Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation's seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation—a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC's recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Sincerely,

Benjamin Zemgast, MD
Department of Anesthesiology
Pacific Anesthesia, Everett

~~JUL 9 2007~~ 2

JUL 10 2007

6504 Greentree Road
Bethesda, Maryland 20817
July 8, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, Maryland 21244-8018

I am writing this letter to voice my strong support for the RUC proposal submitted to CMS to increase the anesthesia conversion factor to account for a calculated 32% work undervaluation. This proposal would help to correct a long standing inequity for anesthesiology reimbursement under these schedules, and would have the long term benefit of ensuring quality anesthesia care for the recipients of anesthesia under these services.

I am bringing my favorable view of the proposed action to the attention of the Maryland Congressional Delegation.

Very truly yours,

Mollyann G. March

Mollyann G. March, M.D.
Division Chief, Suburban Hospital Department of Anesthesiology

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JUL - 9 2007

Date: 7/4/07

To:

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Dear Sirs:

As an anesthesiologist, of course I urge you to support the increase in RUC value for anesthesia. It is long overdue. The $4 proposed increase is so little compared to what would be equitable.

Keep in mind that the insurance industry has long known that anesthesia is severely undervalued compared to all other specialties. When managed care contracts are negotiated, anesthesia is the ONLY specialty whose rates are never based on Medicare, since the minimum acceptable rate would be *over 300%* of Medicare.

An even worse fate has been handed the ACADEMIC anesthesiologists, on whom the supply of future anesthesiologists depends. Incredibly, they only get HALF of the Medicare rate, based on concurrency rules.

I personally do NOT have a stake in Medicare payments, by the way, since my practice is exclusively pediatric anesthesia. Of course, Medicaid pays even less than Medicare! I'm pretty sure you can't hire a plumber for the $52 an hour we are paid by Medicaid.

Thomas M. Wolfe, MD
Pediatric Anesthesiology
Riley Hospital rm 2001
702 Barnhill Dr,
Indianapolis, IN 46202

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JUN - 9 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am an anesthesiologist and am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule.

Anesthesiology is the medical specialty dealing with life and death in the operating room and obstetric suite. It takes an extreme amount of time and money to become one and we are a very proud bunch to climb that mountain and then be able to do what we do. Despite this, Medicare/Medicaid reimbursement for anesthesiologists has been among the lowest in the medical profession, and among the lowest of all payment providers. At $16.19 per unit anesthesiologists are in the demoralizing situation of accepting very low pay for a patient population that is typically very high risk and therefore high liability. This reimbursement typically is not enough to cover the administrative and liability costs and we are left paying out of pocket for the privilege of caring for Medicare/Medicaid patients!

Anesthesiologists love the practice of medicine but not the environment of medicine, one in which we currently can't breathe. We appreciate your budgetary issues, but from the point of view of the individual anesthesiologist the high liability-low pay environment is unsustainable, driving away our finest anesthesiologists and making new recruitment untenable. The RUC recommendation of an increase in the anesthesia conversion factor, providing an estimated $4.00 per unit increase would go a long way in providing a much needed morale boost and financial "breathing room." I say this not as a member of a special interest group lobbying to maintain windfall profits, but as an individual anesthesiologist who feels desperate and genuinely concerned about patient care and the survival of my specialty.

I appreciate your time, effort and wisdom in helping with this serious matter.

Sincerely,

Joseph J. Mannella, M.D.
Fairfield Anesthesia Associates, Inc.
Fairfield Medical Center
401 N. Ewing St.
Lancaster, Ohio 43130

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CLEVELAND CLINIC HEALTH SYSTEM
Huron Hospital

Hinda Abramoff, D.O.
Chairman, Department of Anesthesiology
Office: 216/761-6921
Fax: 216/761-7980

7/16/07

To whom it may concern;

I am emailing my strong support for the proposed increase in medicare payment to anesthesiologists. I am an anesthesiologist in an inner city, underserved area. The patient population is primarily poor, on medicaid or medicare. Anesthesiologist reimbursement from medicare does not cover the cost of physician services. If physicians had to depend on reimbursement from medicare and medicaid, there would be no anesthesiologists covering this hospital. This is not an exaggeration.

Fortunately, Huron Hospital is affiliated with a strong hospital system so the anesthesiologists have been subsidized by Huron Hospital. However, the hospital itself can no longer afford to cover the cost of anesthesiology services, since it has been continually running 'in the red'. I don't know how long the hospital will be able to continue losing money and remain open.

The ones who are the poorest in our society will lose the most by the loss of medical care in this community. For this reason it is essential that the proposed reimbursement increase to anesthesiologists is passed.

Sincerely,

Dr. Hinda Abramoff
Chairman, Department of Anesthesiology

Richard J. Cohen M.D., Ph.D.
Whitaker Professor in Biomedical Engineering
Harvard University-Massachusetts Institute of Technology
Division of Health Sciences and Technology
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July 13, 2007

Amy Bassano
Director, Division of Practitioner Services
Centers for Medicare & Medicaid Services
7500 Security Boulevard, C4-01-26
Baltimore, MD 21244

Re: **Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008 (CMS-1285-P)**

Practice Expense Reimbursement for Microvolt T-Wave Alternans Testing (CPT 93025)

Dear Ms. Bassano:

I am submitting this comment letter on the 2008 Physician Fee Schedule Proposed Rule. This comment focuses on the topic of practice expense reimbursement for Microvolt T-Wave Alternans (MTWA) testing and supplements materials provided to the agency in a meeting on March 30, 2007 and a follow-up letter dated April 19, 2007.

