PALM BEACH SPINE PAIN INSTITUTE
Innovative Solutions to Pain Management

Dr. Lawrence Gorfine, M.D.
Dr. Douglas MacLear, D.O.

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Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P
P.O. Box 801
Baltimore, MD 21244-8051

Dear Sirs:

We are a group of board certified, fellowship trained anesthesiologists who exclusively practice pain management in Palm Beach County Florida. The currently proposed CMS cuts in the Practice Expense side of the new budget will result in decreases in payment to us by up to 52% for some procedures. If these proposed cuts pass as planned then we will not be able to stay in practice as we will be unable to pay our practice overhead. Our practice consists of about 80% Medicare as is generally the rule for physicians in our specialty in South Florida. I urge you to prevent this drastic change in reimbursement to our specialty. I am requesting a one year moratorium until the expense survey is release or do this over a period of 4 years rather than rewarding evaluation and management services immediately to the full extent and punishing us.

As a physician who takes care of Medicare beneficiaries and other patients, I write to urge you to take steps to prevent the scheduled 5.1% decrease to Medicare reimbursement for physicians in 2007. The impending physician payment cuts would be extremely detrimental to my practice and the patients I treat.

Currently, physician payment updates are driven by a flawed formula called the Sustainable Growth Rate (SGR). Instead of the SGR, payment updates should be based on increases in practice costs. If Congress does not pass legislation this year, Medicare payments to physicians will be cut by 5.1%. Some physicians may face cuts as high as 38% as CMS is using bottom-up methodology in calculating practice expense and improving reimbursement for evaluation and management services.

For years physicians have operated under a Medicare reimbursement system that does not keep track with inflation. While we support higher payment for evaluation and management services, substantial cuts in other areas are not acceptable. Physicians cannot continue to operate in an environment of such uncertainty, and as a result more

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and more doctors are electing to stop taking on additional Medicare patients, and an even more threatening issue, all other payers follow Medicare.

Congress must deal with this critical issue before it recesses for the elections. It is extremely frustrating to fight this battle each and every year. Please replace the 5.1% cut with a positive update that reflects increases in practice costs and stabilize Medicare physician payments.

Please take action to prevent these scheduled cuts to Medicare reimbursement for physicians and protect beneficiary access to healthcare.

Sincerely,

Douglas G. MacLear, D.O.
25Sept06

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The University of Utah
Department of Orthopaedics

September 29, 2006

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

RE: BEALS, TIMOTHY

To Whom It May Concern:

I would like to comment upon the proposed reduction in reimbursement for coverage of bone mass measurement tests. I am an orthopedic surgeon, who routinely orders and performs bone densitometry measurements. At this time, it is hardly financially valuable to participate in this and yet it is a very important function to perform for patients. It is one of the few areas in all of preventative medicine where there is proven efficacy of treatment of a problem before it develops into an extensive fracture, and this is in stark contrast to a lot of other things in medicine. This would diminish the impact of the "Healthy People 2010" initiative that your agency is promoting.

I think the assumptions made to recalculate the MPFS are inaccurate and it needs not be a trial-and-error policy, which seems to be where this is headed. The vast majority of systems that are sold are Fan units, which are very reliable and the data is very solid as to utilization, effectiveness and efficacy. The assumption that equipment is in use 50% of the time is a gross overstatement, as it is used less than 20% of the time at the University of Utah Orthopaedic Center at the University of Utah in Salt Lake City, which is a major musculoskeletal treatment center in the intermountain west. I think it would be an error to de-emphasize one of the few areas of success at preventative medicine and with current payment rates, it is only through personal commitment to this as being important that this work is done at our institution. To diminish the reimbursement further financially is probably to cripple the program permanently.

I appreciate you taking my comments into consideration.

Sincerely,

Timothy C. Beals, MD
Associate Professor

Orthopaedic Center
590 Wakara Way
Salt Lake City, Utah 84108
Phone: (801) 587-5400
Fax: (801) 587-5411

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Westside Medical Care, Inc.
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Eva Laukhuf, M.D.
1810 59th St. W.
Bradenton, FL 34209
941-792-1412
941-792-8970
Fax: 941-795-0753

9/15/06

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

RE: Deficit Reduction Act (DRA)

TO WHOM IT MAY CONCERN:

It has come to our attention that you plan to reduce the deficit expense by 10% over the next five years for Bone Densitometry and Bone Mass Measurement testing.

We are a practice of Internal Medicine and Family Practice with a large population of elderly patients with risk of osteoporosis. These patients would benefit from these tests for prevention of this disease and reduce future catastrophic medical expenses.

The DXA was recently added as a preventive service and these cuts go against your own initiative to increase utilization and diminish the impact on your own "Healthy People 2010".

The new methodology should not be a trial and error policy with inaccurate date to calculate bone densitometer (I.e. pencil beam vs. fan beam). The majority of the systems sold are fan beam.

We respectively ask that you delay the DRA until a complete and thorough analysis can be conducted using cost figures based on the appropriate technology. We request that Congress intervene and stop the reduction of the conversion factor before their October adjournment.

It is much more cost effective to treat people before the problem worsens!

Please consider the above before making any further reductions in the treatment of

osteoporosis.

Sincerely,

Satnam Singh, M.D.

Eva Laukhuf, M.D.

SS/pap

Kali S. Eswaran, M.D. Inc
Saras Balasingam, M.D
Josefina Aquino, M.D

58

1995 Zinfandel Dr. #201
Rancho Cordova Ca 95670

Internal Medicine

Phone: 916-852-6001
Fax: 916-852-6007

September 19, 2006

To Whom It May Concern:

The proposed reduction in Medicare reimbursement for DEXA Scans will adversely affect the quality of care, which in turn increase the cost of care and increase risk in fracture.

Sincerely,

Kali Eswaran M.D.

UROLOGY™
ASSOCIATES OF NORTH TEXAS

PHYSICIANS
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Diane C. West, M.D.

September 27, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
PO Box 8015
Baltimore, Maryland 21244-8015

ATTN: CMS-1321-P

www.cms.hhs.gov/erulemaking
File code: CMS-1321-P

Dear Sir or Madam:

I am a partner at Urology Associates of North Texas, LLP (UANT), a 47-physician urologic group practice that provides professional medical services to patients in the Dallas/Fort Worth Metroplex area. In UANT's mission statement, our goal is to provide world-class care for our patients. Thousands of UANT men have undergone prostate screening with exams and a blood screening test, prostate-specific antigen (PSA) and because of an abnormality detected, either by exam and/or PSA, have undergone prostate biopsies. For years, because of third party insurance requirements, these biopsies were sent to a number of different labs for professional pathological interpretation. It became impossible to sit down with a local pathologist and review the slides or discuss their professional interpretations. Furthermore, because UANT had no professional relationship with the pathologist who performed the interpretations, it became increasingly difficult to contact the specific pathologist and discuss the case. Because of that, in 2001 UANT entered into a relationship with an organization, UROPATH. UROPATH assisted UANT in constructing a laboratory and recruiting top-notch histopathologists and cytopathologists to work within our laboratory. Within the UROPATH model, they manage and supervise the staffing of our lab; however, the lab is entirely owned by UANT. We have subleased laboratory premises, we have purchased and/or leased all of the equipment, which is not shared with any other organization group or lab; and we have subcontracted with a pathologist, to perform and oversee our lab processing and preparation and provide us with pathologic interpretations.

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www.uant.com

This office pathology/laboratory services offers the most direct access for our urologists to interact with the pathologist and, therefore, provides the best most reliable and most efficient interpretations for our patients of their biopsy results.

Patients are often referred to us or seek our care because we specialize in urologic diseases. Likewise, when relying on interpretations by a pathologist, we would like to rely on a specialist to provide that information that we depend on so dearly to make the best decision in treatment for our patients. The model that UROPATH has embraced in managing our lab and other laboratories wholly owned by individual urologic practices provides the best model that we know of and provides not only the efficiency but the excellence in pathology services. In fact, our specific uropathologist has written multiple articles and is well respected within the pathology community as being a reference source. Within the UROPATH model, our pathologist, who does live in the state of Florida where our lab is located, is not only licensed within the state in which he resides and performs the services, but is also licensed in the state of Texas where our practice is located. This, in fact, is the requirement established by UROPATH as it is managing our labs. Parenthetically, I often wonder whether the regional and reference labs can certainly say the same thing. In fact, anecdotally, I have been told that multiple pathologists staff a single reference lab site and, as a general rule, the requirement is that at least one of them should be licensed in every state so they can process specimens from every state. This does not mean the physician performing the services necessarily is licensed in the state. Recently, our pathologist gave a keynote address at a Pathologic Society meeting and within the portion of his comments, it was very clear that pathologists are leaning towards sub-specialization. In fact, the general pathologist can no longer expect to keep up with the plethora of pathology literature and newer and improving laboratory techniques.

Our lab is connected with us electronically and our patient records are on electronic medical records. This provides our pathologists with realtime information regarding the specifics of the patient's diagnosis, symptoms and lab values. Consequently, in realtime also, the pathology interpretations are available to us to deliver to the patient in a much more expedient manner. The proposed rule changes CMS is proposing in ths rulemaking would be detrimental to the model of the UROPATH business structure. Therefore, it could affect our patients and, in my opinion, decrease the world-class care that we can provide our Medicare patients. Further, in reading the proposed changes, I do not see any factual information that would warrant the proposed changes that seem to single out urological pathology labs for such harsh treatment.

I am strongly urging that you consider withdrawing the rule changes. We would be happy to discuss your concerns regarding over utilization, medically unnecessary biopsies, and other auses that our competitors have raised. As far as the location of our lab being an issue, we simply set this up where we could find a world-class genitourinary (GU) pathologist, and where he was located we elected to construct our lab at that site. I am told that large reference labs locate their facilities within states that indeed have the highest reimbursement for specific codes. This is not and was never the intention of locating our lab in Florida. The efficiency of the management from UROPATH as well as the location and residence of a qualified pathologist is the sole reason we established our lab there.

Our pathologists are urological pathology experts and only practice urologic pathology. Thus, I think the possibility of over utilization of secondary stainings, i.e. increasing cost, is much decreased simply because of their volume of interpretations and experience. Our lab is open

six days a week and our pathologists are available by electronic correspondence and by telephone at any time.

