporting SMBG data during assessments. Patients' responses within assessments were consistent, and the information they provided during their initial assessments identified groups with poor glycemic control and other health problems. **CONCLUSIONS:** Most low-income patients with diabetes can and will use ATDM calls as part of their care. The information they provide is reliable and has clinical significance. ATDM calls could improve the information base for diabetes management while relieving some of the pressures of delivering diabetes care under cost constraints.

[Reprint (PDF) Version of Piette et al.]

Abstract 3 of 3

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ARTICLES

The feasibility of automated voice messaging as an adjunct to diabetes outpatient care

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OBJECTIVE: To determine whether automated voice messaging (AVM) systems could be used as an adjunct to primary care for diabetic patients, we examined whether patients were able to respond to AVM queries for clinical information, whether sufficient numbers of problems were identified to warrant the implementation of the service, and whether patients found the system helpful. **RESEARCH DESIGN AND METHODS:** The AVM system we examined uses specialized computer technology to

telephone patients, communicate messages, and collect information. Sixty-five diabetic patients participated. Based on a review of the literature and the input of diabetes clinician-researchers, we developed an AVM monitoring protocol to inquire about patients' symptoms, glucose monitoring, foot care, diet, and medication adherence. Patients also were given the option to listen to health promotion messages and to report their satisfaction with the calls. Patients responded by using their touch-tone telephone keypads. **RESULTS:** A total of 216 AVM calls were successfully completed, an average of 3.3 out of four calls per patient. Patients reported a variety of health problems that signaled the need for follow-up. Many patients reported not checking their blood glucose or their feet, and one in four reported problems with medication and diet adherence. Health and self-care problems varied across patient subgroups in ways suggesting that the AVM reports were reliable and valid. Overall, 98% of all patients reported that the calls were helpful, 98% reported that they had no difficulty responding to the calls, and 77% reported that receiving AVM calls would make them more satisfied with their health care. **CONCLUSIONS:** This study demonstrates that diabetic patients can respond to AVM queries and find the calls helpful. Such calls are a feasible strategy for identifying health and self-care problems that would otherwise go unnoticed by clinicians.

HOME	HELP	FEEDBACK	SUBSCRIPTIONS	ARCHIVE	SEARCH	SEARCH RESULT
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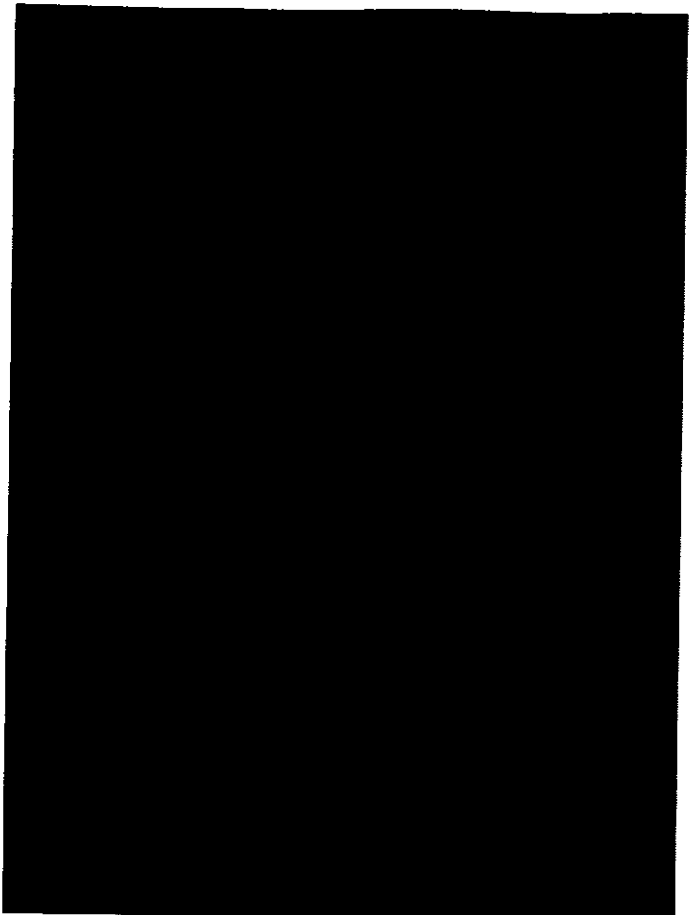
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HealthPartners®

Health Behavior Group

A Call to Change (CTC) Telephone Courses Outcomes Report



A Call to Change (CTC) Telephone Courses

CTC – Healthy Lifestyles, Healthy Weight

Key Outcomes				Supporting References
Date Range: 1/1/2000 – 6/30/2003 1947 enrolled, 785 (40%) completed, 409 (52%) were available for 6-months follow-up				
	Baseline	Post-course	Follow-up	
BMI (kg/m ²)	33.13±7.35	31.77±7.15 *	31.15±6.23 *	- Boucher J, Schumann J, Pronk, N. The Effectiveness of Telephone-Based Counseling for Weight Management. <i>Diabetes Spectrum</i>. 1999;12:121-123. - Jeffery RW, Sherwood NE, Brejle K, Pronk NP, Boyle R, Boucher JL, Hase K. Mail and phone interventions for weight loss in a managed-care setting: Weight-To-Be one-year outcomes. <i>Int J Obes Relat Metab Disord</i>. 2003;27:1584-92.
Body Weight (pounds)	204.76±50.43	196.44±48.81 *	192.21±43.55 *	
Aerobic Exercise (days per week)	2.47±2.13	3.57±1.86 *	3.07±1.98 *	
Physical Activity (days/week)	5.13±2.04	5.75±1.57 *	5.60±1.75 *	
Muscle Conditioning (days per week)	0.97±1.66	1.77±1.72 *	1.45±1.60 *	
Normalized Eating (days per week)	5.58±2.15	6.25±1.34 *	6.23±1.45 *	
Fruit/Vegetable Consumption (servings/day)	3.39±1.54	4.50±1.47 *	4.26±1.51 *	
Dietary Fat Intake Rating (0-high, 2-average, 4-low)	1.59±1.37	2.79±1.19 *	2.81±1.21 *	

* Statistically significant difference (p<0.05) compared to baseline

CTC – Balancing Life with Diabetes

Key Outcomes				Supporting References
Date Range: 7/1/2001 – 6/30/2003 651 enrolled, 298 (46%) completed, 192 (64%) were available for 6-months follow-up				Hayes JT, Boucher JL, Pronk NP, Gehling E, Spencer M, Waslaski J. The role of the certified diabetes educator in telephone counseling. <i>Diabetes Educ.</i> 2001;27:377-386.
	Baseline	Post-course	Follow-up	
BMI (kg/m ²)	33.23±8.12	32.72±8.04 *	31.89±7.72 *	
Body Weight (pounds)	205.74±50.80	202.78±50.34 *	198.39±47.47 *	
Self-reported HbA1c <8%	67%	84% *	82% *	
Physical Activity (days/week)	5.14±2.00	5.55±1.62 *	5.47±1.79	
Fruit/Vegetable Consumption (servings/day)	3.73±1.60	4.44±1.40 *	4.47±1.53 *	
Dietary Fat Intake Rating (0-high, 2-average, 4-low)	2.14±1.25	2.99±1.18 *	2.91±1.71 *	
Self Blood Glucose Monitoring Frequency	Never Monthly Weekly Daily	2% 1% 10% 87% *	3% 2% 16% 79%	
Comfort in Discussing Diabetes with Health Care Provider (1-very, 2-somewhat, 3-not)	1.94±0.44	1.07±0.26 *	1.06±0.26 *	
Knowledge of Diabetes Management (1-poor through 5-excellent)	2.13±0.90	3.12±0.64 *	3.05±0.68 *	

* Statistically significant difference (p<0.05) compared to baseline

CTC – Living Well with Heart Disease

Key Outcomes				Supporting References
Date Range: 12/1/2002 – 6/30/2003 58 enrolled, 28 (48%) completed, 22 (79%) were available for 6-months follow-up				• VanWormer JJ, Boucher JL, Pronk NP, Thoenness JJ. Lifestyle behavior change and coronary artery disease: Effectiveness of a telephone-based counseling program. <i>J Nutr Educ Behav</i> . In press.
	Baseline	Post-course	Follow-up	
BMI (kg/m ²)	29.92±6.52	29.55±6.47	30.13±8.25	
Body Weight (pounds)	183.82±44.60	183.32±44.53	184.33±47.60	
Pedometer Steps (steps per day)	5197.03±2874.11	8311.40±2785.23 *	7698.37±2404.17 *	
Physical Activity (days/week)	5.89±1.77	6.21±1.17	6.20±1.61	
Fruit/Vegetable Consumption (servings/day)	4.11±1.65	4.89±1.07 *	4.47±2.03	
Dietary Fat Intake Rating (0-high, 2-average, 4-low)	3.11±1.01	3.29±0.98	3.33±0.98	
Knowledge of CAD Management (1-poor through 5-excellent)	1.60±1.38	2.79±1.11 *	2.83±1.22 *	
* Statistically significant difference (p<0.05) compared to baseline				

CTC – Partners in Quitting

Key Outcomes				Supporting References
Date Range: 10/1/2001 – 6/30/2003 534 enrolled, 112 (21%) completed, 63 (56%) were available for 6-months follow-up				Boyle RG, Solberg L, Asche SE, Boucher JL, Pronk NP, Jensen C. <i>Offering telephone counseling to smokers using pharmacotherapy.</i> Manuscript submitted for publication (Nicotine Tob Res).
	Baseline	Post-course	Follow-up	
BMI (kg/m ²)	27.20±8.02	28.05±6.71	28.06±8.43	
Body Weight (pounds)	175.35±53.34	179.09±51.60	184.26±58.68	
Aerobic Exercise (days per week)	1.67±2.09	2.71±2.35 *	2.14±2.15	
Smoker †				
Yes	80%	7% *	38% *	
No	20%	93%	62%	
Cigarettes per day	14.22±11.66	0.97±4.06 *	5.02±10.02 *	

* Statistically significant difference (p<0.05) compared to baseline

† Note that some participants enroll immediately after quitting and treat the course as a maintenance program

CTC – Balancing Stress for Healthy Living

Key Outcomes				Supporting References
Date Range: 1/1/2000 – 6/30/2003 119 enrolled, 67 (56%) completed, 37 (55%) were available for 6-months follow-up				
	Baseline	Post-course	Follow-up	
BMI (kg/m ²)	26.55±8.27	27.14±6.73	28.03±9.31	
Body Weight (pounds)	169.07±55.98	171.07±50.90	182.65±60.48	
Physical Activity (days/week)	5.55±2.00	5.51±1.80	5.14±1.97	
Normalized Eating (days per week)	5.42±2.32	5.70±2.03	5.08±2.56	
Sleep (hours per night)	6.12±1.38	6.94±1.22 *	6.89±1.29 *	
Stress Problem Rating (1-none, 2-slight, 3-somewhat, 4-big)	3.24±0.70	2.37±0.74 *	2.41±0.83 *	
Relaxation Techniques Utilization Rating (1-often, 2-sometimes, 3-never)	2.34±0.69	1.58±0.58 *	1.78±0.67 *	
Time Management Skills Utilization Rating (1-often, 2-sometimes, 3-never)	1.75±0.72	1.37±0.49 *	1.46±0.61	

* Statistically significant difference (p<0.05) compared to baseline

CTC – Back to Health

Key Outcomes				Supporting References
Date Range: 1/1/2000 – 6/30/2003 29 enrolled, 14 (48%) completed, 6 (43%) were available for 6-months follow-up				
	Baseline	Post-course	Follow-up	
BMI (kg/m ²)	27.52±7.40	27.66±7.57	24.34±4.00	
Body Weight (pounds)	176.14±47.36	174.79±48.00	153.33±39.75	
Aerobic Exercise (days per week)	1.86±1.92	3.71±1.94 *	3.17±2.93	
Physical Activity (days/week)	5.29±1.68	5.79±1.25	5.83±1.83	
Muscle Conditioning (days per week)	1.00±1.57	2.71±1.54 *	2.17±2.99	
Flexibility Exercises (days per week)	2.14±2.50	4.36±2.13 *	3.83±3.13	
Lifting Limitation Rating (1=very, 2=somewhat, 3=not)	2.43±0.51	2.86±0.36 *	2.67±0.52	
Stair Climbing Limitation Rating (1=very, 2=somewhat, 3=not)	2.57±0.65	2.93±0.27 *	3.00±0.00 *	
Days Absent due to Back Pain				
0	79%	93%	100%	
1-3	14%	0%	0%	
4-7	0%	0%	0%	
> 7	7%	7%	0%	

* Statistically significant difference (p<0.05) compared to baseline

CTC – Managing Your Cholesterol

Key Outcomes				Supporting References
Date Range: 1/1/2000 – 6/30/2003 110 enrolled, 78 (71%) completed, 43 (55%) were available for 6-months follow-up				
	Baseline	Post-course	Follow-up	
BMI (kg/m ²)	28.06±5.44	27.54±4.86	27.04±4.42	
Body Weight (pounds)	175.14±36.95	172.68±34.26	166.43±42.09	
Aerobic Exercise (days per week)	2.85±2.23	3.51±2.20	3.63±2.26	
Physical Activity (days/week)	5.31±1.90	5.61±1.66	5.63±1.70	
Dietary Fat Intake Rating (0-high, 2-average, 4-low)	2.00±1.29	3.19±1.04 *	3.30±1.15 *	
Total Cholesterol (mg/dL)	242.35±39.23	234.69±42.40	212.00±45.93	
HDL Cholesterol (mg/dL)	48.92±14.48	50.79±16.38	44.00±9.82	
LDL Cholesterol (mg/dL)	164.10±34.87	157.51±37.93	135.06±42.94	
Triglycerides (mg/dL)	194.47±168.25	182.17±148.65	148.95±42.94	

* Statistically significant difference (p<0.05) compared to baseline

760
SEP 30 2005

To

September 18 2005

Medicare

Attn: Diane Milstead and Gaysha Brooks, CMS 1502-P

P.O. Box 8017

Baltimore, Maryland 21244-8017

RE: Nuclear Medicine and Positron Emission Tomography

Dear Sir

It is my understanding that CMS is contemplating changes so that PET scans will fall in the realm of "Starke" Laws.

Let me be on record that I respectfully wish to have such a change be opposed.

I state that because presently I am a less than 5% owner in an establishment that provides such a service. Service that was needed by the sick in the area -and was met by local Physicians -the sick benefitted and continue to benefit.

We the Physicians took "risk". We as Americans, as capitalist took risk-created a small business. Our President has talked about this with much passion and fervor. We embrace the notion of competition Now the business is successful and the CMS wishes me to at best divest-at worst lose the money I have invested. This is not fair.

I for one have not abused the "system".

System has checks within it to define under what circumstances it would be considered that the test when done will be reimbursed by CMS. Criteria and ICD codes are well defined. Abuse potential would be considered small. If this is not the case can we ask CMS to provide us with data of such abuse? The notion that we as Physicians collectively should be barred -due to perceived or a few abusers is draconian.

I believe CMS should "grand father" the existing establishments and their present ownership structure.

Can we know if the Hospital Association has taken a position requiring for physicians to not be allowed ownership in these ventures? I will presume the answer to be affirmative. Predictably they have already started to circle above us.

I ask also, because I believe the cost of care goes down as more competitive entities increase in number-regulations to allow mammoth powerful entities to effectively monopolize will have an adverse outcome on the notion of free enterprise, competition and lowering of costs while excelling in service delivered. The forces that are presumed that may lead to abuse in this model merely transform when they come to reside in other entities-but do not completely disappear.

Thus I respectfully request that PET scan and its ownership remain outside of "Starke referral laws". If nothing else "grandfather" it.

Sincerely



Bharat PITHADIA M.D., M.P.H.

2102 E. EVANS AVE.

VALPARAISO IN 46387

219-4761703

September 28, 2005

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

Dear Doctor McClellan:

The American Medical Association/Specialty Society RVS Update Committee (RUC) appreciates the opportunity to comment on the Notice of Proposed Rule for the 2006 Physician Payment Schedule, published in the August 8, 2005 *Federal Register*.

Practice Expense Relative Values

The Centers for Medicare and Medicaid Services (CMS) has proposed to use the direct practice expense data generated by the RUC and its Practice Expense Advisory Committee (PEAC) to determine direct practice expenses at the CPT code level. CMS has stated that they believe this change in methodology will lead toward the following goals:

- To ensure that the PE payments reflect, to the greatest extent possible, the actual relative resources required for each of the services on the physician payment schedule. This could only be accomplished by using the best available data to calculate the PE relative values.
- To develop a payment system for PE that is understandable and at least somewhat intuitive, so that specialties could generally predict the impact of changes in the PE data.
- To stabilize the PE payments so that there are not large fluctuations in the payment for given procedures from year-to-year.

The RUC completely agrees with these goals. Although we do not believe that each of these goals have been completely met, we look forward to our work with you to meet each of these objectives.

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September 28, 2005
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The PEAC completed its review of the direct practice expense data (clinical staff, medical supplies, and medical equipment) for existing codes in March 2004. The RUC, PEAC, and specialty societies have contributed significant resources over the past five years to ensure that the direct practice expense data are fair and relative across all CPT codes. The RUC also congratulates CMS for the sincere and extraordinary effort of your staff in reviewing this data and implementing it in a timely fashion each year. We are proud of this effort and its end result and strongly encourage the continued utilization of this data.

The review of direct practice expense data, however, must continue. The RUC will continue its process of reviewing practice expense data for new and revised codes on an annual basis. In addition, the RUC will be exploring how to best address ongoing practice expense refinement needs, such as new technology that moves into the physician office, at our February 2006 meeting.

In addition, the RUC requests that CMS consider a different approach for payment of high-priced disposable medical supplies, such as the creation of J codes for the separate reporting of such items. The RUC is concerned that under the current payment methodology, these supplies are priced at one point and time and then hidden within the overall physician payment for this service, without further review. Disposable supplies that reflect new technology may reflect pricing changes within the first six months to one year after a wider release into the market. The RUC strongly encourages CMS to review and re-price medical supplies, priced at or above \$200, on an annual basis. We understand that currently there are only 40 such supply items priced above \$200.

Finally, the RUC requests that any savings from any new policies related to imaging multiple procedure reductions to be applied within the practice expense relative values, rather than to all relative values. The RUC has consistently commented that the physician work relative values should remain stable and again request that CMS not apply budget neutrality adjustments to this portion of the RBRVS.

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

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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 are interested in reviewing this data, so the resulting inputs enjoy the same level of scrutiny and cross-specialty refinement that all of the other direct practice expense inputs have.

Implanted Neuraxial Pump and Stimulator Programmer

CMS has proposed eliminating the direct practice expense inputs for the cost of purchasing the programming devices for implanted neuraxial drug infusion pumps and dorsal column stimulators, based on the Medtronic Corporation's contention that these programmers are provided free of charge to physicians. Several organizations representing pain medicine physicians, including ASA, AAPM and ASIPP, performed an e-mail based survey of practicing pain physicians to determine the validity of the Medtronic claim. Of the over 70 responses received thus far, 60% of physicians report paying for the programmers and only 40% reported receiving a programmer without charge.

Given that the majority of the survey responses received indicate that the physicians do pay for these programming units, the RUC believes that Medtronic's claim has questionable validity, payment for these programmers is typical and recommends that the previously RUC approved direct inputs for the programmers be maintained for codes 62367, 62368 and 95970-79. In addition, the RUC recognizes that a number of manufacturers, in addition to Medtronic, also produce pumps and stimulators and is concerned that CMS would base this proposed change solely on the recommendation from a single manufacturer.

Professional Liability Insurance Relative Values

The RUC sent the attached letters to CMS on March 4, 2005 and May 26, 2005 regarding our recommendations on improvements to the methodology to calculate Professional Liability Insurance (PLI) relative value. We appreciate the CMS response to each of these recommendations in the NPRM. Our comments will focus on your proposals and

Mark B. McClellan, MD, PhD
September 28, 2005
Page Four

we offer several suggestions for modification to the PLI relative value methodology for consideration in your Final Rule on the 2006 Medicare Physician Payment Schedule.

Five Percent Specialty Threshold

The RUC has consistently argued that the dominant specialty should be utilized to determine which risk factor to apply to a CPT code. CMS has determined that the dominant approach will not be utilized, but has offered to review other solutions to remove anomalous data from the utilization. In May, the RUC recommended that CMS remove specialties from the methodology if the specialties represent less than a 5% threshold of the utilization. CMS has proposed utilizing this approach, however, the agency has removed the Evaluation and Management (E/M) codes from this threshold approach. The RUC recommends that the 5% threshold approach be applied in determining PLI relative values for all services, including E/M.

Specialty Crosswalk Issues

In March, the RUC recommended that the following professions risk factor be set to 1.00 as conventional wisdom suggests that their PLI premium data is not greater than \$6,152 per year:

Clinical Psychologist
Licensed Clinical Social Worker
Occupational Therapist
Psychologist

Optician
Optometry
Chiropractic
Physical Therapist

CMS has agreed with the RUC's recommendation and proposes to set the 2006 PLI risk factor to 1.00 for each of the above professions. Each of these professions are represented on the RUC's Health Care Professional Advisory Committee (HCPAC). The HCPAC agreed that these professions should review the current available data on their PLI premium data and report back to the HCPAC at their September 29 meeting. Each of these professions has responded with estimated premium data. For all but optometry, the organization has verified that the annual PLI premium is less than \$6,152 per year. Optometry does not provide any data, but requests that CMS assume that the PLI premium is the same as ophthalmology.

The American Physical Therapy Association (APTA) suggests that CMS should utilize PLI premium amount of \$1,500 to compute the risk factor for physical therapy in 2006. The HCPAC will review all of these submissions on September 29 and will forward that information to CMS immediately after the meeting. The RUC recommends that you consider this information in establishing risk factors for all specialties in 2006 and beyond.

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CMS has announced that it agrees the RUC that the following groups should be treated as the other 34 Medicare specialties that were excluded from the analysis of determining PLI relative values: certified clinical nurse specialist; clinical laboratory; multi-specialty clinic or group practice; nurse practitioner; physician assistant; and physiologist laboratory (independent). We agree with CMS determination to establish PLI relative values based upon the mix of specialties exclusive of these professions and specialties. The RUC recommended that certified registered nurse anesthetists (CRNA) be crosswalked to Anesthesiology (currently 2.84), rather than to the "all physicians" category (currently 3.04). CMS has rejected this recommendation. We do not understand this determination and common sense indicates that the PLI premiums for CRNAs are not higher than anesthesiologists. We request that CMS reconsider this decision.

The RUC also recommended the following crosswalks be considered:

- Gynecologist/oncologist (currently 5.63) should be crosswalked to surgical oncology (currently 6.13 – based on a crosswalk to general surgery).
- Colorectal surgery (currently 4.08) should be crosswalked to general surgery (currently 6.13).
- Hand surgery (currently 4.71) be crosswalked to orthopaedic surgery (without spine) (currently 8.06).

CMS rejected the new crosswalk for gynecology oncology and colorectal surgery and did not mention hand surgery in the NPRM. We request that CMS reconsider this action and adopt the RUC recommendations in the Final Rule.

Cardiac Catheterization and Angioplasty Exception

The RUC fully supports the CMS proposal to correct an ACC clerical error, which resulted in the omission of several cardiac catheterization and angioplasty codes from an exception list, where the risk factor should be "surgical" versus "non-surgical" procedures. The RUC supports adding the following codes to the existing exception list: 92975; 92980-92998; and 93618 – 93641.

Dominant Specialty for Low Volume Codes

After an exhaustive review of 1,844 codes with utilization less than 100 Medicare claims per year, the RUC forwarded a suggested dominant specialty for each of these low volume codes to CMS and suggested the use of this list as a substitution for claims data. CMS has indicated that in most cases, the dominant specialty suggested by the RUC is reflected as the specialty with the highest utilization in the most recent dataset. This may

be true, as these errors in claims will impact low volume codes differently each year. Our point is that CMS should not rely on claims data to determine the appropriate PLI specialty risk factor for these very low volume codes, but instead use the list as developed by the RUC.

The selection of the appropriate specialty may have a significant effect, particularly for those specialties with high PLI premiums. The following is an example of this impact:

	<u>Specialty in Medicare Utilization</u>	<u>Work</u>	<u>PE</u>	<u>PLI</u>
61705	Neurosurgery	36.15	19.25	8.76
61708	Diagnostic Radiology	35.25	15.15	2.49

In this case, staff predicted that neurosurgery should be the specialty for this entire family of services 61705, 61708, and 61710. The only way to safeguard these low volume services from this type of error caused by claims data is to assign the specialty for these codes and avoid any year-to-year fluctuations.

We submit the attached list of recommended specialties for low volume codes again and urge its use for establishing PLI relative values for 2006.

PLI Premium Data Collection

The RUC continues to remain concerned regarding the sources of data utilized for PLI premiums. Representatives from our PLI Workgroup have discussed this issue with CMS staff on behalf of the RUC. We understand that CMS staff will review the potential use of other data sources, such as the Physicians Insurers Association of America (PIAA), in determining how best to collect PLI premium data in the future. We look forward to our work with you to improve this data collection effort.

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

The American Academy of Pediatrics has noted that CMS has not yet published relative values for two CPT codes 99173 *Screening test of visual acuity, quantitative, bilateral*) and 92551 *Screening test, pure tone, air only*. The RUC submitted direct practice expense inputs for both of these services. CPT code 99173 was reviewed in May 1999 and CPT code 92551 was reviewed in February 2005. We reaffirm our previously stated position that CMS has a responsibility to publish relative values for all services, regardless of your coverage policies. We urge you to publish practice expense relative values for these services in the *Final Rule*.

Mark B. McClellan, MD, PhD
September 27, 2005
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The RUC appreciates the opportunity to offer these comments to CMS. We look forward to our continued relationship to further improve the RBRVS.

Sincerely,

A handwritten signature in black ink, appearing to read "William L. Rich, III, MD, FACS". The signature is written in a cursive, flowing style.

William L. Rich, III, MD, FACS

cc: RUC participants
Glenn M. Hackbarth, Chairman of MedPAC

Attachment

American Medical Association

Physicians dedicated to the health of America



William L. Rich III, MD, FACS 515 North State Street 312 464-6804
Chairman Chicago, Illinois 60610 312 464-5849 Fax
AMA/Specialty Society RVS
Update Committee

May 26, 2005

Stephen M. Phillips
Director, Division of Practitioner Services
Hospital and Ambulatory Policy Group
Center for Medicare Management, C4-03-06
7500 Security Blvd.
Baltimore, MD 21244

Dear Mr. Phillips:

It is with pleasure that I submit to the Centers for Medicare and Medicaid Services (CMS), on behalf of the American Medical Association (AMA)/Specialty Society RVS Update Committee (RUC), work relative value and direct practice expense inputs for new and revised codes for CPT 2006. Also included in this submission are the practice expense refinement recommendations for existing CPT 2005 codes. The RUC is also formally submitting recommendations related to the Professional Liability Insurance (PLI) methodology. These recommendations were informally shared with your staff immediately following our April 28-May 1, 2005 meeting. The RUC Health Care Professionals Advisory Committee (HCPAC) Review Board is separately forwarding its recommendations to CMS.

CPT 2006 New and Revised Codes

Enclosed are two binders of RUC recommendations for new and revised codes. The total number of coding changes for CPT 2006 is 447, including 221 additions, 129 revisions, and 97 deletions. Forty-Three of these new and revised codes are not payable on the RBRVS (eg, laboratory services and vaccines), and accordingly, the RUC does not submit any information on these codes. In addition, 14 of the new and revised codes were reviewed by the RUC HCPAC Review Board as they describe services provided by non-MD/DO health professionals. Of the remaining 293 new and revised codes, the RUC submits 283 recommendations at this time.

The RUC is recommending that five codes be carrier-priced in 2006. The RUC will not be submitting relative value recommendations for new CPT codes 15431 *Acellular xenograft implant; each additional 100 sq cm, or each additional one percent of body area of infants and children, or part thereof* and 88384 *Array-based evaluation of multiple molecular probes; 11 through 50 probes* and understands that these services will be infrequently performed. Three unlisted codes (45499, 51999, and 90779) will also be carrier priced. In addition, the RUC is unable to provide recommendations for five drug administration codes (90773, 96420, 96422, 96423, and 96425) performed through an

Stephen M. Phillips
May 26, 2005
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intra-arterial route as survey data for these services was not available. The summary table in the attached binder, and in the enclosed CD, specifically identifies CPT code 33548 *Surgical ventricular restoration procedure, includes prosthetic patch, when performed (ventricular remodeling, SVR, SAVER, DOR procedures)* to be re-reviewed at the September 2005 RUC meeting. We will send any new information related to this service to CMS immediately following the meeting.

Also included in this binder, and on the enclosed CD-ROM, are physician time data for each of the CPT codes reviewed at the September 2004, February 2005, and April 2005 RUC meetings. We will be sending you a comprehensive revision to the entire RUC database for physician time by June 30. The RUC continues to review the physician time data to ensure that the most accurate data is utilized in the CMS practice expense methodology.

Practice Expense Refinements

Also enclosed in this submission is one binder and CD-ROM of practice expense refinement recommendations to existing codes resulting from the tremendous efforts of the RUC's Practice Expense Review Committee (PERC) over the past year. The RUC is submitting recommendations on the direct practice expense inputs for more than 200 existing CPT codes. We understand that the practice expense direct inputs for all existing CPT codes have been reviewed. If CMS identifies any services that have not been refined, please contact AMA staff so that we may schedule those codes for review at an upcoming RUC meeting.

Cost estimates for medical supplies and equipment not listed on "CMS's Labor, Supply, and Equipment List for the Year 2005" are based on provided source(s) as noted, such as manufacturer's catalogue prices and may not reflect the wholesale prices, quantity or cash discounts, prices for used equipment or any other factors which may alter the cost estimates.

In the course of reviewing new and revised congenital cardiac procedures, the RUC identified an error in the database of direct practice expense inputs for cardiothoracic surgery. The RUC had previously recommended that all clinical staff time for cardiothoracic surgery be assigned a staff type of RN, rather than the traditional RN/LPN/MTA blend. Unfortunately, our submission only included a spreadsheet with all of the cardiothoracic surgery high volume codes and, therefore, it appears that the application of this standard to all cardiothoracic surgery services was not implemented. We have attached a list of all cardiothoracic services. The RUC recommends that the staff type be modified to RN only for each of these identified codes.

Stephen M. Phillips
May 26, 2005
Page Three

Professional Liability Insurance

The RUC continues to be concerned regarding the Medicare utilization data and its use in the PLI relative value methodology. As we have stated in past comment letters to CMS, we believe that the dominant specialty should be utilized to determine which risk factor to apply to a CPT code. The RUC will continue to advocate that this is preferable to the case mix approach that is currently utilized by CMS. The RUC understands that to date CMS has determined that the dominant approach will not be utilized. However, CMS has offered a number of other solutions to remove anomalous data from the utilization database. The RUC appreciates this consideration.

The first CMS suggestion to improve the data is to remove specialties from the methodology if the specialties represent less than a certain percentage threshold (1%, 3%, or 5%) of the utilization. The RUC has reviewed the CMS request to consider the various threshold levels and the RUC recommends that a 5% level be utilized as it most closely reflects the dominant approach. The RUC considers the recommendation to implement a threshold as an interim step and will continue to advocate the dominant approach.

In addition, CMS has considered a review of anomalous data within low volume codes. The RUC engaged in a project to review CPT codes with Medicare utilization of fewer than 100 services reported. A review of 1,844 CPT codes with total volume less than 100 per year, yielded 240 CPT codes where the specialty who would be expected to be the dominant provider is not indicated as the most frequent provider of the service. In addition, 152 CPT codes have zero Medicare utilization and in this case, the RUC has indicated an expected dominant specialty for each service. The RUC recommends that CMS use the attached spreadsheet on low volume codes for consideration in their 2006 rulemaking process. The RUC strongly recommends that CMS utilize these recommended specialties for low volume codes (i.e., fewer than 100 claims per year), rather than rely on claims data.

On March 4, 2005, the RUC submitted a letter to CMS with several recommendations related to the PLI methodology, including a recommendation to crosswalk gynecologist/oncologist to surgical oncology and colorectal surgery to general surgery. In April 2005, hand surgery also identified themselves as having been assigned an inappropriate risk factor. The RUC recommends that hand surgery be crosswalked to orthopaedic surgery (without spine). The American Society for Hand Surgery has provided additional support in the attached letter to verify that the majority of hand surgeons are orthopaedic surgeons and incur the same PLI premiums as orthopaedic surgeons.

Stephen M. Phillips
May 26, 2005
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We appreciate your consideration of the RUC's recommendations. You may contact Sherry Smith with any questions regarding this submission

Sincerely,

William Rich, MD
William Rich, MD

cc: Ken Simon, MD
Rick Ensor
Edith L Hambrick MD
Carolyn Mullen
Pam West, PT
RUC Participants

American Medical Association

Physicians dedicated to the health of America



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AMA/Specialty Society RVS
Update Committee

March 4, 2005

Stephen Phillips
Director, Division of Practitioner Services
Center for Medicare Management
Centers for Medicare and Medicaid Services
7500 Security Boulevard, C4-03-06
Baltimore, Maryland 21244

Dear Mr. Phillips:

The American Medical Association (AMA)/Specialty Society RVS Update Committee (RUC) has reviewed the current crosswalks and risk factor assignments utilized in the professional liability insurance (PLI) relative value methodology and offers recommendations for revisions for consideration in the rulemaking processes this year.

As you know, the Centers for Medicare and Medicaid Services (CMS) indicated in the November 15 *Final Rule* that the agency was interested in RUC input on the appropriateness of the crosswalk assumptions. The RUC provided all specialty societies and Health Care Professionals Advisory Committee (HCPAC) organizations with the opportunity to submit comments on the crosswalks listed in the November 15 *Final Rule*. The RUC reviewed comments submitted by specialty societies and recommends a number of modifications to the risk factor assignments.

1. The RUC understands that the professions list below would not incur PLI premium rates greater than \$6,152 per year (your current base for a 1.00 risk factor). It would, therefore, be appropriate to assign the current lowest risk factor of 1.00 for both non-surgical and surgical codes for each of these professions. This recommendation should be considered an interim step. The RUC believes that the PLI premium rates for these professions may be substantially less than \$6,152. The RUC also recommends that the RUC HCPAC review and discuss these recommendations. The RUC would be willing to review any data provided by a professional group to refute the understanding that the annual PLI premium data is less than \$6,100. We urge CMS to set the risk factors to 1.00 and then work to collect PLI premium data for the following professions:

Clinical Psychologist
Licensed Clinical Social Worker
Occupational Therapist
Psychologist

Optician
Optometry
Chiropractic
Physical Therapist

Stephen Phillips

March 3, 2005

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2. The RUC expresses concern about a number of specialties/professions that were assigned to an average "all physician" risk factor (currently 3.04 non-surgical / 3.71 surgical). The RUC recommends that the following groups should have been treated as the other 34 Medicare specialties that were excluded from the analysis:

- Certified Clinical Nurse Specialist
- Clinical Laboratory
- Multi-Specialty Clinic or Group Practice
- Nurse Practitioner
- Physician Assistant
- Physiological Laboratory (Independent)

3. The RUC recommends that certified registered nurse anesthetists (CRNA) be crosswalked to Anesthesiology (currently 2.84), rather than to the "all physicians" category.
4. The RUC also notes that the rank order premium data appeared problematic for colorectal surgery and gynecologist/oncologist and recommends that these two specialties be crosswalked as follows:

Gynecologist/oncologist (currently 5.63) should be crosswalked to surgical oncology (currently 6.13 – based on crosswalk to general surgery).

Colorectal surgery (currently 4.08) should be crosswalked to general surgery (currently 6.13).

5. The RUC recommends that CMS publish a separate impact analysis in the *Notice of Proposed Rulemaking (NPRM)*, by specialty, resulting from the acceptance of the above RUC recommended modifications to crosswalks.

Correction of Previous RUC Action

The American College of Cardiology (ACC) requested that the RUC correct a clerical mistake created when the RUC's PLI Workgroup updated exceptions to the surgical risk factor assignment. The PLI Workgroup agreed that it appears that a clerical mistake was made as the society never intended that these services be removed from the exception list. The RUC recommends that CMS add back the following codes to the surgical risk factor list for cardiac catheterization (2.53 in 2005):

92980-92984

92985-92998

93617-93641

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The RUC also recommends that 92975 be added to the cardiac catheterization (surgical risk factor) list based on their own review of the cardiology codes.

The RUC has also engaged in a review of aberrant data in low utilization services. We will review this information at our April 27-May 1, 2005 meeting and plan to forward recommendations related to this issue following this meeting. AMA staff will also be in contact with you to set up a conference call to discuss the Medicare utilization data used in the PLI methodology and the RUC's preferred dominant specialty approach.

We appreciate this opportunity to provide recommendations to improve the methodology utilized in developing PLI relative values. If you have any questions, please contact Sherry Smith at (312) 464-5604.

Sincerely,



William L. Rich, III, MD, FACS

cc: RUC Participants

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
0008T	Upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/or jejunum as appropriate, with suturing of the esophagogastric junction	GASTROENTEROLOGY	10
0010T	Tuberculosis test, cell mediated immunity measurement of gamma interferon antigen response	PATHOLOGY	22
0017T	Destruction of macular drusen, photocoagulation	OPHTHALMOLOGY	18
0023T	Infectious agent drug susceptibility phenotype prediction using genotypic comparison to known genotypic/phenotypic database, HIV 1	PATHOLOGY	22
0024T	Non-surgical septal reduction therapy (eg, alcohol ablation), for hypertrophic obstructive cardiomyopathy, with coronary arteriograms, with or without temporary pacemaker	CARDIOLOGY	06
0027T	Endoscopic lysis of epidural adhesions with direct visualization using mechanical means (eg, spinal endoscopic catheter system) or solution injection (eg, normal saline) including radiologic localization and epidurography	ANESTHESIOLOGY	05
0028T	Dual energy x-ray absorptiometry (DEXA) body composition study, one or more sites	DIAGNOSTIC RADIOLOGY	30
0031T	Speculoscopy;	OB-GYN	16
0033T	Endovascular repair of descending thoracic aortic aneurysm, pseudoaneurysm or dissection; involving coverage of left subclavian artery origin, initial endoprosthesis	VASCULAR SURGERY	77
0034T	Endovascular repair of descending thoracic aortic aneurysm, pseudoaneurysm or dissection; not involving coverage of left subclavian artery origin, initial endoprosthesis	VASCULAR SURGERY	77
0035T	Placement of proximal or distal extension prosthesis for endovascular repair of descending thoracic aortic aneurysm, pseudoaneurysm or dissection; initial extension	VASCULAR SURGERY	77
0036T	Placement of proximal or distal extension prosthesis for endovascular repair of descending thoracic aortic aneurysm, pseudoaneurysm or dissection; each additional extension (List separately in addition to code for primary procedure)	VASCULAR SURGERY	77
0038T	Endovascular repair of descending thoracic aortic aneurysm, pseudoaneurysm or dissection involving coverage of left subclavian artery origin, initial endoprosthesis, radiological supervision and interpretation	VASCULAR SURGERY	77
0039T	Endovascular repair of descending thoracic aortic aneurysm, pseudoaneurysm or dissection not involving coverage of left subclavian artery origin, initial endoprosthesis, radiological supervision and interpretation	VASCULAR SURGERY	77

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
0040T	Placement of proximal or distal extension prosthesis for endovascular repair of descending thoracic aortic aneurysm, pseudoaneurysm or dissection, each extension, radiological supervision and interpretation	VASCULAR SURGERY	77
0042T	Cerebral perfusion analysis using computed tomography with contrast administration, including post-processing of parametric maps with determination of cerebral blood flow, cerebral blood volume, and mean transit time	DIAGNOSTIC RADIOLOGY	30
0044T	Whole body integumentary photography, at request of a physician, for monitoring of high-risk patients; with dysplastic nevus syndrome or familial melanoma	DERMATOLOGY	07
11922	Tattooing, intradermal introduction of insoluble opaque pigments to correct color defects of skin, including micropigmentation; each additional 20.0 sq cm (List separately in addition to code for primary procedure)	PLASTIC AND RECONSTRUCTIVE SURGERY	24
11950	Subcutaneous injection of filling material (eg, collagen); 1 cc or less	PLASTIC AND RECONSTRUCTIVE SURGERY	24
11951	Subcutaneous injection of filling material (eg, collagen); 1.1 to 5.0 cc	PLASTIC AND RECONSTRUCTIVE SURGERY	24
11952	Subcutaneous injection of filling material (eg, collagen); 5.1 to 10.0 cc	PLASTIC AND RECONSTRUCTIVE SURGERY	24
11954	Subcutaneous injection of filling material (eg, collagen); over 10.0 cc	PLASTIC AND RECONSTRUCTIVE SURGERY	24
11975	Insertion, implantable contraceptive capsules	OB-GYN	16
11976	Removal, implantable contraceptive capsules	OB-GYN	16
11977	Removal with reinsertion, implantable contraceptive capsules	OB-GYN	16
12017	Simple repair of superficial wounds of face, ears, eyelids, nose, lips and/or mucous membranes; 20.1 cm to 30.0 cm	EMERGENCY MEDICINE	93
12018	Simple repair of superficial wounds of face, ears, eyelids, nose, lips and/or mucous membranes; over 30.0 cm	EMERGENCY MEDICINE	93
12047	Layer closure of wounds of neck, hands, feet and/or external genitalia; over 30.0 cm	GENERAL SURGERY	02
12056	Layer closure of wounds of face, ears, eyelids, nose, lips and/or mucous membranes; 20.1 cm to 30.0 cm	PLASTIC AND RECONSTRUCTIVE SURGERY	24
12057	Layer closure of wounds of face, ears, eyelids, nose, lips and/or mucous membranes; over 30.0 cm	PLASTIC AND RECONSTRUCTIVE SURGERY	24
15775	Punch graft for hair transplant; 1 to 15 punch grafts	PLASTIC AND RECONSTRUCTIVE SURGERY	24

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
15776	Punch graft for hair transplant; more than 15 punch grafts	PLASTIC AND RECONSTRUCTIVE SURGERY	24
15780	Dermabrasion; total face (eg, for acne scarring, fine wrinkling, rhytids, general keratosis)	DERMATOLOGY	07
15782	Dermabrasion; regional, other than face	DERMATOLOGY	07
15783	Dermabrasion; superficial, any site, (eg, tattoo removal)	DERMATOLOGY	07
15792	Chemical peel, nonfacial; epidermal	DERMATOLOGY	07
15793	Chemical peel, nonfacial; dermal	DERMATOLOGY	07
15810	Salabrasion; 20 sq cm or less	PLASTIC AND RECONSTRUCTIVE SURGERY	24
15811	Salabrasion; over 20 sq cm	PLASTIC AND RECONSTRUCTIVE SURGERY	24
15819	Cervicoplasty	PLASTIC AND RECONSTRUCTIVE SURGERY	24
15824	Rhytidectomy; forehead	PLASTIC AND RECONSTRUCTIVE SURGERY	24
15825	Rhytidectomy; neck with platysmal tightening (platysmal flap, P-flap)	PLASTIC AND RECONSTRUCTIVE SURGERY	24
15826	Rhytidectomy; glabellar frown lines	PLASTIC AND RECONSTRUCTIVE SURGERY	24
15828	Rhytidectomy; cheek, chin, and neck	PLASTIC AND RECONSTRUCTIVE SURGERY	24
15829	Rhytidectomy; superficial musculoaponeurotic system (SMAS) flap	PLASTIC AND RECONSTRUCTIVE SURGERY	24
15832	Excision, excessive skin and subcutaneous tissue (including lipectomy); thigh	PLASTIC AND RECONSTRUCTIVE SURGERY	24
15833	Excision, excessive skin and subcutaneous tissue (including lipectomy); leg	PLASTIC AND RECONSTRUCTIVE SURGERY	24
15834	Excision, excessive skin and subcutaneous tissue (including lipectomy); hip	PLASTIC AND RECONSTRUCTIVE SURGERY	24
15835	Excision, excessive skin and subcutaneous tissue (including lipectomy); buttock	PLASTIC AND RECONSTRUCTIVE SURGERY	24
15836	Excision, excessive skin and subcutaneous tissue (including lipectomy); arm	PLASTIC AND RECONSTRUCTIVE SURGERY	24
15837	Excision, excessive skin and subcutaneous tissue (including lipectomy); forearm or hand	PLASTIC AND RECONSTRUCTIVE SURGERY	24

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
15838	Excision, excessive skin and subcutaneous tissue (including lipectomy); submental fat pad	PLASTIC AND RECONSTRUCTIVE SURGERY	24
15841	Graft for facial nerve paralysis; free muscle graft (including obtaining graft)	PLASTIC AND RECONSTRUCTIVE SURGERY	24
15842	Graft for facial nerve paralysis; free muscle flap by microsurgical technique	PLASTIC AND RECONSTRUCTIVE SURGERY	24
15876	Suction assisted lipectomy; head and neck	PLASTIC AND RECONSTRUCTIVE SURGERY	24
15877	Suction assisted lipectomy; trunk	PLASTIC AND RECONSTRUCTIVE SURGERY	24
15878	Suction assisted lipectomy; upper extremity	PLASTIC AND RECONSTRUCTIVE SURGERY	24
15879	Suction assisted lipectomy; lower extremity	PLASTIC AND RECONSTRUCTIVE SURGERY	24
15922	Excision, coccygeal pressure ulcer, with coccygectomy; with flap closure	PLASTIC AND RECONSTRUCTIVE SURGERY	24
15953	Excision, trochanteric pressure ulcer, with skin flap closure; with ostectomy	PLASTIC AND RECONSTRUCTIVE SURGERY	24
17380	Electrolysis epilation, each 1/2 hour	DERMATOLOGY	07
19220	Mastectomy, radical, including pectoral muscles, axillary and internal mammary lymph nodes (Urban type operation)	GENERAL SURGERY	02
19272	Excision of chest wall tumor involving ribs, with plastic reconstruction; with mediastinal lymphadenectomy	THORACIC SURGERY	33
19324	Mammaplasty, augmentation; without prosthetic implant	PLASTIC AND RECONSTRUCTIVE SURGERY	24
19355	Correction of inverted nipples	PLASTIC AND RECONSTRUCTIVE SURGERY	24
19368	Breast reconstruction with transverse rectus abdominis myocutaneous flap (TRAM), single pedicle, including closure of donor site; with microvascular anastomosis (supercharging)	PLASTIC AND RECONSTRUCTIVE SURGERY	24
19369	Breast reconstruction with transverse rectus abdominis myocutaneous flap (TRAM), double pedicle, including closure of donor site	PLASTIC AND RECONSTRUCTIVE SURGERY	24
19396	Preparation of moulage for custom breast implant	PLASTIC AND RECONSTRUCTIVE SURGERY	24
20101	Exploration of penetrating wound (separate procedure); chest	GENERAL SURGERY	02

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
20150	Excision of epiphyseal bar, with or without autogenous soft tissue graft obtained through same fascial incision	ORTHOPEDIC SURGERY	20
20662	Application of halo, including removal; pelvic	ORTHOPEDIC SURGERY	20
20663	Application of halo, including removal; femoral	ORTHOPEDIC SURGERY	20
20664	Application of halo, including removal, cranial, 6 or more pins placed, for thin skull osteology (eg, pediatric patients, hydrocephalus, osteogenesis imperfecta), requiring general anesthesia	NEUROSURGERY	14
20802	Replantation, arm (includes surgical neck of humerus through elbow joint), complete amputation	ORTHOPEDIC SURGERY	20
20805	Replantation, forearm (includes radius and ulna to radial carpal joint), complete amputation	ORTHOPEDIC SURGERY	20
20808	Replantation, hand (includes hand through metacarpophalangeal joints), complete amputation	ORTHOPEDIC SURGERY	20
20816	Replantation, digit, excluding thumb (includes metacarpophalangeal joint to insertion of flexor sublimis tendon), complete amputation	ORTHOPEDIC SURGERY	20
20822	Replantation, digit, excluding thumb (includes distal tip to sublimis tendon insertion), complete amputation	ORTHOPEDIC SURGERY	20
20824	Replantation, thumb (includes carpometacarpal joint to MP joint), complete amputation	ORTHOPEDIC SURGERY	20
20827	Replantation, thumb (includes distal tip to MP joint), complete amputation	ORTHOPEDIC SURGERY	20
20838	Replantation, foot, complete amputation	ORTHOPEDIC SURGERY	20
20910	Cartilage graft; costochondral	ORTHOPEDIC SURGERY	20
20936	Autograft for spine surgery only (includes harvesting the graft); local (eg, ribs, spinous process, or laminar fragments) obtained from same incision	ORTHOPEDIC SURGERY	20
20956	Bone graft with microvascular anastomosis; iliac crest	ORTHOPEDIC SURGERY	20
20957	Bone graft with microvascular anastomosis; metatarsal	ORTHOPEDIC SURGERY	20
20962	Bone graft with microvascular anastomosis; other than fibula, iliac crest, or metatarsal	ORTHOPEDIC SURGERY	20
20970	Free osteocutaneous flap with microvascular anastomosis; iliac crest	PLASTIC AND RECONSTRUCTIVE SURGERY	24
20972	Free osteocutaneous flap with microvascular anastomosis; metatarsal	ORTHOPEDIC SURGERY	20
20973	Free osteocutaneous flap with microvascular anastomosis; great toe with web space	ORTHOPEDIC SURGERY	20
21010	Arthrotomy, temporomandibular joint	MAXILLOFACIAL SURGERY	85

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
21047	Excision of benign tumor or cyst of mandible; requiring extra-oral osteotomy and partial mandibulectomy (eg, locally aggressive or destructive lesion(s))	OTOLARYNGOLOGY	04
21049	Excision of benign tumor or cyst of maxilla; requiring extra-oral osteotomy and partial maxillectomy (eg, locally aggressive or destructive lesion(s))	OTOLARYNGOLOGY	04
21050	Condylectomy, temporomandibular joint (separate procedure)	MAXILLOFACIAL SURGERY	85
21060	Meniscectomy, partial or complete, temporomandibular joint (separate procedure)	MAXILLOFACIAL SURGERY	85
21070	Coronoidectomy (separate procedure)	MAXILLOFACIAL SURGERY	85
21077	Impression and custom preparation; orbital prosthesis	ORAL SURGERY	19
21082	Impression and custom preparation; palatal augmentation prosthesis	ORAL SURGERY	19
21083	Impression and custom preparation; palatal lift prosthesis	ORAL SURGERY	19
21084	Impression and custom preparation; speech aid prosthesis	ORAL SURGERY	19
21086	Impression and custom preparation; auricular prosthesis	ORAL SURGERY	19
21088	Impression and custom preparation; facial prosthesis	ORAL SURGERY	19
21100	Application of halo type appliance for maxillofacial fixation, includes removal (separate procedure)	ORAL SURGERY	19
21120	Genioplasty; augmentation (autograft, allograft, prosthetic material)	PLASTIC AND RECONSTRUCTIVE SURGERY	24
21121	Genioplasty; sliding osteotomy, single piece	ORAL SURGERY	19
21122	Genioplasty; sliding osteotomies, two or more osteotomies (eg, wedge excision or bone wedge reversal for asymmetrical chin)	PLASTIC AND RECONSTRUCTIVE SURGERY	24
21123	Genioplasty; sliding, augmentation with interpositional bone grafts (includes obtaining autografts)	PLASTIC AND RECONSTRUCTIVE SURGERY	24
21125	Augmentation, mandibular body or angle; prosthetic material	ORAL SURGERY	19
21127	Augmentation, mandibular body or angle; with bone graft, onlay or interpositional (includes obtaining autograft)	ORAL SURGERY	19
21137	Reduction forehead; contouring only	PLASTIC AND RECONSTRUCTIVE SURGERY	24
21138	Reduction forehead; contouring and application of prosthetic material or bone graft (includes obtaining autograft)	PLASTIC AND RECONSTRUCTIVE SURGERY	24
21139	Reduction forehead; contouring and setback of anterior frontal sinus wall	PLASTIC AND RECONSTRUCTIVE SURGERY	24

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
21141	Reconstruction midface, LeFort I; single piece, segment movement in any direction (eg, for Long Face Syndrome), without bone graft	MAXILLOFACIAL SURGERY	85
21142	Reconstruction midface, LeFort I; two pieces, segment movement in any direction, without bone graft	MAXILLOFACIAL SURGERY	85
21143	Reconstruction midface, LeFort I; three or more pieces, segment movement in any direction, without bone graft	MAXILLOFACIAL SURGERY	85
21145	Reconstruction midface, LeFort I; single piece, segment movement in any direction, requiring bone grafts (includes obtaining autografts)	MAXILLOFACIAL SURGERY	85
21146	Reconstruction midface, LeFort I; two pieces, segment movement in any direction, requiring bone grafts (includes obtaining autografts) (eg, ungrafted unilateral alveolar cleft)	MAXILLOFACIAL SURGERY	85
21147	Reconstruction midface, LeFort I; three or more pieces, segment movement in any direction, requiring bone grafts (includes obtaining autografts) (eg, ungrafted bilateral alveolar cleft or multiple osteotomies)	MAXILLOFACIAL SURGERY	85
21150	Reconstruction midface, LeFort II; anterior intrusion (eg, Treacher-Collins Syndrome)	OTOLARYNGOLOGY	04
21151	Reconstruction midface, LeFort II; any direction, requiring bone grafts (includes obtaining autografts)	OTOLARYNGOLOGY	04
21154	Reconstruction midface, LeFort III (extracranial), any type, requiring bone grafts (includes obtaining autografts); without LeFort I	OTOLARYNGOLOGY	04
21155	Reconstruction midface, LeFort III (extracranial), any type, requiring bone grafts (includes obtaining autografts); with LeFort I	OTOLARYNGOLOGY	04
21159	Reconstruction midface, LeFort III (extra and intracranial) with forehead advancement (eg, mono bloc), requiring bone grafts (includes obtaining autografts); without LeFort I	OTOLARYNGOLOGY	04
21160	Reconstruction midface, LeFort III (extra and intracranial) with forehead advancement (eg, mono bloc), requiring bone grafts (includes obtaining autografts); with LeFort I	OTOLARYNGOLOGY	04
21172	Reconstruction superior-lateral orbital rim and lower forehead, advancement or alteration, with or without grafts (includes obtaining autografts)	NEUROSURGERY	14
21175	Reconstruction, bifrontal, superior-lateral orbital rims and lower forehead, advancement or alteration (eg, plagiocephaly, trigonocephaly, brachycephaly), with or without grafts (includes obtaining autografts)	PLASTIC AND RECONSTRUCTIVE SURGERY	24
21179	Reconstruction, entire or majority of forehead and/or supraorbital rims; with grafts (allograft or prosthetic material)	PLASTIC AND RECONSTRUCTIVE SURGERY	24

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
21180	Reconstruction, entire or majority of forehead and/or supraorbital rims; with autograft (includes obtaining grafts)	PLASTIC AND RECONSTRUCTIVE SURGERY	24
21181	Reconstruction by contouring of benign tumor of cranial bones (eg, fibrous dysplasia), extracranial	PLASTIC AND RECONSTRUCTIVE SURGERY	24
21182	Reconstruction of orbital walls, rims, forehead, nasoethmoid complex following intra- and extracranial excision of benign tumor of cranial bone (eg, fibrous dysplasia), with multiple autografts (includes obtaining grafts); total area of bone grafting less than 40 sq cm	PLASTIC AND RECONSTRUCTIVE SURGERY	24
21183	Reconstruction of orbital walls, rims, forehead, nasoethmoid complex following intra- and extracranial excision of benign tumor of cranial bone (eg, fibrous dysplasia), with multiple autografts (includes obtaining grafts); total area of bone grafting greater than 40 sq cm but less than 80 sq cm	PLASTIC AND RECONSTRUCTIVE SURGERY	24
21184	Reconstruction of orbital walls, rims, forehead, nasoethmoid complex following intra- and extracranial excision of benign tumor of cranial bone (eg, fibrous dysplasia), with multiple autografts (includes obtaining grafts); total area of bone grafting greater than 80 sq cm	PLASTIC AND RECONSTRUCTIVE SURGERY	24
21188	Reconstruction midface, osteotomies (other than LeFort type) and bone grafts (includes obtaining autografts)	OTOLARYNGOLOGY	04
21193	Reconstruction of mandibular rami, horizontal, vertical, C, or L osteotomy; without bone graft	ORAL SURGERY	19
21194	Reconstruction of mandibular rami, horizontal, vertical, C, or L osteotomy; with bone graft (includes obtaining graft)	OTOLARYNGOLOGY	04
21195	Reconstruction of mandibular rami and/or body, sagittal split; without internal rigid fixation	OTOLARYNGOLOGY	04
21199	Osteotomy, mandible, segmental; with genioglossus advancement	OTOLARYNGOLOGY	04
21206	Osteotomy, maxilla, segmental (eg, Wassmund or Schuchard)	OTOLARYNGOLOGY	04
21209	Osteoplasty, facial bones; reduction	MAXILLOFACIAL SURGERY	85
21230	Graft; rib cartilage, autogenous, to face, chin, nose or ear (includes obtaining graft)	PLASTIC AND RECONSTRUCTIVE SURGERY	24
21242	Arthroplasty, temporomandibular joint, with allograft	MAXILLOFACIAL SURGERY	85
21243	Arthroplasty, temporomandibular joint, with prosthetic joint replacement	MAXILLOFACIAL SURGERY	85
21245	Reconstruction of mandible or maxilla, subperiosteal implant; partial	OTOLARYNGOLOGY	04
21246	Reconstruction of mandible or maxilla, subperiosteal implant; complete	OTOLARYNGOLOGY	04

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
21247	Reconstruction of mandibular condyle with bone and cartilage autografts (includes obtaining grafts) (eg, for hemifacial microsomia)	ORAL SURGERY	19
21249	Reconstruction of mandible or maxilla, endosteal implant (eg, blade, cylinder); complete	ORAL SURGERY	19
21255	Reconstruction of zygomatic arch and glenoid fossa with bone and cartilage (includes obtaining autografts)	OTOLARYNGOLOGY	04
21256	Reconstruction of orbit with osteotomies (extracranial) and with bone grafts (includes obtaining autografts) (eg, micro-ophthalmia)	PLASTIC AND RECONSTRUCTIVE SURGERY	24
21260	Periorbital osteotomies for orbital hypertelorism, with bone grafts; extracranial approach	PLASTIC AND RECONSTRUCTIVE SURGERY	24
21261	Periorbital osteotomies for orbital hypertelorism, with bone grafts; combined intra- and extracranial approach	PLASTIC AND RECONSTRUCTIVE SURGERY	24
21263	Periorbital osteotomies for orbital hypertelorism, with bone grafts; with forehead advancement	OPHTHALMOLOGY	18
21267	Orbital repositioning, periorbital osteotomies, unilateral, with bone grafts; extracranial approach	PLASTIC AND RECONSTRUCTIVE SURGERY	24
21268	Orbital repositioning, periorbital osteotomies, unilateral, with bone grafts; combined intra- and extracranial approach	PLASTIC AND RECONSTRUCTIVE SURGERY	24
21270	Malar augmentation, prosthetic material	PLASTIC AND RECONSTRUCTIVE SURGERY	24
21275	Secondary revision of orbitocraniofacial reconstruction	PLASTIC AND RECONSTRUCTIVE SURGERY	24
21295	Reduction of masseter muscle and bone (eg, for treatment of benign masseteric hypertrophy); extraoral approach	OTOLARYNGOLOGY	04
21296	Reduction of masseter muscle and bone (eg, for treatment of benign masseteric hypertrophy); intraoral approach	OTOLARYNGOLOGY	04
21300	Closed treatment of skull fracture without operation	NEUROSURGERY	14
21338	Open treatment of nasoethmoid fracture; without external fixation	OTOLARYNGOLOGY	04
21339	Open treatment of nasoethmoid fracture; with external fixation	OTOLARYNGOLOGY	04
21340	Percutaneous treatment of nasoethmoid complex fracture, with splint, wire or headcap fixation, including repair of canthal ligaments and/or the nasolacrimal apparatus	OTOLARYNGOLOGY	04
21343	Open treatment of depressed frontal sinus fracture	OTOLARYNGOLOGY	04
21344	Open treatment of complicated (eg, comminuted or involving posterior wall) frontal sinus fracture, via coronal or multiple approaches	OTOLARYNGOLOGY	04

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
21345	Closed treatment of nasomaxillary complex fracture (LeFort II type), with interdental wire fixation or fixation of denture or splint	OTOLARYNGOLOGY	04
21346	Open treatment of nasomaxillary complex fracture (LeFort II type); with wiring and/or local fixation	OTOLARYNGOLOGY	04
21347	Open treatment of nasomaxillary complex fracture (LeFort II type); requiring multiple open approaches	OTOLARYNGOLOGY	04
21348	Open treatment of nasomaxillary complex fracture (LeFort II type); with bone grafting (includes obtaining graft)	OTOLARYNGOLOGY	04
21355	Percutaneous treatment of fracture of malar area, including zygomatic arch and malar tripod, with manipulation	OTOLARYNGOLOGY	04
21366	Open treatment of complicated (eg, comminuted or involving cranial nerve foramina) fracture(s) of malar area, including zygomatic arch and malar tripod; with bone grafting (includes obtaining graft)	PLASTIC AND RECONSTRUCTIVE SURGERY	24
21385	Open treatment of orbital floor blowout fracture; transantral approach (Caldwell-Luc type operation)	PLASTIC AND RECONSTRUCTIVE SURGERY	24
21386	Open treatment of orbital floor blowout fracture; periorbital approach	PLASTIC AND RECONSTRUCTIVE SURGERY	24
21387	Open treatment of orbital floor blowout fracture; combined approach	PLASTIC AND RECONSTRUCTIVE SURGERY	24
21395	Open treatment of orbital floor blowout fracture; periorbital approach with bone graft (includes obtaining graft)	PLASTIC AND RECONSTRUCTIVE SURGERY	24
21400	Closed treatment of fracture of orbit, except blowout; without manipulation	PLASTIC AND RECONSTRUCTIVE SURGERY	24
21401	Closed treatment of fracture of orbit, except blowout; with manipulation	PLASTIC AND RECONSTRUCTIVE SURGERY	24
21406	Open treatment of fracture of orbit, except blowout; without implant	PLASTIC AND RECONSTRUCTIVE SURGERY	24
21408	Open treatment of fracture of orbit, except blowout; with bone grafting (includes obtaining graft)	PLASTIC AND RECONSTRUCTIVE SURGERY	24
21421	Closed treatment of palatal or maxillary fracture (LeFort I type), with interdental wire fixation or fixation of denture or splint	ORAL SURGERY	19
21423	Open treatment of palatal or maxillary fracture (LeFort I type); complicated (comminuted or involving cranial nerve foramina), multiple approaches	PLASTIC AND RECONSTRUCTIVE SURGERY	24
21431	Closed treatment of craniofacial separation (LeFort III type) using interdental wire fixation of denture or splint	ORAL SURGERY	19

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
21432	Open treatment of craniofacial separation (LeFort III type); with wiring and/or internal fixation	PLASTIC AND RECONSTRUCTIVE SURGERY	24
21433	Open treatment of craniofacial separation (LeFort III type); complicated (eg, comminuted or involving cranial nerve foramina), multiple surgical approaches	PLASTIC AND RECONSTRUCTIVE SURGERY	24
21435	Open treatment of craniofacial separation (LeFort III type); complicated, utilizing internal and/or external fixation techniques (eg, head cap, halo device, and/or intermaxillary fixation)	PLASTIC AND RECONSTRUCTIVE SURGERY	24
21436	Open treatment of craniofacial separation (LeFort III type); complicated, multiple surgical approaches, internal fixation, with bone grafting (includes obtaining graft)	PLASTIC AND RECONSTRUCTIVE SURGERY	24
21445	Open treatment of mandibular or maxillary alveolar ridge fracture (separate procedure)	ORAL SURGERY	19
21451	Closed treatment of mandibular fracture; with manipulation	ORAL SURGERY	19
21452	Percutaneous treatment of mandibular fracture, with external fixation	MAXILLOFACIAL SURGERY	85
21454	Open treatment of mandibular fracture with external fixation	ORAL SURGERY	19
21465	Open treatment of mandibular condylar fracture	ORAL SURGERY	19
21490	Open treatment of temporomandibular dislocation	ORAL SURGERY	19
21493	Closed treatment of hyoid fracture; without manipulation	OTOLARYNGOLOGY	04
21494	Closed treatment of hyoid fracture; with manipulation	OTOLARYNGOLOGY	04
21495	Open treatment of hyoid fracture	OTOLARYNGOLOGY	04
21497	Interdental wiring, for condition other than fracture	ORAL SURGERY	19
21502	Incision and drainage, deep abscess or hematoma, soft tissues of neck or thorax; with partial rib osteotomy	GENERAL SURGERY	02
21510	Incision, deep, with opening of bone cortex (eg, for osteomyelitis or bone abscess), thorax	THORACIC SURGERY	33
21610	Costotransversectomy (separate procedure)	NEUROSURGERY	14
21615	Excision first and/or cervical rib;	THORACIC SURGERY	33
21616	Excision first and/or cervical rib; with sympathectomy	THORACIC SURGERY	33
21632	Radical resection of sternum; with mediastinal lymphadenectomy	THORACIC SURGERY	33
21700	Division of scalenus anticus; without resection of cervical rib	VASCULAR SURGERY	77
21705	Division of scalenus anticus; with resection of cervical rib	VASCULAR SURGERY	77
21720	Division of sternocleidomastoid for torticollis, open operation; without cast application	NEUROSURGERY	14
21725	Division of sternocleidomastoid for torticollis, open operation; with cast application	ORTHOPEDIC SURGERY	20
21740	Reconstructive repair of pectus excavatum or carinatum; open	THORACIC SURGERY	33
21805	Open treatment of rib fracture without fixation, each	THORACIC SURGERY	33

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
21810	Treatment of rib fracture requiring external fixation (flail chest)	THORACIC SURGERY	33
21825	Open treatment of sternum fracture with or without skeletal fixation	THORACIC SURGERY	33
22100	Partial excision of posterior vertebral component (eg, spinous process, lamina or facet) for intrinsic bony lesion, single vertebral segment; cervical	NEUROSURGERY	14
22101	Partial excision of posterior vertebral component (eg, spinous process, lamina or facet) for intrinsic bony lesion, single vertebral segment; thoracic	NEUROSURGERY	14
22110	Partial excision of vertebral body, for intrinsic bony lesion, without decompression of spinal cord or nerve root(s), single vertebral segment; cervical	NEUROSURGERY	14
22112	Partial excision of vertebral body, for intrinsic bony lesion, without decompression of spinal cord or nerve root(s), single vertebral segment; thoracic	NEUROSURGERY	14
22220	Osteotomy of spine, including diskectomy, anterior approach, single vertebral segment; cervical	NEUROSURGERY	14
22222	Osteotomy of spine, including diskectomy, anterior approach, single vertebral segment; thoracic	NEUROSURGERY	14
22319	Open treatment and/or reduction of odontoid fracture(s) and or dislocation(s) (including os odontoideum), anterior approach, including placement of internal fixation; with grafting	NEUROSURGERY	14
22548	Arthrodesis, anterior transoral or extraoral technique, clivus-C1-C2 (atlas-axis), with or without excision of odontoid process	NEUROSURGERY	14
22812	Arthrodesis, anterior, for spinal deformity, with or without cast; 8 or more vertebral segments	ORTHOPEDIC SURGERY	20
22818	Kyphectomy, circumferential exposure of spine and resection of vertebral segment(s) (including body and posterior elements); single or 2 segments	ORTHOPEDIC SURGERY	20
22819	Kyphectomy, circumferential exposure of spine and resection of vertebral segment(s) (including body and posterior elements); 3 or more segments	ORTHOPEDIC SURGERY	20
22847	Anterior instrumentation; 8 or more vertebral segments	ORTHOPEDIC SURGERY	20
23000	Removal of subdeltoid calcareous deposits, open	ORTHOPEDIC SURGERY	20
23100	Arthrotomy, glenohumeral joint, including biopsy	ORTHOPEDIC SURGERY	20
23106	Arthrotomy; sternoclavicular joint, with synovectomy, with or without biopsy	ORTHOPEDIC SURGERY	20
23125	Claviculectomy; total	ORTHOPEDIC SURGERY	20
23145	Excision or curettage of bone cyst or benign tumor of clavicle or scapula; with autograft (includes obtaining graft)	ORTHOPEDIC SURGERY	20
23146	Excision or curettage of bone cyst or benign tumor of clavicle or scapula; with allograft	ORTHOPEDIC SURGERY	20
23155	Excision or curettage of bone cyst or benign tumor of proximal humerus; with autograft (includes obtaining graft)	ORTHOPEDIC SURGERY	20

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
23156	Excision or curettage of bone cyst or benign tumor of proximal humerus; with allograft	ORTHOPEDIC SURGERY	20
23170	Sequestrectomy (eg, for osteomyelitis or bone abscess), clavicle	ORTHOPEDIC SURGERY	20
23172	Sequestrectomy (eg, for osteomyelitis or bone abscess), scapula	ORTHOPEDIC SURGERY	20
23174	Sequestrectomy (eg, for osteomyelitis or bone abscess), humeral head to surgical neck	ORTHOPEDIC SURGERY	20
23182	Partial excision (craterization, saucerization, or diaphysectomy) bone (eg, osteomyelitis), scapula	ORTHOPEDIC SURGERY	20
23190	Ostectomy of scapula, partial (eg, superior medial angle)	ORTHOPEDIC SURGERY	20
23195	Resection, humeral head	ORTHOPEDIC SURGERY	20
23200	Radical resection for tumor; clavicle	ORTHOPEDIC SURGERY	20
23210	Radical resection for tumor; scapula	ORTHOPEDIC SURGERY	20
23220	Radical resection of bone tumor, proximal humerus;	ORTHOPEDIC SURGERY	20
23221	Radical resection of bone tumor, proximal humerus; with autograft (includes obtaining graft)	ORTHOPEDIC SURGERY	20
23222	Radical resection of bone tumor, proximal humerus; with prosthetic replacement	ORTHOPEDIC SURGERY	20
23397	Muscle transfer, any type, shoulder or upper arm; multiple	ORTHOPEDIC SURGERY	20
23400	Scapulopexy (eg, Sprengels deformity or for paralysis)	ORTHOPEDIC SURGERY	20
23406	Tenotomy, shoulder area; multiple tendons through same incision	ORTHOPEDIC SURGERY	20
23460	Capsulorrhaphy, anterior, any type; with bone block	ORTHOPEDIC SURGERY	20
23462	Capsulorrhaphy, anterior, any type; with coracoid process transfer	ORTHOPEDIC SURGERY	20
23465	Capsulorrhaphy, glenohumeral joint, posterior, with or without bone block	ORTHOPEDIC SURGERY	20
23480	Osteotomy, clavicle, with or without internal fixation;	ORTHOPEDIC SURGERY	20
23490	Prophylactic treatment (nailing, pinning, plating or wiring) with or without methylmethacrylate; clavicle	ORTHOPEDIC SURGERY	20
23491	Prophylactic treatment (nailing, pinning, plating or wiring) with or without methylmethacrylate; proximal humerus	ORTHOPEDIC SURGERY	20
23520	Closed treatment of sternoclavicular dislocation; without manipulation	ORTHOPEDIC SURGERY	20
23525	Closed treatment of sternoclavicular dislocation; with manipulation	ORTHOPEDIC SURGERY	20
23530	Open treatment of sternoclavicular dislocation, acute or chronic;	ORTHOPEDIC SURGERY	20
23532	Open treatment of sternoclavicular dislocation, acute or chronic; with fascial graft (includes obtaining graft)	ORTHOPEDIC SURGERY	20
23545	Closed treatment of acromioclavicular dislocation; with manipulation	EMERGENCY MEDICINE	93
23552	Open treatment of acromioclavicular dislocation, acute or chronic; with fascial graft (includes obtaining graft)	ORTHOPEDIC SURGERY	20

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
23575	Closed treatment of scapular fracture; with manipulation, with or without skeletal traction (with or without shoulder joint involvement)	ORTHOPEDIC SURGERY	20
23800	Arthrodesis, glenohumeral joint;	ORTHOPEDIC SURGERY	20
23802	Arthrodesis, glenohumeral joint; with autogenous graft (includes obtaining graft)	ORTHOPEDIC SURGERY	20
23900	Interthoracoscaphular amputation (forequarter)	ORTHOPEDIC SURGERY	20
23920	Disarticulation of shoulder;	ORTHOPEDIC SURGERY	20
23921	Disarticulation of shoulder; secondary closure or scar revision	ORTHOPEDIC SURGERY	20
24100	Arthrotomy, elbow; with synovial biopsy only	ORTHOPEDIC SURGERY	20
24110	Excision or curettage of bone cyst or benign tumor, humerus;	ORTHOPEDIC SURGERY	20
24115	Excision or curettage of bone cyst or benign tumor, humerus; with autograft (includes obtaining graft)	ORTHOPEDIC SURGERY	20
24116	Excision or curettage of bone cyst or benign tumor, humerus; with allograft	ORTHOPEDIC SURGERY	20
24125	Excision or curettage of bone cyst or benign tumor of head or neck of radius or olecranon process; with autograft (includes obtaining graft)	ORTHOPEDIC SURGERY	20
24126	Excision or curettage of bone cyst or benign tumor of head or neck of radius or olecranon process; with allograft	ORTHOPEDIC SURGERY	20
24134	Sequestrectomy (eg, for osteomyelitis or bone abscess), shaft or distal humerus	ORTHOPEDIC SURGERY	20
24136	Sequestrectomy (eg, for osteomyelitis or bone abscess), radial head or neck	ORTHOPEDIC SURGERY	20
24138	Sequestrectomy (eg, for osteomyelitis or bone abscess), olecranon process	ORTHOPEDIC SURGERY	20
24145	Partial excision (craterization, saucerization, or diaphysectomy) bone (eg, osteomyelitis), radial head or neck	ORTHOPEDIC SURGERY	20
24150	Radical resection for tumor, shaft or distal humerus;	ORTHOPEDIC SURGERY	20
24151	Radical resection for tumor, shaft or distal humerus; with autograft (includes obtaining graft)	ORTHOPEDIC SURGERY	20
24152	Radical resection for tumor, radial head or neck;	ORTHOPEDIC SURGERY	20
24153	Radical resection for tumor, radial head or neck; with autograft (includes obtaining graft)	ORTHOPEDIC SURGERY	20
24155	Resection of elbow joint (arthrectomy)	ORTHOPEDIC SURGERY	20
24164	Implant removal; radial head	ORTHOPEDIC SURGERY	20
24301	Muscle or tendon transfer, any type, upper arm or elbow, single (excluding 24320-24331)	ORTHOPEDIC SURGERY	20
24320	Tenoplasty, with muscle transfer, with or without free graft, elbow to shoulder, single (Seddon-Brookes type procedure)	ORTHOPEDIC SURGERY	20
24330	Flexor-plasty, elbow (eg, Steindler type advancement);	ORTHOPEDIC SURGERY	20
24331	Flexor-plasty, elbow (eg, Steindler type advancement); with extensor advancement	ORTHOPEDIC SURGERY	20
24332	Tenolysis, triceps	ORTHOPEDIC SURGERY	20
24340	Tenodesis of biceps tendon at elbow (separate procedure)	ORTHOPEDIC SURGERY	20

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
24344	Reconstruction lateral collateral ligament, elbow, with tendon graft (includes harvesting of graft)	ORTHOPEDIC SURGERY	20
24345	Repair medial collateral ligament, elbow, with local tissue	ORTHOPEDIC SURGERY	20
24346	Reconstruction medial collateral ligament, elbow, with tendon graft (includes harvesting of graft)	ORTHOPEDIC SURGERY	20
24352	Fasciotomy, lateral or medial (eg, tennis elbow or epicondylitis); with annular ligament resection	ORTHOPEDIC SURGERY	20
24354	Fasciotomy, lateral or medial (eg, tennis elbow or epicondylitis); with stripping	ORTHOPEDIC SURGERY	20
24360	Arthroplasty, elbow; with membrane (eg, fascial)	ORTHOPEDIC SURGERY	20
24361	Arthroplasty, elbow; with distal humeral prosthetic replacement	ORTHOPEDIC SURGERY	20
24362	Arthroplasty, elbow; with implant and fascia lata ligament reconstruction	ORTHOPEDIC SURGERY	20
24365	Arthroplasty, radial head;	ORTHOPEDIC SURGERY	20
24410	Multiple osteotomies with realignment on intramedullary rod, humeral shaft (Sofield type procedure)	ORTHOPEDIC SURGERY	20
24420	Osteoplasty, humerus (eg, shortening or lengthening) (excluding 64876)	ORTHOPEDIC SURGERY	20
24470	Hemiepiphyseal arrest (eg, cubitus varus or valgus, distal humerus)	ORTHOPEDIC SURGERY	20
24565	Closed treatment of humeral epicondylar fracture, medial or lateral; with manipulation	ORTHOPEDIC SURGERY	20
24566	Percutaneous skeletal fixation of humeral epicondylar fracture, medial or lateral, with manipulation	ORTHOPEDIC SURGERY	20
24577	Closed treatment of humeral condylar fracture, medial or lateral; with manipulation	ORTHOPEDIC SURGERY	20
24582	Percutaneous skeletal fixation of humeral condylar fracture, medial or lateral, with manipulation	ORTHOPEDIC SURGERY	20
24587	Open treatment of periarticular fracture and/or dislocation of the elbow (fracture distal humerus and proximal ulna and/or proximal radius); with implant arthroplasty	ORTHOPEDIC SURGERY	20
24640	Closed treatment of radial head subluxation in child, nursemaid elbow, with manipulation	EMERGENCY MEDICINE	93
24800	Arthrodesis, elbow joint; local	ORTHOPEDIC SURGERY	20
24802	Arthrodesis, elbow joint; with autogenous graft (includes obtaining graft)	ORTHOPEDIC SURGERY	20
24920	Amputation, arm through humerus; open, circular (guillotine)	ORTHOPEDIC SURGERY	20
24925	Amputation, arm through humerus; secondary closure or scar revision	ORTHOPEDIC SURGERY	20
24930	Amputation, arm through humerus; re-amputation	ORTHOPEDIC SURGERY	20
24931	Amputation, arm through humerus; with implant	ORTHOPEDIC SURGERY	20
24935	Stump elongation, upper extremity	GENERAL SURGERY	02
25025	Decompression fasciotomy, forearm and/or wrist, flexor AND extensor compartment; with debridement of nonviable muscle and/or nerve	ORTHOPEDIC SURGERY	20
25031	Incision and drainage, forearm and/or wrist; bursa	ORTHOPEDIC SURGERY	20

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
25085	Capsulotomy, wrist (eg, contracture)	ORTHOPEDIC SURGERY	20
25100	Arthrotomy, wrist joint; with biopsy	ORTHOPEDIC SURGERY	20
25107	Arthrotomy, distal radioulnar joint including repair of triangular cartilage, complex	ORTHOPEDIC SURGERY	20
25119	Synovectomy, extensor tendon sheath, wrist, single compartment; with resection of distal ulna	ORTHOPEDIC SURGERY	20
25125	Excision or curettage of bone cyst or benign tumor of radius or ulna (excluding head or neck of radius and olecranon process); with autograft (includes obtaining graft)	ORTHOPEDIC SURGERY	20
25126	Excision or curettage of bone cyst or benign tumor of radius or ulna (excluding head or neck of radius and olecranon process); with allograft	ORTHOPEDIC SURGERY	20
25135	Excision or curettage of bone cyst or benign tumor of carpal bones; with autograft (includes obtaining graft)	ORTHOPEDIC SURGERY	20
25136	Excision or curettage of bone cyst or benign tumor of carpal bones; with allograft	ORTHOPEDIC SURGERY	20
25145	Sequestrectomy (eg, for osteomyelitis or bone abscess), forearm and/or wrist	ORTHOPEDIC SURGERY	20
25151	Partial excision (craterization, saucerization, or diaphysectomy) of bone (eg, for osteomyelitis); radius	ORTHOPEDIC SURGERY	20
25170	Radical resection for tumor, radius or ulna	ORTHOPEDIC SURGERY	20
25250	Removal of wrist prosthesis; (separate procedure)	ORTHOPEDIC SURGERY	20
25251	Removal of wrist prosthesis; complicated, including total wrist	ORTHOPEDIC SURGERY	20
25263	Repair, tendon or muscle, flexor, forearm and/or wrist; secondary, single, each tendon or muscle	ORTHOPEDIC SURGERY	20
25265	Repair, tendon or muscle, flexor, forearm and/or wrist; secondary, with free graft (includes obtaining graft), each tendon or muscle	ORTHOPEDIC SURGERY	20
25275	Repair, tendon sheath, extensor, forearm and/or wrist, with free graft (includes obtaining graft) (eg, for extensor carpi ulnaris subluxation)	ORTHOPEDIC SURGERY	20
25300	Tenodesis at wrist; flexors of fingers	ORTHOPEDIC SURGERY	20
25315	Flexor origin slide (eg, for cerebral palsy, Volkmann contracture), forearm and/or wrist;	ORTHOPEDIC SURGERY	20
25316	Flexor origin slide (eg, for cerebral palsy, Volkmann contracture), forearm and/or wrist; with tendon(s) transfer	ORTHOPEDIC SURGERY	20
25335	Centralization of wrist on ulna (eg, radial club hand)	ORTHOPEDIC SURGERY	20
25355	Osteotomy, radius; middle or proximal third	ORTHOPEDIC SURGERY	20
25365	Osteotomy; radius AND ulna	ORTHOPEDIC SURGERY	20
25370	Multiple osteotomies, with realignment on intramedullary rod (Sofield type procedure); radius OR ulna	ORTHOPEDIC SURGERY	20