As set out below, I respectfully request that CMS set the equipment usage of MTWA testing based on actual utilization and also update the data inputs for MTWA testing.

Background on MTWA Testing

MTWA testing is a non-invasive inexpensive test that accurately identifies patients at high or low risk of sudden cardiac death.

In 2006 CMS issued a positive National Coverage Decision for MTWA. The test is recommended in clinical guidelines issued jointly by the American Heart Association, the American College of Cardiology and the European Society of Cardiology, and is supported by hundreds of peer reviewed trials published in the clinical literature. MTWA can accurately predict which Medicare beneficiaries will benefit from implantable cardioverter/defibrillator (ICD) therapy.

Currently, Medicare provides coverage for ICD therapy for essentially all patients with a left ventricular ejection fraction of 35% or less. However, ICD therapy carries with it its own significant morbidity and mortality. A recent study[1] indicates that in Medicare patients the in-hospital complication rate associated with just the ICD implantation itself is 10.8% including a 1% mortality rate. This complication rate is exclusive of all the complications that occur following hospital discharge including lead breakage, inappropriate shocks, infection, perforation, device recall, etc. Another study[2] found that the cumulative ICD complication rate during 46 months of follow-up was 31%. In addition, ICD implantation is extremely costly and represents a substantial expense to the overall Medicare program.

A negative MTWA test can guide a patient with a left ventricular ejection fraction of 35% or less to avoid unnecessary invasive ICD therapy and the documented morbidity and mortality associated with this procedure.

Conversely, a non-negative MTWA test in a patient with a left ventricular ejection fraction of 35% or less, indicates that the patient is at high risk of sudden cardiac death and the test result will appropriately guide the patient to accept life-saving ICD therapy. In the absence of MTWA testing many patients who are eligible for ICD therapy do not receive such therapy because of the complications associated with this therapy and the low likelihood that any given implanted ICD will provide life-saving therapy (it is estimated that, in the absence of MTWA testing, only one in eighteen patients with left ventricular ejection fraction of 35% or less actually receives life saving therapy from his/her implanted ICD).

MTWA Equipment Utilization

At our meeting in March, data were presented to demonstrate that the current 50% equipment usage assumption vastly underestimates the true practice expense of performing the MTWA test and thus greatly discourages its use.

The current 50% equipment utilization assumption will result in physicians losing money every time an MTWA test is performed. This will greatly impede physicians' practices from acquiring this technology and will greatly discourage physicians from performing this test. The result will be that Medicare beneficiaries will not benefit from this low cost non-invasive test and as a result such patients who are at very low risk of sudden cardiac death may receive unneeded and extremely costly ICD therapy and suffer unnecessarily from the morbidity and mortality associated with ICD therapy. Conversely other patients who are in fact at high risk of sudden cardiac death may not receive ICD therapy which would in fact be life saving for them.

In my letter of April 19, 2007 following our meeting, I requested that CMS base MTWA's equipment usage on the known actual utilization. I was disappointed that the proposed rule did not specifically address MTWA testing, but I am delighted that in the proposed rule that CMS indicated its desire to assign appropriate usage rates to different types of equipment.

> *We are interested in receiving comments relating to alternative percentages and approaches that differentially classify equipment into mutually exclusive categories with category specific usage rate assumptions. We are committed to continuing our work with the physician community to examine, equipment usage rate assumptions that ensure appropriate payments and encourage appropriate utilization of equipment. Additionally, we would welcome any empirical data that would assist us in these efforts.*

MTWA equipment utilization is accurately known because each test utilizes single-use disposables for which the manufacturer, Cambridge Heart, Inc., is the sole supplier. Cambridge Heart, Inc. precisely knows how many fielded MTWA systems are in place and how many sensor sets are shipped. Based on these data MTWA equipment is currently used an average of 45 times per year (US data). Using the CMS data input for the usage time for each test, 15 minutes, this corresponds to 675 minutes per year or 0.45% of the maximum 150,000 minutes per year. The company will provide the empirical data requested in the proposed rule by CMS to document the actual utilization of MTWA.

I would suggest to CMS that for those pieces of equipment whose use is precisely metered, as is the case for MTWA testing, that CMS utilize the known actual equipment usage in calculating the practice expense reimbursement. I would suggest that CMS might want to create a separate class of equipment whose usage is precisely metered and for each piece of equipment in this class apply the individual known rate. By applying the actual equipment usage percentage when it is known, CMS will be reimbursing for the actual costs of performing a procedure and not creating artificial incentives to perform or not perform the procedure.

Cambridge Heart, Inc. has informed me that it would be happy to provide updated data on equipment usage to CMS on an annual basis or at any other frequency that CMS desires. The usage will be calculated based on the independently audited company records.