Quality of Care Issue
Because reference labs have general pathologists interpret our slides, as a rule, the variability in interpretations is higher and, therefore, is not in keeping with our definition of providing world-class care to our patients. The accessibility of our urologists to lab personnel six days a week is certainly not present in a reference lab nor, often times, is the availability to speak directly with a pathologist. Within our own personal laboratory, our urologic pathologist has control of the processing of the specimens and, therefore, these processes are more controlled and standardized. Our pathologists are specialized; they only read urologic pathology. Therefore, because of their experience becoming vast, their need for over reads and secondary staining, whereby costs are increased, are diminished. Further, because of the UROPATH model, pathologists with these regionalized labs are available for confirmatory interpretation, thus creating a cost savings. If our lab was specifically in one of our 13 locations and we only had one pathologist available, then certainly secondary out-source for interpretational consultations would increase the costs. By having our own specialized laboratory facility, which is connected by electronic medical records to the patient's record, our results are obtained faster in a streamlined fashion. The pathologists have the ability to view the patient's chart and know the patient's past history and current examination as well. UANT believes some of the proposed rule changes are not founded on any factual information or utilization of these charges, and are intended to single out small remotely located pathology laboratories without any factual findings that support this treatment. There are no current mileage limitations between our offices and reference labs, and most centralized reference labs request specimens to be sent long distances. I am told that most of the larger corporate reference labs have located themselves in specific counties and/or states where the reimbursements are higher. Sending biopsies to a reference lab is fraught with potential possible errors, i.e. packaging, possible loss of specimens, etc. These possible errors are present whether the lab is one mile or across state lines. However, the reporting of the interpretations done electronically between our lab certainly improves safeguards and speeds the process of the information to be available to our patients.

I can only hope that by simply postponing these rule changes for further study, you would consider this as an urgent plea. To proceed forward with these rule changes will certainly affect our ability to continue the excellent care that Urology Associates of North Texas physicians provide from our laboratory to our patients.

Sincerely,

H. Pat Hezmall, M.D.

HPH/sc

ACKNOWLEDGMENT LIST

Harrison Mitchell Abrahams, M.D.
Lawrence J. Alter, M.D.
Aaron M. Amos, M.D.
Jeffrey C. Applewhite, M.D.
Gordon S. Brody, M.D.
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Barney T. Maddox, M.D.
Mark Allan McCurdy, M.D.
Leslie McQuiston, M.D., Pediatric Urology
F.H. (Trey) Moore, III, M.D.
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James Clifton Vestal, M.D., Director, North Texas Center for Urologic Oncology
Keith A. Waguespack, M.D.
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Mark McClellan, MD
Centers for Medicare and Medicaid Services
Department of Health & Human Services
Attention: CMS-1506-P
P.O. Box 8014
Baltimore, MD 21244-8014

Re: Medicare Program: Ambulatory Surgery Centers PPS Proposed Rule

Dear Dr. McClellan:

I am writing you to reconsider the proposed change the way the agency will compensate ambulatory surgery centers. It will in effect markedly reduce access to my Medicare patients to Endoscopic services and cost the agency more money not less.

This decision will shift patients away from low cost efficient ASCs and force them into high cost inefficient HOPD units. In addition HOPDs don't have the capacity to handle this shift in facilities. Long delays or outright denial to life saving colon cancer screening will ensue.

One last issue I would like to bring up, that applies to the entire methodology for health services. I find it extremely unfair that under the capped budget policy, providers are being ratcheted down while the entire cost of medical services skyrockets. If this trend continues, providers will have no other choice but to opt out of Medicare and charge the patient directly.

Sincerely,

Mark Tsuchiyose, MD

610
4

Medical X-Ray Center PC

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September 22, 2006

Office of the Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-1321-P; Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007
Federal Register of August 22, 2006

Dear CMS Administrator:

I am writing today regarding the proposed reduction in professional fees for radiation/oncology brachytherapy services.

The reductions as proposed will have a negative impact on my ability to offer the most appropriate treatment options for my Medicare patients. Brachytherapy is an important treatment option for my breast and prostate cancer patients in that it allows the radiation process to proceed quickly so that other treatments (chemotherapy) can begin as well. With that said, the preparation and effort to properly create a treatment plan is quite time consuming. Additionally, I must reconfirm correct placement before each fraction is given. The proposed reduction to all brachytherapy codes, especially CPT 77781, will not adequately cover the time and involvement required to prepare a patient for brachytherapy. If the reduction does take place, CMS will be limiting access to brachytherapy for Medicare patients as well as limiting access to the use of a Free-Standing radiation oncology center, as a cost effective alternative to the outpatient hospital setting.

I urge CMS to reconsider the proposed RVU reduction for brachytherapy. Please leave the brachytherapy codes as they are, understanding a reduction to the conversion factor is likely inevitable. I appreciate your careful review. Thank you for your time.

Sincerely,

John Griffin, M.D.

Avera Cancer Institute
1000 E. 21st Street
Suite 1000
Sioux Falls, SD 57105

Main # 605-331-3674

cc. Carolyn Mullen, Deputy Director, Division of Practitioner Services
W. Robert Lee, MD, President, American Brachytherapy Society
James Rubenstein, MD, Chairman, American College of Radiation Oncology
David J. Rice, MD, President, Association of Freestanding Radiation Oncology Centers
Prabhakar Tripuraneni, MD, Chair, American Society of Therapeutic Radiation and Oncology

Publishing Relative Value Units for Non-Covered Services

The Academy strongly objects to CMS' failure to publish RUC-recommended relative value units (RVUs) for "N" (non-covered) status codes, namely:

- Code 99173 (*Screening test of visual acuity, quantitative, bilateral*) and
- Code 92551 (*Screening test, pure tone, air only*)
- Codes 99339 and 99340 (*Individual physician supervision of a patient (patient not present) in home, domiciliary or rest home (eg, assisted living facility) requiring complex and multidisciplinary care modalities involving regular physician development and/or revision of care plans, 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 and 30 minutes or more, respectively)*

Vision and Hearing Screening (Codes 99173 and 92551)
Codes 99173 and 92551 have been through the RUC, where direct practice expense inputs were approved and recommended for inclusion in RBRVS. However, vision and hearing screening are Medicare non-covered services. CMS' refusal to publish RVUs for such pediatric services even though the codes have gone through the same validated valuation process as active Medicare codes distinctly disadvantages children, their providers, and children's preventive health services. Vision and hearing screening services are essential and required components of the Medicaid Early Periodic Screening Diagnosis and Treatment (EPSDT) program for the delivery of comprehensive preventive services. Therefore, CMS has a responsibility to publish RVUs for codes even when such services may not be covered under the Medicare program.

Care Plan Oversight (Codes 99339 and 99340)
During its April 2005 meeting, the RUC recommended work values of 1.25 (99339) and 1.80 (99340), where results of surveys were analyzed to ensure that the recommended work values accurately account for physician resources expended with the typical patient. It is our strong belief that the RUC-recommended RVUs should be published for codes 99339-99340. Additionally, in light of the fact that we are urging CMS to reevaluate its current policy with regard to the publishing RUC-recommended RVUs for non-covered services, CMS may consider designating codes 99339-99340 under Status Indicator "N" in order to allow for the RUC-recommended RVUs to be published.

On page 66245 of the 2005 final rule (Vol. 69, No. 219, November 15, 2004), CMS noted, "because we have not yet established a consistent policy regarding the publication of RVUs for non-covered services, we will need to examine this issue further to carefully weigh the pros and cons of publishing these RVUs for non-covered services." The AAP believes that CMS established a precedent on non-covered services when it published RVUs for the preventive medicine services codes (99381-99397). In fact, as

more non-Medicare payors adopt RBRVS, it becomes increasingly important to include non-covered services and their RUC-recommended RVUs on the Medicare physician fee schedule. In fact, one could argue that CMS has a social responsibility to publish such RVUs. The importance of these codes to the delivery of coordinated care to children and youth with special health care needs is paramount. This population is overrepresented in the Medicaid program and CMS' failure in this regard is contradictory to the priority given to physician-directed disease management and care coordination activities provided to its Medicare beneficiaries.

While CMS's failure to publish the RUC-recommended RVUs for these codes represents an egregious omission, the situation is made worse by the fact that CMS has neglected to include these codes altogether on the proposed 2007 RBRVS fee schedule. The Academy questions why these codes were excluded from the fee schedule and wonders whether in doing so, CMS is attempting to shield itself from future comments and actions in this regard. Whatever the intent, CMS must not shy away from its responsibility to publish the RUC-recommended RVUs for all codes, including those designated as non-covered.

Moderate (Conscious) Sedation

The moderate sedation codes (99143-99150) are included on the fee schedule as Status Indicator "C" (Carrier Priced), with no published RVUs. Given CMS' direct involvement in the development of these codes, it disappoints us that the Status Indicator for the codes is "C." Furthermore, we are dismayed that CMS continues not to accept the April 2005 RUC recommendations for the codes and publish them in the 2007 RBRVS proposed rule.

In its November 21, 2005 *Federal Register* 2006 Medicare Physician Fee Schedule comments, CMS stated that it was "uncertain whether the RUC assigned values are appropriate and has carrier priced these codes in order to gather information for utilization and proper pricing." While we appreciate CMS' reconsideration of paying for sedation services not previously covered and understand this is an interim position, we request that CMS consider the following arguments in revising its position.

These CPT codes (99143-99150) were surveyed by several specialty societies in order to provide the RUC with data necessary to appropriately value the service. Codes were developed to simplify reporting these services into age-specific categories. The RUC-recommended values for these six codes were based on valid surveys and carefully vetted through the RUC process. We are confident in the accuracy of the values assigned. While CMS has assigned these codes to Status Indicator "C," the Academy believes that they should be listed with Status Indicator "A" (Active) and their RUC-recommended RVUs published.

Providing moderate sedation to patients undergoing certain outpatient procedures requires a certain level of provider skill and training and incurs medical legal liability, but is also associated with greater patient satisfaction, improved outcomes, and cost savings over similar procedures provided with anesthesia in an operating room. Furthermore, the far-reaching shortage of pediatric anesthesiologists at children's

hospitals has created the need for moderate sedation services provided by other hospital-based physicians. In most metropolitan areas of the United States, these children's hospitals form the safety net for subspecialty care provided to children in the Medicaid program. This critical service is directly supported by the publication of relative values of these codes.