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
25375	Multiple osteotomies, with realignment on intramedullary rod (Sofield type procedure); radius AND ulna	ORTHOPEDIC SURGERY	20
25391	Osteoplasty, radius OR ulna; lengthening with autograft	ORTHOPEDIC SURGERY	20
25392	Osteoplasty, radius AND ulna; shortening (excluding 64876)	ORTHOPEDIC SURGERY	20
25393	Osteoplasty, radius AND ulna; lengthening with autograft	ORTHOPEDIC SURGERY	20
25394	Osteoplasty, carpal bone, shortening	ORTHOPEDIC SURGERY	20
25415	Repair of nonunion or malunion, radius AND ulna; without graft (eg, compression technique)	ORTHOPEDIC SURGERY	20
25420	Repair of nonunion or malunion, radius AND ulna; with autograft (includes obtaining graft)	ORTHOPEDIC SURGERY	20
25425	Repair of defect with autograft; radius OR ulna	ORTHOPEDIC SURGERY	20
25426	Repair of defect with autograft; radius AND ulna	ORTHOPEDIC SURGERY	20
25430	Insertion of vascular pedicle into carpal bone (eg, Hori procedure)	ORTHOPEDIC SURGERY	20
25431	Repair of nonunion of carpal bone (excluding carpal scaphoid (navicular)) (includes obtaining graft and necessary fixation), each bone	ORTHOPEDIC SURGERY	20
25441	Arthroplasty with prosthetic replacement; distal radius	ORTHOPEDIC SURGERY	20
25442	Arthroplasty with prosthetic replacement; distal ulna	ORTHOPEDIC SURGERY	20
25443	Arthroplasty with prosthetic replacement; scaphoid carpal (navicular)	ORTHOPEDIC SURGERY	20
25444	Arthroplasty with prosthetic replacement; lunate	ORTHOPEDIC SURGERY	20
25449	Revision of arthroplasty, including removal of implant, wrist joint	ORTHOPEDIC SURGERY	20
25450	Epiphyseal arrest by epiphysiodesis or stapling; distal radius OR ulna	ORTHOPEDIC SURGERY	20
25455	Epiphyseal arrest by epiphysiodesis or stapling; distal radius AND ulna	ORTHOPEDIC SURGERY	20
25490	Prophylactic treatment (nailing, pinning, plating or wiring) with or without methylmethacrylate; radius	ORTHOPEDIC SURGERY	20
25491	Prophylactic treatment (nailing, pinning, plating or wiring) with or without methylmethacrylate; ulna	ORTHOPEDIC SURGERY	20
25492	Prophylactic treatment (nailing, pinning, plating or wiring) with or without methylmethacrylate; radius AND ulna	ORTHOPEDIC SURGERY	20
25520	Closed treatment of radial shaft fracture and closed treatment of dislocation of distal radioulnar joint (Galeazzi fracture/dislocation)	ORTHOPEDIC SURGERY	20
25526	Open treatment of radial shaft fracture, with internal and/or external fixation and open treatment, with or without internal or external fixation of distal radioulnar joint (Galeazzi fracture/dislocation), includes repair of triangular fibrocartilage complex	ORTHOPEDIC SURGERY	20
25635	Closed treatment of carpal bone fracture (excluding carpal scaphoid (navicular)); with manipulation, each bone	ORTHOPEDIC SURGERY	20

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
25645	Open treatment of carpal bone fracture (other than carpal scaphoid (navicular)), each bone	ORTHOPEDIC SURGERY	20
25651	Percutaneous skeletal fixation of ulnar styloid fracture	ORTHOPEDIC SURGERY	20
25671	Percutaneous skeletal fixation of distal radioulnar dislocation	ORTHOPEDIC SURGERY	20
25676	Open treatment of distal radioulnar dislocation, acute or chronic	ORTHOPEDIC SURGERY	20
25685	Open treatment of trans-scaphoperilunar type of fracture dislocation	ORTHOPEDIC SURGERY	20
25690	Closed treatment of lunate dislocation, with manipulation	ORTHOPEDIC SURGERY	20
25695	Open treatment of lunate dislocation	ORTHOPEDIC SURGERY	20
25805	Arthrodesis, wrist; with sliding graft	ORTHOPEDIC SURGERY	20
25830	Arthrodesis, distal radioulnar joint with segmental resection of ulna, with or without bone graft (eg, Sauve-Kapandji procedure)	ORTHOPEDIC SURGERY	20
25905	Amputation, forearm, through radius and ulna; open, circular (guillotine)	ORTHOPEDIC SURGERY	20
25907	Amputation, forearm, through radius and ulna; secondary closure or scar revision	ORTHOPEDIC SURGERY	20
25909	Amputation, forearm, through radius and ulna; re-amputation	ORTHOPEDIC SURGERY	20
25915	Krukenberg procedure	ORTHOPEDIC SURGERY	20
25920	Disarticulation through wrist;	ORTHOPEDIC SURGERY	20
25922	Disarticulation through wrist; secondary closure or scar revision	ORTHOPEDIC SURGERY	20
25924	Disarticulation through wrist; re-amputation	ORTHOPEDIC SURGERY	20
25927	Transmetacarpal amputation;	ORTHOPEDIC SURGERY	20
25929	Transmetacarpal amputation; secondary closure or scar revision	ORTHOPEDIC SURGERY	20
25931	Transmetacarpal amputation; re-amputation	ORTHOPEDIC SURGERY	20
26035	Decompression fingers and/or hand, injection injury (eg, grease gun)	ORTHOPEDIC SURGERY	20
26100	Arthrotomy with biopsy; carpometacarpal joint, each	ORTHOPEDIC SURGERY	20
26105	Arthrotomy with biopsy; metacarpophalangeal joint, each	ORTHOPEDIC SURGERY	20
26185	Sesamoidectomy, thumb or finger (separate procedure)	ORTHOPEDIC SURGERY	20
26205	Excision or curettage of bone cyst or benign tumor of metacarpal; with autograft (includes obtaining graft)	ORTHOPEDIC SURGERY	20
26215	Excision or curettage of bone cyst or benign tumor of proximal, middle, or distal phalanx of finger; with autograft (includes obtaining graft)	ORTHOPEDIC SURGERY	20
26250	Radical resection, metacarpal (eg, tumor);	ORTHOPEDIC SURGERY	20
26255	Radical resection, metacarpal (eg, tumor); with autograft (includes obtaining graft)	ORTHOPEDIC SURGERY	20
26260	Radical resection, proximal or middle phalanx of finger (eg, tumor);	ORTHOPEDIC SURGERY	20

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
26261	Radical resection, proximal or middle phalanx of finger (eg, tumor); with autograft (includes obtaining graft)	ORTHOPEDIC SURGERY	20
26262	Radical resection, distal phalanx of finger (eg, tumor)	ORTHOPEDIC SURGERY	20
26352	Repair or advancement, flexor tendon, not in zone 2 digital flexor tendon sheath (eg, no man's land); secondary with free graft (includes obtaining graft), each tendon	ORTHOPEDIC SURGERY	20
26357	Repair or advancement, flexor tendon, in zone 2 digital flexor tendon sheath (eg, no man's land); secondary, without free graft, each tendon	ORTHOPEDIC SURGERY	20
26358	Repair or advancement, flexor tendon, in zone 2 digital flexor tendon sheath (eg, no man's land); secondary, with free graft (includes obtaining graft), each tendon	ORTHOPEDIC SURGERY	20
26372	Repair or advancement of profundus tendon, with intact superficialis tendon; secondary with free graft (includes obtaining graft), each tendon	ORTHOPEDIC SURGERY	20
26373	Repair or advancement of profundus tendon, with intact superficialis tendon; secondary without free graft, each tendon	ORTHOPEDIC SURGERY	20
26390	Excision flexor tendon, with implantation of synthetic rod for delayed tendon graft, hand or finger, each rod	ORTHOPEDIC SURGERY	20
26392	Removal of synthetic rod and insertion of flexor tendon graft, hand or finger (includes obtaining graft), each rod	ORTHOPEDIC SURGERY	20
26415	Excision of extensor tendon, with implantation of synthetic rod for delayed tendon graft, hand or finger, each rod	ORTHOPEDIC SURGERY	20
26416	Removal of synthetic rod and insertion of extensor tendon graft (includes obtaining graft), hand or finger, each rod	ORTHOPEDIC SURGERY	20
26420	Repair, extensor tendon, finger, primary or secondary; with free graft (includes obtaining graft) each tendon	ORTHOPEDIC SURGERY	20
26428	Repair of extensor tendon, central slip, secondary (eg, boutonniere deformity); with free graft (includes obtaining graft), each finger	ORTHOPEDIC SURGERY	20
26434	Repair of extensor tendon, distal insertion, primary or secondary; with free graft (includes obtaining graft)	ORTHOPEDIC SURGERY	20
26474	Tenodesis; of distal joint, each joint	ORTHOPEDIC SURGERY	20
26476	Lengthening of tendon, extensor, hand or finger, each tendon	ORTHOPEDIC SURGERY	20
26479	Shortening of tendon, flexor, hand or finger, each tendon	ORTHOPEDIC SURGERY	20
26489	Transfer or transplant of tendon, palmar; with free tendon graft (includes obtaining graft), each tendon	ORTHOPEDIC SURGERY	20

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
26492	Opponensplasty; tendon transfer with graft (includes obtaining graft), each tendon	ORTHOPEDIC SURGERY	20
26494	Opponensplasty; hypothenar muscle transfer	ORTHOPEDIC SURGERY	20
26497	Transfer of tendon to restore intrinsic function; ring and small finger	ORTHOPEDIC SURGERY	20
26498	Transfer of tendon to restore intrinsic function; all four fingers	ORTHOPEDIC SURGERY	20
26499	Correction claw finger, other methods	ORTHOPEDIC SURGERY	20
26502	Reconstruction of tendon pulley, each tendon; with tendon or fascial graft (includes obtaining graft) (separate procedure)	ORTHOPEDIC SURGERY	20
26504	Reconstruction of tendon pulley, each tendon; with tendon prosthesis (separate procedure)	ORTHOPEDIC SURGERY	20
26517	Capsulodesis, metacarpophalangeal joint; two digits	ORTHOPEDIC SURGERY	20
26518	Capsulodesis, metacarpophalangeal joint; three or four digits	ORTHOPEDIC SURGERY	20
26545	Reconstruction, collateral ligament, interphalangeal joint, single, including graft, each joint	ORTHOPEDIC SURGERY	20
26546	Repair non-union, metacarpal or phalanx, (includes obtaining bone graft with or without external or internal fixation)	ORTHOPEDIC SURGERY	20
26550	Pollicization of a digit	ORTHOPEDIC SURGERY	20
26551	Transfer, toe-to-hand with microvascular anastomosis; great toe wrap-around with bone graft	ORTHOPEDIC SURGERY	20
26553	Transfer, toe-to-hand with microvascular anastomosis; other than great toe, single	ORTHOPEDIC SURGERY	20
26554	Transfer, toe-to-hand with microvascular anastomosis; other than great toe, double	ORTHOPEDIC SURGERY	20
26555	Transfer, finger to another position without microvascular anastomosis	ORTHOPEDIC SURGERY	20
26556	Transfer, free toe joint, with microvascular anastomosis	ORTHOPEDIC SURGERY	24
26560	Repair of syndactyly (web finger) each web space; with skin flaps	ORTHOPEDIC SURGERY	20
26561	Repair of syndactyly (web finger) each web space; with skin flaps and grafts	ORTHOPEDIC SURGERY	20
26562	Repair of syndactyly (web finger) each web space; complex (eg, involving bone, nails)	ORTHOPEDIC SURGERY	20
26565	Osteotomy; metacarpal, each	ORTHOPEDIC SURGERY	20
26568	Osteoplasty, lengthening, metacarpal or phalanx	ORTHOPEDIC SURGERY	20
26580	Repair cleft hand	ORTHOPEDIC SURGERY	20
26587	Reconstruction of polydactylous digit, soft tissue and bone	ORTHOPEDIC SURGERY	20
26590	Repair macrodactylia, each digit	ORTHOPEDIC SURGERY	20
26596	Excision of constricting ring of finger, with multiple Z-plasties	ORTHOPEDIC SURGERY	20

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
26665	Open treatment of carpometacarpal fracture dislocation, thumb (Bennett fracture), with or without internal or external fixation	ORTHOPEDIC SURGERY	20
26675	Closed treatment of carpometacarpal dislocation, other than thumb, with manipulation, each joint; requiring anesthesia	ORTHOPEDIC SURGERY	20
26685	Open treatment of carpometacarpal dislocation, other than thumb; with or without internal or external fixation, each joint	ORTHOPEDIC SURGERY	20
26686	Open treatment of carpometacarpal dislocation, other than thumb; complex, multiple or delayed reduction	ORTHOPEDIC SURGERY	20
26706	Percutaneous skeletal fixation of metacarpophalangeal dislocation, single, with manipulation	ORTHOPEDIC SURGERY	20
26820	Fusion in opposition, thumb, with autogenous graft (includes obtaining graft)	ORTHOPEDIC SURGERY	20
26843	Arthrodesis, carpometacarpal joint, digit, other than thumb, each;	ORTHOPEDIC SURGERY	20
26844	Arthrodesis, carpometacarpal joint, digit, other than thumb, each; with autograft (includes obtaining graft)	ORTHOPEDIC SURGERY	20
26863	Arthrodesis, interphalangeal joint, with or without internal fixation; with autograft (includes obtaining graft), each additional joint (List separately in addition to code for primary procedure)	ORTHOPEDIC SURGERY	20
27003	Tenotomy, adductor, subcutaneous, open, with obturator neurectomy	ORTHOPEDIC SURGERY	20
27005	Tenotomy, hip flexor(s), open (separate procedure)	ORTHOPEDIC SURGERY	20
27035	Denervation, hip joint, intrapelvic or extrapelvic intra-articular branches of sciatic, femoral, or obturator nerves	PLASTIC AND RECONSTRUCTIVE SURGERY	24
27050	Arthrotomy, with biopsy; sacroiliac joint	ORTHOPEDIC SURGERY	20
27060	Excision; ischial bursa	PLASTIC AND RECONSTRUCTIVE SURGERY	24
27067	Excision of bone cyst or benign tumor; with autograft requiring separate incision	ORTHOPEDIC SURGERY	20
27075	Radical resection of tumor or infection; wing of ilium, one pubic or ischial ramus or symphysis pubis	ORTHOPEDIC SURGERY	20
27077	Radical resection of tumor or infection; innominate bone, total	ORTHOPEDIC SURGERY	20
27078	Radical resection of tumor or infection; ischial tuberosity and greater trochanter of femur	ORTHOPEDIC SURGERY	20
27079	Radical resection of tumor or infection; ischial tuberosity and greater trochanter of femur, with skin flaps	GENERAL SURGERY	02
27097	Release or recession, hamstring, proximal	ORTHOPEDIC SURGERY	20
27098	Transfer, adductor to ischium	ORTHOPEDIC SURGERY	20
27100	Transfer external oblique muscle to greater trochanter including fascial or tendon extension (graft)	ORTHOPEDIC SURGERY	20

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
27105	Transfer paraspinous muscle to hip (includes fascial or tendon extension graft)	ORTHOPEDIC SURGERY	20
27110	Transfer iliopsoas; to greater trochanter of femur	ORTHOPEDIC SURGERY	20
27111	Transfer iliopsoas; to femoral neck	ORTHOPEDIC SURGERY	20
27120	Acetabuloplasty; (eg, Whitman, Colonna, Haygroves, or cup type)	ORTHOPEDIC SURGERY	20
27146	Osteotomy, iliac, acetabular or innominate bone;	ORTHOPEDIC SURGERY	20
27147	Osteotomy, iliac, acetabular or innominate bone; with open reduction of hip	ORTHOPEDIC SURGERY	20
27151	Osteotomy, iliac, acetabular or innominate bone; with femoral osteotomy	ORTHOPEDIC SURGERY	20
27156	Osteotomy, iliac, acetabular or innominate bone; with femoral osteotomy and with open reduction of hip	ORTHOPEDIC SURGERY	20
27158	Osteotomy, pelvis, bilateral (eg, congenital malformation)	ORTHOPEDIC SURGERY	20
27161	Osteotomy, femoral neck (separate procedure)	ORTHOPEDIC SURGERY	20
27175	Treatment of slipped femoral epiphysis; by traction, without reduction	ORTHOPEDIC SURGERY	20
27176	Treatment of slipped femoral epiphysis; by single or multiple pinning, in situ	ORTHOPEDIC SURGERY	20
27177	Open treatment of slipped femoral epiphysis; single or multiple pinning or bone graft (includes obtaining graft)	ORTHOPEDIC SURGERY	20
27178	Open treatment of slipped femoral epiphysis; closed manipulation with single or multiple pinning	ORTHOPEDIC SURGERY	20
27179	Open treatment of slipped femoral epiphysis; osteoplasty of femoral neck (Heyman type procedure)	ORTHOPEDIC SURGERY	20
27181	Open treatment of slipped femoral epiphysis; osteotomy and internal fixation	ORTHOPEDIC SURGERY	20
27185	Epiphyseal arrest by epiphysiodesis or stapling, greater trochanter of femur	ORTHOPEDIC SURGERY	20
27202	Open treatment of coccygeal fracture	ORTHOPEDIC SURGERY	20
27215	Open treatment of iliac spine(s), tuberosity avulsion, or iliac wing fracture(s) (eg, pelvic fracture(s) which do not disrupt the pelvic ring), with internal fixation	ORTHOPEDIC SURGERY	20
27258	Open treatment of spontaneous hip dislocation (developmental, including congenital or pathological), replacement of femoral head in acetabulum (including tenotomy, etc);	ORTHOPEDIC SURGERY	20
27259	Open treatment of spontaneous hip dislocation (developmental, including congenital or pathological), replacement of femoral head in acetabulum (including tenotomy, etc); with femoral shaft shortening	ORTHOPEDIC SURGERY	20
27280	Arthrodesis, sacroiliac joint (including obtaining graft)	ORTHOPEDIC SURGERY	20
27282	Arthrodesis, symphysis pubis (including obtaining graft)	ORTHOPEDIC SURGERY	20
27284	Arthrodesis, hip joint (including obtaining graft);	ORTHOPEDIC SURGERY	20

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
27286	Arthrodesis, hip joint (including obtaining graft); with subtrochanteric osteotomy	ORTHOPEDIC SURGERY	20
27290	Interpelveabdominal amputation (hindquarter amputation)	ORTHOPEDIC SURGERY	20
27306	Tenotomy, percutaneous, adductor or hamstring; single tendon (separate procedure)	ORTHOPEDIC SURGERY	20
27307	Tenotomy, percutaneous, adductor or hamstring; multiple tendons	ORTHOPEDIC SURGERY	20
27315	Neurectomy, hamstring muscle	ORTHOPEDIC SURGERY	20
27320	Neurectomy, popliteal (gastrocnemius)	ORTHOPEDIC SURGERY	20
27330	Arthrotomy, knee; with synovial biopsy only	ORTHOPEDIC SURGERY	20
27333	Arthrotomy, with excision of semilunar cartilage (meniscectomy) knee; medial AND lateral	ORTHOPEDIC SURGERY	20
27358	Excision or curettage of bone cyst or benign tumor of femur; with internal fixation (List in addition to code for primary procedure)	ORTHOPEDIC SURGERY	20
27390	Tenotomy, open, hamstring, knee to hip; single tendon	ORTHOPEDIC SURGERY	20
27391	Tenotomy, open, hamstring, knee to hip; multiple tendons, one leg	ORTHOPEDIC SURGERY	20
27392	Tenotomy, open, hamstring, knee to hip; multiple tendons, bilateral	ORTHOPEDIC SURGERY	20
27393	Lengthening of hamstring tendon; single tendon	ORTHOPEDIC SURGERY	20
27395	Lengthening of hamstring tendon; multiple tendons, bilateral	ORTHOPEDIC SURGERY	20
27396	Transplant, hamstring tendon to patella; single tendon	ORTHOPEDIC SURGERY	20
27397	Transplant, hamstring tendon to patella; multiple tendons	ORTHOPEDIC SURGERY	20
27400	Transfer, tendon or muscle, hamstrings to femur (eg, Egger's type procedure)	ORTHOPEDIC SURGERY	20
27407	Repair, primary, torn ligament and/or capsule, knee; cruciate	ORTHOPEDIC SURGERY	20
27409	Repair, primary, torn ligament and/or capsule, knee; collateral and cruciate ligaments	ORTHOPEDIC SURGERY	20
27424	Reconstruction of dislocating patella; with patellectomy	ORTHOPEDIC SURGERY	20
27428	Ligamentous reconstruction (augmentation), knee; intra-articular (open)	ORTHOPEDIC SURGERY	20
27429	Ligamentous reconstruction (augmentation), knee; intra-articular (open) and extra-articular	ORTHOPEDIC SURGERY	20
27440	Arthroplasty, knee, tibial plateau;	ORTHOPEDIC SURGERY	20
27441	Arthroplasty, knee, tibial plateau; with debridement and partial synovectomy	ORTHOPEDIC SURGERY	20
27442	Arthroplasty, femoral condyles or tibial plateau(s), knee;	ORTHOPEDIC SURGERY	20
27443	Arthroplasty, femoral condyles or tibial plateau(s), knee; with debridement and partial synovectomy	ORTHOPEDIC SURGERY	20
27454	Osteotomy, multiple, with realignment on intramedullary rod, femoral shaft (eg, Sofield type procedure)	ORTHOPEDIC SURGERY	20

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
27455	Osteotomy, proximal tibia, including fibular excision or osteotomy (includes correction of genu varus (bowleg) or genu valgus (knock-knee)); before epiphyseal closure	ORTHOPEDIC SURGERY	20
27465	Osteoplasty, femur; shortening (excluding 64876)	ORTHOPEDIC SURGERY	20
27466	Osteoplasty, femur; lengthening	ORTHOPEDIC SURGERY	20
27468	Osteoplasty, femur; combined, lengthening and shortening with femoral segment transfer	ORTHOPEDIC SURGERY	20
27475	Arrest, epiphyseal, any method (eg, epiphysiodesis); distal femur	ORTHOPEDIC SURGERY	20
27477	Arrest, epiphyseal, any method (eg, epiphysiodesis); tibia and fibula, proximal	ORTHOPEDIC SURGERY	20
27479	Arrest, epiphyseal, any method (eg, epiphysiodesis); combined distal femur, proximal tibia and fibula	ORTHOPEDIC SURGERY	20
27485	Arrest, hemiepiphyseal, distal femur or proximal tibia or fibula (eg, genu varus or valgus)	ORTHOPEDIC SURGERY	20
27496	Decompression fasciotomy, thigh and/or knee, one compartment (flexor or extensor or adductor);	ORTHOPEDIC SURGERY	20
27497	Decompression fasciotomy, thigh and/or knee, one compartment (flexor or extensor or adductor); with debridement of nonviable muscle and/or nerve	ORTHOPEDIC SURGERY	20
27498	Decompression fasciotomy, thigh and/or knee, multiple compartments;	ORTHOPEDIC SURGERY	20
27499	Decompression fasciotomy, thigh and/or knee, multiple compartments; with debridement of nonviable muscle and/or nerve	ORTHOPEDIC SURGERY	20
27516	Closed treatment of distal femoral epiphyseal separation; without manipulation	ORTHOPEDIC SURGERY	20
27517	Closed treatment of distal femoral epiphyseal separation; with manipulation, with or without skin or skeletal traction	ORTHOPEDIC SURGERY	20
27519	Open treatment of distal femoral epiphyseal separation, with or without internal or external fixation	ORTHOPEDIC SURGERY	20
27556	Open treatment of knee dislocation, with or without internal or external fixation; without primary ligamentous repair or augmentation/reconstruction	ORTHOPEDIC SURGERY	20
27557	Open treatment of knee dislocation, with or without internal or external fixation; with primary ligamentous repair	ORTHOPEDIC SURGERY	20
27558	Open treatment of knee dislocation, with or without internal or external fixation; with primary ligamentous repair, with augmentation/reconstruction	ORTHOPEDIC SURGERY	20
27562	Closed treatment of patellar dislocation; requiring anesthesia	ORTHOPEDIC SURGERY	20
27566	Open treatment of patellar dislocation, with or without partial or total patellectomy	ORTHOPEDIC SURGERY	20
27637	Excision or curettage of bone cyst or benign tumor, tibia or fibula; with autograft (includes obtaining graft)	ORTHOPEDIC SURGERY	20
27638	Excision or curettage of bone cyst or benign tumor, tibia or fibula; with allograft	ORTHOPEDIC SURGERY	20

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
27645	Radical resection of tumor, bone; tibia	ORTHOPEDIC SURGERY	20
27646	Radical resection of tumor, bone; fibula	ORTHOPEDIC SURGERY	20
27656	Repair, fascial defect of leg	ORTHOPEDIC SURGERY	20
27665	Repair, extensor tendon, leg; secondary, with or without graft, each tendon	ORTHOPEDIC SURGERY	20
27676	Repair, dislocating peroneal tendons; with fibular osteotomy	ORTHOPEDIC SURGERY	20
27681	Tenolysis, flexor or extensor tendon, leg and/or ankle; multiple tendons (through separate incision(s))	ORTHOPEDIC SURGERY	20
27696	Repair, primary, disrupted ligament, ankle; both collateral ligaments	ORTHOPEDIC SURGERY	20
27700	Arthroplasty, ankle;	ORTHOPEDIC SURGERY	20
27703	Arthroplasty, ankle; revision, total ankle	ORTHOPEDIC SURGERY	20
27712	Osteotomy; multiple, with realignment on intramedullary rod (eg, Sofield type procedure)	ORTHOPEDIC SURGERY	20
27715	Osteoplasty, tibia and fibula, lengthening or shortening	ORTHOPEDIC SURGERY	20
27722	Repair of nonunion or malunion, tibia; with sliding graft	ORTHOPEDIC SURGERY	20
27725	Repair of nonunion or malunion, tibia; by synostosis, with fibula, any method	ORTHOPEDIC SURGERY	20
27727	Repair of congenital pseudarthrosis, tibia	ORTHOPEDIC SURGERY	20
27730	Arrest, epiphyseal (epiphysiodesis), open; distal tibia	ORTHOPEDIC SURGERY	20
27732	Arrest, epiphyseal (epiphysiodesis), open; distal fibula	ORTHOPEDIC SURGERY	20
27734	Arrest, epiphyseal (epiphysiodesis), open; distal tibia and fibula	ORTHOPEDIC SURGERY	20
27740	Arrest, epiphyseal (epiphysiodesis), any method, combined, proximal and distal tibia and fibula;	ORTHOPEDIC SURGERY	20
27742	Arrest, epiphyseal (epiphysiodesis), any method, combined, proximal and distal tibia and fibula; and distal femur	ORTHOPEDIC SURGERY	20
27830	Closed treatment of proximal tibiofibular joint dislocation; without anesthesia	ORTHOPEDIC SURGERY	20
27831	Closed treatment of proximal tibiofibular joint dislocation; requiring anesthesia	ORTHOPEDIC SURGERY	20
27832	Open treatment of proximal tibiofibular joint dislocation, with or without internal or external fixation, or with excision of proximal fibula	ORTHOPEDIC SURGERY	20
27893	Decompression fasciotomy, leg; posterior compartment(s) only, with debridement of nonviable muscle and/or nerve	ORTHOPEDIC SURGERY	20
28050	Arthrotomy with biopsy; intertarsal or tarsometatarsal joint	PODIATRY	48
28054	Arthrotomy with biopsy; interphalangeal joint	PODIATRY	48
28102	Excision or curettage of bone cyst or benign tumor, talus or calcaneus; with iliac or other autograft (includes obtaining graft)	ORTHOPEDIC SURGERY	20
28103	Excision or curettage of bone cyst or benign tumor, talus or calcaneus; with allograft	PODIATRY	48

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
28106	Excision or curettage of bone cyst or benign tumor, tarsal or metatarsal, except talus or calcaneus; with iliac or other autograft (includes obtaining graft)	PODIATRY	48
28107	Excision or curettage of bone cyst or benign tumor, tarsal or metatarsal, except talus or calcaneus; with allograft	PODIATRY	48
28130	Talectomy (astragalectomy)	ORTHOPEDIC SURGERY	20
28171	Radical resection of tumor, bone; tarsal (except talus or calcaneus)	ORTHOPEDIC SURGERY	20
28202	Repair, tendon, flexor, foot; secondary with free graft, each tendon (includes obtaining graft)	PODIATRY	48
28210	Repair, tendon, extensor, foot; secondary with free graft, each tendon (includes obtaining graft)	PODIATRY	48
28262	Capsulotomy, midfoot; extensive, including posterior talotibial capsulotomy and tendon(s) lengthening (eg, resistant clubfoot deformity)	ORTHOPEDIC SURGERY	20
28264	Capsulotomy, midtarsal (eg, Heyman type procedure)	ORTHOPEDIC SURGERY	20
28302	Osteotomy; talus	ORTHOPEDIC SURGERY	20
28305	Osteotomy, tarsal bones, other than calcaneus or talus; with autograft (includes obtaining graft) (eg, Fowler type)	PODIATRY	48
28307	Osteotomy, with or without lengthening, shortening or angular correction, metatarsal; first metatarsal with autograft (other than first toe)	ORTHOPEDIC SURGERY	20
28309	Osteotomy, with or without lengthening, shortening or angular correction, metatarsal; multiple (eg, Swanson type cavus foot procedure)	ORTHOPEDIC SURGERY	20
28340	Reconstruction, toe, macrodactyly; soft tissue resection	PODIATRY	48
28341	Reconstruction, toe, macrodactyly; requiring bone resection	PODIATRY	48
28344	Reconstruction, toe(s); polydactyly	PODIATRY	48
28345	Reconstruction, toe(s); syndactyly, with or without skin graft(s), each web	PODIATRY	48
28360	Reconstruction, cleft foot	ORTHOPEDIC SURGERY	20
28420	Open treatment of calcaneal fracture, with or without internal or external fixation; with primary iliac or other autogenous bone graft (includes obtaining graft)	ORTHOPEDIC SURGERY	20
28435	Closed treatment of talus fracture; with manipulation	ORTHOPEDIC SURGERY	20
28436	Percutaneous skeletal fixation of talus fracture, with manipulation	ORTHOPEDIC SURGERY	20
28456	Percutaneous skeletal fixation of tarsal bone fracture (except talus and calcaneus), with manipulation, each	ORTHOPEDIC SURGERY	20
28531	Open treatment of sesamoid fracture, with or without internal fixation	PODIATRY	48
28545	Closed treatment of tarsal bone dislocation, other than talotarsal; requiring anesthesia	ORTHOPEDIC SURGERY	20
28546	Percutaneous skeletal fixation of tarsal bone dislocation, other than talotarsal, with manipulation	ORTHOPEDIC SURGERY	20

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
28570	Closed treatment of talotarsal joint dislocation; without anesthesia	PODIATRY	48
28575	Closed treatment of talotarsal joint dislocation; requiring anesthesia	ORTHOPEDIC SURGERY	20
28576	Percutaneous skeletal fixation of talotarsal joint dislocation, with manipulation	ORTHOPEDIC SURGERY	20
28605	Closed treatment of tarsometatarsal joint dislocation; requiring anesthesia	ORTHOPEDIC SURGERY	20
28636	Percutaneous skeletal fixation of metatarsophalangeal joint dislocation, with manipulation	ORTHOPEDIC SURGERY	20
28666	Percutaneous skeletal fixation of interphalangeal joint dislocation, with manipulation	ORTHOPEDIC SURGERY	20
29000	Application of halo type body cast (see 20661-20663 for insertion)	NEUROSURGERY	14
29010	Application of Risser jacket, localizer, body; only	ORTHOPEDIC SURGERY	20
29015	Application of Risser jacket, localizer, body; including head	ORTHOPEDIC SURGERY	20
29020	Application of turnbuckle jacket, body; only	ORTHOPEDIC SURGERY	20
29025	Application of turnbuckle jacket, body; including head	ORTHOPEDIC SURGERY	20
29035	Application of body cast, shoulder to hips;	ORTHOPEDIC SURGERY	20
29040	Application of body cast, shoulder to hips; including head, Minerva type	ORTHOPEDIC SURGERY	20
29044	Application of body cast, shoulder to hips; including one thigh	ORTHOPEDIC SURGERY	20
29046	Application of body cast, shoulder to hips; including both thighs	ORTHOPEDIC SURGERY	20
29049	Application, cast; figure-of-eight	ORTHOPEDIC SURGERY	20
29055	Application, cast; shoulder spica	ORTHOPEDIC SURGERY	20
29305	Application of hip spica cast; one leg	ORTHOPEDIC SURGERY	20
29325	Application of hip spica cast; one and one-half spica or both legs	ORTHOPEDIC SURGERY	20
29710	Removal or bivalving; shoulder or hip spica, Minerva, or Risser jacket, etc.	ORTHOPEDIC SURGERY	20
29715	Removal or bivalving; turnbuckle jacket	ORTHOPEDIC SURGERY	20
29750	Wedging of clubfoot cast	ORTHOPEDIC SURGERY	20
29800	Arthroscopy, temporomandibular joint, diagnostic, with or without synovial biopsy (separate procedure)	ORTHOPEDIC SURGERY	20
29830	Arthroscopy, elbow, diagnostic, with or without synovial biopsy (separate procedure)	ORTHOPEDIC SURGERY	20
29834	Arthroscopy, elbow, surgical; with removal of loose body or foreign body	ORTHOPEDIC SURGERY	20
29835	Arthroscopy, elbow, surgical; synovectomy, partial	ORTHOPEDIC SURGERY	20
29836	Arthroscopy, elbow, surgical; synovectomy, complete	ORTHOPEDIC SURGERY	20
29837	Arthroscopy, elbow, surgical; debridement, limited	ORTHOPEDIC SURGERY	20
29840	Arthroscopy, wrist, diagnostic, with or without synovial biopsy (separate procedure)	ORTHOPEDIC SURGERY	20
29843	Arthroscopy, wrist, surgical; for infection, lavage and drainage	ORTHOPEDIC SURGERY	20

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
29844	Arthroscopy, wrist, surgical; synovectomy, partial	ORTHOPEDIC SURGERY	20
29847	Arthroscopy, wrist, surgical; internal fixation for fracture or instability	ORTHOPEDIC SURGERY	20
29850	Arthroscopically aided treatment of intercondylar spine(s) and/or tuberosity fracture(s) of the knee, with or without manipulation; without internal or external fixation (includes arthroscopy)	ORTHOPEDIC SURGERY	20
29851	Arthroscopically aided treatment of intercondylar spine(s) and/or tuberosity fracture(s) of the knee, with or without manipulation; with internal or external fixation (includes arthroscopy)	ORTHOPEDIC SURGERY	20
29856	Arthroscopically aided treatment of tibial fracture, proximal (plateau); bicondylar, with or without internal or external fixation (includes arthroscopy)	ORTHOPEDIC SURGERY	20
29860	Arthroscopy, hip, diagnostic with or without synovial biopsy (separate procedure)	ORTHOPEDIC SURGERY	20
29861	Arthroscopy, hip, surgical; with removal of loose body or foreign body	ORTHOPEDIC SURGERY	20
29863	Arthroscopy, hip, surgical; with synovectomy	ORTHOPEDIC SURGERY	20
29885	Arthroscopy, knee, surgical; drilling for osteochondritis dissecans with bone grafting, with or without internal fixation (including debridement of base of lesion)	ORTHOPEDIC SURGERY	20
29889	Arthroscopically aided posterior cruciate ligament repair/augmentation or reconstruction	ORTHOPEDIC SURGERY	20
29892	Arthroscopically aided repair of large osteochondritis dissecans lesion, talar dome fracture, or tibial plafond fracture, with or without internal fixation (includes arthroscopy)	ORTHOPEDIC SURGERY	20
29900	Arthroscopy, metacarpophalangeal joint, diagnostic, includes synovial biopsy	ORTHOPEDIC SURGERY	20
29901	Arthroscopy, metacarpophalangeal joint, surgical; with debridement	ORTHOPEDIC SURGERY	20
29902	Arthroscopy, metacarpophalangeal joint, surgical; with reduction of displaced ulnar collateral ligament (eg, Stenar lesion)	ORTHOPEDIC SURGERY	20
30125	Excision dermoid cyst, nose; complex, under bone or cartilage	OTOLARYNGOLOGY	04
30160	Rhinectomy; total	OTOLARYNGOLOGY	04
30320	Removal foreign body, intranasal; by lateral rhinotomy	OTOLARYNGOLOGY	04
30410	Rhinoplasty, primary; complete, external parts including bony pyramid, lateral and alar cartilages, and/or elevation of nasal tip	OTOLARYNGOLOGY	04
30430	Rhinoplasty, secondary; minor revision (small amount of nasal tip work)	OTOLARYNGOLOGY	04
30435	Rhinoplasty, secondary; intermediate revision (bony work with osteotomies)	OTOLARYNGOLOGY	04
30450	Rhinoplasty, secondary; major revision (nasal tip work and osteotomies)	OTOLARYNGOLOGY	04

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
30460	Rhinoplasty for nasal deformity secondary to congenital cleft lip and/or palate, including columellar lengthening; tip only	PLASTIC AND RECONSTRUCTIVE SURGERY	24
30462	Rhinoplasty for nasal deformity secondary to congenital cleft lip and/or palate, including columellar lengthening; tip, septum, osteotomies	PLASTIC AND RECONSTRUCTIVE SURGERY	24
30540	Repair choanal atresia; intranasal	OTOLARYNGOLOGY	04
30545	Repair choanal atresia; transpalatine	OTOLARYNGOLOGY	04
30600	Repair fistula; oronasal	ORAL SURGERY	19
31002	Lavage by cannulation; sphenoid sinus	OTOLARYNGOLOGY	04
31040	Pterygomaxillary fossa surgery, any approach	OTOLARYNGOLOGY	04
31080	Sinusotomy frontal; oblitative without osteoplastic flap, brow incision (includes ablation)	OTOLARYNGOLOGY	04
31081	Sinusotomy frontal; oblitative, without osteoplastic flap, coronal incision (includes ablation)	OTOLARYNGOLOGY	04
31084	Sinusotomy frontal; oblitative, with osteoplastic flap, brow incision	OTOLARYNGOLOGY	04
31086	Sinusotomy frontal; nonoblitative, with osteoplastic flap, brow incision	OTOLARYNGOLOGY	04
31087	Sinusotomy frontal; nonoblitative, with osteoplastic flap, coronal incision	OTOLARYNGOLOGY	04
31230	Maxillectomy; with orbital exenteration (en bloc)	OTOLARYNGOLOGY	04
31291	Nasal/sinus endoscopy, surgical, with repair of cerebrospinal fluid leak; sphenoid region	OTOLARYNGOLOGY	04
31293	Nasal/sinus endoscopy, surgical; with medial orbital wall and inferior orbital wall decompression	OTOLARYNGOLOGY	04
31294	Nasal/sinus endoscopy, surgical; with optic nerve decompression	OTOLARYNGOLOGY	04
31320	Laryngotomy (thyrotomy, laryngofissure); diagnostic	OTOLARYNGOLOGY	04
31367	Laryngectomy; subtotal supraglottic, without radical neck dissection	OTOLARYNGOLOGY	04
31368	Laryngectomy; subtotal supraglottic, with radical neck dissection	OTOLARYNGOLOGY	04
31370	Partial laryngectomy (hemilaryngectomy); horizontal	OTOLARYNGOLOGY	04
31375	Partial laryngectomy (hemilaryngectomy); lateroververtical	OTOLARYNGOLOGY	04
31380	Partial laryngectomy (hemilaryngectomy); anterovertical	OTOLARYNGOLOGY	04
31382	Partial laryngectomy (hemilaryngectomy); antero-latero-vertical	OTOLARYNGOLOGY	04
31395	Pharyngolaryngectomy, with radical neck dissection; with reconstruction	OTOLARYNGOLOGY	04
31420	Epiglottidectomy	OTOLARYNGOLOGY	04
31512	Laryngoscopy, indirect; with removal of lesion	OTOLARYNGOLOGY	04
31520	Laryngoscopy direct, with or without tracheoscopy; diagnostic, newborn	OTOLARYNGOLOGY	04
31527	Laryngoscopy direct, with or without tracheoscopy; with insertion of obturator	OTOLARYNGOLOGY	04

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
31529	Laryngoscopy direct, with or without tracheoscopy; with dilation, subsequent	OTOLARYNGOLOGY	04
31560	Laryngoscopy, direct, operative, with arytenoidectomy;	OTOLARYNGOLOGY	04
31578	Laryngoscopy, flexible fiberoptic; with removal of lesion	OTOLARYNGOLOGY	04
31580	Laryngoplasty; for laryngeal web, two stage, with keel insertion and removal	OTOLARYNGOLOGY	04
31584	Laryngoplasty; with open reduction of fracture	OTOLARYNGOLOGY	04
31585	Treatment of closed laryngeal fracture; without manipulation	OTOLARYNGOLOGY	04
31586	Treatment of closed laryngeal fracture; with closed manipulative reduction	OTOLARYNGOLOGY	04
31587	Laryngoplasty, cricoid split	OTOLARYNGOLOGY	04
31590	Laryngeal reinnervation by neuromuscular pedicle	OTOLARYNGOLOGY	04
31595	Section recurrent laryngeal nerve, therapeutic (separate procedure), unilateral	OTOLARYNGOLOGY	04
31601	Tracheostomy, planned (separate procedure); under two years	OTOLARYNGOLOGY	04
31656	Bronchoscopy, (rigid or flexible); with injection of contrast material for segmental bronchography (fiberscope only)	PULMONARY DISEASE	29
31700	Catheterization, transglottic (separate procedure)	PULMONARY DISEASE	29
31708	Instillation of contrast material for laryngography or bronchography, without catheterization	PULMONARY DISEASE	29
31710	Catheterization for bronchography, with or without instillation of contrast material	PULMONARY DISEASE	29
31715	Transtacheal injection for bronchography	PULMONARY DISEASE	29
31717	Catheterization with bronchial brush biopsy	PULMONARY DISEASE	29
31755	Tracheoplasty; tracheopharyngeal fistulization, each stage	OTOLARYNGOLOGY	04
31760	Tracheoplasty; intrathoracic	THORACIC SURGERY	33
31766	Carinal reconstruction	THORACIC SURGERY	33
31770	Bronchoplasty; graft repair	THORACIC SURGERY	33
31775	Bronchoplasty; excision stenosis and anastomosis	THORACIC SURGERY	33
31780	Excision tracheal stenosis and anastomosis; cervical	OTOLARYNGOLOGY	04
31781	Excision tracheal stenosis and anastomosis; cervicothoracic	OTOLARYNGOLOGY	04
31785	Excision of tracheal tumor or carcinoma; cervical	OTOLARYNGOLOGY	04
31786	Excision of tracheal tumor or carcinoma; thoracic	THORACIC SURGERY	33
31800	Suture of tracheal wound or injury; cervical	OTOLARYNGOLOGY	04
31805	Suture of tracheal wound or injury; intrathoracic	THORACIC SURGERY	33
32151	Thoracotomy, major; with removal of intrapulmonary foreign body	THORACIC SURGERY	33
32200	Pneumonostomy; with open drainage of abscess or cyst	THORACIC SURGERY	33
32442	Removal of lung, total pneumonectomy; with resection of segment of trachea followed by broncho-tracheal anastomosis (sleeve pneumonectomy)	THORACIC SURGERY	33

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
32491	Removal of lung, other than total pneumonectomy; excision-plication of emphysematous lung(s) (bullous or non-bullous) for lung volume reduction, sternal split or transthoracic approach, with or without any pleural procedure	THORACIC SURGERY	33
32522	Resection of lung; with reconstruction of chest wall, without prosthesis	THORACIC SURGERY	33
32603	Thoracoscopy, diagnostic (separate procedure); pericardial sac, without biopsy	THORACIC SURGERY	33
32604	Thoracoscopy, diagnostic (separate procedure); pericardial sac, with biopsy	THORACIC SURGERY	33
32605	Thoracoscopy, diagnostic (separate procedure); mediastinal space, without biopsy	THORACIC SURGERY	33
32654	Thoracoscopy, surgical; with control of traumatic hemorrhage	THORACIC SURGERY	33
32658	Thoracoscopy, surgical; with removal of clot or foreign body from pericardial sac	THORACIC SURGERY	33
32660	Thoracoscopy, surgical; with total pericardiectomy	THORACIC SURGERY	33
32661	Thoracoscopy, surgical; with excision of pericardial cyst, tumor, or mass	THORACIC SURGERY	33
32665	Thoracoscopy, surgical; with esophagomyotomy (Heller type)	THORACIC SURGERY	33
32800	Repair lung hernia through chest wall	THORACIC SURGERY	33
32810	Closure of chest wall following open flap drainage for empyema (Clagett type procedure)	THORACIC SURGERY	33
32820	Major reconstruction, chest wall (posttraumatic)	THORACIC SURGERY	33
32852	Lung transplant, single; with cardiopulmonary bypass	THORACIC SURGERY	33
32853	Lung transplant, double (bilateral sequential or en bloc); without cardiopulmonary bypass	THORACIC SURGERY	33
32854	Lung transplant, double (bilateral sequential or en bloc); with cardiopulmonary bypass	THORACIC SURGERY	33
32905	Thoracoplasty, Schede type or extrapleural (all stages);	THORACIC SURGERY	33
32906	Thoracoplasty, Schede type or extrapleural (all stages); with closure of bronchopleural fistula	THORACIC SURGERY	33
32940	Pneumonolysis, extraperiosteal, including filling or packing procedures	THORACIC SURGERY	33
32960	Pneumothorax, therapeutic, intrapleural injection of air	DIAGNOSTIC RADIOLOGY	30
32997	Total lung lavage (unilateral)	PULMONARY DISEASE	29
33050	Excision of pericardial cyst or tumor	THORACIC SURGERY	33
33130	Resection of external cardiac tumor	CARDIAC SURGERY	78
33236	Removal of permanent epicardial pacemaker and electrodes by thoracotomy; single lead system, atrial or ventricular	CARDIAC SURGERY	78
33237	Removal of permanent epicardial pacemaker and electrodes by thoracotomy; dual lead system	CARDIAC SURGERY	78
33238	Removal of permanent transvenous electrode(s) by thoracotomy	CARDIAC SURGERY	78

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
33250	Operative ablation of supraventricular arrhythmogenic focus or pathway (eg, Wolff-Parkinson-White, atrioventricular node re-entry), tract(s) and/or focus (foci); without cardiopulmonary bypass	CARDIAC SURGERY	78
33261	Operative ablation of ventricular arrhythmogenic focus with cardiopulmonary bypass	CARDIAC SURGERY	78
33310	Cardiotomy, exploratory (includes removal of foreign body, atrial or ventricular thrombus); without bypass	CARDIAC SURGERY	78
33321	Suture repair of aorta or great vessels; with shunt bypass	CARDIAC SURGERY	78
33330	Insertion of graft, aorta or great vessels; without shunt, or cardiopulmonary bypass	THORACIC SURGERY	33
33332	Insertion of graft, aorta or great vessels; with shunt bypass	CARDIAC SURGERY	78
33401	Valvuloplasty, aortic valve; open, with inflow occlusion	CARDIAC SURGERY	78
33403	Valvuloplasty, aortic valve; using transventricular dilation, with cardiopulmonary bypass	CARDIAC SURGERY	78
33404	Construction of apical-aortic conduit	CARDIAC SURGERY	78
33412	Replacement, aortic valve; with transventricular aortic annulus enlargement (Konno procedure)	CARDIAC SURGERY	78
33413	Replacement, aortic valve; by translocation of autologous pulmonary valve with allograft replacement of pulmonary valve (Ross procedure)	CARDIAC SURGERY	78
33414	Repair of left ventricular outflow tract obstruction by patch enlargement of the outflow tract	CARDIAC SURGERY	33
33415	Resection or incision of subvalvular tissue for discrete subvalvular aortic stenosis	CARDIAC SURGERY	78
33420	Valvotomy, mitral valve; closed heart	CARDIAC SURGERY	78
33422	Valvotomy, mitral valve; open heart, with cardiopulmonary bypass	CARDIAC SURGERY	78
33460	Valvectomy, tricuspid valve, with cardiopulmonary bypass	CARDIAC SURGERY	78
33468	Tricuspid valve repositioning and plication for Ebstein anomaly	CARDIAC SURGERY	78
33470	Valvotomy, pulmonary valve, closed heart; transventricular	CARDIAC SURGERY	78
33471	Valvotomy, pulmonary valve, closed heart; via pulmonary artery	CARDIAC SURGERY	78
33472	Valvotomy, pulmonary valve, open heart; with inflow occlusion	CARDIAC SURGERY	78
33474	Valvotomy, pulmonary valve, open heart; with cardiopulmonary bypass	CARDIAC SURGERY	78
33475	Replacement, pulmonary valve	CARDIAC SURGERY	78
33476	Right ventricular resection for infundibular stenosis, with or without commissurotomy	CARDIAC SURGERY	78
33478	Outflow tract augmentation (gusset), with or without commissurotomy or infundibular resection	CARDIAC SURGERY	78
33496	Repair of non-structural prosthetic valve dysfunction with cardiopulmonary bypass (separate procedure)	CARDIAC SURGERY	78

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
33500	Repair of coronary arteriovenous or arteriocardiac chamber fistula; with cardiopulmonary bypass	CARDIAC SURGERY	78
33501	Repair of coronary arteriovenous or arteriocardiac chamber fistula; without cardiopulmonary bypass	CARDIAC SURGERY	78
33502	Repair of anomalous coronary artery; by ligation	CARDIAC SURGERY	78
33503	Repair of anomalous coronary artery; by graft, without cardiopulmonary bypass	CARDIAC SURGERY	78
33504	Repair of anomalous coronary artery; by graft, with cardiopulmonary bypass	CARDIAC SURGERY	78
33505	Repair of anomalous coronary artery; with construction of intrapulmonary artery tunnel (Takeuchi procedure)	CARDIAC SURGERY	78
33506	Repair of anomalous coronary artery; by translocation from pulmonary artery to aorta	CARDIAC SURGERY	78
33600	Closure of atrioventricular valve (mitral or tricuspid) by suture or patch	CARDIAC SURGERY	78
33602	Closure of semilunar valve (aortic or pulmonary) by suture or patch	CARDIAC SURGERY	78
33606	Anastomosis of pulmonary artery to aorta (Damus-Kaye-Stansel procedure)	CARDIAC SURGERY	78
33608	Repair of complex cardiac anomaly other than pulmonary atresia with ventricular septal defect by construction or replacement of conduit from right or left ventricle to pulmonary artery	CARDIAC SURGERY	78
33610	Repair of complex cardiac anomalies (eg, single ventricle with subaortic obstruction) by surgical enlargement of ventricular septal defect	CARDIAC SURGERY	78
33611	Repair of double outlet right ventricle with intraventricular tunnel repair;	CARDIAC SURGERY	78
33612	Repair of double outlet right ventricle with intraventricular tunnel repair; with repair of right ventricular outflow tract obstruction	CARDIAC SURGERY	78
33615	Repair of complex cardiac anomalies (eg, tricuspid atresia) by closure of atrial septal defect and anastomosis of atria or vena cava to pulmonary artery (simple Fontan procedure)	CARDIAC SURGERY	78
33617	Repair of complex cardiac anomalies (eg, single ventricle) by modified Fontan procedure	CARDIAC SURGERY	78
33619	Repair of single ventricle with aortic outflow obstruction and aortic arch hypoplasia (hypoplastic left heart syndrome) (eg, Norwood procedure)	CARDIAC SURGERY	78
33645	Direct or patch closure, sinus venosus, with or without anomalous pulmonary venous drainage	CARDIAC SURGERY	78
33647	Repair of atrial septal defect and ventricular septal defect, with direct or patch closure	CARDIAC SURGERY	78
33660	Repair of incomplete or partial atrioventricular canal (ostium primum atrial septal defect), with or without atrioventricular valve repair	CARDIAC SURGERY	78
33665	Repair of intermediate or transitional atrioventricular canal, with or without atrioventricular valve repair	CARDIAC SURGERY	78
33670	Repair of complete atrioventricular canal, with or without prosthetic valve	CARDIAC SURGERY	78

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
33684	Closure of ventricular septal defect, with or without patch; with pulmonary valvotomy or infundibular resection (acyanotic)	CARDIAC SURGERY	78
33688	Closure of ventricular septal defect, with or without patch; with removal of pulmonary artery band, with or without gusset	CARDIAC SURGERY	78
33690	Banding of pulmonary artery	CARDIAC SURGERY	78
33692	Complete repair tetralogy of Fallot without pulmonary atresia;	CARDIAC SURGERY	78
33694	Complete repair tetralogy of Fallot without pulmonary atresia; with transannular patch	CARDIAC SURGERY	78
33697	Complete repair tetralogy of Fallot with pulmonary atresia including construction of conduit from right ventricle to pulmonary artery and closure of ventricular septal defect	CARDIAC SURGERY	78
33702	Repair sinus of Valsalva fistula, with cardiopulmonary bypass;	CARDIAC SURGERY	78
33710	Repair sinus of Valsalva fistula, with cardiopulmonary bypass; with repair of ventricular septal defect	CARDIAC SURGERY	78
33720	Repair sinus of Valsalva aneurysm, with cardiopulmonary bypass	CARDIAC SURGERY	78
33722	Closure of aortico-left ventricular tunnel	CARDIAC SURGERY	78
33730	Complete repair of anomalous venous return (supracardiac, intracardiac, or infracardiac types)	CARDIAC SURGERY	78
33732	Repair of cor triatriatum or supravalvular mitral ring by resection of left atrial membrane	CARDIAC SURGERY	78
33735	Atrial septectomy or septostomy; closed heart (Blalock-Hanlon type operation)	CARDIAC SURGERY	78
33736	Atrial septectomy or septostomy; open heart with cardiopulmonary bypass	CARDIAC SURGERY	78
33737	Atrial septectomy or septostomy; open heart, with inflow occlusion	CARDIAC SURGERY	78
33750	Shunt; subclavian to pulmonary artery (Blalock-Taussig type operation)	CARDIAC SURGERY	78
33755	Shunt; ascending aorta to pulmonary artery (Waterston type operation)	CARDIAC SURGERY	78
33762	Shunt; descending aorta to pulmonary artery (Potts-Smith type operation)	CARDIAC SURGERY	78
33764	Shunt; central, with prosthetic graft	CARDIAC SURGERY	78
33766	Shunt; superior vena cava to pulmonary artery for flow to one lung (classical Glenn procedure)	CARDIAC SURGERY	78
33767	Shunt; superior vena cava to pulmonary artery for flow to both lungs (bidirectional Glenn procedure)	CARDIAC SURGERY	78
33770	Repair of transposition of the great arteries with ventricular septal defect and subpulmonary stenosis; without surgical enlargement of ventricular septal defect	CARDIAC SURGERY	78
33771	Repair of transposition of the great arteries with ventricular septal defect and subpulmonary stenosis; with surgical enlargement of ventricular septal defect	CARDIAC SURGERY	78

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
33774	Repair of transposition of the great arteries, atrial baffle procedure (eg, Mustard or Senning type) with cardiopulmonary bypass;	CARDIAC SURGERY	78
33775	Repair of transposition of the great arteries, atrial baffle procedure (eg, Mustard or Senning type) with cardiopulmonary bypass; with removal of pulmonary band	CARDIAC SURGERY	78
33776	Repair of transposition of the great arteries, atrial baffle procedure (eg, Mustard or Senning type) with cardiopulmonary bypass; with closure of ventricular septal defect	CARDIAC SURGERY	78
33777	Repair of transposition of the great arteries, atrial baffle procedure (eg, Mustard or Senning type) with cardiopulmonary bypass; with repair of subpulmonic obstruction	CARDIAC SURGERY	33
33778	Repair of transposition of the great arteries, aortic pulmonary artery reconstruction (eg, Jatene type);	CARDIAC SURGERY	78
33779	Repair of transposition of the great arteries, aortic pulmonary artery reconstruction (eg, Jatene type); with removal of pulmonary band	CARDIAC SURGERY	78
33780	Repair of transposition of the great arteries, aortic pulmonary artery reconstruction (eg, Jatene type); with closure of ventricular septal defect	CARDIAC SURGERY	78
33781	Repair of transposition of the great arteries, aortic pulmonary artery reconstruction (eg, Jatene type); with repair of subpulmonic obstruction	CARDIAC SURGERY	78
33786	Total repair, truncus arteriosus (Rastelli type operation)	CARDIAC SURGERY	78
33788	Reimplantation of an anomalous pulmonary artery	CARDIAC SURGERY	78
33800	Aortic suspension (aortopexy) for tracheal decompression (eg, for tracheomalacia) (separate procedure)	THORACIC SURGERY	33
33802	Division of aberrant vessel (vascular ring);	CARDIAC SURGERY	78
33803	Division of aberrant vessel (vascular ring); with reanastomosis	CARDIAC SURGERY	78
33813	Obliteration of aortopulmonary septal defect; without cardiopulmonary bypass	CARDIAC SURGERY	78
33814	Obliteration of aortopulmonary septal defect; with cardiopulmonary bypass	CARDIAC SURGERY	78
33820	Repair of patent ductus arteriosus; by ligation	CARDIAC SURGERY	78
33822	Repair of patent ductus arteriosus; by division, under 18 years	CARDIAC SURGERY	78
33824	Repair of patent ductus arteriosus; by division, 18 years and older	CARDIAC SURGERY	78
33840	Excision of coarctation of aorta, with or without associated patent ductus arteriosus; with direct anastomosis	CARDIAC SURGERY	78
33845	Excision of coarctation of aorta, with or without associated patent ductus arteriosus; with graft	CARDIAC SURGERY	78

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
33851	Excision of coarctation of aorta, with or without associated patent ductus arteriosus; repair using either left subclavian artery or prosthetic material as gusset for enlargement	CARDIAC SURGERY	78
33852	Repair of hypoplastic or interrupted aortic arch using autogenous or prosthetic material; without cardiopulmonary bypass	CARDIAC SURGERY	78
33853	Repair of hypoplastic or interrupted aortic arch using autogenous or prosthetic material; with cardiopulmonary bypass	CARDIAC SURGERY	78
33910	Pulmonary artery embolectomy; with cardiopulmonary bypass	CARDIAC SURGERY	78
33915	Pulmonary artery embolectomy; without cardiopulmonary bypass	CARDIAC SURGERY	78
33916	Pulmonary endarterectomy, with or without embolectomy, with cardiopulmonary bypass	CARDIAC SURGERY	78
33917	Repair of pulmonary artery stenosis by reconstruction with patch or graft	CARDIAC SURGERY	78
33918	Repair of pulmonary atresia with ventricular septal defect, by unifocalization of pulmonary arteries; without cardiopulmonary bypass	CARDIAC SURGERY	78
33919	Repair of pulmonary atresia with ventricular septal defect, by unifocalization of pulmonary arteries; with cardiopulmonary bypass	CARDIAC SURGERY	78
33920	Repair of pulmonary atresia with ventricular septal defect, by construction or replacement of conduit from right or left ventricle to pulmonary artery	CARDIAC SURGERY	78
33922	Transection of pulmonary artery with cardiopulmonary bypass	CARDIAC SURGERY	78
33924	Ligation and takedown of a systemic-to-pulmonary artery shunt, performed in conjunction with a congenital heart procedure (List separately in addition to code for primary procedure)	CARDIAC SURGERY	78
33935	Heart-lung transplant with recipient cardiectomy-pneumonectomy	CARDIAC SURGERY	78
33960	Prolonged extracorporeal circulation for cardiopulmonary insufficiency; initial 24 hours	THORACIC SURGERY	33
33961	Prolonged extracorporeal circulation for cardiopulmonary insufficiency; each additional 24 hours (List separately in addition to code for primary procedure)	CARDIAC SURGERY	78
33976	Insertion of ventricular assist device; extracorporeal, biventricular	THORACIC SURGERY	33
33978	Removal of ventricular assist device; extracorporeal, biventricular	CARDIAC SURGERY	78
33980	Removal of ventricular assist device, implantable intracorporeal, single ventricle	CARDIAC SURGERY	78
34051	Embolectomy or thrombectomy, with or without catheter; innominate, subclavian artery, by thoracic incision	GENERAL SURGERY	02

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
34451	Thrombectomy, direct or with catheter; vena cava, iliac, femoropopliteal vein, by abdominal and leg incision	VASCULAR SURGERY	77
34471	Thrombectomy, direct or with catheter; subclavian vein, by neck incision	GENERAL SURGERY	02
34501	Valvuloplasty, femoral vein	GENERAL SURGERY	02
34510	Venous valve transposition, any vein donor	GENERAL SURGERY	02
34530	Saphenopopliteal vein anastomosis	GENERAL SURGERY	02
34830	Open repair of infrarenal aortic aneurysm or dissection, plus repair of associated arterial trauma, following unsuccessful endovascular repair; tube prosthesis	VASCULAR SURGERY	77
34832	Open repair of infrarenal aortic aneurysm or dissection, plus repair of associated arterial trauma, following unsuccessful endovascular repair; aorto-bifemoral prosthesis	VASCULAR SURGERY	77
34834	Open brachial artery exposure to assist in the deployment of infrarenal aortic or iliac endovascular prosthesis by arm incision, unilateral	VASCULAR SURGERY	77
35002	Direct repair of aneurysm, pseudoaneurysm, or excision (partial or total) and graft insertion, with or without patch graft; for ruptured aneurysm, carotid, subclavian artery, by neck incision	GENERAL SURGERY	02
35005	Direct repair of aneurysm, pseudoaneurysm, or excision (partial or total) and graft insertion, with or without patch graft; for aneurysm, pseudoaneurysm, and associated occlusive disease, vertebral artery	GENERAL SURGERY	02
35021	Direct repair of aneurysm, pseudoaneurysm, or excision (partial or total) and graft insertion, with or without patch graft; for aneurysm, pseudoaneurysm, and associated occlusive disease, innominate, subclavian artery, by thoracic incision	CARDIAC SURGERY	78
35022	Direct repair of aneurysm, pseudoaneurysm, or excision (partial or total) and graft insertion, with or without patch graft; for ruptured aneurysm, innominate, subclavian artery, by thoracic incision	CARDIAC SURGERY	78
35111	Direct repair of aneurysm, pseudoaneurysm, or excision (partial or total) and graft insertion, with or without patch graft; for aneurysm, pseudoaneurysm, and associated occlusive disease, splenic artery	GENERAL SURGERY	02
35112	Direct repair of aneurysm, pseudoaneurysm, or excision (partial or total) and graft insertion, with or without patch graft; for ruptured aneurysm, splenic artery	GENERAL SURGERY	02
35122	Direct repair of aneurysm, pseudoaneurysm, or excision (partial or total) and graft insertion, with or without patch graft; for ruptured aneurysm, hepatic, celiac, renal, or mesenteric artery	GENERAL SURGERY	02
35152	Direct repair of aneurysm, pseudoaneurysm, or excision (partial or total) and graft insertion, with or without patch graft; for ruptured aneurysm, popliteal artery	GENERAL SURGERY	02

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
35180	Repair, congenital arteriovenous fistula; head and neck	GENERAL SURGERY	02
35182	Repair, congenital arteriovenous fistula; thorax and abdomen	GENERAL SURGERY	02
35188	Repair, acquired or traumatic arteriovenous fistula; head and neck	GENERAL SURGERY	02
35189	Repair, acquired or traumatic arteriovenous fistula; thorax and abdomen	GENERAL SURGERY	02
35246	Repair blood vessel with vein graft; intrathoracic, without bypass	CARDIAC SURGERY	78
35271	Repair blood vessel with graft other than vein; intrathoracic, with bypass	CARDIAC SURGERY	78
35276	Repair blood vessel with graft other than vein; intrathoracic, without bypass	CARDIAC SURGERY	78
35311	Thromboendarterectomy, with or without patch graft; subclavian, innominate, by thoracic incision	VASCULAR SURGERY	77
35363	Thromboendarterectomy, with or without patch graft; combined aortoiliiofemoral	VASCULAR SURGERY	77
35480	Transluminal peripheral atherectomy, open; renal or other visceral artery	VASCULAR SURGERY	77
35481	Transluminal peripheral atherectomy, open; aortic	THORACIC SURGERY	33
35482	Transluminal peripheral atherectomy, open; iliac	GENERAL SURGERY	02
35484	Transluminal peripheral atherectomy, open; brachiocephalic trunk or branches, each vessel	GENERAL SURGERY	02
35485	Transluminal peripheral atherectomy, open; tibioperoneal trunk and branches	THORACIC SURGERY	33
35491	Transluminal peripheral atherectomy, percutaneous; aortic	CARDIOLOGY	06
35494	Transluminal peripheral atherectomy, percutaneous; brachiocephalic trunk or branches, each vessel	CARDIOLOGY	06
35507	Bypass graft, with vein; subclavian-carotid	VASCULAR SURGERY	77
35508	Bypass graft, with vein; carotid-vertebral	VASCULAR SURGERY	77
35511	Bypass graft, with vein; subclavian-subclavian	VASCULAR SURGERY	77
35512	Bypass graft, with vein; subclavian-brachial	VASCULAR SURGERY	77
35515	Bypass graft, with vein; subclavian-vertebral	VASCULAR SURGERY	77
35516	Bypass graft, with vein; subclavian-axillary	VASCULAR SURGERY	77
35518	Bypass graft, with vein; axillary-axillary	VASCULAR SURGERY	77
35521	Bypass graft, with vein; axillary-femoral	VASCULAR SURGERY	77
35526	Bypass graft, with vein; aortosubclavian or carotid	VASCULAR SURGERY	77
35533	Bypass graft, with vein; axillary-femoral-femoral	VASCULAR SURGERY	77
35536	Bypass graft, with vein; splenorenal	VASCULAR SURGERY	77
35541	Bypass graft, with vein; aortoiliac or bi-iliac	VASCULAR SURGERY	77
35548	Bypass graft, with vein; aortoiliiofemoral, unilateral	VASCULAR SURGERY	77
35549	Bypass graft, with vein; aortoiliiofemoral, bilateral	VASCULAR SURGERY	77
35551	Bypass graft, with vein; aortofemoral-popliteal	VASCULAR SURGERY	77
35563	Bypass graft, with vein; ilioiliac	VASCULAR SURGERY	77
35612	Bypass graft, with other than vein; subclavian-subclavian	VASCULAR SURGERY	77
35616	Bypass graft, with other than vein; subclavian-axillary	VASCULAR SURGERY	77

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
35636	Bypass graft, with other than vein; splenorenal (splenic to renal arterial anastomosis)	VASCULAR SURGERY	77
35642	Bypass graft, with other than vein; carotid-vertebral	VASCULAR SURGERY	77
35645	Bypass graft, with other than vein; subclavian-vertebral	VASCULAR SURGERY	77
35651	Bypass graft, with other than vein; aortofemoral-popliteal	VASCULAR SURGERY	77
35691	Transposition and/or reimplantation; vertebral to carotid artery	VASCULAR SURGERY	77
35693	Transposition and/or reimplantation; vertebral to subclavian artery	VASCULAR SURGERY	77
35694	Transposition and/or reimplantation; subclavian to carotid artery	VASCULAR SURGERY	77
35695	Transposition and/or reimplantation; carotid to subclavian artery	VASCULAR SURGERY	77
35905	Excision of infected graft; thorax	GENERAL SURGERY	02
36261	Revision of implanted intra-arterial infusion pump	GENERAL SURGERY	02
36400	Venipuncture, under age 3 years, necessitating physician's skill, not to be used for routine venipuncture; femoral or jugular vein	EMERGENCY MEDICINE	93
36405	Venipuncture, under age 3 years, necessitating physician's skill, not to be used for routine venipuncture; scalp vein	EMERGENCY MEDICINE	93
36420	Venipuncture, cutdown; under age 1 year	EMERGENCY MEDICINE	93
36440	Push transfusion, blood, 2 years or under	PEDIATRIC MEDICINE	37
36450	Exchange transfusion, blood; newborn	PEDIATRIC MEDICINE	37
36460	Transfusion, intrauterine, fetal	OB-GYN	16
36468	Single or multiple injections of sclerosing solutions, spider veins (telangiectasia); limb or trunk	GENERAL SURGERY	02
36469	Single or multiple injections of sclerosing solutions, spider veins (telangiectasia); face	PEDIATRIC MEDICINE	37
36510	Catheterization of umbilical vein for diagnosis or therapy, newborn	HEMATOLOGY/ONCOLOGY	83
36660	Catheterization, umbilical artery, newborn, for diagnosis or therapy	PEDIATRIC MEDICINE	37
37145	Venous anastomosis, open; renoportal	GENERAL SURGERY	02
37160	Venous anastomosis, open; caval-mesenteric	GENERAL SURGERY	02
37180	Venous anastomosis, open; splenorenal, proximal	GENERAL SURGERY	02
37181	Venous anastomosis, open; splenorenal, distal (selective decompression of esophagogastric varices, any technique)	GENERAL SURGERY	02
37195	Thrombolysis, cerebral, by intravenous infusion	NEUROLOGY	13
37606	Ligation; internal or common carotid artery, with gradual occlusion, as with Selverstone or Crutchfield clamp	NEUROSURGERY	14
37615	Ligation, major artery (eg, post-traumatic, rupture); neck	GENERAL SURGERY	2
37616	Ligation, major artery (eg, post-traumatic, rupture); chest	CARDIAC SURGERY	78
37660	Ligation of common iliac vein	GENERAL SURGERY	02
37788	Penile revascularization, artery, with or without vein graft	UROLOGY	34

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
37790	Penile venous occlusive procedure	UROLOGY	34
38101	Splenectomy; partial (separate procedure)	GENERAL SURGERY	02
38200	Injection procedure for splenoportography	DIAGNOSTIC RADIOLOGY	30
38242	Bone marrow or blood-derived peripheral stem cell transplantation; allogeneic donor lymphocyte infusions	HEMATOLOGY/ONCOLOGY	83
38380	Suture and/or ligation of thoracic duct; cervical approach	OTOLARYNGOLOGY	04
38381	Suture and/or ligation of thoracic duct; thoracic approach	THORACIC SURGERY	33
38382	Suture and/or ligation of thoracic duct; abdominal approach	GENERAL SURGERY	02
38550	Excision of cystic hygroma, axillary or cervical; without deep neurovascular dissection	GENERAL SURGERY	02
38555	Excision of cystic hygroma, axillary or cervical; with deep neurovascular dissection	GENERAL SURGERY	02
38794	Cannulation, thoracic duct	DIAGNOSTIC RADIOLOGY	30
39503	Repair, neonatal diaphragmatic hernia, with or without chest tube insertion and with or without creation of ventral hernia	GENERAL SURGERY	02
39530	Repair, diaphragmatic hernia (esophageal hiatal); combined, thoracoabdominal	GENERAL SURGERY	02
39531	Repair, diaphragmatic hernia (esophageal hiatal); combined, thoracoabdominal, with dilation of stricture (with or without gastroplasty)	GENERAL SURGERY	02
39540	Repair, diaphragmatic hernia (other than neonatal), traumatic; acute	GENERAL SURGERY	02
39545	Imbrication of diaphragm for eventration, transthoracic or transabdominal, paralytic or nonparalytic	THORACIC SURGERY	33
40700	Plastic repair of cleft lip/nasal deformity; primary, partial or complete, unilateral	PLASTIC AND RECONSTRUCTIVE SURGERY	24
40701	Plastic repair of cleft lip/nasal deformity; primary bilateral, one stage procedure	PLASTIC AND RECONSTRUCTIVE SURGERY	24
40702	Plastic repair of cleft lip/nasal deformity; primary bilateral, one of two stages	PLASTIC AND RECONSTRUCTIVE SURGERY	24
40720	Plastic repair of cleft lip/nasal deformity; secondary, by recreation of defect and reclosure	PLASTIC AND RECONSTRUCTIVE SURGERY	24
40761	Plastic repair of cleft lip/nasal deformity; with cross lip pedicle flap (Abbe-Estlander type), including sectioning and inserting of pedicle	PLASTIC AND RECONSTRUCTIVE SURGERY	24
40805	Removal of embedded foreign body, vestibule of mouth; complicated	ORAL SURGERY	19
40806	Incision of labial frenum (frenotomy)	ORAL SURGERY	19
40840	Vestibuloplasty; anterior	ORAL SURGERY	19
40842	Vestibuloplasty; posterior, unilateral	OTOLARYNGOLOGY	04

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
40843	Vestibuloplasty; posterior, bilateral	OTOLARYNGOLOGY	04
40844	Vestibuloplasty; entire arch	OTOLARYNGOLOGY	04
40845	Vestibuloplasty; complex (including ridge extension, muscle repositioning)	OTOLARYNGOLOGY	04
41005	Intraoral incision and drainage of abscess, cyst, or hematoma of tongue or floor of mouth; sublingual, superficial	ORAL SURGERY	19
41006	Intraoral incision and drainage of abscess, cyst, or hematoma of tongue or floor of mouth; sublingual, deep, supramylohyoid	ORAL SURGERY	19
41007	Intraoral incision and drainage of abscess, cyst, or hematoma of tongue or floor of mouth; submental space	ORAL SURGERY	19
41010	Incision of lingual frenum (frenotomy)	OTOLARYNGOLOGY	04
41015	Extraoral incision and drainage of abscess, cyst, or hematoma of floor of mouth; sublingual	ORAL SURGERY	19
41018	Extraoral incision and drainage of abscess, cyst, or hematoma of floor of mouth; masticator space	ORAL SURGERY	19
41115	Excision of lingual frenum (frenectomy)	OTOLARYNGOLOGY	04
41140	Glossectomy; complete or total, with or without tracheostomy, without radical neck dissection	OTOLARYNGOLOGY	04
41145	Glossectomy; complete or total, with or without tracheostomy, with unilateral radical neck dissection	OTOLARYNGOLOGY	04
41251	Repair of laceration 2.5 cm or less; posterior one-third of tongue	EMERGENCY MEDICINE	93
41500	Fixation of tongue, mechanical, other than suture (eg, K-wire)	OTOLARYNGOLOGY	04
41510	Suture of tongue to lip for micrognathia (Douglas type procedure)	OTOLARYNGOLOGY	04
41520	Frenoplasty (surgical revision of frenum, eg, with Z-plasty)	OTOLARYNGOLOGY	04
41820	Gingivectomy, excision gingiva, each quadrant	ORAL SURGERY	19
41821	Operculectomy, excision pericoronal tissues	ORAL SURGERY	19
41822	Excision of fibrous tuberosities, dentoalveolar structures	ORAL SURGERY	19
41823	Excision of osseous tuberosities, dentoalveolar structures	ORAL SURGERY	19
41850	Destruction of lesion (except excision), dentoalveolar structures	ORAL SURGERY	19
41870	Periodontal mucosal grafting	ORAL SURGERY	19
41872	Gingivoplasty, each quadrant (specify)	ORAL SURGERY	19
42000	Drainage of abscess of palate, uvula	OTOLARYNGOLOGY	04
42180	Repair, laceration of palate; up to 2 cm	OTOLARYNGOLOGY	04
42182	Repair, laceration of palate; over 2 cm or complex	OTOLARYNGOLOGY	04
42200	Palatoplasty for cleft palate, soft and/or hard palate only	PLASTIC AND RECONSTRUCTIVE SURGERY	24
42205	Palatoplasty for cleft palate, with closure of alveolar ridge; soft tissue only	PLASTIC AND RECONSTRUCTIVE SURGERY	24

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
42210	Palatoplasty for cleft palate, with closure of alveolar ridge; with bone graft to alveolar ridge (includes obtaining graft)	PLASTIC AND RECONSTRUCTIVE SURGERY	24
42215	Palatoplasty for cleft palate; major revision	PLASTIC AND RECONSTRUCTIVE SURGERY	24
42220	Palatoplasty for cleft palate; secondary lengthening procedure	PLASTIC AND RECONSTRUCTIVE SURGERY	24
42225	Palatoplasty for cleft palate; attachment pharyngeal flap	PLASTIC AND RECONSTRUCTIVE SURGERY	24
42226	Lengthening of palate, and pharyngeal flap	OTOLARYNGOLOGY	04
42227	Lengthening of palate, with island flap	OTOLARYNGOLOGY	04
42235	Repair of anterior palate, including vomer flap	OTOLARYNGOLOGY	04
42260	Repair of nasolabial fistula	PLASTIC AND RECONSTRUCTIVE SURGERY	24
42281	Insertion of pin-retained palatal prosthesis	OTOLARYNGOLOGY	04
42320	Drainage of abscess; submaxillary, external	OTOLARYNGOLOGY	04
42325	Fistulization of sublingual salivary cyst (ranula);	OTOLARYNGOLOGY	04
42326	Fistulization of sublingual salivary cyst (ranula); with prosthesis	OTOLARYNGOLOGY	04
42340	Sialolithotomy; parotid, extraoral or complicated intraoral	OTOLARYNGOLOGY	04
42409	Marsupialization of sublingual salivary cyst (ranula)	OTOLARYNGOLOGY	04
42505	Plastic repair of salivary duct, sialodochoplasty; secondary or complicated	OTOLARYNGOLOGY	04
42507	Parotid duct diversion, bilateral (Wilke type procedure);	OTOLARYNGOLOGY	04
42508	Parotid duct diversion, bilateral (Wilke type procedure); with excision of one submandibular gland	OTOLARYNGOLOGY	04
42509	Parotid duct diversion, bilateral (Wilke type procedure); with excision of both submandibular glands	OTOLARYNGOLOGY	04
42510	Parotid duct diversion, bilateral (Wilke type procedure); with ligation of both submandibular (Wharton's) ducts	OTOLARYNGOLOGY	04
42600	Closure salivary fistula	OTOLARYNGOLOGY	04
42665	Ligation salivary duct, intraoral	OTOLARYNGOLOGY	04
42725	Incision and drainage abscess; retropharyngeal or parapharyngeal, external approach	OTOLARYNGOLOGY	04
42810	Excision branchial cleft cyst or vestige, confined to skin and subcutaneous tissues	OTOLARYNGOLOGY	04
42820	Tonsillectomy and adenoidectomy; under age 12	OTOLARYNGOLOGY	04
42825	Tonsillectomy, primary or secondary; under age 12	OTOLARYNGOLOGY	04
42830	Adenoidectomy, primary; under age 12	OTOLARYNGOLOGY	04
42835	Adenoidectomy, secondary; under age 12	OTOLARYNGOLOGY	04
42836	Adenoidectomy, secondary; age 12 or over	OTOLARYNGOLOGY	04

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
42844	Radical resection of tonsil, tonsillar pillars, and/or retromolar trigone; closure with local flap (eg, tongue, buccal)	OTOLARYNGOLOGY	04
42845	Radical resection of tonsil, tonsillar pillars, and/or retromolar trigone; closure with other flap	OTOLARYNGOLOGY	04
42860	Excision of tonsil tags	OTOLARYNGOLOGY	04
42900	Suture pharynx for wound or injury	OTOLARYNGOLOGY	04
42955	Pharyngostomy (fistulization of pharynx, external for feeding)	OTOLARYNGOLOGY	04
42961	Control oropharyngeal hemorrhage, primary or secondary (eg, post-tonsillectomy); complicated, requiring hospitalization	OTOLARYNGOLOGY	04
42971	Control of nasopharyngeal hemorrhage, primary or secondary (eg, postadenoidectomy); complicated, requiring hospitalization	OTOLARYNGOLOGY	04
42972	Control of nasopharyngeal hemorrhage, primary or secondary (eg, postadenoidectomy); with secondary surgical intervention	OTOLARYNGOLOGY	04
43020	Esophagotomy, cervical approach, with removal of foreign body	GENERAL SURGERY	02
43045	Esophagotomy, thoracic approach, with removal of foreign body	THORACIC SURGERY	33
43100	Excision of lesion, esophagus, with primary repair; cervical approach	OTOLARYNGOLOGY	04
43101	Excision of lesion, esophagus, with primary repair; thoracic or abdominal approach	GENERAL SURGERY	02
43108	Total or near total esophagectomy, without thoracotomy; with colon interposition or small intestine reconstruction, including intestine mobilization, preparation and anastomosis(es)	GENERAL SURGERY	02
43113	Total or near total esophagectomy, with thoracotomy; with colon interposition or small intestine reconstruction, including intestine mobilization, preparation, and anastomosis(es)	THORACIC SURGERY	33
43116	Partial esophagectomy, cervical, with free intestinal graft, including microvascular anastomosis, obtaining the graft and intestinal reconstruction	THORACIC SURGERY	33
43118	Partial esophagectomy, distal two-thirds, with thoracotomy and separate abdominal incision, with or without proximal gastrectomy; with colon interposition or small intestine reconstruction, including intestine mobilization, preparation, and anastomosis(es)	GENERAL SURGERY	02
43121	Partial esophagectomy, distal two-thirds, with thoracotomy only, with or without proximal gastrectomy, with thoracic esophagogastrostomy, with or without pyloroplasty	THORACIC SURGERY	33
43123	Partial esophagectomy, thoracoabdominal or abdominal approach, with or without proximal gastrectomy; with colon interposition or small intestine reconstruction, including intestine mobilization, preparation, and anastomosis(es)	THORACIC SURGERY	02