CMS Time and Data Practice Expense Inputs for MTWA Testing CPT Code (93025)

I have reviewed the CMS data inputs for MTWA testing and the amount of time assigned to the equipment utilization seems to me far from adequate for MTWA testing according to current clinical standards. It appears to me that the equipment usage may have been crosswalked from assigned equipment and exam table times for stress testing (CPT 93015 and 93017) – this simple crosswalk would not be appropriate.

An MTWA test takes longer than a standard stress for many reasons. A standard stress involves using ten electrodes. An MTWA test requires seven specialized noise-reducing sensors each of which contains four contact electrodes plus seven standard electrodes all of which are connected through a cable to the MTWA equipment. The skin preparation for applying both the MTWA multi-contact sensors and the standard electrodes is much more demanding than for a standard stress test and much more time consuming. Once the sensors and electrodes are initially applied the equipment is used to check the impedance of every contact electrode (total of 35 contact electrodes). Any contact electrode whose contact impedance exceeds an acceptable value is flagged and the operator must re-prepare the skin and/or readjust the contact electrode until the contact impedance is satisfactory. The exercise protocol also requires the operator to precisely control the heart rate by adjusting the incline of the treadmill or its speed. Failure to maintain the heart rate within designated bands at different stages of the test requires the operator to extend the test until this task is satisfactorily accomplished. Finally, if a determinate test is not obtained the operator is instructed to let the patient rest for 15 minutes (with the sensors/electrodes on and connected to the equipment) and then repeat the entire test.

A realistic clinical scenario is that all the MTWA associated equipment is located in a room in a physician's office and that this room can be used at most for one patient at a time to perform MTWA testing. I believe that such a room can be used to test not more than one patient per hour. I believe therefore that it is accurate to estimate that all of the MTWA associated equipment is used for at least

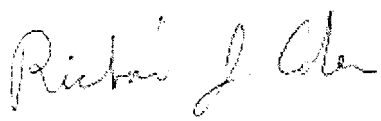
the 53 minutes currently assigned for the nurse conducting the testing, although I believe one hour would be more accurate, and that the nurse time to conduct the stress test is at least 53 minutes, but again more accurately one hour. In addition, I noticed that the current staff type assigned to the test ((L037D RN/LPN/MTA) is a lower level than for the staff type (LO51A RN) assigned to conduct a standard stress test (CPT 93015 and CPT 93017). This is clearly inappropriate because conducting an MTWA test requires a higher level of training and expertise than required for conducting a standard stress test. Thus the staff type assigned to MTWA testing should be upgraded to LO51A RN. I believe Cambridge Heart, Inc will separately detail the recommended changes on data inputs on an item by item basis.

At present a physician may not bill for the practice expense of an MTWA test and a stress test on the same date of service. I believe the reason for this is that it was believed that the data collected during an MTWA test could also be used for purposes of stress testing. In fact this is not the case. As I indicated in my previous letter the exercise protocols for the two tests are entirely different. If a physician wanted to perform a standard stress test on the same day as an MTWA test, I would advise the physician to perform the MTWA test, let the patient rest for at least 15 minutes, and then perform a standard stress test protocol.

I believe Cambridge Heart, Inc. will be requesting through the CMS CCI edit contractor a change from 0 to 1 to allow for the appropriate times a standard stress test would be performed on the same day as an MTWA study.

Please feel free to contact me if I can be of further assistance in any way.

Sincerely,



Richard J. Cohen, M.D., Ph.D.
Whitaker Professor in Biomedical Engineering
Harvard-MIT Division of Health Sciences and Technology
Director and Consultant, Cambridge Heart, Inc.

P.S. This letter reflects the views only of the author and Cambridge Heart, Inc. and should not be construed to represent the views of Harvard or MIT or any other organization or person. The data presented in this letter were provided to the author by Cambridge Heart, Inc.

cc: Donald Thompson
Pamela West

References

1. Reynolds MR, Cohen DJ, Kugelmass AD, et al. The frequency and incremental cost of major complications among medicare beneficiaries receiving implantable cardioverter-defibrillators. *J Am Coll Cardiol.* Jun 20 2006;47(12):2493-2497.
2. Alter P, Waldhans S, Plachta E, et al. Complications of implantable cardioverter defibrillator therapy in 440 consecutive patients. *Pacing Clin Electrophysiol.* Sep 2005;28(9):926-932.

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Fletcher Allen HEALTH CARE

DAVID C. ADAMS, M.D.

Vice Chairman, Research and Education
Department of Anesthesiology

Program Director
Residency in Anesthesiology

The University of Vermont

July 19, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strong support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. As I am sure you are aware, when the RBRVS was instituted a decade ago, it created a huge payment disparity for anesthesia care relative to other physician services. I am grateful that CMS is taking steps to address this issue.

Currently, Medicare payment for anesthesia services does not cover the cost of caring for our nation's seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations. As an Anesthesiology residency program director, this is a particularly important issue, since the future of academic departments and its graduates will be significantly affected by this measure.

The American Medical Association Relative Value Scale Update Committee (RUC) has recommended that CMS increase the anesthesia conversion factor to offset the pre-existing anesthesia work undervaluation. This would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing underpayment for anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC's recommendation.

Thank you for your consideration of this serious matter.

Sincerely,

David C. Adams, M.D.