Appendix G ("Summary of CPT Codes That Include Moderate Sedation") in the CPT manual was developed to identify services where sedation is an inherent part of the procedure. We firmly believe that any service performed that is *not* listed in Appendix G should be appropriately paid when reported with a moderate sedation code. There is significant additional cognitive skill required and this is reflected in JCAHO mandates addressing specific credentialing criteria for individuals providing moderate sedation. The work involved in providing sedation is *not* included in the RVUs for any procedure not included in Appendix G and the Academy believes that physicians should be adequately compensated for providing such services.

For these reasons, the Academy respectfully requests that CMS reconsider its decision to list the moderate sedation codes as carrier-priced. We urge CMS to publish the RUC-approved RVUs and assign these codes as Status Indicator "A" (Active) codes.

Preventive Medicine Services and the Medicare Primary Care Exception

Over the past three years, the Academy has made several requests for CMS to consider including preventive medicine services as part of the Medicare primary care exception. We take this opportunity to reiterate our request.

When CMS revised teaching physician rules (Medicare Carriers Manual Transmittal 1780, November 22, 2002), a "primary care exception" was established (§15016(C)(3)). This exception permitted the teaching physician to submit claims to Medicare for certain low and medium intensity Evaluation and Management services (99201-99203, 99211-99213) furnished by residents, subject to certain oversight rules, in a primary care clinic.

While the transmittal names pediatrics as one of the "residency programs most likely qualifying for this exception..." the rule itself has actually placed these residencies at a disadvantage. The primary reason is the available exempt codes. Medicare generally does not pay for the preventive medicine visits (99381-99387, 99391-99397). However, these are among the most common codes to be used in the pediatric primary care clinic.

Preventive well child care and EPSDT visits are responsible for a significant number of pediatric primary care clinic visits. By their nature, they are similar in intensity to the codes already included in the exempt list. Because these codes are not listed on the primary care exception list, it places an undue burden on the pediatric teaching physician who is unable to report these codes in the pediatric primary care setting under the exception. The fact that the primary care exception does not presently include preventive medicine services prohibits pediatric residents from partaking of the educational advantages enjoyed by their adult-based colleagues. Furthermore, given

that the "introduction to Medicare" exam was added to the exempted list last year establishes a precedent for other preventive services of similar intensity and importance to be included.

Preventive services are key services in the teaching setting, particularly considering that most children's hospitals serve as the Medicaid safety net for children in their service regions and deliver preventive services for children through age 18 under the federal EPSDT program.

While the original intent of Transmittal 1780 was for Medicare reimbursement, it has become the de facto standard for many Medicaid and commercial payers, and the compliance policies of teaching hospitals now reflect these rules.

For these reasons, we ask that the pediatric preventive medicine and EPSDT codes be added to the primary care exception list. This will have no financial impact on Medicare or residency GME reimbursement, but will help improve and make more equal the educational experience for the pediatric resident as compared to non-pediatric residencies.

Preventive Medicine Service	New	Established
Infant (<1 year)	99381	99391
Early childhood (1-4 years)	99382	99392
Late childhood (5-11 years)	99383	99393
Adolescence (12-17 years)	99384	99394

S0302 Early Periodic Screening Diagnosis and Treatment (EPSDT)

Pulse Oximetry

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

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

non-Medicare payors to utilize the RVUs to determine their fee schedules independent of Medicare payment policy.

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

The Academy appreciates the opportunity to provide comments on the August 22nd proposed rule and looks forward to working with CMS to ensure that the physician fee schedule accurately reflects the work value of physician practice and pediatric care.

Sincerely,

Eileen M. Ouellette, M.D., J.D. FAAP

Eileen M. Ouellette, MD, JD, FAAP
President

EMO/ljw

62-02

JIMMY PONDER, MD, FIPP ★ ✝ + ● ⚜
ADOLFO CUADRA, MD ✝ ⚜
MIML P. WILSON, OT, PA-C ◆ ◂
BRAD P. MANUEL, MMS, PA-C ◆
CHRISTINE THISTLETHWAITE, PA-C ◆

Headache & PAIN CENTER amc

September 19, 2006

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

Dear Sir or Madam:

As a local practicing physician, employing over 40 individuals, and former president of the Louisiana Society of Interventional Pain Physicians, I am writing to let you know of my strong support for H.R. 5866, the "Medicare Physician Payment reform and Quality Improvement Act of 2006."

For years interventional pain doctors, as well as other physicians have operated under a Medicare reimbursement system that does not keep track with inflation, while our business costs have risen steadily. Unless intervention takes place, this year payments to physicians will be cut by 5.1%. Some physicians may face cuts as high as 38%, as CMS is using bottom-up methodology in calculating practice expense and improving reimbursement for evaluation and management services. While we support higher payment for these services, substantial cuts in other areas are not acceptable. Physicians cannot continue to operate in an environment of such uncertainty, and as a result more and more doctors are electing to stop taking on and limiting additional Medicare patients, and an even more threatening issue, all other payers follow Medicare, which may affect many health care related services.

We need to address this flawed system so seniors and disabled Americans can continue to receive the care they deserve and physicians can receive adequate reimbursement for their services and continue to run their medical practices. H.R 5866 will end the application of the Sustainable Growth Rate formula and replace it with a single conversion factor, helping to ensure that payments keep pace with inflation.

In an effort to improve patient care, the bill also sets up a system that encourages physicians to voluntarily report data to the Center for Medicare and Medicaid Services. In addition, the legislation would create a system of Quality Measures, which would be developed in conjunction with specialty organizations. These measures are designed to help improve the quality of care to Medicare patients through a working collaboration between government and medical organizations.

We request your leadership on this issue and request your support and cosponsorship of H.R. 5866.

Sincerely,

Adolfo J. Cuadra, MD

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September 25, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 443-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

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

Dear Dr McClellan:

The American Academy of Pediatrics (AAP) appreciates the opportunity to provide comments on the August 22nd Notice of Proposed Rulemaking entitled "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B; Proposed Rule." Although very few pediatric services are included in the Medicare program, payment policies introduced in Medicare are frequently adopted by the Medicaid program and eventually by private payers. Therefore, the Academy offers these comments on the proposed rule to ensure that new policies appropriately accommodate the unique aspects of health care services delivered by primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists.

Lumbar Puncture

The Academy strongly applauds CMS for agreeing with the American Medical Association/Specialty Society Relative Value Scale Update Committee (RUC)-recommended relative value units (RVUs) for the lumbar puncture code (62270). We look forward to having the new work value of 1.37 published in the final rule and become effective on January 1, 2007.

Evaluation and Management

The Academy was part of a specialty society coalition that developed recommendations in support of revaluing thirty-five (35) evaluation and management (E/M) codes, including 99201-99205, 99211-99215, 99221-99223, 99231-99233, 99238-99239, 99241-99245, 99251-99255, 99281-99285, and 99291-99292. Given the breadth and depth of deliberations undertaken by the RUC in determining its final recommendations, we are pleased that CMS has agreed with all of the RUC recommendations on the E/M codes. We look forward to having the new work values published in the final rule and become effective on January 1, 2007.

Publishing Relative Value Units for Non-Covered Services

The Academy strongly objects to CMS' failure to publish RUC-recommended relative value units (RVUs) for "N" (non-covered) status codes, namely:

- Code 99173 (*Screening test of visual acuity, quantitative, bilateral*) and
- Code 92551 (*Screening test, pure tone, air only*)
- Codes 99339 and 99340 (*Individual physician supervision of a patient (patient not present) in home, domiciliary or rest home (eg, assisted living facility) requiring complex and multidisciplinary care modalities involving regular physician development and/or revision of care plans, 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 and 30 minutes or more, respectively)*

Vision and Hearing Screening (Codes 99173 and 92551)
Codes 99173 and 92551 have been through the RUC, where direct practice expense inputs were approved and recommended for inclusion in RBRVS. However, vision and hearing screening are Medicare non-covered services. CMS' refusal to publish RVUs for such pediatric services even though the codes have gone through the same validated valuation process as active Medicare codes distinctly disadvantages children, their providers, and children's preventive health services. Vision and hearing screening services are essential and required components of the Medicaid Early Periodic Screening Diagnosis and Treatment (EPSDT) program for the delivery of comprehensive preventive services. Therefore, CMS has a responsibility to publish RVUs for codes even when such services may not be covered under the Medicare program.

Care Plan Oversight (Codes 99339 and 99340)
During its April 2005 meeting, the RUC recommended work values of 1.25 (99339) and 1.80 (99340), where results of surveys were analyzed to ensure that the recommended work values accurately account for physician resources expended with the typical patient. It is our strong belief that the RUC-recommended RVUs should be published for codes 99339-99340. Additionally, in light of the fact that we are urging CMS to reevaluate its current policy with regard to the publishing RUC-recommended RVUs for non-covered services, CMS may consider designating codes 99339-99340 under Status Indicator "N" in order to allow for the RUC-recommended RVUs to be published.

On page 66245 of the 2005 final rule (Vol. 69, No. 219, November 15, 2004), CMS noted, "because we have not yet established a consistent policy regarding the publication of RVUs for non-covered services, we will need to examine this issue further to carefully weigh the pros and cons of publishing these RVUs for non-covered services." The AAP believes that CMS established a precedent on non-covered services when it published RVUs for the preventive medicine services codes (99381-99397). In fact, as

more non-Medicare payors adopt RBRVS, it becomes increasingly important to include non-covered services and their RUC-recommended RVUs on the Medicare physician fee schedule. In fact, one could argue that CMS has a social responsibility to publish such RVUs. The importance of these codes to the delivery of coordinated care to children and youth with special health care needs is paramount. This population is overrepresented in the Medicaid program and CMS' failure in this regard is contradictory to the priority given to physician-directed disease management and care coordination activities provided to its Medicare beneficiaries.