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
43124	Total or partial esophagectomy, without reconstruction (any approach), with cervical esophagostomy	THORACIC SURGERY	33
43300	Esophagoplasty (plastic repair or reconstruction), cervical approach; without repair of tracheoesophageal fistula	OTOLARYNGOLOGY	04
43312	Esophagoplasty (plastic repair or reconstruction), thoracic approach; with repair of tracheoesophageal fistula	THORACIC SURGERY	33
43313	Esophagoplasty for congenital defect (plastic repair or reconstruction), thoracic approach; without repair of congenital tracheoesophageal fistula	THORACIC SURGERY	33
43314	Esophagoplasty for congenital defect (plastic repair or reconstruction), thoracic approach; with repair of congenital tracheoesophageal fistula	THORACIC SURGERY	33
43320	Esophagogastrostomy (cardioplasty), with or without vagotomy and pyloroplasty, transabdominal or transthoracic approach	GENERAL SURGERY	02
43325	Esophagogastric fundoplasty; with fundic patch (Thal-Nissen procedure)	GENERAL SURGERY	02
43331	Esophagomyotomy (Heller type); thoracic approach	THORACIC SURGERY	33
43340	Esophagojejunostomy (without total gastrectomy); abdominal approach	GENERAL SURGERY	02
43341	Esophagojejunostomy (without total gastrectomy); thoracic approach	GENERAL SURGERY	02
43350	Esophagostomy, fistulization of esophagus, external; abdominal approach	GENERAL SURGERY	02
43351	Esophagostomy, fistulization of esophagus, external; thoracic approach	THORACIC SURGERY	33
43352	Esophagostomy, fistulization of esophagus, external; cervical approach	THORACIC SURGERY	33
43360	Gastrointestinal reconstruction for previous esophagectomy, for obstructing esophageal lesion or fistula, or for previous esophageal exclusion; with stomach, with or without pyloroplasty	GENERAL SURGERY	02
43361	Gastrointestinal reconstruction for previous esophagectomy, for obstructing esophageal lesion or fistula, or for previous esophageal exclusion; with colon interposition or small intestine reconstruction, including intestine mobilization, preparation, and anastomosis(es)	GENERAL SURGERY	02
43400	Ligation, direct, esophageal varices	GENERAL SURGERY	02
43401	Transection of esophagus with repair, for esophageal varices	GENERAL SURGERY	02
43405	Ligation or stapling at gastroesophageal junction for pre-existing esophageal perforation	GENERAL SURGERY	02
43410	Suture of esophageal wound or injury; cervical approach	GENERAL SURGERY	02
43420	Closure of esophagostomy or fistula; cervical approach	GENERAL SURGERY	02

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
43425	Closure of esophagostomy or fistula; transthoracic or transabdominal approach	GENERAL SURGERY	02
43460	Esophagogastric tamponade, with balloon (Sengstaaken type)	GASTROENTEROLOGY	10
43496	Free jejunum transfer with microvascular anastomosis	PLASTIC AND RECONSTRUCTIVE SURGERY	24
43502	Gastrotomy; with suture repair of pre-existing esophagogastric laceration (eg, Mallory-Weiss)	GENERAL SURGERY	02
43510	Gastrotomy; with esophageal dilation and insertion of permanent intraluminal tube (eg, Celestin or Mousseaux-Barbin)	GENERAL SURGERY	02
43634	Gastrectomy, partial, distal; with formation of intestinal pouch	GENERAL SURGERY	02
43641	Vagotomy including pyloroplasty, with or without gastrostomy; parietal cell (highly selective)	GENERAL SURGERY	02
43651	Laparoscopy, surgical; transection of vagus nerves, truncal	GENERAL SURGERY	02
43652	Laparoscopy, surgical; transection of vagus nerves, selective or highly selective	GENERAL SURGERY	02
43752	Naso- or oro-gastric tube placement, requiring physician's skill and fluoroscopic guidance (includes fluoroscopy, image documentation and report)	DIAGNOSTIC RADIOLOGY	30
43810	Gastroduodenostomy	GENERAL SURGERY	02
43831	Gastrostomy, open; neonatal, for feeding	GENERAL SURGERY	02
43850	Revision of gastroduodenal anastomosis (gastroduodenostomy) with reconstruction; without vagotomy	GENERAL SURGERY	02
43855	Revision of gastroduodenal anastomosis (gastroduodenostomy) with reconstruction; with vagotomy	GENERAL SURGERY	02
43865	Revision of gastrojejunal anastomosis (gastrojejunostomy) with reconstruction, with or without partial gastrectomy or intestine resection; with vagotomy	GENERAL SURGERY	02
44126	Enterectomy, resection of small intestine for congenital atresia, single resection and anastomosis of proximal segment of intestine; without tapering	GENERAL SURGERY	02
44127	Enterectomy, resection of small intestine for congenital atresia, single resection and anastomosis of proximal segment of intestine; with tapering	GENERAL SURGERY	02
44128	Enterectomy, resection of small intestine for congenital atresia, single resection and anastomosis of proximal segment of intestine; each additional resection and anastomosis (List separately in addition to code for primary procedure)	GENERAL SURGERY	02
44151	Colectomy, total, abdominal, without proctectomy; with continent ileostomy	GENERAL SURGERY	02

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
44156	Colectomy, total, abdominal, with proctectomy; with continent ileostomy	GENERAL SURGERY	02
44203	Laparoscopy, surgical; each additional small intestine resection and anastomosis (List separately in addition to code for primary procedure)	GENERAL SURGERY	02
44211	Laparoscopy, surgical; colectomy, total, abdominal, with proctectomy, with ileoanal anastomosis, creation of ileal reservoir (S or J), with loop ileostomy, with or without rectal mucosectomy	GENERAL SURGERY	02
44212	Laparoscopy, surgical; colectomy, total, abdominal, with proctectomy, with ileostomy	GENERAL SURGERY	02
44239	Unlisted laparoscopy procedure, rectum	GENERAL SURGERY	02
44316	Continent ileostomy (Kock procedure) (separate procedure)	GENERAL SURGERY	02
44322	Colostomy or skin level cecostomy; with multiple biopsies (eg, for congenital megacolon) (separate procedure)	GENERAL SURGERY	02
44370	Small intestinal endoscopy, enteroscopy beyond second portion of duodenum, not including ileum; with transendoscopic stent placement (includes predilation)	GASTROENTEROLOGY	10
44379	Small intestinal endoscopy, enteroscopy beyond second portion of duodenum, including ileum; with transendoscopic stent placement (includes predilation)	GASTROENTEROLOGY	10
44390	Colonoscopy through stoma; with removal of foreign body	GASTROENTEROLOGY	10
44397	Colonoscopy through stoma; with transendoscopic stent placement (includes predilation)	GASTROENTEROLOGY	10
44680	Intestinal plication (separate procedure)	GENERAL SURGERY	02
44850	Suture of mesentery (separate procedure)	GENERAL SURGERY	02
45108	Anorectal myomectomy	GENERAL SURGERY	02
45113	Proctectomy, partial, with rectal mucosectomy, ileoanal anastomosis, creation of ileal reservoir (S or J), with or without loop ileostomy	GENERAL SURGERY	02
45114	Proctectomy, partial, with anastomosis; abdominal and transsacral approach	GENERAL SURGERY	02
45116	Proctectomy, partial, with anastomosis; transsacral approach only (Kraske type)	GENERAL SURGERY	02
45120	Proctectomy, complete (for congenital megacolon), abdominal and perineal approach; with pull-through procedure and anastomosis (eg, Swenson, Duhamel, or Soave type operation)	GENERAL SURGERY	02
45121	Proctectomy, complete (for congenital megacolon), abdominal and perineal approach; with subtotal or total colectomy, with multiple biopsies	GENERAL SURGERY	02

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
45126	Pelvic exenteration for colorectal malignancy, with proctectomy (with or without colostomy), with removal of bladder and ureteral transplantations, and/or hysterectomy, or cervicectomy, with or without removal of tube(s), with or without removal of ovary(s), or any combination thereof	GENERAL SURGERY	02
45135	Excision of rectal procidentia, with anastomosis; abdominal and perineal approach	GENERAL SURGERY	02
45136	Excision of ileoanal reservoir with ileostomy	COLORECTAL SURGERY	28
45150	Division of stricture of rectum	GENERAL SURGERY	02
45327	Proctosigmoidoscopy, rigid; with transendoscopic stent placement (includes predilation)	GENERAL SURGERY	02
45563	Exploration, repair, and presacral drainage for rectal injury; with colostomy	GENERAL SURGERY	02
45805	Closure of rectovesical fistula; with colostomy	GENERAL SURGERY	02
45820	Closure of rectourethral fistula;	GENERAL SURGERY	02
45825	Closure of rectourethral fistula; with colostomy	GENERAL SURGERY	02
46070	Incision, anal septum (infant)	GENERAL SURGERY	02
46210	Cryptectomy; single	GENERAL SURGERY	02
46211	Cryptectomy; multiple (separate procedure)	GENERAL SURGERY	02
46612	Anoscopy; with removal of multiple tumors, polyps, or other lesions by hot biopsy forceps, bipolar cautery or snare technique	GENERAL SURGERY	02
46705	Anoplasty, plastic operation for stricture; infant	GENERAL SURGERY	02
46715	Repair of low imperforate anus; with anoperineal fistula (cut-back procedure)	GENERAL SURGERY	02
46716	Repair of low imperforate anus; with transposition of anoperineal or anovestibular fistula	GENERAL SURGERY	02
46730	Repair of high imperforate anus without fistula; perineal or sacroperineal approach	GENERAL SURGERY	02
46735	Repair of high imperforate anus without fistula; combined transabdominal and sacroperineal approaches	GENERAL SURGERY	02
46740	Repair of high imperforate anus with rectourethral or rectovaginal fistula; perineal or sacroperineal approach	GENERAL SURGERY	02
46742	Repair of high imperforate anus with rectourethral or rectovaginal fistula; combined transabdominal and sacroperineal approaches	GENERAL SURGERY	02
46744	Repair of cloacal anomaly by anorectovaginoplasty and urethroplasty, sacroperineal approach	GENERAL SURGERY	02
46746	Repair of cloacal anomaly by anorectovaginoplasty and urethroplasty, combined abdominal and sacroperineal approach;	GENERAL SURGERY	02
46748	Repair of cloacal anomaly by anorectovaginoplasty and urethroplasty, combined abdominal and sacroperineal approach; with vaginal lengthening by intestinal graft or pedicle flaps	GENERAL SURGERY	02
46751	Sphincteroplasty, anal, for incontinence or prolapse; child	GENERAL SURGERY	02

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
46754	Removal of Thiersch wire or suture, anal canal	GENERAL SURGERY	02
46760	Sphincteroplasty, anal, for incontinence, adult; muscle transplant	COLORECTAL SURGERY	28
46762	Sphincteroplasty, anal, for incontinence, adult; implantation artificial sphincter	COLORECTAL SURGERY	28
46937	Cryosurgery of rectal tumor; benign	GENERAL SURGERY	02
46938	Cryosurgery of rectal tumor; malignant	GENERAL SURGERY	02
47015	Laparotomy, with aspiration and/or injection of hepatic parasitic (eg, amoebic or echinococcal) cyst(s) or abscess(es)	GENERAL SURGERY	02
47360	Management of liver hemorrhage; complex suture of liver wound or injury, with or without hepatic artery ligation	GENERAL SURGERY	02
47362	Management of liver hemorrhage; re-exploration of hepatic wound for removal of packing	GENERAL SURGERY	02
47371	Laparoscopy, surgical, ablation of one or more liver tumor(s); cryosurgical	GENERAL SURGERY	02
47381	Ablation, open, of one or more liver tumor(s); cryosurgical	GENERAL SURGERY	02
47400	Hepaticotomy or hepaticostomy with exploration, drainage, or removal of calculus	GENERAL SURGERY	02
47425	Choledochotomy or choledochostomy with exploration, drainage, or removal of calculus, with or without cholecystotomy; with transduodenal sphincterotomy or sphincteroplasty	GENERAL SURGERY	02
47561	Laparoscopy, surgical; with guided transhepatic cholangiography with biopsy	GENERAL SURGERY	02
47570	Laparoscopy, surgical; cholecystoenterostomy	GENERAL SURGERY	02
47700	Exploration for congenital atresia of bile ducts, without repair, with or without liver biopsy, with or without cholangiography	GENERAL SURGERY	02
47701	Portoenterostomy (eg, Kasai procedure)	GENERAL SURGERY	02
47712	Excision of bile duct tumor, with or without primary repair of bile duct; intrahepatic	GENERAL SURGERY	02
47715	Excision of choledochal cyst	GENERAL SURGERY	02
47716	Anastomosis, choledochal cyst, without excision	GENERAL SURGERY	02
47740	Cholecystoenterostomy; Roux-en-Y	GENERAL SURGERY	02
47765	Anastomosis, of intrahepatic ducts and gastrointestinal tract	GENERAL SURGERY	02
47800	Reconstruction, plastic, of extrahepatic biliary ducts with end-to-end anastomosis	GENERAL SURGERY	02
47802	U-tube hepaticoenterostomy	GENERAL SURGERY	02
48001	Placement of drains, peripancreatic, for acute pancreatitis; with cholecystostomy, gastrostomy, and jejunostomy	GENERAL SURGERY	02
48020	Removal of pancreatic calculus	GENERAL SURGERY	02
48145	Pancreatectomy, distal subtotal, with or without splenectomy; with pancreaticojejunostomy	GENERAL SURGERY	02
48146	Pancreatectomy, distal, near-total with preservation of duodenum (Child-type procedure)	GENERAL SURGERY	02
48148	Excision of ampulla of Vater	GENERAL SURGERY	02

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
48152	Pancreatectomy, proximal subtotal with total duodenectomy, partial gastrectomy, choledochoenterostomy and gastrojejunostomy (Whipple-type procedure); without pancreatojejunostomy	GENERAL SURGERY	02
48154	Pancreatectomy, proximal subtotal with near-total duodenectomy, choledochoenterostomy and duodenojejunostomy (pylorus-sparing, Whipple-type procedure); without pancreatojejunostomy	GENERAL SURGERY	02
48155	Pancreatectomy, total	GENERAL SURGERY	02
48400	Injection procedure for intraoperative pancreatography (List separately in addition to code for primary procedure)	GENERAL SURGERY	02
48500	Marsupialization of pancreatic cyst	GENERAL SURGERY	02
48545	Pancreatorrhaphy for injury	GENERAL SURGERY	02
48547	Duodenal exclusion with gastrojejunostomy for pancreatic injury	GENERAL SURGERY	02
48550	Donor pancreatectomy (including cold preservation), with or without duodenal segment for transplantation	GENERAL SURGERY	02
48556	Removal of transplanted pancreatic allograft	GENERAL SURGERY	02
49220	Staging laparotomy for Hodgkins disease or lymphoma (includes splenectomy, needle or open biopsies of both liver lobes, possibly also removal of abdominal nodes, abdominal node and/or bone marrow biopsies, ovarian repositioning)	GENERAL SURGERY	02
49428	Ligation of peritoneal-venous shunt	GENERAL SURGERY	02
49491	Repair, initial inguinal hernia, preterm infant (less than 37 weeks gestation at birth), performed from birth up to 50 weeks postconception age, with or without hydrocelectomy; reducible	GENERAL SURGERY	02
49492	Repair, initial inguinal hernia, preterm infant (less than 37 weeks gestation at birth), performed from birth up to 50 weeks postconception age, with or without hydrocelectomy; incarcerated or strangulated	GENERAL SURGERY	02
49495	Repair, initial inguinal hernia, full term infant under age 6 months, or preterm infant over 50 weeks postconception age and under age 6 months at the time of surgery, with or without hydrocelectomy; reducible	GENERAL SURGERY	02
49496	Repair, initial inguinal hernia, full term infant under age 6 months, or preterm infant over 50 weeks postconception age and under age 6 months at the time of surgery, with or without hydrocelectomy; incarcerated or strangulated	GENERAL SURGERY	02
49500	Repair initial inguinal hernia, age 6 months to under 5 years, with or without hydrocelectomy; reducible	GENERAL SURGERY	02
49501	Repair initial inguinal hernia, age 6 months to under 5 years, with or without hydrocelectomy; incarcerated or strangulated	GENERAL SURGERY	02

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
49580	Repair umbilical hernia, under age 5 years; reducible	GENERAL SURGERY	02
49600	Repair of small omphalocele, with primary closure	GENERAL SURGERY	02
49605	Repair of large omphalocele or gastroschisis; with or without prosthesis	GENERAL SURGERY	02
49606	Repair of large omphalocele or gastroschisis; with removal of prosthesis, final reduction and closure, in operating room	GENERAL SURGERY	02
49610	Repair of omphalocele (Gross type operation); first stage	GENERAL SURGERY	02
49611	Repair of omphalocele (Gross type operation); second stage	GENERAL SURGERY	02
49906	Free omental flap with microvascular anastomosis	GENERAL SURGERY	02
50045	Nephrotomy, with exploration	UROLOGY	34
50060	Nephrolithotomy; removal of calculus	UROLOGY	34
50065	Nephrolithotomy; secondary surgical operation for calculus	UROLOGY	34
50070	Nephrolithotomy; complicated by congenital kidney abnormality	UROLOGY	34
50075	Nephrolithotomy; removal of large staghorn calculus filling renal pelvis and calyces (including anatomic pyelolithotomy)	UROLOGY	34
50100	Transection or repositioning of aberrant renal vessels (separate procedure)	GENERAL SURGERY	02
50120	Pyelotomy; with exploration	UROLOGY	34
50125	Pyelotomy; with drainage, pyelostomy	UROLOGY	34
50135	Pyelotomy; complicated (eg, secondary operation, congenital kidney abnormality)	UROLOGY	34
50290	Excision of perinephric cyst	UROLOGY	34
50380	Renal autotransplantation, reimplantation of kidney	GENERAL SURGERY	02
50500	Nephrorrhaphy, suture of kidney wound or injury	GENERAL SURGERY	02
50520	Closure of nephrocutaneous or pyelocutaneous fistula	UROLOGY	34
50525	Closure of nephrovisceral fistula (eg, renocolic), including visceral repair; abdominal approach	UROLOGY	34
50526	Closure of nephrovisceral fistula (eg, renocolic), including visceral repair; thoracic approach	UROLOGY	34
50540	Symphysiotomy for horseshoe kidney with or without pyeloplasty and/or other plastic procedure, unilateral or bilateral (one operation)	UROLOGY	34
50544	Laparoscopy, surgical; pyeloplasty	UROLOGY	34
50555	Renal endoscopy through established nephrostomy or pyelostomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with biopsy	UROLOGY	34
50557	Renal endoscopy through established nephrostomy or pyelostomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with fulguration and/or incision, with or without biopsy	UROLOGY	34

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
50562	Renal endoscopy through established nephrostomy or pyelostomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with resection of tumor	UROLOGY	34
50570	Renal endoscopy through nephrotomy or pyelotomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service;	UROLOGY	34
50572	Renal endoscopy through nephrotomy or pyelotomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with ureteral catheterization, with or without dilation of ureter	UROLOGY	34
50574	Renal endoscopy through nephrotomy or pyelotomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with biopsy	UROLOGY	34
50576	Renal endoscopy through nephrotomy or pyelotomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with fulguration and/or incision, with or without biopsy	UROLOGY	34
50580	Renal endoscopy through nephrotomy or pyelotomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with removal of foreign body or calculus	UROLOGY	34
50610	Ureterolithotomy; upper one-third of ureter	UROLOGY	34
50620	Ureterolithotomy; middle one-third of ureter	UROLOGY	34
50660	Ureterectomy, total, ectopic ureter, combination abdominal, vaginal and/or perineal approach	UROLOGY	34
50686	Manometric studies through ureterostomy or indwelling ureteral catheter	UROLOGY	34
50722	Ureterolysis for ovarian vein syndrome	OB-GYN	16
50725	Ureterolysis for retrocaval ureter, with reanastomosis of upper urinary tract or vena cava	UROLOGY	34
50728	Revision of urinary-cutaneous anastomosis (any type urostomy); with repair of fascial defect and hernia	UROLOGY	34
50740	Ureteropyelostomy, anastomosis of ureter and renal pelvis	UROLOGY	34
50750	Ureterocalycostomy, anastomosis of ureter to renal calyx	UROLOGY	34
50770	Transureteroureterostomy, anastomosis of ureter to contralateral ureter	UROLOGY	34
50782	Ureteroneocystostomy; anastomosis of duplicated ureter to bladder	UROLOGY	34
50783	Ureteroneocystostomy; with extensive ureteral tailoring	UROLOGY	34
50810	Ureterosigmoidostomy, with creation of sigmoid bladder and establishment of abdominal or perineal colostomy, including intestine anastomosis	GENERAL SURGERY	02

51080	Drainage of perivesical or prevesical space abscess	UROLOGY	34

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
50815	Ureterocolon conduit, including intestine anastomosis	UROLOGY	34
50830	Urinary undiversion (eg, taking down of ureteroileal conduit, ureterosigmoidostomy or ureteroenterostomy with ureteroureterostomy or ureteroneocystostomy)	UROLOGY	34
50840	Replacement of all or part of ureter by intestine segment, including intestine anastomosis	UROLOGY	34
50845	Cutaneous appendico-vesicostomy	UROLOGY	34
50860	Ureterostomy, transplantation of ureter to skin	UROLOGY	34
50920	Closure of ureterocutaneous fistula	UROLOGY	34
50930	Closure of ureterovisceral fistula (including visceral repair)	UROLOGY	34
50940	Deligation of ureter	UROLOGY	34
50945	Laparoscopy, surgical; ureterolithotomy	UROLOGY	34
50947	Laparoscopy, surgical; ureteroneocystostomy with cystoscopy and ureteral stent placement	UROLOGY	34
50948	Laparoscopy, surgical; ureteroneocystostomy without cystoscopy and ureteral stent placement	UROLOGY	34
50949	Unlisted laparoscopy procedure, ureter	UROLOGY	34
50955	Ureteral endoscopy through established ureterostomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with biopsy	UROLOGY	34
50957	Ureteral endoscopy through established ureterostomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with fulguration and/or incision, with or without biopsy	UROLOGY	34
50970	Ureteral endoscopy through ureterotomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service;	UROLOGY	34
50972	Ureteral endoscopy through ureterotomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with ureteral catheterization, with or without dilation of ureter	UROLOGY	34
50974	Ureteral endoscopy through ureterotomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with biopsy	UROLOGY	34
50976	Ureteral endoscopy through ureterotomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with fulguration and/or incision, with or without biopsy	UROLOGY	34
50980	Ureteral endoscopy through ureterotomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with removal of foreign body or calculus	UROLOGY	34
51030	Cystotomy or cystostomy; with cryosurgical destruction of intravesical lesion	UROLOGY	34
51060	Transvesical ureterolithotomy	UROLOGY	34
51080	Drainage of perivesical or prevesical space abscess	UROLOGY	34

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
51500	Excision of urachal cyst or sinus, with or without umbilical hernia repair	UROLOGY	34
51520	Cystotomy, for simple excision of vesical neck (separate procedure)	UROLOGY	34
51535	Cystotomy for excision, incision, or repair of ureterocele	UROLOGY	34
51580	Cystectomy, complete, with ureterosigmoidostomy or ureterocutaneous transplantations;	UROLOGY	34
51585	Cystectomy, complete, with ureterosigmoidostomy or ureterocutaneous transplantations; with bilateral pelvic lymphadenectomy, including external iliac, hypogastric, and obturator nodes	UROLOGY	34
51820	Cystourethroplasty with unilateral or bilateral ureteroneocystostomy	UROLOGY	34
51900	Closure of vesicovaginal fistula, abdominal approach	UROLOGY	34
51920	Closure of vesicouterine fistula;	UROLOGY	34
51925	Closure of vesicouterine fistula; with hysterectomy	OB-GYN	16
51940	Closure, exstrophy of bladder	UROLOGY	34
51980	Cutaneous vesicostomy	UROLOGY	34
52301	Cystourethroscopy; with resection or fulguration of ectopic ureterocele(s), unilateral or bilateral	UROLOGY	34
52343	Cystourethroscopy; with treatment of intra-renal stricture (eg, balloon dilation, laser, electrocautery, and incision)	UROLOGY	34
52346	Cystourethroscopy with ureteroscopy; with treatment of intra-renal stricture (eg, balloon dilation, laser, electrocautery, and incision)	UROLOGY	34
52402	Cystourethroscopy with transurethral resection or incision of ejaculatory ducts	UROLOGY	34
52510	Transurethral balloon dilation of the prostatic urethra	UROLOGY	34
52700	Transurethral drainage of prostatic abscess	UROLOGY	34
53025	Meatotomy, cutting of meatus (separate procedure); infant	UROLOGY	34
53040	Drainage of deep periurethral abscess	UROLOGY	34
53060	Drainage of Skene's gland abscess or cyst	OB-GYN	16
53080	Drainage of perineal urinary extravasation; uncomplicated (separate procedure)	UROLOGY	34
53210	Urethrectomy, total, including cystostomy; female	UROLOGY	34
53235	Excision of urethral diverticulum (separate procedure); male	UROLOGY	34
53240	Marsupialization of urethral diverticulum, male or female	UROLOGY	34
53250	Excision of bulbourethral gland (Cowper's gland)	UROLOGY	34
53270	Excision or fulguration; Skene's glands	UROLOGY	34
53405	Urethroplasty; second stage (formation of urethra), including urinary diversion	UROLOGY	34
53420	Urethroplasty, two-stage reconstruction or repair of prostatic or membranous urethra; first stage	UROLOGY	34
53425	Urethroplasty, two-stage reconstruction or repair of prostatic or membranous urethra; second stage	UROLOGY	34

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
53431	Urethroplasty with tubularization of posterior urethra and/or lower bladder for incontinence (eg, Tenago, Leadbetter procedure)	UROLOGY	34
53442	Removal or revision of sling for male urinary incontinence (eg, fascia or synthetic)	UROLOGY	34
53448	Removal and replacement of inflatable urethral/bladder neck sphincter including pump, reservoir, and cuff through an infected field at the same operative session including irrigation and debridement of infected tissue	UROLOGY	34
53460	Urethromeatoplasty, with partial excision of distal urethral segment (Richardson type procedure)	UROLOGY	34
53502	Urethrorrhaphy, suture of urethral wound or injury, female	UROLOGY	34
53505	Urethrorrhaphy, suture of urethral wound or injury; penile	UROLOGY	34
53510	Urethrorrhaphy, suture of urethral wound or injury; perineal	UROLOGY	34
53515	Urethrorrhaphy, suture of urethral wound or injury; prostaticmembranous	UROLOGY	34
53520	Closure of urethrostomy or urethrocutaneous fistula, male (separate procedure)	UROLOGY	34
54000	Slitting of prepuce, dorsal or lateral (separate procedure); newborn	UROLOGY	34
54110	Excision of penile plaque (Peyronie disease);	UROLOGY	34
54111	Excision of penile plaque (Peyronie disease); with graft to 5 cm in length	UROLOGY	34
54112	Excision of penile plaque (Peyronie disease); with graft greater than 5 cm in length	UROLOGY	34
54115	Removal foreign body from deep penile tissue (eg, plastic implant)	UROLOGY	34
54130	Amputation of penis, radical; with bilateral inguino-femoral lymphadenectomy	UROLOGY	34
54135	Amputation of penis, radical; in continuity with bilateral pelvic lymphadenectomy, including external iliac, hypogastric and obturator nodes	UROLOGY	34
54150	Circumcision, using clamp or other device; newborn	UROLOGY	34
54160	Circumcision, surgical excision other than clamp, device or dorsal slit; newborn	UROLOGY	34
54164	Frenulotomy of penis	UROLOGY	34
54205	Injection procedure for Peyronie disease; with surgical exposure of plaque	UROLOGY	34
54300	Plastic operation of penis for straightening of chordee (eg, hypospadias), with or without mobilization of urethra	UROLOGY	34
54304	Plastic operation on penis for correction of chordee or for first stage hypospadias repair with or without transplantation of prepuce and/or skin flaps	UROLOGY	34
54308	Urethroplasty for second stage hypospadias repair (including urinary diversion); less than 3 cm	UROLOGY	34
54312	Urethroplasty for second stage hypospadias repair (including urinary diversion); greater than 3 cm	UROLOGY	34

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
54316	Urethroplasty for second stage hypospadias repair (including urinary diversion) with free skin graft obtained from site other than genitalia	UROLOGY	34
54318	Urethroplasty for third stage hypospadias repair to release penis from scrotum (eg, third stage Cecil repair)	UROLOGY	34
54322	One stage distal hypospadias repair (with or without chordee or circumcision); with simple meatal advancement (eg, Magpi, V-flap)	UROLOGY	34
54324	One stage distal hypospadias repair (with or without chordee or circumcision); with urethroplasty by local skin flaps (eg, flip-flap, prepuce flap)	UROLOGY	34
54326	One stage distal hypospadias repair (with or without chordee or circumcision); with urethroplasty by local skin flaps and mobilization of urethra	UROLOGY	34
54328	One stage distal hypospadias repair (with or without chordee or circumcision); with extensive dissection to correct chordee and urethroplasty with local skin flaps, skin graft patch, and/or island flap	UROLOGY	34
54332	One stage proximal penile or penoscrotal hypospadias repair requiring extensive dissection to correct chordee and urethroplasty by use of skin graft tube and/or island flap	UROLOGY	34
54336	One stage perineal hypospadias repair requiring extensive dissection to correct chordee and urethroplasty by use of skin graft tube and/or island flap	UROLOGY	34
54340	Repair of hypospadias complications (ie, fistula, stricture, diverticula); by closure, incision, or excision, simple	UROLOGY	34
54344	Repair of hypospadias complications (ie, fistula, stricture, diverticula); requiring mobilization of skin flaps and urethroplasty with flap or patch graft	UROLOGY	34
54348	Repair of hypospadias complications (ie, fistula, stricture, diverticula); requiring extensive dissection and urethroplasty with flap, patch or tubed graft (includes urinary diversion)	UROLOGY	34
54352	Repair of hypospadias cripple requiring extensive dissection and excision of previously constructed structures including re-release of chordee and reconstruction of urethra and penis by use of local skin as grafts and island flaps and skin brought in as flaps or grafts	UROLOGY	34
54380	Plastic operation on penis for epispadias distal to external sphincter;	UROLOGY	34
54385	Plastic operation on penis for epispadias distal to external sphincter; with incontinence	UROLOGY	34
54390	Plastic operation on penis for epispadias distal to external sphincter; with exstrophy of bladder	UROLOGY	34

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
54417	Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue	UROLOGY	34
54420	Corpora cavernosa-saphenous vein shunt (priapism operation), unilateral or bilateral	UROLOGY	34
54430	Corpora cavernosa-corpus spongiosum shunt (priapism operation), unilateral or bilateral	UROLOGY	34
54435	Corpora cavernosa-glans penis fistulization (eg, biopsy needle, Winter procedure, rongeur, or punch) for priapism	UROLOGY	34
54440	Plastic operation of penis for injury	UROLOGY	34
54500	Biopsy of testis, needle (separate procedure)	UROLOGY	34
54535	Orchiectomy, radical, for tumor; with abdominal exploration	UROLOGY	34
54550	Exploration for undescended testis (inguinal or scrotal area)	UROLOGY	34
54560	Exploration for undescended testis with abdominal exploration	UROLOGY	34
54600	Reduction of torsion of testis, surgical, with or without fixation of contralateral testis	UROLOGY	34
54620	Fixation of contralateral testis (separate procedure)	UROLOGY	34
54650	Orchiopexy, abdominal approach, for intra-abdominal testis (eg, Fowler-Stephens)	UROLOGY	34
54660	Insertion of testicular prosthesis (separate procedure)	UROLOGY	34
54670	Suture or repair of testicular injury	UROLOGY	34
54680	Transplantation of testis(es) to thigh (because of scrotal destruction)	UROLOGY	34
54690	Laparoscopy, surgical; orchiectomy	UROLOGY	34
54692	Laparoscopy, surgical; orchiopexy for intra-abdominal testis	UROLOGY	34
54699	Unlisted laparoscopy procedure, testis	UROLOGY	34
54800	Biopsy of epididymis, needle	UROLOGY	34
54820	Exploration of epididymis, with or without biopsy	UROLOGY	34
54861	Epididymectomy; bilateral	UROLOGY	34
54900	Epididymovasostomy, anastomosis of epididymis to vas deferens; unilateral	UROLOGY	34
54901	Epididymovasostomy, anastomosis of epididymis to vas deferens; bilateral	UROLOGY	34
55200	Vasotomy, cannulization with or without incision of vas, unilateral or bilateral (separate procedure)	UROLOGY	34
55300	Vasotomy for vasograms, seminal vesiculograms, or epididymograms, unilateral or bilateral	UROLOGY	34
55400	Vasovasostomy, vasovasorrhaphy	UROLOGY	34
55450	Ligation (percutaneous) of vas deferens, unilateral or bilateral (separate procedure)	UROLOGY	34
55535	Excision of varicocele or ligation of spermatic veins for varicocele; abdominal approach	UROLOGY	34
55550	Laparoscopy, surgical, with ligation of spermatic veins for varicocele	UROLOGY	34

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
55605	Vesiculotomy; complicated	UROLOGY	34
55650	Vesiculectomy, any approach	UROLOGY	34
55680	Excision of Mullerian duct cyst	UROLOGY	34
55725	Prostatotomy, external drainage of prostatic abscess, any approach; complicated	UROLOGY	34
55801	Prostatectomy, perineal, subtotal (including control of postoperative bleeding, vasectomy, meatotomy, urethral calibration and/or dilation, and internal urethrotomy)	UROLOGY	34
55812	Prostatectomy, perineal radical; with lymph node biopsy(s) (limited pelvic lymphadenectomy)	UROLOGY	34
55862	Exposure of prostate, any approach, for insertion of radioactive substance; with lymph node biopsy(s) (limited pelvic lymphadenectomy)	UROLOGY	34
55865	Exposure of prostate, any approach, for insertion of radioactive substance; with bilateral pelvic lymphadenectomy, including external iliac, hypogastric and obturator nodes	UROLOGY	34
55870	Electroejaculation	UROLOGY	34
56634	Vulvectomy, radical, complete; with unilateral inguofemoral lymphadenectomy	GYNECOLOGY/ONCOLOGY	98
56640	Vulvectomy, radical, complete, with inguofemoral, iliac, and pelvic lymphadenectomy	GYNECOLOGY/ONCOLOGY	98
56700	Partial hymenectomy or revision of hymenal ring	OB-GYN	16
56720	Hymenotomy, simple incision	OB-GYN	16
56805	Clitoroplasty for intersex state	OB-GYN	16
57000	Colpotomy; with exploration	OB-GYN	16
57010	Colpotomy; with drainage of pelvic abscess	OB-GYN	16
57022	Incision and drainage of vaginal hematoma; obstetrical/postpartum	OB-GYN	16
57023	Incision and drainage of vaginal hematoma; non-obstetrical (eg, post-trauma, spontaneous bleeding)	OB-GYN	16
57109	Vaginectomy, partial removal of vaginal wall; with removal of paravaginal tissue (radical vaginectomy) with bilateral total pelvic lymphadenectomy and para-aortic lymph node sampling (biopsy)	GYNECOLOGY/ONCOLOGY	16
57111	Vaginectomy, complete removal of vaginal wall; with removal of paravaginal tissue (radical vaginectomy)	GYNECOLOGY/ONCOLOGY	16
57112	Vaginectomy, complete removal of vaginal wall; with removal of paravaginal tissue (radical vaginectomy) with bilateral total pelvic lymphadenectomy and para-aortic lymph node sampling (biopsy)	GYNECOLOGY/ONCOLOGY	98
57130	Excision of vaginal septum	OB-GYN	16
57230	Plastic repair of urethrocele	OB-GYN	16
57291	Construction of artificial vagina; without graft	OB-GYN	16
57292	Construction of artificial vagina; with graft	OB-GYN	16
57307	Closure of rectovaginal fistula; abdominal approach, with concomitant colostomy	GENERAL SURGERY	02

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
57308	Closure of rectovaginal fistula; transperineal approach, with perineal body reconstruction, with or without levator plication	OB-GYN	16
57310	Closure of urethrovaginal fistula;	UROLOGY	34
57311	Closure of urethrovaginal fistula; with bulbo-cavernosus transplant	UROLOGY	34
57330	Closure of vesicovaginal fistula; transvesical and vaginal approach	UROLOGY	34
57335	Vaginoplasty for intersex state	OB-GYN	16
57531	Radical trachelectomy, with bilateral total pelvic lymphadenectomy and para-aortic lymph node sampling biopsy, with or without removal of tube(s), with or without removal of ovary(s)	OB-GYN	16
57540	Excision of cervical stump, abdominal approach;	OB-GYN	16
57545	Excision of cervical stump, abdominal approach; with pelvic floor repair	OB-GYN	16
57550	Excision of cervical stump, vaginal approach;	OB-GYN	16
57555	Excision of cervical stump, vaginal approach; with anterior and/or posterior repair	OB-GYN	16
57700	Cerclage of uterine cervix, nonobstetrical	OB-GYN	16
57720	Trachelorrhaphy, plastic repair of uterine cervix, vaginal approach	OB-GYN	16
58146	Myomectomy, excision of fibroid tumor(s) of uterus, 5 or more intramural myomas and/or intramural myomas with total weight greater than 250 grams, abdominal approach	OB-GYN	16
58285	Vaginal hysterectomy, radical (Schauta type operation)	GYNECOLOGY/ONCOLOGY	98
58291	Vaginal hysterectomy, for uterus greater than 250 grams; with removal of tube(s) and/or ovary(s)	OB-GYN	16
58292	Vaginal hysterectomy, for uterus greater than 250 grams; with removal of tube(s) and/or ovary(s), with repair of enterocele	OB-GYN	16
58293	Vaginal hysterectomy, for uterus greater than 250 grams; with colpo-urethrocystopexy (Marshall-Marchetti-Krantz type, Pereyra type) with or without endoscopic control	OB-GYN	16
58294	Vaginal hysterectomy, for uterus greater than 250 grams; with repair of enterocele	OB-GYN	16
58300	Insertion of intrauterine device (IUD)	OB-GYN	16
58321	Artificial insemination; intra-cervical	OB-GYN	16
58322	Artificial insemination; intra-uterine	OB-GYN	16
58323	Sperm washing for artificial insemination	OB-GYN	16
58345	Transcervical introduction of fallopian tube catheter for diagnosis and/or re-establishing patency (any method), with or without hysterosalpingography	OB-GYN	16
58346	Insertion of Heyman capsules for clinical brachytherapy	GYNECOLOGY/ONCOLOGY	98
58350	Chromotubation of oviduct, including materials	OB-GYN	16

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
58410	Uterine suspension, with or without shortening of round ligaments, with or without shortening of sacrouterine ligaments; with presacral sympathectomy	OB-GYN	16
58520	Hysterorrhaphy, repair of ruptured uterus (nonobstetrical)	OB-GYN	16
58540	Hysteroplasty, repair of uterine anomaly (Strassman type)	OB-GYN	16
58545	Laparoscopy, surgical, myomectomy, excision; 1 to 4 intramural myomas with total weight of 250 grams or less and/or removal of surface myomas	OB-GYN	16
58546	Laparoscopy, surgical, myomectomy, excision; 5 or more intramural myomas and/or intramural myomas with total weight greater than 250 grams	OB-GYN	16
58553	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 grams;	OB-GYN	16
58560	Hysteroscopy, surgical; with division or resection of intrauterine septum (any method)	OB-GYN	16
58562	Hysteroscopy, surgical; with removal of impacted foreign body	OB-GYN	16
58579	Unlisted hysteroscopy procedure, uterus	OB-GYN	16
58600	Ligation or transection of fallopian tube(s), abdominal or vaginal approach, unilateral or bilateral	OB-GYN	16
58605	Ligation or transection of fallopian tube(s), abdominal or vaginal approach, postpartum, unilateral or bilateral, during same hospitalization (separate procedure)	OB-GYN	16
58615	Occlusion of fallopian tube(s) by device (eg, band, clip, Falope ring) vaginal or suprapubic approach	OB-GYN	16
58672	Laparoscopy, surgical; with fimbrioplasty	OB-GYN	16
58673	Laparoscopy, surgical; with salpingostomy (salpingoneostomy)	OB-GYN	16
58679	Unlisted laparoscopy procedure, oviduct, ovary	OB-GYN	16
58750	Tubotubal anastomosis	OB-GYN	16
58752	Tubouterine implantation	OB-GYN	16
58760	Fimbrioplasty	OB-GYN	16
58770	Salpingostomy (salpingoneostomy)	OB-GYN	16
58800	Drainage of ovarian cyst(s), unilateral or bilateral, (separate procedure); vaginal approach	OB-GYN	16
58820	Drainage of ovarian abscess; vaginal approach, open	OB-GYN	16
58822	Drainage of ovarian abscess; abdominal approach	OB-GYN	16
58825	Transposition, ovary(s)	OB-GYN	16
58900	Biopsy of ovary, unilateral or bilateral (separate procedure)	OB-GYN	16
58920	Wedge resection or bisection of ovary, unilateral or bilateral	OB-GYN	16
58970	Follicle puncture for oocyte retrieval, any method	OB-GYN	16
58974	Embryo transfer, intrauterine	OB-GYN	16
58976	Gamete, zygote, or embryo intrafallopian transfer, any method	OB-GYN	16

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
59001	Amniocentesis; therapeutic amniotic fluid reduction (includes ultrasound guidance)	OB-GYN	16
59012	Cordocentesis (intrauterine), any method	OB-GYN	16
59015	Chorionic villus sampling, any method	OB-GYN	16
59020	Fetal contraction stress test	OB-GYN	16
59030	Fetal scalp blood sampling	OB-GYN	16
59050	Fetal monitoring during labor by consulting physician (ie, non-attending physician) with written report; supervision and interpretation	OB-GYN	16
59070	Transabdominal amnioinfusion, including ultrasound guidance	OB-GYN	16
59072	Fetal umbilical cord occlusion, including ultrasound guidance	OB-GYN	16
59074	Fetal fluid drainage (eg, vesicocentesis, thoracocentesis, paracentesis), including ultrasound guidance	OB-GYN	16
59076	Fetal shunt placement, including ultrasound guidance	OB-GYN	16
59100	Hysterotomy, abdominal (eg, for hydatidiform mole, abortion)	OB-GYN	16
59120	Surgical treatment of ectopic pregnancy; tubal or ovarian, requiring salpingectomy and/or oophorectomy, abdominal or vaginal approach	OB-GYN	16
59121	Surgical treatment of ectopic pregnancy; tubal or ovarian, without salpingectomy and/or oophorectomy	OB-GYN	16
59130	Surgical treatment of ectopic pregnancy; abdominal pregnancy	OB-GYN	16
59135	Surgical treatment of ectopic pregnancy; interstitial, uterine pregnancy requiring total hysterectomy	OB-GYN	16
59136	Surgical treatment of ectopic pregnancy; interstitial, uterine pregnancy with partial resection of uterus	OB-GYN	16
59140	Surgical treatment of ectopic pregnancy; cervical, with evacuation	OB-GYN	16
59150	Laparoscopic treatment of ectopic pregnancy; without salpingectomy and/or oophorectomy	OB-GYN	16
59151	Laparoscopic treatment of ectopic pregnancy; with salpingectomy and/or oophorectomy	OB-GYN	16
59160	Curettage, postpartum	OB-GYN	16
59300	Episiotomy or vaginal repair, by other than attending physician	OB-GYN	16
59320	Cerclage of cervix, during pregnancy; vaginal	OB-GYN	16
59325	Cerclage of cervix, during pregnancy; abdominal	OB-GYN	16
59350	Hysterorrhaphy of ruptured uterus	OB-GYN	16
59412	External cephalic version, with or without tocolysis	OB-GYN	16
59414	Delivery of placenta (separate procedure)	OB-GYN	16
59525	Subtotal or total hysterectomy after cesarean delivery (List separately in addition to code for primary procedure)	OB-GYN	16

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
59610	Routine obstetric care including antepartum care, vaginal delivery (with or without episiotomy, and/or forceps) and postpartum care, after previous cesarean delivery	OB-GYN	16
59612	Vaginal delivery only, after previous cesarean delivery (with or without episiotomy and/or forceps);	OB-GYN	16
59614	Vaginal delivery only, after previous cesarean delivery (with or without episiotomy and/or forceps); including postpartum care	OB-GYN	16
59618	Routine obstetric care including antepartum care, cesarean delivery, and postpartum care, following attempted vaginal delivery after previous cesarean delivery	OB-GYN	16
59620	Cesarean delivery only, following attempted vaginal delivery after previous cesarean delivery;	OB-GYN	16
59622	Cesarean delivery only, following attempted vaginal delivery after previous cesarean delivery; including postpartum care	OB-GYN	16
59821	Treatment of missed abortion, completed surgically; second trimester	OB-GYN	16
59830	Treatment of septic abortion, completed surgically	OB-GYN	16
59840	Induced abortion, by dilation and curettage	OB-GYN	16
59841	Induced abortion, by dilation and evacuation	OB-GYN	16
59850	Induced abortion, by one or more intra-amniotic injections (amniocentesis-injections), including hospital admission and visits, delivery of fetus and secundines;	OB-GYN	16
59851	Induced abortion, by one or more intra-amniotic injections (amniocentesis-injections), including hospital admission and visits, delivery of fetus and secundines; with dilation and curettage and/or evacuation	OB-GYN	16
59852	Induced abortion, by one or more intra-amniotic injections (amniocentesis-injections), including hospital admission and visits, delivery of fetus and secundines; with hysterotomy (failed intra-amniotic injection)	OB-GYN	16
59855	Induced abortion, by one or more vaginal suppositories (eg, prostaglandin) with or without cervical dilation (eg, laminaria), including hospital admission and visits, delivery of fetus and secundines;	OB-GYN	16
59856	Induced abortion, by one or more vaginal suppositories (eg, prostaglandin) with or without cervical dilation (eg, laminaria), including hospital admission and visits, delivery of fetus and secundines; with dilation and curettage and/or evacuation	OB-GYN	16

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
59857	Induced abortion, by one or more vaginal suppositories (eg, prostaglandin) with or without cervical dilation (eg, laminaria), including hospital admission and visits, delivery of fetus and secundines; with hysterotomy (failed medical evacuation)	OB-GYN	16
59866	Multifetal pregnancy reduction(s) (MPR)	OB-GYN	16
59870	Uterine evacuation and curettage for hydatidiform mole	OB-GYN	16
59871	Removal of cerclage suture under anesthesia (other than local)	OB-GYN	16
60000	Incision and drainage of thyroglossal duct cyst, infected	OTOLARYNGOLOGY	04
60281	Excision of thyroglossal duct cyst or sinus; recurrent	OTOLARYNGOLOGY	04
60605	Excision of carotid body tumor; with excision of carotid artery	VASCULAR SURGERY	77
61000	Subdural tap through fontanelle, or suture, infant, unilateral or bilateral; initial	NEUROSURGERY	14
61001	Subdural tap through fontanelle, or suture, infant, unilateral or bilateral; subsequent taps	NEUROSURGERY	14
61120	Burr hole(s) for ventricular puncture (including injection of gas, contrast media, dye, or radioactive material)	NEUROSURGERY	14
61150	Burr hole(s) or trephine; with drainage of brain abscess or cyst	NEUROSURGERY	14
61151	Burr hole(s) or trephine; with subsequent tapping (aspiration) of intracranial abscess or cyst	NEUROSURGERY	14
61250	Burr hole(s) or trephine, supratentorial, exploratory, not followed by other surgery	NEUROSURGERY	14
61253	Burr hole(s) or trephine, infratentorial, unilateral or bilateral	NEUROSURGERY	14
61305	Craniectomy or craniotomy, exploratory; infratentorial (posterior fossa)	NEUROSURGERY	14
61316	Incision and subcutaneous placement of cranial bone graft (List separately in addition to code for primary procedure)	NEUROSURGERY	14
61321	Craniectomy or craniotomy, drainage of intracranial abscess; infratentorial	NEUROSURGERY	14
61322	Craniectomy or craniotomy, decompressive, with or without duraplasty, for treatment of intracranial hypertension, without evacuation of associated intraparenchymal hematoma; without lobectomy	NEUROSURGERY	14
61323	Craniectomy or craniotomy, decompressive, with or without duraplasty, for treatment of intracranial hypertension, without evacuation of associated intraparenchymal hematoma; with lobectomy	NEUROSURGERY	14
61330	Decompression of orbit only, transcranial approach	NEUROSURGERY	14
61332	Exploration of orbit (transcranial approach); with biopsy	NEUROSURGERY	14
61333	Exploration of orbit (transcranial approach); with removal of lesion	NEUROSURGERY	14

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
61334	Exploration of orbit (transcranial approach); with removal of foreign body	NEUROSURGERY	14
61340	Subtemporal cranial decompression (pseudotumor cerebri, slit ventricle syndrome)	NEUROSURGERY	14
61345	Other cranial decompression, posterior fossa	NEUROSURGERY	14
61440	Craniotomy for section of tentorium cerebelli (separate procedure)	NEUROSURGERY	14
61450	Craniectomy, subtemporal, for section, compression, or decompression of sensory root of gasserian ganglion	NEUROSURGERY	14
61460	Craniectomy, suboccipital; for section of one or more cranial nerves	NEUROSURGERY	14
61470	Craniectomy, suboccipital; for medullary tractotomy	NEUROSURGERY	14
61480	Craniectomy, suboccipital; for mesencephalic tractotomy or pedunculotomy	NEUROSURGERY	14
61490	Craniotomy for lobotomy, including cingulotomy	NEUROSURGERY	14
61521	Craniectomy for excision of brain tumor, infratentorial or posterior fossa; midline tumor at base of skull	NEUROSURGERY	14
61522	Craniectomy, infratentorial or posterior fossa; for excision of brain abscess	NEUROSURGERY	14
61524	Craniectomy, infratentorial or posterior fossa; for excision or fenestration of cyst	NEUROSURGERY	14
61526	Craniectomy, bone flap craniotomy, transtemporal (mastoid) for excision of cerebellopontine angle tumor;	NEUROSURGERY	14
61530	Craniectomy, bone flap craniotomy, transtemporal (mastoid) for excision of cerebellopontine angle tumor; combined with middle/posterior fossa craniotomy/craniectomy	NEUROSURGERY	14
61531	Subdural implantation of strip electrodes through one or more burr or trephine hole(s) for long term seizure monitoring	NEUROSURGERY	14
61534	Craniotomy with elevation of bone flap; for excision of epileptogenic focus without electrocorticography during surgery	NEUROSURGERY	14
61535	Craniotomy with elevation of bone flap; for removal of epidural or subdural electrode array, without excision of cerebral tissue (separate procedure)	NEUROSURGERY	14
61536	Craniotomy with elevation of bone flap; for excision of cerebral epileptogenic focus, with electrocorticography during surgery (includes removal of electrode array)	NEUROSURGERY	14
61539	Craniotomy with elevation of bone flap; for lobectomy, other than temporal lobe, partial or total, with electrocorticography during surgery	NEUROSURGERY	14
61541	Craniotomy with elevation of bone flap; for transection of corpus callosum	NEUROSURGERY	14
61542	Craniotomy with elevation of bone flap; for total hemispherectomy	NEUROSURGERY	14
61543	Craniotomy with elevation of bone flap; for partial or subtotal (functional) hemispherectomy	NEUROSURGERY	14

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
61544	Craniotomy with elevation of bone flap; for excision or coagulation of choroid plexus	NEUROSURGERY	14
61545	Craniotomy with elevation of bone flap; for excision of craniopharyngioma	NEUROSURGERY	14
61546	Craniotomy for hypophysectomy or excision of pituitary tumor, intracranial approach	NEUROSURGERY	14
61550	Craniectomy for craniosynostosis; single cranial suture	NEUROSURGERY	14
61552	Craniectomy for craniosynostosis; multiple cranial sutures	NEUROSURGERY	14
61556	Craniotomy for craniosynostosis; frontal or parietal bone flap	NEUROSURGERY	14
61557	Craniotomy for craniosynostosis; bifrontal bone flap	NEUROSURGERY	14
61558	Extensive craniectomy for multiple cranial suture craniosynostosis (eg, cloverleaf skull); not requiring bone grafts	NEUROSURGERY	14
61559	Extensive craniectomy for multiple cranial suture craniosynostosis (eg, cloverleaf skull); recontouring with multiple osteotomies and bone autografts (eg, barrel-stave procedure) (includes obtaining grafts)	NEUROSURGERY	14
61563	Excision, intra and extracranial, benign tumor of cranial bone (eg, fibrous dysplasia); without optic nerve decompression	NEUROSURGERY	14
61564	Excision, intra and extracranial, benign tumor of cranial bone (eg, fibrous dysplasia); with optic nerve decompression	NEUROSURGERY	14
61570	Craniectomy or craniotomy; with excision of foreign body from brain	NEUROSURGERY	14
61571	Craniectomy or craniotomy; with treatment of penetrating wound of brain	NEUROSURGERY	14
61575	Transoral approach to skull base, brain stem or upper spinal cord for biopsy, decompression or excision of lesion;	NEUROSURGERY	14
61576	Transoral approach to skull base, brain stem or upper spinal cord for biopsy, decompression or excision of lesion; requiring splitting of tongue and/or mandible (including tracheostomy)	NEUROSURGERY	14
61581	Craniofacial approach to anterior cranial fossa; extradural, including lateral rhinotomy, orbital exenteration, ethmoidectomy, sphenoidectomy and/or maxillectomy	OTOLARYNGOLOGY	04
61582	Craniofacial approach to anterior cranial fossa; extradural, including unilateral or bifrontal craniotomy, elevation of frontal lobe(s), osteotomy of base of anterior cranial fossa	NEUROSURGERY	14
61585	Orbitocranial approach to anterior cranial fossa, extradural, including supraorbital ridge osteotomy and elevation of frontal and/or temporal lobe(s); with orbital exenteration	NEUROSURGERY	14
61586	Bicoronal, transzygomatic and/or LeFort I osteotomy approach to anterior cranial fossa with or without internal fixation, without bone graft	NEUROSURGERY	14

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
61591	Infratemporal post-auricular approach to middle cranial fossa (internal auditory meatus, petrous apex, tentorium, cavernous sinus, parasellar area, infratemporal fossa) including mastoidectomy, resection of sigmoid sinus, with or without decompression and/or mobilization of contents of auditory canal or petrous carotid artery	OTOLARYNGOLOGY	04
61596	Transcochlear approach to posterior cranial fossa, jugular foramen or midline skull base, including labyrinthectomy, decompression, with or without mobilization of facial nerve and/or petrous carotid artery	OTOLARYNGOLOGY	04
61598	Transpetrosal approach to posterior cranial fossa, clivus or foramen magnum, including ligation of superior petrosal sinus and/or sigmoid sinus	NEUROSURGERY	14
61606	Resection or excision of neoplastic, vascular or infectious lesion of infratemporal fossa, parapharyngeal space, petrous apex; intradural, including dural repair, with or without graft	NEUROSURGERY	14
61607	Resection or excision of neoplastic, vascular or infectious lesion of parasellar area, cavernous sinus, clivus or midline skull base; extradural	NEUROSURGERY	14
61609	Transection or ligation, carotid artery in cavernous sinus; without repair (List separately in addition to code for primary procedure)	NEUROSURGERY	14
61610	Transection or ligation, carotid artery in cavernous sinus; with repair by anastomosis or graft (List separately in addition to code for primary procedure)	NEUROSURGERY	14
61611	Transection or ligation, carotid artery in petrous canal; without repair (List separately in addition to code for primary procedure)	NEUROSURGERY	14
61612	Transection or ligation, carotid artery in petrous canal; with repair by anastomosis or graft (List separately in addition to code for primary procedure)	NEUROSURGERY	14
61613	Obliteration of carotid aneurysm, arteriovenous malformation, or carotid-cavernous fistula by dissection within cavernous sinus	NEUROSURGERY	14
61615	Resection or excision of neoplastic, vascular or infectious lesion of base of posterior cranial fossa, jugular foramen, foramen magnum, or C1-C3 vertebral bodies; extradural	NEUROSURGERY	14
61619	Secondary repair of dura for cerebrospinal fluid leak, anterior, middle or posterior cranial fossa following surgery of the skull base; by local or regionalized vascularized pedicle flap or myocutaneous flap (including galea, temporalis, frontalis or occipitalis muscle)	NEUROSURGERY	14
61680	Surgery of intracranial arteriovenous malformation; supratentorial, simple	NEUROSURGERY	14

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
61684	Surgery of intracranial arteriovenous malformation; infratentorial, simple	NEUROSURGERY	14
61686	Surgery of intracranial arteriovenous malformation; infratentorial, complex	NEUROSURGERY	14
61690	Surgery of intracranial arteriovenous malformation; dural, simple	NEUROSURGERY	14
61692	Surgery of intracranial arteriovenous malformation; dural, complex	NEUROSURGERY	14
61698	Surgery of complex intracranial aneurysm, intracranial approach; vertebrobasilar circulation	NEUROSURGERY	14
61702	Surgery of simple intracranial aneurysm, intracranial approach; vertebrobasilar circulation	NEUROSURGERY	14
61703	Surgery of intracranial aneurysm, cervical approach by application of occluding clamp to cervical carotid artery (Selverstone-Crutchfield type)	NEUROSURGERY	14
61705	Surgery of aneurysm, vascular malformation or carotid-cavernous fistula; by intracranial and cervical occlusion of carotid artery	NEUROSURGERY	14
61708	Surgery of aneurysm, vascular malformation or carotid-cavernous fistula; by intracranial electrothrombosis	NEUROSURGERY	14
61711	Anastomosis, arterial, extracranial-intracranial (eg, middle cerebral/cortical) arteries	NEUROSURGERY	14
61735	Creation of lesion by stereotactic method, including burr hole(s) and localizing and recording techniques, single or multiple stages; subcortical structure(s) other than globus pallidus or thalamus	NEUROSURGERY	13
61760	Stereotactic implantation of depth electrodes into the cerebrum for long term seizure monitoring	NEUROSURGERY	14
61850	Twist drill or burr hole(s) for implantation of neurostimulator electrodes, cortical	NEUROSURGERY	14
61860	Craniectomy or craniotomy for implantation of neurostimulator electrodes, cerebral, cortical	NEUROSURGERY	14
61870	Craniectomy for implantation of neurostimulator electrodes, cerebellar; cortical	NEUROSURGERY	14
61875	Craniectomy for implantation of neurostimulator electrodes, cerebellar; subcortical	NEUROSURGERY	14
62000	Elevation of depressed skull fracture; simple, extradural	NEUROSURGERY	14
62005	Elevation of depressed skull fracture; compound or comminuted, extradural	NEUROSURGERY	14
62010	Elevation of depressed skull fracture; with repair of dura and/or debridement of brain	NEUROSURGERY	14
62115	Reduction of craniomegalic skull (eg, treated hydrocephalus); not requiring bone grafts or cranioplasty	NEUROSURGERY	14
62116	Reduction of craniomegalic skull (eg, treated hydrocephalus); with simple cranioplasty	NEUROSURGERY	14
62117	Reduction of craniomegalic skull (eg, treated hydrocephalus); requiring craniotomy and reconstruction with or without bone graft (includes obtaining grafts)	NEUROSURGERY	04

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
62120	Repair of encephalocele, skull vault, including cranioplasty	NEUROSURGERY	14
62121	Craniotomy for repair of encephalocele, skull base	NEUROSURGERY	14
62146	Cranioplasty with autograft (includes obtaining bone grafts); up to 5 cm diameter	NEUROSURGERY	14
62147	Cranioplasty with autograft (includes obtaining bone grafts); larger than 5 cm diameter	NEUROSURGERY	14
62148	Incision and retrieval of subcutaneous cranial bone graft for cranioplasty (List separately in addition to code for primary procedure)	NEUROSURGERY	14
62161	Neuroendoscopy, intracranial; with dissection of adhesions, fenestration of septum pellucidum or intraventricular cysts (including placement, replacement, or removal of ventricular catheter)	NEUROSURGERY	14
62162	Neuroendoscopy, intracranial; with fenestration or excision of colloid cyst, including placement of external ventricular catheter for drainage	NEUROSURGERY	14
62163	Neuroendoscopy, intracranial; with retrieval of foreign body	NEUROSURGERY	14
62164	Neuroendoscopy, intracranial; with excision of brain tumor, including placement of external ventricular catheter for drainage	NEUROSURGERY	14
62165	Neuroendoscopy, intracranial; with excision of pituitary tumor, transnasal or trans-sphenoidal approach	NEUROSURGERY	14
62180	Ventriculocisternostomy (Torkildsen type operation)	NEUROSURGERY	14
62190	Creation of shunt; subarachnoid/subdural-atrial, -jugular, -auricular	NEUROSURGERY	14
62194	Replacement or irrigation, subarachnoid/subdural catheter	NEUROSURGERY	14
62200	Ventriculocisternostomy, third ventricle;	NEUROSURGERY	14
62201	Ventriculocisternostomy, third ventricle; stereotactic, neuroendoscopic method	NEUROSURGERY	14
62292	Injection procedure for chemonucleolysis, including diskography, intervertebral disk, single or multiple levels, lumbar	ANESTHESIOLOGY	05
62294	Injection procedure, arterial, for occlusion of arteriovenous malformation, spinal	NEUROSURGERY	14
63066	Costovertebral approach with decompression of spinal cord or nerve root(s), (eg, herniated intervertebral disk), thoracic; each additional segment (List separately in addition to code for primary procedure)	NEUROSURGERY	14
63170	Laminectomy with myelotomy (eg, Bischof or DREZ type), cervical, thoracic, or thoracolumbar	NEUROSURGERY	14
63173	Laminectomy with drainage of intramedullary cyst/syrinx; to peritoneal or pleural space	NEUROSURGERY	14
63180	Laminectomy and section of dentate ligaments, with or without dural graft, cervical; one or two segments	NEUROSURGERY	14

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
63182	Laminectomy and section of dentate ligaments, with or without dural graft, cervical; more than two segments	NEUROSURGERY	14
63185	Laminectomy with rhizotomy; one or two segments	NEUROSURGERY	14
63190	Laminectomy with rhizotomy; more than two segments	NEUROSURGERY	14
63191	Laminectomy with section of spinal accessory nerve	NEUROSURGERY	14
63194	Laminectomy with cordotomy, with section of one spinothalamic tract, one stage; cervical	NEUROSURGERY	14
63195	Laminectomy with cordotomy, with section of one spinothalamic tract, one stage; thoracic	NEUROSURGERY	14
63196	Laminectomy with cordotomy, with section of both spinothalamic tracts, one stage; cervical	NEUROSURGERY	14
63197	Laminectomy with cordotomy, with section of both spinothalamic tracts, one stage; thoracic	NEUROSURGERY	14
63198	Laminectomy with cordotomy with section of both spinothalamic tracts, two stages within 14 days; cervical	NEUROSURGERY	14
63199	Laminectomy with cordotomy with section of both spinothalamic tracts, two stages within 14 days; thoracic	NEUROSURGERY	14
63200	Laminectomy, with release of tethered spinal cord, lumbar	NEUROSURGERY	14
63250	Laminectomy for excision or occlusion of arteriovenous malformation of spinal cord; cervical	NEUROSURGERY	14
63251	Laminectomy for excision or occlusion of arteriovenous malformation of spinal cord; thoracic	NEUROSURGERY	14
63252	Laminectomy for excision or occlusion of arteriovenous malformation of spinal cord; thoracolumbar	NEUROSURGERY	14
63268	Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; sacral	NEUROSURGERY	14
63270	Laminectomy for excision of intraspinal lesion other than neoplasm, intradural; cervical	NEUROSURGERY	14
63273	Laminectomy for excision of intraspinal lesion other than neoplasm, intradural; sacral	NEUROSURGERY	14
63278	Laminectomy for biopsy/excision of intraspinal neoplasm; extradural, sacral	NEUROSURGERY	14
63283	Laminectomy for biopsy/excision of intraspinal neoplasm; intradural, sacral	NEUROSURGERY	14
63285	Laminectomy for biopsy/excision of intraspinal neoplasm; intradural, intramedullary, cervical	NEUROSURGERY	14
63286	Laminectomy for biopsy/excision of intraspinal neoplasm; intradural, intramedullary, thoracic	NEUROSURGERY	14
63287	Laminectomy for biopsy/excision of intraspinal neoplasm; intradural, intramedullary, thoracolumbar	NEUROSURGERY	14
63290	Laminectomy for biopsy/excision of intraspinal neoplasm; combined extradural-intradural lesion, any level	NEUROSURGERY	14

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
63300	Vertebral corpectomy (vertebral body resection), partial or complete, for excision of intraspinal lesion, single segment; extradural, cervical	NEUROSURGERY	14
63301	Vertebral corpectomy (vertebral body resection), partial or complete, for excision of intraspinal lesion, single segment; extradural, thoracic by transthoracic approach	NEUROSURGERY	14
63302	Vertebral corpectomy (vertebral body resection), partial or complete, for excision of intraspinal lesion, single segment; extradural, thoracic by thoracolumbar approach	NEUROSURGERY	14
63303	Vertebral corpectomy (vertebral body resection), partial or complete, for excision of intraspinal lesion, single segment; extradural, lumbar or sacral by transperitoneal or retroperitoneal approach	NEUROSURGERY	14
63304	Vertebral corpectomy (vertebral body resection), partial or complete, for excision of intraspinal lesion, single segment; intradural, cervical	NEUROSURGERY	14
63305	Vertebral corpectomy (vertebral body resection), partial or complete, for excision of intraspinal lesion, single segment; intradural, thoracic by transthoracic approach	NEUROSURGERY	14
63306	Vertebral corpectomy (vertebral body resection), partial or complete, for excision of intraspinal lesion, single segment; intradural, thoracic by thoracolumbar approach	NEUROSURGERY	14
63307	Vertebral corpectomy (vertebral body resection), partial or complete, for excision of intraspinal lesion, single segment; intradural, lumbar or sacral by transperitoneal or retroperitoneal approach	NEUROSURGERY	14
63308	Vertebral corpectomy (vertebral body resection), partial or complete, for excision of intraspinal lesion, single segment; each additional segment (List separately in addition to codes for single segment)	NEUROSURGERY	14
63610	Stereotactic stimulation of spinal cord, percutaneous, separate procedure not followed by other surgery	NEUROSURGERY	14
63615	Stereotactic biopsy, aspiration, or excision of lesion, spinal cord	NEUROSURGERY	14
63700	Repair of meningocele; less than 5 cm diameter	NEUROSURGERY	14
63702	Repair of meningocele; larger than 5 cm diameter	NEUROSURGERY	14
63704	Repair of myelomeningocele; less than 5 cm diameter	NEUROSURGERY	14
63706	Repair of myelomeningocele; larger than 5 cm diameter	NEUROSURGERY	14
63746	Removal of entire lumbosubarachnoid shunt system without replacement	NEUROSURGERY	14
64410	Injection, anesthetic agent; phrenic nerve	ANESTHESIOLOGY	05
64508	Injection, anesthetic agent; carotid sinus (separate procedure)	ANESTHESIOLOGY	05
64553	Percutaneous implantation of neurostimulator electrodes; cranial nerve	NEUROSURGERY	14

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
64560	Percutaneous implantation of neurostimulator electrodes; autonomic nerve	NEUROSURGERY	14
64577	Incision for implantation of neurostimulator electrodes; autonomic nerve	NEUROSURGERY	14
64580	Incision for implantation of neurostimulator electrodes; neuromuscular	NEUROSURGERY	14
64605	Destruction by neurolytic agent, trigeminal nerve; second and third division branches at foramen ovale	NEUROSURGERY	14
64732	Transection or avulsion of; supraorbital nerve	NEUROSURGERY	14
64734	Transection or avulsion of; infraorbital nerve	NEUROSURGERY	14
64736	Transection or avulsion of; mental nerve	ORAL SURGERY	19
64738	Transection or avulsion of; inferior alveolar nerve by osteotomy	MAXILLOFACIAL SURGERY	85
64740	Transection or avulsion of; lingual nerve	MAXILLOFACIAL SURGERY	85
64742	Transection or avulsion of; facial nerve, differential or complete	OPHTHALMOLOGY	18
64746	Transection or avulsion of; phrenic nerve	THORACIC SURGERY	33
64752	Transection or avulsion of; vagus nerve (vagotomy), transthoracic	GENERAL SURGERY	02
64755	Transection or avulsion of; vagus nerves limited to proximal stomach (selective proximal vagotomy, proximal gastric vagotomy, parietal cell vagotomy, supra- or highly selective vagotomy)	GENERAL SURGERY	02
64760	Transection or avulsion of; vagus nerve (vagotomy), abdominal	GENERAL SURGERY	02
64761	Transection or avulsion of; pudendal nerve	OB-GYN	16
64763	Transection or avulsion of obturator nerve, extrapelvic, with or without adductor tenotomy	PLASTIC AND RECONSTRUCTIVE SURGERY	24
64766	Transection or avulsion of obturator nerve, intrapelvic, with or without adductor tenotomy	OB-GYN	16
64771	Transection or avulsion of other cranial nerve, extradural	NEUROSURGERY	14
64778	Excision of neuroma; digital nerve, each additional digit (List separately in addition to code for primary procedure)	ORTHOPEDIC SURGERY	20
64783	Excision of neuroma; hand or foot, each additional nerve, except same digit (List separately in addition to code for primary procedure)	ORTHOPEDIC SURGERY	20
64786	Excision of neuroma; sciatic nerve	PLASTIC AND RECONSTRUCTIVE SURGERY	24
64802	Sympathectomy, cervical	NEUROSURGERY	14
64804	Sympathectomy, cervicothoracic	NEUROSURGERY	14
64809	Sympathectomy, thoracolumbar	NEUROSURGERY	14
64821	Sympathectomy; radial artery	ORTHOPEDIC SURGERY	20
64822	Sympathectomy; ulnar artery	ORTHOPEDIC SURGERY	20

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
64823	Sympathectomy; superficial palmar arch	ORTHOPEDIC SURGERY	20
64835	Suture of one nerve, hand or foot; median motor thenar	ORTHOPEDIC SURGERY	20
64836	Suture of one nerve, hand or foot; ulnar motor	ORTHOPEDIC SURGERY	24
64837	Suture of each additional nerve, hand or foot (List separately in addition to code for primary procedure)	ORTHOPEDIC SURGERY	24
64840	Suture of posterior tibial nerve	ORTHOPEDIC SURGERY	24
64858	Suture of sciatic nerve	ORTHOPEDIC SURGERY	20
64859	Suture of each additional major peripheral nerve (List separately in addition to code for primary procedure)	ORTHOPEDIC SURGERY	20
64861	Suture of; brachial plexus	NEUROSURGERY	14
64862	Suture of; lumbar plexus	NEUROSURGERY	14
64865	Suture of facial nerve; infratemporal, with or without grafting	OTOLARYNGOLOGY	04
64866	Anastomosis; facial-spinal accessory	PLASTIC AND RECONSTRUCTIVE SURGERY	24
64868	Anastomosis; facial-hypoglossal	OTOLARYNGOLOGY	04
64870	Anastomosis; facial-phrenic	OTOLARYNGOLOGY	04
64872	Suture of nerve; requiring secondary or delayed suture (List separately in addition to code for primary neurotaphy)	ORTHOPEDIC SURGERY	20
64874	Suture of nerve; requiring extensive mobilization, or transposition of nerve (List separately in addition to code for nerve suture)	ORTHOPEDIC SURGERY	20
64876	Suture of nerve; requiring shortening of bone of extremity (List separately in addition to code for nerve suture)	ORTHOPEDIC SURGERY	20
64885	Nerve graft (includes obtaining graft), head or neck; up to 4 cm in length	OTOLARYNGOLOGY	04
64886	Nerve graft (includes obtaining graft), head or neck; more than 4 cm length	OTOLARYNGOLOGY	04
64890	Nerve graft (includes obtaining graft), single strand, hand or foot; up to 4 cm length	ORTHOPEDIC SURGERY	20
64891	Nerve graft (includes obtaining graft), single strand, hand or foot; more than 4 cm length	ORTHOPEDIC SURGERY	20
64892	Nerve graft (includes obtaining graft), single strand, arm or leg; up to 4 cm length	ORTHOPEDIC SURGERY	20
64893	Nerve graft (includes obtaining graft), single strand, arm or leg; more than 4 cm length	ORTHOPEDIC SURGERY	20
64895	Nerve graft (includes obtaining graft), multiple strands (cable), hand or foot; up to 4 cm length	ORTHOPEDIC SURGERY	20
64896	Nerve graft (includes obtaining graft), multiple strands (cable), hand or foot; more than 4 cm length	ORTHOPEDIC SURGERY	20

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
64897	Nerve graft (includes obtaining graft), multiple strands (cable), arm or leg; up to 4 cm length	ORTHOPEDIC SURGERY	20
64898	Nerve graft (includes obtaining graft), multiple strands (cable), arm or leg; more than 4 cm length	ORTHOPEDIC SURGERY	20
64901	Nerve graft, each additional nerve; single strand (List separately in addition to code for primary procedure)	ORTHOPEDIC SURGERY	20
64902	Nerve graft, each additional nerve; multiple strands (cable) (List separately in addition to code for primary procedure)	ORTHOPEDIC SURGERY	20
64905	Nerve pedicle transfer; first stage	PLASTIC AND RECONSTRUCTIVE SURGERY	24
64907	Nerve pedicle transfer; second stage	PLASTIC AND RECONSTRUCTIVE SURGERY	24
65110	Exenteration of orbit (does not include skin graft), removal of orbital contents; only	OPHTHALMOLOGY	18
65112	Exenteration of orbit (does not include skin graft), removal of orbital contents; with therapeutic removal of bone	OPHTHALMOLOGY	18
65114	Exenteration of orbit (does not include skin graft), removal of orbital contents; with muscle or myocutaneous flap	OPHTHALMOLOGY	18
65125	Modification of ocular implant with placement or replacement of pegs (eg, drilling receptacle for prosthesis appendage) (separate procedure)	OPHTHALMOLOGY	18
65130	Insertion of ocular implant secondary; after evisceration, in scleral shell	OPHTHALMOLOGY	18
65135	Insertion of ocular implant secondary; after enucleation, muscles not attached to implant	OPHTHALMOLOGY	18
65140	Insertion of ocular implant secondary; after enucleation, muscles attached to implant	OPHTHALMOLOGY	18
65150	Reinsertion of ocular implant; with or without conjunctival graft	OPHTHALMOLOGY	18
65155	Reinsertion of ocular implant; with use of foreign material for reinforcement and/or attachment of muscles to implant	OPHTHALMOLOGY	18
65260	Removal of foreign body, intraocular; from posterior segment, magnetic extraction, anterior or posterior route	OPHTHALMOLOGY	18
65272	Repair of laceration; conjunctiva, by mobilization and rearrangement, without hospitalization	OPHTHALMOLOGY	18
65273	Repair of laceration; conjunctiva, by mobilization and rearrangement, with hospitalization	OPHTHALMOLOGY	18
65290	Repair of wound, extraocular muscle, tendon and/or Tenon's capsule	OPHTHALMOLOGY	18
65760	Keratomileusis	OPHTHALMOLOGY	18
65765	Keratophakia	OPHTHALMOLOGY	18
65767	Epikeratoplasty	OPHTHALMOLOGY	18

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
65771	Radial keratotomy	OPHTHALMOLOGY	18
65780	Ocular surface reconstruction; amniotic membrane transplantation	OPHTHALMOLOGY	18
65781	Ocular surface reconstruction; limbal stem cell allograft (eg, cadaveric or living donor)	OPHTHALMOLOGY	18
65782	Ocular surface reconstruction; limbal conjunctival autograft (includes obtaining graft)	OPHTHALMOLOGY	18
65820	Goniotomy	OPHTHALMOLOGY	18
66155	Fistulization of sclera for glaucoma; thermocauterization with iridectomy	OPHTHALMOLOGY	18
66165	Fistulization of sclera for glaucoma; iridencleisis or iridotaxis	OPHTHALMOLOGY	18
66220	Repair of scleral staphyloma; without graft	OPHTHALMOLOGY	18
66505	Iridotomy by stab incision (separate procedure); with transfixion as for iris bombe	OPHTHALMOLOGY	18
66605	Iridectomy, with comeoscleral or corneal section; with cyclectomy	OPHTHALMOLOGY	18
66700	Ciliary body destruction; diathermy	OPHTHALMOLOGY	18
66920	Removal of lens material; intracapsular	OPHTHALMOLOGY	18
67250	Scleral reinforcement (separate procedure); without graft	OPHTHALMOLOGY	18
67334	Strabismus surgery by posterior fixation suture technique, with or without muscle recession (List separately in addition to code for primary procedure)	OPHTHALMOLOGY	18
67340	Strabismus surgery involving exploration and/or repair of detached extraocular muscle(s) (List separately in addition to code for primary procedure)	OPHTHALMOLOGY	18
67350	Biopsy of extraocular muscle	OPHTHALMOLOGY	18
67415	Fine needle aspiration of orbital contents	OPHTHALMOLOGY	18
67430	Orbitotomy with bone flap or window, lateral approach (eg, Kroenlein); with removal of foreign body	OPHTHALMOLOGY	18
67440	Orbitotomy with bone flap or window, lateral approach (eg, Kroenlein); with drainage	OPHTHALMOLOGY	18
67599	Unlisted procedure, orbit	OPHTHALMOLOGY	18
67906	Repair of blepharoptosis; superior rectus technique with fascial sling (includes obtaining fascia)	OPHTHALMOLOGY	18
68500	Excision of lacrimal gland (dacryoadenectomy), except for tumor; total	OPHTHALMOLOGY	18
68505	Excision of lacrimal gland (dacryoadenectomy), except for tumor; partial	OPHTHALMOLOGY	18
68510	Biopsy of lacrimal gland	OPHTHALMOLOGY	18
68540	Excision of lacrimal gland tumor; frontal approach	OPHTHALMOLOGY	18
68550	Excision of lacrimal gland tumor; involving osteotomy	OPHTHALMOLOGY	18
68745	Conjunctivorhinostomy (fistulization of conjunctiva to nasal cavity); without tube	OPHTHALMOLOGY	18
68770	Closure of lacrimal fistula (separate procedure)	OPHTHALMOLOGY	18
69155	Radical excision external auditory canal lesion; with neck dissection	OTOLARYNGOLOGY	04

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
69300	Otoplasty, protruding ear, with or without size reduction	OTOLARYNGOLOGY	04
69320	Reconstruction external auditory canal for congenital atresia, single stage	OTOLARYNGOLOGY	04
69405	Eustachian tube catheterization, transtympanic	OTOLARYNGOLOGY	04
69501	Transmastoid antrotomy (simple mastoidectomy)	OTOLARYNGOLOGY	04
69511	Mastoidectomy; radical	OTOLARYNGOLOGY	04
69530	Petrous apicectomy including radical mastoidectomy	OTOLARYNGOLOGY	04
69550	Excision aural glomus tumor; transcanal	OTOLARYNGOLOGY	04
69552	Excision aural glomus tumor; transmastoid	OTOLARYNGOLOGY	04
69554	Excision aural glomus tumor; extended (extratemporal)	OTOLARYNGOLOGY	04
69601	Revision mastoidectomy; resulting in complete mastoidectomy	OTOLARYNGOLOGY	04
69602	Revision mastoidectomy; resulting in modified radical mastoidectomy	OTOLARYNGOLOGY	04
69603	Revision mastoidectomy; resulting in radical mastoidectomy	OTOLARYNGOLOGY	04
69604	Revision mastoidectomy; resulting in tympanoplasty	OTOLARYNGOLOGY	04
69605	Revision mastoidectomy; with apicectomy	OTOLARYNGOLOGY	04
69650	Stapes mobilization	OTOLARYNGOLOGY	04
69670	Mastoid obliteration (separate procedure)	OTOLARYNGOLOGY	04
69676	Tympanic neurectomy	OTOLARYNGOLOGY	04
69700	Closure postauricular fistula, mastoid (separate procedure)	OTOLARYNGOLOGY	04
69711	Removal or repair of electromagnetic bone conduction hearing device in temporal bone	OTOLARYNGOLOGY	04
69715	Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; with mastoidectomy	OTOLARYNGOLOGY	04
69717	Replacement (including removal of existing device), osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy	OTOLARYNGOLOGY	04
69718	Replacement (including removal of existing device), osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; with mastoidectomy	OTOLARYNGOLOGY	04
69725	Decompression facial nerve, intratemporal; including medial to geniculate ganglion	OTOLARYNGOLOGY	04
69740	Suture facial nerve, intratemporal, with or without graft or decompression; lateral to geniculate ganglion	OTOLARYNGOLOGY	04
69745	Suture facial nerve, intratemporal, with or without graft or decompression; including medial to geniculate ganglion	OTOLARYNGOLOGY	04

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
69802	Labyrinthotomy, with or without cryosurgery including other nonexcisional destructive procedures or perfusion of vestibuloactive drugs (single or multiple perfusions); with mastoidectomy	OTOLARYNGOLOGY	04
69805	Endolymphatic sac operation; without shunt	OTOLARYNGOLOGY	04
69820	Fenestration semicircular canal	OTOLARYNGOLOGY	04
69840	Revision fenestration operation	OTOLARYNGOLOGY	04
69905	Labyrinthectomy; transcanal	OTOLARYNGOLOGY	04
69915	Vestibular nerve section, translabyrinthine approach	OTOLARYNGOLOGY	04
69950	Vestibular nerve section, transcranial approach	OTOLARYNGOLOGY	04
69955	Total facial nerve decompression and/or repair (may include graft)	OTOLARYNGOLOGY	04
69960	Decompression internal auditory canal	OTOLARYNGOLOGY	04
69970	Removal of tumor, temporal bone	OTOLARYNGOLOGY	04
72159	Magnetic resonance angiography, spinal canal and contents, with or without contrast material(s)	DIAGNOSTIC RADIOLOGY	30
74235	Removal of foreign body(s), esophageal, with use of balloon catheter, radiological supervision and interpretation	DIAGNOSTIC RADIOLOGY	30
74440	Vasography, vesiculography, or epididymography, radiological supervision and interpretation	UROLOGY	34
74445	Corpora cavernosography, radiological supervision and interpretation	UROLOGY	34
74710	Pelvimetry, with or without placental localization	DIAGNOSTIC RADIOLOGY	30
75803	Lymphangiography, extremity only, bilateral, radiological supervision and interpretation	DIAGNOSTIC RADIOLOGY	30
75805	Lymphangiography, pelvic/abdominal, unilateral, radiological supervision and interpretation	DIAGNOSTIC RADIOLOGY	30
75807	Lymphangiography, pelvic/abdominal, bilateral, radiological supervision and interpretation	DIAGNOSTIC RADIOLOGY	30
75810	Splenoportography, radiological supervision and interpretation	DIAGNOSTIC RADIOLOGY	30
75840	Venography, adrenal, unilateral, selective, radiological supervision and interpretation	DIAGNOSTIC RADIOLOGY	30
75880	Venography, orbital, radiological supervision and interpretation	DIAGNOSTIC RADIOLOGY	30
76150	Xeroradiography	ORTHOPEDIC SURGERY	20
76802	Ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation, first trimester (14 weeks 0 days), transabdominal approach; each additional gestation (List separately in addition to code for primary procedure)	DIAGNOSTIC RADIOLOGY	30
76812	Ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation plus detailed fetal anatomic examination, transabdominal approach; each additional gestation (List separately in addition to code for primary procedure)	OB-GYN	16