MCHV CAMPUS 111 Colchester Avenue Burlington, VT 05401-1429 802.847.2415 Fax 802.847.5324

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July 20, 2007

Department of Health and Human Services
Attention: CMS-1385-P
PO Box 8018
Baltimore, MD 21244-8018

CMS 1385-P: 2008 Medicare Fee Schedule
Coding-Multiple Procedure Reduction For Mohs Surgery

Dear Administrator Norwalk,

I write you to express my opposition of the proposed Multiple Procedure Payment Reduction for Mohs Micrographic Surgery (CMS 1385-P: 2008 Medicare Fee Schedule).

I practice general dermatology, Mohs Micrographic surgery and cosmetic dermatology. Presently, I perform Mohs surgery 2 days a week. I would prefer to perform Mohs surgery one day a week but there is a large need for this procedure and the need is growing. I project that by 2009, I may need to perform Mohs surgery 3 days a week. If this law is placed I will consider limiting the number of Mohs surgery cases so that I only will offer this procedure once a week. My rational is as follows.

Typically, I allot for 10 Mohs surgeries a day. This past Monday, I had a patient that had seven skin cancers requiring Mohs surgery. He did not take up one of the 9 slots available. Rather, he took 7 of the 9 slots available. If the Multiple Procedure Payment Reduction Rule was in effect, treating him would not have met the costs of operating the office that day.

When I perform Mohs surgery, each cancer is treated individually. There is separate paper work for each cancer on a patient and the cancer is given its own number. Each cancer is measured and photographed which often requires repositioning the patient. Once the lesion is excised, it is taken to our in office laboratory and processed into a slide. The highly trained histotech, will process each lesion without regards to the next lesion. Once the slide is made which can take 30-45 minutes, I look at it under the microscope. I make sure there is no microscopic cancer present on the slide. As I do this I do not take into consideration any other lesion on the patient that my be receiving Mohs surgery that day.

Often times one lesion on the patient is cleared with 1-2 stages while other ones are cleared with 4-5 stages. As soon as a lesion is categorized as negative, I plan for closure. In considering closure, I focus on one lesion. The lesion that is cleared is closed with whatever technique I deem will leave the patient with the best cosmetic result. That lesion is prepped for sterile procedure. Once the closure is complete, the sterile field is taken down and the area is bandaged. When the other lesion(s) are cleared a new sterile field and instruments are needed to perform the procedure.

If the new law is put into place, it would no longer be feasible for Mohs surgeons to perform more than one procedure per visit. Patients would need to return to the office for each procedure requiring more time off of work and more travel time to and from the office. Many Mohs patients drive up to 3-4 hours for their procedure since there is not an abundance of Mohs surgeons. I hate to see these patients so inconvenienced, when even now, it is an inconvenience for them. Also, patients will often lose access to Mohs surgery since the wait time for the procedure will increase. Presently with me doing Mohs surgery twice weekly, it is a 3-4 week wait. As I stated previously, the wait is increasing annually.

Presently, I would prefer to perform Mohs surgery once a week instead of twice a week. The need is there so I do so. If the new law goes into place, it will no longer be financially feasible for me to perform Mohs surgery two times a week. Moreover, I definitely would not be able to care for the patients with multiple cancers with one visit as I do now. I know patients will be very upset, sad, and angry when I have to notify them that they need to return multiple times to my office to have their multiple skin cancers taken care of because the laws have changed reimbursement and the office as a whole cannot afford to treat multiple skin cancers with Mohs surgery at one visit.

Respectfully,

Julie Pena

Julie Pena, MD
jpena@ssdermandlaser.com

BELLE MEADE DERMATOLOGY
Laser & Aesthetic Center

August-16-2007

Department of Health and Human Services
Attention: CMS-1385-P
PO Box 8018
Baltimore, MD 21244-8018

CMS 1385-P: 2008 Medicare Fee Schedule
CODING – MULTIPLE PROCEDURE REDUCTION FOR MOHS SURGERY

Dear Administrator Norwalk,

I am against the proposed application of the Multiple Procedure Payment Reduction for Mohs Micrographic Surgery (CPT codes 17311 through 17315).

As a Mohs Micrographic Surgeon with 8 years of experience, I appreciate this opportunity to offer comment on section II.E.2 (P-122) of the 2008 Medicare Fee Schedule Proposed Rule.

> For each mohs surgery, even if on the same day: Pre-service positioning. While the lab work is being done, in most every case, the patient gets up off the operating table.
> Each lesion must be separately identified, marked and scrubbed. For lesions on separate anatomic locations, the sterile field created for the first procedure must be broken down and then a second, new sterile field created for the second cancer.
> Laboratory work. Each tumor is dealt with as a distinct entity. Each tumor must be separately anesthetized, and excised. Once the tumor enters the pathology portion of the procedure, there is absolutely no efficiency gained in performing multiple procedures. Each tumor must be processed and prepared independently of the other tumor. The interpretation of the tissue for residual cancer and tumor mapping are also independent events for each tumor. For two cancers, this portion of the physician work and practice expense is doubled. As this intra-service work comprises approximately 80% of the total amount of work and resources for the procedure, applying a reduction to the code will significantly undervalue the code. Moreover, of the total intra-service time, the laboratory/pathology proportion consumes the majority of the time and resources of the procedure.