While CMS's failure to publish the RUC-recommended RVUs for these codes represents an egregious omission, the situation is made worse by the fact that CMS has neglected to include these codes altogether on the proposed 2007 RBRVS fee schedule. The Academy questions why these codes were excluded from the fee schedule and wonders whether in doing so, CMS is attempting to shield itself from future comments and actions in this regard. Whatever the intent, CMS must not shy away from its responsibility to publish the RUC-recommended RVUs for all codes, including those designated as non-covered.

Moderate (Conscious) Sedation

The moderate sedation codes (99143-99150) are included on the fee schedule as Status Indicator "C" (Carrier Priced), with no published RVUs. Given CMS' direct involvement in the development of these codes, it disappoints us that the Status Indicator for the codes is "C." Furthermore, we are dismayed that CMS continues not to accept the April 2005 RUC recommendations for the codes and publish them in the 2007 RBRVS proposed rule.

In its November 21, 2005 *Federal Register* 2006 Medicare Physician Fee Schedule comments, CMS stated that it was "uncertain whether the RUC assigned values are appropriate and has carrier priced these codes in order to gather information for utilization and proper pricing." While we appreciate CMS' reconsideration of paying for sedation services not previously covered and understand this is an interim position, we request that CMS consider the following arguments in revising its position.

These CPT codes (99143-99150) were surveyed by several specialty societies in order to provide the RUC with data necessary to appropriately value the service. Codes were developed to simplify reporting these services into age-specific categories. The RUC-recommended values for these six codes were based on valid surveys and carefully vetted through the RUC process. We are confident in the accuracy of the values assigned. While CMS has assigned these codes to Status Indicator "C," the Academy believes that they should be listed with Status Indicator "A" (Active) and their RUC-recommended RVUs published.

Providing moderate sedation to patients undergoing certain outpatient procedures requires a certain level of provider skill and training and incurs medical legal liability, but is also associated with greater patient satisfaction, improved outcomes, and cost savings over similar procedures provided with anesthesia in an operating room. Furthermore, the far-reaching shortage of pediatric anesthesiologists at children's

hospitals has created the need for moderate sedation services provided by other hospital-based physicians. In most metropolitan areas of the United States, these children's hospitals form the safety net for subspecialty care provided to children in the Medicaid program. This critical service is directly supported by the publication of relative values of these codes.

Appendix G ("Summary of CPT Codes That Include Moderate Sedation") in the CPT manual was developed to identify services where sedation is an inherent part of the procedure. We firmly believe that any service performed that is *not* listed in Appendix G should be appropriately paid when reported with a moderate sedation code. There is significant additional cognitive skill required and this is reflected in JCAHO mandates addressing specific credentialing criteria for individuals providing moderate sedation. The work involved in providing sedation is *not* included in the RVUs for any procedure not included in Appendix G and the Academy believes that physicians should be adequately compensated for providing such services.

For these reasons, the Academy respectfully requests that CMS reconsider its decision to list the moderate sedation codes as carrier-priced. We urge CMS to publish the RUC-approved RVUs and assign these codes as Status Indicator "A" (Active) codes.

Preventive Medicine Services and the Medicare Primary Care Exception

Over the past three years, the Academy has made several requests for CMS to consider including preventive medicine services as part of the Medicare primary care exception. We take this opportunity to reiterate our request.

When CMS revised teaching physician rules (Medicare Carriers Manual Transmittal 1780, November 22, 2002), a "primary care exception" was established (§15016(C)(3)). This exception permitted the teaching physician to submit claims to Medicare for certain low and medium intensity Evaluation and Management services (99201-99203, 99211-99213) furnished by residents, subject to certain oversight rules, in a primary care clinic.

While the transmittal names pediatrics as one of the "residency programs most likely qualifying for this exception..." the rule itself has actually placed these residencies at a disadvantage. The primary reason is the available exempt codes. Medicare generally does not pay for the preventive medicine visits (99381-99387, 99391-99397). However, these are among the most common codes to be used in the pediatric primary care clinic.

Preventive well child care and EPSDT visits are responsible for a significant number of pediatric primary care clinic visits. By their nature, they are similar in intensity to the codes already included in the exempt list. Because these codes are not listed on the primary care exception list, it places an undue burden on the pediatric teaching physician who is unable to report these codes in the pediatric primary care setting under the exception. The fact that the primary care exception does not presently include preventive medicine services prohibits pediatric residents from partaking of the educational advantages enjoyed by their adult-based colleagues. Furthermore, given

that the "introduction to Medicare" exam was added to the exempted list last year establishes a precedent for other preventive services of similar intensity and importance to be included.

Preventive services are key services in the teaching setting, particularly considering that most children's hospitals serve as the Medicaid safety net for children in their service regions and deliver preventive services for children through age 18 under the federal EPSDT program.

While the original intent of Transmittal 1780 was for Medicare reimbursement, it has become the de facto standard for many Medicaid and commercial payers, and the compliance policies of teaching hospitals now reflect these rules.

For these reasons, we ask that the pediatric preventive medicine and EPSDT codes be added to the primary care exception list. This will have no financial impact on Medicare or residency GME reimbursement, but will help improve and make more equal the educational experience for the pediatric resident as compared to non-pediatric residencies.

Preventive Medicine Service	New	Established
Infant (<1 year)	99381	99391
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S0302 Early Periodic Screening Diagnosis and Treatment (EPSDT)

Pulse Oximetry

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

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

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The Academy appreciates the opportunity to provide comments on the August 22nd proposed rule and looks forward to working with CMS to ensure that the physician fee schedule accurately reflects the work value of physician practice and pediatric care.

Sincerely,

Eileen M. Ouellette, M.D., J.D. FAAP

Eileen M. Ouellette, MD, JD, FAAP
President

EMO/ljw

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e+ HEALTHCARE

SEP 27 2006

September 25, 2006

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

Re: Comments by e+ healthcare, LLC -- File Code CMS-1321-P/Proposed Rule for the Medicare Program regarding Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 – IDTF Issues; Reassignment Issues

Dear Administrator McClellan:

e+ healthcare (e+) thanks you for the opportunity to comment on the proposed Physician Fee Schedule Rule, as published in the Federal Register on August 22, 2006 by CMS. e+ is commenting on the portions of the proposed rule concerning supervising physicians in IDTFs and reassignment rules for professional interpretations of diagnostic procedures. e+ develops and operates imaging centers that offer PET scanning services. The proposed changes could have an adverse effect on the thousands of Medicare beneficiaries who receive care at e+ facilities and the physicians who utilize those facilities.

In the Proposed Rule, CMS proposes to amend the applicable portions of the Medicare regulations governing independent diagnostic testing facilities ("IDTFs"). Specifically, CMS proposes to establish operating standards for IDTFs, limit the number of IDTFs that a supervising physician may supervise, and expand the obligations of a supervising physician. If the Proposed Rule becomes final, it could have a significant impact on the operation of legitimate IDTFs such as those operated by e+.

The Proposed Rule also indicates that CMS is considering incorporating the requirements of the purchased interpretations rule into the contractual arrangement exception to the reassignment rules in 42 C.F.R. §424.80. This potential change could have a significant impact on the provision of diagnostic imaging services and the ability of Medicare beneficiaries to access such services.

For the reasons discussed below, e+ respectfully submits that the proposed changes regarding supervising physicians in IDTFs are inappropriate. Accordingly, e+ asks CMS to reconsider its proposal and to maintain the existing requirements for supervising physicians in IDTFs.

104 Woodmont Boulevard, Suite 500 Nashville, Tennessee 37205
[615] 467-7400 *fax* [615] 467-7401
website eplushealthcare.com

IDTF Issues

1. Proposed Supplier Standards for IDTFs

The Proposed Rule includes the establishment of 14 supplier standards that an IDTF would be required to meet in order to obtain and retain enrollment as a Medicare supplier. The preamble to the Proposed Rule indicates that CMS is proposing to adopt supplier standards for IDTFs similar to those currently in place for suppliers of durable medical equipment, prosthetics, orthotics, and supplies ("DMEPOS). However, the liability insurance obligations under the proposed IDTF supplier standards vary significantly from those included in the DMEPOS supplier standards.

While the DMEPOS supplier standards require that a DMEPOS supplier maintain comprehensive liability insurance in the minimum amount of $300,000, the IDTF supplier standards require that an IDTF maintain liability insurance with minimum coverage amounts equal to the **greater of** $300,000 or 20% of the IDTF's average annual Medicare billings. The preamble to the Proposed Rule does not include an explanation of, or justification for, the distinction between the obligations for IDTFs and DMEPOS suppliers. The preamble also does not provide any rationale for how CMS determined that 20% of an IDTF's Medicare "billings" is a reasonable or appropriate method of calculating the proper amount of insurance to be maintained by an IDTF. Moreover, the use of the term "billings" in this provision could be misleading. Since the usual and customary charges of most Medicare suppliers are well in excess of the Medicare allowable amount for most services, if CMS insists upon retaining the 20% minimum threshold, the term "billings" should be replaced with "collections." We would urge CMS not to impose a 20% minimum threshold, since collections bear no relation to the size of a potential claim. Instead, we urge CMS to apply the DMEPOS standard of $300,000.

The proposed supplier standards also require that an IDTF's liability insurance policy must be carried by a "non-relative owned company." This requirement is not included in the DMEPOS supplier standards, and the preamble to the Proposed Rule includes no justification for the distinction between the requirements for IDTFs and DMEPOS suppliers. Many healthcare systems and large organizations procure liability insurance coverage for their affiliates and subsidiaries through captive insurance companies, rather than by purchasing coverage from third-parties. Without any further justification from CMS, it would be unfair to prohibit the use of liability insurance provided by captive insurance companies.

2. Limitation on Number of IDTFs Supervised

The Proposed Rule includes a proposal to revise 42 C.F.R. §410.33(b)(1) to provide that a supervising physician may provide supervision to no more than three (3) IDTF sites. CMS states that the purpose of this proposed revision is to ensure quality care is provided to Medicare beneficiaries. However, CMS does not provide any additional support for this position or any evidence that the supervision of more than three IDTF sites by a supervising physician is likely to have a detrimental impact on the quality of services provided in such IDTFs.