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
76826	Echocardiography, fetal, cardiovascular system, real time with image documentation (2D), with or without M-mode recording; follow-up or repeat study	OB-GYN	16
76885	Ultrasound, infant hips, real time with imaging documentation; dynamic (requiring physician manipulation)	DIAGNOSTIC RADIOLOGY	30
76886	Ultrasound, infant hips, real time with imaging documentation; limited, static (not requiring physician manipulation)	DIAGNOSTIC RADIOLOGY	30
76940	Ultrasound guidance for, and monitoring of, visceral tissue ablation	DIAGNOSTIC RADIOLOGY	30
76941	Ultrasonic guidance for intrauterine fetal transfusion or cordocentesis, imaging supervision and interpretation	OB-GYN	16
76945	Ultrasonic guidance for chorionic villus sampling, imaging supervision and interpretation	OB-GYN	16
76948	Ultrasonic guidance for aspiration of ova, imaging supervision and interpretation	OB-GYN	16
78135	Red cell survival study; differential organ/tissue kinetics, (eg, splenic and/or hepatic sequestration)	DIAGNOSTIC RADIOLOGY	30
78160	Plasma radioiron disappearance (turnover) rate	DIAGNOSTIC RADIOLOGY	30
78170	Radioiron red cell utilization	NUCLEAR MEDICINE	36
78230	Salivary gland imaging;	NUCLEAR MEDICINE	36
78231	Salivary gland imaging; with serial images	NUCLEAR MEDICINE	36
78232	Salivary gland function study	NUCLEAR MEDICINE	36
78351	Bone density (bone mineral content) study, one or more sites; dual photon absorptiometry, one or more sites	DIAGNOSTIC RADIOLOGY	30
78647	Cerebrospinal fluid flow, imaging (not including introduction of material); tomographic (SPECT)	DIAGNOSTIC RADIOLOGY	30
78890	Generation of automated data: interactive process involving nuclear physician and/or allied health professional personnel; simple manipulations and interpretation, not to exceed 30 minutes	NUCLEAR MEDICINE	36
78891	Generation of automated data: interactive process involving nuclear physician and/or allied health professional personnel; complex manipulations and interpretation, exceeding 30 minutes	NUCLEAR MEDICINE	36
79200	Radiopharmaceutical therapy, by intracavitary administration	DIAGNOSTIC RADIOLOGY	30
79440	Radiopharmaceutical therapy, by intra-articular administration	DIAGNOSTIC RADIOLOGY	30
88125	Cytopathology, forensic (eg, sperm)	PATHOLOGY	22
88349	Electron microscopy; scanning	PATHOLOGY	22
88355	Morphometric analysis; skeletal muscle	PATHOLOGY	22
89132	Gastric intubation and aspiration, diagnostic, each specimen, for chemical analyses or cytopathology; after stimulation	GASTROENTEROLOGY	10
89135	Gastric intubation, aspiration, and fractional collections (eg, gastric secretory study); one hour	GASTROENTEROLOGY	10

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
89136	Gastric intubation, aspiration, and fractional collections (eg, gastric secretory study); two hours	GASTROENTEROLOGY	10
89140	Gastric intubation, aspiration, and fractional collections (eg, gastric secretory study); two hours including gastric stimulation (eg, histalog, pentagastrin)	GASTROENTEROLOGY	10
90829	Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an inpatient hospital, partial hospital or residential care setting, approximately 75 to 80 minutes face-to-face with the patient; with medical evaluation and management services	PSYCHIATRY	26
90875	Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient), with psychotherapy (eg, insight oriented, behavior modifying or supportive psychotherapy); approximately 20-30 minutes	PSYCHIATRY	26
90876	Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient), with psychotherapy (eg, insight oriented, behavior modifying or supportive psychotherapy); approximately 45-50 minutes	PSYCHIATRY	26
90885	Psychiatric evaluation of hospital records, other psychiatric reports, psychometric and/or projective tests, and other accumulated data for medical diagnostic purposes	PSYCHIATRY	26
90887	Interpretation or explanation of results of psychiatric, other medical examinations and procedures, or other accumulated data to family or other responsible persons, or advising them how to assist patient	PSYCHIATRY	26
91060	Gastric saline load test	GASTROENTEROLOGY	10
91133	Electrogastrography, diagnostic, transcutaneous; with provocative testing	GASTROENTEROLOGY	10
92015	Determination of refractive state	OPTOMETRY	41
92310	Prescription of optical and physical characteristics of and fitting of contact lens, with medical supervision of adaptation; corneal lens, both eyes, except for aphakia	OPTOMETRY	41
92314	Prescription of optical and physical characteristics of contact lens, with medical supervision of adaptation and direction of fitting by independent technician; corneal lens, both eyes except for aphakia	OPTOMETRY	41
92316	Prescription of optical and physical characteristics of contact lens, with medical supervision of adaptation and direction of fitting by independent technician; corneal lens for aphakia, both eyes	OPTOMETRY	41

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
92317	Prescription of optical and physical characteristics of contact lens, with medical supervision of adaptation and direction of fitting by independent technician; corneoscopic lens	OPTOMETRY	41
92335	Prescription of ocular prosthesis (artificial eye) and direction of fitting and supply by independent technician, with medical supervision of adaptation	OPHTHALMOLOGY	18
92340	Fitting of spectacles, except for aphakia; monofocal	OPTOMETRY	41
92341	Fitting of spectacles, except for aphakia; bifocal	OPTOMETRY	41
92342	Fitting of spectacles, except for aphakia; multifocal, other than bifocal	OPTOMETRY	41
92352	Fitting of spectacle prosthesis for aphakia; monofocal	OPTOMETRY	41
92353	Fitting of spectacle prosthesis for aphakia; multifocal	OPTOMETRY	41
92354	Fitting of spectacle mounted low vision aid; single element system	OPTOMETRY	41
92355	Fitting of spectacle mounted low vision aid; telescopic or other compound lens system	OPTOMETRY	41
92358	Prosthesis service for aphakia, temporary (disposable or loan, including materials)	OPTOMETRY	41
92370	Repair and refitting spectacles; except for aphakia	OPTOMETRY	41
92371	Repair and refitting spectacles; spectacle prosthesis for aphakia	OPTOMETRY	41
92573	Lombard test	AUDIOLOGIST (BILLING INDEPENDENTLY)	64
92596	Ear protector attenuation measurements	AUDIOLOGIST (BILLING INDEPENDENTLY)	64
92601	Diagnostic analysis of cochlear implant, patient under 7 years of age; with programming	AUDIOLOGIST (BILLING INDEPENDENTLY)	64
92602	Diagnostic analysis of cochlear implant, patient under 7 years of age; subsequent reprogramming	AUDIOLOGIST (BILLING INDEPENDENTLY)	64
92608	Evaluation for prescription for speech-generating augmentative and alternative communication device, face-to-face with the patient; each additional 30 minutes (List separately in addition to code for primary procedure)	OTOLARYNGOLOGY	04
92613	Flexible fiberoptic endoscopic evaluation of swallowing by cine or video recording; physician interpretation and report only	OTOLARYNGOLOGY	04
92614	Flexible fiberoptic endoscopic evaluation, laryngeal sensory testing by cine or video recording;	OTOLARYNGOLOGY	04
92615	Flexible fiberoptic endoscopic evaluation, laryngeal sensory testing by cine or video recording; physician interpretation and report only	OTOLARYNGOLOGY	04
92617	Flexible fiberoptic endoscopic evaluation of swallowing and laryngeal sensory testing by cine or video recording; physician interpretation and report only	OTOLARYNGOLOGY	04
92970	Cardioassist-method of circulatory assist; internal	CARDIOLOGY	06
92977	Thrombolysis, coronary; by intravenous infusion	CARDIOLOGY	06

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
92990	Percutaneous balloon valvuloplasty; pulmonary valve	CARDIOLOGY	06
92992	Atrial septectomy or septostomy; transvenous method, balloon (eg, Rashkind type) (includes cardiac catheterization)	CARDIOLOGY	06
92993	Atrial septectomy or septostomy; blade method (Park septostomy) (includes cardiac catheterization)	CARDIOLOGY	06
92997	Percutaneous transluminal pulmonary artery balloon angioplasty; single vessel	CARDIOLOGY	06
92998	Percutaneous transluminal pulmonary artery balloon angioplasty; each additional vessel (List separately in addition to code for primary procedure)	CARDIOLOGY	06
93581	Percutaneous transcatheter closure of a congenital ventricular septal defect with implant	CARDIOLOGY	06
93615	Esophageal recording of atrial electrogram with or without ventricular electrogram(s);	CARDIOLOGY	06
93890	Transcranial Doppler study of the intracranial arteries; vasoreactivity study	NEUROLOGY	13
94150	Vital capacity, total (separate procedure)	PULMONARY DISEASE	29
95071	Inhalation bronchial challenge testing (not including necessary pulmonary function tests); with antigens or gases, specify	ALLERGY/IMMUNOLOGY	03
95130	Professional services for allergen immunotherapy in prescribing physicians office or institution, including provision of allergenic extract; single stinging insect venom	ALLERGY/IMMUNOLOGY	03
95132	Professional services for allergen immunotherapy in prescribing physicians office or institution, including provision of allergenic extract; three stinging insect venoms	ALLERGY/IMMUNOLOGY	03
95858	Tensilon test for myasthenia gravis; with electromyographic recording	NEUROLOGY	13
95875	Ischemic limb exercise test with serial specimen(s) acquisition for muscle(s) metabolite(s)	NEUROLOGY	13
95965	Magnetoencephalography (MEG), recording and analysis; for spontaneous brain magnetic activity (eg, epileptic cerebral cortex localization)	NEUROLOGY	13
95966	Magnetoencephalography (MEG), recording and analysis; for evoked magnetic fields, single modality (eg, sensory, motor, language, or visual cortex localization)	NEUROLOGY	13
96000	Comprehensive computer-based motion analysis by video-taping and 3-D kinematics;	PHYSICAL THERAPIST (INDEP. PRACTICE)	65
96003	Dynamic fine wire electromyography, during walking or other functional activities, 1 muscle	PHYSICAL THERAPIST (INDEP. PRACTICE)	65
96440	Chemotherapy administration into pleural cavity, requiring and including thoracentesis	HEMATOLOGY/ONCOLOGY	83

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
96571	Photodynamic therapy by endoscopic application of light to ablate abnormal tissue via activation of photosensitive drug(s); each additional 15 minutes (List separately in addition to code for endoscopy or bronchoscopy procedures of lung and esophagus)	GASTROENTEROLOGY	10
96902	Microscopic examination of hairs plucked or clipped by the examiner (excluding hair collected by the patient) to determine telogen and anagen counts, or structural hair shaft abnormality	DERMATOLOGY	07
97010	Application of a modality to one or more areas; hot or cold packs	PHYSICAL THERAPIST (INDEP. PRACTICE)	65
98943	Chiropractic manipulative treatment (CMT); extraspinal, one or more regions	CHIROPRACTIC	35
99141	Sedation with or without analgesia (conscious sedation); intravenous, intramuscular or inhalation	PEDIATRIC MEDICINE	37
99142	Sedation with or without analgesia (conscious sedation); oral, rectal and/or intranasal	PEDIATRIC MEDICINE	37
99170	Anogenital examination with colposcopic magnification in childhood for suspected trauma	PEDIATRIC MEDICINE	37
99175	Ipecac or similar administration for individual emesis and continued observation until stomach adequately emptied of poison	FAMILY PRACTICE	08
99186	Hypothermia; total body	NEUROLOGY	13
99290	Critical care services delivered by a physician, face-to-face, during an interfacility transport of critically ill or critically injured pediatric patient, 24 months of age or less; each additional 30 minutes (List separately in addition to code for primary service)	PEDIATRIC MEDICINE	37
99293	Initial inpatient pediatric critical care, per day, for the evaluation and management of a critically ill infant or young child, 29 days through 24 months of age	PEDIATRIC MEDICINE	37
99296	Subsequent inpatient neonatal critical care, per day, for the evaluation and management of a critically ill neonate, 28 days of age or less	PEDIATRIC MEDICINE	37
99298	Subsequent intensive care, per day, for the evaluation and management of the recovering very low birth weight infant (present body weight less than 1500 grams)	PEDIATRIC MEDICINE	37
99299	Subsequent intensive care, per day, for the evaluation and management of the recovering low birth weight infant (present body weight of 1500-2500 grams)	PEDIATRIC MEDICINE	37

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
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	INTERNAL MEDICINE/FAMILY MEDICINE	11/08
99375	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; 30 minutes or more	INTERNAL MEDICINE/FAMILY MEDICINE	11/08
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	INTERNAL MEDICINE/FAMILY MEDICINE	11/08

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
99378	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; 30 minutes or more	INTERNAL MEDICINE/FAMILY MEDICINE	11/08
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	INTERNAL MEDICINE/FAMILY MEDICINE	11/08
99380	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; 30 minutes or more	INTERNAL MEDICINE/FAMILY MEDICINE	11/08
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)	PEDIATRIC MEDICINE/FAMILY MEDICINE	37/08

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
99382	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; early childhood (age 1 through 4 years)	PEDIATRIC MEDICINE/FAMILY MEDICINE	37/08
99383	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; late childhood (age 5 through 11 years)	PEDIATRIC MEDICINE/FAMILY MEDICINE	37/08
99384	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; adolescent (age 12 through 17 years)	PEDIATRIC MEDICINE/FAMILY MEDICINE	37/08
99385	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; 18-39 years	PEDIATRIC MEDICINE/FAMILY MEDICINE	11/08
99386	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; 40-64 years	PEDIATRIC MEDICINE/FAMILY MEDICINE	11/08
99387	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; 65 years and over	PEDIATRIC MEDICINE/FAMILY MEDICINE	11/08

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
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)	PEDIATRIC MEDICINE/FAMILY MEDICINE	37/08
99392	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; early childhood (age 1 through 4 years)	PEDIATRIC MEDICINE/FAMILY MEDICINE	37/08
99393	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; late childhood (age 5 through 11 years)	PEDIATRIC MEDICINE/FAMILY MEDICINE	37/08
99394	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; adolescent (age 12 through 17 years)	PEDIATRIC MEDICINE/FAMILY MEDICINE	37/08
99395	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; 18-39 years	INTERNAL MEDICINE/FAMILY MEDICINE	11/08
99396	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; 40-64 years	INTERNAL MEDICINE/FAMILY MEDICINE	11/08

Review of CPT Codes with Medicare Utilization of fewer than 100 per year - Recommended Specialty to use in PLI methodology

CPT Code	CPT Descriptor	Recommended Specialty for PLI Methodology	Rec. Medicare ID
99397	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; 65 years and over	INTERNAL MEDICINE/FAMILY MEDICINE	11/08
99401	Preventive medicine counseling and/or risk factor reduction intervention(s) provided to an individual (separate procedure); approximately 15 minutes	INTERNAL MEDICINE/FAMILY MEDICINE	11/08
99402	Preventive medicine counseling and/or risk factor reduction intervention(s) provided to an individual (separate procedure); approximately 30 minutes	INTERNAL MEDICINE/FAMILY MEDICINE	11/08
99403	Preventive medicine counseling and/or risk factor reduction intervention(s) provided to an individual (separate procedure); approximately 45 minutes	INTERNAL MEDICINE/FAMILY MEDICINE	11/08
99404	Preventive medicine counseling and/or risk factor reduction intervention(s) provided to an individual (separate procedure); approximately 60 minutes	INTERNAL MEDICINE/FAMILY MEDICINE	11/08
99411	Preventive medicine counseling and/or risk factor reduction intervention(s) provided to individuals in a group setting (separate procedure); approximately 30 minutes	INTERNAL MEDICINE/FAMILY MEDICINE	11/08
99412	Preventive medicine counseling and/or risk factor reduction intervention(s) provided to individuals in a group setting (separate procedure); approximately 60 minutes	INTERNAL MEDICINE/FAMILY MEDICINE	11/08
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.)	PEDIATRIC MEDICINE/FAMILY MEDICINE	37/08
99432	Normal newborn care in other than hospital or birthing room setting, including physical examination of baby and conference(s) with parent(s)	PEDIATRIC MEDICINE/FAMILY MEDICINE	37/08
99433	Subsequent hospital care, for the evaluation and management of a normal newborn, per day	PEDIATRIC MEDICINE/FAMILY MEDICINE	37/08
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.)	PEDIATRIC MEDICINE/FAMILY MEDICINE	37/08
99436	Attendance at delivery (when requested by delivering physician) and initial stabilization of newborn	PEDIATRIC MEDICINE/FAMILY MEDICINE	37/08
99440	Newborn resuscitation: provision of positive pressure ventilation and/or chest compressions in the presence of acute inadequate ventilation and/or cardiac output	PEDIATRIC MEDICINE/FAMILY MEDICINE	37/08

SEP 30 2005

**DIALYSIS CLINIC, INC.****A Non-Profit Corporation**

H. Keith Johnson, M.D., Chairman of the Board
James Perry, President
Ed Attrill, Secretary and Treasurer

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September 29, 2005

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-P, Section G
P.O. Box 8012
Baltimore, MD 21244-8012

Regarding: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2006, Section G. End Stage Renal Disease (ESRD) Related Provisions

Dear Dr. McClellan:

Dialysis Clinic, Inc. (DCI) is a non-profit provider of dialysis care founded in 1971, with rehabilitation of the ESRD patient and constant improvement of the patient's care as the principal thrust of its efforts. DCI presently operates 190 free-standing dialysis facilities in 27 states, and serves more than 12,300 patients. Approximately 78% of our patients are Medicare recipients. DCI is pleased to have the opportunity to submit this comment letter to the Centers for Medicare and Medicaid Services (CMS) in response to the proposed rule; End Stage Renal Disease (ESRD) Related Provisions.

DCI has the following comments about the proposed rules:

- 1) The fourth quarter 2005 average sale price (ASP) better represents average payments for drugs during 2005 than does an average of the values for the four calendar quarters.
- 2) Reimbursing ASP + 6 % for erythropoietin will exacerbate disparities in patient outcomes.
- 3) The drug add-on should be an absolute dollar amount, not a percentage of the composite rate.
- 4) We oppose applying the proposed wage index because it will jeopardize access to care.
- 5) We agree that it would be preferable to use the same payment method for drugs in independent and in hospital-based dialysis units.

1) The fourth quarter 2005 average sale price (ASP) better represents average payments for drugs during 2005 than does an average of the values for the four calendar quarters.

The final rule states that CMS “will have prices for all 4 quarters of CY 2005 and plans to develop prices representing the average CY 2005 ASP payments”. It appears from this statement that CMS intends to average the four quarterly ASPs for CY 2005. However, ASP reporting requirements dictate that any quarter’s ASP data include the previous four quarters. The ASP for the fourth quarter of any calendar year thus represents the average sale price for the entire year. Therefore, CMS should use the fourth quarter CY 2005 ASP to calculate the difference in aggregate payments between estimated payment based on 95% AWP pricing and estimated payment based on ASP +6 % pricing.

2) Reimbursing average sale price (ASP) + 6 % for erythropoietin will exacerbate disparities in patient outcomes.

We agree that except for erythropoietin, separately billable drugs should be reimbursed at ASP + 6%. As the rule notes, aggregate payments for drugs other than erythropoietin have varied widely. This variation in payments reflects the effect of market forces. For the drugs other than erythropoietin, there are competing brand name and generic drugs. Erythropoietin has one manufacturer, there are no alternatives, and the drug is so effective that all providers are ethically bound to use it no matter what the cost. As the rule notes, payment for erythropoietin accounts for a large proportion of drug reimbursement to independent dialysis facilities. Furthermore, the growth in payments for erythropoietin accounts for substantially all of the growth in payment to freestanding facilities for separately billable drugs. Soon, the two largest dialysis providers will represent approximately seventy percent of the market. Large provider contracts already heavily influence the ASP for erythropoietin and for these large providers, acquisition price is close to ASP. Smaller dialysis providers are not able to negotiate such favorable contracts for erythropoietin, and the manufacturer of erythropoietin typically does not offer significant price relief in group purchasing arrangements. For all but the largest providers, the acquisition price for erythropoietin will exceed ASP. The two large providers will profit inordinately from erythropoietin administration, while other providers will lose money on the drug. Those providers who continue to profit will have less incentive to control drug administration. Those facilities that must pay more for these drugs than they are reimbursed will have a significant incentive to under-utilize the drug. This new disparity will further complicate efforts to achieve quality improvement by the development and application of practice guidelines. DCI does not believe that CMS intended its reimbursement policies to exacerbate disparities in patient outcomes.

Moreover, the proposed rule will unfairly and unreasonably penalize dialysis providers when erythropoietin prices increase. Because reimbursement is recalculated only quarterly, adjustments may occur only 6 to 9 months following a price increase. It is not financially possible to provide erythropoietin at or below cost for such prolonged periods. It must also be noted that there has never been a list price decrease in erythropoietin.

The ESRD industry needs stability in erythropoietin reimbursement. Apart from the two largest dialysis providers, the industry cannot influence the ASP by usual market mechanisms therefore, for erythropoietin; the current reimbursement system should be maintained until the introduction of alternative drugs brings usual market forces into play.

3) The "drug add-on" should be an absolute dollar amount, not a percentage of the composite rate.

The Medicare Modernization Act (MMA) recognized that separately billable drugs have subsidized an inadequate ESRD composite rate and that this subsidy could create an incentive to over-utilize separately billable drugs. To correct this potential incentive, without changing overall reimbursement, the drug add-on methodology was introduced. In the simplest terms, MMA calculated the difference between the estimated aggregate payments based on ninety five percent of AWP pricing and the estimated aggregate payments based on Average Acquisition Price (AAP). This difference was distributed over projected treatments and expressed as a percentage increase to the composite rate. Dialysis facilities receiving a higher composite rate thus currently receive more for administering the same doses of the same drugs than do facilities receiving a lower composite rate. There is no reason to suppose that dialysis facility drug acquisition costs vary geographically like other costs do, in particular labor. (In addition, labor costs associated with drug administration are reimbursed by the drug administration fee associated with each separately billable drug.) Therefore, the current percent add-on methodology needs to be replaced with a more equitable absolute add-on methodology.

The proposed modernization of the ESRD wage index will further exacerbate this inequitably because the drug add-on percentage will be applied to a new composite rate that is either significantly higher or lower due to the modernized wage indexes. If the "drug add-on" is calculated as a percentage of the composite rate, facilities receiving a low composite rate will be unfairly penalized, and facilities receiving a relatively high composite rate will receive a windfall.

Take for example DCI's facility in Columbia, Missouri and assume that the over all case mix does not change. Presently, the adjusted composite rate is \$135.32 per treatment (CY 2004 Composite base rate of \$136.56 times 1.087 add-on times 0.9116 budget neutrality factor).

If the drug add-on adjustment is calculated as a percentage of the composite rate, when the proposed modernized wage index is applied, the non labor portion of the composite rate will be \$59.41 and the labor portion will be reduced from \$68.94 to \$59.95 ($\$68.94 \times .8696$) yielding a new base composite rate of \$119.36. Application of the drug add-on percentage of 11.3% and the budget neutrality factor of 0.9116 will yield a reimbursement rate of \$121.10 per treatment. Thus, reimbursement will be reduced by \$14.22 in a facility where the new wage index alone should only have reduced the rate by \$8.99 ($\$68.94 - \$59.95$).

There is no logical reason to subject the drug component of the rate to a wage index. If the drug adjustment were an absolute dollar amount instead of a percentage, it would result in a more equitable application of the drug component. For example, using the Columbia Missouri illustration above, the non labor portion of the composite rate will be \$59.41 and the labor portion will be reduced from \$68.94 to \$59.95 ($\$68.94 \times .8696$), yielding a new base composite rate of \$119.36. If CMS has determined that the appropriate drug add-on is 11.3% of the base composite rate, then the value of the drug add-on is \$14.50 ($11.3\% \times \$128.35$). A more equitable composite rate for Columbia Missouri would be the wage adjusted base rate of \$119.36, times the budget neutrality factor of 0.9116, plus the absolute dollar value of the drug add-on adjustment of \$14.50. This would yield a new composite rate of \$123.31. Thus, reimbursement will be reduced by \$12.01 instead of \$14.22.

While these calculations illustrate that an absolute dollar adjustment for the drug add-on is superior to a percentage adjustment, it also points out a considerable fallacy in the proposed changes. In Columbia Missouri, the composite rate could decrease by an excess of \$14 per treatment. This illustrates the importance of maintaining a floor and ceiling on the wage index adjustment to prevent disproportionate differences in composite rates between geographic areas.

4) We oppose applying the proposed wage index because it will jeopardize access to care.

As a non-profit corporation, DCI serves a significant rural population who travel long distances for medical care. The proposed modernization of the wage index will result in a lower base composite rate for more than two thirds of DCI facilities. Because the proposed rule will not be budget neutral to DCI and other rural facilities, we oppose applying the proposed wage index until more accurate labor, non-labor and drug components of the composite rate are identified.

If the proposed rule becomes final without significant changes, shifting the under funded composite rate dollars, without a floor wage value, from rural to urban facilities will leave no protections for the rural facilities. To protect the beneficiaries in rural areas, the floor values for wage indexing needs to be maintained. Unfortunately, to maintain budget neutrality, preservation of a floor requires preservation of a ceiling value. Moreover, we agree with CMS that additional time is needed to adjust to the lower payment amount. The two year phase-in period does not give adequate time for rural facilities to adapt to an unsustainable economic burden. Some of these areas will experience a substantial reduction in revenue and serious consideration should be given to the potential impact on the patients, the clinic, and the community. In addition, the phase-in proposal begs the question of what will happen when the rate continues to fall over the phase in period. Consider again the same facility in Columbia, Missouri assuming that the wage index floor falls to 0.8 in 2007. If the wage index budget neutrality factor of 1.023024 and case mix remain the same, with a 11.3 % add-on, the Columbia, Missouri facility's adjusted composite rate will decrease by \$3.56 to \$117.52. This clinic will lose \$14.22 in CY 2006 and \$3.56 more in CY 2007 for a total loss of \$17.78 per treatment. How is losing \$17.78 per treatment on the same patients, with same non labor cost, with break even or loss in drug administration, with nursing wages rising, modernizing this Columbia facility? If the wage index floor is lowered and/or eliminated, it seems very likely that many rural facilities will be forced to close. At a substantial economic and personal burden, patients will be constrained to travel long distances for dialysis. Most likely they will be transported to urban facilities, at which CMS will pay higher rates for their dialysis treatments.

5) We agree that it would be preferable to use the same payment method for drugs in independent and in hospital-based dialysis units.

We agree with MedPAC in recommending that payment differences be eliminated for separately billed drugs furnished in independent and hospital-based facilities. We, also, agree with the method to estimate the drug add-on amount for drugs furnished in hospital-based facilities described in the propose rule. Hospital-based units have no unique characteristics that would justify a payment difference. Case mix was addressed on April, 1 2004. Financially, the hospital composite rate already exceeds that for independent facilities by 4%. Furthermore, the hospital industry and therefore hospital-based dialysis units have received annual industry updates to account for inflation. From 1990 to 2004, the Medical Hospital Operating Update has yielded a total increase of 32.15%. In

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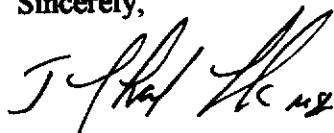
We are opposed to the 4.5% cut in the 2006 Medicare Fee Schedule.

Please consider these reasons of our oppositions to the cuts:

1. SGR calculation includes outpatient drugs administered in the office which negatively impacts the equation to harm physicians by the use of cuts.
2. Physicians, unlike hospitals, do not receive State and local subsidies for treating the poor and uninsured population.
3. Commercial insurance carriers base fee schedules upon Medicare fee schedules and, therefore, the overall negative impact from Medicare will be compounded via Commercial payers.
4. The severe cuts that Medicare is proposing only serve to penalize the physicians and staff who currently serve the elderly population.

Please contact me should you have further questions.

Sincerely,



J. Charles Lock, MSA
Executive Director

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PREVENTIVE INTERNAL MEDICINE GROUP, P.L.L.C.

SEP 30 2005

"Commitment To Caring"

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September 29, 2005

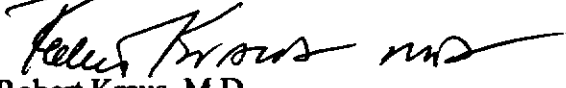
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, Maryland 21244-1850

Dear Sirs:

The physicians of Preventive Internal Medicine Group are deeply concerned about the proposed 4.5 to 5.5% decrease in the 2006 Medicare Fee Reimbursement. We have cared for Medicare patients for approximately 20 years. During this time the cost of providing care has continued to rise while the reimbursement in the age of managed care had decreased. While we care about our patients, we view the proposed reductions as a threat to the economic viability of the practice. With continued reductions it will be very difficult to reward loyal employees with minimal wage increases and impossible to make the technological advances such as Electronic Health Records.

While we support Medicare Reform, making these types of drastic cuts does nothing to reform Medicare or improve the quality of care. This is just another means to manage costs as opposed to rewarding providers for excellent care.

Respectfully,


Robert Kraus, M.D.


Tom Rawlinson, M.D.

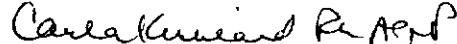
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Transplant Pharmacy Coalition

September 29, 2005

Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
Room 445-G
200 Independence Avenue, SW.
Washington, DC 20201

Re: CMS-1502-P, Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2006

I. INTRODUCTION

The Transplant Pharmacy Coalition (TPC) is pleased to provide comments on 42 CFR Part 405 et al. *Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006*. TPC's comments focus on implementation of the pharmacy supply fee for Medicare Part B immunosuppressant drugs. These comments show that CMS does not overpay pharmacies when it provides a \$24 per prescription supply fee.

This year, TPC worked with national chain pharmacy corporations to determine the cost to dispense Medicare Part B prescriptions. The data collected prove that the proposed \$8 supply fee is absolutely insufficient to cover costs associated with supplying immunosuppressants. TPC data, analyzed by the Lewin Group, show that the average cost to supply **each** Medicare Part B immunosuppressant is \$35.48. On average, chain pharmacy data collected in a mechanism similar to TPC data show that fees average approximately \$21 per prescription. This figure appears somewhat lower than the Lewin Group's analysis determined as the chain pharmacies have averaged in costs for supplying other Medicare-covered items, such as diabetic test strips. The costs of providing these items are lower than those associated with immunosuppressants.

TPC's policy analysis shows that CMS' rationale for establishing the \$8 supply fee is flawed and recommends that CMS review actual cost to supply data to understand the entire picture of pharmacy reimbursement.

These comments also provide an overview of the administrative burdens that result in additional costs for pharmacies that bill for Medicare Part B pharmaceuticals. For example, pharmacies continue to experience problems in receiving payment from state Medicaid agencies and private third parties for the requisite 20% co-insurance. Also, CMS has not yet eliminated the DMERC information form (DIF) and assignment of benefits form (AOB) as promised in the rule last year as a mechanism to streamline Medicare billing. Finally, these comments also briefly consider the implications of the average sales price (ASP) methodology to transplant specialty pharmacies.

TPC would like to thank representatives from the Centers for Medicare & Medicaid Services (CMS) and the Department of Health and Human Services (HHS) for their willingness to address our concerns regarding the pharmacy supply fee for immunosuppressant medications. TPC has been working with CMS since early 2004 to develop the pharmacy supplying fee. TPC appreciates the efforts of CMS and HHS, particularly the Center for Medicare Management for the continued work with TPC members.

TPC is a coalition of eight specialty transplant pharmacies that are both independently owned and public companies. The members of the coalition are Amber Pharmacy (Omaha, NE); BioScrip, Inc (Minneapolis, MN); Echo Drugs (Flushing, NY); F&M Specialty Pharmacy (New Orleans, LA); PharmaCare, Inc (Lincoln, RI); Skyemed Pharmacy (Pompano Beach, FL); Transcript Pharmacy (Jackson, MS); and Two Thousand Ten (2010) Pharmacy (Los Angeles, CA). Contact information for each of these pharmacies is found in *Appendix 1*. These companies supply immunosuppressant medications and associated, necessary pharmacy services to approximately 30% of all US organ transplant recipients and approximately 40% of Medicare Part B beneficiaries who have received an organ transplant. TPC determined its market share for providing Medicare Part B pharmaceuticals based upon CMS' regulatory impact analysis which concluded that 2004 pharmacy revenues for pharmacy-dispensed Medicare Part B immunosuppressive, oral anti-cancer, and oral anti-emetic drugs totaled \$350 million in 2004.

In 2005, TPC worked with the National Association of Chain Drug Stores (NACDS) and several of its individual member companies to gather data and information regarding the cost to supply Medicare Part B immunosuppressant agents. This collaborative effort provides a broader base of participants to CMS with more comprehensive information regarding the cost to supply immunosuppressant medications. Some of these individual chain pharmacies will also provide these figures as part of the public comment period. As described in comments below, the costs to dispense Medicare Part B pharmaceuticals are several times more than the proposed \$8 fee that pharmacies receive after dispensing the initial prescription.

II. OVERVIEW OF PHARMACY REIMBURSEMENT AND FLAWED METHODOLOGY USED BY CMS TO ESTABLISH \$8 SUPPLYING FEE

TPC understand that CMS arrived at the \$8 supply fee by examining dispensing fees associated with Medicaid and private third party pharmacy programs. This is a flawed mechanism because dispensing fees alone do not provide an adequate measure of the actual cost to dispense medications covered by Medicare. Supplying Medicare Part B drugs is more expensive than processing Medicaid and private third party claims. The reasons for the difference are two-fold:

- 1) Third party claims are billed through on-line adjudication removing the risks of denied claims from pharmacy providers, and
- 2) Medicaid plans and Commercial payors pay pharmacies, in part, through a pricing methodology that compensates some of the costs associated with drug procurement and dispensing. In general, this methodology is based on average wholesale price (AWP) not the flawed Average Sales Price methodology, as these comments later consider.

This section provides a policy analysis of the actual impact of drug reimbursement and dispensing costs in relationship to the entire picture of pharmacy reimbursement. The analysis in *Section III* below describes TPC and chain labor costs for a Medicare Part B prescription alone exclusive of product cost. CMS should use these cost analyses as a basis for establishing the supply fee and not simply the published Medicaid and third party dispensing fees.

A. Dispensing Fees Do Not Reflect the Actual Costs of Dispensing Medications

The traditional pharmacy reimbursement methodology consists of two parts: product cost and dispensing fee. Typically, pharmacy reimbursement methodology assumes that pharmacies receive a discount in acquisition price and therefore, dispensing fees are lowered to compensate for the spread between product reimbursement and acquisition. Pharmacies have fixed labor and other costs associated with dispensing any prescription. These labor costs are generally greater than the dispensing fee but are subsidized by the product acquisition discount. Currently, Medicare Part B product reimbursement is closer to or even below acquisition cost. Therefore, CMS must properly recognize pharmacy labor and clinical costs.

When Congress changed Medicare Part B methodology to lower payments for pharmaceuticals, it also intended for CMS to simultaneously implement a supplying fee for pharmacies. Congress intended the supplying fee to be different from a Medicaid or third party dispensing fee. In the Medicare Modernization Act and accompanying report, Congress recognized that lowering pharmacy

product reimbursement requires an additional payment to compensate for the unique requirements of supplying patients with immunosuppressant medications.

In reality, other payers accurately recognize the costs associated with supplying immunosuppressants. *Appendix 2* provides an analysis of Medicaid and private third party reimbursement methodology including a Medicare-equivalent supply fee for two of the most commonly prescribed immunosuppressants, Prograf® (tacrolimus, J7507), and CellCept® (mycophenolate mofetil, J7517). TPC arrived at these figures by calculating actual Medicaid and private third party reimbursement cost for the drug product and dispensing fee versus the difference in Medicare Part B reimbursement of ASP+6%+\$24.

Based on August 2005 Medicaid figures, a select state Medicaid supply fee equivalent average is \$60.37. Using a sample of 20 private third party payers, the equivalent supply fee averaged \$39.71. Details are provided in the relevant Appendix. Obviously, these figures are well above the \$8 proposed supply fee.

B. Supplying Medicare Part B Pharmaceuticals More Labor Intensive Than Claims Adjudicated On-Line in Real Time

The third party and Medicaid reimbursement analyses described above are based on claims paid by real time, on-line adjudication. The term adjudication refers to the process where pharmacy enters a patient's insurance coverage information and prescription information into a computer at the point of sale. The pharmacy then transmits the claim in real time and on-line to the payer. Almost instantly, the payer sends information back to the pharmacy related to the person's eligibility for coverage, co-payment amount and reimbursement to the pharmacy. Unfortunately, the process for billing Medicare Part B claims is much more complex, and unlike adjudicated claims, payment is not guaranteed.

CMS cannot underestimate the cost burdens of Medicare Part B billing on pharmacy operations. For example, a mid-size independently owned specialty pharmacy noted that it currently employs eight people in its billing department. Medicare comprises 40% of the company's overall business but accounts for 90% of billing staff time. Staff members that bill Medicare must continually receive education to remain current with Medicare's manual and complex billing processes. In contrast, third party system changes are integrated into the pharmacy's computer system as software updates.

Under Medicare Part B, presenting the prescription to a patient at the point of sale in the pharmacy or using home delivery is only the first of many steps pharmacies must take to receive payment. Each time a Medicare Part B prescription is filled, the pharmacy is unaware of whether or not Medicare will pay for the claim. Long after the patient receives a prescription, the pharmacy must still determine whether or if Medicare Part B will pay it. This is simply not

the case with an adjudicated claim where the pharmacy knows the amount of payment at the point of sale.

On-line adjudicated claims also do not require the extensive paperwork necessary to bill each and every Medicare prescription. First, all Medicare prescriptions required an individually signed, original prescription from a physician. Today's physician and pharmacy practice standards do not generally require a physician's original signed order for each and every prescription. The requirement for a written, signed prescription often takes extra work on the pharmacy to communicate with physicians and ensure compliance with Medicare standards.

Part B claims for immunosuppressants continue to be billed by pharmacies using HCPCS codes in ANSI X837 standard format. Most other pharmacy claims use NDCs and no HCFA form needs to be completed for these claims. This process must either be completed by an outside billing entity or internally by the pharmacy. Either way, this is a significant cost burden to the pharmacy because of the amount of manual labor necessary to complete the forms. In the 2005 proposed rule, CMS suggested that it would eliminate certain cumbersome paperwork associated with Medicare Part B billing, including the elimination of the DMERC Information Form (DIF) and assignment of benefits (AOB). In part, CMS rationalized the \$24 fee by suggesting the elimination of these forms as a way to streamline Part B billing. To date, these changes have not been made and TPC looks forward to working with CMS to make these changes. Further details regarding the costs and problems associated with the Medicare manual billing process are found in *Section III* below.

In addition to manual billing claims, specialty pharmacies that provide immunosuppressants to transplant patients also provide additional clinical and other critical patient care services to enhance the medication use process. *Section III* below provides an extensive overview of these billing and clinical services and corresponding costs.

III. OVERVIEW OF COSTS AND SERVICES ASSOCIATED WITH SUPPLYING MEDICARE PART B PHARMACEUTICALS

A. Analysis of TPC's Costs and Services Associated with Medicare Part B Prescriptions

In the summer of 2004, TPC commissioned the Lewin Group, a national health care and human services consulting firm, to study immunosuppressant reimbursement and prepare a report on the cost of supplying Part B medications. The Lewin Group has extensive experience in providing data verification and information to the federal government. The full Lewin Group report is provided with these comments, as *Appendix 3*. The Lewin Group report finds that an appropriate supply fee for Part B immunosuppressants is \$35.48 per prescription

regardless of when the prescription is filled—whether it is the first prescription filled per month or any subsequent prescription.

The Lewin Group surveyed TPC members using a “top down” approach to identify costs associated with providing immunosuppressant pharmacy services. Below is a summary of the Lewin findings. *Section II.B* describes these services in relationship to cost. This information was presented in public comment by TPC last year, but is important to repeat. Briefly, the Lewin Group Report finds the following:

- **Transplant pharmacies have higher supply costs than retail chain pharmacies to supply immunosuppressant medications because these pharmacies provide more “extensive” services.** These services are described below and in *Appendix 3*.
- **Specialty transplant pharmacies routinely stock immunosuppressant medications.** Immunosuppressants are costly for pharmacies to acquire and maintain in inventory. TPC member pharmacies fill an average of 28,000 prescriptions per month for immunosuppressants alone. Given the volume of dispensing, specialty transplant pharmacies must maintain regular stock of immunosuppressant medications. Most retail chain and other community pharmacies do not regularly stock immunosuppressants at the same level as specialty transplant pharmacies. Considering costs to maintain an inventory of these medications and the low dispensing volume, patients cannot be assured that retail community pharmacies or large mail-order PBMs will have medications in stock to suit their needs.
- **Specialty transplant pharmacies provide valuable professional services to patients, including regular contact and refill reminders.** These reminders encourage compliance with prescribed immunosuppressant regimens. A recent study shows that pharmacy services are integral to the social support services necessary to ensure compliance. This prospective study entitled *Study on Late Consequences of Subclinical Noncompliance with Immunosuppressive Therapy in Renal Transplant Patients*, conducted by Vlaminc, H; Maes, B; et al. (Am J Transplant 4(9):1509-1513, 2004) finds that these special interactions can help reduce the possibility of late-transplant organ rejection from nearly 30% to 8%. Also, Medicare direct billing services by specialty transplant pharmacies help to lower payments for beneficiaries and reduce economic barriers to receipt of transplant medications.

B. TPC's Costs Associated with Providing Medications and Services under Medicare Part B

- **Direct patient care through frequent contact with the pharmacist**
Pharmacists provide transplant patients and transplant center professionals with information related to their medications. Services include regular, proactive contact with the patient to ensure proper compliance and response to medication therapy. Patient contact includes regular phone calls to discuss therapy and actual and potential side effects, to monitor compliance, and to determine the need for changes in medications or dosage. These contacts are critical to ensuring appropriate patient medication utilization. **On average, the labor costs associated with these services comprise 24% of overall costs or \$8.73. See Appendix 3, The Lewin Group Report page 27.**

- **Expeditious processing and turnaround of medication orders**
Specialty transplant pharmacies provide the following services just to process a prescription:

Receipt, processing, and immediate shipping of prescription order. While this process might be similar for most pharmacies, specialty transplant pharmacies have developed systems and order formats to receive the prescription order in an expeditious manner from transplant centers and process orders immediately, rather than the one or two days required by large mail-order PBMs. New prescription orders received from a transplant center are often shipped on the same day or are hand-delivered to the patient at the transplant center and in time for discharge. Refill orders must be timed to ensure both compliance with Medicare processing rules and a continuous, uninterrupted, supply of medications for the patient. Even a minor error in these processes might result in delivery delay to patients.

Direct Medicare billing and coordination of benefits on patients' behalf lower costs to Medicare beneficiaries. Specialty transplant pharmacies will coordinate reimbursement with an individual patient's supplementary insurance companies, including private, third party payers, retiree plans, and Medicaid, to lower the cost of a patient's immunosuppressant medications. As described previously, transplant medications are expensive and the regimens cost approximately \$1200 per month. Coordination of benefits with third parties often results in a substantial decrease in the patient's 20% co-insurance responsibility. Other pharmacies and PBMs routinely require patients to pay the 20% co-insurance up front and then navigate the system on their own to obtain secondary coverage of these significant costs. Patient compliance

is greatly improved if economic barriers to receiving immunosuppressants are removed.

Medicare's claim submission process adds significant cost that does not exist in the private insurance environment. Medicare billing is not adjudicated on-line in real time. These billing problems are compounded by the too frequent inaccuracies in coverage verification by regional DMERCs at the time of billing. On average, not including bad debt expenses, Medicare billing processes comprise 21% of overall costs, or an average of \$7.64. *See Appendix 3, The Lewin Group Report, page 27.*

All major public (Medicaid) and private (PBM and other) pharmacy claim payors, except Medicare, allow and require on-line claims submission prior to the dispensing of a prescription. The eliminates risk of claim denial to pharmacies.

In some cases, Medicare denies claims submitted by pharmacies three to four weeks after submission. These pharmacies have already dispensed, shipped, and expended labor and capital on processing and shipping these prescriptions. Pharmacies absorb these losses. CMS recognizes valid bad debt associated with Medicare Part B when patients fail to pay their co-insurance or when secondary insurers fail to pay the 20% of the allowable costs not paid by Medicare. Both of these instances happen often enough to result in burdensome bad debt for specialty transplant pharmacies. Bad debt as a result of denied claims equals approximately 5% of Medicare supply costs. *See Appendix 3, The Lewin Group Report, page 27.*

Expensive immunosuppressant medications must remain in stock for timely delivery by beneficiaries. Specialty transplant pharmacies' maintain immunosuppressants in stock because transplant comprises the bulk of their business. Most retail community pharmacies or large mailorder PBMs do not stock these medications because of high inventory costs and low turnover. Therefore, it is difficult to ensure that patients who use non-specialty pharmacies will receive these medications consistently. Skipping even a single dose of medication can begin a rejection process in the patient ultimately leading to a return to dialysis or the need for a new transplant. In summary, specialty transplant pharmacies provide services above and beyond most retail and PBM mail-order pharmacies. These services result in improved patient compliance and reduce the possibility of rejection and other adverse health consequences. Given the critical patient compliance with immunosuppressant regimens and the overall

costs, the pharmacy supply fee derived by TPC is more than reasonable.

C. Other Pharmacies' Data Related to Cost of Dispensing Medicare Part B Pharmaceuticals

In response to CMS' request to gain a better understanding of supplying costs for chains and other pharmacies, TPC worked with NACDS and its individual members to obtain data and information related to supplying costs for Medicare Part B immunosuppressants. TPC received information from several chain pharmacies. TPC then used independent consultants to review the information and determine the straight average of the cost to dispense immunosuppressant agents. The results were not incorporated into the Lewin report, but independent review of the information showed that the data were compiled in a manner consistent with the Lewin Group report. The average of chain pharmacies to dispense immunosuppressant agents is a multiple of the proposed \$8 fee and is fully consistent with the current \$24 per-prescription supply fee. These averages far exceed CMS' proposed \$8 supply fee for each prescription dispensed after the first one per month.

While the average cost for chain pharmacies to dispense Medicare Part B medications is lower than TPC's overall average, there are certain factors causing differences in the compilation of TPC's data and the chains' data. TPC used only supplying costs for immunosuppressants. The chains' data include the cost to dispense for all Medicare Part B medications and does not differentiate between the costs of dispensing immunosuppressants alone. While Medicare Part B billing is a labor-intensive process for all medications, the costs for dispensing immunosuppressants, oral anticancer agents, and anti-emetics exceed that of dispensing other medications and diabetic testing supplies. Some of the requirements for documenting immunosuppressant orders do not apply to diabetic testing supplies. Additionally, these are generally much less expensive than immunosuppressants and the costs incurred by denied claims are therefore less. Lastly, many of these products, unlike immunosuppressants, may be purchased below the Average Sales Price and pharmacies' costs are somewhat covered by these purchase discounts. This is NOT the case with the immunosuppressants.

TPC believes that if the chains were able to extrapolate only Medicare Part B immunosuppressant information, costs might be slightly higher.

All chain pharmacies reported to TPC that Medicare Part B billing for immunosuppressants is a relatively small part of its overall retail pharmacy business. Despite the small number of patients served by these chain pharmacies, all find that the billing process is labor intensive and costly and that transplant patients often require a higher level of care than other patients.

IV. SPECIFIC COMMENTS ON SUPPLY FEE PROVISIONS IN PROPOSED RULE & PREAMBLE

A. Dispensing Fees for Non-Medicare Part B Claims

In the preamble, CMS indicates that the costs to fill a non-Medicaid third party or cash prescriptions range from \$7.50 to \$8.00 per prescription. This is lower than current data from NACDS showing that the average cost to fill a retail, adjudicated prescription is \$9.62 per prescription (University of Texas Center for Pharmacoeconomic Studies, July 2005 and data from the National Community Pharmacists' Association (NCPA) showing that the average cost to dispense a prescription for an adjudicated claim is \$9.24. (*NCPA-Pfizer Digest*). These figures represent the **per prescription cost for an adjudicated claim**. These rates presume the labor costs with the assumption that the pharmacy receives adequate reimbursement on the drug product. As described above, pharmacy costs are significantly higher for processing non-adjudicated Part B immunosuppressant claims.

B. Payment of Supply Fee for Different Dosages of Same Drug

TPC appreciates CMS' understanding that in some cases, particularly in the case of Prograf® [J7507], an individual receives different dosages of the same medications on the same day. Under the revisions suggested in the Preamble, "[w]e are now proposing to pay a supplying fee for each prescription, even if the prescriptions are for different strengths of the same drug. This change is intended to recognize the costs involved in filling separate prescriptions for different strengths of a drug." Again, as described above, pharmacies must undertake the same labor-intensive process for these individual prescriptions as it does for all other medications dispensed under Medicare Part B.

C. Inclusion of One-Time \$50 Payment in Regulatory Language

CMS indicates in the Preamble that it intends to continue allowing for a one-time \$50 supply fee to be provided to pharmacies that dispense the first immunosuppressant post-transplant. However, under the regulatory language in §414.1001, Basis of Payment, this one time supply fee is not mentioned and this section should be corrected to add this provision.

D. TPC's Suggestions to Amend §414.1001, Basis of Payment

Based on analysis and comments related to the supply fee, TPC suggests the following amendments to the regulatory language implementing the supply fee:

"(a) A supplying fee of \$24 is paid to a supplier for **each the first** prescription of drugs and biologicals described in sections 1861(s)(2)(J), 1861(s)(2)(Q), and 1861(s)(2)(T) of the Act that that supplier provided to

a beneficiary during a month (or \$50 for the first oral immunosuppressive prescription supplied in the first month after a transplant). ~~A supplying fee of \$8 is paid to a supplier for each prescription of drugs and biologicals described in sections 1861(s)(2)(J), 1861(s)(2)(Q), and 1861(s)(2)(T) of the Act, after the first one, that that supplier provided to a beneficiary during a month.~~

V. TPC'S OTHER CONCERNS WITH BILLING FOR MEDICARE PART B PHARMACEUTICALS

While not specifically in the proposal, TPC would like CMS to consider other concerns with Medicare Part B billing during the comment period for the proposed rule.

A. Establishing Permanent JCodes for Supply Fee Billing

As an interim measure, CMS implemented temporary GCodes 0369 and 0370 to bill the supply fee for immunosuppressant agents. TPC appreciates the expedited process CMS used to establish these codes in time for January 2005 implementation. TPC understands that these codes will be replaced with permanent codes in November 2005. If CMS does not publish the codes in the final rule, TPC recommends clarification in the Preamble regarding the status of publication, expected dates and the reporting mechanism for this information.

B. Continued Need to Submit DIF and AOB Proposed for Elimination in 2005 Rule

In the 2005 proposed rule, CMS suggested changes to eliminate certain cumbersome paperwork associated with Medicare Part B billing. The suggested changes include the elimination of the DIF and AOB. To date, neither of these changes has been made and therefore, TPC members and other pharmacies that bill for Medicare Part B TPC would like CMS to provide a status report of efforts to eliminate these forms.

C. Continued Problems in Receiving 20% Co-Insurance from State Medicaid Programs and Private Third Party Payers

TPC appreciates CMS' efforts to communicate with state Medicaid agencies and third party payers regarding the responsibility of paying the beneficiary's 20% co-insurance for immunosuppressants. TPC members find that the situation has improved over the past several months, but continue to experience problems receiving payment in some cases. TPC recommends that CMS include specific language in the preamble of the final rule that once again explains the responsibility of Medicaid programs and third party payers to cover the beneficiary's 20% co-insurance amount.

VI. CONCERNS WITH ASP PRICING METHODOLOGY

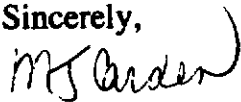
TPC and other pharmacy suppliers have continually expressed concerns that ASP pricing methodology places pharmacies at a disadvantage in guarding against increases in acquisition prices. This reimbursement methodology is not based on a real-time assessment of market prices for drugs. Therefore, pharmacies face the risk of manufacturer acquisition price increases during a quarter without corresponding increases in reimbursement. Throughout the first year of ASP implementation, some manufacturers increased acquisition cost above the ASP+6% reimbursement rate after CMS' publication of the preceding quarter's ASP figures. As a result, in some cases throughout the year, pharmacies' purchase price was above the ASP. CMS should implement a system of monitoring pricing by pharmaceutical manufacturers to ensure that pharmacies are not significantly under reimbursed for medications. Other payors, such as Medicaid plans and pharmacy benefit managers (PBMs) have not begun to utilize ASP to reimburse pharmacies because of these significant problems.

VII. SUMMARY

TPC again thanks CMS for the opportunity to comment on this proposed rule. TPC reiterates that CMS should maintain the \$24 supply fee for each Medicare Part B immunosuppressant dispensed. Even at \$24, TPC members on average lose money on each prescription. CMS' proposal for an \$8 supply fee after the first prescription per month does not even meet the dispensing fee required for an adjudicated pharmacy claim. At this level of reimbursement, CMS can expect patient access to be compromised.

Therefore, TPC requests that CMS maintain or increase the \$24 supply fee throughout 2006 while it works with TPC members and other interested pharmacies and associations to develop an on-line adjudication system for Medicare Part B. If you have further questions regarding this comment letter, please contact Dumbarton Group & Associates, LLC, and TPC's Washington representation, Mary Jo Carden (Mcarden@dumbartonassociates.com; 202-744-2773) or Leigh Davitian (ldavitian@dumbartonassociates.com; 202-669-7114).

Sincerely,



Mary Jo Carden, RPh, JD

On behalf of the Transplant Pharmacy Coalition

**The Transplant Pharmacy Coalition
Comments Medicare Part B Supply Fee**

Appendix 1
Transplant Pharmacy Coalition Members

Transplant Pharmacy Coalition
Members and Contact Information
As of September 2005

Amber Pharmacy

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Transcript Pharmacy, Inc.
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Los Angeles, CA
213-483-5910

**The Transplant Pharmacy Coalition
Comments Medicare Part B Supply Fee**

Appendix 2
**Medicaid and Third Party Analysis of Immunosuppressant
Reimbursement**

Medicaid Reimbursements

Aug-06

Oct 05 ASP

Payor	Description	Item	Strength	Qty	Medicaid Reimbursement	CMS ASP+6%+\$24	Difference	Medicaid Equivalent Supply Fee
IL	Illinois	Prograf	1mg	240	\$ 877.24	\$ 851.76	\$ 25.48	\$ 49.48
IN	Indiana	Prograf	1mg	240	\$ 868.74	\$ 851.76	\$ 16.98	\$ 40.98
KY	Kentucky	Prograf	1mg	240	\$ 862.04	\$ 851.76	\$ 10.28	\$ 34.28
MD	Maryland	Prograf	1mg	240	\$ 859.82	\$ 851.76	\$ 8.06	\$ 32.06
MI	Michigan	Prograf	1mg	240	\$ 861.45	\$ 851.76	\$ 9.69	\$ 33.69
MIK	Maryland Kidney	Prograf	1mg	240	\$ 862.80	\$ 851.76	\$ 11.04	\$ 35.04
MO	Missouri	Prograf	1mg	240	\$ 877.93	\$ 851.76	\$ 26.17	\$ 50.17
NE	Nebraska	Prograf	1mg	240	\$ 903.12	\$ 851.76	\$ 51.36	\$ 75.36
OH	Ohio	Prograf	1mg	240	\$ 873.08	\$ 851.76	\$ 21.32	\$ 45.32
SD	South Dakota	Prograf	1mg	240	\$ 894.96	\$ 851.76	\$ 43.20	\$ 67.20
VG	Virginia	Prograf	1mg	240	\$ 899.22	\$ 851.76	\$ 47.46	\$ 71.46
AR	Arkansas	Prograf	1mg	240	\$ 859.50	\$ 851.76	\$ 7.74	\$ 31.74
TK	Texas Kidney	Prograf	1mg	240	\$ 871.60	\$ 851.76	\$ 19.84	\$ 43.84
TM	Texas Childrens	Prograf	1mg	240	\$ 866.22	\$ 851.76	\$ 14.46	\$ 38.46
TX	Texas	Prograf	1mg	240	\$ 871.60	\$ 851.76	\$ 19.84	\$ 43.84
Avg								\$ 46.19

CO	Colorado	Cellcept	250mg	240	\$ 679.94	\$ 634.08	\$ 45.76	\$ 69.76
IL	Illinois	Cellcept	250mg	240	\$ 666.95	\$ 634.08	\$ 32.87	\$ 76.87
KY	Kentucky	Cellcept	250mg	240	\$ 669.20	\$ 634.08	\$ 35.12	\$ 59.12
MI	Michigan	Cellcept	250mg	240	\$ 681.94	\$ 634.08	\$ 47.76	\$ 71.76
MIK	Maryland Kidney	Cellcept	250mg	240	\$ 674.77	\$ 634.08	\$ 40.69	\$ 64.69
MO	Missouri	Cellcept	250mg	240	\$ 687.59	\$ 634.08	\$ 53.51	\$ 77.51
NE	Nebraska	Cellcept	250mg	240	\$ 696.10	\$ 634.08	\$ 62.02	\$ 86.02
OH	Ohio	Cellcept	250mg	240	\$ 690.98	\$ 634.08	\$ 56.90	\$ 70.90
OK	Oklahoma	Cellcept	250mg	240	\$ 687.65	\$ 634.08	\$ 53.57	\$ 77.57
SD	South Dakota	Cellcept	250mg	240	\$ 699.86	\$ 634.08	\$ 65.78	\$ 89.78
VG	Virginia	Cellcept	250mg	240	\$ 705.08	\$ 634.08	\$ 71.00	\$ 95.00
AR	Arkansas	Cellcept	250mg	240	\$ 675.12	\$ 634.08	\$ 41.04	\$ 65.04
TK	Texas Kidney	Cellcept	250mg	240	\$ 678.71	\$ 634.08	\$ 44.63	\$ 68.63
TM	Texas Childrens	Cellcept	250mg	240	\$ 681.84	\$ 634.08	\$ 47.76	\$ 71.76
TX	Texas	Cellcept	250mg	240	\$ 694.08	\$ 634.08	\$ 50.00	\$ 74.00
Avg								\$ 74.54

Combined Avg \$ 60.37

NOT \$8 !!

3rd Party Payment Analysis
 Sep-06

Oct 05 ASP

Payor	Description	Item	Strength	Qty	Commercial		CMS		Difference	Commercial Equivalent Supply Fee
					Pay	ASP+6%+\$24	ASP+6%+\$24	Pay		
AE	Aetna	Prograf	1mg	240	\$ 846.05	\$ 851.76	\$ 851.76	\$ 846.05	\$ (5.71)	\$ 18.29
AN	Anthem	Prograf	1mg	240	\$ 836.62	\$ 851.76	\$ 851.76	\$ 836.62	\$ (15.14)	\$ 8.88
AO	Argus	Prograf	1mg	240	\$ 856.08	\$ 851.76	\$ 851.76	\$ 856.08	\$ 4.32	\$ 28.32
AX	Alla	Prograf	1mg	240	\$ 848.56	\$ 851.76	\$ 851.76	\$ 848.56	\$ (3.20)	\$ 20.80
BA	BCBS AL	Prograf	1mg	240	\$ 852.00	\$ 851.76	\$ 851.76	\$ 852.00	\$ 0.24	\$ 24.24
BB	BCBS AR	Prograf	1mg	240	\$ 858.48	\$ 851.76	\$ 851.76	\$ 858.48	\$ 6.72	\$ 30.72
BM	BCBS Anthem	Prograf	1mg	240	\$ 835.68	\$ 851.76	\$ 851.76	\$ 835.68	\$ (16.08)	\$ 7.92
CK	Caremark	Prograf	1mg	240	\$ 845.55	\$ 851.76	\$ 851.76	\$ 845.55	\$ (6.21)	\$ 17.79
CL	Claimspro	Prograf	1mg	240	\$ 865.91	\$ 851.76	\$ 851.76	\$ 865.91	\$ 14.15	\$ 38.15
EX	Express Script	Prograf	1mg	240	\$ 841.18	\$ 851.76	\$ 851.76	\$ 841.18	\$ (10.58)	\$ 13.42
JD	John Deere	Prograf	1mg	240	\$ 866.41	\$ 851.76	\$ 851.76	\$ 866.41	\$ 14.65	\$ 38.65
OB	Regence	Prograf	1mg	240	\$ 857.04	\$ 851.76	\$ 851.76	\$ 857.04	\$ 5.28	\$ 29.28
PC	PCS	Prograf	1mg	240	\$ 855.53	\$ 851.76	\$ 851.76	\$ 855.53	\$ 3.77	\$ 27.77
PD	Paid	Prograf	1mg	240	\$ 845.55	\$ 851.76	\$ 851.76	\$ 845.55	\$ (6.21)	\$ 17.79
PH	Pharmalink	Prograf	1mg	240	\$ 865.20	\$ 851.76	\$ 851.76	\$ 865.20	\$ 13.44	\$ 37.44
PY	Prime Therapeutics	Prograf	1mg	241	\$ 852.00	\$ 851.76	\$ 851.76	\$ 852.00	\$ 0.24	\$ 24.24
RK	Rocky Mt Health	Prograf	1mg	242	\$ 852.98	\$ 851.76	\$ 851.76	\$ 852.98	\$ 1.20	\$ 25.20
RX	RX Nebraska	Prograf	1mg	243	\$ 848.06	\$ 851.76	\$ 851.76	\$ 848.06	\$ (3.70)	\$ 20.30
WH	Walgreens	Prograf	1mg	244	\$ 845.80	\$ 851.76	\$ 851.76	\$ 845.80	\$ (5.96)	\$ 18.04
BT	BCBS TX	Prograf	1mg	245	\$ 835.27	\$ 851.76	\$ 851.76	\$ 835.27	\$ (16.49)	\$ 7.51

Avg \$ 22.74

AE	Aetna	Cellcept	250mg	240	\$ 662.19	\$ 634.08	\$ 634.08	\$ 662.19	\$ 28.11	\$ 52.11
AN	Anthem	Cellcept	250mg	240	\$ 653.68	\$ 634.08	\$ 634.08	\$ 653.68	\$ 19.60	\$ 43.60
BA	BCBS AL	Cellcept	250mg	240	\$ 684.20	\$ 634.08	\$ 634.08	\$ 684.20	\$ 50.12	\$ 54.12
BF	BCBS Illinois	Cellcept	250mg	240	\$ 676.08	\$ 634.08	\$ 634.08	\$ 676.08	\$ 42.00	\$ 66.00
CK	Caremark	Cellcept	250mg	240	\$ 693.36	\$ 634.08	\$ 634.08	\$ 693.36	\$ 59.28	\$ 83.28
CR	Coram	Cellcept	250mg	240	\$ 658.42	\$ 634.08	\$ 634.08	\$ 658.42	\$ 24.34	\$ 48.34
EX	Express Script	Cellcept	250mg	240	\$ 658.42	\$ 634.08	\$ 634.08	\$ 658.42	\$ 24.34	\$ 48.34
PC	PCS	Cellcept	250mg	240	\$ 664.18	\$ 634.08	\$ 634.08	\$ 664.18	\$ 30.10	\$ 54.10
PD	Paid	Cellcept	250mg	240	\$ 664.18	\$ 634.08	\$ 634.08	\$ 664.18	\$ 30.10	\$ 54.10
RX	RX Nebraska	Cellcept	250mg	240	\$ 662.20	\$ 634.08	\$ 634.08	\$ 662.20	\$ 28.12	\$ 52.12
BT	BCBS TX	Cellcept	250mg	240	\$ 653.68	\$ 634.08	\$ 634.08	\$ 653.68	\$ 19.60	\$ 43.60
TM	TX Childrens	Cellcept	250mg	241	\$ 660.72	\$ 634.08	\$ 634.08	\$ 660.72	\$ 26.64	\$ 50.64

Avg \$ 56.69

Combined Avg \$ 39.71

**The Transplant Pharmacy Coalition
Comments Medicare Part B Supply Fee**

Appendix 3

The Lewin Group Report

Assessing the Cost of Dispensing Immunosuppressive Drugs to Medicare Transplant Recipients

Developed for the Transplant Pharmacy Coalition

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

September 24, 2004



Table of Contents

- ◆ Executive Summary
- ◆ Coalition & Study Introduction
- ◆ Transplant Pharmacy Overview
- ◆ Transplant Drug Reimbursement
- ◆ Study Design
- ◆ Study Results
- ◆ Conclusions

Executive Summary (1 of 2)

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

Executive Summary (2 of 2)

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

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

Coalition & Study Introduction

The Transplant Pharmacy Coalition

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

Study Purpose

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

Transplant Pharmacy Overview

Transplants and Immunosuppressive Drugs

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

Pharmacies and Immunosuppressive Drugs

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

Special Features of Transplant Pharmacies

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

Pharmacy Claims Procedures

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

Transplant Drug Reimbursement

Current Medicare Payments

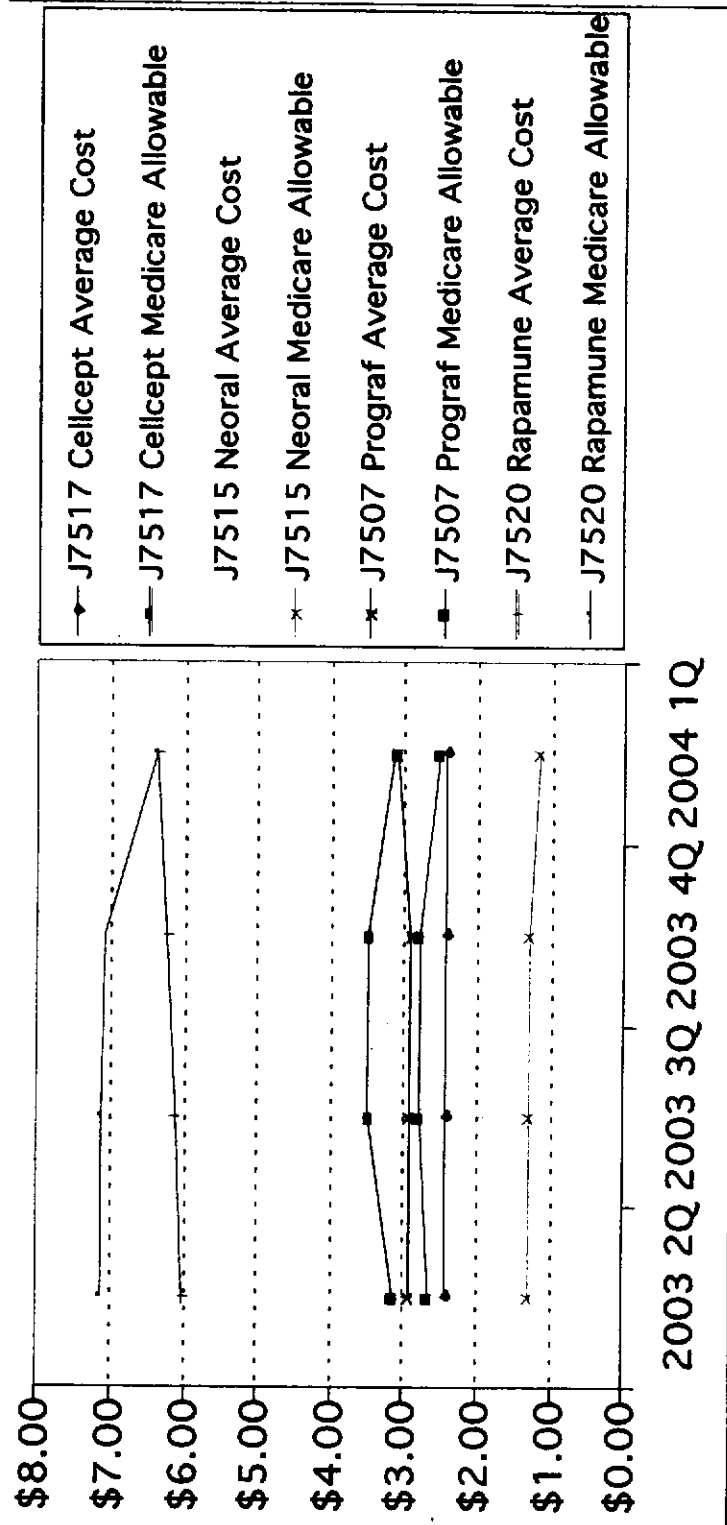
- ◆ Medicare spent about \$174 M on immunosuppressive drugs in CY2002.
- ◆ Until recently, Medicare allowed 95% of average wholesale price (AWP).
- ◆ Currently, Medicare allows 85% of April 2003 AWP.
 - AWP is a list price, not a price based on actual wholesale transaction data
 - Medicare allows 85%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

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

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

Medicare Allowables and Drug Prices

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



Proposed 2005 Medicare Payment Method

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

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

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

Cost Differences

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

Proposed Changes in Billing Requirements

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

* Coalition estimates

Study Design

Process Overview

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

Sample

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

Survey Instrument

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

Survey Analysis (1 of 3)

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

Survey Analysis (2 of 3)

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

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

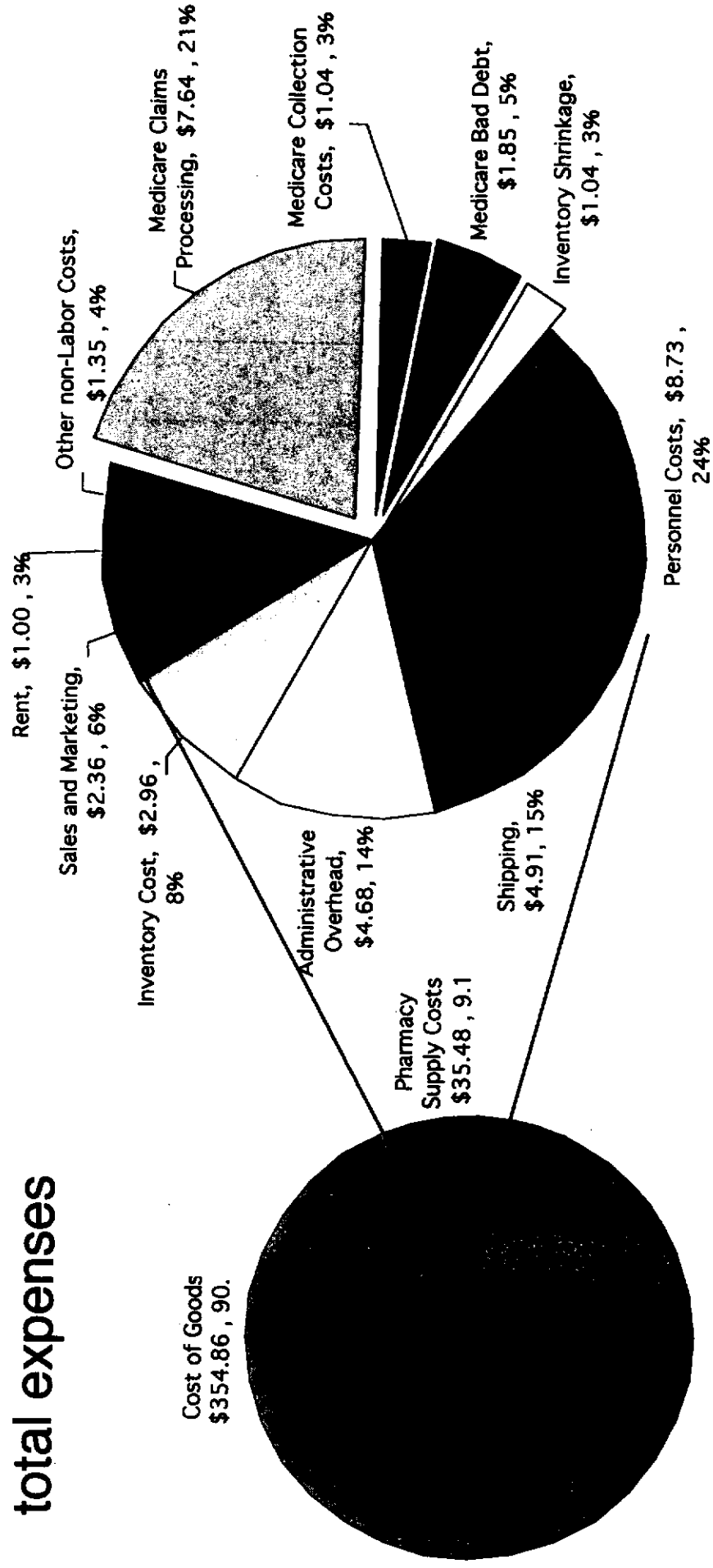
Study Results

Key Calculations

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

Allocation of Costs

Product costs account for 90.9% of total expenses



Conclusions

Conclusions

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

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SEP 30 2005

SEP 30 2005

September 28, 2005

ATTENTION: CMS

RE: Medicare reimbursement to pharmacies

My name is Judy Normoyle, I reside in Bakersfield, CA. (County of Kern) I am a Kidney/Pancreas recipient.

Kern County has a transplant support group, K.A.T.S. (Kern Area Transplant Support). I am currently the president of this support group. Our group has approximately eighty to one hundred members at this time. Anyone interested in Transplantation is invited to attend our meetings. We are also partners with Onelegacy, the donor network program for Southern California.

I just became aware of Medicare's decision to cut back the reimbursement to the transplant pharmacies. This causes great concern. Pharmacies that have this decrease will choose not to accept patients on Medicare.

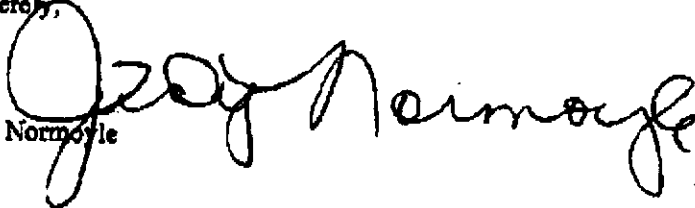
The majority of our transplant recipients are on Medicare and depend on this coverage to help with their immunosuppressant medications. Many of us only have the 80 percent coverage that Medicare provides. We must pay out of our pockets the remaining 20%. As we all know, immunosuppressants are very expensive.

I am very happy with my transplant pharmacy (2010 Transplant Pharmacy in Los Angeles). I do not wish to lose my Pharmacy due to this purposed cutback.

I speak for many of our members of (K.A.T.S), in urging you not to make this cutback.

Sincerely,

Judy Normoyle





Bristol-Myers Squibb Company

P.O. Box 4500 Princeton, NJ 08543-4500 609-897-2000

SEP 30 2005

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September 29, 2005

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

**Re: CMS-1502-P: Medicare Program; Revisions to Payment
Policies Under the Physician Fee Schedule for Calendar Year
2006 – ASP Issues**

Dear Administrator McClellan:

Bristol-Myers Squibb Company ("BMS") appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services ("CMS") proposed rule regarding revisions to payment policies under the physician fee schedule for calendar year 2006, published in the Federal Register on August 8, 2005 ("Proposed Rule").¹ BMS is dedicated to extending and enhancing human life by providing the highest quality pharmaceutical and related health care products. The company provides innovative and effective products in many areas including cardiology, infectious disease, oncology, and psychiatry. Our products make a difference in the lives of millions of people and, given our strong commitment to research and development of new treatments, we expect the reach of our products to continue to grow over time.

The Proposed Rule includes possible revisions to the calculation methodology for manufacturers' reported average sales price ("ASP") data. As required by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), CMS uses ASP data to set reimbursement rates for drugs not paid on a cost or prospective payment

¹ 70 Fed. Reg. 45764.



Bristol-Myers Squibb Company

P.O. Box 4500 Princeton, NJ 08543-4500 609-897-2000

basis. If these rates fail to reflect providers' costs, beneficiary access to innovative therapies may be harmed. Therefore, it is critical that CMS establish reporting requirements that enable the agency to collect the data it needs to set appropriate rates. Additionally, because manufacturers may face substantial penalties for submission of incorrect data, it also is essential that CMS provide clear guidance regarding its ASP-reporting requirements.

CMS proposes to require manufacturers to calculate the ASP for direct sales independently from the ASP for indirect sales and report the weighted average of the two ASPs to CMS. BMS is concerned that this proposal improves neither the accuracy nor the clarity of CMS' ASP calculation and reporting requirements. Based on our own internal analysis, BMS does not see any predictable improvement to the accuracy of reported ASP figures as a result of implementing CMS' proposed changes. Instead, we believe this new methodology will only make an already complicated calculation even more difficult to perform. By requiring manufacturers to calculate a direct sales ASP, an indirect sales ASP, and a weighted average of the two, the proposal makes the data analysis, quality control, and calculation processes much more complex and burdensome. This added complexity increases the risk of error and the likelihood of ASP resubmissions.

BMS recommends that CMS not finalize this proposal. However, if CMS decides that the revised methodology's substantially increased complexity is offset by marginal improvements in ASP accuracy, we recommend that CMS allow manufacturers to choose whether to apply it. Each manufacturer should be allowed to elect to use the current methodology or the new methodology for all of its ASP drugs on a calendar year basis.

If CMS finalizes the proposal, we also request that the agency provide much more detailed definitions of "direct sales" and "indirect sales." The Proposed Rule's definitions are ambiguous, and we have identified many situations in which sales could be classified in either category. One example relates to sales of Erbitux. BMS takes orders for this drug from the wholesaler but ships the product directly to the end customer. The invoice is sent to the wholesaler. It is not clear whether we should determine whether the sales are direct or indirect based on where the product is shipped or where the product is billed. We recommend that this determination be based on the "billed to" entity.

Additionally, if CMS decides to implement the proposed methodology, we strongly recommend that it be made effective no sooner than the April 2006 submission deadline for ASP data for the first quarter of 2006. Manufacturers will need a reasonable amount of time to develop, test, and review the changes to their information systems needed to perform calculations under the proposed methodology. We expect that these changes cannot be implemented between the publication of the final rule in November and the January 2006 (fourth quarter of 2005) reporting period.



Bristol-Myers Squibb Company

P.O. Box 4500 Princeton, NJ 08543-4500 609-897-2000

BMS appreciates the opportunity to comment on the Proposed Rule. We hope our comments will help CMS protect beneficiary access to innovative therapies through the use of a fair and accurate ASP reporting system. Please feel free to contact me at 609-897-4555 if you have any questions regarding these comments. Thank you for your attention to this very important matter.

Sincerely,

Zoltan Szabo

Senior Director, Pricing and Reimbursement

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The Monterey Bay Psychological Association 2005

1406 Mission Street • Santa Cruz • California • 95060 831 • 426 • 4735
www.montereybaypsychologicalassociation.com

September 17, 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:

I am writing this letter on behalf of, and at the request of the Monterey Bay Psychological Association (MBPA) Board to strongly support the proposed revision of the physician payment localities in California recently published in the reference rule.

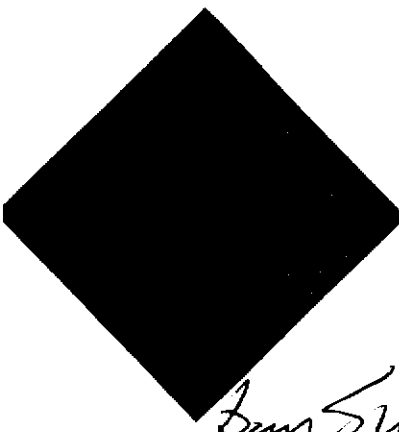
The Center for Medicare and Medicaid Services (CMS) acknowledges their responsibility to manage physician (and other provider) payment localities and I understand that there have been no revisions to the localities since 1996. You have selected two of the most highly impacted areas in our state, Santa Cruz and Sonoma Counties, to begin correcting the problems of payment inequities. We 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. There are other providers, such as Psychologists, who also have a considerable interest in the outcome of this change. The Monterey Bay Psychological Association, of which I am the President, represents 127 psychologists in Santa Cruz, Monterey and San Benito Counties. The reimbursement inequity among neighboring counties, particularly Santa Clara County, has a negative impact on the availability of mental health services to Medicare recipients in our area. As practicing psychologists, many of us work closely with physicians, though we are beginning to see a shortage and anticipate, under the present rules, a serious problem. The cost of living in Santa Cruz County is one of the highest in the country, yet we have one of the lowest reimbursement rates in the state. Obviously, this disparity makes it difficult to attract physicians and other service providers to the area. It appears clear to us that you are on the right track to solve this serious problem, one that has an impact on Medicare beneficiaries and providers alike.

Though we 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 our organization also represents. 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. We ask that you seriously consider including Monterey County future revisions.

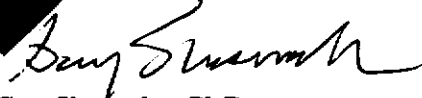
Once again, we strongly support your proposed revision to the physician payment localities in California.

Respectfully yours,



The Monterey Bay Psychological Association 2005

1406 Mission Street • Santa Cruz • California • 95060 831 • 426 • 4735
www.montereybaypsychologicalassociation.com



Gary Shoemaker, Ph.D.
President
Monterey Bay Psychological Association

SEP 30 2005

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Supporting Quality Health Care Services at Home



Via Federal Express

September 29, 2005

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

Re: Medicare Program Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006; Proposed Rule [CMS-1502 – P] (RIN- 0938- AN84), 70 F.R. 45764 (August 8, 2005).