The Mohs procedure may also be accompanied by a reconstructive effort by the same surgeon on the same day of service. As the patient has been waiting bandaged in the waiting room, the Mohs defect reconstruction contains all of the elements of a stand alone procedure.

BELLE MEADE DERMATOLOGY
Laser & Aesthetic Center

Pre-Service evaluation. Prior to the reconstruction, the patient must be evaluated to determine optimal wound management. The nature of the wound cannot be known until the completion of the Mohs procedure, thus, there is no substantial reduction in the pre-service evaluation of the reconstruction.
Pre-service positioning. Given the long time of the Mohs intra-service work, the patient is removed from the operating table and waits in the waiting room during the Mohs intra-service work. Once the Mohs procedure is complete, the patient must be repositioned for any reconstruction.
Pre-service scrub, dress and wait time. Given the long time of the Mohs intra-service work, the area must be scrubbed and prepared as if it where a new surgical procedure.
Intra-service time. The intra-service time and resources for the reconstruction is not reduced by the prior Mohs procedure. The area must be re-anesthetized as any anesthesia from the Mohs procedure is inadequate for the reconstruction. Additionally, separate and additional instrumentation is required for the reconstruction.
Post service time. The post service time is not reduced by the Mohs procedure as the post service work is now dictated by the reconstruction.

In short, given the significant duplication of work and resource utilization when a subsequent procedure is performed in conjunction with Mohs surgery, I believe that applying the Multiple Procedure Payment Reduction for Mohs Micrographic Surgery (CPT codes 17311 through 17315) will significantly undervalue the codes.

I ask that you reconsider removal of the Mohs Micrographic Surgery codes from the exempt list and retain their longstanding exemption from the multiple procedure payment reduction.

Sincerely,

T. Wayne Day, MD

24 White Bridge Road, Nashville TN 37205 (615) 352-0011 Fax (615) 352-0085

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ARIZONA SOCIETY OF ANESTHESIOLOGISTS
810 W. BETHANY HOME RD. • PHOENIX, ARIZONA 85013 • (602) 246-8901

July 12, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Dear Ms. Norwalk:

RE: CMS-1385-P, Anesthesia Coding (Part of 5-Year Review)

I am writing on behalf of the 700 physician members of the Arizona Society of Anesthesiologists. We strongly support the RUC's recommendation to increase anesthesia payments in 2008.

Current Medicare payments for anesthesia services do not cover the cost of providing care to America's seniors. As patients' age and co-morbidities continue to increase, more advanced skills, training, and technology are required to provide appropriate levels of care.

Thank you for considering the problem of undervaluation of anesthesiology services. It is very important that anesthesiologists are not prevented from practicing in areas with high numbers of Medicare beneficiaries. Many Arizona practices are forced to limit Medicare patient services or receive subsidies to provide care to those patients. We urge you to immediately implement the RUC's recommended full anesthesia conversion factor increase.

Thank you for your time.

Respectfully,

Jeff Mueller, MD
President
Arizona Society of Anesthesiologists

LAUREL SURGICAL CENTER

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2/18/07

Dear Sir / Madam,

This is to state my support for the recommendation by the AMA specialty committee (RUC) to increase the anesthesia conversion factor. This has been undervalued for years, so the recommendation seems reasonable.

I'm an anesthesiologist and feel it is proper and will help high quality providers in the field of anesthesia which is a direct benefit to the patients

Thank you for your consideration,

Daniel W. Beyer MD

348 Donohoe Road • Greensburg, PA 15601 • 724-552-0068 • Fax: 724-552-0130

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JUL 17 RECD 2007

MUSC
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Jerry Reves, MD
Vice President for Medical Affairs and Dean

July 12, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385P
P.O. Box 8018
Baltimore MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I wish to go on record with my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. As the dean of a medical school and an anesthesiologist I am double happy that CMS has recognized the gross, long-standing undervaluation of anesthesia services that has placed burdens on our physicians and on our academic health centers.

Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services nationwide stands at just $16.19 per unit. Here in South Carolina our current conversion factor is even lower, only $15.02. In an effort to rectify this unfortunate situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation—a move that would result in an increase of nearly $4.00 per anesthesia unit. This would begin to redress the long-standing undervaluation of anesthesia services. Given our Medicare workload at this hospital in Charleston, South Carolina, this has meant that in the past we have been under-compensated by about $560,000 per year.

Restated with an grateful eye to the future, the additional legitimate Medicare collections that this proposed change would bring to our institution stand at about $560,000 per year. In academic medicine, with its especially high burden of uncompensated care, that permits us to staff more operating suites each day for safe care of the poor and elderly and all the patients who come to our doors.

I am pleased that the CMS has accepted this recommendation in its proposed rule, and I completely support full implementation of the RUC's recommendation.

Again, please follow through with the proposal in the Federal Register by fully and immediately implementing the increased anesthesia conversion factor as recommended by the RUC.

I stand ready to speak with you or provide additional information of the beneficial impact of the proposed changes on our College of Medicine.