The regulations governing IDTFs do not currently include any limit on the number of IDTF sites that may be supervised by a single physician. CMS has left it to the discretion of individual Medicare contractors to determine any appropriate limits for supervising physicians, and has created guidelines in Chapter 10 of the Medicare Program Integrity Manual (CMS Pub. 100-8) for Medicare contractors to determine whether supervising physicians are able to provide adequate supervision over IDTFs. Moreover, each supervising physician is required to sign an attestation statement confirming that the physician is providing supervision to the IDTF, the falsification of which could subject the physician to significant penalties and exclusion from the Federal health care programs.

Absent any meaningful justification for this proposed change, it is inappropriate for CMS to arbitrarily select a maximum number of IDTFs for which a physician may serve as a supervising physician. The discretion over this issue should remain with the individual Medicare contractors.

3. Expansion of Supervising Physician's Obligations in IDTFs

The Proposed Rule also includes a major change to the obligations of supervising physicians in the operation of IDTFs.

The current version of 42 C.F.R. §410.33(b)(1) provides as follows regarding the obligations of the supervising physicians of an IDTF:

> An IDTF must have one or more supervising physicians who are responsible for the direct and ongoing oversight of the quality of the testing performed, the proper operation and calibration of the equipment used to perform tests, and the qualification of nonphysician personnel who use the equipment. This level of supervision is that required for general supervision set forth in § 410.32(b)(3)(i).

The proposed revised version of §410.33(b)(1) would provide as follows:

> Each supervising physician must be limited to providing supervision to no more than three (3) IDTF sites. The IDTF supervising physician is responsible for the overall operation and administration of the IDTFs, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations.

The proposed revised version of paragraph (b)(1) appears to contemplate that each IDTF must have a single supervising physician, as opposed to the current version, which permits up to three supervising physicians to share the supervision responsibilities. In addition, the proposed revised version provides that the IDTF supervising physician must be responsible for the overall operation and administration of the IDTF, including compliance responsibilities.

The preamble to the Proposed Rule does not include any explanation or rationale for this proposed change. It does not make sense to require the supervising physician to be responsible for the administrative operations of an IDTF. Physicians are in no better position than laypersons to ensure that IDTFs comply with administrative operations of healthcare providers. To the contrary, physicians often engage laypersons to manage their physician practices and other healthcare related business ventures specifically because the physicians recognize their shortcomings with respect to managing the administrative aspects of business operations. Physicians likewise are generally ill-suited to perform compliance roles within many healthcare organizations. Due to the time constraints on most physicians, they often simply do not have time to manage compliance issues within an organization. Moreover, physicians do not have any special knowledge or ability that makes them better suited to perform compliance functions than laypersons.

We certainly agree that it is appropriate for physicians to serve a supervisory role in IDTFs with regard to issues in which they have clinical or technical expertise; however, it does not make sense to require physicians to serve in administrative positions within IDTFs. This proposed change is inconsistent with the requirements applicable to other Medicare providers and suppliers. For example, hospitals, skilled nursing facilities, home health agencies, physician practices, DME suppliers, and a

variety of other providers and suppliers are permitted to be operated by layperson administrators. Without some additional justification or rationale, the requirement that the supervising physician of an IDTF be responsible for the overall operation and administration of an IDTF is arbitrary and unfair. It also is likely to have a chilling effect on the ability of IDTFs to obtain physicians to serve as supervising physicians.

Reassignment

In the Proposed Rule, CMS notes that it is considering amending the contractual arrangement exception to the reassignment prohibition in 42 C.F.R. §424.80(b)(2), to incorporate the requirements under the purchased interpretation rules set forth in Section 30.2.9.1 of Chapter 1 of the Medicare Claims Processing Manual (CMS Pub. 100-4). The stated purpose for the potential change is to guard against patient and program abuse. However, the change contemplated by CMS will have a far-reaching impact on the ability of providers and suppliers to furnish imaging services and, in turn, the ability of Medicare beneficiaries to obtain necessary imaging services.

Currently, the contractual arrangement exception to the reassignment prohibition permits an entity to accept reassignment from a physician provided there is a contractual arrangement between the entity and the physician under which the entity bills for the physician's services, provided certain conditions are satisfied. In the context of professional interpretations of diagnostic procedures, the contractual arrangement exception permits a supplier to bill for professional interpretations by a physician as long as the billing entity has a contract with the physician performing the interpretation.

CMS is considering adding the following requirements to the contractual arrangement exception for the reassignment of the right to bill and collect for professional interpretations:

- The test must be ordered by a physician that is financially independent of the person or entity performing the test and also of the physician or medical group performing the interpretation.
- The physician or medical group performing the interpretation does not see the patient.
- The physician or medical group billing for the interpretation must have performed the technical component of the test.

This change would have a significant impact on the current practice of physicians and other suppliers in the industry.

First, in the case of an IDTF in which a referring physician has an ownership interest (e.g., a facility located in a rural area), the IDTF would not be permitted to obtain professional interpretations and bill for such interpretations through an independent contractor physician. Instead, the IDTF would be required to employ a physician to provide the interpretations (which may not be permitted under some state laws) or the physician would be required to bill and collect for the services. This alternative may not be attractive to many interpreting physicians, who often prefer to receive payment directly from the IDTF and allow the IDTF to bill for the services. This result could have an adverse effect on the ability of Medicare beneficiaries residing in rural areas to obtain necessary diagnostic services.

Second, the proposed change would eliminate the ability of traditional hospital-based radiology groups from using independent contractor radiologists to perform professional interpretations. Because the technical component of the diagnostic procedure is performed by the hospital, the radiology group

would fail to satisfy the proposed requirements, thereby prohibiting the radiology group from billing for services provided by the independent contractor radiologists. This could impact the ability of hospitals to provide certain diagnostic imaging services and the access to such services by Medicare beneficiaries.

Third, non-radiology physician group practices who provide diagnostic services to patients within their offices would be prohibited from billing for professional interpretations provided by independent contractor radiologists. Currently, physicians in such group practices are able to self-refer patients within the group practice pursuant to the in-office ancillary services exception to the Stark Law and bill for professional interpretations provided by on-site independent radiologists under a contractual arrangement. Because the referring physician (a member of the group practice) would be financially related to the entity performing the test (the group practice), the practice would not satisfy the proposed additional criteria, thereby prohibiting the group practice from billing for the interpretation. This would require the IDTF and the interpreting physician to issue separate bills, which is both inefficient and costly. Moreover, the issuance of two bills for a single imaging procedure can be confusing to patients, who often perceive the procedure as a single service, and do not understand that an imaging procedure consists of both the technical component and the professional component.

Conclusion

For all of the foregoing reasons, *e* hereby respectfully requests that CMS (i) not implement the proposed changes to the standards for supervising physicians of IDTFs in 42 C.F.R. §410.33(b)(1) and (ii) not incorporate the criteria under the purchased interpretation rule into the contractual arrangement exception to the reassignment prohibition in 42 C.F.R. §424.80(b)(2).

Sincerely,

Timothy M. Petrikin
President and CEO

1090 Vermont Avenue NW, Suite 510, Washington D.C. 20005 ph 202 414 0140 | 800 962 9008

65

October 4, 2006

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

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment under Part B. Proposed Rule.

Thank you for the opportunity to comment on the 2007 Medicare Physician Fee Schedule proposed rule.

The Medicare program's central tenet is the physician-patient relationship. Beneficiaries rely upon their physician for access to all aspects of the Medicare program. Over the past decade, this relationship has become compromised by dramatic reductions in reimbursements, increased regulatory burdens, and escalating practice costs.

Continued cuts in reimbursement will result in a loss of physician services for Medicare beneficiaries. The AOA surveyed its members in July, asking what actions they would take if the projected Medicare payment reductions were implemented. Twenty-one percent said they would stop providing services to Medicare patients. Twenty-six percent said they would stop accepting new Medicare beneficiaries in their practice and 38 percent said they would limit the number of Medicare patients accepted in their practice. Here is a sampling of our physicians' reactions:

- ***Family Practice and Geriatrics Physician, Largo, Fla.:*** *I have two practice locations; both have stopped accepting new Medicare patients. With continued cuts, we will be forced to stop caring for these patients altogether. As it stands now I have to see more patients with less time for each. I will continue to scale back time intensive nursing home work.*

- ***Family Practice Physician Fort Lauderdale, Fla.:*** *Medicine is a calling, but the business of medicine is generally a small business. No business can survive when its expense is more than income. The continued trend will move medicine into a corporate mentality that will be detrimental to the patient and destroy the emphasis on wellness and primary care that our improvements in longevity and quality of life have been based on for the past 50 years.*

- ***Family Practice Physician Bloomfield, Iowa:*** *I find a frightening trend in America today, to sacrifice quality health care in the name of lowering the cost of healthcare. If I can't pay my staff a competitive wage because of cuts in reimbursement, they find another job and I am forced to find someone*

less qualified, less efficient. It becomes a vicious cycle of decreased efficiency and decreasing reimbursement that puts many physicians in a situation where they cannot afford to treat Medicare patients. I have not reached that point yet, but I do not want to get there either.

- ***Family Practice Physician Winterset, Iowa:*** *I will have no choice but to stop accepting new Medicare patients. I am already losing money every time a Medicare patient walks in the door. My overhead is approximately $0.65 for every dollar billed. Medicare is paying me approximately $0.52 on the dollar billed. It is a matter of continuing to see Medicare patients and go broke or limit access and survive to serve my existing patients. I live in a rural area and half of my patient visits are Medicare visits. If cuts continue I will not be able to continue in business. I cannot meet my cost of doing business with any further cuts! I have not taken an increase in pay in the last six years and continue to lose ground every year.*

Physicians cannot afford to have the gap between cost and reimbursement continues to grow at the current rate. Many osteopathic physicians practice in solo or small group settings. These small businesses have difficulty absorbing losses. Eventually, the deficit between cost and reimbursement will be too great and physicians will be forced to limit, if not eliminate, services to Medicare patients.