Inhalation Drugs and Dispensing Fee

Dear Dr. McClellan:

The American Association for Homecare (AAHomecare) submits the following comments in response to the Centers for Medicare and Medicaid Services' (CMS') request for comments on the above captioned proposed rule. AAHomecare is the only national association representing every line of service within the homecare community. AAHomecare members include home health agencies and providers and manufacturers of durable medical equipment (DME), prosthetics, orthotics, and supplies (collectively "DMEPOS"), rehab and assistive technologies, and pharmacies that provide home infusion and inhalation drug therapies to patients in their homes.

Our membership reflects a cross-section of homecare providers, including national, regional, and local providers and suppliers. With approximately 800 member companies with 3,000 locations nationwide, AAHomecare and its members are committed to advancing the value and practice of quality health care services at home. AAHomecare members service hundreds of thousands of Medicare beneficiaries who use inhalation drug therapy. Our members are committed to providing beneficiaries with high quality inhalation drug therapy services that promote positive patient outcomes.

As you know, Medicare reimbursement for inhalation drug therapy includes a dispensing fee of \$57.00 for a thirty (30) day drug supply and \$80.00 for a ninety (90) day supply. The preamble to the proposed rule states that the dispensing fee in 2006 is likely to be lower than the 2005 dispensing fee amount. AAHomecare is surprised by this statement because CMS has not shared

any data to support a reduction of any size in the dispensing fee. Moreover, CMS' experience with the current dispensing fee is too limited to conclude that the current payment amount is excessive. We strongly believe that it is too soon to consider a reduction in the dispensing fee payment.

In response to the August 8, 2005, notice of proposed rulemaking (NPRM), AAHomecare requested that Muse & Associates examine the services providers furnish to beneficiaries who use nebulized drug therapy and the impact a reduced dispensing fee would have on those services.¹ The September 2005 Muse study shows that there is no evidence to support a reduction in the current Medicare dispensing fee payment. Providers have experienced cost increases despite regulations intended to produce savings such as guidelines slightly relaxing the restrictions on the timing of deliveries for drug refills. The survey data shows that providers have not benefited from the new guidelines and that shipping costs have increased since 2004. A copy of the September 2005 Muse report is enclosed for your review.

Importantly, almost half of the inhalation drug therapy providers responding stated that they would not be able to continue to service Medicare beneficiaries if CMS reduced the dispensing fee by more than a nominal amount. Fifty percent (50%) stated that they would reduce services to Medicare beneficiaries in the event of a reduction in the dispensing fee. As a whole, providers responding to the survey furnish a comprehensive array of services to beneficiaries receiving inhalation drug therapy. These services encompass every one of the administrative and support functions that Muse & Associates identified in its 2004 report on the costs of delivering services to Medicare inhalation therapy drug patients.² The overwhelming majority of providers believe that the services identified by Muse & Associates are essential to dispensing inhalation drugs. On average, the pharmacies responding to the survey reported that a dispensing fee of \$66.55 for a 30-day drug supply and \$138.80 for a 90-day supply would be adequate in 2006.

These comments address the issues raised by CMS in the NPRM in light of the Muse & Associates' findings. As we discuss in greater detail below, AAHomecare recommends that CMS pay a dispensing fee of \$66.55 for a 30-day supply of inhalation drugs and \$138.80 for a 90-day supply in 2006.

I. BACKGROUND

A. Medicare Reimbursement for Inhalation³ Drugs

Inhalation drugs differ significantly from other outpatient drugs because they require an array of professional and administrative services, including delivery, education, oversight, and monitoring to ensure that the drug therapy is administered safely and effectively in the home. Although these professional and administrative activities are an essential component of furnishing inhalation drugs, Medicare has not explicitly paid for these services. Until 2004,

¹ Muse & Associates, Examination of Inhalation Drug Services to Medicare Beneficiaries Under the Average Sales Price Methodology In Response to the CMS Notice of Proposed Rulemaking (CMS – 1502- P), September 2005, prepared for the American Association for Homecare.

² Muse & Associates, The Costs of Delivering Inhalation Drug Services to Medicare Beneficiaries, August 2004, prepared for the American Association for Homecare.

³ The terms "inhalation drugs" in these comments refer to respiratory drugs used with a nebulizer.

Medicare reimbursed inhalation drugs at 95% of the drug's average whole sale price (AWP), an amount that exceeded the acquisition cost for the drugs. As a consequence, Medicare payment for these drugs came to be viewed as excessive because the supplier's acquisition costs were typically well below the Medicare reimbursement amount. However, suppliers used the difference between the drug acquisition cost and the Medicare reimbursement, the so called "spread," to cover the cost of the professional and administrative functions that were not otherwise reimbursable by Medicare. Industry studies in 2001⁴ and 2002⁵ showed that drug acquisition costs accounted for only a modest portion of the overall costs of servicing Medicare beneficiaries who use inhalation drugs.

The Medicare Modernization Act of 2003 (MMA) reformed Medicare payment for inhalation drugs. Starting in 2005, Medicare pays for inhalation drugs at 106% of the average sales price (ASP) for the drug, or ASP plus a 6% mark-up (ASP + 6%). In calculating the ASP, manufacturers are required to exclude volume discounts, prompt pay discounts, cash discounts, free goods, charge backs and rebates, other than Medicaid rebates. Generally, ASP is a wholesale price, representing the transfer price of the drug from manufacturer to wholesale distributor. Since the great majority of suppliers acquire drugs through distributors, not directly from the manufacturer, ASP + 6% alone is inadequate to cover the professional and administrative costs of furnishing inhalation drugs to beneficiaries in their homes.

B. Muse and Associates' 2004 Study Documenting the Professional and Support Services Furnished to Beneficiaries Receiving Inhalation Drug Therapies and the Costs of those Services

The move to an ASP reimbursement system represented a significant reduction in reimbursement for inhalation drugs. For example, in the preamble to the proposed rule implementing the ASP methodology, CMS projected that the 2005 ASP + 6% payment amount for albuterol sulfate and ipratropium bromide, the two most widely prescribed inhalation drugs, would be \$0.04 and \$0.30 per milligram respectively. CMS projected that 2005 payment amounts for these drugs would result in an 89% reduction in Medicare payments compared to 2003 levels. CMS acknowledged its concern that the overall payment reductions for inhalation drugs would result in access problems for nearly one million Medicare beneficiaries. CMS also recognized that the ASP + 6% methodology was inadequate to cover the costs of the services necessary to furnish inhalation drugs to Medicare beneficiaries. CMS proposed adding a dispensing fee to the ASP + 6% payment amount to account for these services and requested data on the services and their costs.

In response, AAHomecare requested that Muse & Associates document the professional and support services performed by providers and the costs of those services. The 2004 Muse study concluded that an additional payment of \$68.10 per service encounter was necessary for

⁴ The Lewin Group published a study in 2001 showing that the acquisition cost of inhalation drugs accounts for only 26 percent (%) of the total costs of furnishing inhalation drug therapy to Medicare beneficiaries. The Lewin Group, Product and Service Costs of Providing Respiratory and Infusion Therapies to Medicare Patients in the Home, prepared for the American Association for Homecare, September 10, 2001.

⁵ In 2003, Lewin found that the drug costs for inhalation therapy account for 27% of the total costs of furnishing this therapy to Medicare beneficiaries. The Lewin Group, Operating and Service Costs of Providing Inhalation and Infusion Therapies to Medicare Patients in the Home: 2003 Update, prepared for the American Association for Homecare, October 13, 2003.

suppliers to continue to provide 2004 service levels and maintain a reasonable operating margin of 7% in 2005.^{6 7} AAHomecare recommended an additional payment of \$68.10 per service encounter as defined by Muse as the amount necessary for an adequate dispensing fee in 2005.⁸

The 2004 Muse & Associates study analyzed data from 109 pharmacies representing 2,448 branch locations that provided respiratory and/or medical equipment under Medicare Part B. These 2,448 branches provided inhalation drug therapy to 337,348 Medicare beneficiaries per month in the first quarter of 2004. These Medicare beneficiaries, in turn, were estimated to be 61% of all Medicare inhalation drug therapy patients during the same period. The Muse study documented the professional and administrative components of furnishing inhalation drugs to Medicare beneficiaries, providing support for prior industry studies.

Specifically, Muse identified several key activities required to service new and existing inhalation drug patients. These critical functions included the following: clinical intake; establishing and revising the plan of care; care coordination; patient education; caregiver training; compliance monitoring; in-home visits; delivery of services and billings and collections. The majority of pharmacies that responded to the Muse survey indicated that they would be unable to continue to service Medicare beneficiaries if the Medicare payment amount was only ASP + 6%. Using the Muse data, CMS included a \$57.00 dispensing fee for a 30-day supply of inhalation drugs in 2005. CMS also established an \$80.00 dispensing fee for a 90-day supply.

C. The August 8, 2005 NPRM

On August 8, 2005, CMS published an NPRM stating that it expected the 2006 dispensing fee for inhalation drugs to be lower than what it was in 2005. CMS noted that, beginning in 2006, Medicare beneficiaries would have the option of using metered dose inhalers (MDIs) covered under Medicare Part D. Given the expanded options that will be available to beneficiaries in 2006, CMS suggested that it may be appropriate to reduce the dispensing fee amount for nebulized inhalation drugs. CMS also questioned whether the current dispensing fee amount encompassed an appropriate scope of service. The NPRM solicited public comments on what services should fall within a dispensing fee for inhalation drugs and the dispensing fee amount that would be adequate in 2006.

Specifically, CMS asked for data in response to the following questions:

- What is an appropriate dispensing fee level for 2006?
- What services do suppliers currently furnish as part of inhalation drug therapy and what are the costs of those services?
- Are suppliers using the 90-day shipping option to reduce unit shipping costs, and if not, the reasons why?

⁶Muse & Associates, *supra*, footnote 2.

⁷ Muse defined "service encounter" as each instance the J-code was used to bill Medicare. Muse determined that a service encounter occurred 8.8 times a year.

⁸ The Muse study refers to "an additional payment amount" per service encounter, that terminology is interchangeable with "dispensing fee."

- Have suppliers shifted their shipping to ground services utilizing the revised guidelines regarding the timeframe for delivery?
- What will be the impact of a reduction in the dispensing fee for 2006?
- What will be the impact of the new Medicare Part D benefit on access to inhalation drugs?

D. The September 2005 Muse Study

On behalf of AAHomecare, Muse & Associates surveyed approximately 850 homecare pharmacies in August and September 2005. The survey sample included a cross-section of homecare pharmacies: large national pharmacies, mid-sized regional operations, and small local providers. Eighty-nine pharmacies responded to the survey. Seven responses were eliminated because the pharmacies either did not provide inhalation drugs or they missed the deadline for responding, resulting in a final sample of 82 pharmacies. Using demographic data comparing respondents from the 2004 study, Muse estimated that 55% to 60% of all Medicare inhalation drug therapy patients are served by the pharmacies responding to the 2005 survey. The 2005 Muse report is the first report to analyze the impact of Medicare reimbursement on inhalation drug pharmacies since the implementation of the ASP methodology.

Muse asked providers to respond to specific questions based on the issues CMS raised in the NPRM. Section 1 asked providers about the introduction of the 90-day supply schedule for inhalation drugs. Section 2 asked providers to identify the services that CMS *should* include in the dispensing fee payment. This section also solicited information about *the services that providers actually furnish to beneficiaries* receiving inhalation drug therapy. Finally, Section 3 asked providers about the impact of a reduction in the dispensing fee on access to inhalation drug therapy. Section 3 also asked providers about the impact of the Medicare Part D benefit on access to inhalation drugs. We discuss the Muse findings in more detail below.

II. COMMENTS

A. There is No Evidence to Support a Reduction in the Dispensing Fee Amount for 2006.

1. *Providers Perform a Broad and Comprehensive Array of Services for Inhalation Drug Therapy Patients and These Services are Essential to Administer Inhalation Drug Therapies Safely and Effectively in the Home*

The NPRM solicited comments on what services *should* be included in the dispensing fee amount. CMS raised its concern that the current dispensing fee may be too high because it includes services that are not appropriately within the scope of a dispensing fee. CMS also expressed an interest in understanding the scope of services that providers *in fact* furnish to Medicare beneficiaries. It appears that CMS may be considering reducing the scope of services that beneficiaries receive by excluding some of these services from the dispensing fee payment. We urge caution in undertaking this approach. It is extremely difficult to pick and choose among the services that beneficiaries currently receive to include one and exclude another without affecting the overall quality of care beneficiaries receive.

To address this issue, Muse asked pharmacies to identify the services that *should be within the scope of the Medicare dispensing fee* and to identify the services that *are actually within their own scope of service*. The 2005 Muse survey further refined the service categories identified in 2004, using the following broad categories:

- Intake
- Compounding, dispensing, and pharmacy assessment
- Delivery, set-up, and patient education
- Follow-up and compliance monitoring
- Quality assurance, accreditation, licensing, and regulatory compliance,
- Medicare billing and compliance
- Other direct and indirect costs and expenses

Muse worked with industry experts to breakdown these broad categories into discrete services, arriving at a total of 117 services that fell within one of each of the seven categories. A majority of suppliers responding to the survey agreed that each of the services within the seven categories should be included for reimbursement under the dispensing fee.^{9 10} Similarly, a majority of respondents are actually furnishing nearly all of the inhalation drug therapy services that Muse identified in the survey.^{11 12}

The responses show a remarkable consensus across the provider community both in terms of what providers believe *should be* within the scope of service and what *actually is* within the scope of service providers deliver. This level of agreement among providers is evidence that the services are generally viewed as part of the appropriate standard of care for inhalation drug therapy. They are also significant given the fact that CMS has never required adherence to any meaningful standards from this segment of the healthcare community. Based on these findings, it is clear to us that CMS cannot simply pick and choose the services that it will reimburse as part

⁹ Muse, at 9-16.

¹⁰ For each service category, the proportion of suppliers agreeing that all of the services identified in the survey fell within the scope of a dispensing fee, using the weighted average of positive responses:

Intake	97.3%
Compounding, Dispensing, and Pharmacy Assessment	96.8%
Delivery, Set-up, and Patient Education	95.8%
Follow-up and Compliance Monitoring	91.4%
Quality Assurance, Accreditation, Licensing and Regulatory Compliance	88.8%
Medicare Billing and Compliance	96.7%
Other Direct and Indirect Costs and Expenses	87.5%

¹¹ Muse, at 17-23.

¹² For each service category, the proportion of pharmacies currently providing all of the inhalation drug therapy services identified by Muse to Medicare beneficiaries, using the weighted average of positive responses:

Intake	97.2%
Compounding, Dispensing, and Pharmacy Assessment	97.4%
Delivery, Set-up, and Patient Education	96.5%
Follow-up and Compliance Monitoring	95.3%
Quality Assurance, Accreditation, Licensing and Regulatory Compliance	94.5%
Medicare Billing and Compliance	99.7%
Other Direct and Indirect Costs	94.6%

of the dispensing fee for inhalation drugs. Inasmuch as providers are currently furnishing the vast majority of these services, excluding some of them from the dispensing fee payment effectively reduces the level of care and service that beneficiaries using inhalation drugs currently receive.

2. Reducing the Dispensing Fee for Inhalation Drug Therapy by more than a Nominal Amount will Either Reduce Access or Compromise Services

Almost half of the respondents, 44.4%, stated they would stop offering inhalation drugs to Medicare beneficiaries if CMS reduces the dispensing fee by more than a nominal amount. Half of the respondents, 50.4% stated they would be forced to curtail services to beneficiaries. A small portion of providers, 2.5%, indicated that they would cease to operate entirely if CMS reduces the dispensing fee by more than a nominal amount. Thus, a reduction in the dispensing fee amount is likely to affect Medicare beneficiary access to the inhalation drug therapy services that they currently receive.

3. Providers Have Experienced Cost Increases Despite Regulations Intended to Streamline Some Provider Operations

Muse also surveyed providers on the impact of the new option to ship a 90-day supply of inhalation drugs and the guidelines relaxing restrictions on shipping and billing for refills. The NPRM indicates that CMS expected that the new guidelines would reduce provider operating costs related to shipping. As we noted above, providers have not realized the cost savings CMS expected. The 2005 Muse study indicates that supplier's costs have increased, not decreased. The use of overnight shipping services actually increased slightly since 2004, from 56.3% to 56.9%. The average overall daily cost per shipment increased 18.8% from \$12.13 in 2004 to \$14.41 in 2005.

These results are understandable given the patient population that these providers serve.

According to respondents, hospitals discharge patients with only enough medication for one or two doses. Depending on the provider's service area, overnight shipping may be the fastest and most reliable option for delivering the remaining doses. Another factor that influences delivery costs is beneficiary behavior. A number of pharmacies surveyed explained that many beneficiaries wait until they run out of doses to order refills, creating a crisis that requires the provider to respond with an overnight delivery. These operational trends, combined with publicly-acknowledged record prices for fuel, which translate into higher delivery costs in the form of rate increases and/or fuel surcharges, have resulted in higher in-home delivery costs than in the original study year of CY 2003.

Muse also found that 90-day drug supply shipments constitute a very small portion of total shipments for inhalation drugs. Nearly seventy-seven percent (76.8%) of the pharmacies responding to the survey *do not* ship 90-day drug supplies at all. Of the remaining 23.2% that do, the 90-day shipments represent only 2.67% of their total business. A majority of providers use a 30-day shipping cycle either because monthly shipments foster more frequent patient contact

which promotes compliance on the patient's part (96.1%), or because patients' prescriptions often change within the 90-day cycle (96.2%).¹³ We note that in the latter scenario, the supplier cannot bill for a dispensing fee again during the 90-day cycle. Less than 1% of respondents indicated that they use a 30-day shipping cycle because it is more profitable than the 90-day cycle. About two-thirds of the respondents, 76.4%, stated that the payment for a 90-day drug supply was inadequate in light of the support services they continue to provide on a monthly basis. Clearly, there are business and clinical factors influencing provider's shipping costs that cannot be easily resolved.

4. The September 2005 Muse Study Findings Support a 2006 Dispensing Fee of \$66.55 for a 30-Day Drug Supply and \$138.80 for a 90-Day Drug Supply

There is no evidence to support a reduction in the dispensing fee amount for inhalation drugs in 2006. Rather the September 2005 Muse study indicates that providers furnish a comprehensive scope of services to beneficiaries receiving inhalation drug therapies. The survey also revealed a high level of agreement among providers with respect to the services that should be reimbursed under the inhalation drug dispensing fee. At the same time, the Muse & Associates findings indicate that Medicare beneficiaries already receive most of these services from their providers. Providers' costs have increased. The increased costs for shipping are not surprising given trends in the overall economy relating to gas prices. However, the Muse study also identifies a number of factors that influence shipping costs such as patient demographics that providers cannot easily control. Together these findings support the conclusion that providers continue to deliver high quality and comprehensive services to Medicare beneficiaries even in the face of rising costs. Providers surveyed by Muse believe that an appropriate dispensing fee for a 30-day drug supply is \$66.55 and that a dispensing fee of \$138.80 would be adequate for a 90-day drug supply in 2006. AAHomecare supports these recommendations.

B. There is No Evidence to Suggest that Clinicians will Shift Elderly Patients with Chronic Obstructive Lung Disease (COPD) from Nebulizers to MDIs

Beginning in 2006, Medicare Part D will cover and pay for respiratory medications delivered via MDIs. The preamble to the proposed rule implies that many beneficiaries may shift from nebulized inhalation drugs to MDIs in 2006. CMS cites no evidence to support such a shift nor are we aware that such data exists. As we discussed in our comments last year, the weight of clinical experience strongly supports inhalation drug therapy as the treatment of choice for individuals with moderate to severe COPD. While studies may not reveal significant differences in the use of nebulized inhalation drugs versus those delivered via an MDI, the research does raise concerns about the ability of MDIs to adequately deposit the medication in the lungs, which is necessary for effective treatment, especially for patients suffering from acute exacerbations. In addition, numerous studies cite efficacy and delivery issues associated with MDI use in the elderly.¹⁴

¹³ Muse, at 8.

¹⁴ See, Roche N, Huchon GJ. Rationale for the Choice of Aerosol Delivery System. J Aerosol Medicine. 2000 Winter;13(4):393-404: (MDI is often ill used in the elderly); Goodman DE, et al. The Influence of Age, Diagnosis and Gender on Proper use of MDIs. Am J Respir Crit Care Med. 1994 Nov;150:1219-21: (Most patients use their MDIs incorrectly).

The state of research is such that there simply are no conclusive studies to show the greater effectiveness of nebulized inhalation drugs over MDIs, especially for the very young and the old. However, the clinical standard of practice for the delivery of inhalation drugs to manage patients with COPD and other chronic pulmonary disorders has long been and continues to be *nebulized medications*. While MDI therapy can be useful, especially during the early stages of the disease and as an adjunct to nebulizer therapy, the use of nebulized medications has been established as the treatment of choice and the current standard of practice in the later, moderate to severe stages. The projection that beneficiaries will shift to MDIs when the new drug benefit is effective is nothing more than speculation at this time.

III. CONCLUSION

AAHomecare strongly believes that it is premature to consider reducing the dispensing fee for inhalation drug therapy. There is no supporting data that would prompt a payment reduction. Moreover, both providers and CMS have had only limited experience with the current dispensing fee amount. As a result, there is no basis on which to conclude the payment amount is excessive. AAHomecare data shows that providers continue to furnish a comprehensive array of inhalation drug therapy services to Medicare beneficiaries even in the face of rising costs. A reduction in the dispensing fee amount will reduce access and compromise the services that beneficiaries are getting now. AAHomecare recommends that CMS pay a dispensing fee of \$66.55 for a 30-day supply of inhalation drugs and \$138.80 for a 90-day supply in 2006.

We sincerely appreciate the opportunity to submit these comments and remain available to discuss them further with you at your convenience. Please do not hesitate to call me if you have any questions.

Sincerely yours,



Kay Cox
President & CEO

cc: Herb B. Kuhn, Director, Center for Medicare Management
Lawrence D. Wilson, Director, Chronic Care Policy Group

Enclosure (1)

**Examination of Inhalation Drug Services
to Medicare Beneficiaries
Under the Average Sales Price Reimbursement Methodology
in Response to the CMS Notice of Proposed Rule Making
(CMS-1502-P)**

September 2005



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Executive Summary

The Centers for Medicare and Medicaid Services (CMS) is revisiting the issue of the dispensing fee for nebulized inhalation drug services for CY 2006. In a Notice of Proposed Rulemaking (NPRM) released in early August 2005, CMS stated that they believe the CY 2006 dispensing fee for nebulized inhalation drugs will be lower than the current \$57 per 30-day supply and \$80 per 90-day supply dispensing fees established for 2005. They have requested information to help them determine an appropriate dispensing fee for CY 2006 and beyond. They are also seeking input regarding the utilization of inhalation drug services, the 90-day supply schedule, and other associated data in order to determine an appropriate 2006 dispensing fee for CY 2006.

In response to the NPRM, Muse & Associates, under contract to the American Association for Homecare (AAHomecare), conducted a survey to study the services delivered to Medicare beneficiaries using nebulized inhalation drug therapy and the impact of a reduced dispensing fee on homecare pharmacies and beneficiaries.

The objective of the study is to provide CMS with relevant data associated with inhalation drug services in order to determine an appropriate dispensing fee for CY 2006 and beyond that will enable homecare pharmacies to provide quality services to Medicare beneficiaries. The study is based on 89 respondents who serve between 55 percent and 60 percent of all Medicare inhalation drug therapy patients. It responds to each of the specific questions raised by CMS in its NPRM.

90-Day Supply Schedule

Examination of the responses indicates that only 0.62 percent of all shipments utilized 90-day supply schedule.¹ Approximately 77 percent of homecare pharmacies do not utilize the 90-day supply schedule at all. Of the 23.2 percent of pharmacies that do ship using a 90-day supply schedule, this option represented only 2.67 percent of their total shipments.

Under the revised shipping guidelines, respondents reported that the use of overnight/express shipping increased only slightly between 2004 and 2005, from 56.3 percent to 56.9 percent. In addition, the overall average delivery cost per shipment increased from \$12.13 in 2004 to \$14.41 in 2005, an increase of 18.8 percent.

Nebulized Inhalation Drug Services

Inhalation therapy services were grouped into seven major service categories representing 117 discrete services. Respondents indicated that all of the seven major service categories, which included 117 discrete services, should be offered under the dispensing fee. Overall, respondents indicated that 93.2 percent of all listed services should be included in the dispensing fee.

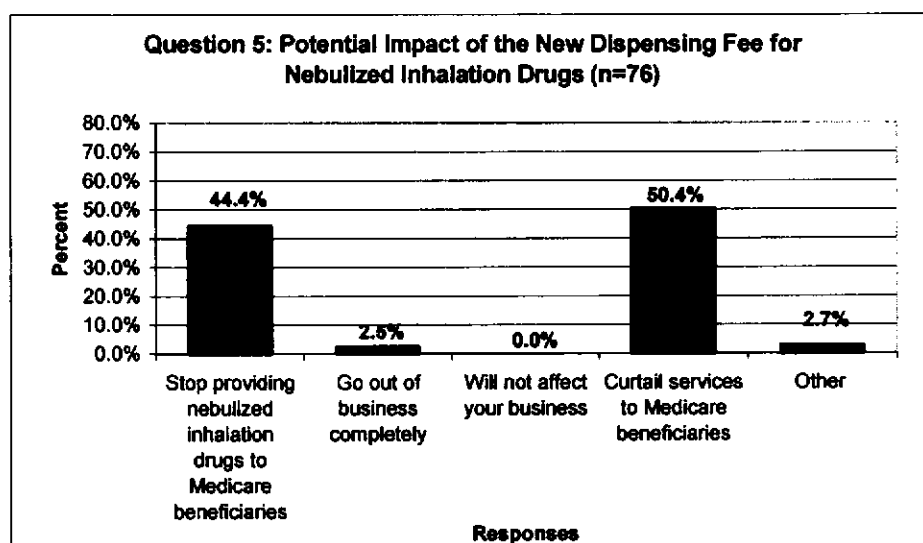
¹ Based on 23.2 percent of the respondents who indicated that they used a 90-day supply schedule. The 90-day supply schedule represented 2.6 percent of their shipments and 0.5 percent of all shipments ($0.232 \times .0267$).

Almost all respondents felt that the scope of services they are currently providing to Medicare beneficiaries is what should be reimbursed under the dispensing fee.

Appropriate Dispensing Fee for 30-Day and 90-Day Shipments

On average, pharmacies reported that an appropriate dispensing fee for a 30-day supply schedule should be \$66.55. Likewise, for a 90-day supply schedule, they indicated that the appropriate dispensing fee should be \$138.80.

If the dispensing fee were to be reduced by more than a nominal amount, nearly 45 percent of respondents stated that they would stop providing inhalation drugs to Medicare beneficiaries. Fifty percent of respondents stated that they would curtail services to Medicare beneficiaries. Other pharmacies stated that they would ask beneficiaries to pay for these services or go out of business.



Potential Impact on Medicare Part D

Most respondents believe that new Medicare Part D prescription drug benefit will not affect access to nebulized inhalation drugs because it is a Medicare Part B benefit and is not covered under Part D at this time. Other pharmacies were unsure about the impact of Part D on nebulized inhalation drug therapy and stated that they did not know enough about the new benefit to comment. Among respondents, there is some concern about the potential increase in the use of MDIs as a substitute for nebulized inhalation drug therapy, and some noted that nebulized medication use in the COPD population typically occurs after the use of MDIs has been determined by the treating physician to be ineffective in relieving symptoms of respiratory disease.

Purpose of the Study

CMS is revisiting the issue of the dispensing fee for nebulized inhalation drug services for CY 2006. In a Notice of Proposed Rulemaking (NPRM) released in early August 2005, CMS stated that they believe the CY 2006 dispensing fee for nebulized inhalation drugs will be lower than the current \$57 per 30-day supply and \$80 per 90-day supply dispensing fees established for 2005. They have requested information to help them determine an appropriate dispensing fee for CY 2006 and beyond. They are also seeking input regarding the utilization of inhalation drug services, the 90-day supply schedule, and other associated data in order to determine an appropriate 2006 dispensing fee for CY 2006.

In response to the NPRM, Muse & Associates, under contract to the American Association for Homecare (AAHomecare), conducted a survey to study the services delivered to Medicare beneficiaries using nebulized inhalation drug therapy and the impact of a reduced dispensing fee on homecare pharmacies and beneficiaries.

The objective of this study is to provide CMS with relevant data associated with inhalation drug services in order to determine an appropriate dispensing fee for CY 2006 and beyond that will enable homecare pharmacies to provide quality services to Medicare beneficiaries. The purpose of this study, which reflects current business practices, is to gain an understanding of the various inhalation drug services that are currently offered to Medicare beneficiaries and what services homecare pharmacies believe should fall within the scope of the dispensing fee. In addition, we also collected data on the utilization of the 90-day supply schedule and its impact on shipping costs since its implementation in January 2005. The study represents one of the first efforts to collect current information to address the impact of the recently introduced ASP + 6% reimbursement methodology on the provision of prescription drug services to Medicare beneficiaries.

Background

Under provisions contained in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), the Centers for Medicare and Medicaid Services (CMS) was tasked with the responsibility for reforming the reimbursement methodology for prescription drugs covered under Medicare Part B, including inhalation therapy drugs. Through the end of CY 2004, Part B drugs were reimbursed under a system based on Average Wholesale Price (AWP). Beginning in CY 2005, CMS changed the reimbursement methodology for Part B drugs from AWP to Average Sales Price plus six percent (ASP + 6%).

Unlike most other types of drug administration, inhalation therapy requires an array of professional services, including delivery, education, oversight, and monitoring, in order to guarantee that the drugs can be safely administered in patients' homes. Because of the perception that reimbursement of inhalation therapy drugs at ASP + 6% would be inadequate to meet these costs, AHomecare commissioned a study in 2004 to determine the impact of changing the reimbursement methodology and the costs associated with inhalation drug services that would no longer be funded through the drug reimbursement.² The objective of the study was to quantify the costs of providing inhalation therapy care to Medicare Beneficiaries in their homes, including those costs associated with the initial visit, ongoing visits, and administration/operational/overhead activities. Based on the cost, time, and services information collected from 109 homecare care pharmacies, we concluded that the appropriate dispensing fee for inhalation drug services would be \$68.10 per service encounter in 2005. In the 2005 final rule, CMS established dispensing fees of \$57 per 30-day supply schedule and \$80 per 90-day supply schedule fees for CY 2005.

The current study responds to CMS' request for information on the services delivered to Medicare beneficiaries using nebulized inhalation therapy, use of 90-day supply schedule, and the impact of a reduced dispensing fee on homecare pharmacies and beneficiaries.

² Muse & Associates, op. cit.

Survey Methodology

To respond to CMS' request and gather relevant information on utilization of nebulized inhalation drug services, the 90-day supply schedule, and other associated data, a survey instrument was developed (Appendix A). The survey instrument consisted of three sections:

- Section 1: Questions regarding the introduction of the 90-day supply schedule for nebulized inhalation drugs in 2005
- Section 2: Questions about the specific services that are included when dispensing nebulized inhalation drugs and the specific costs associated with providing them
- Section 3: Questions on the impact of potential changes to the dispensing fee in CY 2006.

The survey was administered between mid-August and early September 2005 to a diverse national sample of approximately 850 homecare pharmacies. The sample included most of the large national, multi-state homecare pharmacy suppliers as well as medium-sized regional operations and small local providers. Technical assistance by Muse & Associates staff was provided to answer questions about the study and to help respondents complete the survey form.

A total of 89 completed surveys were received. However, seven respondents were eliminated because they either did not dispense inhalation drugs or missed the submission deadline. Therefore, the final set of responses used for analysis consisted of 82 surveys. Participating pharmacies represent 55 percent and 60 percent of all Medicare inhalation drug therapy patients.³

Section 1: 90-Day Supply Option (Questions 1 and 2)

The survey first inquires about utilization of the 90-day supply option for nebulized inhalation drugs. CMS introduced this supply schedule in the 2005 Physician Fee Schedule as an option to reduce pharmacies' dispensing and shipping costs. Prior to CY 2004, inhalation drugs were shipped only on a 30-day supply schedule. The survey asked pharmacies if they have utilized the 90-day supply schedule and what percent of their shipments were 90-day supply shipments. If pharmacies did not use the option, reasons for not utilizing the options were requested. As part of the revised guidelines, the survey also requested information on percent of inhalation drugs shipped overnight/express or ground in CY 2004 and CY 2005. Pharmacies were also asked to list the average delivery costs per shipment in CY 2004 and CY 2005.

Section 2: Services Included in the Dispensing Nebulized Inhalation Drugs (Questions 3 and 4)

Section 2 of the survey deals specifically with nebulized inhalation drug services. Unlike the 2004 Muse & Associates survey, which only outlined broad service categories, this follow up

³ The 55 to 60 percent figures were derived from the Muse & Associates 2004 study on "The Costs of Delivering Inhalation Drug Services to Medicare Beneficiaries," August 2004.

survey enumerated all services within each category, providing a more detailed list. Service categories include:

- Intake;
- Compounding, Dispensing, and Pharmacy Assessment;
- Delivery, Set-up and Patient Education;
- Follow-up and Compliance Monitoring;
- Quality Assurance, Accreditation, Licensing, and Regulatory Compliance;
- Medicare Billing and Compliance; and
- Other Direct and Indirect Costs and Expenses.

Working with industry experts, Muse & Associates compiled a comprehensive list of inhalation drug services offered to Medicare beneficiaries in their homes. The final list consisted of 117 discrete services provided to or on the behalf of Medicare beneficiaries. We asked respondents to identify services that 1) should fall within the scope of the dispensing fee and 2) services they currently provide Medicare beneficiaries. Data on the percent of total cost of inhalation drug services for each category was also requested. We also requested information on total costs for nebulized inhalation drug services for the first quarter of CY 2005.

In the NPRM, CMS also solicited comments on what an appropriate dispensing fee would be for inhalation drug services for Medicare beneficiaries. In response, we asked respondents to provide what they considered to be the appropriate dispensing fee for a 30-day supply and a 90-day supply based on their current business practices.

Section 3: Impact of Potential Changes to the Dispensing Fee (Question 5)

In Section 3, the survey seeks to understand the potential impact of a reduced dispensing fee for nebulized inhalation drug services on beneficiaries and pharmacies.

compliance protocols, (2) patient prescriptions often change within a 90-day period, (3) termination of therapy resulting in unused supplies, and (4) the 90-day supply dispensing fee is inadequate to cover the costs of dispensing a 90-day supply while providing regular monthly services.

Table 1: Reasons for Not Utilizing the 90-day Supply Schedule

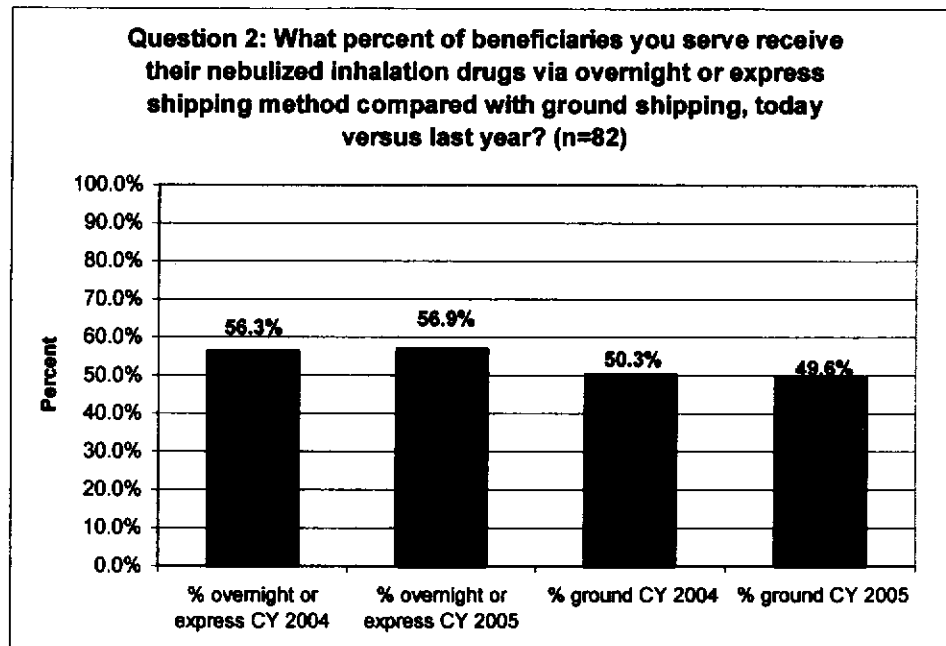
Responses	Percent
Monthly shipments foster more frequent patient contact and correspond better with patient compliance protocols.	96.1%
Patient prescriptions (type of drug, dosage, frequency of administration) often change within a 90-day period due to side effects or other factors.	96.2%
The 90-day dispensing fee rate (\$80.00) is inadequate to cover the costs of dispensing a 90-day supply while providing regular monthly services.	76.4%
The 90-day dispensing fee rate (\$80.00) is adequate, but it is more profitable to ship monthly and bill the 30-day dispensing fee rate (\$57.00).	0.8%
My billing system or internal processes can not handle a 90-day shipment schedule.	14.8%
Patients may terminate therapy due to death or other circumstances within a 90-day period with unused supplies of drugs on hand.	94.0%
Other	29.3%

Some respondents also stated that they did not utilize the 90-day supply option because most doctors designate 30-day supply versus 90-day supply on prescriptions, a higher risk of unused supplies accumulating, and patients' inability to pay a 3-month co-pay at one time.

Effect of Revised Shipping Guidelines

CMS expressed interest in the effect of the revised shipping guidelines on the use of overnight/express delivery services. Examination of the survey responses indicates that the revised guidelines appear to have had little effect. As shown in Figure 2, 56.3 percent of all shipments were delivered using overnight or express shipping in 2004. Respondents reported that overnight or express shipments increased slightly, to 56.9 percent, in 2005. In addition, the overall average cost of delivery services per shipment increased from \$12.13 in 2004 to \$14.41 in 2005, an 18.8 percent increase.

Figure 2



Some respondents commented that they serve a local geographic area and that use of overnight/express shipping is unnecessary because patients usually receive their nebulized inhalation drugs within one day using ground shipping or the pharmacy delivers the medicine to them directly. However other pharmacies commented that overnight/express shipping is still necessary to patient care because many older beneficiaries do not re-order their inhalation drugs until they have run out. Therefore, overnight/express delivery is necessary to prevent hospitalization. Another respondent stated that overnight/express delivery is necessary because patients often need their medications immediately after discharge from the hospital. In these situations, overnight/express shipping method may be the only option for getting the medication to certain beneficiaries.

Section 2: Nebulized Inhalation Drug Services

Services that Should Fall within the Scope of the Dispensing Fee

CMS has repeatedly questioned whether some of the nebulized inhalation drug services offered to Medicare beneficiaries may be outside the scope of a dispensing fee. Therefore, respondents were asked to designate which of 117 discrete services they believed should fall within the dispensing fee and the services they currently offer to Medicare beneficiaries. Presented in Table 2 are data on the proportion of respondents who believe that the various services listed should be included in the 2006 dispensing fee for inhalation drug services. Responses are displayed by total weighted average.⁴

⁴ Weighting is based on total nebulized inhalation drug services costs for the first quarter of CY 2005.

**Table 2: Proportion of Pharmacies that believe Inhalation Drug Services
Should Fall within the Scope of the Dispensing Fee**

	Intake	Total Weighted Average
<i>a. Local service center</i>		
i) Receipt of patient demographics from referral source		97.4%
ii) Receipt of physician information from referral source		97.7%
iii) Notification of central pharmacy re: medication order		95.3%
iv) Use of contracted interpreter services ⁵		90.1%
v) Verification of patient demographic information, confirmation of Medicare number, secondary insurer information		98.4%
vi) Verification of patient emergency contact information obtained		98.6%
vii) Verification of patient caregiver and/or conservator information		97.5%
viii) Secondary insurance information verified		98.2%
ix) Patient set-up in service center computerized MIS		97.4%
x) Patient Assessment- Clinical and Home		98.5%
xi) Discussed patient's deductible and/or co-payments with patient/caregiver		98.4%
<i>b. Pharmacy</i>		
i) Receipt of verbal or written (FAX) order for nebulized medications ⁶		99.1%
ii) Physician contacted for verification of demographic information and license number		98.8%
iii) Independent database contacted for physician UPTN number		94.6%
iv) Patient set-up in pharmacy computerized MIS		99.8%
	Average	97.3%

⁵ For those Medicare beneficiaries who are non-English speaking (i.e., Chinese, Vietnamese, Tagalog (Philippino), Russian, etc).

⁶ Only a licensed pharmacist can receive a verbal order for a medication.

Compounding, Dispensing, and Pharmacy Assessment		Total Weighted Average
<i>a. Compounding</i>		
i)	Specialized facilities (separate from drug storage and dispensing area) required for <i>de novo</i> pharmacy compounding including clean rooms, dedicated air handling equipment, sterile processing equipment, and special clean room garb	97.9%
ii)	Validation, and regular revalidation, of the compounding process to assure sterility and potency to beyond-use-date of the compounded inhalation medication	97.9%
iii)	Sterility and dose potency testing of compounded doses	97.9%
iv)	Specialized training and testing of pharmacists and pharmacy technicians.	93.5%
v)	Annual staff competency reevaluation and testing	92.8%
vi)	Environmental monitoring and testing (some weekly, some monthly)	93.5%
<i>b. Dispensing</i>		
i)	Verification of patient demographic information	98.6%
ii)	Prescription review and verification of qualifying diagnosis (for the ordered medication); dose size and strength; daily dosing frequency ("SIG"); length of therapy	99.0%
iii)	Preparation of dispensing label	99.2%
iv)	Counting and packaging unit doses of medication	99.2%
v)	Pharmacist verification of dose count	99.2%
vi)	Pharmacist verification of five-"Rs" – right patient, right drug, right dose, right time (SIG), right route of administration	99.2%
vii)	Pharmacist verification and "wet-ink" initialing of prescription label	98.4%
<i>c. Pharmacy assessment</i>		
i)	Obtaining information on other medications that the patient may be self-administering	98.0%
ii)	Assurance that inhalation medications are compatible with other medications the patient is taking	97.2%
iii)	Determining other diagnoses and co-morbidities that the patient may be subject to	97.0%
iv)	Assuring that the inhalation medications aren't contraindicated for those secondary diagnoses	96.9%
v)	Making patient aware that pharmacy consulting services are available	93.1%
vi)	Providing a secure, physical space in the pharmacy for patient consulting if a "walk-in" patient requests it	98.9%
vii)	Assessing side effects from the prescribed medication	93.1%
viii)	Assessing patient's dexterity	92.3%
<i>Average</i>		96.8%

Delivery, Set-up, and Patient Education		Total Weighted Average
<i>a. Delivery</i>		
i)	Managing express delivery services	97.7%
ii)	Delivery vehicles for DME and supplies	88.3%
iii)	Packaging and handling of prescriptions for delivery	98.5%
iv)	Delivery staff	96.9%
v)	Obtaining and documenting proof of delivery	98.1%
vi)	After hours/on-call medication delivery	93.9%
vii)	Coordinated and delivered first dose of medications	98.0%
viii)	Delivery Costs: Next day air, Second day air, company vehicle	98.0%
ix)	Changes in delivery schedule	89.7%
<i>b. Set-up</i>		
i)	Completing patient documentation including medical information release forms, HIPAA instruction and compliance forms, certification of patient and/or caregiver training and instruction	98.0%
<i>c. Patient education- written and verbal</i>		
i)	Instruction of patient and/or care giver on implementation of drug treatment regimen, anticipated therapeutic outcome, and potential side-effects	98.5%
ii)	Instruction of patient and/or caregiver on proper infection control in the home	97.7%
iii)	Instruction of patient and/or caregiver on safe handling and storage of medications	98.5%
iv)	Instruction of patient and/or caregiver on emergency preparedness	93.8%
v)	After hours/on-call in-home visit to conduct patients education	89.3%
vi)	Patient charts	98.3%
<i>Average</i>		95.8%

Follow-up and Compliance Monitoring		Total Weighted Average
<i>a. Follow-up</i>		
i)	Assessing patient's retained knowledge of equipment use and purpose of therapy	97.5%
ii)	Assessing retained knowledge of safety and infection control procedures	97.3%
iii)	Dealing with beneficiary change of address, disconnected telephone, change of secondary insurer, illness requiring re-hospitalization, and death	98.1%
iv)	Dealing with changes in physician orders and new prescription	98.2%
v)	Checking for changes in clinical conditions that should be reported to the physician	97.6%
vi)	Conducting periodic reports to the physician	93.1%
<i>b. Compliance monitoring</i>		
i)	Monthly call to verify patient's ongoing medical status and determine if any changes have occurred in either medical condition, other (than nebulizer drugs) medication regime, or both	98.1%
ii)	Verification of number of doses consumed since last dispensing and number of doses remaining	98.2%
iii)	Monthly in-home visits to patients/beneficiaries who have no telephone	76.7%
iv)	Collaboration with physician if medication regime has changed or patient determined to be non compliant	98.1%
v)	After hour/on-call in-home visit to repair exchange equipment	52.6%
<i>Average</i>		91.4%

Quality Assurance, Accreditation, Licensing, and Regulatory Compliance		Total Weighted Average
<i>a. Quality Assurance</i>		
i) Periodic validation of all service delivery and record keeping systems		93.4%
ii) Employee training		92.4%
iii) Periodic validation of employee competency		91.6%
iv) Complaint investigation		91.3%
v) Compliance monitoring and auditing of company service and support systems		91.2%
vi) Customer Satisfaction		92.5%
vii) P.I. Plan		91.2%
viii) Equipment Management		91.1%
ix) Facility Management		91.5%
x) Audits		92.4%
<i>b. Accreditation</i>		
i) Joint Commission for the Accreditation of Health Organizations (JCAHO) or other accreditation		86.3%
ii) Demonstration of adherence to pharmacy operations, compounding, and sterile compounding guidelines promulgated by the United States Pharmacopeia (USP <797>)		90.0%
<i>c. Licensing</i>		
i) Separate pharmacy licenses for nearly all states into which inhalation medications are dispensed. Some states require dual licensing – as a standard retail pharmacy and as a pharmacy that prepares and dispenses sterile products		93.5%
ii) Separate pharmacist licenses for a number of states into which medications are dispensed.		92.5%
iii) Special local water and sewage disposal licensing		70.5%
iv) Licensing of special equipment such as air compressors and water treatment systems		70.4%
v) DME distributor license		87.9%
<i>Average</i>		88.8%

Medicare Billing and Compliance		Total Weighted Average
<i>a. Collation of all required documentation</i>		
i)	Verbal order documentation	97.3%
ii)	Written order documentation	97.3%
iii)	Patient demographics and insurance information	98.1%
iv)	Physician demographics and license information	97.3%
v)	Delivery tickets and signed proof of delivery	98.0%
vi)	Proof of medical necessity	96.9%
vii)	Medical information releases	92.9%
viii)	Proof of receipt of information privacy notice	92.9%
ix)	Proper HCPCS coding of all items dispensed and delivered	92.9%
<i>b. Verification of all required documentation and information</i>		
<i>c. Preparation of an invoice to:</i>		
i)	Medicare	97.8%
ii)	Secondary Insurer	97.0%
iii)	Patient for co-payment and/or deductible	96.9%
<i>d. Computer systems for electronic batching and transmission of invoices to Medicare</i>		97.1%
<i>e. Submission of claim to supplemental insurance plan</i>		97.1%
<i>f. Printing and mailing of deductible/co-payment amount to patient</i>		97.1%
<i>g. Personal financial assessment in the event waiver of co-payment is requested or required</i>		97.1%
<i>h. Collection follow-up with Medicare, secondary insurance and patient</i>		97.0%
<i>i. Posting of reimbursement receipts to individual patient accounts</i>		97.1%
<i>j. Management of co-payment collection hardship waivers</i>		97.1%
<i>k. Review of denials by reason and submission activity</i>		97.1%
<i>l. After appropriate appeals and collection efforts, write off unpaid bills as bad debt</i>		97.1%
<i>Average</i>		96.7%

Other Direct and Indirect Costs and Expenses		Total Weighted Average
a. Medical waste management and removal		92.3%
b. Foreign language interpreter services		89.8%
c. 24-hour, 7-day per week emergency services for medication problems provided by the pharmacy		73.9%
d. Corporate oversight of quality and regulatory systems		72.8%
e. Employee benefits management		92.2%
f. Professional and business liability insurance		93.7%
g. Mileage reimbursement for field staff making home visits		93.3%
h. Telephone expenses		98.0%
i. Uniforms		56.5%
j. Rent		97.1%
k. Repairs		93.0%
l. Utilities		97.1%
Average		87.5%

The overall weighted average suggests that pharmacies accounting for approximately 90 percent of Medicare beneficiaries included in the survey feel that the all 117 services listed in Table 2 should fall within the dispensing fee.

Inhalation Drug Services Currently Provided to Medicare Beneficiaries

Whereas Table 2 presents information on which services homecare pharmacies believe should be covered by the dispensing fee, Table 3 summarizes responses about the services that homecare pharmacies currently provide to Medicare beneficiaries.

**Table 3: Proportion of Pharmacies
Currently Providing Inhalation Drug Services to Medicare Beneficiaries**

	Intake	Total Weighted Average
<i>a. Local service center</i>		
i) Receipt of patient demographics from referral source		98.8%
ii) Receipt of physician information from referral source		91.1%
iii) Notification of central pharmacy re: medication order		95.0%
iv) Use of contracted interpreter services ⁷		90.5%
v) Verification of patient demographic information, confirmation of Medicare number, secondary insurer information		89.9%
vi) Verification of patient emergency contact information obtained		99.6%
vii) Verification of patient caregiver and/or conservator information		98.8%
viii) Secondary insurance information verified		99.3%
ix) Patient set-up in service center computerized MIS		98.5%
x) Patient Assessment- Clinical and Home		98.4%
xi) Discussed patient's deductible and/or co-payments with patient/caregiver		99.6%
<i>b. Pharmacy</i>		
i) Receipt of verbal or written (FAX) order for nebulized medications ⁸		99.5%
ii) Physician contacted for verification of demographic information and license number		99.5%
iii) Independent database contacted for physician UPIN number		99.9%
iv) Patient set-up in pharmacy computerized MIS		99.3%
	<i>Average</i>	97.2%

⁷ For those Medicare beneficiaries who are non-English speaking (i.e., Chinese, Vietnamese, Tagalog (Philippino), Russian, etc).

⁸ Only a licensed pharmacist can receive a verbal order for a medication.

Compounding, Dispensing, and Pharmacy Assessment		Total Weighted Average
<i>a. Compounding</i>		
i) Specialized facilities (separate from drug storage and dispensing area) required for <i>de novo</i> pharmacy compounding including clean rooms, dedicated air handling equipment, sterile processing equipment, and special clean room garb		98.9%
ii) Validation, and regular revalidation, of the compounding process to assure sterility and potency to beyond-use-date of the compounded inhalation medication		98.9%
iii) Sterility and dose potency testing of compounded doses		98.9%
iv) Specialized training and testing of pharmacists and pharmacy technicians.		99.0%
v) Annual staff competency reevaluation and testing		98.2%
vi) Environmental monitoring and testing (some weekly, some monthly)		98.8%
<i>b. Dispensing</i>		
i) Verification of patient demographic information		99.1%
ii) Prescription review and verification of qualifying diagnosis (for the ordered medication); dose size and strength; daily dosing frequency ("SIG"); length of therapy		99.1%
iii) Preparation of dispensing label		98.9%
iv) Counting and packaging unit doses of medication		98.9%
v) Pharmacist verification of dose count		98.9%
vi) Pharmacist verification of five-"Rs" – right patient, right drug, right dose, right time (SIG), right route of administration		98.9%
vii) Pharmacist verification and "wet-ink" initialing of prescription label		98.3%
<i>c. Pharmacy assessment</i>		
i) Obtaining information on other medications that the patient may be self-administering		99.4%
ii) Assurance that inhalation medications are compatible with other medications the patient is taking		99.4%
iii) Determining other diagnoses and co-morbidities that the patient may be subject to		99.3%
iv) Assuring that the inhalation medications aren't contraindicated for those secondary diagnoses		99.2%
v) Making patient aware that pharmacy consulting services are available		98.6%
vi) Providing a secure, physical space in the pharmacy for patient consulting if a "walk-in" patient requests it		78.1%
vii) Assessing side effects from the prescribed medication		95.2%
viii) Assessing patient's dexterity		90.5%
<i>Average</i>		97.4%

Delivery, Set-up, and Patient Education		Total Weighted Average
<i>a. Delivery</i>		
i)	Managing express delivery services	99.5%
ii)	Delivery vehicles for DME and supplies	86.4%
iii)	Packaging and handling of prescriptions for delivery	99.4%
iv)	Delivery staff	95.3%
v)	Obtaining and documenting proof of delivery	99.6%
vi)	After hours/on-call medication delivery	95.0%
vii)	Coordinated and delivered first dose of medications	99.3%
viii)	Delivery Costs: Next day air, Second day air, company vehicle	99.4%
ix)	Changes in delivery schedule	95.6%
<i>b. Set-up</i>		
i)	Completing patient documentation including medical information release forms, HIPAA instruction and compliance forms, certification of patient and/or caregiver training and instruction	92.6%
<i>c. Patient education- written and verbal</i>		
i)	Instruction of patient and/or care giver on implementation of drug treatment regimen, anticipated therapeutic outcome, and potential side-effects	99.4%
ii)	Instruction of patient and/or caregiver on proper infection control in the home	99.0%
iii)	Instruction of patient and/or caregiver on safe handling and storage of medications	99.6%
iv)	Instruction of patient and/or caregiver on emergency preparedness	94.8%
v)	After hours/on-call in-home visit to conduct patients education	90.0%
vi)	Patient charts	99.5%
<i>Average</i>		96.5%

Follow-up and Compliance Monitoring		Total Weighted Average
<i>a. Follow-up</i>		
i)	Assessing patient's retained knowledge of equipment use and purpose of therapy	98.4%
ii)	Assessing retained knowledge of safety and infection control procedures	98.7%
iii)	Dealing with beneficiary change of address, disconnected telephone, change of secondary insurer, illness requiring re-hospitalization, and death	99.5%
iv)	Dealing with changes in physician orders and new prescription	99.5%
v)	Checking for changes in clinical conditions that should be reported to the physician	98.8%
vi)	Conducting periodic reports to the physician	94.2%
<i>b. Compliance monitoring</i>		
i)	Monthly call to verify patient's ongoing medical status and determine if any changes have occurred in either medical condition, other (than nebulizer drugs) medication regime, or both	99.1%
ii)	Verification of number of doses consumed since last dispensing and number of doses remaining	99.5%
iii)	Monthly in-home visits to patients/beneficiaries who have no telephone	71.2%
iv)	Collaboration with physician if medication regime has changed or patient determined to be non compliant	99.4%
v)	After hour/on-call in-home visit to repair exchange equipment	90.0%
<i>Average</i>		95.3%

Quality Assurance, Accreditation, Licensing, and Regulatory Compliance		Total Weighted Average
<i>a. Quality Assurance</i>		
i) Periodic validation of all service delivery and record keeping systems		98.7%
ii) Employee training		99.6%
iii) Periodic validation of employee competency		99.6%
iv) Complaint investigation		99.6%
v) Compliance monitoring and auditing of company service and support systems		99.5%
vi) Customer Satisfaction		99.6%
vii) P.I. Plan		98.5%
viii) Equipment Management		98.2%
ix) Facility Management		98.6%
x) Audits		99.4%
<i>b. Accreditation</i>		
i) Joint Commission for the Accreditation of Health Organizations (JCAHO) or other accreditation		93.6%
ii) Demonstration of adherence to pharmacy operations, compounding, and sterile compounding guidelines promulgated by the United States Pharmacopeia (USP <797>)		93.2%
<i>c. Licensing</i>		
i) Separate pharmacy licenses for nearly all states into which inhalation medications are dispensed. Some states require dual licensing – as a standard retail pharmacy and as a pharmacy that prepares and dispenses sterile products		98.8%
ii) Separate pharmacist licenses for a number of states into which medications are dispensed.		98.3%
iii) Special local water and sewage disposal licensing		69.1%
iv) Licensing of special equipment such as air compressors and water treatment systems		68.3%
v) DME distributor license		94.6%
<i>Average</i>		94.5%

Medicare Billing and Compliance		Total Weighted Average
<i>a. Collation of all required documentation</i>		
i)	Verbal order documentation	99.7%
ii)	Written order documentation	99.7%
iii)	Patient demographics and insurance information	99.7%
iv)	Physician demographics and license information	99.7%
v)	Delivery tickets and signed proof of delivery	99.7%
vi)	Proof of medical necessity	99.5%
vii)	Medical information releases	99.5%
viii)	Proof of receipt of information privacy notice	99.5%
ix)	Proper HCPCS coding of all items dispensed and delivered	99.7%
<i>b. Verification of all required documentation and information</i>		
<i>c. Preparation of an invoice to:</i>		99.0%
i)	Medicare	99.9%
ii)	Secondary Insurer	99.9%
iii)	Patient for co-payment and/or deductible	99.9%
<i>d. Computer systems for electronic batching and transmission of invoices to Medicare</i>		99.7%
<i>e. Submission of claim to supplemental insurance plan</i>		99.7%
<i>f. Printing and mailing of deductible/co-payment amount to patient</i>		99.7%
<i>g. Personal financial assessment in the event waiver of co-payment is requested or required</i>		
<i>h. Collection follow-up with Medicare, secondary insurance and patient</i>		99.7%
<i>i. Posting of reimbursement receipts to individual patient accounts</i>		99.7%
<i>j. Management of co-payment collection hardship waivers</i>		99.7%
<i>k. Review of denials by reason and submission activity</i>		99.7%
<i>l. After appropriate appeals and collection efforts, write off unpaid bills as bad debt</i>		99.7%
<i>Average</i>		99.7%

Other Direct and Indirect Costs and Expenses		Total Weighted Average
a. Medical waste management and removal		97.3%
b. Foreign language interpreter services		94.1%
c. 24-hour, 7-day per week emergency services for medication problems provided by the pharmacy		99.0%
d. Corporate oversight of quality and regulatory systems		99.1%
e. Employee benefits management		98.7%
f. Professional and business liability insurance		99.4%
g. Mileage reimbursement for field staff making home visits		94.4%
h. Telephone expenses		99.6%
i. Uniforms		56.9%
j. Rent		98.7%
k. Repairs		98.7%
l. Utilities		98.7%
Average		94.6%

Examination of the data in Table 3 indicates similar response patterns to what is observed in Table 2. Almost all respondents believe that what is currently being provided to Medicare beneficiaries is what should be included in the dispensing fee.

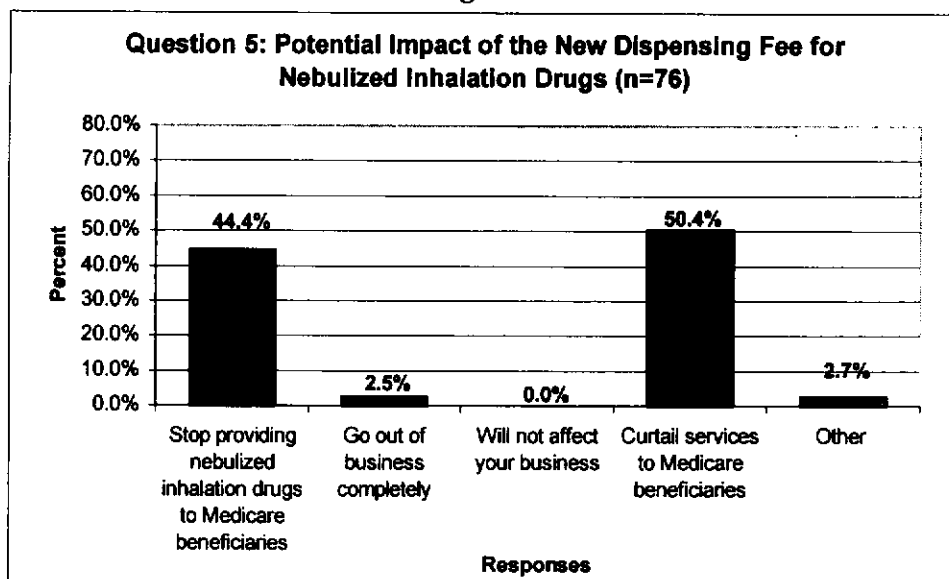
Appropriate CY 2006 Dispensing Fee

CMS expressed interest in the respondents' opinions of what the appropriate dispensing fee should be given the services currently provided to Medicare beneficiaries. On average, pharmacies reported that an appropriate dispensing fee for a 30-day and 90- supply schedules should be \$66.55 and \$138.80, respectively.

Section 3: Potential Impact of a Reduced Dispensing Fee

CMS expressed interest in the potential impact of a reduced dispensing fee on beneficiaries and providers of inhalation drug services. Respondents were asked about how they might react if the CY 2006 dispensing fee were to be reduced by more than a nominal amount. The responses are summarized in Figure 3.

Figure 3



Slightly less than half of respondents (44.4%) stated that they would stop providing nebulized inhalation drugs to Medicare beneficiaries if the dispensing fee were to be reduced by more than a nominal amount. Fifty percent of respondents stated that they would curtail services to Medicare beneficiaries. Some pharmacies commented that they would ask beneficiaries to pay for these services. Other pharmacies expressed frustration and felt they were out of additional options to further reduce their costs.

Medicare Part D

We were also interested in collecting information on how the new Medicare Part D benefit will affect access to nebulized inhalation drugs. Most respondents answered that Medicare Part D will have no affect on access to nebulized inhalation drugs because these drugs fall under the Medicare Part B benefit and will not be covered under Part D at this time. However, some pharmacies felt unsure about the impact of Part D on inhalation drug therapy and stated that they did not know enough about the new benefit to gauge its impact.

Others believe that the Part D benefit will encourage more beneficiaries to use Metered Dose Inhalers (MDIs) instead of nebulizers. Some pharmacies expressed concern that many Medicare beneficiaries suffering from Chronic Obstructive Pulmonary Disease (COPD) have

DO YOU NEED HELP WITH THIS SURVEY?

*If you have any questions, please email
Jaclyn Kuwada at
jkuwada@muse-associates.com.*

Electronic Submission is Available!!!

**Please contact Jaclyn Kuwada at
jkuwada@muse-associates.com
for more information about submitting
responses in Word.**

AAHomecare Follow Up Survey
on Inhalation Drug Services for Medicare Beneficiaries

Please complete the following survey. If you have any questions, please email Jaclyn Kuwada at jkuwada@muse-associates.com.

Confidentiality

Information provided to Muse & Associates will remain confidential. All information provided by respondents will be presented in aggregate and individual company's information will not be disclosed.

Returning the Survey

Please mail the completed survey to Jaclyn Kuwada at Muse & Associates, 1775 I Street NW, Suite 320, Washington, DC 20006 in the enclosed envelope or email it to jkuwada@muse-associates.com. Please return the survey by **September 6, 2005**. You may also fax the survey to 202-496-0201.

This follow-up survey instrument involves three sections:

- Questions 1 and 2 request information about the introduction of a 90-day supply schedule for nebulized inhalation drugs in 2005. We are interested in knowing what has happened as a result of this change.
- Questions 3 and 4 request detailed information about the specific services that are included when dispensing nebulized inhalation drugs; which of these services you provide; and, how much it costs you to provide them.
- Question 5 requests information about the impact of potential changes to the dispensing fee in 2006.

AAHomecare Follow Up Survey
on Inhalation Drug Services for Medicare Beneficiaries

Contact Information

Please staple a business card, or complete the requested information of the contact person for this survey.

**Please Staple Business Card of Contact
Person(s) Here**

Pharmacy Name:		
First Name	MI	Last Name
Title		
Street Address 1		
Street Address 2		
City	State	Zip
Phone		Fax
Email		Webpage

PLEASE NOTE:

INHALATION DRUGS REFER ONLY TO DRUGS INHALED THROUGH A NEBULIZER AND DO NOT INCLUDE METERED DOSE INHALERS (MDIs).

AAHomecare Follow Up Survey
on Inhalation Drug Services for Medicare Beneficiaries

The following questions relate to providing a 90-day supply of nebulized inhalation drugs.

Question 1: In CY 2005, CMS introduced a 90-day supply option for dispensing nebulized inhalation drugs in order to reduce pharmacies' dispensing and shipping costs. They are interested in collecting information on pharmacies' utilization of the 90-day supply schedule and reasons why some pharmacies have not utilized it.

Has your pharmacy utilized the 90-day supply schedule?

_____ Yes _____ No

If yes, approximately what percentage of your shipments in 2005 were on a 90-day schedule?

_____ %

If it was not utilized, or if less than 20% of your shipments in 2005 were on a 90-day schedule, please indicate the primary reason(s) why:

(Check All That Apply):

- _____ Monthly shipments foster more frequent patient contact and correspond better with patient compliance protocols.
- _____ Patient prescriptions (type of drug, dosage, frequency of administration) often change within a 90-day period due to side effects or other factors.
- _____ The 90-day dispensing fee rate (\$80.00) is inadequate to cover the costs of dispensing a 90-day supply while providing regular monthly services.
- _____ The 90-day dispensing fee rate (\$80.00) is adequate, but it is more profitable to ship monthly and bill the 30-day dispensing fee rate (\$57.00).
- _____ My billing system or internal processes can not handle a 90-day shipment schedule.
- _____ Patients may terminate therapy due to death or other circumstances within a 90-day period with unused supplies of drugs on hand.
- _____ Other (please explain).

AAHomecare Follow Up Survey
on Inhalation Drug Services for Medicare Beneficiaries

Question 2: CMS is also interested in knowing how revised guidelines on delivery of nebulized inhalation drugs have affected overnight delivery services.

What percent of beneficiaries you serve receive their nebulized inhalation drugs via an overnight or express shipping method compared with ground shipping, today versus last year? If this number is unavailable, please give us your best estimate.

_____ % overnight or express CY 2004

_____ % overnight or express CY 2005

_____ % ground CY 2004

_____ % ground CY 2005

What is your average delivery cost per shipment today vs. last year?

\$ _____ CY 2004

\$ _____ CY 2005

If your pharmacy has not converted from overnight or express shipping to ground shipping, please tell us why.

AA Homecare Follow Up Survey
on Inhalation Drug Services for Medicare Beneficiaries

The following questions relate to nebulized inhalation drugs services.

Questions 3: CMS has repeatedly questioned whether some of the nebulized inhalation drug services offered to Medicare beneficiaries may be outside the scope of a dispensing fee. Therefore, they would like information on what services should fall within the scope of the dispensing fee. They would also like information on services currently provided to Medicare beneficiaries and how much those services cost.

On the following pages is a list of services typically provided to patients receiving nebulized inhalation drug therapy at home.

Column A

Please check the appropriate boxes for services that you believe should fall within the scope of the dispensing fee.

Column B

Please check the appropriate boxes for services that you currently provide Medicare beneficiaries.

Column C

Please provide the percentage of total costs for inhalation drug services spent within the various categories listed below for the first quarter of CY 2005 (January 1- March 31, 2005). If this number is unavailable, please provide us with your best estimate. Please note that the total of Column C should equal 100% of your nebulized inhalation drug services costs. Grey boxes do not require an answer.

(please check boxes to the right if you wish to select all services listed below)

i) Local service center

	Column A	Column B	Column C
	Should Fall within the Scope Dispensing Fee	Currently Provided to Medicare Beneficiaries	% of Total Cost of Inhalation Drug Services
1. Intake (please check boxes to the right if you wish to select all services listed below)			%
i) Local service center	☐	☐	
i) Receipt of patient demographics from referral source			
ii) Receipt of physician information from referral source			
iii) Notification of central pharmacy re: medication order			
iv) Use of contracted interpreter services ⁹			
v) Verification of patient demographic information, confirmation of Medicare number, secondary insurer information			
vi) Verification of patient emergency contact information obtained			
vii) Verification of patient caregiver and/or conservator information			
viii) Secondary insurance information verified			
ix) Patient set-up in service center computerized MIS			
x) Patient Assessment- Clinical and Home			
xi) Discussed patient's deductible and/or co-payments with patient/caregiver			
ii) Pharmacy			
i) Receipt of verbal or written (FAX) order for nebulized medications ¹⁰			
ii) Physician contacted for verification of demographic information and license number			
iii) Independent database contacted for physician UPIN number			
iv) Patient set-up in pharmacy computerized MIS			

⁹ For those Medicare beneficiaries who are non-English speaking (i.e., Chinese, Vietnamese, Tagalog (Philippino), Russian, etc.

¹⁰ Only a licensed pharmacist can receive a verbal order for a medication.

2. Compounding, Dispensing, and Pharmacy Assessment

(please check boxes to the right if you provide all services listed below)

	Column A	Column B	Column C
i) <i>Compounding</i>	☐	☐	%
i) Specialized facilities (separate from drug storage and dispensing area) required for <i>de novo</i> pharmacy compounding including clean rooms, dedicated air handling equipment, sterile processing equipment, and special clean room garb			
ii) Validation, and regular revalidation, of the compounding process to assure sterility and potency to beyond-use-date of the compounded inhalation medication			
iii) Sterility and dose potency testing of compounded doses			
iv) Specialized training and testing of pharmacists and pharmacy technicians.			
v) Annual staff competency reevaluation and testing			
vi) Environmental monitoring and testing (some weekly, some monthly)			
ii) <i>Dispensing</i>			
i) Verification of patient demographic information			
ii) Prescription review and verification of qualifying diagnosis (for the ordered medication); dose size and strength; daily dosing frequency ("SIG"); length of therapy			
iii) Preparation of dispensing label			
iv) Counting and packaging unit doses of medication			
v) Pharmacist verification of dose count			
vi) Pharmacist verification of five-"Rs" – right patient, right drug, right dose, right time (SIG), right route of administration			
vii) Pharmacist verification and "wet-ink" initialing of prescription label			
iii) <i>Pharmacy assessment</i>			
i) Obtaining information on other medications that the patient may be self-administering			
ii) Assurance that inhalation medications are compatible with other medications the patient is taking			
iii) Determining other diagnoses and co-morbidities that the patient may be subject to			
iv) Assuring that the inhalation medications aren't contraindicated for those secondary diagnoses			
v) Making patient aware that pharmacy consulting services are available			
vi) Providing a secure, physical space in the pharmacy for patient consulting if a "walk-in" patient requests it			
vii) Assessing side effects from the prescribed medication			
viii) Assessing patient's dexterity			

3. Delivery, Set-up, and Patient Education
(please check boxes to the right if you provide all services listed below)

i) Delivery

Column A	Column B	Column C
☐	☐	%
3. Delivery, Set-up, and Patient Education (please check boxes to the right if you provide all services listed below)		
i) Delivery		
i) Managing express delivery services		
ii) Delivery vehicles for DME and supplies		
iii) Packaging and handling of prescriptions for delivery		
iv) Delivery staff		
v) Obtaining and documenting proof of delivery		
vi) After hours/on-call medication delivery		
vii) Coordinated and delivered first dose of medications		
viii) Delivery Costs: Next day air, Second day air, company vehicle		
ix) Changes in delivery schedule		
ii) Set-up		
i) Completing patient documentation including medical information release forms, HIPAA instruction and compliance forms, certification of patient and/or caregiver training and instruction		
iii) Patient education- written and verbal		
i) Instruction of patient and/or care giver on implementation of drug treatment regimen, anticipated therapeutic outcome, and potential side-effects		
ii) Instruction of patient and/or caregiver on proper infection control in the home		
iii) Instruction of patient and/or caregiver on safe handling and storage of medications		
iv) Instruction of patient and/or caregiver on emergency preparedness		
v) After hours/on-call in-home visit to conduct patients education		
vi) Patient charts		

Assessment of Patient Compliance
to Initiation of the Services of Home Health Agencies

	Column A	Column B	Column C
	☐	☐	%
4. Follow-up and Compliance Monitoring (please check boxes to the right if you provide all services listed below)			
i) <i>Follow-up</i>			
i) Assessing patient's retained knowledge of equipment use and purpose of therapy			
ii) Assessing retained knowledge of safety and infection control procedures			
iii) Dealing with beneficiary change of address, disconnected telephone, change of secondary insurer, illness requiring re-hospitalization, and death			
iv) Dealing with changes in physician orders and new prescription			
v) Checking for changes in clinical conditions that should be reported to the physician			
vi) Conducting periodic reports to the physician			
ii) <i>Compliance monitoring</i>			
i) Monthly call to verify patient's ongoing medical status and determine if any changes have occurred in either medical condition, other (than nebulizer drugs) medication regime, or both			
ii) Verification of number of doses consumed since last dispensing and number of doses remaining			
iii) Monthly in-home visits to patients/beneficiaries who have no telephone			
iv) Collaboration with physician if medication regime has changed or patient determined to be non compliant			
v) After hour/on-call in-home visit to repair exchange equipment			

	Column A	Column B	Column C
	☐	☐	%
5. Quality Assurance, Accreditation, Licensing, and Regulatory Compliance (please check boxes to the right if you provide all services listed below)			
i) Quality Assurance			
i) Periodic validation of all service delivery and record keeping systems			
ii) Employee training			
iii) Periodic validation of employee competency			
iv) Complaint investigation			
v) Compliance monitoring and auditing of company service and support systems			
vi) Customer Satisfaction			
vii) P.I. Plan			
viii) Equipment Management			
ix) Facility Management			
x) Audits			
ii) Accreditation			
i) Joint Commission for the Accreditation of Health Organizations (JCAHO) or other accreditation			
ii) Demonstration of adherence to pharmacy operations, compounding, and sterile compounding guidelines promulgated by the United States Pharmacopeia (USP <797>)			
iii) Licensing			
i) Separate pharmacy licenses for nearly all states into which inhalation medications are dispensed. Some states require dual licensing – as a standard retail pharmacy and as a pharmacy that prepares and dispenses sterile products			
ii) Separate pharmacist licenses for a number of states into which medications are dispensed.			
iii) Special local water and sewage disposal licensing			
iv) Licensing of special equipment such as air compressors and water treatment systems			
v) DME distributor license			

	Column A	Column B	Column C
6. Medicare Billing and Compliance (please check boxes to the right if you provide all services listed below)	☐	☐	%
i) Collation of all required documentation			
i) Verbal order documentation			
ii) Written order documentation			
iii) Patient demographics and insurance information			
iv) Physician demographics and license information			
v) Delivery tickets and signed proof of delivery			
vi) Proof of medical necessity			
vii) Medical information releases			
viii) Proof of receipt of information privacy notice			
ix) Proper HCPCS coding of all items dispensed and delivered			
ii) Verification of all required documentation and information			
iii) Preparation of an invoice to:			
i) Medicare			
ii) Secondary Insurer			
iii) Patient for co-payment and/or deductible			
iv) Computer systems for electronic batching and transmission of invoices to Medicare			
v) Submission of claim to supplemental insurance plan			
vi) Printing and mailing of deductible/co-payment amount to patient			
vii) Personal financial assessment in the event waiver of co-payment is requested or required			
viii) Collection follow-up with Medicare, secondary insurance and patient			
ix) Posting of reimbursement receipts to individual patient accounts			
x) Management of co-payment collection hardship waivers			
xi) Review of denials by reason and submission activity			
xii) After appropriate appeals and collection efforts, write off unpaid bills as bad debt			

Attachment to Form CD-800-01
on Inhalation Drug Services for Medicare Beneficiaries

7. Other Direct and Indirect Costs and Expenses

(please check boxes to the right if you provide all services listed below)

	Column A	Column B	Column C
i) Medical waste management and removal	☐	☐	%
ii) Foreign language interpreter services			
iii) 24-hour, 7-day per week emergency services for medication problems provided by the pharmacy			
iv) Corporate oversight of quality and regulatory systems			
v) Employee benefits management			
vi) Professional and business liability insurance			
vii) Mileage reimbursement for field staff making home visits			
viii) Telephone expenses			
ix) Uniforms			
x) Rent			
xi) Repairs			
xii) Utilities			
		Total=	100%

Comments:

Please report your total costs for inhalation drug services for the first quarter of CY 2005 (January 1- March 31, 2005). If this number is unavailable, please provide us with your best estimate.

Total Costs for Inhalation Drug Services for the first quarter of CY 2005

\$ _____

AA Homecare Follow Up Survey
on Inhalation Drug Services for Medicare Beneficiaries

The following question relates to the dispensing fee for nebulized inhalation drugs.

Question 4: CMS seeks comments on what an appropriate dispensing fee would be for inhalation drug services for Medicare beneficiaries. The current dispensing fee for inhalation drug services in CY 2005 is \$57 for a 30-day supply and \$80 for a 90-day supply.

Based on the total costs reported in Questions 3 and the services you identified that you provide regarding nebulized inhalation drug services, please tell us what your dispensing costs are per shipment under both a 30-day and 90-day supply schedule:

\$ _____ for a 30-day supply

\$ _____ for a 90-day supply

Please note: If you do not currently provide inhalation drugs on a 90-day supply schedule, your response above should be an estimate of what your costs would be to dispense drugs on a 90-day schedule.

Comments:

AAHomecare Follow Up Survey
on Inhalation Drug Services for Medicare Beneficiaries

The following questions relate to the potential impact of the new dispensing fee for nebulized inhalation drugs.

Question 5: CMS is interested in collecting information on the potential impact on beneficiaries and providers of inhalation drug services of possible changes to the dispensing fee in CY 2006, as well as the impact of the new drug benefit on inhalation drug access.

If the current dispensing fee were reduced by more than a nominal amount and no other reimbursement is available from Medicare, how would this impact your business and Medicare beneficiaries?

- ☐ Stop providing nebulized inhalation drugs to Medicare beneficiaries
- ☐ Go out of business completely
- ☐ Will not affect your business
- ☐ Curtail services to Medicare beneficiaries
- ☐ Other (please specify)

How will the new Medicare prescription drug Part D benefit affect access to nebulized inhalation drugs?

THANK YOU FOR PARTICIPATING IN THIS SURVEY.



SEP 30 2005

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Cardiology

Duane C. Berkompas, MD, FACC
T. Michael Brown, DO
Mark D. Castellani, MD, FACC
Nam S. Cho, DO
Joel M. Cohn, MD, FACC
Christopher M. D'Haem, DO, FACC
Edward T. Helble, DO, FACC
Juan O. Hernandez, MD, FACC
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Kirk B. Laman, DO, FACC
Maria A. Markarian, DO, FACC
Daryl R. Melvin, MD, FACC
James A. Schafer, MD, FACC
David J. Strobl, DO
Joni R. Summitt, DO, FACC
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Matthew D. Wilcox, DO

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Cardiac, Thoracic, & Vascular
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September 28, 2005

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:

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%. 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 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.

Thoracic & Cardiovascular Institute (TCI) provides nearly two thirds of the cardiology services in the greater Lansing, Michigan area. Within the past year we have evaluated the usefulness and efficacy of the First Pass imaging and, based on that evaluation, we have invested heavily in the equipment and training necessary to provide this valuable service to our patients. The cost of each of our first pass cameras was more than \$250,000. In addition, we have invested in two addition nuclear technicians and training for each of our existing technicians. There are clearly cost associated with the installation and maintenance of our special first pass cameras.

Clinically, we found the addition of rest/stress RNA to perfusion imaging has increased our diagnostic accuracy and sensitivity for detecting coronary artery disease. We have several examples of patients who have had normal perfusion imaging, but had abnormal stress ejection fractions and it turns out that the patient has had severe three-vessel coronary artery disease. It is well known that balanced ischemia can give you a false-negative perfusion study. We have also found the stress RNA to be useful in reducing our number of false-positive perfusion studies, particularly in women with breast attenuation. Again, we have several examples of patients who have had what appears to be ischemia and areas of attenuation who have had normal stress RNA's. In these situations, we have actually avoided having to send patients in for catheterizations to confirm their normal coronaries. As I am sure you are aware, a heart catheterization, by the time it is all said and done, is much more expensive than the stress RNA.

As you can see, there are, in fact, equipment costs that I and my colleagues 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. Without appropriate reimbursement, my practice will no longer be able to provide this valuable diagnostic test to the cardiac patients in the greater Lansing area. This would truly be a step backward for the cardiac patients in our community.

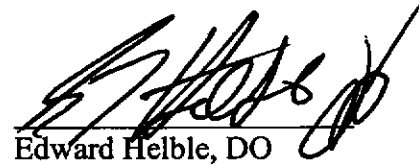
For these reasons, I ask that CMS reassess the equipment costs for CPT codes 78481 and 78483. At the very least, CMS can use the equipment costs for other codes, such as 78465, to quantify the equipment costs used in these procedures and to then compute the 2006 payment rates for the codes utilizing this information.

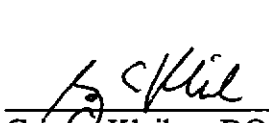
Thank you for your consideration of this matter. I look forward to a favorable resolution to the payment rates in the final rule. If you have questions, please do not hesitate to contact me at (517) 483-7550.

Sincerely,

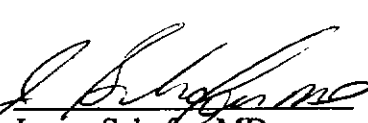

Daryl Melvin, MD, FACC


Michael Brown, DO


Edward Helble, DO


George Kleiber, DO FACC


Kirk Laman, DO


James Schafer, MD


Ronald Voice, MD

VIA OVERNIGHT MAIL

September 29, 2005

Centers for Medicare and 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: File Code CMS-1502-P

Proposed Centers for Medicare and Medicaid Services ("CMS") rule for
the Medicare Program regarding Revisions to Payment Policies Under the
Physician Fee Schedule for Calendar Year 2006 –
NUCLEAR MEDICINE SERVICES

Dear Administrator McClellan:

On behalf of MedCath Corporation, we wish to comment specifically on that part of the proposed rule that would reclassify nuclear medicine services as Designated Health Services (DHS) for purposes of the Stark physician self-referral law. MedCath is concerned that this proposal would unfairly penalize those who have invested in entities providing such services in reliance upon the statute and CMS' prior interpretation of the statute. We also have concerns this proposed rule would significantly limit beneficiary access to nuclear services particularly in rural areas. We request that this proposed change not be included in the final rule on the grounds that Congress did not intend for the physician self-referral law to apply to nuclear medicine services and that nuclear medicine is a distinct and separate field from radiology. In the event that CMS reclassifies nuclear medicine services as DHS, we further respectfully request that the final rule should grandfather prior ownership arrangements entered into good-faith based on the existing regulations.