Sincerely,

Jerry Reves, M.D.
Dean, College of Medicine
Professor of Anesthesiology
Vice-President for Medical Affairs,
Medical University of South Carolina

Copies: Raymond Greenberg, M.D., Ph.D.
Hon. Lindsey Graham
Hon. Jim DeMint
Scott Reeves, M.D

Two additional copies for CMS routing

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Markbrown6797@sbcglobal.net

JUL 17 REC'D 2007

July 5, 2007

To whom it may concern,

I am writing to in support of CMS-1385-P. I have been appalled by the Medicare reimbursement rate for anesthesia care since I started practice in 1997. Many Medicare patients have complex and difficult medical conditions which can make the anesthetic the riskiest and most skill intensive part of their care. Yet reimbursement is less than a plumber or electrician! As the population ages and a greater portion of the payor mix is Medicare, we will again see medical school graduates avoid the specialty as they did shortly after the initial DRG fiasco in the early 90's. Sicker patients taken care of by last-resort, foreign-trained doctors is the direction we'll go if we don't start to tangibly appreciate the importance of skilled anesthesia care. This bill is start.

Thank you.

Sincerely,

Mark A. Brown, M.D.

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD
21244-8018

P.O. 159087
Nashville, Tennessee 37205

Dear CMS:

I am writing in support of the proposed increase in payment for anesthesiology fees. The proposed increase will allow us to continue to serve the Medicare population while still maintaining financial viability for both practicing physicians and hospitals.

Thank you.

Dr. MacGregor Poll
Anesthesiologist
ASA

15

Vanderbilt University Medical Center

JUL 2007

Department of Medicine
Division of Dermatology
Mohs Micrographic Surgery
Dermatologic Surgery
Thomas Stasko, M.D.
Director, Associate Professor
Michel McDonald, M.D.
Assistant Professor
Brent Moody, M.D.
Assistant Professor

Vanderbilt Mohs Surgery at Patterson Street
1900 Patterson Street, Suite 111
Nashville, TN 37203
(615) 320-6647
Fax: (615) 329-1507
tom.stasko@vanderbilt.edu
michel.mcdonald@vanderbilt.edu
brent.moody@vanderbilt.edu

Department of Health and Human Services
Attention: CMS-1385-P
PO Box 8018
Baltimore, MD 21244-8018

CMS 1385-P: 2008 Medicare Fee Schedule
CODING – MULTIPLE PROCEDURE REDUCTION FOR MOHS SURGERY

July 13, 2007

Dear Administrator Norwalk,

I am in opposition to the proposed application of the Multiple Procedure Payment Reduction for Mohs Micrographic Surgery (CPT codes 17311 through 17315).

I am a Mohs Micrographic Surgeon with seven years of experience. I appreciate this opportunity to offer comment on section II.E.2 (P-122) of the 2008 Medicare Fee Schedule Proposed Rule.

The logical basis for the multiple procedure payment reduction is that in certain procedures, when an additional procedure is performed at the same operative setting, efficiency in the performance of the procedures can be gained. In the practice of Mohs Micrographic Surgery, there is little efficiency gained when performing more than one Mohs procedure on the same patient in the same day.

Greater than 80% of the work is duplicated for a second procedure. Aspects of the procedure that do not gain efficiency with multiple procedures are:

1. Pre-service positioning. In many instances, the anatomic location of the tumors requires patient re-positioning for each tumor.
2. Pre-Service scrub, dress and wait time. Each lesion must be separately identified, marked and scrubbed. For lesions on separate anatomic locations, the sterile field created for the first procedure must be broken down and then a second, new sterile field created for the second cancer.
3. Intra-Service work. Each tumor is dealt with as a distinct entity. Each tumor must be separately anesthetized, and excised. Once the tumor enters the pathology portion of the procedure, there is absolutely no efficiency gained in performing multiple procedures. Each tumor must be processed and prepared independently of the other tumor. The interpretation of the tissue for residual cancer and tumor mapping are also independent

events for each tumor. For two cancers, this portion of the physician work and practice expense is doubled. As this intra-service work comprises approximately 80% of the total amount of work and resources for the procedure, applying a reduction to the code will significantly undervalue the code. Moreover, of the total intra-service time, the laboratory/pathology proportion consumes the majority of the time and resources of the procedure.

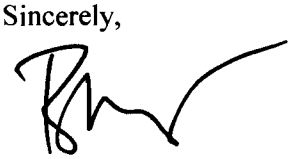
The Mohs procedure may also be accompanied by a reconstructive effort by the same surgeon on the same day of service. The reconstruction is covered under a separate code from the Mohs surgery series of codes. When a reconstruction is performed after the Mohs procedure, there is little efficiency gained. The reconstruction stands on its own as a separate surgical procedure. As the patient has been waiting in the waiting room, the Mohs defect reconstruction contains all of the elements of a stand alone procedure.