The AOA represents the nation's 59,000 osteopathic physicians (DOs). Approximately 65 percent of all osteopathic physicians practice in primary care areas such as pediatrics, family practice, obstetrics/gynecology, and internal medicine. We share the concerns of the American College of Physicians, which released a comprehensive report January 30, 2006: *The Impending Collapse of Primary Care Medicine and its Implications for the State of the Nation's Health Care.*

As more physicians retire within the next five to 10 years, there may not be an adequate supply of primary care physicians to treat an aging population with growing incidences of chronic diseases. According to the ACP report, "Factors affecting the supply of primary care physicians and general internists in particular include excessive administrative hassles, high patient loads, and declining revenue coupled with the increased cost of providing care. As a result, many primary care physicians are choosing to retire early. These factors, along with increased medical school tuition rates, high levels of indebtedness, and excessive workloads, have dissuaded many medical students from pursuing careers in general internal medicine and family practice."

IMPACT: Physician Payment Reduction/Sustainable Growth Rate

According to the Centers for Medicare & Medicaid Services (CMS), physicians will experience a 5.1 percent reduction in the payment update in 2007. CMS attributes the –5.1 percent update to a much faster spending rate on physician services and other Part B services than previously projected. Expenditures for physicians' services in 2005 increased 10 percent over 2004, according to CMS. The Agency cited more frequent and intensive office visits, and rapid growth in the use of imaging techniques, laboratory tests, and physician-administered drugs.

Coupled with changes to the physician work relative value units, practice expense, and changes mandated by the Deficit Reduction Act (DRA), physicians face reimbursement reductions ranging from –1 percent to –16 percent in 2007. Additional cuts are predicted through 2015.

Physicians face a 39 percent reduction in Medicare reimbursements over the next eight years. During this same period, physicians will continue to face increases in their practice costs. If the

2007 cut is realized, Medicare physician payment rates will fall 20 percent below the government's measure of inflation in medical practice costs over the past six years. Since many health care programs, such as TRICARE, Medicaid, and private insurers link their payments to Medicare, cuts in other systems will compound the impact of the projected Medicare cuts.

Reform of the Medicare physician payment formula, specifically, the repeal of the sustainable growth rate (SGR) formula, is one of the AOA's top priorities. The SGR formula is unpredictable, inequitable, and fails to account accurately for physician practice costs. Three central problems associated with the current formula are utilization of physician services, the economic volatility of the formula, and physician administered drugs.

Utilization of Physician Services—The SGR penalizes physicians with lower payments when utilization exceeds the SGR spending target. However, utilization is often beyond the control of the individual physician or physicians as a whole.

Over the past twenty years, public and private payers successfully moved the delivery of health care away from the hospital into physicians' offices. They did so through a shift in payment policies, coverage decisions, and a move away from acute based care to a more ambulatory based delivery system. This trend continues today. As a result, fewer patients receive care in an inpatient hospital setting. Instead, they rely upon their physicians for more health care services, leading to greater utilization of physician services.

For the past several years, CMS has failed to account for the numerous policy changes and coverage decisions in the SGR spending targets. With numerous new beneficiary services, the agency's promotion of preventive services, and an expected growth in the number of national coverage decisions, utilization is certain to increase over the next decade.

Gross Domestic Product—The use of the GDP as a factor in the physician payment formula subjects physicians to the fluctuating national economy. We support the altered the use of the GDP to a 10-year rolling average versus an annual factor. However, we are concerned that a downturn in the economy will have an adverse impact on the formula.

We argue that the health care needs of beneficiaries do not change based upon the economic environment. Physician reimbursements should be based upon the costs of providing health care services to seniors and the disabled, not the ups and downs of the economy.

Another cause for the deeper reduction relates to the Medicare Economic Index – a measure of inflation faced by physicians with respect to practice costs and wage levels. The MEI includes a productivity adjustment based on calculations by the Bureau of Labor Statistics. The bureau recently made some changes to its productivity data, which affect the MEI. Based on the bureau's new data series and lower projections of inflation, the MEI is now 0.5 of a percentage point lower than originally estimated. This translates into a lower payment update of -5.1percent.

Physician Administered Drugs—The other major contributor to increased utilization of physician services is the inclusion of the costs of physician-administered drugs in the SGR. Because of the rapidly increasing costs of these drugs, their inclusion greatly affects the amount of actual expenditures and reduces payments for physician services.

Over the past few years, Congress has encouraged the Administration to remove the cost of physician-administered drugs from the formula. We do not believe the definition of physician services included in Section 1848 of Title XVIII includes prescription drugs or biological products. Removal of these costs would ease the economic constraints that face Congress and CMS and make reform of the physician payment formula more feasible.

The SGR methodology is broken and, in our opinion, beyond repair. Physicians are the only Medicare providers subjected to the flawed SGR formula. Since the SGR is tied to flawed methodologies, it routinely produces negative updates based upon economic factors, not the health care needs of beneficiaries. And, it has never demonstrated the ability to reflect increases in physicians' costs of providing care.

Every Medicare provider, except physicians, receives annual positive updates based upon increases in practice costs. Hospitals and other Medicare providers do not face the possibility of "real dollar" cuts—only adjustments in their rates of increase. Steps must be taken to eliminate the year-to-year uncertainty that has plagued the Medicare physician payment formula for the past five years.

As Congress and CMS establish new quality improvement programs, it is imperative for Medicare to reflect fairly the increased role of physicians and outpatient services as cost savers to the Part A Trust Fund. Quality improvement programs may increase spending in Part B, but very well could result in savings in Part A or Part D. These savings should be credited to physicians through a program between Parts A, B, and D. We commend CMS for exploring gain-sharing initiatives to determine its efficacy in improving care and look forward to working with you as the demonstration project moves forward.

GEOGRAPHIC PRACTICE COST INDEX (GPCI)

The Medicare Prescription Drug, Modernization and Improvement Act (MMA) (P.L. 108-173) included a three-year floor of 1.0 on all work GPCI adjustments. The AOA was pleased that the MMA included this adjustment that provided equity in how the Medicare program views and evaluates the work of physicians regardless of geographic location. The gap between urban and rural payment rates for identical services has exacerbated the mal-distribution of physicians in urban versus rural areas.

By establishing a 1.0 floor for the work geographic practice cost indices (GPCI) under the Medicare physician fee schedule, the MMA reversed years of inequities in payments between rural physicians and those in larger urban communities. This resulted in an increase of 1 percent or more in payments for physicians practicing in 58 of the 89 Medicare regions. Physicians practicing in 17 of the 89 regions saw their payments increase over 2 percent.

This provision is set to expire on December 31, 2006. If this provision is not extended many physicians, especially those in rural areas, will experience additional cuts. The healthcare needs of

Americans living in many rural areas often go unmet. An extension of the MMA provision will enhance beneficiary access and improve the quality of care available.

DRA PROPOSALS

Physicians have been asked to be more proactive in diagnosing and treating illnesses, and in disease prevention. This is evidenced by screening services that have been added to the Medicare program in recent years. For 2007, CMS plans to expand its prevention benefits as mandated by the DRA. For example, CMS proposes to cover ultrasound screening for abdominal aortic aneurysm and eliminate the Part B deductible for colorectal cancer screening.

The AOA commends the extension of preventive benefits. Prevention is a key component of the osteopathic approach to medicine. Doctors of osteopathic medicine help patients develop attitudes and lifestyles that don't just fight illness, but help prevent it.

Unfortunately, Medicare's physician payment formula penalizes physicians for providing the services that the government promotes. CMS is calling on the physician community to close the prevention gap. However, as the volume of services increases, payments decrease, thus creating a vicious cycle for the physician and the patient in need of care.

The DRA also included provisions that reduced payments for imaging services. One provision of the DRA reverses previous CMS policy that required the redistribution of savings from reductions in imaging services to other physician services. These cuts involved payments when multiple images on contiguous body parts are performed during a single session with the same patient. The policy resulted in average cuts of 4 percent in 2006. As required by budget neutrality provisions included in the RBRVS system, CMS "increased the CY 2006 PE RVUs by 0.3 percent to offset the estimated savings generated by the multiple imaging payment reduction policy." However, under the DRA provision, the savings redistributed in 2006 will be reclaimed.

The DRA also included a provision that stipulated that Medicare payments for the technical component (the image itself; not the physician's interpretation) of imaging services cannot exceed payment for the same service when it is provided by a hospital outpatient department. The savings resulting from this mandate also will not be redistributed to other physician services. The Congressional Budget Office (CBO) estimates the total impact of the two imaging provisions at $2.8 billion over 5 years.

The AOA appreciates the need to control costs where possible. However, CMS needs to recognize the greater complexity of volume. As mentioned earlier, the delivery of care has shifted from the hospital to physicians' offices. As fewer patients receive care in a hospital setting, more rely upon their physicians for services, including diagnostic imaging.

In addition, physicians are forced to practice defensive medicine due to the threat of malpractice lawsuits. Liability issues have a significant impact on the volume of physician services. Until spiraling malpractice premiums and lawsuit awards are brought under control, defensive medicine will continue to have an impact on the volume of services provided. Finally, imaging services should not be reimbursed at a rate below what it costs physicians to provide the exam.

OTHER ISSUES: PUBLISH RELATIVE VALUE UNITS FOR NON-COVERED SERVICES

The AOA concurs with the AMA's Relative Value Update Committee's (RUC) position and a recent recommendation by the Practicing Physicians Advisory Council that CMS should publish relative values for all services, including non-covered services. Since many private payers base their payments on the RBRVS formula, it is important for CMS to publish all of the values that the RUC approves and submits to CMS. The American Osteopathic Pediatric Association and other osteopathic specialties have indicated to us their need to have values published for fair and equitable payments.

PROMOTING EFFECTIVE USE OF HEALTH INFORMATION TECHNOLOGY

According to CMS, "there are mixed signals about the potential of HIT to reduce costs. Some studies have indicated that HIT adoption does not lead necessarily to lower costs and improved quality. In addition, some industry experts have stated that factors such as an aging population, medical advances, and increasing provider expenses would make any projected savings impossible."

The AOA remains concerned about the costs of health information systems for individual physicians, especially those in rural communities. According to a 2005 study published in Health Affairs, the average costs of implementing electronic health records was $44,000 per fulltime equivalent provider, with ongoing costs of $8,500 per provider per year for maintenance of the system. This is not an insignificant investment.

With physicians already facing deep reductions in reimbursements, without financial assistance, many physicians will be prohibited from adopting and implementing new technologies. The July 2006 survey conducted by the AOA demonstrates this concern. According to the survey, 90 percent of osteopathic physicians responding agreed that "decreased reimbursements will hinder their ability to purchase and implement new health information technologies in their practice."