It is clear from the statutory text, legislative history, and CMS's own long-standing interpretation of the physician self-referral law that nuclear medicine was not intended to be included in the definition of DHS. Section 1877(h)(6) of the Social Security Act specifically includes only the following services as DHS:

*clinical laboratory services; physical therapy services; occupational therapy services;
radiology 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.*¹

Congress further specifically defines radiology services as: *“magnetic resonance imaging, computerized axial tomography, and ultrasound services.”*

As nuclear medicine is not in the statute as a DHS, CMS would need to determine that nuclear medicine is encompassed in one of the congressionally enumerated categories of DHS. CMS proposes to accomplish this by re-designating nuclear medicine procedures under what it calls *“radiology and certain other imaging services.”*² This proposal is beyond the scope of the statutory language.

Importantly, the words *“certain other imaging services”* do not even appear in Section 1877(h)(6) and, in fact, Congress previously rejected statutory phrasing virtually identical to language in the proposed rule. The original statutory 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 1993.³ 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.”*⁴ This language does not mention nuclear medicine.

CMS now seeks to rely on language Congress has previously rejected. If Congress had intended to broaden the scope to a “radiology service,” it would have retained the earlier, broadly drawn category or would have listed nuclear medicine services with MRI and CT. Rather, in amending the statute, Congress affirmatively defined the scope of radiology services to omit nuclear medicine.

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, in its January 4, 2001 final rule, decided to *“exclude[] nuclear medicine [from DHS] because those services are not commonly considered to be radiology.”*⁵ This judgment was based on a specific factual finding with respect to the proper classification of nuclear medicine.

Nuclear medicine services are clinically and technically distinct from the services that Congress enumerated in defining the scope of “radiology services” under 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*

¹ 42 U.S.C. § 1395nn(h)(6) (2005).

² 70 Fed. Reg. 151 (Aug. 8, 2005).

³ Public Law 103-66, Sec. 13,562 (Aug. 10, 1993).

⁴ Public Law 103-432, Sec. 152 (October 31, 1994).

⁵ 66 Fed. Reg. 927 (Jan. 4, 2001).

*conditions of the body for the purposes of diagnosis, therapy and research.”*⁶ In a typical procedure, a physician trained as a nuclear medicine specialist supervises the administration of a radioactive material into a patient. The distribution of this administered material is determined by special device that detects the radioactivity coming from the patient. The nuclear medicine physician makes a diagnosis based on that distribution.⁷

The injection of radioisotopes into patients distinguishes nuclear medicine from radiology. Although radiologists sometimes do inject “contrast agents,” these agents are biologically inert, and their function is entirely different from that of radioisotopes in a nuclear medicine procedure. As noted in the ABNM definition, some of the procedures performed in nuclear medicine are for therapeutic purposes, and therefore, specialized training, such as that obtained in programs leading to certification by the ABNM, is a prerequisite for clinically appropriate use.

CMS 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.⁸ According to the ABMS, Nuclear Medicine and Radiology each possess “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, only after successfully completing a nuclear medicine residency program do physicians become eligible to take the American Board of Nuclear Medicine examination.

We are also concerned that CMS states in the proposed rule, that nuclear medicine 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.*”⁹ CMS has not considered that, unlike most radiology services, nuclear medicine imaging introduces potentially harmful radioactive material directly into the body. As a result, no physician would use nuclear procedures in clinically inappropriate circumstances.

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

⁶ <http://www.abnm.org/>

⁷ See, e.g., <http://www.radiochemistry.org/nuclearmedicine/definition.htm>.

⁸ 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 their respective certifying boards.

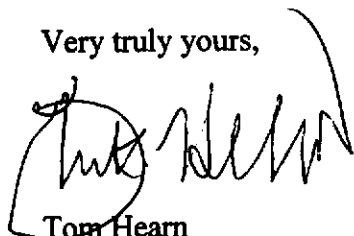
⁹ 70 Fed. Reg. 151 (Aug. 8, 2005).

proposed rule reports that while physician services grew 22 percent between 1999 and 2003, imaging services grew 45 percent, and nuclear medicine grew an impressive 85 percent. The suggestion is that the absence of self-referral restrictions on nuclear medicine services referrals has made such services subject to over-utilization. This implication is unwarranted. CMS appears to have failed to consider that as nuclear medicine represents only a tiny fraction of all diagnostic imaging, even modest numerical growth can appear dramatic when it is presented in the form of a percentage increase.

Many investors have entered into ownership and other arrangements with physicians in good-faith reliance on the existing regulations, as well as CMS's express exclusion of nuclear imaging from DHS. Accordingly, CMS recognizes in the proposed rule 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 specify a delayed effective date or grandfathering certain arrangements. We respectfully request that CMS exempt existing physician ownership interests from reclassification as DHS.

We appreciate your attention to this request that in the final rule CMS maintain its present policy that nuclear medicine is not a DHS or in the alternative, grandfather existing arrangements.

Very truly yours,

A handwritten signature in black ink, appearing to read 'Tom Hearn', with a large, stylized flourish extending upwards and to the right.

Tom Hearn
Chief Development Officer
President, Diagnostics Division

Peter S. Reichertz
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September 29, 2005

VIA FEDERAL EXPRESS

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

Re: Medicare Program: Revisions to Payment Policies Under the Physicians Fee
Schedule for Calendar Year 2006
FILE CODE: CMS-1502-P

Dear Dr. McClellan:

We represent Luitpold Pharmaceuticals, Inc., ("Luitpold") and American Regent, Inc., ("American Regent") of Shirley, New York (collectively "Luitpold"). On behalf of Luitpold and American Regent, we submit the following comments on the above-referenced rule. Luitpold's and American Regent's comments are directed towards payment issues involving the product VENOFR® (iron sucrose injection, USP), a separately reimbursable ESRD drug product, reimbursed under J Code-J1756, manufactured by Luitpold and distributed by American Regent.

PAYMENT FOR COVERED OUTPATIENT DRUGS AND BIOLOGICALS:

ASP Issues:

1. Fees Used in Calculation of ASP. Under Section 1847(A)(c)(5)(A) of the Medicare Prescription Drug Improvement and Modernization Act of 2003 ("MMA"), Average Sales Prices

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("ASP") is to be calculated on a quarterly basis, with said price to reflect price concessions including:

- Volume discounts
- Prompt pay discounts
- Cash discounts
- Free goods contingent on a purchase requirement
- Rebates, other than Medicaid rebate.

There are three types of payments made by manufacturers, the status of which as price concessions remains unclear under the rules in force. They are administrative fees, distribution fees and data purchase fees. For the following reasons, Luitpold believes the first two should not be considered as price concessions reflected in calculating ASP. As to data purchase fees, Luitpold believes it is imperative that CMS determine whether they are price concessions, since some companies, like Luitpold treat them as such in calculating ASP, while others do not, based on information available to Luitpold. Please note the following:

a. Administrative Fees: Administrative fees are fees paid by manufacturers to entities such as Group Purchasing Organizations (GPO's) to cover the costs associated with contract maintenance. Administrative fees could also include fees paid to a dialysis chain by a manufacturer for the chain's services in contract maintenance, distribution and other administrative services with regard to all of the chain's individual facilities. While these fees may appear to be a discount since they are usually calculated as a percentage of sales, Luitpold

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does not believe they should be considered in the calculation of ASP since these amounts are not passed on to the purchaser and are not reflected in a purchase price. They are instead the payment for a service rendered by the GPO, dialysis chain, or other entity, and should not be considered a discount/price concession deductible in calculation of ASP. Luitpold believes that 42 C.F.R. § 414.804 should be amended to specify that such administrative fees, paid by a manufacturer for services provided, should not be deducted in calculating ASP as they are not price concessions.

b. Distribution Fees: Increasingly, wholesalers are transitioning to arrangements with manufacturers whereby the manufacturers are required to enter into "Fee for Service" agreements with the wholesalers. These fees are being charged by a wholesaler to cover the wholesaler's cost for distribution, contract management, chargeback maintenance and other fees associated with wholesaler distribution of prescription drugs. These fees are also generally based on a percentage of sales. While it is not commonly the case yet, distributors, such as specialty distributors, may in the future charge a manufacturer similar fees for their services in distribution of the manufacturer's product(s). As with administrative fees, these distribution fees do not result in any discount passed on to the customer, and, therefore, should not be considered a discount calculated in determining ASP as they are merely a fee paid by a service. As with administrative fees, Luitpold believes CMS should clarify that such fees, which may on their face appear to be a discount, not be required to be calculated in the determination of ASP as long as they are reasonable.

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Given the penalties and consequences of improper reporting of ASP under the MMA, and related statutes, Luitpold believes it is imperative that 42 C.F.R. § 414.804 be as clear as possible that fees that are based on a percentage of sales, and which may therefore appear to be a discount but which are instead reasonable fees for services paid, not be required to be calculated in determining ASP.

c. Data Purchase Fees: Increasingly end use customers, such as dialysis chains, are charging a manufacturer fees for use of data on usage of the manufacturer's product(s) at their individual facilities. These fees also are usually calculated based on a percentage of sales and, thus, on their face, may appear to be a discount. Indeed, in many cases, these fees are being requested in lieu of or in addition to current volume discounts, with the thought that may not have an affect on ASP as they are not called "discounts", i.e. price concessions. The manufacturer is not paying for a service per se but for data owned by the provider.

Because these data purchase fees could be considered a price concession, Luitpold has, until now, treated them as such in calculating ASP. It is, however, aware that other companies do not consider them price concessions as the manufacturer is getting something of value for them, although, not a service per se such as administrative and distribution fees. Luitpold has, until now, due to lack of clarity of their status, taken the position that these data purchase fees are price concessions that should be deducted in calculating ASP. It takes no position on whether they should or should not be price concessions; *but*, Luitpold believes that *CMS must rule* whether data purchase fees should be calculated as price concessions calculated

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in ASP. As noted, Luitpold is aware that some companies, including competitors, may not be calculating these fees in determining ASP. It is, therefore, imperative that CMS clarify whether these data purchase fees should be considered as price concessions to be calculated in determining ASP, or whether they are not, so that all manufacturers are calculating ASP on the same basis.

2. Methodology to Calculation of ASP. Luitpold does not believe the rules found at 42 C.F.R. § 414.804 are sufficiently clear and specific such that each manufacturer can calculate ASP on the same basis. Luitpold believes that these rules needs to be as specific as possible as to how each company should calculate ASP, what payments to purchasers are and are not included as price concessions, and how ASP is then calculated. Luitpold believes the only fair and equitable way - that results in consistent, and, hence, fair reporting - is for CMS to provide a specific formula for calculating ASP, including each and every price concession that must be used (and to otherwise specify payments that need not be included as discussed above). Given the current vagueness of the rule found at 42 C.F.R. § 414.804, Luitpold believes that different companies are reporting ASP differently, resulting in pricing between competing products that favors certain products over others because companies have no clarity as to each and every fee that should be treated as a price concession in calculating ASP.

PAYMENT FOR ESRD DRUGS

Luitpold agrees with the decision by CMS to base payment for drugs furnished in connection with renal dialysis services and separately billed by freestanding renal dialysis

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facilities based on ASP + 6% in CY 2006. Luitpold believes that payment based on AAC as was the case in CY 2005 was based on outdated, inaccurate data, resulting in overpaying for sodium ferric gluconate, a drug competitive to VENOFER® (iron sucrose injection, USP). These concerns were reflected in its comments filed in File No. CMS-1429-FC on January 3, 2005.

Luitpold believes that, provided CMS clarifies the appropriate way to calculate ASP as discussed herein, ASP + 6% is a more accurate reflection of current pricing and a more equitable method of reimbursement for these ESRD drugs. Luitpold does not believe this change will have any affect on the access by beneficiaries or providers to injectable iron products; it will merely more accurately reflect current pricing data and discourage overpayment for sodium ferric gluconate as it believed occurred in CY 2005 resulting from use of outdated pricing data.

* * * * *

Luitpold appreciates the opportunity to comment on 2006 Payment for ESRD drugs, and calculation of ASP relating thereto. Should there be any questions, please contact the undersigned.

Sincerely,

SONNENSCHN NATH & ROSENTHAL LLP

By:


Peter S. Reichertz

773
SEP 30 2006

9-15-2005

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

Comment on Item P -- "Physician Referrals for Nuclear Medicine Services and Supplies to Health Care Entities with which they have Financial Relationship"

Background: The Oklahoma PET Center @ Deaconess pioneered the introduction of PET technology in the State of Oklahoma in November of 1998. The facility has no referring physician ownership since its inception to comply with potential Stark or Anti-kickback violations. Since 2001 it has noticed a loss of 80% of its traditional referring physicians -- mainly oncologists- to outside joint venture arrangements made between these groups & both out-of-state and in-state venture capitalists. There has been a very rapid hemorrhaging of the center's business following the proliferation of joint ventures between the centers traditional referring sources -- ie referring physicians and venture capitalists. Is this the price that this honest, ethical corporation has to pay for playing by the rules? It is the lack of enforcement of the Anti-kickback Statute by the Federal Government that has made this come to pass- it has looked the other way while abuses have taken place on a large scale. Our database has evidence that there is the 3 to 5 fold increase in utilization of PET or PET/CT services when referring physician investors are involved in the project as a joint venture. While this may not occur where there is a joint venture between a group of ethical referring physicians groups and an imaging entity most of these joint ventures have been established by venture capitalists whose motivation is throughput or profit not quality. Why not level the playing field and replace these non-physician venture capitalists by physician groups and distribute the Nuclear Medicine Imaging pie to all physicians irrespective of their speciality. Here are some of my comments on the above proposal.

It is my opinion as a qualified Nuclear Medicine Physician who has practiced in the State of Oklahoma since 1989 that the failure to include 'Nuclear Medicine Services as a designated service under the Stark Law' has lead to a significant over-utilization & abuse of this imaging modality in the State of Oklahoma. The problems have become more acute with the proliferation PET & PET/CT imaging centers in the state set up as joint ventures between select groups of referring physicians and businessmen (venture capitalists) in the state. This phenomenon in the state of Oklahoma started in late 2000 with the entry of a Knoxville, Tennessee based company 'E-Healthcare Systems' who started soliciting joint ventures with select groups of oncologists in the state based mainly in Oklahoma City & Tulsa. They were quickly joined by their Oklahoma based clones embarking on very similar ventures and together they account for 85% of the PET & PET/CT business in the state. Their emphasis seems to be on throughput and not quality and revenue generation and the return on investment they provide to their referring physicians which in the long run may bankrupt Medicare & Medicaid.

These problems now seem to be compounded by the fact that both for-profit & not-for-profit health care institutions have started to embark on similar joint ventures with these referring physician groups, thus institutionalizing such an abusive relationship with CMS. If the Centers for Medicare & Medicaid does not put a stop to such joint ventures or at the very least, include Nuclear Medicine Services (including PET & PET/CT) under the purview of Stark as a designated service -- one can and should expect a significant over utilization of these services. Further, 'the site of practice loop hole' that enables referring physician groups to circumvent Stark should be modified or amended to prevent such groups and their creative attorneys from circumventing the Stark Law and its provisions.

The institutions that have been at the receiving end of some of the above mentioned arrangements have been the general, non-niche, hospitals and institutions in the state who traditionally have looked after the vast majority of Medicare & Medicaid patients. The general hospital where I practice for instance saw a 40% decline in its oncological CT business when an influential local oncology group started a PET/CT center right across the street. Today they continue to practice at our institution unmindful of the economic damage to the institution. The motivating factor here has been a significant decline in their income stream when Medicare reduced their mark up on the oncological drugs that they dispense to their patients, so they rationalize that it is okay to do so, if they can exploit a flaw in the law. The situation in Oklahoma has reached such alarming proportions where powerful physician groups have exploited or circumvented Stark by using the site of practice loophole as well as funneling the more lucrative third party payers that it prompted the outgoing president of the Oklahoma State Medical Association to write an interesting editorial in the state medical journal entitled " Skimming the Cream". It prompted as should be expected such an irate response from physician groups with vested interests that he joked that he might have to go into a witness protection program.

Do all the oncological practices or other groups of physicians in the state indulge in such behaviour? Absolutely not, there are many ethical, honest, physicians in this state that practice great medicine who will not get into relationships that would harm the institutions in which they work or which may be violation of Stark or the Antikickback Statute. These are the groups that should be rewarded for good behavior – give them a 20% or 25% bonus at the end of year, if they do not invest in imaging centers or punish the errant ones by imposing a 20% or 25% penalty. Why do I suggest the 20 to 25% bonus/ penalty system ? Its because that's the figure that these venture capitalists who engineer such joint ventures have dangled as a carrot to these referring physician groups. If this may seem too drastic a step, give all referring physicians a piece of the imaging pie - may be 30 to 40% and no more so as to curtail the incentive for too much self referral because there are areas in the state that would benefit from physician involvement in order to bring good high technology like PET to Medicare & Medicaid beneficiaries. However, if CMS decides to give referring physicians a piece of the imaging pie—it must in the sake of being fair eliminate - the site of practice loophole. Is it fair to allow cardiologists to benefit from doing nuclear cardiovascular studies in their practice and not allow pulmonologists to perform nuclear lung scans ? Is it good public policy to give the politically powerful physician groups such a loophole while placing other physician groups in a straightjacket? Any government policy that perpetuates such an injustice is doomed to fail ultimately causing the entire system to collapse. Public retribution and judgement will be swift and they the public will be mindful as to whose watch on which all this has occurred – the Republicans or the Democrats!

These are my comments on the proposed rule change, I have enclosed with this letter a copy of the article titled "Skimming the Cream" by the editor in chief of the Oklahoma State Medical Journal J. Michael Pontious M.D. It makes interesting 7 insightful reading and is published in " the Oklahoma State Medical Journal., Vol 98, No3, March 2005.

Sincerely,

George N. Chacko M.D.
Oklahoma City – OK 73112

My contact information: Phone: 405 604 4439 e-mail: geochacko@sbcglobal.net

EDITORIAL

Skimming the Cream

Most of you knew that it would be inevitable, but I am having problems holding my pen about the latest fad in the business of medicine: Specialty Hospitals and bouquet medical services. When you take anything but the most supportive of positions, get ready to be charged with being downright un-American and possessing unprofessional thought.

I for one am not going to buy the "spin". I cannot see how this phenomenon benefits our profession or the common good. In many ways it challenges the very definition of professionalism.

You will find a rebuttal article in this edition of the *Journal*. Burman, in *Specialty Hospitals: The Truth Regarding Their Impact on Healthcare* (pages 106-109) has now published a perspective supporting the development of specialty hospitals in Oklahoma. The previous article written by Robert Eli Smith spoke of the risks involved with the specialty hospital movement within our state.

I find it interesting to see that the Federal Government has put a moratorium on further development of specialty hospitals, while the AMA has embraced this concept with open arms. I suppose as a member of organized medicine, I should be angered by this obvious Federal restraint of free trade and business development. I should stand up and cry foul and be an advocate for this wonderful new way of providing quality health care in an efficient manner.

I just can't do it.

In reality, I am embarrassed by the way that this is "spun" to make the patient believe that this is a quality issue, or much more cost effective, or better care somehow. The fact of the matter is that it is a scheme to avoid regulation. I also sense that it avoids medicine's responsibility for the greater good.

But alas there is gold in them there specialty hospitals, surgery centers and bouquet medical practices.

Because of the economics involved, I am supposed to turn my head and avoid confronting the bouquet phenomenon that won't pass the "smell" test. I have not lost my mind

here. I have not abandoned my professional tenets and I am not stating heresy. Simply this movement is wrong in each and every one of its motivations and someone needs to stand up and say so.

In our profession's seeking after the almighty dollar, we have decided that managing the market, limiting the risk and ignoring the larger picture, is the way to offer improved health care. When did professional value place all decisions on the business bottom line. When did we walk away from the greater good of providing care for all of our citizens.

The analogy of skimming the cream off of the top of the barrel comes to mind.

Community hospitals are sensitive to the needs of their communities. Specialty hospitals seems to be sensitive to the market and public relations campaigns that set them apart from their competition.. The so-called quality markers that are touted as proof positive of improved care received in these institutions are so tainted with selection bias that it is something that fits better into round bites than scientific credibility. I am pretty sure if you gave many community hospitals the same set of patients, the quality markers would be comparable.

So I envision the day where the major cities in Oklahoma have a hospital for each organ system. The nephrology hospital would be kidney shaped, the gastrointestinal hospital would be tubular. I am not even going to imagine the urology hospital. I guess for multi-system disease one would be in a bit of a dilemma. Maybe we could farm many of the lesser organ system hospitals out to rural Oklahoma and stimulate economic development.

Bottom line, the specialty hospital trend does not provide for the common good.



J. Michael Pontious, MD
Editor-in-Chief

"...I am embarrassed by the way that this is "spun" to make the patient believe that this is a quality issue, or much more cost effective, or better care somehow. The fact of the matter is that it is a scheme to avoid regulation..."



An editorial is a column of personal opinion that may or may not reflect the official position of the OSMA.



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September 29, 2005

BY OVERNIGHT DELIVERY

Mark McClellan, M.D., Ph.D.
Administrator of Centers for Medicare and 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: Comments on Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006 (CMS-1502-P)

Dear Dr. McClellan:

On behalf of CDL Medical Tech, Inc. ("CDL"), our clients, and the patients we serve, I am submitting the following comments in response to the proposed rule for the physician fee schedule for calendar year (CY) 2006 published in the Federal Register on August 8, 2005 (70 Fed. Reg. 45764) - the "Proposed Rule." Our comments focus solely on the proposed practice expense relative value units ("RVUs") for two Current Procedural Terminology ("CPT") codes - 78481 and 78483.¹ According to the Proposed Rule and information that the Centers for Medicare and Medicaid Services ("CMS") has released concurrently, these codes appear to be subject to payment rate decreases in the range of 66% to 77% over the next four years, largely because of errors in the Clinical Practice Expert Panel ("CPEP") data that the agency used to develop the proposed practice expense RVU values. If the data are not corrected, the resulting payment rates likely will be so low that these important diagnostic services will no longer be provided to Medicare beneficiaries, depriving physicians of enhanced diagnostic information on cardiac function and causing an increase in unnecessary cardiac catheterization procedures. To avoid this result, we are providing data that CMS can use to determine practice expense RVUs that reflect the unique equipment and supply costs to physicians in performing these services.

I. BACKGROUND

CDL is the distributor of the innovative CDLCAM Nuclear Medicine Gamma Camera. The CDLCAM is used to perform a service that is known as "Gated First Pass Imaging" (and is sometimes simply referred to as "First Pass"). The service is a modality that facilitates evaluation of left ventricular function both at rest and at peak exercise, yet also allows for an assessment of right ventricular function. The First Pass imaging service and its clinical benefits, which are well

¹ Our comments pertain most closely to the portion of the Proposed Rule entitled "Resource-Based Practice Expense (PE) RVUs." However, the Proposed Rule does not include a specific caption for commenters to identify.

established, cannot be obtained without the use of the CDLCAM (or a similar device) because of the quality of images and diagnostic/prognostic information that this device produces. The codes utilized for the service are:

- 78481 – Cardiac blood pool imaging, (planar), first pass technique; single study, at rest or with stress (exercise and/or pharmacologic), wall motion study plus ejection fraction, with or without quantification
- 78483 – Cardiac blood pool imaging, (planar), first pass technique; multiple studies, at rest and with stress (exercise and/or pharmacologic), wall motion study plus ejection fraction, with or without quantification.

In addition to being the distributor of the CDLCAM, CDL has been a supplier of Nuclear Cardiology imaging services for nearly 12 years. We serve as a Medicare supplier in 10 sites, providing about 500 patient studies per month. In addition, CDL has First Pass camera installations in 13 states being used by over 300 physicians providing nearly 6000 patient studies per month (more than half of which are performed on Medicare beneficiaries).

A. Use and Benefits of First Pass

First Pass imaging is used primarily in conjunction with nuclear cardiology stress testing protocols. It is now the standard of care to assess left ventricular contractile function in patients undergoing myocardial perfusion imaging, which is done typically by gated SPECT (single photon emission computed tomography) and/or First Pass imaging. Gated SPECT imaging, in conjunction with perfusion-SPECT imaging, evaluates resting left ventricular function, providing some clinical and prognostic data. However, it cannot offer the ability to compare resting left ventricular function to peak exercise left ventricular function, so called contractile reserve, which has significant prognostic value and can also reduce false positive and false negative results from standard perfusion scans. Moreover, SPECT imaging is performed using a different device than is used for First Pass, which requires a camera with much higher count rate capability as well as a unique architectural design to facilitate the acquisition of true peak exercise first pass data. The use of First Pass imaging in conjunction with perfusion-SPECT testing is well documented, most recently in a 2005 research paper from Duke University.² In addition, the use of First Pass imaging in conjunction with perfusion-SPECT testing is supported by the American Society of Nuclear Cardiology (“ASNC”).³

Up to one-third of myocardial perfusion scans are of sub-optimal technical quality and thus can be difficult to interpret. Soft tissue attenuation, patient movement during image acquisition, and extra-cardiac uptake of perfusion tracer all yield suboptimal image quality and contribute to reducing the quality of a perfusion scan. As a result, physicians often take an understandably cautious approach when reading these sub-optimal images and do not interpret them as normal but report a suggestion that “coronary artery disease (“CAD”) cannot be excluded.” That, in turn, often leads to patients being referred for cardiac catheterization to exclude CAD, which places the patient

² “Prediction of Death and Nonfatal Myocardial Infarction in High-Risk Patients: A Comparison Between the Duke Treadmill Score, Peak Exercise Radionuclide Angiography, and SPECT Perfusion Imaging,” The Journal of Nuclear Medicine, Vol. 46, No. 1.

³ See September 9, 2005 Letter from Dr. Kim A. Williams to Dr. Niles R. Rosen (copy attached).

at undue risk as well as burdening the health care system with unwarranted cost. The use of First Pass imaging, however, can prevent unnecessary arteriography procedures, as the physician interpreting the image acquired through First Pass can look at both perfusion and function *both at rest and at true peak exercise*. This allows interpreting physicians whose patients present with myocardial regions that have questionable perfusion abnormalities but normal augmentation of function at peak exercise to be interpreted as normal. Conversely, patients with diffuse CAD may appear to have normal perfusion in some cases based solely on a review of left ventricular function. When First Pass is used, the fall in left ventricular ejection fraction at peak exercise as a result of widespread hypo-perfusion, signals the physician that further investigation is necessary for a proper diagnosis. Proper diagnosis of patients with so called "balanced ischemia" can help clinicians and patients avoid both long term costs associated with post-myocardial infarction and, most tragically, death and morbidity resulting from massive myocardial infarction.

B. Performance of a First Pass Procedure

The following is an example of how a typical day of nuclear cardiac imaging for one patient *may* be scheduled. This is only a basic example and actual activities may vary depending on many factors. This example will show the time of day that each activity will be performed. It is based on one patient scheduled for the day and performing the complete SPECT/First Pass protocol. Times may vary according to varying circumstances (e.g., additional support personnel, elderly or uncooperative patients, weather, etc.).

Rest/Stress Protocol (*Procedure specific to First Pass is Italicized*)

7:00 AM	Patient arrives, is greeted and patient identity is confirmed. Patient begins paperwork, <i>Nuclear Medicine Technologist explains entire test and answers any questions.</i> A brief history and physical is obtained.
7:10 AM	<i>Intravenous (IV) set up initiated using a Special IV Kit.</i>
7:15 AM	<i>Intravenous access is initiated using aseptic technique. A large IV is needed, which requires more specialized knowledge from the health care practitioner. Antecubital is mandated for bolus injection of isotope.</i>
7:25 AM	<i>Dedicated First-Pass Gamma Camera "Rest Acquisition" parameters entered into camera system computer workstation (e.g., patient name, medical record number, study type, height, weight, physician). Camera start sequence ready.</i>
7:30 AM	<i>The Resting First Pass isotope dose is obtained and the dose is checked for accuracy in the dose calibrator/ dose amount and time is entered into the dose tracking system.</i>

7:35 AM	<i>The patient is asked to stand directly in front of and in contact with the gamma camera in a 30° right anterior oblique ("RAO") projection so that better separation in the RV/LV anatomic structures may be visualized.</i>
7:40 AM	<i>The Nuclear Technologist verifies the gamma camera is ready in the start sequence-a quick but steady bolus of the isotope is required to maintain a reliable FWHM (Full Width/Half Max) within the SVC (Superior Vena Cava). Injection time should be no longer than 1.5 seconds. The bolus is kept as tight as possible to maintain the integrity of the bolus and increased tension on the syringe until the successful acquisition of the First Pass Radionuclide Angiography ("FPRNA"). Once injected, move the patient to a seated position.</i>
7:45 AM	Ensure the IV area is secure on the patient. The patient may now leave the testing area and is encouraged to drink fluids to assist in circulating the perfusion isotope. (Waiting time: 45 – 60 minutes)
8:30 AM	Upon the patients return to the testing area, the Resting SPECT image is taken. (Image time: 20 minutes)
9:00 AM	The patient is prepped for the Stress Electrocardiogram ("ECG") Test in the normal fashion.
9:15 AM	The patient is assisted on to the treadmill if indicated; or made comfortable on an exam table if a pharmacologic test is indicated. <i>Throughout the entire Treadmill Exercise study the Nuclear Technologist must be present. The following sequence must be followed until the cessation of exercise:</i>
	<i>The Resting First Pass isotope dose is obtained and the dose is checked for accuracy in the dose calibrator/ dose amount and time is entered into the dose tracking system.</i>
	<i>Intravenous access is checked. Bolus injection of isotope.</i>
	<i>Dedicated First-Pass Gamma Camera "Stress Acquisition" parameters entered into camera system computer workstation. Patient Name/Medical record #/Study Type/Height/Weight/Physician-Camera start sequence ready.</i>

	<i>The patient is now exercising (walking on the treadmill) directly in front of and in contact with the dedicated First Pass Gamma camera in a 30° RAO projection so that better separation in the RV/LV anatomic structures may be visualized. Prior to the start of the Treadmill, the "Auto Track" is initiated to maintain the proper height of the camera.</i>
	<i>The Nuclear Technologist ensures proper gamma camera height throughout the Treadmill First Pass procedure. If camera height adjustment is necessary, the Nuclear Technologist can adjust via manual control on the hand-held pendent.</i>
	<i>When the physician informs the Nuclear Technologist to inject the isotope, the Nuclear Technologist verifies the gamma camera is ready in the start sequence. A quick but steady bolus of the isotope is required to maintain a reliable FWHM (Full Width/Half Max) within the SVC (Superior Vena Cava). Injection time should be no longer than 1.5 second to keep the bolus as tight as possible, maintain the integrity of the bolus, and maintain increased tension on the syringe until the successful acquisition of the FPRNA</i>
9:45 AM	Completion of Treadmill Exercise exam-Assist Patient to exam table.
10:15 AM	SPECT images are taken (if 85% of maximum predicted heart rate is not achieved the patient is encouraged to drink fluids to reduce GI interference then the images will be performed.) (Image time: 20 minutes.)
10:35 AM	The Exam is now complete.

After all patient examinations are completed, those Physicians qualified to interpret images would begin review of all data and image interpretation with a Nuclear Technologist, on the computer system. Interpreting physicians should schedule an appropriate time for this activity in advance with a Nuclear Technologist. In our facilities, we average approximately 4 First Pass imaging studies per day.

C. First Pass Under the Proposed Rule

Currently under the 2005 physician fee schedule, the national average payment rates for the two First Pass codes that are pertinent, 78481 and 78483, are \$260.73 and \$391.86, respectively. The non-facility RVUs assigned to these codes are as follows:

Current RVU Figures

Code	Work RVUs	Practice Expense RVUs	Malpractice RVUs	Total RVUs
78481	0.98	5.58	0.32	6.88
78483	1.47	8.41	0.46	10.34

Neither of these codes is discussed specifically in the preamble, however, the applicable practice expense RVU for each under the proposed methodology is dramatically lower than the current value. Under CMS' proposal to move from a "top-down" methodology for determining practice expense values to a "bottom-up" methodology, the agency has released the "Fully Implemented Proposed 2006 Practice Expense Relative Value Units" on its website and the figures for these codes are as follows:

Proposed Fully Implemented RVU Figures

Code	Work RVUs	Practice Expense RVUs	Malpractice RVUs	Total RVUs
78481	0.98	1.11	0.31	2.40
78483	1.47	1.47	0.46	2.41

Comparing the above tables, the work and malpractice RVUs are virtually identical, but there is a dramatic reduction in the practice expense RVUs for 78481 (from 5.58 to 1.11 for a reduction of 80%) and 78483 (from 8.41 to 1.47 for a reduction of 88%).

As you know, the proposed change to the practice expense methodology places greater reliance on the CPEP data than the current method for determine practice expense values for these codes. CMS appropriately makes the CPEP data available through its website and a review of the cost inputs for these codes is revealing, in particular, the "2006 NPRM Equipment Cost Inputs" as well as the "2006 NPRM Supply Cost Inputs" information. According to these CMS files, there are no equipment or supply costs for either of these codes. As discussed above in the description of the First Pass procedure and in more detail below, in fact, there are certain equipment and supplies that are necessary only to perform the services billed under 78481 and 78483, which likely accounts for the significant, and unwarranted, drop in the listed practice expense RVU values. In addition, in comparison to similar testing methodologies, the labor inputs appear inaccurate.

II. DISCUSSION

Under the Proposed Rule, First Pass imaging would be subject to reimbursement cuts so significant that those providing the service, including CDL, likely would discontinue providing the service. As a result, Medicare beneficiaries would be deprived of the important clinical benefits of this procedure – improved diagnostic information on cardiac anatomy and physiology that may prevent unneeded cardiac catheterizations or identify the existence of a cardiac ailment that might otherwise remain undiagnosed. Ultimately, the lack of First Pass imaging could be costlier to the Medicare program as more Catheterizations are undertaken than are necessary. Significantly, CDL believes that the proposed cuts are the result of erroneous CPEP data that shows no equipment or

supply costs involved in two First Pass imaging codes. In addition, we believe that the labor costs for these codes are understated. By correcting these errors, CMS can ensure that beneficiaries and their physicians continue to have access to this important diagnostic tool.

A. Equipment and Supply Costs Are Incurred When Conducting First Pass Imaging

As noted earlier, the files on the CMS website identifying the CPEP equipment and supply cost inputs for 78481 and 78483 indicate that there is no equipment or supplies utilized for these codes. Looking at the typical protocol in Section I(B) above, the CPEP data are simply incorrect regarding equipment and supplies for these codes.

With regard to equipment, the largest expenditure for physicians and suppliers furnishing CPT codes 78481 and 78483 is for a dedicated First Pass gamma camera, such as the CDLCAM. Indeed, only a dedicated First Pass gamma camera such as the CDLCAM is able to image a patient at peak exercise stress levels. Both codes are intended to produce an image for diagnostic purposes and a specialized dedicated camera is needed to acquire the image. Further, as noted, a computer workstation is utilized in the procedure for data entry purposes and for capturing the First Pass image. Likewise, the protocol set forth earlier includes a number of supplies, both to introduce the isotope into the body and for the acquisition of the First Pass image. For example, a specialized IV kit is needed to perform the First Pass imaging service because a large intravenous access must be utilized to introduce the First Pass isotope into the patient's body.

These equipment and supply costs are real expenditures that physicians and suppliers that provide First Pass imaging services incur. In particular, it is imperative that a dedicated First Pass gamma camera, such as the CDLCAM, be used to obtain a high quality First Pass image. The use of such a camera is unique to First Pass imaging and is used separate and apart from the central imaging device for SPECT testing. The costs simply are not zero, as the CPEP data suggest.

B. Appropriate Equipment, Supply, and Labor Cost Inputs for First Pass Imaging

Given that equipment and supply costs are incurred in performing First Pass imaging and that the CPEP data do not reflect such costs and that the labor costs for 78481 and 78483 are understated, CDL provides cost information that CMS can use to determine practice expense values under the proposed methodology. CDL is in a unique position to do so in that it both supplies the equipment and it has been a Medicare participating supplier furnishing First Pass imaging exams, billing Medicare for the services, and being reimbursed under the physician fee schedule.

Based on experience with the equipment, supply, and labor costs and our familiarity with other similar services, we believe that CMS can use existing CPEP data to determine the appropriate practice expense RVU values for these codes. Attached we provide five separate tables containing the proper equipment, supply, and labor input costs for 78481 and 78483 that CMS should use in the final rule (should it finalize the practice expense methodology change): (1) Equipment Cost Inputs for 78481; (2) Equipment Cost Inputs for 78483; (3) Supply Cost Inputs for 78481; (4) Supply Cost Inputs for 78483; and (5) Labor Cost Inputs for 78481 and 78483. The inputs in all of these tables were taken from the input data for four other similar codes used in

nuclear medicine imaging:

- 78428 (*Cardiac shunt detection*): This is the code for a cardiac shunt study. This study utilizes First Pass technology and its equipment and supply costs are virtually identical to the First Pass single study code 78481.
- 78472 (*Cardiac blood pool imaging, gated equilibrium; planar, single study at rest or stress (exercise or pharmacologic), wall motion study plus ejection fraction, with or without additional quantitative processing*): This code, usually referred to as a "MUGA" (Multi-Gated Acquisition) code, is a common test that provides almost identical data to 78481. The equipment and supply costs are virtually identical. However, unlike First Pass, a MUGA study cannot be performed on the same day as perfusion-SPECT imaging.
- 78473 (*Cardiac blood pool imaging, gated equilibrium; multiple studies, wall motion study plus ejection fraction, at rest and stress (exercise and/or pharmacologic) with or without additional quantification*): This code is for multiple MUGA studies performed during the same exam. This service is similar to the multi-study First Pass code, 78483, and is offered only for purposes of showing the differential labor input for 78483 compared to 78481.

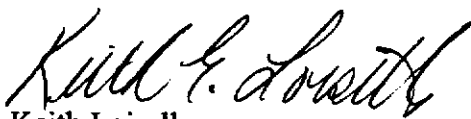
Importantly, the listed equipment and supply cost inputs are for items that are used solely when providing the First Pass imaging service billed under 78481 or 78483. These items are not used in providing any other service that a physician may furnish on the same day to a beneficiary undergoing the First Pass imaging service.

III. CONCLUSION

First Pass imaging is an important diagnostic tool for Cardiologists, Radiologists, and other Nuclear Medicine Physicians, and access to it must be preserved so that physicians and Medicare beneficiaries can benefit from the greater information that it affords. CMS has proposed a revision to the manner in which it determines practice expense values which places greater emphasis on CPEP data. Unfortunately, the CPEP data are inaccurate for First Pass imaging codes 78481 and 78483, as they reflect no equipment or supply costs for either code, and the labor inputs appear inaccurate. As explained above, these are serious flaws in the data that CMS must correct in order to pay accurately for these codes. CDL offers the cost information necessary for the agency to do so and we urge the agency to revise the practice expense RVU values to reflect this information.

On behalf of CDL, I appreciate your consideration of this important issue. If we can provide any additional assistance, please call either Herb Clauhs at (215) 453-1612, or me at 724-933-5570 at any time.

Sincerely,



Keith Loiselle
President
CDL Medical Tech, Inc.

Attachments

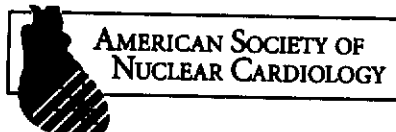
2008 NPRM equipment cost inputs

[illegible]

2008 NPRM equipment cost inputs

[illegible]

HCS	Source	GPEP	Start Type	Description	Rate	Pre Time Hr	Post Time Hr	Type	Time F	Time P	Time E	Time F	Time P	Time E	Value	X-axis	Crossed	Prior	Task
78428	PEAC	RUC	L049A	Nuclear Medicine Technologist	0.49	23	58	14	0	0	0	Y	Y	Y	2		XXX	Jan04	25
78445	PEAC	RUC	L049A	Nuclear Medicine Technologist	0.49	23	58	13	0	0	0	Y	Y	Y	2		XXX	Jan04	25
78465	PEAC	RUC	L049A	Nuclear Medicine Technologist	0.49	28	118	18	0	0	0	Y	Y	Y	2		XXX	Jan04	25
78466	PEAC	RUC	L049A	Nuclear Medicine Technologist	0.49	23	55	13	0	0	0	Y	Y	Y	2		XXX	Jan04	25
78472	PEAC	RUC	L049A	Nuclear Medicine Technologist	0.49	23	59	13	0	0	0	Y	Y	Y	2		XXX	Jan04	25
78473	PEAC	RUC	L049A	Nuclear Medicine Technologist	0.49	23	81	14	0	0	0	Y	Y	Y	2		XXX	Jan04	25
78481	PEAC	RUC	L049A	Nuclear Medicine Technologist	0.49	0	58	14	0	0	0	Y	Y	Y	2		XXX	Jan04	25
78483	PEAC	RUC	L049A	Nuclear Medicine Technologist	0.49	0	116	16	0	0	0	Y	Y	Y	2		XXX	Jan04	25
78486	PEAC	RUC	L049A	Nuclear Medicine Technologist	0.49	0	12	11	0	0	0	Y	Y	Y	2		ZZZ	Jan04	25



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September 9, 2005

Niles R. Rosen, MD
Medical Director
National Correct Coding Initiative
AdminaStar Federal
PO Box 50469
Indianapolis, IN 46250-0469

Dear Dr. Rosen:

It is our understanding that AMA RUC staff has requested, at the behest of CMS, that a number of groups, including the American Society of Nuclear Cardiology (ASNC), provide comments regarding appropriate utilization of CPT codes 78481 and 78483 (cardiac first pass studies).

These two procedures were historically the first nuclear medicine imaging procedures used in clinical practice to evaluate cardiac structure and function. As nuclear cardiology continued to develop during the 1980's and 1990's, these procedures were generally supplanted by the gated blood pool cardiac nuclear medicine studies (CPT 78472-3), followed by ultrasound and other procedures since. In the early 1990's, myocardial perfusion imaging (MPI) studies became the primary method for evaluating function as well as wall motion and ejection fraction.

In terms of using first pass technology (CPT 78481, 78483) in conjunction with SPECT MPI studies (CPT 78465) for wall motion and ejection fraction assessment, ASNC believes, and published scientific literature supports, that the use of both approaches on the same day would be clinically appropriate, because rest/exercise first-pass with a perfusion tracer adds diagnostic and prognostic information to SPECT MPI by capturing peak exercise ventricular function. On an issue that is closely related to the above, ASNC believes that coupling 78465 and 78483, together with 78478 or 78480, is not appropriate and does not conform to the current standard of practice in nuclear cardiology.

Again, we appreciate CMS involving ASNC in the NCCI update process. Should you have any questions or need additional information, please contact me at kwilliam@medicine.bsd.uchicago.edu.

Thank you.

Sincerely,

Kim A. Williams, MD, FACC, FAHA, FCCP
President



A steady pulse of excellence.

September 26, 2005

SEP 30 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 expense 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.

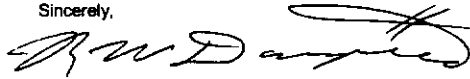
95 Arch Street, STE 350, Akron OH 44304, Phone: (330) 255-3405, Email: rtavenport@heartgroupohio.com

MARK MCCORMACK, M.D., F.H.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,

A handwritten signature in black ink, appearing to read "RWD", followed by a stylized flourish.

Richard W. Davenport CMPE
Chief Administrative Officer



September 29, 2005

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
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-1502-P: Proposed Revisions to Medicare Payment Policies Under the Physician Fee Schedule for Calendar Year ("CY") 2006

Dear Dr. McClellan:

Abbott Laboratories welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services' ("CMS's") Proposed Revisions to Medicare Payment Policies Under the Physician Fee Schedule for Calendar Year 2006¹ (the "Proposed Rule").

I. SUMMARY

As discussed in greater detail below, Abbott's comments concentrate on the following areas of the Proposed Rule: payment for end-stage renal disease ("ESRD") drugs and biologicals, the sustainable growth rate, average sales price ("ASP") reporting, and the Medicare cancer quality demonstration project.

ESRD Drugs and Biologicals

- Abbott supports establishing an ESRD drug reimbursement methodology that accurately reflects actual drug costs to ESRD facilities and enables Medicare patients with ESRD to have access to appropriate and high quality care.
- Abbott supports the CMS proposal, and recommends that CMS adopt a reimbursement level for separately billable ESRD drugs of at least ASP plus 6 percent ("ASP+6"). Moreover, CMS should consider establishing an exception process whereby rural or inner city ESRD facilities could request an alternate payment based on their actual drug acquisition costs as a result of unique economic circumstances.
- If CMS adopts an ASP-based methodology, we agree that payment allowances should be updated quarterly. Likewise, if CMS continues to rely on Office of Inspector General ("OIG") acquisition cost data, such data should be updated for inflation and other appropriate acquisition costs not reflected in the OIG data (e.g., inventory costs, working capital costs, spoilage/waste costs, and bad debt).

¹ 70 Fed. Reg. 45,764 (Aug. 8, 2005).



- With regard to hospital-based facilities, we agree that there is insufficient data regarding drug costs upon which to establish an alternative to the current reasonable cost methodology for separately billable ESRD drugs other than EPO. We therefore support continuing reasonable cost payment in 2006 while reliable data is developed, the validity of the methodology is tested, and compensation for hospital pharmacy handling costs is appropriately calculated.
- ESRD facilities have raised concerns that CMS's Proposed Rule underestimates the magnitude of the ESRD drug reimbursement reductions, and thus underestimates the corresponding budget-neutrality add-on payment to ESRD facilities. On September 1, 2005, CMS announced that the Proposed Rule included errors that resulted in an insufficient drug add-on amount. We commend CMS for quickly acknowledging the under compensation of drug expenses in the Proposed Rule. We urge CMS to ensure that in the final rule, any ESRD drug reimbursement reductions are fully offset by the composite-rate add-on to enable ESRD facilities to continue to provide high-quality care to Medicare beneficiaries.

Sustainable Growth Rate

- The Proposed Rule would institute a 4.3 percent across-the-board reduction in Medicare reimbursement for physicians' services in 2006, with further cuts forecast in future years. We share the concern of the health care community regarding the impact this payment reduction will have on the ability of physicians to provide high-quality services to Medicare beneficiaries. We therefore encourage CMS to work closely with Congress to develop a new reimbursement formula that provides appropriate and adequate payment to physicians while promoting high-quality services to Medicare beneficiaries.

ASP Issues

- CMS proposes to require manufacturers to calculate the ASP for direct sales independently from the ASP for indirect sales. In some cases, however, it is difficult for a manufacturer to discern whether the purchaser will be serving as a reseller or not, which complicates classification of the sales. Moreover, the proposed change would substantially increase the resources necessary to account for and calculate ASP without necessarily resulting in meaningful changes to ASP amounts, making the additional burden unjustified.
- CMS should carefully tailor any reporting changes to address significant fluctuations without imposing an additional reporting burden on all manufacturers and all Part B drugs and biologicals. For instance, CMS could impose the segregation requirement only when the ratio of direct to indirect sales changes more than an established threshold percentage from one quarter to the next. Alternatively, CMS could exempt from the segregation requirement any drug for which there is a *de minimis* level of direct (or indirect) sales, as defined by CMS.
- We also propose certain technical refinements to the definitions of direct sales and indirect sales to enhance clarity.
- CMS states that it is planning to collect the "Date the NDC was first marketed" and the date of first sale for products first marketed or sold on or after October 1, 2005. We agree that the date of first sale is necessary to determine when payment for a new drug may be based on the wholesale acquisition cost ("WAC"). The Medicare Modernization Act ("MMA") does not require marketing information, however, and the lack of a uniform definition of "date first marketed" could result in the



agency receiving inconsistent data. While there is no need for CMS to request marketing date information, if CMS decides to proceed with collecting this information, it should clearly define what it means by "date first marketed." Moreover, CMS should explicitly provide in the final rule that any information on first marketing or first sales date would be required only on the first submission for a new drug, as it has stated in separate guidance.

Impact/Cancer Quality Demonstration Project

- On November 1, 2004, CMS announced the establishment of a one-year demonstration project on improved quality of care for cancer patients undergoing chemotherapy. While the Proposed Rule states that CMS intends to end the demonstration during CY 2005, CMS may be considering refining and extending the demonstration. Members of Congress also have expressed their support for extending the demonstration project.
- We also understand that the medical community has expressed an interest in expanding the demonstration project beyond cancer care to include, for example, rheumatoid arthritis ("RA"). Self-administered biologicals play an important role in high-quality, cost-effective therapy for individuals with RA, and should be included in any demonstration project seeking to promote high quality care for Medicare beneficiaries with RA.
- CMS must ensure that any new quality demonstration project for RA beneficiaries does not provide disincentives for patients who use self-injected drugs, which may be lower-cost, more medically appropriate, or more convenient than physician-infused drugs. Medicare reimbursement policy should not favor one clinically appropriate mode of delivery over another.
- Likewise, CMS should collect quality of care information regardless of whether the beneficiary receives their RA drug or biological treatment through Part B (infused) or Part D (self-administered). Indeed, CMS has an interest in ensuring and documenting that treatment options, such as self-administered RA biologicals, provided under the Part D program foster high-quality care for Medicare beneficiaries.
- Thus, under any expanded quality program, CMS should provide associated payments to physicians for collecting RA quality data regardless of whether the physician prescribes an infused or a self-injected drug or biological. To enhance patient convenience, telephone consultations in which the quality indicator information is obtained should qualify for the demonstration project payment to reduce Medicare program and beneficiary expenses related to physician office visits.

II. COMMENTS ON PROPOSED RULE

A. ESRD—Drugs and Biologicals and Payment for ESRD Drugs

1. Background

Section 623(d) of the MMA established new Medicare reimbursement requirements for separately billable ESRD drugs. In short, the MMA requires CMS to reimburse ESRD facilities for separately billable drugs in 2005 at their "acquisition cost" as determined by the OIG. The MMA directs CMS to transfer any savings from this provision to ESRD facilities in the form of an add-on to the composite rate. In the event that the OIG does not determine acquisition cost for a particular drug, then the Secretary must determine acquisition cost. Beginning in 2006, the Secretary is directed to set payment for all separately billed ESRD drugs and biologicals at either acquisition cost or ASP+6.



In May 2004, the OIG issued a report under the MMA mandate, "Medicare Reimbursement for Existing End-Stage Renal Disease Drugs" (OEI-03-04-00120). In the report, the OIG set forth 2003 "acquisition costs" of sampled facilities for the top 10 ESRD drugs and biologicals compared to current Medicare reimbursement amounts.²

In the final physician fee schedule rule for CY 2005, CMS based payments for the top 10 ESRD drugs and biologicals billed by freestanding facilities (and EPO billed by hospital-based facilities) on the OIG-reported acquisition costs, updated to 2005 by the producer price index. Separately billable ESRD drugs not contained in the OIG report are paid at ASP+6. CMS did not modify the reasonable-cost based payment for separately billable ESRD drugs and biologicals other than EPO billed by hospital-based ESRD facilities.

In the CY 2006 Proposed Rule, CMS is proposing to reimburse all separately-billable drugs and biologicals furnished by ESRD facilities at ASP+6, updated quarterly based on manufacturer-reported ASP data. CMS has not proposed to pay hospital-based facilities for non-EPO separately billable ESRD drugs under the ASP+6 methodology, but it invites comments on such an approach.

CMS also is proposing a change in the drug add-on adjustment to the composite rate to account for the difference between estimated drug payments under the average wholesale price ("AWP") payment system and the payment methodology for drugs adopted by CMS for 2006. Under the Proposed Rule, the drug add-on adjustment for CY 2006 would be 8.9 percent.

2. Abbott Comments

a. Drug Reimbursement for Freestanding Facilities

Abbott appreciates CMS's interest in developing a reimbursement methodology for ESRD drugs that will "reflect current market conditions," and that avoids situations in which Medicare "will either overpay or underpay for drugs." Abbott shares the goal of establishing a drug reimbursement methodology that complies with statutory requirements, accurately reflects actual drug costs to ESRD facilities, and enables Medicare patients with ESRD to have access to appropriate and high quality care.

We would caution, however, that any reimbursement policy adopted by CMS should accurately capture all the factors, which constitute "actual costs" to all ESRD facilities. For instance, in its ESRD drug report, the OIG warned that independent facilities surveyed paid 3 to 19 percent more than the ASP reported to the OIG. We would point out that if Medicare reimbursement policy results in facilities being under compensated for their drug costs, it could potentially jeopardize patient access to needed ESRD drugs, particularly in smaller facilities and in rural areas where acquisition costs may be higher. Patients could then be forced to switch to less-effective therapies simply because they are considered cheaper. Inadequate compensation might even ultimately force rural and independent facilities to close, severely limiting a patient's ability to receive life-sustaining care. Thus, CMS should ensure that the final rule does not result in drug reimbursement levels below actual costs to facilities.

²

Note that the OIG report itself specified that its findings did not include all actual acquisition costs reported by facilities (e.g., inventory costs, working capital costs, and spoilage/waste costs).



Abbott supports the CMS proposal, and recommends that CMS adopt a reimbursement level for separately billable ESRD drugs of at least ASP+6. Moreover, CMS should consider whether to establish an exception process whereby rural or inner city ESRD facilities could request an alternate payment based on their actual drug acquisition costs as a result of unique economic circumstances.

Should CMS determine that an ASP-based methodology most accurately captures actual acquisition costs to ESRD facilities, we agree with CMS that payment allowances should be updated quarterly to better reflect the most recently available data. Likewise, if CMS continues to rely on the OIG acquisition cost data, such data should be updated for inflation and other appropriate acquisition costs not reflected in the OIG data (e.g., inventory costs, working capital costs, spoilage/waste costs, and bad debt).

b. ESRD Drugs (Other than EPO) in Hospital-Based Facilities

With regard to hospital-based facilities, we agree that there is insufficient data regarding drug costs upon which to establish an alternative to the current reasonable cost methodology for separately billable ESRD drugs other than EPO. As CMS points out:

While we agree with MedPAC that paying the same rates in both settings would be the preferable policy, we have not proposed this policy because data on dosing units for drugs furnished by hospital-based facilities are not available. This data is needed to estimate the drug payments using ASP+6 percent pricing. That is a key component of the calculation of the drug add-on adjustment.

70 Fed. Reg. at 45792. CMS states that it is examining approaches for obtaining this important information, and we urge CMS to continue its efforts to establish solid data before adopting a new payment methodology. Nevertheless, CMS is requesting comments on a potential method to estimate the drug add-on amount for drugs furnished in hospital-based facilities instead of waiting to collect data on dosing units. Under this approach, CMS would extrapolate drug payment amounts based on two assumptions: (1) that the pricing differential for drugs other than EPO furnished in hospital based facilities is the same as for those drugs in independent facilities, and (2) that the add-on amount for drugs other than EPO furnished in hospital-based facilities results in the same relative amount of drugs furnished as for those drugs in independent facilities.

We believe that there is insufficient data currently available to confirm the validity of these two proposed assumptions. In fact, the patient populations served by freestanding and hospital-based ESRD facilities are very different, with hospital-based facilities providing care for patients with higher levels of comorbidities and complications. CMS must ensure that its payment policies do not undermine access to care for high-acuity patients. We are concerned that CMS's proposed estimates and extrapolations could result in inaccurate payment levels to hospital-based facilities. Instead, CMS should continue its course of collecting accurate dosing unit data on which to develop an appropriate reimbursement policy, rather than bypass the data collection process and adopt an estimation and extrapolation plan that could result in skewed payment levels.

Moreover, in establishing reimbursement rates for ESRD drugs used in hospital-based facilities, CMS should consider hospital pharmacy handling costs, as it has in its proposed Medicare hospital outpatient prospective payment system update for CY 2006.³ In that regulation, CMS is proposing to unbundle payment for pharmaceutical handling costs related to providing Part B drugs and biologicals in hospital outpatient departments. To implement this policy, CMS would begin collecting claims data in 2006 with

³ 70 Fed. Reg. 42674.



these costs separately identified for use in setting payment rates for 2008. In the meantime, CMS would pay an additional 2 percent over the drug/biological payment to cover these costs. CMS states that this additional payment is necessary and appropriate to compensate hospitals for overhead costs related to drugs and biologicals and to better approximate historical hospital costs for drug acquisition and handling. Specifically, CMS states that:

We believe that payment for drugs and biologicals and overhead at a combined ASP+8 percent would serve as a proxy for representing both the acquisition cost and overhead cost of each of these products. Moreover, as we are proposing to pay for all separately payable drugs and biologicals using the ASP methodology, where payment rates for most of these items are set at the ASP+6 percent, we believe that an additional 2 percent of the ASP would provide adequate additional payment for the overhead cost of these products and be consistent with historical hospital costs for drug acquisition and handling.

CMS must likewise examine the extent to which similar overhead/handling costs are applicable to hospital-based ESRD facilities, and establish an equitable method to compensate facilities for those costs in addition to any ASP-based payment for the drug or biological. CMS should begin to collect claims data to facilitate developing appropriate compensation for these costs.

In sum, we support continuing reasonable cost payment for separately billable ESRD drugs other than EPO provided in hospital-based facilities in 2006 while reliable data is developed, the validity of the methodology is tested, and compensation for handling costs is appropriately calculated.

c. ESRD Drug Add-On Adjustment

With respect to the drug add-on to the composite rate, the MMA mandated that the adjustment equal the difference in the ESRD drug payments that would have been made under the AWP system in 2006 and the ESRD drug payments anticipated to be made under the new 2006 drug reimbursement methodology.

ESRD facilities have raised concerns that CMS's Proposed Rule underestimates the magnitude of the ESRD drug reimbursement reductions, and thus underestimates the corresponding budget-neutrality add-on payment to ESRD facilities. We were pleased that in a September 1, 2005 CMS internet announcement,⁴ CMS acknowledged that there were errors in the calculation of the proposed drug add-on adjustment for 2006 that resulted in an insufficient drug add-on amount. In its Internet announcement, CMS states that the corrected total drug add-on adjustment for 2006 is 11.3 percent (subject to revision in the final rule based upon more recent billing data), up from 8.9 percent in the Proposed Rule.

We commend CMS for quickly acknowledging the under compensation of drug expenses in the Proposed Rule. We urge CMS to ensure that in the final rule, any ESRD drug reimbursement reductions are fully offset by the composite-rate add-on, as is mandated by the MMA, to enable ESRD facilities to continue to provide high-quality care to Medicare beneficiaries.

B. Sustainable Growth Rate ("SGR")

The Proposed Rule would institute a 4.3 percent across-the-board reduction in Medicare reimbursement for physicians' services in 2006, with further cuts forecast in future years. The reduction is triggered by the statutory SGR formula, which requires CMS to adjust the Medicare fee schedule update depending

⁴ http://www.cms.hhs.gov/providers/esrd/090105_ESRD_Correction.pdf.



on how actual expenditures compare to the target rate – regardless of whether increased expenditures reflect expanded Medicare coverage policies or other factors beyond the control of individual providers.

We share the concern of the health care community regarding the impact this payment reduction will have on the ability of physicians to provide high-quality services to Medicare beneficiaries. We therefore encourage CMS to work closely with Congress to develop a new reimbursement formula that provides appropriate and adequate payment to physicians while promoting high-quality services to Medicare beneficiaries.

C. ASP Issues

In the Proposed Rule, along with a related August 19, 2005 information collection notice ("Information Collection Notice"),⁵ CMS proposes to, among other things, (1) modify the methodology manufacturers use to account for wholesaler chargebacks in the ASP calculation, and (2) revise the format manufacturers use to submit ASP data.

1. Price Concessions: Wholesaler Chargebacks

CMS proposes to require manufacturers to calculate the ASP for direct sales independently from the ASP for all other sales subject to the ASP reporting requirement (indirect sales). Manufacturers then would calculate a weighted average of the direct sales ASP and the indirect sales ASP to submit to CMS. CMS states that this separate calculation would improve the "overall accuracy of the ASP calculation, particularly for NDCs with significant fluctuations in the percentage of sales that are direct sales."

We are concerned, however, that there are impediments to manufacturers segregating certain direct and indirect sales information. For instance, in some cases it is difficult for a manufacturer to discern whether the purchaser – such as a specialty pharmacy – will be reselling the drug or will be furnishing the drug directly to patients. This complicates manufacturer's ability to classify the sale as direct or indirect.

Moreover, we believe that the proposed change in ASP methodology would substantially increase the resources necessary to account for and calculate ASP without necessarily resulting in meaningful changes to ASP amounts, making the additional burden unjustified. In fact, we tested the new methodology on one drug, which had a change in its ratio of direct to indirect sales and found that the impact on ASP was *de minimis*.

If CMS seeks to address potential inaccuracies that could result from "significant fluctuations in the percentage of sales that are direct sales," CMS should carefully tailor any solution to address such significant fluctuations without imposing an additional reporting burden on all manufacturers and all Part B drugs and biologicals. For instance, CMS could impose the segregation requirement only when the ratio of direct to indirect sales changes more than an established threshold percentage from one quarter to the next. Alternatively, CMS could exempt from the segregation requirement any drug for which there is a *de minimis* level of direct (or indirect) sales, as defined by CMS.

CMS also seeks comments on its proposed definitions of direct and indirect sales. Specifically, CMS proposes the following definitions:

⁵ 70 Fed. Reg. 48,770.



- Direct Sales means sales directly from the manufacturer to the provider (for example, physician or other health care provider) or supplier.
- Indirect Sales means [products sold] from the manufacturer to a wholesaler, distributor, or similar entity that sells to others in the distribution chain. Indirect sales also include any sale subject to the average sales price-reporting requirement that is not a direct sale.

We would recommend the following refinements to the definitions to enhance clarity:

- Direct Sales means products sold directly from the manufacturer to all customers, excluding sales to wholesalers, distributors, or similar entities that are intended for resale to a third party (for example, providers).
- Indirect Sales means products sold to wholesalers, distributors, or similar entities that are intended for resale to a third party (for example, providers). Indirect sales also include any sale subject to the average sales price-reporting requirement that is not a direct sale.

2. Revised Format for Submitting ASP Data

In the Proposed Rule and in the Information Collection Notice, CMS states that it is planning to collect the "Date the NDC was first marketed" and the date of first sale for products first marketed or sold on or after October 1, 2005. We have several concerns about this proposed requirement.

First, in a question and answer document issued with the Information Collection Notice, CMS asserts that it is "proposing to collect the date the NDC was first marketed and the date of the first sale (for NDCs first marketed or sold on or after October 1, 2005) because we must identify the initial period during which the payment is based on WAC." However, the date the NDC is first marketed is immaterial for identifying when payment is based on WAC; the only date that is relevant is the date of first sale. Section 303(c) of the MMA provides that WAC may be used "In the case of a drug or biological during an initial period (not to exceed a full calendar quarter) in which data on the **prices for sales** for the drug or biological is not sufficiently available from the manufacturer to compute an average sales price for the drug or biological." Likewise, the MMA conference report explanation states that "The Secretary will be able to disregard the average sales price **during the first quarter of a new drug's sales** if the price data is not sufficient to determine an average amount payable." Indeed, the whole drug payment framework established under Section 1847A applies to drugs "that are **furnished**" on or after January 1, 2005 – not drugs that are marketed but not sold after that period.

Medicare payment, whether it be under WAC or ASP, is predicated on the **sale** of the drug or biological. If a company markets a drug during a quarter but there are no sales during that quarter, it does not bear on ASP reporting or WAC calculations. CMS therefore should not seek marketing date information; instead, the date of first sales should be sufficient.

While we would strongly recommend that CMS reconsider its proposed collection of the marketing date, if CMS nonetheless decides to collect the "date first marketed," several refinements to the proposal are necessary. First, there is no uniform definition of what CMS considers to be the "date first marketed." Marketing can include many components over a long period of time, and companies do not typically have a "bright-line" first marketing date, as there would be for the date of Food and Drug Administration ("FDA") approval, for instance. With no uniform standard for the definition of first marketing, CMS likely would receive inconsistent data that would not support the goal of accurately calculating payment rates. Therefore, if CMS collects information on the date a drug is first marketed, the agency should clearly



define what it means by "date first marketed." Alternatively, the agency could collect the date of FDA approval of the drug, since that is a clearly defined event that is not subject to interpretation. In either case, however, the date of first sale should be used to determine when WAC applies.

In addition, CMS states in the Information Collection Notice that the date the NDC was first marketed and the date of first sale only would be submitted "once with the first data submission for new NDCs." CMS does not include this limitation in the Proposed Rule. We therefore also recommend that CMS explicitly state in the final rule that any information on first marketing or first sales date would be required **only** on the first submission for a new NDC.

D. Impact/Cancer Quality Demonstration Project

On November 1, 2004, CMS announced the establishment of a one-year demonstration project on improved quality of care for cancer patients undergoing chemotherapy. The purpose of this demonstration project is to assess and provide new support for the quality of care for cancer patients. Under the demonstration project, physicians who report certain data on three patient symptom areas (nausea and/or vomiting, pain, and fatigue) in conjunction with Medicare chemotherapy services are eligible for an additional payment of \$130 per encounter. To facilitate the collection of this information, CMS established 12 new G-codes to be reported by program participants. By billing the designated codes, the practitioner self-enrolls in the project.

According to the CY 2006 Proposed Rule, CMS intends to complete the demonstration project at the end of CY 2005 and not extend it through 2006. An August 1, 2005 CMS fact sheet on the cancer quality demonstration project⁶ indicates, however, that CMS is continuing to examine ways to promote quality cancer care through certain data efforts, which implies that CMS may be considering refining and extending the demonstration project. For instance, according to the Fact Sheet, CMS is considering whether there are "more effective alternatives to collecting data on quality of life than focusing exclusively on cancer patients receiving intravenous chemotherapy treatment in physicians' offices." Moreover, members of Congress have expressed their support for extending the demonstration project, with appropriate refinements.⁷ We also understand that CMS has received numerous recommendations by the medical community to extend the demonstration project and expand the demonstration project to other disease states that impact the Medicare population, such as RA.

We agree that Medicare policy should promote high quality care for Medicare beneficiaries with RA, which is why Abbott actively supported the MMA "Section 641" demonstration project providing temporary Medicare coverage of self-injected biologicals for RA and certain other indications until implementation of the new Part D outpatient prescription drug benefit on January 1, 2006. RA is a costly and debilitating autoimmune disorder that particularly impacts the Medicare population. The economic costs of RA are considerable, as the estimated direct and indirect costs of related care in the US total \$19 billion annually. Given the advent of new and innovative anti-tumor necrosis factor ("TNF") biologic therapies in this disease area, there is a significant opportunity to investigate ways to cost-effectively improve quality of care provided to RA patients.

⁶ See <http://www.cms.hhs.gov/media/press/release.asp?Counter=1525>.

⁷ For instance, on July 20, 2005, the House Energy & Commerce Committee approved H. Res. 261, which urges CMS to extend the demonstration project, at least through 2006, subject to any appropriate modifications.



We therefore support CMS expanding the demonstration project to investigate opportunities to improve care provided to RA patients undergoing therapy with self-administered anti-TNF biologics. This would provide CMS with a significant opportunity to investigate ways to improve quality of care provided to RA patients through determining patient status and preferences; outlining appropriate therapeutic regimens; assessing patient symptoms, complications, and quality of life; and supporting and educating caregivers.

Any expansion of the demonstration project into the area of RA should include an evaluation of **all** anti-TNF therapeutic options, including self-injected biologics that are covered under the upcoming Medicare Part D program. The introduction of self-injected anti-TNF biologics has had a profound and positive impact on the quality of care provided to patients with RA. These therapies offer RA patients efficacious, convenient, cost-efficient, and sustained control of their disease, while avoiding the infusion-related reactions often associated with physician-administered biologics. An expansion of the demonstration project into RA that includes an analysis of self-injected anti-TNF biologics would be a great service to Medicare beneficiaries and yield results that would characterize more completely the quality of care provided to RA patients.

Most importantly, the Medicare program itself could more fully optimize the cost-efficiencies and sustain disease control offered by self-inject anti-TNF biologics. A number of studies have shown that physician-infused biologics are, in total, more costly compared to self-injected biologics. In an analysis⁸ of pharmacy and medical claims data of RA patients within managed care plans, Gilbert and colleagues found that:

- 60% of patients receiving physician-infused therapy increased their dose at one year compared to 18% of patients treated with self-inject therapies;
- Dose escalations in patients treated with physician-infused therapies resulted in a 25% increase in mean one-year costs (\$25,915 versus \$16,713 with no dose increase);
- Cost for patients treated with self-injected therapies did not differ based on dose escalation (\$14,482 versus \$13,866 with no dose increase);
- Overall, costs for patients initiating physician-infused therapy were higher than cost for self-injected therapy (\$19,144 versus \$13,977), a 37% difference; and
- Patients treated with physician-infused products incurred higher cost for:
 - Physician management visits (\$691 versus \$381), a 81% difference;
 - Ancillary services (\$1511 versus \$866), a 74% difference; and
 - Hospitalizations (\$2277 versus \$1322), a 72% difference.

Given the cost-effectiveness of self-administered biologicals for RA, along with the clinical and health economic benefits associated with these products, CMS policies should not provide disincentives for the use of self-administered biologicals. To that end, CMS must ensure that any new quality demonstration

⁸ Gilbert T, et al. Patterns of use, dosing, and economic impact of biologic agent use in patients with rheumatoid arthritis: a retrospective cohort study. *BMC Musculoskeletal Disorders* 2004; 5:36.



project for RA beneficiaries recognizes the value of self-administered biologicals. If the quality payments are available only if a physician infuses an RA drug, but not available when the drugs that are self-injected, this could jeopardize beneficiary access to the particular RA drug that is most effective for him or her. Medicare reimbursement policy should not favor one clinically appropriate mode of delivery over another.

Moreover, it is important for CMS to collect quality of care information regardless of whether the beneficiary receives their RA drug or biological treatment through Medicare Part B (infused) or Part D (self-administered). Indeed, patient care options are changing dramatically for Medicare beneficiaries with the implementation of the new Part D drug benefit in 2006. CMS has an interest in ensuring and documenting that the treatment options provided under the Part D program foster high-quality care for Medicare beneficiaries. An examination of the quality of care for patients receiving self-administered RA biologicals under Part D would help CMS meet this goal.

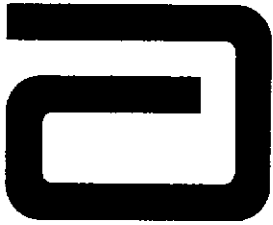
With regard to the design of an expanded demonstration project, physicians who report patient status for identified quality indicators in connection with anti-TNF biologic therapy would be eligible for payment, regardless of whether the treatment is delivered via infusion or is self-administered. CMS should use quality measures that have been identified by patients as important and that have been validated by the rheumatology community as indicative of quality care. Measures that have been identified by American College of Rheumatology's "Guidelines for the Management of Rheumatoid Arthritis" include:

- Symptom relief (e.g., degree of joint pain, duration of morning stiffness, duration of fatigue, and limitation of function);
- Side-effects (e.g., infections, adverse events, and infusion-related reactions); and
- Sustainability of result (e.g., treatment efficacy, dose escalation, treatment switching).

To prevent the need for patients to make unnecessary and costly physician visits, telephone consultations in which the quality indicator information is obtained should also qualify for the quality demonstration project payment.

Such an RA quality care demonstration project would build on the important work started in the Section 641 demonstration project and would supplement the information being collected in the associated evaluation report. Specifically, Section 641 requires CMS to evaluate patient access to care and patient outcomes of the project, as well as an analysis of the cost-effectiveness of the project, including an evaluation of any costs savings to the Medicare program attributable to reduced physicians' services and hospital outpatient departments' services for administration of the biological. Continued quality information collection would supplement the Section 641 patient outcome and cost-effectiveness information and enhance CMS's ability to monitor the impact of the new Part D program on care for Medicare beneficiaries.

In sum, Abbott would support CMS extending the cancer quality demonstration project to RA treatments if CMS includes reimbursement for quality information collected in connection with both self-injected and physician-infused RA drugs and biologicals. This would ensure that the demonstration project provides a full and comprehensive analysis of quality of care provided to patients with RA, provides incentives to prescribe the most clinically-appropriate therapy for the patient, enables CMS to monitor quality of care for beneficiaries with RA treated with anti-TNF biologics under the new Part D program, and preserves Medicare beneficiary access to important, medically-appropriate treatment options.



We would be pleased to discuss any of these issues with you in greater detail. Please feel free to contact me if you have any questions or if you need additional information.

Sincerely,

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September 29, 2005

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

Dear Dr. McClellan:

The American Society for Therapeutic Radiology and Oncology, Inc. (ASTRO)¹ appreciates the opportunity to provide written comments on the "Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006" published in the *Federal Register* as a proposed rule on August 8, 2005. Our comments will address the proposed revisions to the practice expense (PE) methodology, the proposed multiple procedure reduction for diagnostic imaging, physician referrals for nuclear medicine services and the sustainable growth rate (SGR).

Practice Expense (PE) Proposals for CY 2006 (70 Fed. Reg., 45774)

1. Supplemental PE Surveys

In early 2004, ASTRO submitted a supplemental PE survey to CMS for use in the calculation of PE relative value units (RVUs) under the 2005 fee schedule. The survey was conducted because the practice expense data used by CMS under the current top-down methodology is inaccurate and inconsistent with the actual costs of maintaining a radiation oncology practice. However, CMS

¹ASTRO has more than 8,000 members, including physicians (radiation oncologists), radiation scientists (radiobiologists, radiological physicists), radiation therapy technologists, and radiation oncology nurses. These specialists make up the expert medical team that uses radiation to treat patients with cancer. Radiation therapy is recognized as one of the most effective methods of treating cancer and other diseases. Between 50 and 60 percent of cancer patients are treated with radiation at some time during the course of their disease. ASTRO's membership represents community cancer centers and hospitals as well as major education and research centers from the U.S. and around the world. ASTRO publishes the leading scientific journal in radiation oncology in the world.

concluded the survey data did not meet the strict precision criteria established for supplemental surveys and it was not used.

We continued to work with CMS to meet the precision criteria and we are pleased that CMS has proposed to blend the data from our survey with the data submitted by the Association of Freestanding Radiation Oncology Centers (AFROC) to calculate a revised practice expense per hour (PE/hr) that is comparable to the results obtained from our own survey. We strongly support this proposal and urge that the new PE/hr data be used in calculating the 2006 PE RVUs.

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 is proposing 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.

We believe more information on the new methodology should be provided so that it can be more fully understood. However, we are opposed to any delay in the implementation of the new methodology and we view the four-year transition as providing sufficient opportunity for CMS to both provide additional information and resolve identified problems. For example, we have identified 16 codes whose non-facility PE RVUs are proposed to be significantly and inappropriately reduced over the period of the four-year transition.

The following table lists the codes, the current PE RVUs and the proposed fully implemented PE RVUs that were recently posted on the CMS website:²

CPT® Code	Mod	DESCRIPTION	2005 Non-Facility PE RVUs	Proposed Fully Implemented Non-Facility PE RVUs	Change in Non-Facility PE RVUs	% Change in Non-Facility PE RVUs
77295	TC	Set radiation therapy field	27.93	7.26	-20.67	-74%
77300	TC	Radiation therapy dose plan	1.34	1.10	-0.24	-18%
77305	TC	Teletx isodose plan simple	1.86	0.78	-1.08	-58%
77310	TC	Teletx isodose plan intermed	2.33	1.05	-1.28	-55%
77315	TC	Teletx isodose plan complex	2.66	1.82	-0.84	-32%
77321	TC	Special teletx port plan	4.04	1.34	-2.70	-67%
77333	TC	Radiation treatment aid(s)	1.89	0.35	-1.54	-81%
77334	TC	Radiation treatment aid(s)	3.25	2.78	-0.47	-14%
77336		Radiation physics consult	2.98	1.28	-1.70	-57%
77370		Radiation physics consult	3.49	3.25	-0.24	-7%

² "Addendum B FULL NPRM06 08-25-2005.xls". Downloaded from <http://www.cms.hhs.gov/physicians/pfs/default.asp> on Sept. 18, 2005.

77401		Radiation treatment delivery	1.77	0.78	-0.99	-56%
77417		Radiology port film(s)	0.59	0.44	-0.15	-25%
77418		Radiation tx delivery, imrt	18.02	12.68	-5.34	-30%
77470	TC	Special radiation treatment	11.15	1.81	-9.34	-84%
77781	TC	High intensity brachytherapy	20.30	4.77	-15.53	-77%
77782	TC	High intensity brachytherapy	20.30	13.92	-6.38	-31%

These changes are not discussed in the preamble of the proposed rule and they clearly represent significant errors. The reason they must be errors is that the direct costs of these codes either stayed the same or were increased in the proposed rule. This is shown in the following table which includes the total direct costs for each of the codes that are listed in the practice expense data files available on the CMS website:³

CPT® Code	Mod	DESCRIPTION	2005 Non-Facility Total Direct Costs	2006 Non-Facility Total Direct Costs	Change in Non-Facility Total Direct Costs
77295	TC	Set radiation therapy field	\$210.43	\$210.43	\$0.00
77300	TC	Radiation therapy dose plan	\$33.08	\$35.45	\$2.37
77305	TC	Teletx isodose plan simple	\$23.40	\$25.48	\$2.08
77310	TC	Teletx isodose plan intermed	\$31.76	\$34.58	\$2.82
77315	TC	Teletx isodose plan complex	\$55.16	\$60.06	\$4.90
77321	TC	Special teletx port plan	\$40.34	\$43.31	\$2.97
77333	TC	Radiation treatment aid(s)	\$7.65	\$7.65	\$0.00
77334	TC	Radiation treatment aid(s)	\$91.31	\$91.31	\$0.00
77336		Radiation physics consult	\$31.73	\$31.73	\$0.00
77370		Radiation physics consult	\$80.01	\$80.01	\$0.00
77401		Radiation treatment delivery	\$14.34	\$14.34	\$0.00
77417		Radiology port film(s)	\$13.06	\$13.06	\$0.00
77418		Radiation tx delivery, imrt	\$524.43	\$539.20	\$14.77
77470	TC	Special radiation treatment	\$40.80	\$40.80	\$0.00
77781	TC	High intensity brachytherapy	\$167.02	\$171.00	\$3.99
77782	TC	High intensity brachytherapy	\$479.63	\$486.71	\$7.08

Under the proposed bottom-up methodology, these codes should not have lower direct PE RVUs since the direct costs are the same or increased. Also, since the PE/hr figure used for the indirect costs has increased significantly over last year, these codes should not have lower indirect PE RVUs.

Reductions of the magnitudes shown in the above table threaten continued access to these valuable services. For example, Intensity Modulated Radiation Therapy (IMRT) is a relatively new technology that allows radiation oncologists to treat difficult cases optimally because it minimizes, or avoids altogether, radiation to adjacent normal critical structures. Because tumor cells can be targeted precisely and normal tissues can be spared, the dose concentration to the tumor itself can be enhanced. Enhancing the dose concentrations to the target gives radiation oncologists a much greater chance of completely eradicating the tumor, rather than simply causing a temporary regression. In addition, increased

³ "2006 NPRM Practice Expense Inputs.mdb" Downloaded from <http://www.cms.hhs.gov/physicians/pfs/default.asp> on Sept. 18, 2005.

optimization enables clinicians to use radiation to treat areas that would have been considered too risky just a few years ago.

All these benefits would be jeopardized if the proposed payment reductions are put in place. These services are complex and require the use of highly specialized clinical staff such as radiation physicists and expensive equipment such as accelerators and multi-leaf collimators with costs that exceed \$2 million. It would be difficult for some practices to absorb the losses associated with the proposed reductions and those practices may be forced to revert to the older traditional external beam therapy. In the interest of maintaining access to the services proposed for significant reductions, we ask that CMS review these codes, identify the causes of the reduced RVUs and make the necessary adjustments in the final rule. ASTRO remains in strong support of the proposed bottom-up methodology and the proposed implementation for January 1, 2006.

3. Changes in PE Designations

There are several radiation oncology related services with listed PE RVUs in the 2005 National Physician Fee Schedule Relative Value File that are assigned the designation "NA" in the 2006 proposed rule. This designation is not defined in the proposed rule but it is defined in a documentation file available on the CMS website.⁴ The definition is: "An 'NA' in this field indicates that this procedure is rarely or never performed in the non-facility setting." The services in question are:

CPT® Code	Description
19297	Placement of radiotherapy afterloading balloon catheter into the breast for interstitial radioelement application following partial mastectomy, includes imaging guidance; concurrent with partial mastectomy (List separately in addition to code for primary procedure)
31643	Bronchoscopy, rigid or flexible; with placement of catheter(s) for intracavitary radioelement application
43241	Upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/or jejunum as appropriate; with transendoscopic intraluminal tube or catheter placement
57155	Insertion of uterine tandems and/or vaginal ovoids for clinical brachytherapy
58346	Insertion of Heyman capsules for clinical brachytherapy
76001	Fluoroscopy, physician time more than one hour, assisting a non-radiologic physician (e.g., nephrostolithotomy, ERCP, bronchoscopy, transbronchial biopsy)

We acknowledge that these services are infrequently performed in a non-facility setting relative to a facility setting. Unfortunately, the "NA" designation is often interpreted to mean that payment for a procedure with this designation will not be made. However, there are circumstances when this setting is appropriate or existing CMS payment policy would permit payment. For example, partial mastectomies are on the list of covered ASC procedures but code 19297 is not. In accordance with CMS policy, a

⁴ "RVUPUF05.pdf." Downloaded from <http://www.cms.hhs.gov/providers/pufdownload/rvudown.asp>. Sept. 18, 2005.

procedure performed in an ASC that is not on the list of covered procedures can be paid, but payment is at the non-facility rate.