1. Pre-Service evaluation. Prior to the reconstruction, the patient must be evaluated to determine optimal wound management. The nature of the wound cannot be known until the completion of the Mohs procedure, thus, there is no substantial reduction in the pre-service evaluation of the reconstruction.
2. Pre-service positioning. Given the long time of the Mohs intra-service work, the patient is removed from the operating table and waits in the waiting room during the Mohs intra-service work. Once the Mohs procedure is complete, the patient must be repositioned for any reconstruction.
3. Pre-service scrub, dress and wait time. Given the long time of the Mohs intra-service work, the area must be scrubbed and prepared as if it where a new surgical procedure.
4. Intra-service time. The intra-service time and resources for the reconstruction is not reduced by the prior Mohs procedure. The area must be re-anesthetized as any anesthesia from the Mohs procedure is inadequate for the reconstruction. Additionally, separate and additional instrumentation is required for the reconstruction.
5. Post service time. The post service time is not reduced by the Mohs procedure as the post service work is now dictated by the reconstruction.

In summary, given the significant duplication of work and resource utilization when a subsequent procedure is performed in conjunction with Mohs surgery, I believe that applying the Multiple Procedure Payment Reduction for Mohs Micrographic Surgery (CPT codes 17311 through 17315) will significantly undervalue the codes.

I would ask that you reconsider removal of the Mohs Micrographic Surgery codes from the exempt list and retain their longstanding exemption from the multiple procedure payment reduction.

Sincerely,



Brent R. Moody, MD
Assistant Professor

16-1

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
PO Box 8018
Baltimore, Maryland 21244-8018

Re: "TECHNICAL CORRECTIONS"

Date: 07-20-2007

To whom it may concern,

The proposed rule dated July 12th contained an item under the technical corrections section calling for the current regulation that permits a beneficiary to be reimbursed by Medicare for an X-ray taken by a MD or DO and used by a Doctor of Chiropractic to determine a subluxation, be eliminated. I am writing in strong opposition to this proposal.

While subluxation does not need to be detected by an X-ray, in some cases the patient clinically will require an X-ray to identify a subluxation or to rule out any "red flags," or to also determine diagnosis and treatment options. X-rays may also be required to help determine the need for further diagnostic testing, i.e. MRI or for a referral to the appropriate specialist.

By limiting a Doctor of Chiropractic from referring for an X-ray study, the costs for patient care will go up significantly due to the necessity of a referral to another provider (orthopedist or rheumatologist, etc.) for duplicative evaluation prior to referral to the radiologist. As it is now, these duplicative services and expenses are not required. With fixed incomes and limited resources seniors may choose to forgo X-rays and thus needed treatment. If treatment is delayed illnesses that could be life threatening may not be discovered. Simply put, it is the patient that will suffer as result of this proposal.

I strongly urge you to table this proposal. These X-rays, if needed, are integral to the overall treatment plan of Medicare patients and, again, it is ultimately the patient that will suffer should this proposal become standing regulation.

Sincerely,

Harold B. Allen D. C.
204 West Main St.
Clinton, Illinois 61727

I attached two copies

17

July 9 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244

Sirs:

I graduated from residency ten years ago and have a busy private practice in anesthesiology. About 20% of my patients are Medicare at this time. For a brief period of time I practiced in a rural setting near my hometown where 45% of my patients were Medicare. I have always personally performed anesthesia without CRNAs.

Unfortunately anesthesiology is not viable taking care of Medicare patients. Even in a rural setting with low costs Medicare does not cover costs adequately, and real reimbursement has decreased over time. Rural practices with older patients have a hard time recruiting anesthesiologists when Medicare burdens are heavy.

I enjoy taking care of my elderly patients and don't want to ever feel they are a burden. I want my friends in rural settings to have the resources they need to care for geriatric populations.

The RUC committee has recommended a Medicare increase based on a "32 percent work undervaluation." This is an accurate and critical assessment.

Please accept the RUC recommendation for anesthesiology.

Thank you,

Sean S. Adams

Sean S. Adams, M.D.
3123 Aviara Ct
Naperville, IL 60564
ssadamss@mac.com

I am an experienced anesthesiologist and I worry about the future.
Thank you.
phone 3129610348

18

Gerald H. Wade, M.D., FACA ..... *816 South Street*
(530) 842-3013 *Yreka, CA 96097-2871*

JUL 13

July 9, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: Anesthesia Conversion Factor

Dear CMS Rule Making Committee,

I urge you to accept the changes proposed by the AMA RUC which make corrections in the conversion factors for anesthesia services.

Thank You,

Gerald H. Wade

Gerald H. Wade, M.D.

7/2/07

Donald C Brown, MD
PO Box 50579
Albuquerque, New Mexico
87122

CONCERNING: CMS recommendation for anesthesia reimbursement increase

To whom it may concern:

I am an anesthesiologist practicing in New Mexico. Many of our patients are Medicare insured.

I'll keep this letter very short and to the point.

If something isn't done to increase our reimbursement many anesthesiologists (or all) will find other fields of work. What is the point of working in a very stressful field with horrible hours to make less? Not to mention the high liability of taking care of Medicare patients. Meanwhile, the cost if living, inflation and medical malpractice insurance continues to rise.

I hope the American public enjoys having surgery without anesthesia. That is what his country is headed for if you continue to reduce reimbursements.

Thank you

Donald C. Brown, M.D.

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD
21244-8018

P.O. 159087
Nashville, Tennessee 37205

To Whom It May Concern:

I am writing in support of the proposed increase in payment for anesthesiology fees. The proposed increase will allow us to continue to serve the Medicare population while still maintaining financial viability.

Thank you for your attention on this subject.