HEALTH CARE INFORMATION TRANSPARENCY INITIATIVE

CMS plans to post on its web site geographically-based Medicare payment information for common outpatient hospital and physician services this fall. The AOA supports empowering patients with information about their medical care and related costs. However, providing price information on health care services should not be put in the same class as comparative shopping for airline tickets or hotel accommodations.

We are concerned that publishing fees for physician services will not reflect accurately what is involved in the level of service provided. In addition, as CMS notes, "list prices, or charges, generally differ from the actual prices negotiated and paid by different health plans." We also question whether comparative pricing plays a significant role in choosing a hospital or physician, particularly when a patient is facing a life-threatening illness.

As CMS moves forward in making quality and price information available to Medicare patients, we ask that if any physician profiling data is made public, assurances must be in place that promise rigorous evaluation of the measures to be used and that only measures deemed sensitive and specific to the care being delivered are used. The validity, reliability, sensitivity, and specificity of information intended for private or public reporting must be very high.

The AOA appreciates the opportunity to comment on the 2007 Medicare physician fee schedule proposed rule. We look forward to working with CMS in the future on this and other issues of concern to the osteopathic medical profession.

Sincerely,

John A. Strosnider DO.

John A. Strosnider, DO
AOA President

66

VNUS MEDICAL TECHNOLOGIES, INC.

October 2, 2006

Via Express Mail

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

RE: CMS -1321-P
Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007

Dear Dr. McClellan:

In keeping with the provisions of the Deficit Reduction Act of 2005 (DRA) of acceptable customary Medicare spending for services rendered, we urge CMS to review and appropriately correct the calculation of the Non-Facility Practice Expense (NFPE) supply costs for CPT code **36478** that has been reported in the 2006 federal regulation rule PE values, the five-year direct expense practice input and the proposed 2007 practice expense input supply codes; CMS-1321-P.

Issue: Incorrect input cost used for endovenous laser treatment kit for CPT 36478

Due to an initially incorrect input cost in the NPRM direct practice expense input file, CMS may be paying significantly more than the manufacturer's advertised or quoted prices for endovenous laser kits used in CPT 36478. The supply item in question is **SA074,** endovascular laser treatment kit, which has an input cost of $677.00 as used by CMS for the NFPE RVU determination. However advertised and quoted prices from suppliers who sell both lasers and endovenous laser kits are usually in the $210 to $435 range with the most common prices in the $275 to $315 range. Therefore the NFPE for 36478 is over-valued and should be adjusted to accurately reflect the current actual typical costs based on manufacturer's information. A reference list of market prices for endovenous laser kits is contained in the footnote at the end of this letter.

Non-Facility practice expense cost input for supply associated with CPT procedure code 36478

PROC CODE	CATEGORY	SUPPLY CODE	DESCRIPTION	[illegible]	[illegible]	Input Cost	Issue for 2007
36478	Kit, pack, tray	**SA074**	Kit, endovascular laser treatment	1	Kit	$677.00	Over-valued: Typical costs for laser kits range from $275-$315

Recommendation: Correct the NFPE cost inputs for CPT code 36478

- The current non-facility practice expense RVUs for laser ablation procedures should be adjusted and reduced to reflect the appropriate cost of the endovenous laser treatment kit.
- Based on the current typical purchase prices, CMS should decrease the cost input for the endovenous laser kit (SA074) from $677.00 to $300.00 for a total reduction of $377.00
- The 2007 non-facility practice expense for CPT 36478 should be reduced by $377.00 to reflect a corrected NPRM Direct Practice expense input for endovenous laser treatment kit (to $300.00).

We are proposing these changes so the payment system is updated to both correct initial inaccuracies in SA074 input cost as well as to reflect changes in pricing over the last two years since the RUC received these inputs. By

revising the assignment of the **SA074** PE values, the overall practice expenses will more accurately reflect the actual current resources being utilized for the Laser Ablation Procedure and thus decrease Medicare expenditures accordingly.

We appreciate the opportunity to submit these comments and to work with CMS. Should you have any questions please contact me or Gail Daubert at 202-414-9241 and we may be able to provide further information such as the names of doctors who purchase the supply item in question. This could be helpful if CMS wishes to perform an independent cost assessment of NFPE supply cost inputs for endovenous laser kits used with CPT code 36478.

Thank you for your prompt consideration in this matter.

Very truly yours,

Brian Farley
President and CEO
VNUS Medical Technologies, Inc.

cc: Pam R. West, Health Insurance Specialist Division of Practitioner Services Centers for Medicare and Medicaid Services

Table of prices for endovenous laser treatment kits

Endovenous laser treatment kit price	Supplier Company	Type of Document	Reference location
$377 ($435 less $58 pack price)	Angiodynamics	Economic analysis by supplier	Exhibit 1
$315	Vascular Solutions	Advertisement by supplier	Exhibit 2
$275 to $360	Diomed	Diomed Corporate presentation April 6, 2006	Exhibit 3
$295	Diomed	Diomed Comparison of EVLT and VNUS Closure Systems	Exhibit 4
$210	Angiodynamics	Price quote by supplier	Exhibit 5
$175 ($120 for TVS laser fiber with Spin-Lock + $27 for micro-introducer kit + $28 for 45cm introducer kit)	Total Vein Solutions	Advertisement & sell sheets from supplier	Exhibit 6

Enclosures:
Exhibit 1- ANGIODYAMICS (Venacure) profitability profile & procedure pack (Surgpak) cost sheet
Exhibit 2-VASCULAR SOLUTIONS laser kit pricing advertisement
Exhibit 3-Slides from DIOMED Corporate Overview from diomedinc.com website; price of endovenous laser kits
Exhibit 4-DIOMED Comparison of EVLT and VNUS Closure Systems
Exhibit 5-ANGIODYAMICS endovenous laser treatment kit price quote May 13, 2005
Exhibit 6-Excerpts from TOTAL VEIN SOLUTIONS Catalog 2006 & sell sheets

Business in a Box

VenaCure™
Laser Vein Treatment

ANGIODYNAMICS®
INCORPORATED

VenaCure™ System, Business Model

Profitability Profile

	$
Lease Payment:	$ 1,010
Disposable Expenses:	$ 435
Procedure Reimbursment	$ 3,500

Proc / Week	Proc / Month	Monthly Income	Kit Cost	Lease Payment	Monthly Profit	1 Year Income	2 Year Income	3 Year Income
2	8	$ 28,000	$ 3,480	$ 1,010	$ 23,510	$ 282,120	$ 564,240	$ 846,360
3	12	$ 42,000	$ 5,220	$ 1,010	$ 35,770	$ 429,240	$ 858,480	$ 1,287,720
4	16	$ 56,000	$ 6,960	$ 1,010	$ 48,030	$ 576,360	$ 1,152,720	$ 1,729,080
5	20	$ 70,000	$ 8,700	$ 1,010	$ 60,290	$ 723,480	$ 1,446,960	$ 2,170,440
6	24	$ 84,000	$ 10,440	$ 1,010	$ 72,550	$ 870,600	$ 1,741,200	$ 2,611,800
7	28	$ 98,000	$ 12,180	$ 1,010	$ 84,810	$ 1,017,720	$ 2,035,440	$ 3,053,160
8	32	$ 112,000	$ 13,920	$ 1,010	$ 97,070	$ 1,164,840	$ 2,329,680	$ 3,494,520
9	36	$ 126,000	$ 15,660	$ 1,010	$ 109,330	$ 1,311,960	$ 2,623,920	$ 3,935,880

Lease payment is just a way to amortize out equipment cost over 36 mo.

SurgPak

Angiodynamics

[redacted]

SurgPak has a simple vision: To help physicians focus on the medicine and not the logistics. Our products are designed to give physicians a new streamlined approach for their in-office surgical procedures. Each of these sterilized packs contains nearly all the parts you will need to complete your procedures.

Special Partnership Pricing:

AD Pack				Item AD1000		Pricing	
Quantity	Item Description	Quantity	Item Description	Quantity	Item Description	Order by Case (4/Case)	
1	Table Cover 44x76	1	Skin Marker	1	5 cc Syringe		
1	Drape U Split w/4x40	1	Tray Prep 10x5x2 Deep/Lg	1	10 cc Syringe		
2	1000 cc Bowl	1	Steri Strip 5x4 3/card	1	20 cc Syringe	$58.00	1 - 8 Packs
1	500 cc Bowl	1	Decanter	2	30 cc Syringe	$55.10	8-16 Packs
20	Sponge Gauze 4x4s	2	Absorbant Towels	2	18 Guage Needle 1.5	$54.14	16 and Up
1	Scalpel #11 w/Long Handle	1	Probe Cover w/ Gel 96cm	2	22 Guage Needle 1.5		
6	Blue OR Towels	1	Xylocaine 1% 5ml amp	1	25 Guage Needle 5/8		
2	Gowns	1	Half Sheet Dim (TBD)				

Surg Pak				Item SP1000		Pricing	
Quantity	Item Description	Quantity	Item Description	Quantity	Item Description	Order by Case (4/Case)	
1	Table Cover 44x76	2	Surgical Glove 8	1	Smallbore Extension Set		
1	Drape U Split w/4x40	1	Surgical Glove 7.5	1	Probe Cover w/ Gel 96cm		
1	500 cc Bowl	1	Bag Header 17" x 30" 2ml/4ml MULTIPE	1	3 cc Syringe (BD only)	$58.00	1 - 8 Packs
20	Sponge Gauze 4x4s	1	Light Handle Cover Soft	1	10 cc Syringe (BD only)	$55.10	8-16 Packs
1	Scalpel #11 w/ Handle	1	Rubber Band	1	30 cc Syringe (BD only)	$54.14	16 and Up
6	Blue OR Towels	1	Tray Foam 14x18	1	18 Guage Needle 1.5		
2	Gowns XL	1	Admin Set w/Vented IV TBG L/L	1	20 Guage Needle 1.5		
1	Tray Prep 10x5x2 Deep/Lg			1	25 Guage Needle 5/8		

Every doctor will have a different way of doing each procedure and the packs above cover the vast majority of the universal components that will be needed. The significant differences between the two above are things such as the type and quantity of needles and the inclusion of an ultrasound probe cover in the AD pack.