We ask that CMS list the RVUs for these codes in the final rule so that it will be clear that payment is not precluded in the non-facility setting.

Proposed Multiple Procedure Reduction for Diagnostic Imaging (70 Fed. Reg., 45849)

CMS proposes to extend the multiple procedure payment reduction to the technical component (TC) of global services in 11 families of imaging procedures by imaging modality (ultrasound, CT and computed tomographic angiography (CTA), MRI and magnetic resonance angiography (MRA) and contiguous body area (for example, CT and CTA of Chest/Thorax/Abdomen/Pelvis). Under this proposal, when multiple procedures within the same family are performed in the same session, CMS would make full payment for the TC of the highest priced procedure and payment at 50 percent of the TC for each additional procedure.

CMS believes that the following clinical labor activities are not duplicated for subsequent procedures:

- Greeting the patient
- Positioning and escorting the patient
- Providing education and obtaining consent
- Retrieving prior exams
- Setting up the IV
- Preparing and cleaning the room.

In addition, CMS considers that supplies, with the exception of film, are not duplicated for subsequent procedures. CMS concludes that the above practice expense inputs, along with the corresponding portion of equipment time and indirect costs, supports a 50 percent reduction in the payment for the TC of subsequent procedures.

ASTRO acknowledges there may be some efficiencies associated with the performance of certain imaging procedures. However, we believe the proposal for a 50 percent reduction in subsequent procedures overestimates these efficiencies. We also believe there are significant differences between CT and MRI studies as far as potential efficiencies in positioning for subsequent procedures.

We recommend that CMS examine more closely the 11 imaging families slated for the reductions and work with the American College of Radiology and the AMA RUC Committee to determine what, if any, reductions are appropriate for any of the imaging families identified.

Physician Referrals for Nuclear Medicine Services (70 Fed. Reg., 45854)

CMS proposes to revise the list of health services for which physicians are prohibited from self-referring their patients (the physician self-referral rules) to include diagnostic nuclear medicine services and therapeutic nuclear medicine services.

We wish to express our concern about this proposal. The practice of radiation oncology is an ever growing and evolving area of medicine. Every day, researchers and physicians are looking for new and innovative ways to treat cancer and benign diseases with radiation. As the practice continues to

technologically advance, the use of medical imaging devices and combined therapies such as PET and radiopharmaceuticals have become an integral component of the overall treatment plan. We ask CMS to protect and maintain the ability of radiation oncologists to order, perform and use as needed, diagnostic and therapeutic nuclear medicine services for radiation treatment planning and treatment delivery.

Sustainable Growth Rate (SGR) (70 Fed. Reg., 45856)

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.

When actual spending exceeds targeted spending, the following year's update is modified to bring actual spending back in line with the targets. Unfortunately, actual spending has exceeded targeted spending, and the formula results in negative updates to physician payments to correct this disparity. In the proposed rule, CMS projects a negative 4.3 percent update to physician payment rates for 2006.

The 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. Physicians simply cannot absorb these severe payment cuts and, unless CMS or Congress acts, physicians 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. CMS must ensure that government-induced increases in spending on physicians' services are accurately reflected in the SGR target

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.

CMS has not provided details of how these estimates were calculated, and certain questions remain. Further, CMS reportedly considers multiple year impacts and costs of related services, but the agency has not provided any itemized descriptions of how the agency determined estimated costs. Without these details, it is impossible to judge the accuracy of CMS' law and regulation allowances. For example, per beneficiary utilization of code G0105, colorectal cancer screening of a high-risk patient, which was enacted in the Balanced Budget Act of 1997 was up 13%. These impacts should be taken into account in revising the 2005 and 2006 SGR.

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.

ASTRO 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.

Error in Addendum B

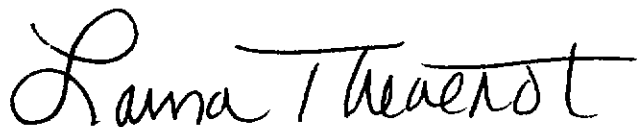
CPT Code 57155: *Insertion of uterine tandems and/or vaginal ovoids for clinical brachytherapy* [Page 45936]

After reviewing Addendum B in the Federal Register, we believe the Physician Work RVUs are not listed properly for CPT Code 57155. In Addendum B the work RVUs are listed as 0.27, with the Facility PE RVUS listed at 4.44 and the Malpractice RVUs listed as 0.43. The Facility Total is listed at 11.15. Therefore, we believe the Physician Work RVUs should be 6.28, which would very similar to the 2005 value of 6.26. We ask that CMS correct this error and reflect the 6.28 value in the Final Rule for 2006, to be published later this year.

Conclusion

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

Respectfully,



Laura Thevenot
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September 29, 2005

Mark McClellan, MD, Ph.D., Administrator
Centers for Medicare and 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: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006 [CMS-1502-P]

Dear Dr. McClellan:

St. Jude Medical, Inc. appreciates the opportunity to comment on the proposed revisions to the practice expense (PE) relative value units (RVUs) for certain monitoring services under the Medicare physician fee schedule for calendar year 2006, published in the Federal Register August 8, 2005 (70 Fed. Reg. 45764). St. Jude Medical is dedicated to the design, manufacture, and distribution of cardiovascular medical devices of the highest quality. These devices offer physicians, patients, and payers unmatched clinical performance and demonstrated economic value. The Company's product portfolio includes pacemakers, implantable cardioverter defibrillators, catheters and heart valves.

Our comments will be limited to the proposed PE changes for certain critical cardiac and internal normalized ratio (INR) monitoring service codes. These proposed changes will result in drastic payment reductions, including some cuts of up to 90 percent, over the next four years. We encourage CMS to defer implementation of the new RVUs applied to these codes until more complete information is available to ensure that the PE payments reflect the actual relative resources required for these services. The codes at issue are those for holter monitoring, cardiac event monitoring, pacemaker monitoring, and INR monitoring (see attached list for codes and descriptors).

All of these services require sophisticated monitoring and telecommunications equipment; establishment of extensive networks; and highly trained personnel. Because of the expense and sophistication of the networks that are required, these services generally cannot be performed cost efficiently by a single practice or institution. Consequently, physicians rely heavily upon Independent Diagnostic Testing Facilities (IDTFs) to provide cardiac monitoring services (and other related services) to their

patients. In fact, these providers perform up to 85% of the most critical cardiac monitoring services—over a half million procedures for Medicare beneficiaries alone in 2003. IDTFs operate their facilities, including a supervising physician and certified ECG technicians, on a 24 hours a day, 7 days a week basis.

However, CMS is proposing to use survey data from physicians' offices submitted by the American College of Cardiology (ACC) in the PE calculations for these codes. We believe that ACC practice expense survey is not representative of the IDTF segment – which provides the majority of these services – and significantly understates the actual resources required to perform these services.

We are concerned that the severity of the cuts for these codes would threaten patient access to these important monitoring services, jeopardizing quality of care for beneficiaries, and resulting in overall long-term cost increases for the Medicare program. Without these services, patients are more likely to require expensive hospitalizations or emergency care.

We urge CMS to recognize that there are outstanding issues related to these monitoring services that require further consideration, and that consequently, CMS should not change the RVUs for these codes. We believe that additional study regarding the practice expense associated with these services is needed to ensure adequate payment. CMS has proposed this approach for the codes associated with audiology and medical nutrition therapy, ESRD visits, and drug administration (70 Fed. Reg. 45777). The monitoring services captured in the codes listed above should be treated similarly.

Sincerely,

A handwritten signature in cursive script that reads "Susan Walker".

Susan Walker
Director, Reimbursement

<u>CPT CODE</u>	<u>CODE DESCRIPTION</u>
HOLTER	
93224	Electrocardiographic Monitoring For 24 Hours By Continuous Original ECG Waveform Recording And Storage, With Visual Superimposition Scanning; Includes Recording, Scanning Analysis With Report, Physician Review And Interpretation
93225	Recording (Includes Hook-Up, Recording, And Disconnection)
93226	Scanning Analysis And Report
93230	Electrocardiographic Monitoring For 24 Hours By Continuous Original ECG Waveform Recording And Storage Without Superimposition Scanning Utilizing A Device Capable Of Producing A Full Miniaturized Printout; Includes Recording, Microprocessor-Based Analysis With Report, Physician Review And Interpretation
93231	Recording (Includes Hook-Up, Recording, And Disconnection)
93232	Microprocessor-Based Analysis And Report
CARDIAC EVENT	
93012	Telephonic Transmission Of Post-Symptom Electrocardiogram Rhythm Strip(S), 24-Hour Attended Monitoring, Per 30 Day Period Of Time; Tracing Only
93268	Patient Demand Single Or Multiple Event Recording With Presymptom Memory Loop, 24-Hour Attended Monitoring, Per 30 Day Period Of Time; Includes Transmission, Physician Review And Interpretation
93270	Patient Demand Single Or Multiple Event Recording With Presymptom Memory Loop, 24-Hour Attended Monitoring, Per 30 Day Period Of Time; Recording (Includes Hook-Up, Recording, And Disconnection)
93271	Patient Demand Single Or Multiple Event Recording With Presymptom Memory Loop, 24-Hour Attended Monitoring, Per 30 Day Period Of Time; Monitoring, Receipt Of Transmissions, And Analysis
PACEMAKER	
93733	Electronic Analysis Of Dual Chamber Internal Pacemaker System (May Include Rate, Pulse Amplitude And Duration, Configuration Of Wave Form And/Or Testing Of Sensory Function Of Pacemaker, Telephonic Analysis
93736	Electronic Analysis Of Single Chamber Internal Pacemaker System (May Include Rate, Pulse Amplitude And Duration, Configuration Of Wave Form And/Or Testing Of Sensory Function Of Pacemaker, Telephonic Analysis
INTERNATIONAL NORMALIZED RATIO (INR)	
G0248	Demonstration, At Initial Use, Of Home INR Monitoring For Patient With Mechanical Heart Valve(S) Who Meets Medicare Coverage Criteria, Under The Direction Of A Physician; Includes; Demonstrating Use And Care Of The INR Monitor, Obtaining At Least One Blood Sample, Provision Of Instructions For Reporting Home INR Test Results, And Documentation Of Patient Ability To Perform Testing
G0249	Provision Of Test Materials An Equipment For Home INR Monitoring To Patient With Mechanical Heart Valve(S) Who Meets Medicare Coverage Criteria; Includes Provision Of Materials For Use In The Home And Reporting Of Test Results To Physician; Per Four Tests



OFFICE OF
GENERAL COUNSEL

ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, N.J. 08933-7002

September 29, 2005

By Federal Express

Mark B. McClellan, MD
Administrator, Centers for Medicare and Medicaid Services
United States Department of Health and Human Services
Attn: CMS-1502-P,
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Program; CMS-1502-P; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006; Payment for Covered Outpatient Drugs and Biologicals; ASP Changes

Dear Dr. McClellan:

On behalf of Johnson & Johnson (J&J) operating companies, we are providing the following comments in response to the Proposed Rule—Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2006—issued by the Centers for Medicare and Medicaid Services (CMS) and published in the Federal Register on August 8, 2005.¹ Our comments are specific to the proposed changes to the Average Sales Price (ASP) calculation methodology and associated reporting requirements for Part B drugs and biologics.

J&J is the world's most comprehensive and broadly based manufacturer of health care products, as well as a provider of related services, for the consumer, pharmaceutical and medical devices and diagnostics markets. J&J has more than 200 operating companies in 57 countries around the world employing approximately 109,000 employees and selling products in more than 175 countries. The fundamental objective of Johnson & Johnson is to provide scientifically sound, high quality products and services to help heal, cure disease and improve the quality of life. J&J operating companies manufacture and market some of the most important drugs and biologics covered under Part B of the Medicare program, including PROCRT[®] (epoetin alfa), REMICADE[®] (infliximab), RISPERDAL CONSTA[®] (risperidone) and NATRECOR[®] (nesiritide). Including these, J&J operating companies currently calculate and report ASP on a total of forty NDCs per quarter across seven different J&J Operating Companies.

¹ 70 Fed.Reg. 45764.

CMS established a methodology for calculating the ASP in the Manufacturer Submission of Manufacturer's ASP Data for Medicare Part B Drugs and Biologicals final rule published on September 16, 2004.² Pursuant to the resulting regulation at 42 CFR Section 414.804 (a)(3) and as explained in the preamble to this proposed rule, manufacturer's are required to estimate lagged price concessions for the most recent 12-month period available associated with *all* sales subject to the ASP reporting requirement. The manufacturer then calculates a percentage using this summed amount as the numerator and the corresponding total sales data as the denominator. This results in a 12-month rolling average price concession percentage that is applied to the total in dollars for the sales subject to the ASP reporting requirement for the quarter to determine the price concession estimate for the quarter.

CMS proposes an alternative method for estimating the lagged price concessions related to chargebacks with the intention of improving the accuracy of this estimate.³ We strongly support CMS' desire to refine the lagged price concession estimate because an overstatement in this quarterly estimate drives the ASP downward with the potential to negatively impact patient's access to the Medicare Part B drugs. We believe, however, that the proposed changes and their impact go beyond chargebacks and affect *all* lagged price concessions. Further, we do not agree that this proposed change in the lagged price concession estimate improves the accuracy of the ASP calculation for the vast majority of Part B drugs, although in some cases it may smooth fluctuations in the ASP from quarter to quarter. Furthermore, the additional complexity and resources required to implement the proposed change outweigh the potential improvement in the accuracy of the ASP-calculation for the small number of situations in which there may be an improvement in accuracy. Our specific comments and recommendations follow.

I. Calculation of ASP for Direct Sales Independently from the ASP for All Other Sales Subject to the ASP Reporting Requirement [Indirect Sales]

As CMS properly explains, under the current ASP methodology, 'the ratio of lagged price concessions to sales is calculated over all sales, both indirect sales (sales to wholesalers and distributors and other similar entities that sells [sic] to others in the distribution chain) and direct sales (sales directly from manufacturers to providers such as hospitals or HMOs.)'⁴ CMS posits that this methodology may overstate or understate "wholesaler chargebacks," which it deems lagged, for a particular reporting period if the relationship between total dollars for indirect sales and total dollars for all sales is different for the reporting quarter and the 12-month period used. CMS contends that the impact that the quarterly variation in the relationship between indirect sales to total sales might have on the estimate of lagged price concessions will be mitigated if the ASP for direct sales is calculated independently from the ASP for all other sales subject to the ASP reporting requirement (indirect sales) and then a weighted average of the two ASPs

² 69 Fed. Reg. 55763

³ 70 Fed. Reg. 45843

⁴ Id.

is calculated and submitted. CMS acknowledges that this change in methodology will benefit primarily those NDCs with significant fluctuations in a particular quarter of sales that are direct sales.

In an effort to better understand the quantitative impact that the proposed ASP calculation methodology change might have, we modeled a variety of scenarios. (We do not suggest that our modeling included all possible scenarios.) It was obvious that if there are no, or relatively minimal, "direct sales," as defined in the proposed rule, the proposed methodology change would have virtually no impact on the resulting ASP. Our modeling showed that the calculated ASP may be closer to the "True ASP" using either the current or the proposed calculation, depending on the situation. An impact was observed when the volume mix was different between the current and the prior four quarters and the lagged ratios are different. This might occur in situations where sales are fluctuating and the following conditions exist:

- Different offerings are given to different customers
- Change in offering type (off-invoice/chargeback/rebate) that may affect lagged ratio due to timing of recognition
- Change in selling model ("direct" to "indirect" or vice-versa) that may affect lagged ratio due to timing of recognition

Notably, these scenarios all involve *changes* in selling or contracting methods ("direct" vs. "indirect" or "off-invoice" vs. "rebate") or discount levels that are within the discretion of the manufacturer. We found no quantitative impact to the ASP in the absence of these factual predicates.

We also evaluated the impact to existing processes, automated tools and other resource requirements associated with the proposed methodology change. There will be a substantial amount of additional resources required to calculate the ASP on a quarterly basis in the manner proposed, as well as a significant additional layer of complexity added to an already challenging calculation.

We also note that the ASP calculation is not a precise portrayal of the average price at which a provider may purchase Medicare Part B products. This is because price concessions that do not directly benefit the provider must be included in the calculation pursuant to the language of the statute. This imprecision cannot be corrected by the proposed methodology.

J&J Recommendation:

We appeal to CMS to *not* mandate the proposed change to the ASP methodology requiring separate calculation of an ASP for direct and indirect sales. Our position is based on a balancing of the significant additional burden it will impose on nearly all

manufacturers in return for a negligible impact on ASP accuracy in the vast majority of circumstances.

A. Estimation Methodology for Lagged Price Concessions

CMS proposes conforming changes in the estimated lagged price concessions methodology, meaning that the lagged price concessions should be calculated separately for indirect and direct sales. In addition to the considerations raised above, a very significant complexity surfaces when attempting to apply the proposed methodology change to lagged price concessions. Specifically, it is not always possible to segregate utilization-based rebates along the lines of direct versus indirect sales. Consider, for example, that utilization-based rebates are paid on the basis of units of a drug utilized by the beneficiary under a particular managed care plan. The manufacturer has little or no visibility to the channel of trade through which some units of product pass. A particular unit may be sold "directly" from the manufacturer to a specialty pharmacy provider or may be sold first to a wholesaler and then to a physician (an "indirect sale.") In today's environment, utilization data provided by managed care plans typically would not allow a manufacturer to determine with a high level of confidence whether units should be considered direct or indirect (under the proposed definitions) and correspondingly, whether the associated rebate should be treated as a direct or indirect lagged price concession in the calculation.

The preamble to the proposed rule suggests that any sale or price concession not clearly identifiable to a direct sale should be considered to be indirect for purposes of the calculation. If this default position were applied to utilization-based rebates, excessive managed care rebates may end up in the numerator of the lagged price concessions for indirect sales. The consequence could be a lower indirect ASP, and a distorted final ASP. In sum, the proposed approach is likely to overburden the lagged price concessions for indirect sales when utilization-based rebates are involved in the calculation.

J&J Recommendation:

Consistent with our comments on the overall ASP methodology change, it is our position that the proposed approach does not necessarily result in a more accurate ASP calculation or estimate of lagged price concessions and that this methodology change should not be implemented.

B. Definition of Direct versus Indirect Sales

In the preamble to the proposed rule, CMS proposes that "direct sales" are those sales from manufacturers to the provider or supplier and that "indirect sales" are the remaining sales subject to the ASP reporting requirement.⁵ In this context, provider refers to a

⁵ 70 Fed. Reg. 45844

physician or other health care provider.⁶ Indirect sales are more specifically defined in the proposed text for the revised regulation as sales “from the manufacturer to a wholesaler, distributor, or similar entity that sells to others in the distribution chain.”⁷

These proposed definitions employ terms that are used elsewhere, and with significantly different meanings, in financial accounting and the trade. We are concerned that using these terms but giving them a unique construct for the ASP calculation may cause confusion for manufacturers and potentially errors in their calculations. In addition, the proposed definitions do not always align with common financial interpretations regarding direct and indirect sales. This is likely to create additional complexity when attempting to validate the accuracy of these sales figures by comparison to existing financial records and business records.

Also, it is notable that utilization-based rebates, such as those payable to pharmaceutical benefit managers (PBMs), do not correspond with the definitions of direct or indirect sales that CMS has proposed as specific text for the regulation. This is because PBMs and other managed care type entities most often do not purchase a product; they are not direct or indirect purchasers of a product.

J&J Recommendation:

Although we do not support the change in methodology that CMS advocates in this proposed rule, if CMS determines to implement the proposed rule, the definitions of direct and indirect sales must be clarified to (1) assure that a mechanism is established to add new types of entities to the definitions of direct and indirect sales and (2) make clear that direct sales refers to sales to entities that bill and are reimbursed directly by Medicare with no intermediaries in the process.

II. Implementation of Proposed ASP Calculation Changes

A. Effective Date(s) for Implementing Proposed Calculation and Reporting Changes

The proposed rule does not include a proposed effective date specific to the ASP calculation changes. As is, the ASP calculation is complex. We surmise that the existing ASP calculation strains the capabilities of many manufacturers automated systems and manual business processes. This and every other change to the ASP calculation methodology that will be implemented over time by CMS will require manufacturers to modify automated price calculation tools that they may employ, re-educate individuals responsible for the calculation as well as those who must certify the calculation, make

⁶ 70 Fed. Reg. 45874

⁷ Id.

changes in policies, processes and procedures, and more. A surge in information management resources and human resources is needed with each required change.

J&J Recommendation:

If CMS determines to finalize the calculation changes as proposed, we recommend that CMS allow sufficient time for manufacturers to implement the required changes, a minimum of six months. (CMS should consider for example, that it is not always possible to take the results from an automated price calculation system and manually make adjustments to the system output to reflect internal methodology changes.)

In considering what would be an appropriate period of time, we urge CMS to evaluate the possibility of implementing a process whereby changes to the ASP calculation and reporting requirements are made effective no more frequently than one time per year to allow manufacturers reasonable time to obtain the financial and human resources to implement the proposed changes. We further appeal to CMS to give serious consideration to establishing an annual rule-making focused on ASP calculation and reporting and to further consider coordinating such an approach with a similar rule-making approach for the Medicaid Rebate program. Many aspects of the pricing calculation and reporting requirements under these two programs are intertwined. We believe that such an approach would enhance compliance under both programs by facilitating greater clarity on the program requirements over time and would help to ensure consistent interpretations are being applied under the two programs, to the extent intended by the respective statutory provisions.

A predictable, annual rule-making also would allow manufacturers to design and test the new processes once per year rather than on a more frequent, ad-hoc basis. It would result in a more efficient use of resources, both government and private, and would facilitate the institutionalization of an annual regulatory process that ensures guidance is provided to manufacturers in a uniform and timely manner on the appropriate treatment of new developments (such as new distribution arrangements, new types of purchasers, other statutory changes, etc.) in the calculation and reporting of ASP.

B. Other Anticipated Calculation Changes

In concert with considering the comments on the specific change to the ASP calculation addressed in this proposed rule, we urge CMS to provide manufacturers with timely guidance on the issues described below. We believe that these issues, more than the limited issues addressed in the proposed rule, have the potential of affecting manufacturer's compliance with the existing ASP calculation methodology if they are not addressed in the very near term.

1. Methodology for Excluding Medicare Part D Sales and Discounts

Medicare Part D is scheduled to be operational on January 2006, little more than three months from now. It is clear that sales under the Medicare Part D program may be excluded from the ASP calculation, but to date no guidance has been forthcoming from CMS as to the appropriate methodology for excluding these sales. From our analysis of how these sales and their associated discounts and price concessions could be excluded from the ASP calculation, it is clear that different approaches may be taken with considerably different impacts on the ASP calculation. To the extent that Medicare Part D sales are discounted, it is reasonable to expect that some portion if not all of those discounts will be lagged. While it will be possible to identify the lagged discounts (chargebacks or back-end rebates) associated with Medicare Part D sales at such time as the chargeback or utilization data is reported from a wholesaler or Part D plan, respectively, the Medicare Part D sale will not always be identifiable as such in the current ASP reporting period. In other words, at the time that a unit of product is sold to a wholesaler, it may not be possible to identify that unit as a Part D sale to permit its exclusion from the ASP calculation for that quarter. There will be a lag in identifying sales as Medicare Part D transactions. Accordingly, if CMS' intention is that only the discount or price concessions component of the Part D sales be excluded from the ASP calculation, the existing ASP methodology can be followed. If it is CMS' intent that the base sale including the sale to the wholesaler and the associated unit, be excluded from the ASP calculation, an estimation methodology will need to be established for excluding Medicare Part D sales and units in any reporting quarter.⁸

2. Adjustments/Errors in ASP calculations for Prior Periods

It is foreseeable that manufacturers will make unintentional errors in the calculation of their ASPs from time to time. To date, no industry-wide guidance has been issued advising manufacturers *how* to correct for such errors when they are identified. Is there a materiality threshold for reporting such errors to CMS? Does CMS expect manufacturers to notify it of errors in prior period ASPs or only for current period ASPs? What is the procedure expected by CMS upon a manufacturer's identification of an error in an ASP calculation? Potential violations could be avoided if CMS would establish a mechanism for manufacturers to submit revised ASPs or otherwise account for discrepancies identified in prior period ASPs.

3. Changes in Methodology

It is equally foreseeable that manufacturers may encounter situations requiring that they make changes in their ASP calculation methodology. This may occur as a result of new or changed business practices that need to be taken into consideration, changes in

⁸ This same issue applies with respect to State Pharmaceutical Assistant Program (SPAP) rebates. While SPAP rebates are not material to the overall calculation, we believe that Medicare Part D sales and rebates may have a more significant impact on the calculation.

accounting practices, or changes in information management tools. Will manufacturers be permitted to make in-scope changes in their methodology simply by notifying CMS of the changes in their 'assumptions' or 'methodology' document? Will CMS notify manufacturers within a reasonable period of time that its methodology or changes to its methodology are not acceptable? We respectfully request that CMS issue more direction on this issue.

4. Settlement of Payment Disputes for Prior Periods impacting Current Period Payments

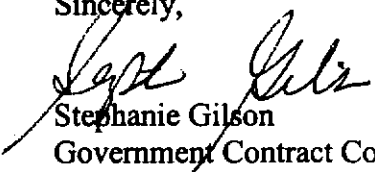
A related but distinct issue on which CMS should provide guidance is how payments made to purchasers to settle disputes or to adjust sales in periods more than 12-months previous, should be accounted for in the ASP calculation. Depending on the magnitude of the settlement or adjustment, there may or may not be a material impact if the payment is included in the current quarter ASP. To assure a level playing field, it is our recommendation that CMS issue direction to manufacturers that payments related to settlements or adjustments for periods prior to the 12-month period used in the calculation of the lagged price concessions estimate be excluded from the calculation.

J&J Recommendation

We reiterate the concerns expressed above and implore CMS to address the issues identified here, prior to finalizing any other changes to the ASP calculation or reporting requirements. These issues impact the immediate and very near term accuracy of the ASP calculation.

Conclusion: J&J appreciates the opportunity to submit comments and recommendations to CMS. We look forward to working with you and your staff to further improve the accuracy of the ASP calculation methodology to assure that it most closely reflects the true average selling price to purchasers of our products. If you have any questions related to these comments, please contact Stephanie Gilson at 202-589-1024.

Sincerely,



Stephanie Gilson

Government Contract Compliance Counselor

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J.N.W.

September 28, 2005

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

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

**American College of Chest Physicians Comments on: SGR, Supplemental
Practice Expense Surveys, Inhalation Drugs and Dispensing Fee, Respiratory
Therapy G0237-G0239, Missing Equipment Pricing Data, and NCD
Timeframes**

Dear Dr. McClellan:

I am writing on behalf of the American College of Chest Physicians (ACCP). The ACCP is comprised of over 16,500 physicians and allied health professionals, whose everyday practice involves diseases of the chest in the specialties of pulmonology, cardiology, thoracic and cardiovascular surgery, critical care medicine, sleep and anesthesiology. These health care professionals practice in virtually every hospital in this country, and many of the physicians head major departments in these hospitals. As a multidisciplinary society, the ACCP offers broad viewpoints on matters of public health and clinical policy in cardiopulmonary medicine and surgery. We appreciate the opportunity to submit comments for consideration as CMS finalizes its rule regarding Medicare's Revisions to Payment Policies under the Physician Fee Schedule for CY 2006 based upon proposals set forth in the Notice of Proposed Rule Making (NPRM) published on August 8, 2005.

First, thank you for the new Smoking and Tobacco Cessation Counseling benefit that was implemented in July. It is important that our members are recognized for their important work in this area. This patient counseling stresses the importance of a healthy lifestyle.

The ACCP offers the following comments and wishes to again challenge the calculation of the SGR formula on the basis of preventive service benefits increasing

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additional physician visits, the effect of National Coverage Decisions (NCD) and Medicare-covered drugs driving up costs.

I. SUSTAINABLE GROWTH RATE (SGR) FORMULA

Permanently fix the formula by taking into account the actual costs of providing care to Medicare patients. The ACCP remains concerned about both using a flawed formula to calculate the SGR, and CMS' inflexibility in applying the formula to the Medicare physician fee schedule.

The 2005 physician fee schedule conversion factor is \$37.8975. The 2005 CF represents a 1.5% increase over the 2004 CF. The Medicare Modernization Act (MMA) mandated a 1.5 percent increase in both the 2004 and 2005 conversion factor. We are again asking Congress to intervene and provide a true update to the Medicare physician fee schedule.

To address these flaws in the SGR formula, ACCP recommends the following:

Appropriate Accounting for Changes in Law and Regulation

Medicare law requires CMS to make adjustments to the SGR calculation to reflect increases (or decreases) in physician spending resulting from changes in law or regulation. The ACCP believes that CMS has mistakenly underestimated the financial impact of increased spending on physician services under Medicare without an increase in the total Medicare budget.

Preventive Medicare Benefits

Congress has added new preventive service benefits available to beneficiaries under the Medicare program, and we are pleased about these new benefits for our patients as they will help prevent illness and disease. The ACCP strongly supports increased awareness of the value of preventative medicine, and reimbursement for preventive measures, such as the 2005 Smoking and Tobacco Cessation Counseling benefit. However, adding these and future preventive service benefits to the Medicare program, without new additional revenues, results in the physician fee schedule subsidizing the direct cost for providing these preventative services to our patients. Furthermore, additional costs are incurred when these preventive benefits produce the early detection of possible illness or disease, possibly causing additional physician visits, diagnostic tests, laboratory services, and monitoring of therapies. CMS needs to fully account for the direct costs and the ancillary costs resulting from providing these preventive services in their calculation of the SGR.

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Medicare National Coverage Decisions

CMS must fully account for the increase in physician services driven by their National Coverage Decisions (NCDs) and their contractor's Local Coverage Decisions (LCDs) because these Decisions drive up costs.

For example, ACCP supports the CMS decision to cover lung volume reduction surgery (LVRS) for appropriately screened patients with emphysema. LVRS coverage for Medicare beneficiaries will add the direct as well as the ancillary costs of this service to the Medicare physician expenditures. The ACCP estimates that there are 3 million Americans with emphysema, and most of these are Medicare patients. ***Not all of these patients are candidates for LVRS.*** However, by making LVRS available to the Medicare population, we expect to review and evaluate additional emphysema patients to assess LVRS suitability to their clinical situation. Even though the majority of these patients are not suitable for LVRS, the evaluation process will increase cost of physician services. Any Medicare policy change has a ripple effect on other services and procedures, and these additional costs are not reflected in the SGR calculations.

We remain convinced that CMS is not fully accounting for the increase in physician services due to these coverage guidelines in the SGR.

Remove Medicare-Covered Drugs from the SGR Calculation

ACCP strongly recommends that CMS exercise its discretionary authority to remove the costs of Medicare-covered physician-administered drugs from the SGR calculation. Nearly the entire medical community has commented on this issue and remains frustrated that this SGR-adjustment has not been made.

ACCP notes that expenditures for Medicare-covered physician-administered drugs have increased from \$1.8 billion in 1996 to \$8.7 billion in 2004. Including this tremendous increase in the SGR formula adversely affects the calculated update factor for the Medicare physician fee schedule. Furthermore, physician-administered drugs are clearly not "physician services" as the term is described in the Medicare statute.

II. SUPPLEMENTAL PRACTICE EXPENSE SURVEYS (page 45774)

The ACCP supports the bottom-up methodology for creating direct practice expense inputs. The initial review completed by the Practice Expense Advisory Committee (PEAC) and continued refinement through the Practice Expense Review Committee (PERC) of the American Medical Association is appropriate.

However, the ACCP is concerned with the significant shifts in practice expense that would necessitate another four-year transition and suggests that no change in

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practice expense occurs until all specialties can complete supplemental practice expense surveys. Therefore, we are requesting the deadline for collection of supplemental practice expense surveys be extended until December 31, 2006, so that ACCP can conduct a supplemental practice expense survey.

III. RESPIRATORY THERAPY CODES G0237-G0239 (Appendix B)

Last year, the ACCP expressed concern about the low total relative values for the respiratory therapy codes, G0237, G0238 and G0239, which were created in the 2001 final rule. Again, ACCP is concerned that these codes are under valued. We are also concerned that they continue to be included in the nonphysician work-pool, which we understand is being abolished.

CPT	Descriptor	Total RVU
G0237	Therapeutic procedures to increase strength or endurance of respiratory muscles, face-to-face, one-on-one, each 15 minutes (includes monitoring)	0.42
G0238	Therapeutic procedures to improve respiratory function, other than described by G0237, one-on-one, face-to-face, per 15 minutes (includes monitoring)	0.49
G0239	Therapeutic procedures to improve respiratory function or increase strength or endurance of respiratory muscles, two or more individuals (includes monitoring)	0.33

In 2004, CPT added a new 15 minute assessment code 97755, and the proposed total RVU in the NPRM for this code is 0.93. We believe a rank order anomaly now exists in the relative value units of physician work assigned by CMS to codes G0237-G0239, and specifically request that CMS evaluate these codes appropriately.

ACCP will be submitting a CPT proposal for these three codes. We believe that there are populations outside of Medicare that would need a CPT code to report these services such as a pediatric pulmonologist caring for a young cystic fibrosis patient. Therefore we request that these temporary G Codes become CPT codes.

IV. SUPPLIES AND EQUIPMENT REQUESTS (page 45782)

Table 18 – Supply Items Needing Specialty Input for Pricing (refer to NPRM)

In Table 18, SA091 Tray, scoop, fast track system Unit Price \$750 is listed as ENT for CPT 31730. That same tray is listed in Table 16 Proposed Practice Expense Supply Item Additions for 2006. ATS and ACCP provided manufacturer

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information to CMS staff through the RUC Practice Expense Review Committee (PERC) for that supply item.

Table 19 - Equipment Items Needing Specialty Input (abstracted items for discussion below)

Code	Description	Price	Specialty	CPT Codes Associated with Equipment
EQ131	Hyperbaric chamber	\$125,000	FP, IM, EM	99183
EQ212	Pulse oximetry recording Software (prolonged monitoring)	\$3,660	Pulmonary Disease, IM	94762
EQ221	Review master	\$23,500	Pulmonary disease, Neurology	95805, 95807-11, 95816, 95822, 95955-95956

Hyperbaric Oxygen Chamber

ACCP recommends that CMS check the Web site of the undersea and hyperbaric medical society at www.uhms.org and select the Links choice on the list on the left and then click on Chamber Manufacturers to find many vendors listed. The monoplace chamber is the most frequently purchased.

Pulse Oximetry

ACCP appends a quote from SAW Medical Systems for the purchase of equipment for Overnight Oxygen Studies which totals \$3,890.

Review Master

We have checked with three sleep practices and cannot find any information on a review master.

**V. PAYMENT FOR INHALATION DRUGS AND A DISPENSING FEE
(pp 45847-45848)**

The ACCP again wishes to support the DME suppliers on their need for an administrative dispensing fee for supplying nebulized medicine as treatment for respiratory diseases.

We appreciate CMS allowing for 90-day prescriptions of inhalation drugs, and CMS response to ours and others' comments that most patients who receive nebulized medicine require medication to manage their disease for prolonged periods. These patients suffer from chronic lung disease, most commonly COPD and asthma. Allowing the 90-day prescription refills reduces paperwork and redundant efforts on the part of patients, physicians and DME suppliers.

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In 2006 with the advent of coverage of metered-dose inhalers (MDIs), many Medicare beneficiaries will migrate to MDIs. Those patients who do not migrate to MDIs will more likely be frail and require the level of personal service provided by DMEs.

We support the American Association for Homecare who requests that the dispensing fee not be lowered from the 2005 fees of \$57 for a \$30 day supply and \$80 for a 90-day supply of inhalation therapies. There are no data that supports the reduction mentioned in the proposed rule.

The ACCP appreciates the opportunity to comment on the proposed policies under the Medicare Physician Fee Schedule. Should you or your staff have any questions, please do not hesitate to contact me or Lynne Marcus at lmarcus@chestnet.org or (847) 498-8331.

Sincerely,

Paul A. Kvale, MD, FCCP
President
American College of Chest Physicians

cc ACCP Practice Management Committee

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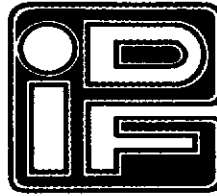
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9/21/2005 9/21/2005	4 Weeks ARO	Dan Walton	30 Days	Rolling Meadows, IL	20% with order balance on delivery

Qty	Product #	Product Description	Unit Price	Extended Total
		NorthEast Monitoring Holter Products The Creator of "Holter for Windows" Now Distributed by SAW Medical Systems Overnight Oxygen Studies		
1	NESWLXB	NorthEast Monitoring Basic full disclosure software	\$995.00	\$995.00
1	NEDR180+	NorthEast DR180+ Digital Recorder	\$1,695.00	\$1,695.00
1	NEUGOXY	Upgrade Digital Recorder to include: Oxygen Electronics, Software License, OxyHolter cable, Nonin Oxygen Probe, Nonin Adult Flexi-wrap, OxyHolter carry Pouch, Pouch Shoulder Strap, etc. Operating Guide.	\$1,200.00	\$1,200.00

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	System Total	847-498-5460	\$3,890.00
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IMMUNE DEFICIENCY FOUNDATION

The National Organization Devoted To Research And Education For The Primary Immune Deficiency Diseases.

**40 West Chesapeake Avenue, Suite 308
Towson, Maryland 21204**

September 28, 2005

BY HAND DELIVERY

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

**RE: CMS-1502-P (Medicare Program; Revisions to Payment Policies
Under the Physician Fee Schedule for Calendar Year 2006)**

Dear Administrator McClellan:

On behalf of the Immune Deficiency Foundation (IDF), a national, nonprofit organization providing service to patients and family members affected by primary immune deficiency diseases, I would like to take this opportunity to comment on the proposed Rule #CMS-1502-P regarding changes to payment policies under the physician fee schedule for calendar year 2006, and request that CMS take special consideration in its reimbursement of intravenous immune globulin (IVIG) due to the current access problems facing patients that rely on this lifesaving therapy.

Primary immune deficiency diseases (PIDD) are disorders in which part of the body's immune system is missing or does not function properly. The World Health Organization recognizes over 130 primary immune deficiency diseases. Many of these disorders are caused by intrinsic or genetic defects in the immune system, which require chronic replacement therapy consisting of intravenous immune globulin infusions to protect individuals from frequent life-threatening infections and debilitating illnesses. Most primary immune deficiency patients do not have an alternative therapeutic option. Therefore, survival depends on access to IVIG.

Patient access to care is essential as IVIG is life-saving, as well as life-sustaining. Earlier this year, CMS implemented the new average sales price (ASP) payment methodology (ASP + 6 percent) under Medicare Part B. This revision in the payment methodology has not been adequate for health care providers under Medicare Part B to continue to purchase and administer IVIG in physicians' offices, infusion suites, and home care settings. IDF has seen the invoices from the physicians' offices showing that cost for IVIG exceeds the reimbursement payment from CMS. This has caused hundreds of patients to be moved out of their optimal site of care to a new site of care, the hospital, when available. Additionally, due to the shift in patients to new sites of care, the hospitals have been overburdened by the increase in demand for IVIG, which has not been easily accessible. Therefore, patients are facing a reduction in product or in frequency of infusions and higher exposure to infections, which has led to an increase in adverse health impacts of up to forty percent of these patients.

IDF supports comparable reimbursement in all sites of care, as long as it is adequate. The goal should be to ensure that patients have access to all brands of IVIG in all sites of care. Currently, most sites of care under Medicare Part B have been eliminated and we are concerned that if the reimbursement under Medicare Part B is not increased, patients are going to continue to be adversely affected. We wish to work closely with CMS to reopen access to care in physicians' offices and infusion centers, often the most appropriate sites of care for patients with primary immune deficiencies.

Since November 2004, IDF has worked closely with Herb Kuhn, Don Thompson, and Amy Bassano of your staff on the access to care issues facing our community. I am pleased to say that your staff has been both receptive and helpful. However, many patients continue to have their care compromised, impacting their health. We have recently submitted comments on the hospital outpatient payment system (HOPPS) and our concern regarding the hospital reimbursement being reduced to a level that has the potential to eliminate access to IVIG in the final site of care that is currently available.

Additionally, a letter was sent to Secretary Leavitt on September 6, 2005 by approximately thirty Members of Congress requesting that the Secretary act upon the recommendations made by the HHS Advisory Committee on Blood Safety and Availability (ACBSA) on May 16, 2005 to declare a public health emergency to enable CMS to apply alternative mechanisms for determination of the reimbursement schedule of IVIG products. ACBSA recognized the "worsening crisis" of IVIG access and how the crisis places "patients' lives at risk." Additionally, on September 19, 2005, ACBSA re-addressed the issue on access to IVIG for Medicare beneficiaries. The Committee recommended that the Secretary take immediate steps to increase reimbursement for non-hospital IVIG therapy to a level consistent with current market pricing by reclassifying IVIG as a biologic response modifier and declaring a public health emergency to

address the short-term problem. Moreover, the Committee recommended that CMS work with Congress to establish a long-term stable and sustainable reimbursement structure.

Therefore, we request that you work with the Secretary to help increase access to IVIG in all sites of care.

RECOMMENDATIONS:

IDF requests that CMS use any and all authority and flexibility to address the existing reimbursement problems that we are currently witnessing under Medicare Part B. Most recently, CMS has worked with the hemophilia, dialysis and chemotherapy communities in order to assure that reimbursement does not deter patient access and care. We request that CMS use this same flexibility so that those Medicare beneficiaries reliant on IVIG are not endangered by a further deterioration in their access to this life sustaining therapy.

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

1. Establish an add-on payment rate for IVIG. PPTA has recently commissioned the Lewin Group to do a study to determine an add-on payment rate for the hospital outpatient payment system and Medicare Part B for the physician's office.
2. Properly classify IVIG as a biologic response modifier (BRM) and reimburse its administration in a high complexity category.
3. Enhance the representativeness of the payment rate for each IVIG product by establishing unique HCPCS codes for each product.
4. Increase the reimbursement rate for IVIG under inherent reasonableness.

I. Provide an Add-on Payment

The Lewin Group is studying the complex issue of IVIG reimbursement. The data they collect will demonstrate the actual, market-based pricing of IVIG, which is the price at which broadly based, national samples of hospitals are routinely able to procure it. The first stage of this comprehensive study is scheduled to be completed by December 2005 and will identify, catalogue, and estimate the cost of the full range of services that are related to the provision of IVIG to ensure that reimbursement covers these costs as well as the prices providers must actually pay for the therapy itself. These cost estimates will help policymakers better understand the issues related to supply, pricing policy, and payment. The study will also determine the magnitude of an appropriate "add-on" payment for IVIG,

as well as the relative distribution of costs across product acquisition, handling, and administration.

II. Classify IVIG as A Biologic Response Modifier (BRM)

IVIG has been proven to modify the course of several diseases for which there are no other viable therapeutic options. Unfortunately, however, administering IVIG to these patients is a complex undertaking, taking between three to eight hours, and requiring careful monitoring by a trained infusion nurse. In part this relates to the role that IVIG serves as a **biological response modifier (BRM)** in these diseases. A BRM is defined by the National Library of Medicine as: "a treatment intended to stimulate or restore the ability of the immune system to fight infection and disease". **IVIG is a BRM for patients with primary immunodeficiency as it enhances the missing and defective components of immunity to fight and protect against infection and complications of infection.** As the administration of IVIG is complex, like other BRMs, the process of administering the product should be reimbursed using higher complexity codes. This will allow for the effective and most importantly safe administration of IVIG to patients dependent upon it.

In primary immune deficiencies and in other indications, IVIG modifies aberrant immune response to protect, maintain and restore normal physiology to prevent disease. As is commonplace with BRM therapy adverse events (AE) occur frequently, and the risk of severe AEs is real. For example, the FDA licensing studies of IVIG for patients with PIDD (for which all currently available IVIG products are licensed) include an occurrence of AEs as high as in 72% of patients. There are also severe AEs many of which are acute, including thromboembolism, hypotension, seizures, aseptic meningitis syndrome, anaphylaxis, acute respiratory distress syndrome, and transfusion associated lung injury. All IVIG products also include a black box warning regarding acute renal failure. The proper diagnosis of acute AEs in the context of IVIG infusions requires expert supervision and skilled intervention. This is necessary to minimize the impact of the AEs to the patient receiving treatment and in some cases can be life saving.

The 2002 IDF survey of 1170 patients with primary immunodeficiency directly documented the significance of IVIG AEs as well as the inherent complexity in administering IVIG. This survey found that 61% of patients have infusion rate related AEs and 44% have had serious AEs. These data demonstrate AE rates higher than those found in licensing studies, but importantly represent actual patient experience from an adequately sized and randomly obtained sample. Unfortunately, however, the incidence of serious AEs is not predictable. The IDF survey found that 34% of AEs occurred during a first infusion with a new product, but the remainder occurred in patients who have previously tolerated that particular brand of IVIG. Thus, vigilance needs to be maintained for detecting and managing AEs irrespective of an individual patient's personal experience

with IVIG. The pervasive and unpredictable nature of AEs in patients receiving IVIG demands a high level of care to insure patient safety.

Given the gravity and acuity of risks in administering IVIG special precautions are required. These include careful monitoring of the entire infusion process which can be as short as three to four hours, but as long as eight hours. Expert nursing care by registered nurses skilled in the administration and risks of IVIG is essential. Nurse to patient ratios of 1:1 and never less than 1:2 are essential to allow frequent clinical assessment (including neurological checks), measurement of vital signs every 15 minutes (including temperature, respirations, heart rate and blood pressure) and comprehensive documentation. Physician and nurse assessment of a patient to determine suitability for the infusion is also necessary as certain comorbidities of the primary diagnoses can preclude, or alter the administration of IVIG. The immediate availability of the physician to evaluate the patient at any point during the infusion for assessment of potential complications is also critical. Finally, preparedness for a number of interventions to manage common infusion-related complications, including adjustment of the infusion rate, supplementation with physiological fluids, and provision of analgesics, non-steroidal anti-inflammatories, bronchodilators, antihistamines, steroidal anti-inflammatories, or occasionally systemic sympathomimetics is also required. Clearly, the safe and effective prescription and administration of IVIG requires a highly skilled and coordinated effort from both nurse and physician.

Currently, administration of IVIG under the non-chemotherapy codes G0347 for the first hour and G0348 for subsequent hours provides \$77.29 and \$25.76, respectively. Given the aforementioned concerns and standard of care this rate fails to meet even nursing labor expense. Reimbursement using the chemotherapy codes G0359 for the first hour and G0360 for subsequent hours would provide \$173.54 and \$39.40, respectively. Clearly these differences are not enormous, but will allow continued access to the standard of care required by the IVIG patient receiving treatment in the physician setting. Most importantly they will allow patients to receive IVIG safely and will allow practitioners to minimize the significant risks incurred by patients who depend upon therapy for their sustenance.

III. Establish Unique HCPCS Codes for Each Brand of IVIG

To the extent that CMS finalizes its proposal to pay for all separately payable drugs under OPPS based on ASP information, we believe that CMS could enhance the representativeness of the payment rate for each IVIG product by establishing unique HCPCS codes for each product. That would allow CMS to determine an ASP for each product based on its own ASP information, yielding rates that are pertinent to each product and thus may enhance access to IVIG products.

Unfortunately, there has been an assumption among many policymakers that all eight licensed IVIG products in the United States are exactly the same and the manufacturers' processes have no significant impact on patient care. It is absolutely critical that they understand that IVIG therapies are not interchangeable. Therapies differ in terms of donor pools, manufacturing and final formulation. Indeed, a number of these differences can, and do, affect individuals' tolerability, risk of adverse events, infusion rate, and potential efficacy.

However, Congress understood the uniqueness of IVIG by exempting it from the competitive acquisition program (CAP). There are currently eight licensed IVIG products in the United States, but each of the formulations of these products are different, and more importantly patients react differently to each brand of IVIG. Although this class of therapeutics may be equivalent in some aspect, the U.S. Food and Drug Administration (FDA) recognizes each IVIG brand as unique, and actually makes each drug go through individual clinical trial protocol to receive licensure, even if it is from the same manufacturer. This is because of the differences in basic fractionation and the addition of various modifications for further purification, stabilization and virus inactivation/removal that have yielded products clearly different from one to the other. In addition, there are well-established differences in chemical structure, antibody content, subclass distribution and electrophoretic profile. Clearly, the composition of the final product differs widely.

Additionally, IVIG is a blood product, and goes through the same donation and fractionation process as albumin, clotting factor, and alpha-one prohibitase.

When treating primary immune deficiency patients, many factors need to be taken into consideration when deciding which IVIG product should be used. For example:

- Patients with congestive heart failure or compromised renal function may be better off receiving a product with a low osmolality and low volume;
- Patients who are diabetic are better off with a product containing no sugars;
- Patients receiving products with sucrose may be at a higher risk for renal failure;
- Patients with immunoglobulin A (IgA) deficiencies should only receive products with the lowest amount of IgA or they could have anaphylactic reactions; and
- Patients with small peripheral vascular access or a tendency toward phlebitis may want to avoid preparations with a low pH.

These are just a few examples of some of the adverse effects that physicians are trying to avoid. Physicians often have to prescribe two or more brands of IVIG for infusion at different times in order to monitor for side effects. Having access

to all brands of IVIG is vital to treat a patient without incurring unacceptable serious and often life threatening side effects.

IVIG therapy is prepared from plasma pooled from thousands of donors. Most production processes begin with sequential precipitation and fractionation with ethanol to isolate IgG from other plasma proteins. The IgG concentrates from initial fractionation are subjected to additional processing to produce material suitable for intravenous administration. This is where major differences exist among products and where biologic function is most susceptible to alteration.

The major differences, which lead to the product characteristics are as follows:

- **Liquid vs. Lyophilized**

The manufacturing process impacts whether the final product is in liquid or lyophilized (freeze-dried powder) form. Liquid preparations are potentially easier to use and may be associated with fewer adverse events. In ready-to-use form, the liquid preparations shorten preparation time and delays for patients. However, lyophilized preparations may have a longer shelf life without the need of refrigeration and are often less costly.

- **Product Concentration**

The manufacturing process also affects product concentration. Products that can be given at higher concentrations decrease volume load, an important aspect in certain patient populations. Concentrating certain products by reconstitution in a smaller volume will increase the osmolality of the final solution and may contribute to significant adverse events such as renal complications or thromboembolic episodes. However, patients that can tolerate rapid infusions can receive higher concentrations of IgG, which would result in shorter infusion times.

- **Product Composition**

The variety of manufacturing processes, as well as starting materials, leads to differences among preparations that may be clinically important. Choosing the preparation of IVIG must take into account specific differences that can significantly impact the outcome in recipients.

- **Fluid Volumes**

The ability to deliver higher amounts of IgG in lower volumes has a major impact on recipients who may be intolerant of large fluid volumes, such as infants or patients with congestive heart failure or renal insufficiency.

- **Sugar Content**

Various sugars, such as: sorbitol, glucose, and sucrose have been added to some preparations as a stabilizer and preservative in order to prevent aggregate formation. Some products contain no sugar. A major concern associated with sugar content is the incidence of significant adverse events, particularly acute renal failure or insufficiency. Although rare, the

CDC reported that 90% of the IVIG-associated renal adverse events in the United States occurred with sucrose-containing IVIG preparations.

- **Sodium Content**

In IVIG solutions, the major contributors to osmolality include sodium, sugars, and other excipient proteins. Solutions of IVIG range from physiologic osmolality to solutions that far exceed these levels. Some sugar-stabilized products have higher osmolalities than other sugar stabilized and sugar-free preparations. In reconstituting lyophilized preparations, careful attention to osmolality is required as adverse events may occur with solutions exceeding the physiologic range. With some lyophilized preparations, reconstitution to higher concentrated solutions results in hyperosmolar solutions.

- **pH**

The pH optimum for IVIG to prevent aggregation is 4.0–4.5. As a consequence, for preparations at higher pH, agents are added to maintain stability and prevent aggregation. There are various reports that low pH may be associated with phlebitis.

- **IgA Content**

Patients with selective IgA deficiency and the ability to produce antibodies may be at risk for developing IgE or IgG anti-IgA antibodies resulting in reactions, possibly anaphylaxis.

- **Antibody Titers**

There are marked differences in the levels of some antibodies among correctly licensed products, which could significantly determine efficacy of intervention with IVIG.

Patients affected by primary immune deficiency diseases depend on IVIG as a life saving therapy for the rest of their lives. Each individual needs to have maximum access to the specific formulation which best meets their unique needs and does not pose serious and potentially life threatening complications. I want to reemphasize the adverse events that can occur while being treated with IVIG: renal dysfunction or failure (kidney problems), thromboembolic events (excessive blood clotting), hypertension (elevated blood pressure), phlebitis (irritation of veins used for infusions), and anaphylaxis (life threatening allergy). While a patient may experience an adverse event with a particular product, (s)he may tolerate other products quite well. This situation is addressed by prescribing two or more brands of IVIG for infusion at different times and monitoring for side effects. With the current changes in reimbursement under Medicare Part B, patients are not receiving the optimal brand of IVIG and in many incidences are having their brands switched every time the patient is infused. This is leading to devastating results.

IV. Inherent Reasonableness

CMS can increase the reimbursement rate for IVIG under the inherent reasonableness concept. IVIG reimbursement has been reduced dramatically. The reduction in price has caused undue hardship to the primary immune deficiency community. Access to physicians' offices, infusion suites and home care settings has been eliminated to many patients under the new payment structure. Inherent reasonableness allows CMS to increase reimbursement by up to 15% when patient access has been harmed due to reimbursement.

IMPACT OF MEDICARE PAYMENT REDUCTIONS:

Since January 1, 2005, IDF has received hundreds of calls and letters from patients, physicians, home health care companies and other treatment sites regarding access problems related to Medicare reimbursement for IVIG treatment. In order to obtain a fair and unbiased assessment of the current impact of changes in Medicare reimbursement since January 2005 on patients with primary immune deficiency diseases who are being treated with IVIG and who are Medicare patients, IDF conducted an independent survey of a sample of this population. This survey was not sponsored or supported by any third party outside of IDF.

The IDF identified a subset of patients from its two national surveys and ongoing web survey of new patients, who reported Medicare coverage. 202 patients with primary immune deficiency diseases, who were currently on Medicare and IVIG users, were interviewed about their treatment experiences in the past 12 months. The survey finds that nearly two out of five (39%) PIDD patients on Medicare being treated with IVIG have experienced a wide variety of IVIG treatment problems -- most commonly changed locations for infusions (12%) and postponed infusions (16%), but also increased intervals between infusions (11%), lower dosage (6%), switched to less preferred product (7%) and/or less tolerated product (4%). 3% reported having had to stop infusions. Of the 12% who changed site of infusion, 51% reported receiving their infusions in a doctor's office a year ago, as opposed to 9% now. At the same time, 17% reported receiving infusions in a hospital outpatient setting, and 49% do so now.

According to the survey, the health of 40% of patients experiencing problems getting IVIG in the past 12 months and 15% of all PIDD Medicare patients on IVIG has been negatively affected. The survey provides verbatim reports from patients experiencing these problems on the role of the new reimbursement standards in these problems and the nature of the adverse health effects they have suffered as a result.

The experience of problems obtaining IVIG is adversely affecting patient confidence in whether they are currently getting optimal treatment, but much

more dramatically their confidence in their ability to get appropriate treatment in the future. Those who are aware of the problems most commonly blame industry (18%), Medicare (17%), and Government (23%). Less than half (47%) of those who have experienced problems in getting their IVIG treatment in the past 12 months rate the job that the U.S. health care system is doing in getting proper treatment for them as excellent, very good or even adequate.

The experience of Medicare patients at the time this survey was conducted (primarily May-July 2005) may have been muted by the efforts of many physicians, home health care companies and hospitals to help patients cope with the initial impact of the reimbursement rules. IDF is now receiving more calls about home health care companies and physician offices that had tried to maintain treatment of their Medicare patients since January and are now transitioning them to the hospital setting.

The information is consistent with the May-June 2005 IDF national survey of 287 physicians having patients using IVIG, totaling 4189 patients with a primary immune deficiency disease, and 935 patients with other disorders. The survey found that 31% of physicians that treat PIDD patients with IVIG reported patients experiencing significant problems related to reimbursement of IVIG. Of this group, 43% reported adverse health effects on patients as a result of reimbursement. The impact on patients included: 21% switched to a different site of care, 22% postponed infusions, 13% switched brands, and 8% had the interval between infusions increased.

Prior to the implementation of the Medicare Modernization Act (MMA), according to IDF's surveys, 30% of primary immune deficient patients relied on hospital outpatient facilities to receive their IVIG. Since the implementation of the MMA, that number has reportedly increased due at least in part to the fact that health care providers reimbursed under Medicare Part B have had difficulty purchasing IVIG at Medicare's reimbursable rates. We are concerned that under the proposed rule, hospitals will be subject to a similar reimbursement formula, which will put them in the position of administering IVIG at a loss, and will likely adversely affect access to care for all patients in need of this life-saving product. CMS must prevent the elimination, or even restriction, of access to this important site of care. Each individual needs to have maximum access to the specific formulation which best meets their unique needs and that does not pose serious and potentially life threatening complications.

I have enclosed a copy of these surveys for your review.

CONCLUSION:

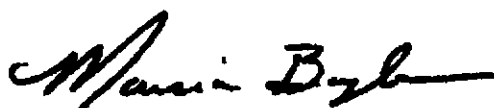
Since the implementation of the Medicare Modernization Act, access to IVIG for patients with primary immune deficiency diseases has decreased dramatically,

putting patients' lives at risk. Your attention to this situation as CMS prepares its final rules for 2006 will be greatly appreciated, as well as your input with the Congressional Committees of jurisdiction to implement an add-on payment or an alternate mechanism to ensure that patients that rely on IVIG as their life-saving therapy have access to all brands of IVIG in all sites of care. Reimbursement should never dictate when, where, and/or if a patient receives their life-sustaining therapy.

We look forward to continuing to work closely with your staff and would welcome the opportunity to discuss the access problems our community is having in receiving their lifesaving therapy in all sites of service. Michelle Vogel, Director of Government Affairs and Reimbursement Services, is available to answer any questions you or your staff may have in regards to reimbursement issues affecting primary immune deficiency patients' access to care. She can be reached at (202) 329-8643.

Thank you for your attention to these very important issues.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Marcia Boyle", with a stylized, flowing script.

Marcia Boyle
President and Chair

***Survey of Intravenous Immunoglobulin
Availability and Access among Medicare Patients
with Primary Immune Deficiency Diseases:
May-July 2005***

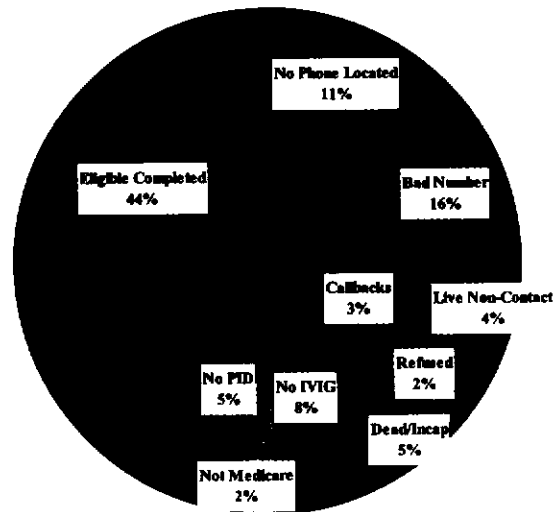
Immune Deficiency Foundation

September 19, 2005

Medicare Patient Survey: Methodology

- Medicare patients from 1996-7 survey
- Medicare patients from 2002 survey
- Medicare patients from IDF online survey
- Total Medicare patients = 471
- Directory assistance for telephone numbers
- Screening to determine Medicare and IVIG status
- Maximum of 40 contact attempts
- Telephone interview: average length 15 minutes
- Interviewing begins on 5/25/05
- Interviewing 90% complete on 7/05/05
- Last completed interview on 8/06/05

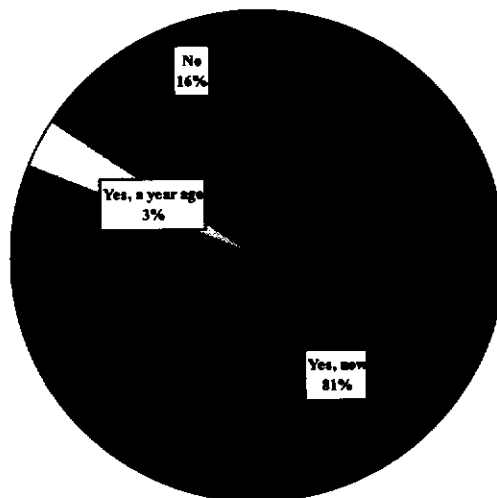
Sample Disposition for Medicare Patient Survey: 2005



Cases from previous national surveys N=471

3

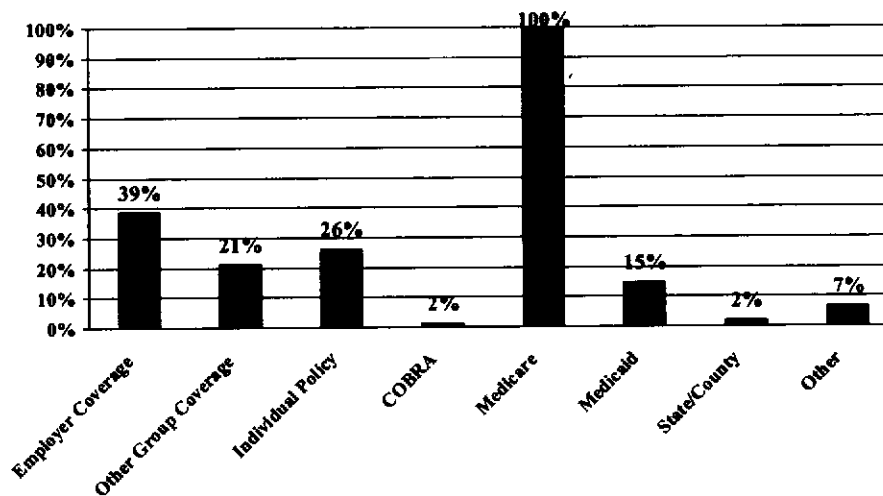
IVIG Use: Medicare Patients



Q3a. Is he/she currently being treated with IVIG for this condition?
Q3b. Was he/she being treated with IVIG a year ago? N=239

4

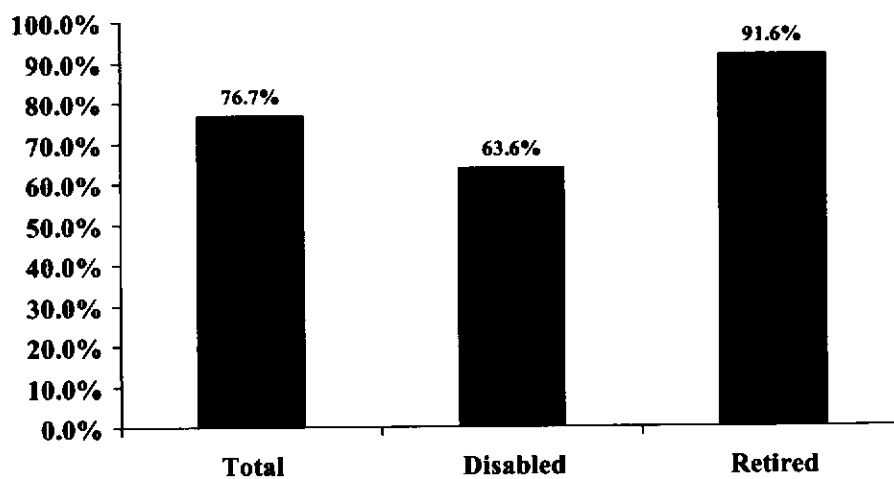
Source of Current Health Insurance



Q2. What is the current source(s) of the patient's health care coverage?
(Base: Have Medicare and Use IVIG a Year Ago N=202)

5

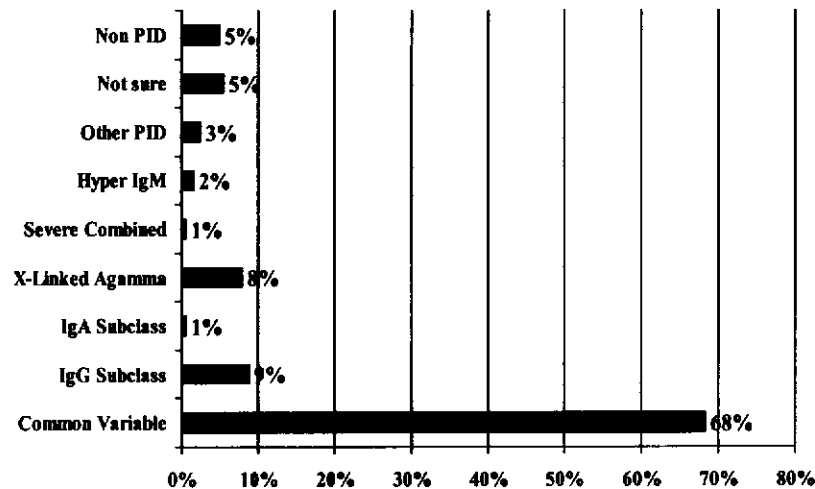
Have Private Health Insurance



Q2. What is the current source(s) of the patient's health care coverage?
(Base: Medicare and IVIG Use N=202)

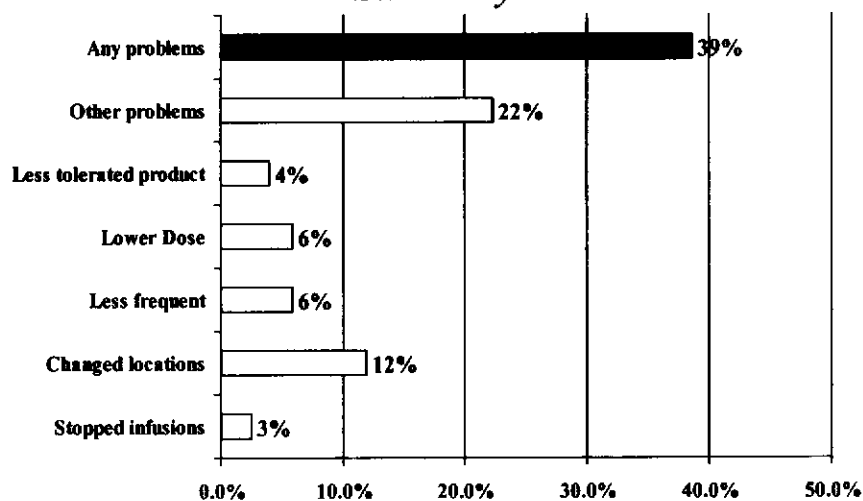
6

Type of Primary Immune Deficiency



Q1. What specific type of primary immune deficiency disease have you been diagnosed with? 7
N=202 (Base: Medicare patients using IVIG one year ago)

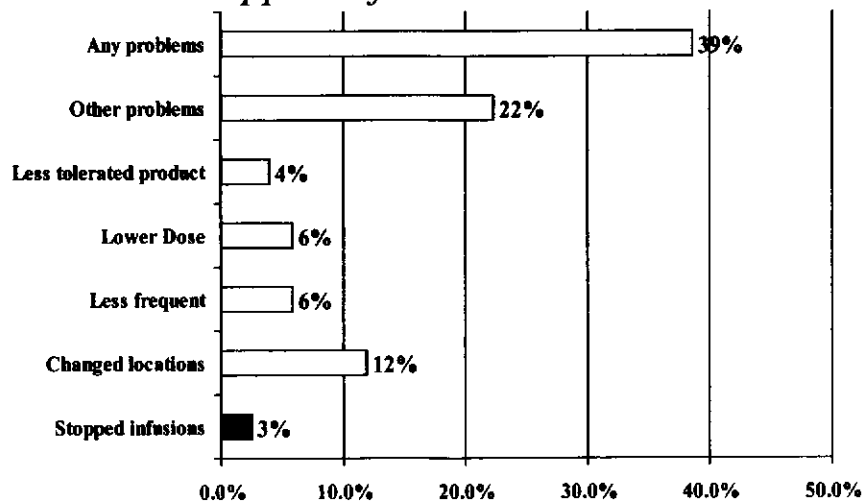
IVIG Problems For Medicare Patients: Summary



Q3d; Q4d; Q6c; Q8c; Q10c1, and Q14b Base: Medicare Patients using IVIG a year ago N=202

8

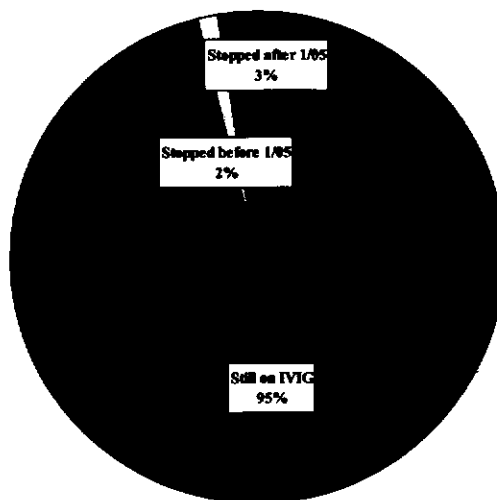
IVIG Problems For Medicare Patients: Stopped Infusions since 1/05



Q3a. Is he/she currently being treated with IVIG for this condition? Q3b. Was he/she being treated with IVIG a year ago? Q3d. When did he/she stop being treated with IVIG? N=202

9

No Longer Getting IVIG



Q3a. Is he/she currently being treated with IVIG for this condition? Q3b. Was he/she being treated with IVIG a year ago? Q3d. When did he/she stop being treated with IVIG? N=202

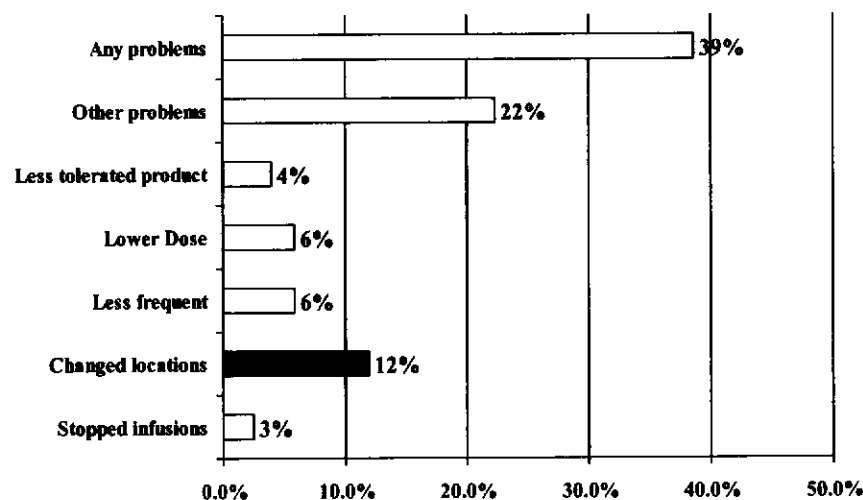
10

Why No Longer Getting IVIG

- “Because I was no longer able to get my gammaglobulin in doctor’s office as of April 1st because Medicare changing law that send doctors payment for gammaglobulin. They lowered the amount of payment for doctors.”

11

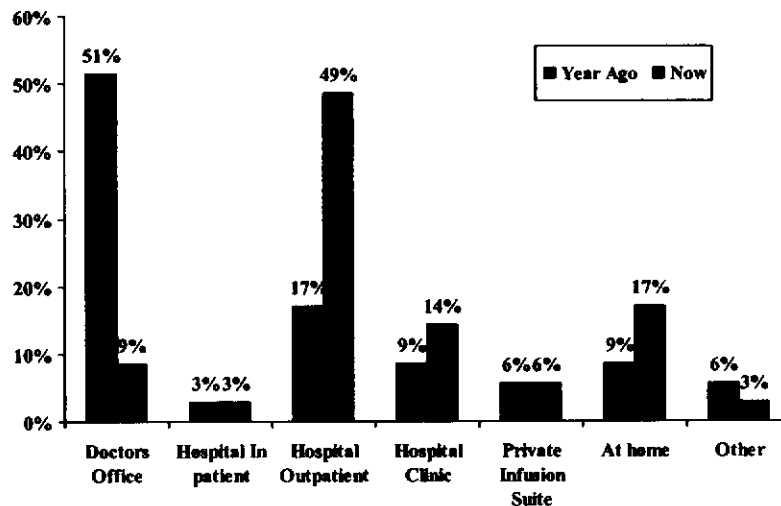
IVIG Problems For Medicare Patients: Site of Infusion Changed since 1/05



Q4a. A year ago, where did the patient usually receive his/her infusions? Q4b. Does he/she still get his/her infusions at the same location? Q4d. When did the location change (most recently). N=202

12

Change in Site of Infusions



Q4a. A year ago, where did the patient usually receive his/her infusions? Q4b. Does he/she still get his/her infusions at the same location? Q4c. Where does he/she get his/her infusions now?
Base: Has changed infusion site N=35

13

Why Changed Site of Infusion (1)

Because Medicare reimbursement rates were lowered
 Because Medicare changed the funding and policies changed.
 Because Medicare wouldn't pay the private doctor anymore.
 Because of the Medicare modernization act (specific) the reimbursement was too low at doctors office

 Because the doctor was not getting sufficient money from Medicare to cover the cost of treatment.
 Because the doctors are no longer reimbursed for the cost of the gamma globulin
 Because the government said I couldn't take the infusions as his office anymore. We informed about this by the IDF in December.
 Because the government said i had to (why) didn't say why
 Because the government through home health fixed it where we could infusions at home through home health
 Because they are charging so much for the product when you can buy it cheaper, charging \$16,000 for the product when it's usually less than \$3,000(else)no that was the reason, my husband is a teacher and didn't see giving the other teachers a raise in premium
 Dr X asked this company to accept Medicare & they don't take everybody. because Medicare cut the doctors payment.
 Due to Medicare change in what they are paying the doctor per gram in the infusions
 Medicare was refusing to pay for amount of medication and when they got better deal the distributors went up and the doctors losing money
 Medicare would no longer pay for the private physician.

14

Why Changed Site of Infusion (2)

The change in the Medicare payments. They cut the amount that they would pay to doctors and as a result the doctor's could not buy the gamma at a price that they could make any profit on and the doctor also told me that in some cases they would actually

The doctors were no longer being reimbursed for gamma globulin by Medicare. They reduced the amount so low that it would have cost the doctors more, they would have lost money on it. The cost of the gamma globulin was for example \$50 a gram and they wo

The explanation i got from my doctor was that Medicare had started not reimbursing enough to cover the doctors office cost. That sort of floored me because Medicare and my insurance is now paying about \$648 more than they were paying the doctors office.

The reimbursement rate for the doctor was lowered by Medicare

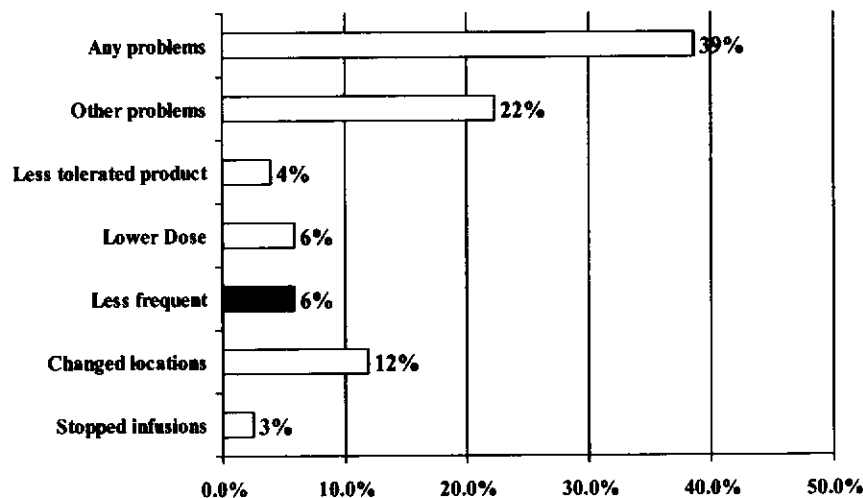
They cut the costs to the doctor, he was getting 59 cents per gram, now getting 39 cents

Because Medicare would not cover it at physicians office

Because Dr. X can't afford to pay for all these pts treatments; he couldn't get reimbursed

15

IVIG Problems For Medicare Patients: Less Frequent Infusions since 1/05



Q6a. Has the frequency of his/her infusions been changed in the past 12 months? Q6b. Were the infusions changed to more frequent or less frequent? Q6c. When did that happen? Current user N=194

16

Why Less Frequent Infusions

Because of Medicare's new ruling (elab) the hospital just said that because of Medicare's new ruling they will give it to me every 3-4 weeks.

Because the hospital was having problems with Medicare paying for this and they would not treat me unless my level was below 600 and normal is 1000...My doctors decided to extend it to 8 weeks hoping levels would stay below 600 but having sinus infection

Due to lack of medicine (elab) no, the clinic i was at stopped getting it so i called IDF and they didn't know how they could help

Medicare is dictating the frequency to the doctors and taking the care out of the doctors hands for the patient. Because i was chemically poisoned, i was a fire fighter for 21 years and was exposed to a chemical exposure which gave me common variable im

The hospital doesn't have enough IGG so they postponed the frequency because of the shortage

The hospital had new Medicare rules that said that we were only to get it every 3-4 weeks.

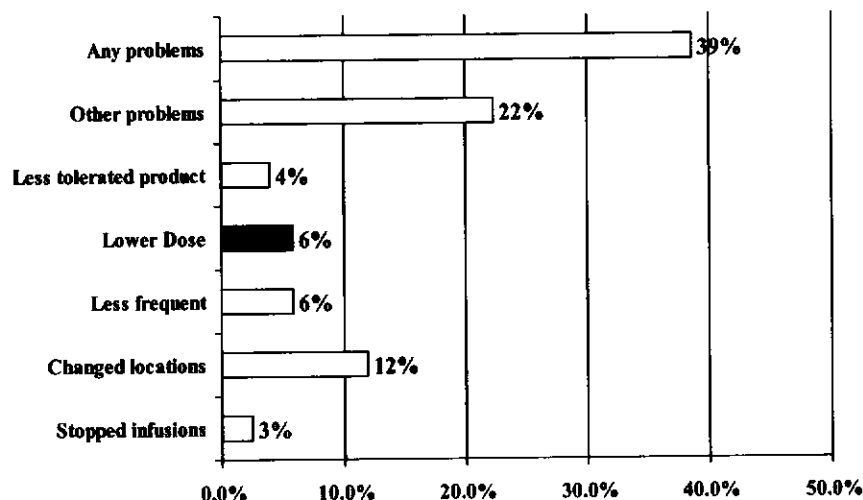
The hospital said due to shortage in the gamma, in buying it, so they were going to put me off for 4 weeks instead of 2 weeks until i notified the hospital that i was in contact with idf and my congressman. Then they switched me back to every 3 weeks in

They decided to try me at every 2 mo & after 3wks they figured out that wasn't going to wk. (It was related to the Medicare reimbursement & i offered to make up the difference in \$\$, but they never accepted any money)

They didn't give me an answer as to why, my bill was so high because each month that one line takes thousands of dollars, it varies, there for a while it was 10 thousand and sometimes 11 thousand per month.

17

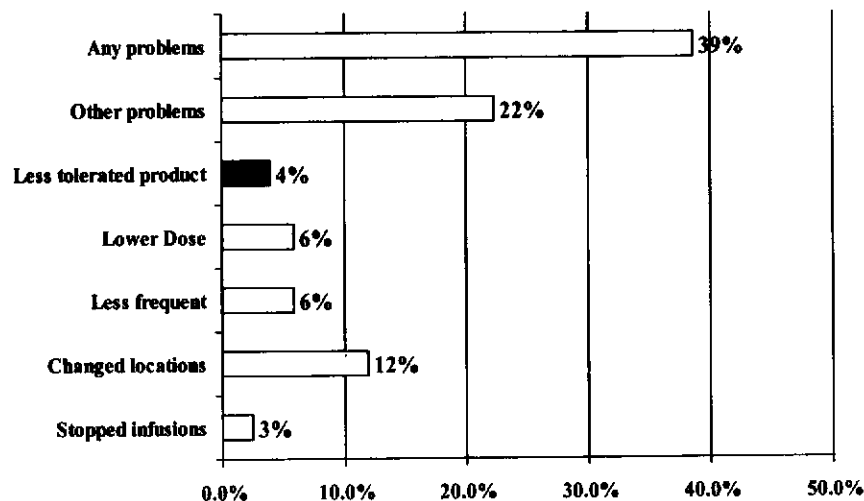
IVIG Problems For Medicare Patients: Lower Dosage since 1/05



Q8a. Has the number of grams he/she infuses been changed in the past 12 months? Q8b. Was the amount increased or reduced? Q8c. When did that happen? N=194

18

IVIG Problems For Medicare Patients: Less Tolerated Product Substitute since 1/05



Q10a. Has the product he/she infuses been changed in the past 12 months? Q10b. Was he/she changed to a product he/she tolerated better, tolerated worse or did it not making any difference? Q10c. When did that happen? Current user N=194

Why Changed to Less Tolerated Product

Based on availability, Polygam simply happens to be the drug that this particular hospital had. When I'm here in Ohio I have no idea what product they'll give me, based on availability.

Because I had to change locations because of the Medicare pricing change I had to change locations...Also didn't react well to last medication at doctor's office which was Gammar P, that was changed due to pricing...Haven't gotten blood work on most recent

Because it meant that the doctors got reimbursed more.

Because that's the only product that the hospital had, that's all they had to offer.

Because the doctor was very arrogant and didn't listen and I was getting a product without that

Because the hospital buys it in bulk..If they bought the product that works well in my doctor's office

Because they didn't have the other one.

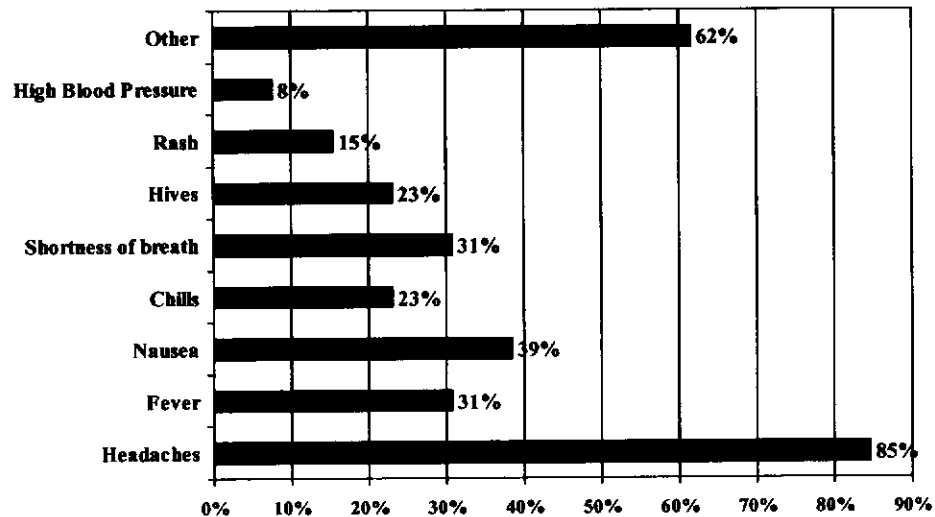
Because they quit making IVEEGam and I was taking it

Because when I changed hospitals the new hospital stocks a different brand.

I believe that there were issues of supply and the ability purchase it at a rate covered by reimbursement guidelines by Medicare

The hospital gives you what they have available in their pharmacy

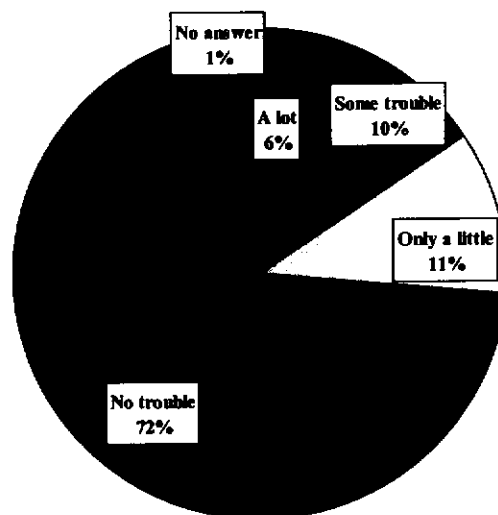
Side Effects from New Product



Q10c. What types of (non-rate related) serious side effects or reactions from IGIV has he/she had? (N=13)

21

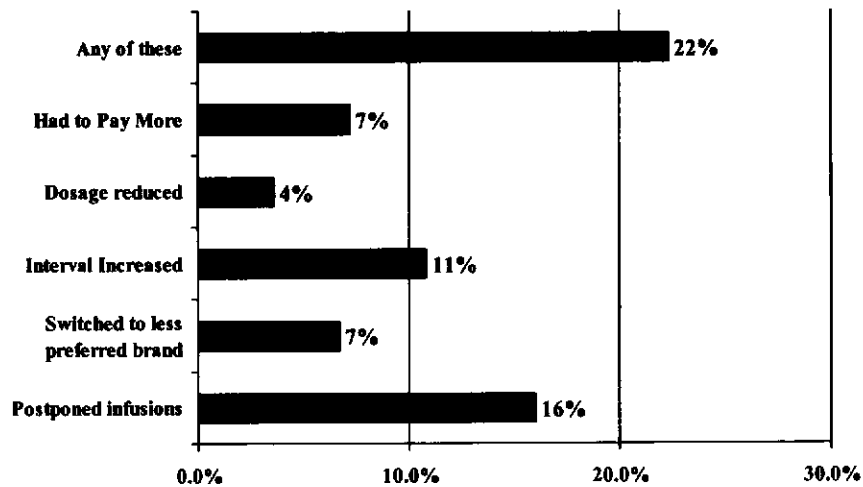
Trouble in Getting IVIG Infusions



Q14a. Overall, how much trouble have you had in getting IVIG infusions in the past 12 months?
Current user N=194

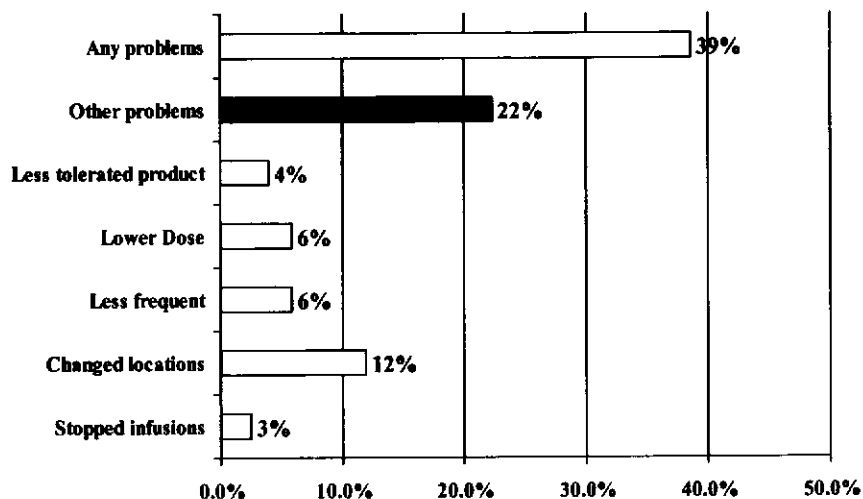
22

Impact of IVIG Problems in Past 12 months



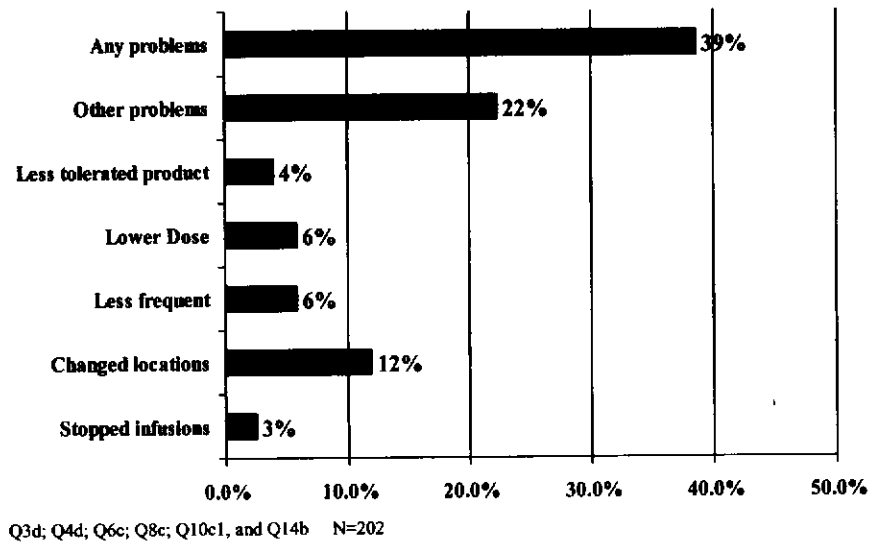
Q14B. As a result of these problems during the past 12 months have you? Current user N=194

IVIG Problems For Medicare Patients: Postponed Infusions and Other Problems

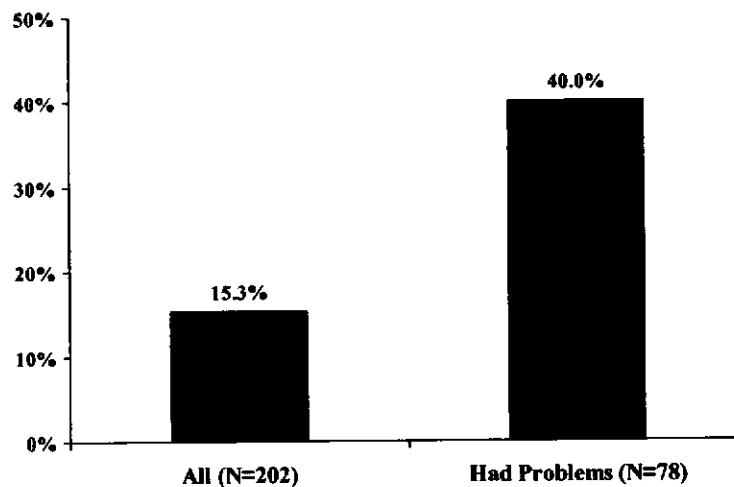


Q14B. As a result of these problems during the past 12 months have a) Infusions had to be postponed; b) Have you been switched to a less preferred brand; c) Has the time between dosage been increased; d) Has dosage at infusion been reduced; e) Have you had to pay more? Current user N=194

IVIG Problems For Medicare Patients: Total



Negative Health Effects as a Result of Problems Getting IVIG



Q14c. Have these problems getting IVIG in the past 12 months had any negative effects on your health?

26

Negative Health Effects (1)

Bed-ridden for 1 and 1/2 years because i couldn't get product for 6 months because the act being passed doctor didn't want to start me on new medication until he knew he could get it for me (else) numerous symptoms throughout the body, fever, joint pain, colds-
 Before i went to critcare, i went to another hospital for treatment and they gave me the wrong kind and i had little spots on me (else) i had a really bad reaction and they (the doctors) mentioned kidney failure (else)no
 Began to symptoms from immunoneuropathy, had neurosensory deficits (mean) had increase in pain from immunoneuropathy, tingling, numbness, inability to function at level i once was (else) fatigue much more quickly and feel very tired and run down
 Constant infections (kind) skin infections, bronchial infections, a stomach infection, severe joint pains and fatigue so bad you could hardly lift your head off the pillow
 Constant infections (type) bronchial, skin, stomach. My neutrophils have had to have bone marrow stimulating shots of a cost of \$7000 per shot and terrible joint pain to the point where you could hardly walk
 Feel worse (specific) low-grade infections, sinus problems, pneumonia, it's related to what i'm getting and the frequency, because they were switching products on me
 Getting sick more frequently, more frequent infections, my joint pains have increased. (Else) no.
 Have continuous cold and infections and osteomyelitis (bone infection) (else) no
 I've become weaker. (Else) no.
 I've been coming up with more respiratory infections and also i have suffered after effects from the gamma because it's not the brand that i normally take.
 I've problems with my breathing that hits me always when i'm receiving my transfusion which lingers now. Also my general stamina and my ability to resist colds and such has gone down. (Else) some of my main medications have not been able to regulate.
 I begin to have dysentery in which i tend to get infections in the intestinal and stomach areas.
 I can hardly walk or pick anything up (other) no
 I ended up w/secondary infection (respiratory/sinus) after rx was postponed

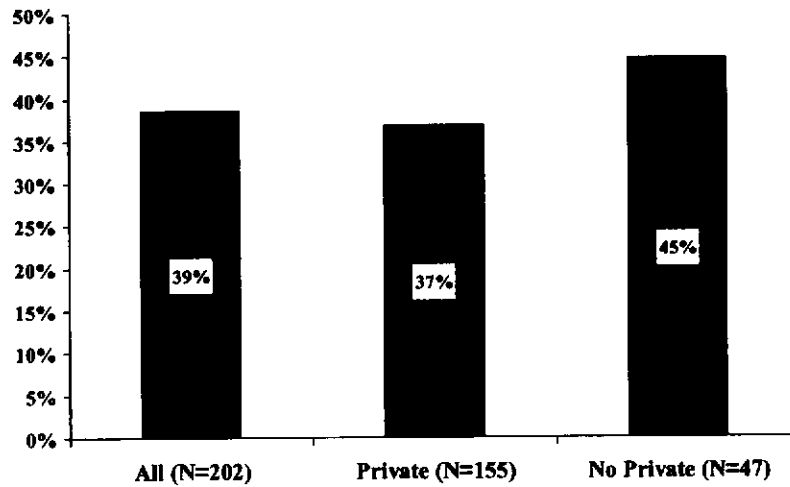
27

Negative Health Effects (2)

I get a flair up of symptoms (ex) increased stomach upset (others) no
 I got sick in mid February with a flu like that and i still have the cough to this day. It goes from yellow sputum to clear, it depends on whether i've had antibiotics or not. (Problems) i had a problem with the hospital where i'm getting the gamma.
 I suffer from chronic depression, i've felt very depressed. I have upset stomach. (Else) diarrhea and i've had headaches. (Else) no.
 I was supposed to go on field trip with kids but can't because of breathing problems and on aerosol (else) a lot of flu and asthma attacks (else) my joints hurt when KGG's are low and have headaches (else) all round sick
 In the past 2 months i've had to go 22-25 miles one way to a medical center in a different town where they didn't appreciate having someone from another town, a patient from another town. The nurse didn't like my having antiscram on my hand and wrist to
 infections (sinus & bronchitis & pneumonia) & my disability from the joint pain when my levels are low is 'pretty overwhelming'
 Like when i was in hospital i couldn't get my IVIG & i think it delayed my improvement enough to go home so i had to stay
 Lot of stress, when i was overdue in April, i called the IDF & Dr.X and they may cancel me--that is very stressful
 More frequent infections (type) urinary tract infections and skin abscesses in my body. Also auto immune disorders
 Pneumonia, bronchitis, sinusitis, (else) usual fevers and just general malaise
 Pneumonia, bronchitis, thrush infection (yeast infection that people with PID get), fevers, (else) no
 Right now i'm in the middle of 8 or 9 weeks without the treatment because of ability to pay and i'm struggling, i'm very sick without it. (Kinds) recurrent shingles, extreme fatigue, joint pain, that's enough right now.
 Sick all the month of January after the infusion. Not sure if they gave me the right treatment
 Sinus infections (else) my asthma is worse
 Stress (specific) my gamma levels have dropped to where i have been sick and catching illness (else) no
 UT & sinus infects & common infects & i was on antibiotics a lot & i have no energy & have to stay away from people to avoid catching anything

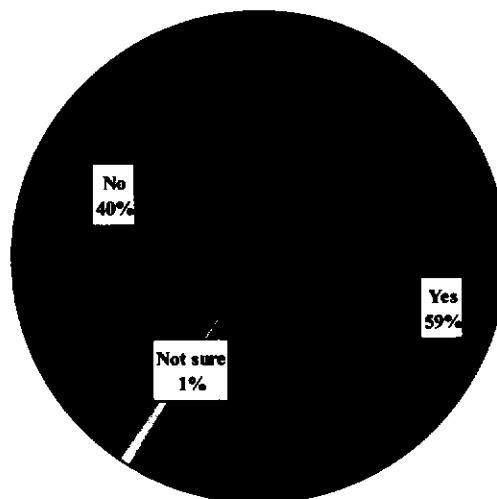
28

Trouble in Getting IVIG Infusions for Medicare Only and Additional Coverage



29

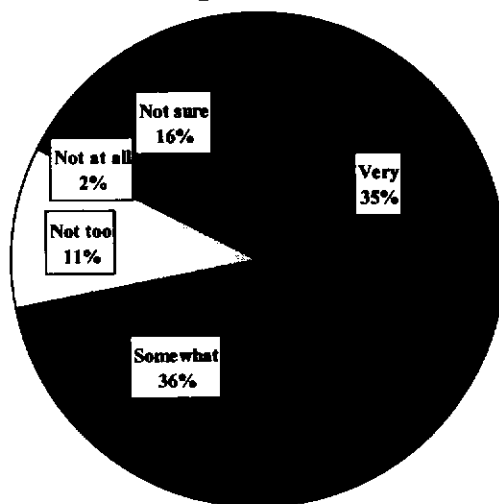
Aware of Difficulties Getting IVIG



Q13a. Were you aware that some patients have had difficulties in getting IVIG in the past few months? N=194

30

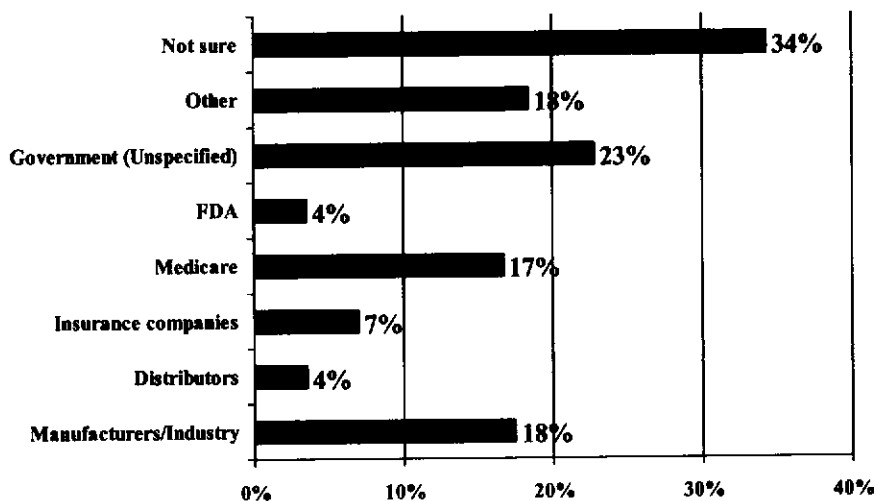
How Widespread are Problems Getting IVIG Infusions



Q13b. Based on what you know or have heard, how widespread are these problems in getting IVIG? Base: Have heard of Problems N=114

31

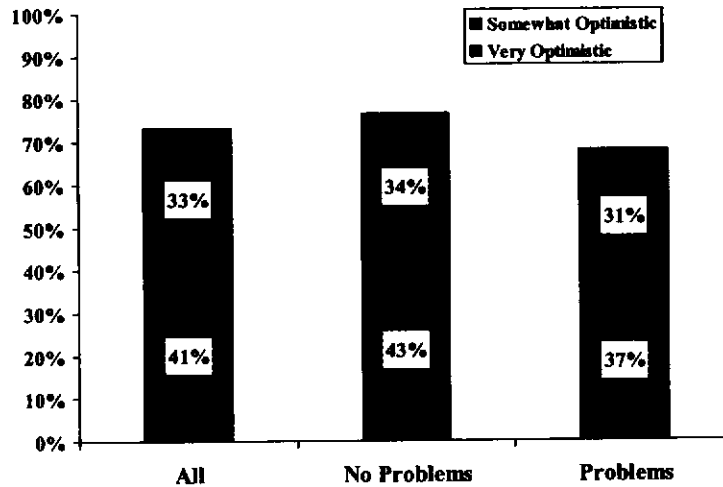
Who is Responsible for Problem in Getting IVIG



Q13d. Who is the cause of the problem? Base: Aware of problems getting IVIG N=114

32

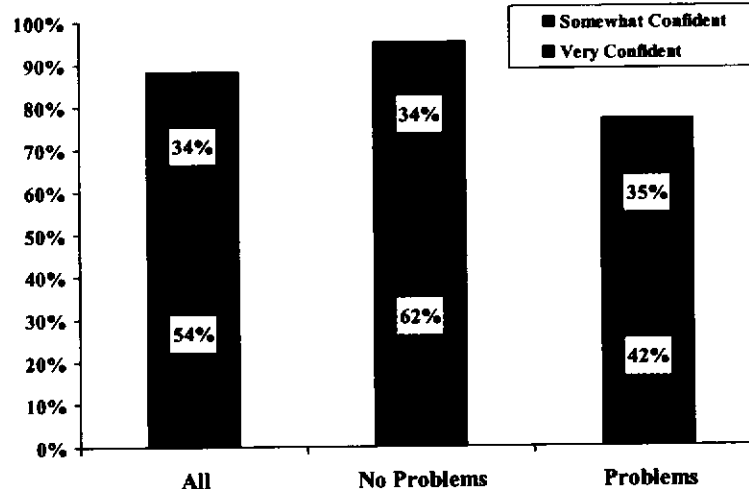
Long Term Health Outlook by Experience with IVIG Problems



Q15. With proper treatment how do you feel about the long term outlook for (your/his/her) health – very optimistic, somewhat optimistic, neither optimistic nor pessimistic, somewhat pessimistic, very pessimistic? N=202

33

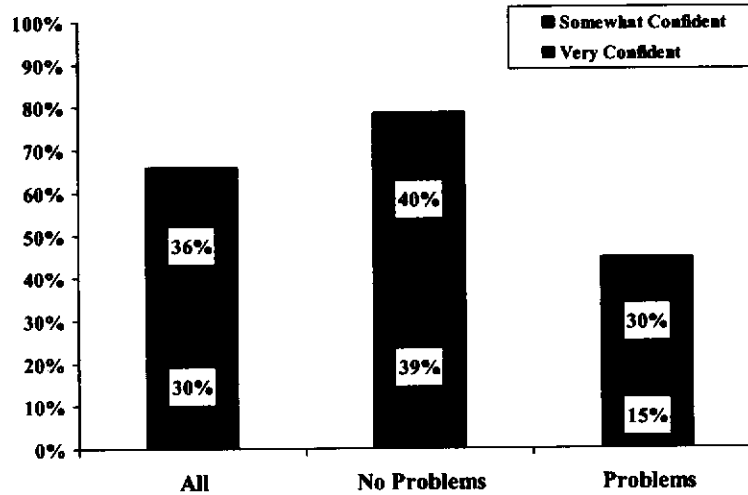
Confidence in Current Treatment by Experience with IVIG Problems



Q11. How confident are you that your current IVIG dosage and infusion schedule are optimal for maintaining (you/his/her) health – very confident, somewhat confident, not too confident, not at all confident? N=202

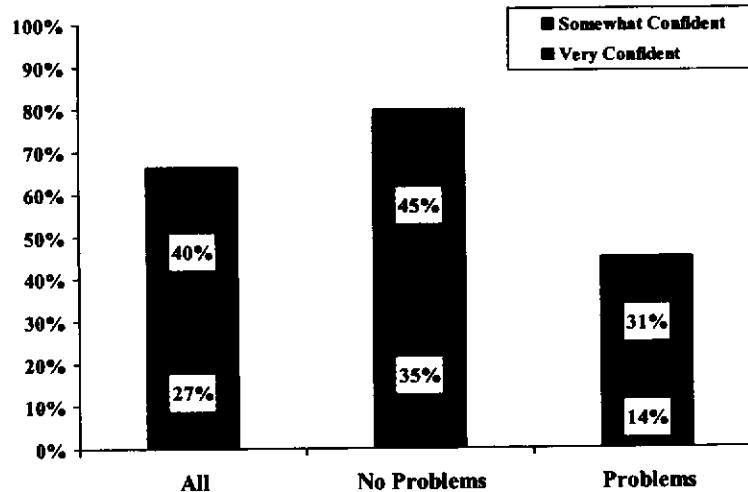
34

Confidence in Future Treatment by Experience with IVIG Problems



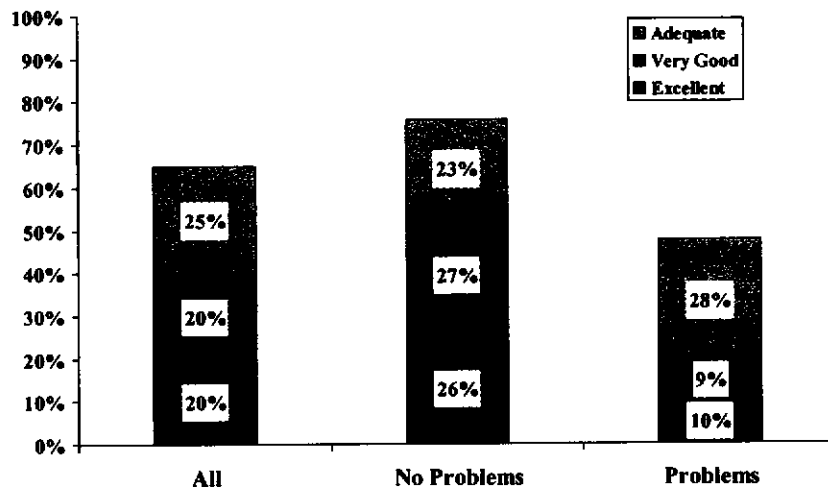
Q12. How confident are you that (you/he/she) will be able to have a dosage and infusion level necessary to keep (you/him/her) healthy in the future – very confident, somewhat confident, not too confident, not at all confident? 35
N=202

Confidence in Future Ability to Get Appropriate Treatment by Experience with IVIG Problems



Q16. How confident are you that (you/he/she) will be able to get appropriate treatment to keep (you/him/her) healthy in the future – very confident, somewhat confident, not too confident, not at all confident? 36
N=202

Rating of US Health Care System by Experience with IVIG Problems



Q17. How good a job do you feel that the U.S. health care system is doing in getting proper treatment for (you/him/her) --- excellent, very good, adequate, less than adequate, poor or very poor? N=202 37

Physician Survey of Intravenous Immunoglobulin Availability and Access for Patients: June 2005

Immune Deficiency Foundation

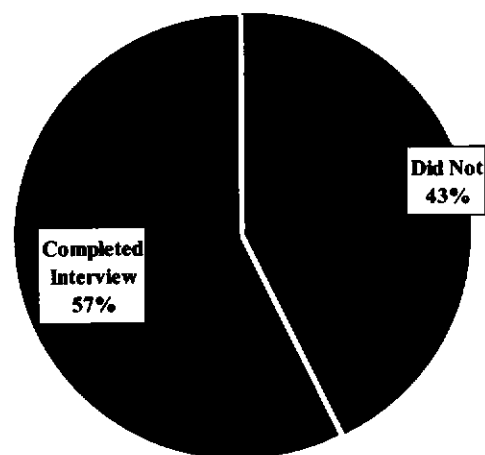
September 12, 2005

Preliminary and Confidential: Not for Citation

IDF Survey of Physicians: 2005

Faxed to a national sample of 558
physicians reporting PID patients
in IDF 2003 Physician Survey

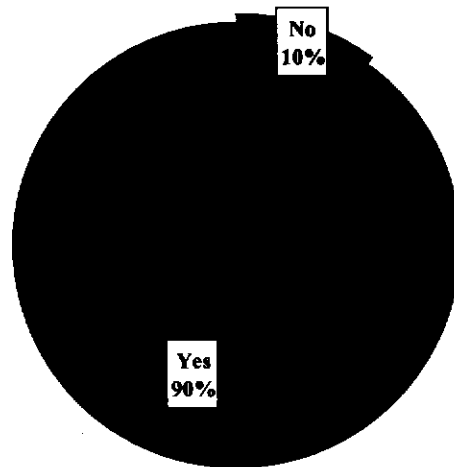
Response Rate to Fax Survey



N=558 physicians with good fax number between May 20 and June 28, 2005

40

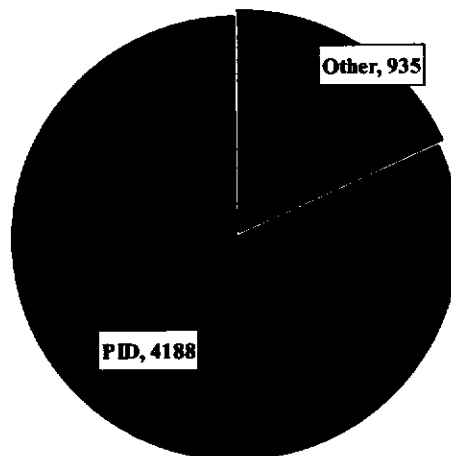
Any Patients Treated with IVIG



Q1. Do you see any patients who are treated with intravenous gammaglobulin (IVIG)?
N=320 reporting physicians

41

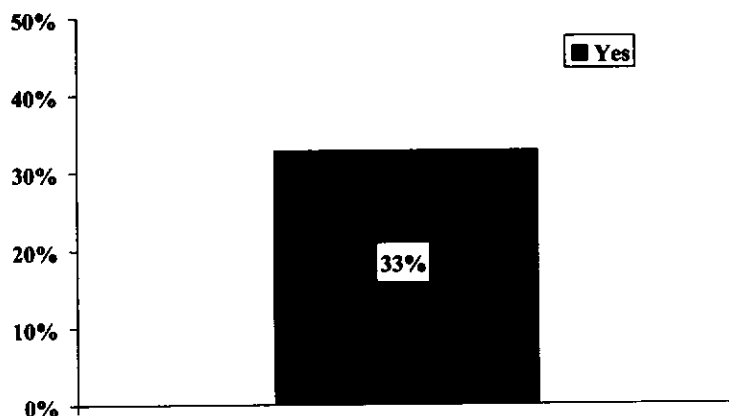
Number of Patients Treated with IVIG



Q2. Approximately how many patients do you see who receive IVIG therapy for a primary immune deficiency disease, how many receive IVIG for something else?
N=287 with IVIG using patients

42

Significant Difficulty in Obtaining IVIG Products for Patients since 1/1/05

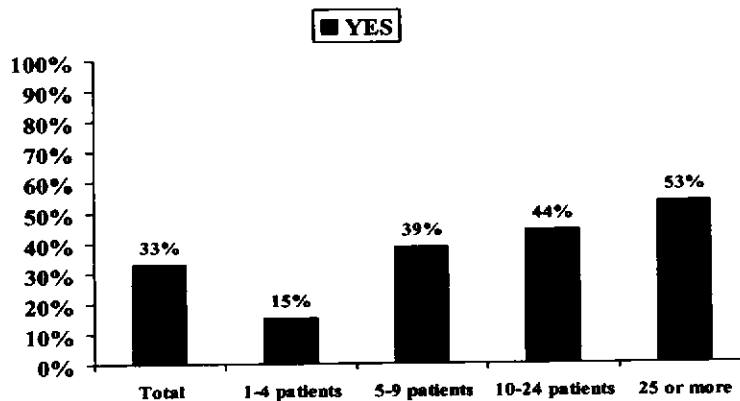


Q3. Since January 1, 2005, have any of your patients experienced any significant difficulty in obtaining IVIG treatment as a result of REIMBURSEMENT FOR TREATMENT rather than supply?

N=287 doctors with IVIG patients

43

Significant Difficulty in Obtaining IVIG Products by Number of PID Patients

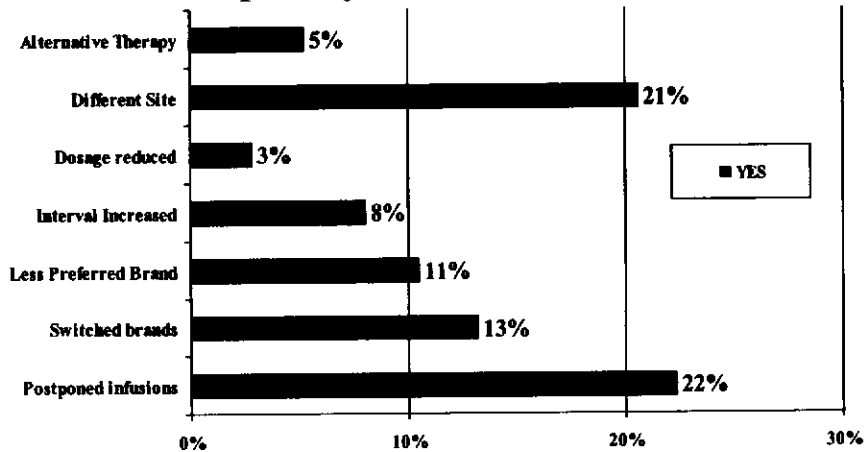


Q3. Since January 1, 2005, have any of your patients experienced any significant difficulty in obtaining IVIG treatment as a result of REIMBURSEMENT FOR TREATMENT rather than supply?

N=285 doctors with IVIG patients

44

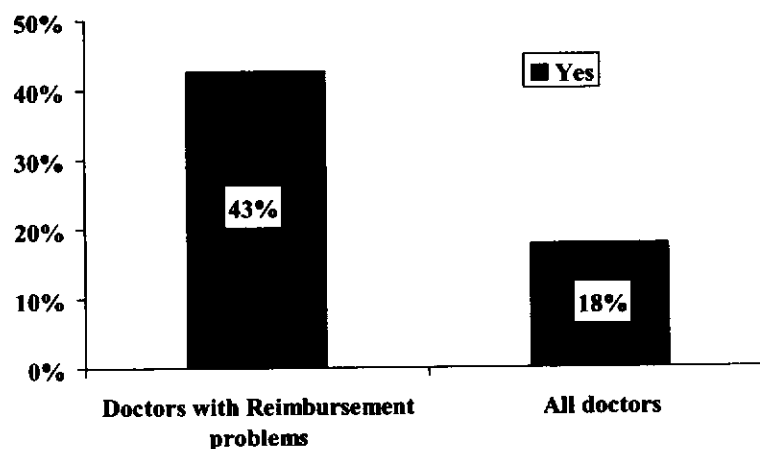
Patient Impact of Problems of Availability



Q5. As a result of problems of REIMBURSEMENT for IVIG since the beginning of the year, which of the following (if any) has happened to your patients? N=285 Doctors with IVIG using patients

45

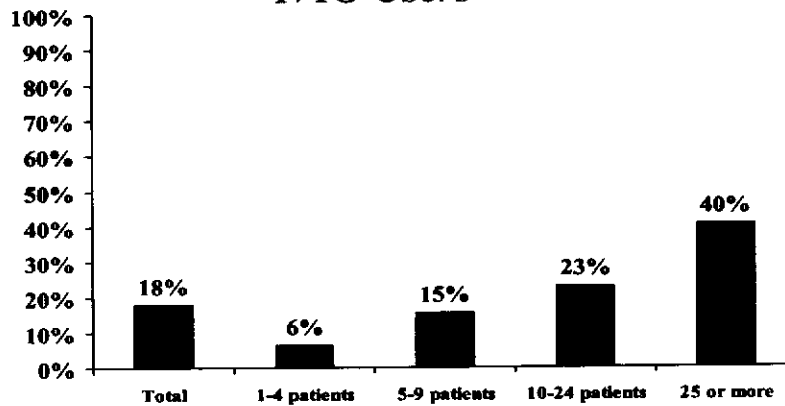
Adverse Health Effects on Patients as a Result of Availability of IVIG



Q6a. Since January 1, 2005, have problems of availability or access to IVIG supply had any ADVERSE EFFECTS on the health of any of your patients? N=287 doctors with IVIG patients

46

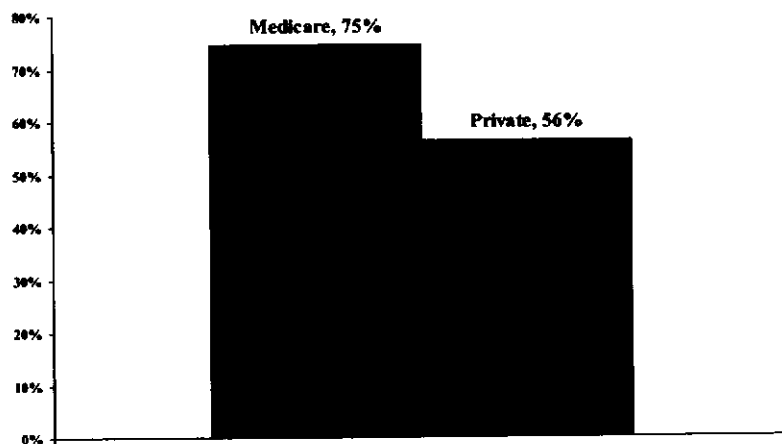
Adverse Health Effects by Number of PID IVIG Users



Q6a. Since January 1, 2005, have problems of availability or access to IVIG supply had any ADVERSE EFFECTS on the health of any of your patients? N=287 doctors with IVIG using patients

47

Types of Patients Experiencing Problems in Getting IVIG as Prescribed



Q7. What types of patients, if any, are experiencing problems in getting IVIG treatment as prescribed? N=287 doctors with IVIG using patients

48

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SEP 30 2005

September 26, 2005

VIA U.S. PRIORITY MAIL

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

Re: NUCLEAR MEDICINE AND POSITION EMISSION TOMOGRAPHY
SERVICES

Dear Ms. Milstead and Ms. Brooks:

Upon review of the comments relating to nuclear medicine services set forth in the Federal Register, Volume 70, Number 151, p. 45854, published August 8, 2005, we feel compelled to address what we believe are problematic aspects of the commentary. The Centers for Medicare & Medicaid Services ("CMS") proposes to categorize nuclear medicine services and positron emission tomography ("PET") as designated health services. We would discourage the outright designation of such services as designated health services for several reasons and suggest reasonable alternatives to the immediate designation of such services.

First, the propensity of CMS to tie physician investment and increased referrals to financial incentives does not take into account the various factors that drive physician use of improved technology. Notably, CMS fails to consider the correlation of increased usage to advances in technology and leading thought on disease diagnosis and treatment. In its commentary, CMS acknowledges that technological improvements have been made with respect to nuclear medicine and PET scanner services and also notes its expanding Medicare coverage of such services. However, CMS accepts as dispositive that increased referrals to physician-owned entities which provide such services are due to financial incentives rather than the improved services and diagnosis achieved by utilizing better equipment. The failure of CMS to consider the potential correlation of increased usage and improved technology may ultimately have a negative impact on the future provision of quality health care as physicians may hesitate to invest in new technology or services for fear that CMS will ultimately decide to prohibit such investment.

CMS' commentary does not provide examples of the extent to which advances in nuclear medicine and PET scan services have improved the quality of care and drive physician decision-making. However, examples exist which support the claim that increased

referrals for such services are not based on financial incentives. For example, oncologists are using PET scanner technology to identify and localize cancers. In the case of nuclear medicine services, certain types of scans which today are used to measure how the stomach empties its contents for patients with gastroparesis were not typically used in a gastroenterologist's practice a mere five years ago. Such scans allow for better diagnoses and avoid invasive procedures. Accordingly, increased referrals for PET scans or nuclear medicine services by oncologists and gastroenterologists, respectively, are often not indicative of overutilization but rather indicate the effective utilization of new or improved technology to treat or diagnose traditional problems. Again, the propensity of CMS to correlate physician investment to increased referrals, while an easy correlation to draw, is not accurate and does not take into account the full picture of improved technology and patient care.

Second, patient care has improved due to physician investment in entities providing nuclear medicine and PET services. Specifically, the ability to invest in new technology and bring such technology to use has led to improved diagnostic and treatment ability. As scans today provide greater clarity in images, specialists have been able to utilize nuclear medicine and PET scan services for purposes never previously considered. This results in lower costs and improved patient care.

Third, not only does physician investment in entities providing nuclear medicine and PET scan services lead to better quality care at a lower cost, physician investment in such entities has also allowed for increased access to such services. Specifically, nuclear medicine and PET scan services that were not otherwise available to certain patient populations have been made available because of provider investment in nuclear medicine and PET scan services. Nuclear medicine and PET scan services require more expensive equipment than traditional radiology services and therefore physician investment in such equipment fills a necessary gap where large health care providers have been unable to afford such equipment or choose not to acquire such equipment. Accordingly, to the extent large health care providers decide not to invest in or cannot afford to invest in such equipment, physician investment in such equipment has filled the gap.

In the alternative, if CMS decides that is in the best interest of the current and future patient population to categorize nuclear health services and PET scan services as designated health services, we encourage CMS to set forth an extensive grandfather provision in the new rule which will allow physician investors in entities currently performing nuclear medicine and PET services to continue referring to such entities.

In conclusion, we ask that you strongly reconsider categorizing nuclear medicine and PET services as designated health services. We encourage CMS to consider that studies regarding increased usage to which it cites its commentary is also a function of improved technology and better diagnostic and treatment modalities which ultimately improve the quality of patient care. Moreover, in situations where treatment or diagnostic modalities are expensive or require the specific skill of a trained expert such as in the case of nuclear

September 26, 2005

Page 3

medicine and PET services, physician investment can help bring new technology to areas which otherwise would not have access. Finally, to the extent that medical technology is constantly evolving and changing, we urge that CMS alter its pattern of retroactively prohibiting physician investment in new technology and services. This pattern of retroactively prohibiting the latest technology or service growth area will dampen the spirit of innovation in the provision of quality patient care and may inhibit the ability to provide the highest quality care. If this pattern continues, physicians will hesitate to make the investments needed to continue to provide high quality care for fear that CMS will ultimately determine that such investments present fraud and abuse risks.

Should you have any questions regarding the above, please do not hesitate to contact me at (312)750-6016.

Very truly yours,


Scott Becker

\\HEA\113493.1

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ATHENS CANCER CENTER

MITCHELL D. ANDERSON, M.D.

BOARD CERTIFIED RADIATION ONCOLOGIST

September 28, 2005

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

Dear Sir:

As a relatively low volume free-standing radiation oncology center in a rural town of 11,000, it is beneficial to our Medicare cancer patients for us to now offer IMRT which can be reimbursed with cross-walk of compensator-based IMRT delivery (0073T) to CPT 77418. Compensator-based IMRT is superior to multi-leaf collimator IMRT with greater accuracy of dose delivery, better safety with a lack of moving parts, any of which could fail during treatment delivery, and shorter treatment times resulting in more comfort to the patients and less scattered dose to the entire body. Of course IMRT in general is the best treatment for some patients, producing fewer side-effects in many, and thereby also limiting the number of treatment breaks to control side-effects, which can compromise cancer control.

Please consider issuance of a Medicare Program Transmittal to include compensator-based IMRT delivery code 0073T and coding guidance for IMRT planning and delivery.

Sincerely,

Mitchell D. Anderson, MD
Medical Director
Athens Cancer Center

784

SEP 30 2005

Wal-Mart Stores, Inc.
702 SW 8th Street
Bentonville, AR 72716-0230
Phone (479)277-0471
E-mail: Bob.Dufour@Wal-Mart.com



WAL★MART PHARMACY DEPARTMENT

September 28, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
P.O. Box 8017
Baltimore, MD 21244-1850

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

To Whom It May Concern:

I am writing to provide comments on the proposed regulation that would change the supplying fees paid to pharmacies by Medicare Part B in 2006. Wal-Mart currently has over 3,600 pharmacies Nationwide, who currently accept assignment for Medicare Part B covered drugs and supplies.

Currently CMS rule requires that "a supplying fee of \$24 shall be paid to a pharmacy for each supplied prescription of drugs and biologicals...and a supplying fee of \$50 is paid to a pharmacy for the initial supplied prescription of drugs and biologicals...provided to a patient during the first month following a transplant." CMS does not currently pay a fee for Part B prescriptions for the same drug but a different strength supplied in the same day.

The proposal to reduce the supplying fee for each part B prescription from \$24 to \$8 would represent a significant reduction in reimbursement for these prescriptions. This reduction to the supplying fee, coupled with the ASP-based reimbursement for the product cost would result in a total reimbursement at less than the cost required for a pharmacy to fill these prescriptions.

In the proposed rule, CMS indicates that in the November 2004 final regulation, it "established a supplying fee that was higher than that of other payers due to the lack of online claims adjudication for Medicare Part B oral drugs." In fact, our own internal cost of dispensing survey (see attached) indicates the cost to dispense these drugs is over \$19 per prescription.

Factors that drive up costs to dispense Medicare Part B items and differentiate these prescriptions from other Third Party prescriptions include:

.....
Wal-Mart Stores, Inc.

September 28, 2005

Page 2

- Lack of online adjudication system which results in inability to promptly and accurately determine deductible status, eligibility, or to coordinate benefits with other online payers.
- Time required to execute Assignment of Benefit Forms and DMERC information forms (DIF's)
- Obtaining additional data requirements prior to billing (i.e. diagnosis codes)
- Manual process of applying for Medicare Provider Numbers and re-enrolling every 3 years.
- Higher than average Bad Debt due to opportunities with obtaining all necessary information at time of dispensing
- Additional time required for correcting and resubmitting claims, filing appeals, or refunding customers because deductible information could not be accurately obtained at the time of service.
- Additional costs involved to submit the claims in the 837 Batch format. Many pharmacies, including Wal-Mart must utilize an outside vendor to properly submit the claims on our behalf.

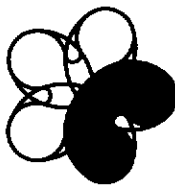
In summary, we are concerned that the recent reimbursement reductions experienced under the ASP-based system, the proposed reductions in the Medicare Part B supplying fees that will be paid in 2006, the uncertainty of a possible move to Competitive Bidding for some Part B products, and the administrative burdens of participating in Part B will make this business less than desirable for Retail Pharmacy. We ask that CMS not consider lowering the supplying fee until such time as these prescriptions can be processed using a real time, online adjudicated system, which would in turn, lower the pharmacy's cost to dispense these items.

Thank you in advance for your consideration of these comments, and we look forward to your response regarding a resolution.

Sincerely,



Bob Dufour
Director, Pharmacy Professional Services
and Government Relations



National Kidney Foundation

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September 28, 2005

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

Dear Sir or Madam:

I am pleased to provide the comments of the National Kidney Foundation (NKF), on the Proposed Rule, Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006, that was published in the *Federal Register*, on August 8, 2005, CMS-1502-P. I am filing this response on behalf of NKF's 50,000 members across the country, including kidney patients, their families, and the health care professionals who strive to meet the goal of "Making Lives Better" for our constituents.

Our comments will be presented in the order that issues appear in the Preamble to the Proposed Rule.

TELEHEALTH

The National Kidney Foundation supports Medicare reimbursement for Medical Nutrition Therapy (MNT) services, provided via telehealth arrangements, for individuals with chronic kidney disease (Stage 3 or 4), including kidney transplant recipients. The National Kidney Foundation supported the MNT provision in the Benefits Improvement and Protection Act because MNT is one of the factors that can improve long term outcomes of kidney patients. Furthermore, we have been concerned that the MNT benefit appears to be underutilized. Telehealth will enhance access to this important service for chronic kidney disease (CKD) patients who live in parts of the country where distance would constitute a barrier to keeping appointments with providers of MNT services who are approved Medicare practitioners.

If there is appropriate equipment, the following settings could be used for MNT telehealth, either as the originating site or the receiving site: CKD clinics, specialty group practice offices, hospital outpatient departments, rural health clinics, centers approved for Diabetes Self Management Training, and dialysis facilities, provided that there is dedicated space in the dialysis unit for telehealth.

Case Mix Adjustments to the Composite Rate

Section 623 of the Medicare Modernization Act required the establishment of basic case-mix adjustments to the composite payment rate for dialysis services. The November 15, 2004 Final Rule implemented three categories of patient characteristic adjustments (age, body mass index (BMI), and body surface area (BSA)) that were effective April 1, 2005. CMS is proposing to retain these categories and patient characteristics as case-mix adjustments for 2006. The National Kidney Foundation urges CMS to evaluate different case-mix adjustments, and the coding changes that may be necessary to effect them. The existing case-mix adjustments will not improve survival rates or patient quality of life. They mainly reflect the additional time on dialysis that is required for larger patients. Conversely, they do not compensate providers for other resource utilization demands or the intensity of care required by frail, elderly dialysis patients or other dialysis patients with ambulatory problems or severe comorbidities. Consequently, we suggest that CMS develop a new code to reimburse dialysis providers for the care of ESRD patients with diabetes, for example. Similarly, CMS should consider an adjustment for the first six months after commencing ESRD treatment because these beneficiaries require additional attention, especially those whose dialysis was initiated as an emergency start.

ESRD – Pricing Methodology

Starting January 1, 2006, CMS proposes to reimburse dialysis providers for separately billable ESRD drugs based upon average sales price (ASP), rather than the Average Acquisition Payment (AAP) methodology which has been the basis of reimbursement for these drugs during the 2005 calendar year. The advantage of the ASP methodology, as opposed to the use of AAP, is that ASP can be updated periodically, calculated from data routinely provided by pharmaceutical companies. Nevertheless, price increases are not reflected in ASP until six months after they are effective. Moreover, small and independent dialysis providers are unable to acquire ESRD drugs at average sales price, even when they participate in purchasing groups. The National Kidney Foundation is concerned that small and independent dialysis providers may have to close if they lose money on ESRD drugs or that they will be forced to cut back on services provided to

dialysis patients. In either case, patients will suffer, especially if the small, independent dialysis provider operates the only dialysis facility in a remote or rural area.

ESRD – Drugs and Biologicals

A drug add-on adjustment to the composite rate was established by the Medicare Modernization Act (MMA) to account for the difference between Medicare payments for ESRD drugs before January 1, 2004, when MMA became effective, and payment methodologies in effect after that date. CMS proposes that hospital-based dialysis facilities should receive the same add-on adjustment as independent dialysis providers, even though independent providers were reimbursed on the basis of average wholesale price (AWP) before 1, 2004, for all drugs excepting erythropoietin, and hospital-based facilities were reimbursed for these same drugs at cost, and will continue to be reimbursed at cost in 2006, if the provision in the current draft Physician Fee Schedule rule is finalized. As emphasized in our comments on the Proposed Physician Fee Schedule for Calendar Year 2005, NKF recommends that the drug add-on adjustment be designed to compensate both hospital-based and independent dialysis facilities for the actual loss of revenue due to changes in reimbursement for separately billable drugs.

ESRD – Composite Payment Rate Wage Index

The current composite payment rates are calculated using a blend of two wage indexes, one based on hospital wage data for fiscal years ending in 1982, and the other developed from 1980 data from the Bureau of Labor Statistics (BLS). The failure to update the ESRD Wage Index has made it difficult to recruit and retain nursing personnel, especially in areas where the cost of living is high and hospitals can afford to offer nurses more attractive compensation packages. Therefore, the National Kidney Foundation congratulates CMS on its decision to address this issue in the Proposed Rule. On the other hand, the proposed revisions will dramatically reduce the payments that many facilities, especially those in rural areas, will receive. It has been estimated that reimbursement for rural facilities could be cut by as much as \$22 per treatment. If that is the case, we doubt that these facilities will be able to survive and are concerned that dialysis patients in remote areas may be required to travel long distances, three times per week, for treatment at more distant units. The National Kidney Foundation recommends that composite rate wage index adjustments be phased in over five years and that CMS provide annual updates of the wage index in each of these years.

ESRD – Exceptions Process

The current regulations contain procedures whereby dialysis providers can request exceptions to ESRD facility composite payment rates, and establish five criteria for approval of exception requests. The five criteria are as follows:

- Atypical service intensity
- Isolated essential facility
- Extraordinary circumstances
- Self-dialysis training costs
- Frequency of dialysis

CMS should retain the exceptions process for all five criteria in order to preserve access to care for dialysis patients and to foster evolution in the patterns of dialysis care. The recent experience with Hurricane Katrina underscores the need for an exceptions process to provide continuity of dialysis care during extraordinary circumstances. Self dialysis and more frequent dialysis should be preserved as options for appropriate patients. In particular, patients with congestive heart failure may require four dialysis treatments per week, and this is a growing segment of the ESRD population. Finally, the exception for isolated essential facilities should be retained because of the potential impact on access to care resulting from the proposed changes in the composite payment rate wage index and reimbursement for ESRD drugs. (Please see above.)

Payment for ESRD Drugs

CMS proposed that dialysis facilities be reimbursed for ESRD drugs at ASP + 6%. However, as noted above, that payment level does not take the different purchasing power of the various segments of the provider community into account. Moreover, because of the lag in adjusting ASP for price increases, ASP +6 does not adequately compensate providers for their true acquisition costs. We note that CMS has proposed to pay hospital outpatient departments at ASP+6%+2% for administration of the same drugs and are concerned that the disparate levels of reimbursement might provide an incentive for shifting the locus of care.

Supplying Fee

The Medicare Modernization Act requires the Secretary of the Department of Health and Human Services to pay a supplying fee (less applicable deductible and coinsurance) when immunosuppressive drugs, which beneficiaries need to prevent rejection of transplanted organs,

are dispensed. Beginning with CY 2005, CMS established a supplying fee of \$24 per prescription for these drugs, with a higher fee of \$50 for the initial immunosuppressive prescription supplied in the first month after a transplant. When multiple drugs are supplied to a beneficiary, a separate supplying fee is paid for each prescription, except when different strengths of the same drug are supplied on a single day. However, CMS is proposing changes to the supplying fee for multiple prescriptions supplied during the same month. The agency would continue paying \$24 for the first prescription supplied during a month (or \$50 for the first oral immunosuppressive prescription supplied in the first month after a transplant) but is proposing to pay a supplier an \$8 supplying fee per prescription for any prescription, after the first one that pharmacy dispenses to a beneficiary during a month. This proposal would reduce a pharmacy's supplying fees by 66%. As a result, community drug stores will be less inclined to stock these expensive drugs for a relatively small consumer group, and specialty pharmacies will not be able to afford beneficiary counseling that is essential in the management of patients using critical dose drugs and requiring polypharmacy. One year ago CMS agreed that pharmacies deserved compensation for providing these services, and for the additional cost of billing the DMERCs who process Medicare payments for immunosuppressive drugs. These inputs have not changed in the interim. Therefore, we must question the proposed drastic reduction in reimbursement. The proposed cuts should not be implemented. Otherwise access to, and quality of, care for transplant recipients who are Medicare beneficiaries will be compromised.

We appreciate the opportunity to respond to the request for comments in the Proposed Physician Fee Schedule for 2006. Please let me know if the National Kidney Foundation can provide any additional assistance to CMS as the agency develops the Final Rule.

Sincerely,



David G. Warnock, MD
President, National Kidney Foundation
Professor and Director
Division of Nephrology
Department of Medicine
University of Alabama at Birmingham

SEP 30 2005

786

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September 26, 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: File Code CMS-1502-P
Issue Identifier: GPCI's/Payment Localities

Dear Sirs:

I am writing in support of the proposed revision to the physician payment localities designation in California. Specifically, I believe the adjustment to the classification that allows Santa Cruz County to be placed into a unique payment locality is an equitable and fair decision that addresses the current under-reimbursement of physicians throughout the County.

As a State legislator, I have the distinction of representing portions of San Mateo, Santa Clara and Santa Cruz counties. This unique perspective underscores the discrepancies between these contiguous counties.

Public health officials, seniors and others in the Santa Cruz healthcare profession have all expressed their concern about the migration of physicians to neighboring counties. And other area physicians have been forced to make the tough decision to decline Medicare payments. But by implementing the proposed changes, current Medicare patients can be

assured of access to quality healthcare. In addition, the proposed revision will ensure a well-served senior community for many years to come.

I know that our entire system is struggling for funds, but the current designation applied to Santa Cruz County is clearly inappropriate. I strongly encourage your support of the proposed revision.

Sincerely,

A handwritten signature in black ink, appearing to read "S. Joseph Simitian". The signature is stylized with a large, sweeping "S" and a long horizontal line extending to the right.

S. Joseph Simitian
Senator, Eleventh District

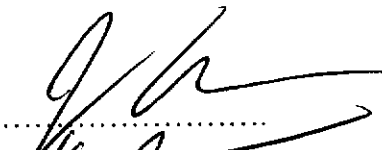
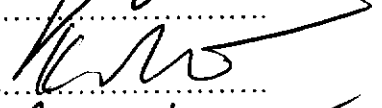
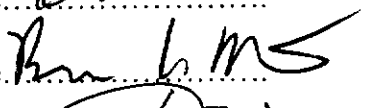
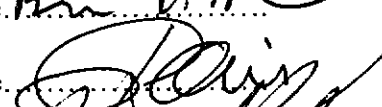
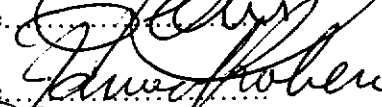
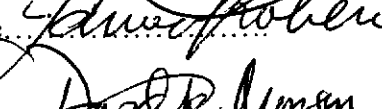
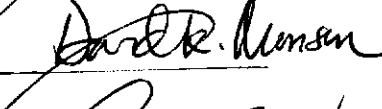
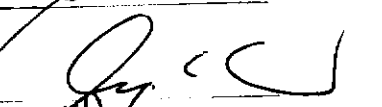
SJS:gre

Mail: (one original and two copies) : Centers for Medicare and Medicaid
Services, Dept. of Health and Human Services, Attention: CMS-1502-P, P.O.
Box 8017, Baltimore, MD 21244-8017 .

59 Executive Park
Suite 1000
Atlanta, Georgia 30329
Phone 404-778-3350
Fax 404-778-3835

Dear Congressman/ Congresswoman,

We, members of the Emory University Department of Orthopedics, are writing you to express our deep concern for the planned payment cuts in Medicare reimbursements. As a tertiary care referral center and academic facility, we are often the physicians taking care of the critically ill and injured. At Emory, we have been the hospital of last resort for many in our geographical area. Appropriate care for this patient population demands greater time and effort that we are happy to provide to fulfill our mission. In our experience, the great majority of those patients are Medicare patients due to advanced age or disability. They are the most vulnerable in a healthcare environment that has seen decreasing profit margins and rising operating costs. In addition, many private practice groups are not accepting Medicare patients due to low levels of reimbursement. As a result, we are seeing a disproportionate number of patients being referred to tertiary care centers that neither have the capacity nor the financial means to accept this increased burden. With the planned cuts, we are deeply concerned that access to appropriate subspecialty care for Medicare beneficiaries will be severely compromised. In conclusion, we believe that the current formula for adjusting Medicare reimbursement for physician services is flawed and should be fixed. We ask you to reconsider the planned cuts and help us care for our patients.

Signed,		
John Xerogeanes	orthopaedic Surgeon	
Name.....	Specialty.....	Signature.....
Ken Mautner	Physiatry	
Name.....	Specialty.....	Signature.....
Brandon Mines	Family Medicine	
Name.....	Specialty.....	Signature.....
Sam Lubin	orthopaedic surgeon	
Name.....	Specialty.....	Signature.....
James Roberson	Orthopaedics	
Name.....	Specialty.....	Signature.....
DAVID MONSON	ORTHOPAEDIC SURGERY	
Michael Schaufele	Physiatry	
Howard Levy	PM & R	

HEMMER PANGBURN DEFRAK PLLCmdefrank@hemmerlaw.com

Direct Dial: 859-578-3867, ext. 205

SUITE 200
250 GRANDVIEW DRIVE
FT. MITCHELL, KENTUCKY 41017
(859) 344-1188
Fax: (859) 578-3869

September 27, 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: CMS-1502-P; Proposed Rule – Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006 – Nuclear Medicine Services

Dear Sir or Madam:

This letter is submitted in response to the Proposed Rule with Comment Period published by CMS in the August 8, 2005 Federal Register (referred to herein as the "Proposed Regulations") regarding the addition of nuclear medicine services, and in particular PET scans, to the list of designated health services.

One of our clients owns several PET scanners. Most of the ownership of this client is made up of physicians many of whom to a varying degree refer patients, including those participating in federal health programs, to these PET scanners. All of these investors relied on the current Stark regulations to invest in our client. Our client's PET scanners and the associated facility improvements represent a multi-million dollar investment. While we continue to believe that the CMS utilization guidelines are sufficient to prevent abuse and therefore there is no need to include PET scans in the list of designated health services, in the event that PET scans are included, we urge CMS to permanently grandfather all existing investments in PET scan entities. Unless these investments are grandfathered, our client's investors will be forced to sell their investment at a fire sale price.

**PROPOSED REGULATIONS WILL CAUSE FINANCIAL HARDSHIP TO
INVESTORS**

Issue: The forced sale by investors in PET Scans will cause financial hardship to our client's investors.

Discussion: The Proposed Regulations including PET Scans as designated health services will force our client's investors to sell or otherwise divest their ownership interest. Since there is no ready market or stock exchange in which to sell ownership interests in our client, these investors will need to seek out purchasers. These purchasers will understand that the investors need to sell and therefore in all likelihood the sales price will reflect the forced nature of the sale and be significantly below the price that would be obtained if neither party were forced to take part in the transaction.

A more troubling scenario is one in which purchasers cannot be found at all. Such a scenario poses two troubling outcomes. The most troubling is that patients of investors who participate in federal health programs may not be able to receive needed PET scans or will need to travel a considerable distance to obtain a scan when one is available at a close and convenient location. This result is clearly not acceptable. The other outcome is that the existing PET scan centers may no longer operate on a profitable basis because of the limitations imposed on the owners. In such a case, the investors may be forced to close the centers and personally pay the Company's obligations under leases and bank debt.

Our client's PET scanners and required facility improvements to house the scanners represent an investment of several million dollars. The investors made equity investments and guaranteed debt in reliance on the existing Stark regulations. As the price that the investors will be paid for the units is reduced, or if the centers must be closed, it has the potential for resulting in a substantial loss for the investors. Even if CMS allowed a three to five year period to divest, the investors may still not receive full value of their investment.

Recommendation: We urge CMS to permanently grandfather existing PET centers.

We appreciate the opportunity to comment on the Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2006 – Nuclear Medicine Services. We would be happy to meet with agency representatives to discuss all or any aspects of these comments. In the meantime, please feel free to contact me at 859-578-3850 if you have any questions or require further information in this regard.

Sincerely,



Michael E. DeFrank

MED/hck



COUNTY OF SANTA CRUZ

HEALTH SERVICES AGENCY
POST OFFICE BOX 962, 1080 EMELINE AVENUE
SANTA CRUZ, CA 95061-0962
(831) 454-4587 FAX: (831) 454-4893
TDD: (831) 454-4123

3

September 14, 2005

Centers of Medicare and 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 County's Public Health Clinic at Emeline to strongly support your proposed revision to physician payment localities in California recently published in the reference rule. We have long been very concerned about the viability of the health care system which serves our residents. The great difference between the cost of medical practice in Santa Cruz County as measured by GAP 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 be of great help in ensuring access to necessary health care services. The proposed rule is fair. Neighboring counties to Santa Cruz and to 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,

Carol Griffith, MSPH, Clinic Director
Santa Cruz County Public Health
Clinic at Emeline
1080 Emeline Avenue
Santa Cruz, CA 95060
(831) 454-4491

Enclosure: two copies of letter



COUNTY OF SANTA CRUZ

HEALTH SERVICES AGENCY
POST OFFICE BOX 962, 1080 EMELINE AVENUE
SANTA CRUZ, CA 95061-0962
(831) 454-4587 FAX: (831) 454-4893
TDD: (831) 454-4123

790
SEP 30 2005

September 14, 2005

Centers of Medicare and 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

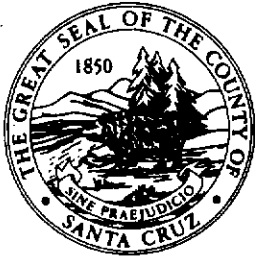
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Sincerely,

Rose Marie Hendrix, D.O.
Medical Director
Santa Cruz County Public Health
Clinic at Emeline
1080 Emeline Avenue
Santa Cruz, CA 95060
(831) 454-4100
Enclosure: two copies of letter



COUNTY OF SANTA CRUZ

HEALTH SERVICES AGENCY
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SANTA CRUZ, CA 95061-0962
(831) 454-4587 FAX: (831) 454-4893
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791
SEP 30 2005

September 14, 2005

Centers of Medicare and 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

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Sincerely,

Duncan Gillies
Director of Laboratory Services
Santa Cruz County Health Services Agency
1080 Emeline Avenue
Santa Cruz, CA 95060
(831) 454-4100
Enclosure: two copies of letter

September 27, 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

Dear Sir/Madam:

We are pleased to submit these comments on the proposed rule for Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2006 on behalf of the American Association for Geriatric Psychiatry (AAGP). The AAGP is a professional membership organization dedicated to promoting the mental health and well-being of older people and improving the care of those with late-life mental disorders. Our membership consists of more than 2,000 geriatric psychiatrists as well as other health care professionals who focus on the mental health problems faced by senior citizens.

SGR

Once again we must express our deep concern with the Agency's failure to propose any steps to address the forecasted negative update to the conversion factor for the physician fee schedule. The preamble to this proposed rule estimates the update for calendar year 2006 to the conversion factor will be a minus 4.3 percent. We understand that the Agency believes that it has no discretion in the calculation of Medicare physician expenditures under the provisions of the sustainable growth rate (SGR). However, we respectfully disagree with this position and strongly recommend that you consider changes in the way you estimate spending increases under the Medicare fee schedule.

Specifically, we do not think physician expenditures should include the cost of prescription drugs furnished incident to a physician's service. As you know, such drugs are excluded from the physician fee schedule; including them in the estimates of spending under the fee schedule holds physicians accountable for an expense that is largely outside their control, and one that is rising very rapidly. In addition, we believe that the SGR should be adjusted to account for outlays related to new national coverage decisions. Coverage decisions that expand beneficiary access to advancements in medical diagnosis and treatment should be treated in a manner similar to changes in law and regulation that are expected to affect outlays for physicians' services.

For psychiatry, a negative update to the fee schedule and other changes in practice expense relative value units (RVUs) results in a 4.2 percent reduction in total Medicare payments for the specialty in 2006. This cut comes at a time

Dan G. Blazer, M.D., M.P.H., Ph.D.
President

Christopher C. Colenda, M.D., M.P.H.
President-Elect

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Past President

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Thomas E. Oxman, M.D.
Charles F. Reynolds, III, M.D.
Susan Schultz, M.D.

Christine M. deVries
Executive Director

Annual Meeting:
March 10-13, 2006

Publications:
*American Journal of
Geriatric Psychiatry and
Geriatric Psychiatry News*

when practice costs including malpractice premiums are rising 8.4 percent, as reflected in the estimated Medicare Economic Index (MEI) for this year.¹ It's important to underscore that this proposed negative update to the fee schedule is not merely a slowing in the rate of increase in fees – it's a reduction in actual payments and, taking into account the estimated MEI for 2006, the total impact is a 7.8 percent decline in the value of Medicare physician payments. In other words, if Medicare payments were adjusted to be consistent with the increased costs of running a practice as represented in the MEI, then payments should be 3.5 percent higher in 2006 than in 2005. Instead, the payments for psychiatrists will be 4.2 percent lower in 2006, which amounts to a net loss of 7.7 percent (- 3.5 percent -4.2 percent).

If, as predicted these negative updates continue through the end of this decade, the fee schedule conversion factor will be reduced to a level near that in place for 1993. Clearly, this cannot continue without significant adverse effects on beneficiary access to care. While we do not have evidence of a significant increase in the number of psychiatric practices that have placed limits on new Medicare patients, our members are especially vulnerable to these reductions as a substantial part of their income derives from the diagnosis and treatment of Medicare beneficiaries. We do know that a number of geriatric psychiatry practices are near bankruptcy or have been forced to close. Many other geriatric psychiatrists are actively re-evaluating the financial viability of their practice. At a time when there is growing evidence of undiagnosed and untreated mental illness in the senior population, these policies are likely to erode access to mental health care for growing numbers of elderly and disabled beneficiaries.

Malpractice RVUs

We also want to call your attention to the continuing under-recognition of the cost of malpractice insurance in fee schedule payments. While we are pleased that you are using more recent premium data, we regret this information is not available for assessment at this time. The impact table 33 included in the proposed rule shows a reduction of 0.1% resulting from malpractice RVU changes for psychiatry. We cannot identify the reason for this reduction, and we certainly have no information from our members suggesting a decline in malpractice premiums. We continue to believe that the weight given to malpractice costs in the overall fee schedule should be increased.

Telehealth

Finally, we would like to comment on two issues identified in the proposed rule relating to telehealth services. Currently, Medicare covers telehealth services for individual psychotherapy, medication management, and psychiatric diagnostic interviews. In order to increase the access of beneficiaries to psychiatric services in rural or underserved areas, we would recommend a modification to the current definition of an interactive telecommunications system. In our view, the example cited in the preamble to the proposed regulation of a two-way audio system in combination with a one-way real time video connection would permit a consulting physician to conduct a valid patient evaluation or therapeutic intervention. This change would likely make

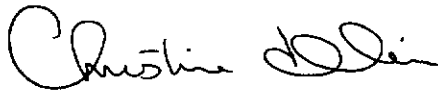
¹ Medicare Payment Advisory Commission. "Report to the Congress: Medicare Payment Policy." p. 81. March 2005.

such telehealth services more available to patients who would otherwise not be able to have a face-to-face visit. We also recommend that skilled nursing facilities (SNFs) be added to the definition of a telehealth originating site. Again, this would permit psychiatrists to treat patients in facilities where access to a consulting psychiatrist is not feasible.

Current trends in Medicare payments for physician services combined with the limited and discriminatory Medicare benefit for mental illness care can further burden Medicare beneficiaries and jeopardize their access to effective treatment. We believe that CMS should take every opportunity to exercise its discretion to expand access to psychiatric services. We hope you will reconsider your options for updating the fee schedule to avoid further reductions and will expand the availability of telehealth consultations for Medicare beneficiaries.

Thank you for this opportunity to comment on the proposed rule.

Sincerely,

A handwritten signature in black ink, appearing to read "Christine deVries". The signature is fluid and cursive, with the first name "Christine" written in a larger, more prominent script than the last name "deVries".

Christine M. deVries
Executive Director

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

We are commenting on proposed changes in the 2006 Physician Fee Schedule, specifically related to CPT codes 34101, 34111, 37204, 37205, 37607, 75710, 75827, 75894, 75898, 75960, 75962, 75978, 75827.

Item 1

The proposed 2006 Physician Fee Schedule has removed payment for the following codes in the non-facility setting:

34101	Embolectomy or thrombectomy, with or without catheter; axillary, brachial, innominate, subclavian artery, by arm incision
34111	Embolectomy or thrombectomy, with or without catheter; radial or ulnar artery, by arm incision
37607	Ligation or banding of angioaccess arteriovenous fistula
37204	Transcatheter occlusion or embolization (eg, for tumor destruction, to achieve hemostasis, to occlude a vascular malformation), percutaneous, any method, non-central nervous system, non-head or neck
75894	Transcatheter therapy, embolization, any method, radiological supervision and interpretation.
37205	Transcatheter placement of an intravascular stent(s), (except coronary, carotid, and vertebral vessel), percutaneous; initial vessel
75960	Transcatheter introduction of intravascular stent(s), (except coronary, carotid, and vertebral vessel), percutaneous and/or open, radiological supervision and interpretation, each vessel
75898	Angiography through existing catheter for follow-up study for transcatheter therapy, embolization or infusion

All of these codes have been available for use in the non-facility setting in the past. They have been shown to be effective and safe in the free standing facility. They have been routinely used by Interventional Radiologist and Nephrologists.

If these changes take effect, it will materially interfere with medical care offered by Interventional Radiologist and Nephrologists, most of who operate in free-standing facilities. It will result in a degradation of the quality of medical care and interfere with the patient's right to choose their medical care provider. Additionally, it will increase the cost of vital medical services to CMS by requiring fragmentation of bundled procedures, duplication of services and a shift from an out-patient environment to the hospital.

Codes 34101 and 34111 are codes for procedures that are used to treat complications of other vascular access procedures, namely thrombectomy. The major complication of a percutaneous thrombectomy is the migration of an embolus to the feeding artery. When this occurs it blocks blood flow to the hand and to the digits. If not treated in a timely manner, it can have disastrous results. Fortunately, the complication is rare and fortunately, it can be treated in a timely manner resulting in a complete resolution. However, if the code is no longer included, there will be a tendency to delay treatment and refer to the hospital. This will result in increased risk to the patient, prolongation of the accompanying discomfort, duplication of services and a significant increase in cost. In these instances, instead of the patient being returned to the dialysis clinic for their regular dialysis, they will be sitting at the hospital in pain for several hours without dialysis waiting for a treatment at an alternative site.

Codes 37607, 37204, 75894, and 75898 all relate to the treatment of fistula failures by Interventional Radiologist and Nephrologists. The nephrology community and especially those involved with dialysis access intervention have seen the need for increasing the number of functioning fistulas in our dialysis patient community and have made a real commitment to this effort. A significant number of fistulas that are created have early or primary function. This means that they never develop adequately for use. It has been shown through a number of publications that a very large percentage of these failed fistulas can be salvaged. This effort is critical to the development of a fistula based strategy in the US. Interventional Radiologist and Nephrologists have and continue to take the lead in this effort. Since most work in free standing facilities, removing these codes will materially affect this effort.

Unfortunately, it is at times not obvious until the case is underway that such a procedure will be required. This means that if they are necessary for the success of the case, the procedure will be only partially done. The patient will then be referred to the hospital for a duplication of services and added expense, inconvenience and discomfort with no added benefit as it relates to success or safety.

Codes 37205 and 75898 are codes that relate to a procedure used to treat a complication. The major complication seen with venous angioplasty is rupture of the vein. Fortunately, this is not a common occurrence and fortunately, in the vast majority of cases it is a minor complication requiring no change in medical management. However; occasionally, this complication requires the placement of a stent. This can be easily done at the time and doing so saves a vascular access that would otherwise be lost. If it is not done at the time, a situation which deleting this

code would create, then it very likely can not be accomplished. In this instance the patient would lose their access, require a dialysis catheter with all of its complications, be referred to the hospital and require the placement of a new access.

Item 2

Additionally, the proposed 2006 Physician Fee Schedule has reduced the RVRBS unit value for the following codes in the non-facility setting:

75710 Angiography, extremity, unilateral, radiological supervision and interpretation
75827 Venography, caval, superior, with serialography, radiological supervision and interpretation

75962 Transluminal balloon angioplasty, peripheral artery, radiological supervision and interpretation

75978 Transluminal balloon angioplasty, venous (eg, subclavian stenosis), radiological supervision and interpretation

These are codes that are very commonly used by Interventional Radiologist and Nephrologists. Since most of these practitioners operate in the free standing, non-facility setting, they must support the facilities operation without the benefit of facility charges. This is accomplished through the use of the fees generated by these radiological supervision and interpretation codes. Since the cost of these facilities is continuing to rise, cutting the payment for these commonly used codes will jeopardize their economic viability. Simply stated, they will be required to close. This will result in a degradation of the quality of medical care and interfere with the patient's right to choose their medical care provider. Additionally, it will increase the cost of vital medical services to CMS by requiring a shift from an out-patient environment to the hospital for the patients currently being served and will slow the migration of patients currently locked into a hospital based environment to the out patient setting.

We do not feel that these changes are in the best interest of the patients that we serve.

Sincerely,



Israel Schur, MD

Medical Director of American Access Care - NYC

SEP 3

794

August 23, 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 CMS1502-P

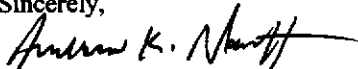
Issue Identifier: GPCI's / Payment Localities

Dear Sirs:

I am writing 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. As a medical staff officer for our hospital, I am very aware of the struggle to keep our on-call roster adequate. Presently we have at least one specialty that is covered less than 50% of the time.

I was 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 a unique locality. I strongly encourage your efforts to rectify this long-standing inequity. Your proposal will be 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.

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Andrew K. Nevitt, M.D.

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Department of Health and Human Services
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PO Box 8017
Baltimore, Md. 21244-8017

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If these changes take effect, it will materially interfere with medical care offered by Interventional Nephrologists, most of whom operate in free-standing facilities. It will result in a degradation of the quality of medical care and interfere with the patient's right to choose their medical care provider. Additionally, it will increase the cost of vital medical services to CMS by requiring fragmentation of bundled procedures, duplication of services and a shift from an out-patient environment to the hospital.

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We do not feel that these changes are in the best interest of the patients that we serve.

Sincerely,



William D. Yu, MD
Interventional Nephrologist
12208 Summer Sky Path
Clarksville, MD 21029

SEP 3 1966

796

To Medicare:
Center for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS 1052 P
P.O. Box 8017
Baltimore Md. 21244-8017

I am writing to support Medicare's proposal to increase the reimbursement rate for Sonoma County by 8%.

It is long overdue. Sonoma County is the largest both by population and business activity in the Northwestern section of the State. Originally it was an agricultural area but it has long outgrown that status. It deserves to be known for and credited by its true active communities. Thank you for your anticipated action.

Dorothy De Lario
2308 Bellam Ct.
Santa Rosa, CA. 95401

September 27, 2005
Bodega Bay, California

Medicare Administrators:

Please increase the reimbursement to Sonoma County (California) Medical Doctors in order to permit the high standards of medical care to be maintained in Sonoma County.

Medical costs in our county have risen faster than in other comparable areas.

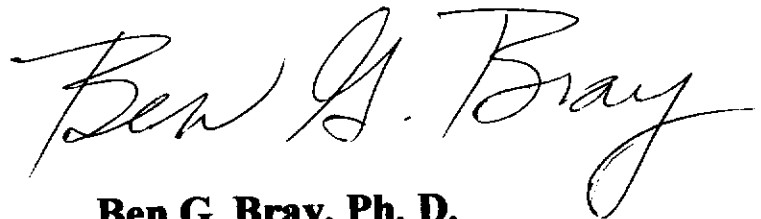
Our principle city, Santa Rosa, is sixth in the United States of 100,000 population for having residents of 85 years of age and over.

Seniors (60 years and over) represent more than 16% of our population, with projected increases to twice that percentage by 2020.

Many of our doctors have moved to other more lucrative locations; others have stopped accepting new Medicare patients.

I am very fortunate at age 72 to have an extremely competent, caring physician. If she were to move from the county, I would probably not be able to find a satisfactory replacement. **Please increase allowed reimbursements to doctors to legal limits as soon as possible.**

Thanking you in advance,

A handwritten signature in cursive script that reads "Ben G. Bray". The signature is fluid and elegant, with the first and last names being more prominent than the middle initial.

Ben G. Bray, Ph. D.

SEP 3 1977

798

Administrator Mark McClellan
Center for Medicare and Medicaid Services
U.S. Department of Health and Human Services
P.O. Box 8017
Baltimore, MD 21244-8017

Dear Administrator McClellan:

I join with the United States Senator Barbara Boxer in support for her CMS' proposed revision to the physician payment localities for Santa Cruz and Sonoma counties.

There is currently a large payment discrepancy for physicians in Santa Cruz and Sonoma counties due to their being classified as "rural" counties. Counties neighboring Santa Cruz and Sonoma counties have some of the highest payment levels for physicians in the nation. The discrepancy is causing physicians to leave Santa Cruz and Sonoma counties, and quality health care has suffered as a result. This reassignment will help the counties provide sufficient health care services for its residents.

I join with Senator Boxer in supporting the CMMS in all you can do to undo the discrepancy in payment for physicians, and for proposing a change to correct the situation.

Sincerely,



PK Michaels
PO Box 4025
Santa Rosa, Cal. 95402

SEP 30 2005

799



STANFORD UNIVERSITY MEDICAL CENTER • LUCILE PACKARD CHILDREN'S HOSPITAL

Anita Honkanen, M.D.

Director, General Pediatric Anesthesia

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September 26, 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 anesthesiologist at Lucile Packard Children's Hospital at Stanford University to urge the Centers for Medicare and Medicaid Services (CMS) to change the Medicare anesthesiology teaching payment policy.

I returned to academic medicine 2 years ago partially because I was concerned that there was an obvious shortage of well trained anesthesia personnel. I wished to help educate the next generation of US trained expert anesthesiologists. Now in practicing at Stanford, I feel even more strongly that academic programs must be supported in every way possible to ensure expert care for ourselves and our children and our children's children. We are training physicians not only to care for patients but to be ready to supervise and educate the physicians who will follow them.

Academic centers have great difficulty in recruiting and keeping expert staff to complete this essential educational task. The current Medicare regulations are directly impacting on the ability of our academic institutions to continue with this vital mission. Without adequate payment for clinical tasks completed, we can not afford to hire the staff we need.

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. I see no adequate reason to support full payment of concurrently supervised cases for surgeons and internists while forcing anesthesiologists to care for patients at 50% reimbursement rate when they engage in teaching. In reality, the amount of care and effort it takes to provide patient care while teaching is greater than when working alone. The patient also benefits greatly, as they have 2 sets of hands and eyes, caring for them and watching them during the critical portions of the case.

Mark McClellan, M.D., Ph.D.
September 26, 2005
Page 2

Correcting this inequity is essential to assure 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. Without a change in this discriminatory policy, I fear the future of our great academic teaching programs is at risk.

Please end the anesthesiology teaching payment penalty.

Sincerely,

A handwritten signature in black ink, appearing to read 'Anita Honkanen', with a long horizontal flourish extending to the right.

Anita Honkanen, MD
Director, General Pediatric Anesthesia

LAW OFFICES OF



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BARBARA L. BOZMAN-MOSS
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NANCY E. WATSON
Admitted in California and Maryland

JOSHUA KATZ
of Counsel
Admitted in California and Massachusetts

September 26, 2005

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

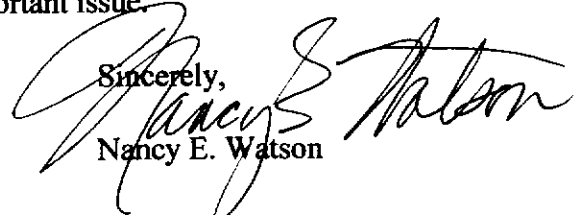
Re: GPCIs

I understand that Medicare is proposing to create a new payment locality for Sonoma County, which is an increasingly expensive place to live and work. In fact, Sonoma County is one of the most expensive places to live in the country, and it is increasingly difficult to find physicians and other professionals who are able to move here. Certainly, those physicians cannot afford to accept Medicare reimbursement rates which are based on faulty information regarding the cost of living in this County, information which mistakenly categorizes Sonoma as a rural county. As I understand it, in the new locality, the Medicare reimbursement rate would be more closely matched to actual practice expenses than it is now.

Right now, the situation regarding health care in this County is one of distress and will only get worse absent help. The number of practicing physicians in Sonoma County has not kept pace with local population growth. From 1995 to 2002, the general population increased 13%, but the number of practicing physicians increased by only 4%. The population of seniors is growing much faster and it estimated to increase by 196% in the next twenty years. Aside from this projection, the current state of medical care for seniors is in crisis. As of July 2005, 60% of Sonoma County primary care physicians were NOT accepting new Medicare patients, and we have only two gerontologists in the County for more than 76,000 seniors. Sonoma County cannot afford to have a further brain drain of physicians who feel that they cannot afford to live in the County and treat out most vulnerable population.

The new locality rate would be one step to help Sonoma County physicians improve the quantity and quality of care they deliver to Medicare beneficiaries and other patients. I fully support your proposal to change Sonoma County's payment locality, and I appreciate the opportunity to comment on this important issue.

Sincerely,


Nancy E. Watson