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In order to take advantage of the savings above your account will be setup specifically for this application and only needs to be setup once for automated processing. Customers must contact our office (or wait to be contacted) for initial account setup.

Other Discounts:

All Packs have order discounts built in. Discounts will be given at the end of the checkout process in the following manner:

Order Quantity:	Discount:
8-16	5%
16-24	7%
24 and Up	10%

Shipping charges do apply. Please contact the MedQuest team for exact rates. Please allow 5-7 business days for shipping. New customers must pre-pay all orders.

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www.surgpak.com

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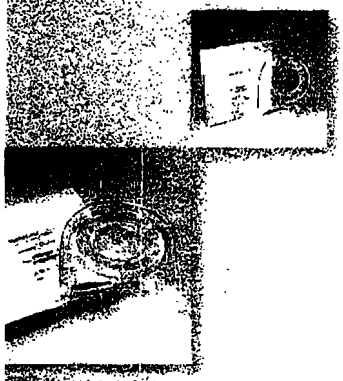

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Per 10 cases	$3,150	$7,500	Save $4,350
Per 25 cases	$7,875	$18,750	Save $10,875
Per 100 cases	$31,500	$75,000	Save $43,500
Per 250 cases	$78,750	$187,500	Save $108,750
Pullback Rates:	1cm every 6 seconds	Varies according to temperature and impedance.	
Total Pullback Times:	30cm vessel ≈ 3 minutes 50cm vessel ≈ 5 minutes	Approximately 20 minutes (Varies according to length, temperature, and impedance.)	Per 10 cases, save up to: 2.67 hours Per 100 cases, save up to: 26.7 hours 3.4 eight-hour days Per 500 cases, save up to: 133.5 hours 16.6 eight-hour days

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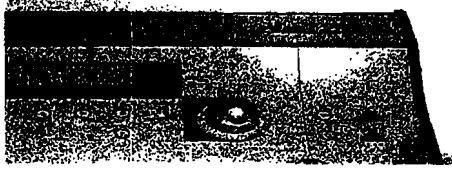

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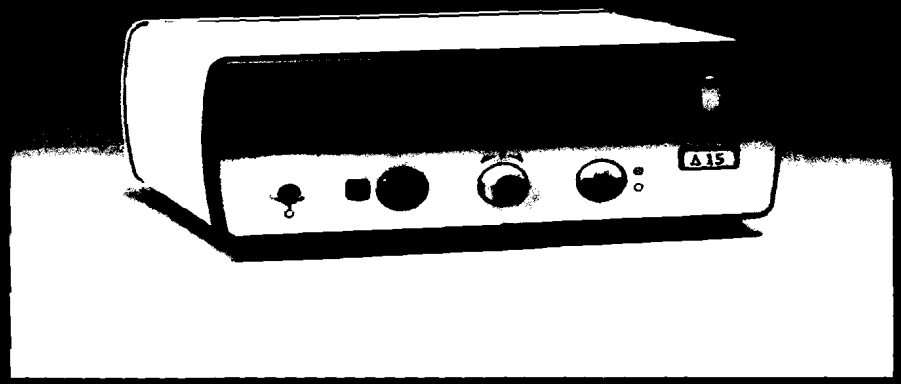
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The Greatest Experience in Eliminating Varicose Veins™

Comparison of EVLT and VNUS Closure Systems

	EVLT	VNUS
Procedure Cost	*$295/kit	$725/catheter

A Clinician performing 5 cases/month using the EVLT procedure will save **$25,800/yr** in consumable expenses vs. VNUS Closure. Flexible financing packages allow savings with no capital investment!

	EVLT	VNUS
Procedure time	45minutes	1 hour plus

- This allows the physicians to perform more cases/day.
- EVLT total laser firing time is approximately 2 minutes vs. 10-15 minutes.

Treatment Restrictions	EVLT	VNUS
Heparin infusion necessary?	NO	YES
Effective on veins >12mm?	YES	NO
Can you perform on patients with implantable cardiac devices? (ie: ICD or Pacemaker)	YES	NO

	EVLT	VNUS
Complications/Efficacy		
Saphenous Vein Occlusion	95%	86.8%
Pulmonary Embolism	0%	1 case
Clinical Thrombophlebitis	0%	6.9%
Thrombus Propagation	0%	1.4%
Skin Burns (heat included)	0%	2.7%
Skin Burns with Scarring	0%	0.8%
Skin Burns with Infection	0%	2 cases
Paresthesia (24 months)	0%	4-5%
DVT's	0%	17 cases

* Incentives towards additional savings (approx. $3500 annually.)

QUOTE

Angio Dynamics

bio LITEC
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East Longmeadow, MA 01028
(413) 525-0600

ORDER NUMBER: 0012774
ORDER DATE: 5/13/2005

SALESPERSON: AK
CUSTOMER NO: CIRCCTR

__ Check if this is an Unconfirmed Issue

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ITEM NUMBER	UNIT	ORDERED	SHIPPED	B/O	PRICE	AMOUNT
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ELVeS 600um Procedure Kit - 55						
*	EACH	1.00	0.00	0.00	10.00	10.00
shipping charges						
ship date: 6/1/05						
ELVES600-19-2	BX10	1.00	0.00	0.00	2,100.00	2,100.00
ELVeS 600um Procedure Kit - 55						
*	EACH	1.00	0.00	0.00	10.00	10.00
shipping charges						
ship date: 7/1/05						
ELVES600-19-2	BX10	1.00	0.00	0.00	2,100.00	2,100.00
ELVeS 600um Procedure Kit - 55						
*	EACH	1.00	0.00	0.00	10.00	10.00
shipping charges						
ship date: 8/1/05						
ELVES600-19-2	BX10	2.00	0.00	0.00	2,100.00	4,200.00
ELVeS 600um Procedure Kit - 55						
*	EACH	1.00	0.00	0.00	15.00	15.00
shipping charges						
ship date: 9/1/05						

CONTINUED

QUOTE

bio LITEC
515 Shaker Road
East Longmeadow, MA 01028
(413) 525-0600

ORDER NUMBER: 0012774
ORDER DATE: 5/13/2005

SALESPERSON: AK
CUSTOMER NO: CIRCCTR

__ Check if this is an Unconfirmed Issue

SOLD TO:	SHIP TO:
Circulatory Centers of America 1601 Motor Inn Drive Girard, OH 44420	Circulatory Centers of America Fairlawn Office 3618 West Market St. Suite102 Fairlawn, OH 44333

CONFIRM TO:
Annette/330-759-6760

CUSTOMER PO	SHIP VIA	F.O.B.	TERMS
5051305A	UPS GROUND	FACTORY	Net 30 Days

ITEM NUMBER	UNIT	ORDERED	SHIPPED	B.O.	UNIT PRICE	EXTENSION
ELVES600-19-2	BX10	2.00	0.00	0.00	2,100.00	4,200.00
ELVeS 600um Procedure Kit - 55						
*	EACH	1.00	0.00	0.00	15.00	15.00
shipping charges						
ship date: 10/3/05						
ELVES600-19-2	BX10	2.00	0.00	0.00	2,100.00	4,200.00
ELVeS 600um Procedure Kit - 55						
*	EACH	1.00	0.00	0.00	15.00	15.00
shipping charges						
ship date: 11/1/05						
ELVES600-19-2	BX10	2.00	0.00	0.00	2,100.00	4,200.00
ELVeS 600um Procedure Kit - 55						
*	EACH	1.00	0.00	0.00	15.00	15.00
shipping charges						
ship date: 12/1/05						

- Quotation is valid for 30 days
- Delivery dates are firm and fixed as stated; dates may be brought in, but they may not be pushed out.

Sales AEK Purchaser

Net Order:	23,190.00
Less Discount:	0.00
Freight:	0.00
Sales Tax:	0.00
Order Total:	$23,190.00

TOTAL P.03

TotalVein™
SOLUTIONS

PRODUCT CATALOG

APRIL 2006

Total Vein Solutions • 901 Yale Street • Houston, Texas 77008
888 868-8346 • 713 863-1600 office • 713 863-1601 fax
e-mail: info@totalvein.com
www.totalvein.com

CUT YOUR VEIN SURGERY SUPPLY COSTS

Reduce your vein surgery supply costs by up to 50% or more with Total Vein Solutions™

Sample prices below:

Laser Fiber	Micro-Introducer Kit	45cm 5F Introducer Kit	TVS ™ Total Cost
$99.95	**$26.95**	**$27.95**	**$154.85**

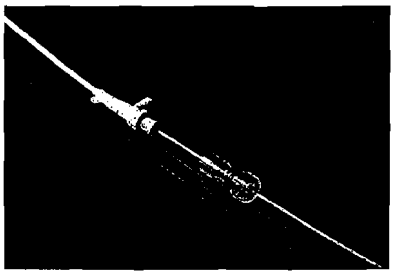
Laser Fiber	19 g UTW Needle	45cm 5F Introducer Kit	TVS ™ Total Cost
$99.95	**$3.95**	**$27.95**	**$131.85**

You will be very pleased with the premium quality of our products as well as our prices!

TotalVein™
SOLUTIONS

Product Bulletin

TVS LASER FIBERS with SPIN-LOCK®



EXCITING NEWS!

We have added a Touhy Borst w/Spin-Lock® adapter (TVS# 3060) to our laser fibers. The Spin-Lock® is used for locking the TVS fiber in place with any TVS luer introducers.

You can now use the TVS# 3060 with the following introducer kits:

TVS#3103	4F x 25cm	TVS#3003	5F x 25cm
TVS#3104	4F x 35cm	TVS#3004	5F x 35cm
TVS#3105	4F x 45cm	TVS#3005	5F x 45cm
TVS#3106	4F x 65cm	TVS#3006	5F x 65cm
TVS#3107	4F x 85cm	TVS#3007	5F x 85cm

TVS#2020 4F x 20cm One Step Introducer

Pricing

P0063	P0064
5.....119.95 ea	5.....124.95 ea
10.....109.95 ea	10.....119.95 ea
15+.....99.95 ea	15+.....111.95 ea

TO ORDER CALL 888 868-8346