Dr. Steven Dickerson

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

As a senior citizen, I can tell you first-hand just how difficult it has become to find an anesthesiologist that will accept Medicare in my community. If it were not for the fact that my son is an anesthesiologist, I fear that might not be able to find someone to take care of me during surgery. How scary is that?

Please take action to implement the anesthesia factor increase. Thank you for your consideration.

Sincerely,

Hugh S Parkhill

Hugh Parkhill
14 Woodmen Lane
Colorado Springs, CO 80919

July 4, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services,
Attention: CMS-1385-P,
P.O. Box 8018,
Baltimore, MD 21244-8018

Dear Sirs:

For more than thirty years, the published literature has bees crystal clear: Physicians who refer diagnostic imaging studies to equipment they own do so at a vastly higher rate than similar specialty physicians referring to an independent facility. Furthermore, there is no difference in patient outcome and the imaging is of lower quality than what is provided at an independent facility. Most of this self-referral diagnostic imaging is done under the In-Office Ancillary Services Exception.

As CMS looks at this exception for 2008 Medicare reimbursement, a careful look at the role of the In-Office Ancillary Services Exception on diagnostic imaging is clearly warranted. This is especially true in light of Medicare's recent focus on quality and the Tax Relief and Health Care Act of 2006. The amount of wasted money involved is truly staggering.

If you have any interest in pursuing this topic, I have included a partial list of references that addresses this important subject.

Very truly yours,

John A. Boyes, MD, MBA

July 9, 2007

Terry Kay
Director, Division of Hospital and Ambulatory Policy Group
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008 CMS-1285-P
CLINICAL LABORATORY ISSUES

Dear Mr. Kay,

XDx submits these comments on the 2008 Physician Fee Schedule Proposed Rule, released by CMS on July 2, 2007, with regard to the provisions in Section G. relating to clinical laboratory services. XDx appreciates CMS' attention to appropriate billing for clinical laboratory tests over the past year. This letter requests further clarification that clinical laboratories can bill for testing on specimens drawn outside the hospital outpatient setting and by non-hospital personnel on the same date of service as a hospital outpatient visit.

Background on the AlloMap® Molecular Expression Test

XDx developed AlloMap molecular expression testing, which analyzes the complex signals of the immune system's multiple genes and pathways to distinguish between rejection and quiescence in heart transplant patients. AlloMap testing offers clinicians an additional tool to monitor and predict rejection beyond the traditional invasive endomyocardial biopsy currently used by transplant cardiologists.

Numerous leading U.S. heart transplant centers have incorporated AlloMap testing into their patient management protocols. AlloMap testing requires a blood sample, obtained by routine phlebotomy. The sample is processed by the draw station, and shipped frozen directly to XDx. The test can only be performed at the XDx CLIA-certified high complexity laboratory in Brisbane, California. Testing is usually performed within 1 to 2 business days and the results are returned to the ordering transplant cardiologist.

Overview of Current Medicare Part B Billing Guidance

Generally, CMS policy states the date a specimen is collected is the date of service (DoS) for claims review and adjudication. In the CY 2007 Physician Fee Schedule Final Rule, however, CMS added §414.510, making an exception for the date of service of a clinical diagnostic laboratory test that uses a stored specimen.

For a laboratory test that uses a specimen stored for more than 30 days before testing, the date of service is the date the specimen was obtained from storage. Specimens stored 30 days or less have a date of service noted as the date the test is actually performed only if

(a) The test is ordered by the patient's physician at least 14 days following the date of the patient's discharge from the hospital;
(b) The specimen was collected while the patient was undergoing a hospital surgical procedure;
(c) It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted;
(d) The results of the test do not guide treatment provided during the hospital stay; and
(e) The test was reasonable and medically necessary for the treatment of an illness.[1]

CMS established this exception to the general date of service rule to clarify billing for certain tests where a specimen is taken while the patient is treated in a hospital setting, but then later used for testing after the patient has been discharged.

Clarification for Specimens Collected Outside the Hospital

This rule has created some uncertainty about how the date of service provision will be applied in a related situation when a specimen is collected on the same day as an outpatient visit, but is collected outside of the hospital outpatient setting and by non-hospital personnel. In some instances, the blood sample for the AlloMap test may be collected outside of the hospital but occur on the same day as the outpatient visit. In these instances the patient is a non-hospital patient. XDx wants to confirm that the above referenced rules for stored specimens will not indirectly affect payment for claims for laboratory tests performed on a specimen collected on the same day as an outpatient visit.

Medicare currently "bundles" outpatient services for certain clinical laboratory tests for payment purposes. Bundling has generally been intended to include only those services associated directly with an outpatient visit. The hospital billing rules require that services be bundled solely if the beneficiary is an outpatient "at the time the service is furnished."[2] In the initial Hospital Outpatient Prospective Payment System Final Rule implementing the bundled payment system, CMS stated,

> *The hospital is not responsible for billing for [a] diagnostic test if a hospital patient leaves the hospital and goes elsewhere to obtain the test. . . A free standing entity, that is, one that is not provider-based, may bill for services furnished to beneficiaries who do not*

[1] In addition, § 414.510(b)(3) specifies the conditions for the date of service for a chemosensitivity test.
[2] 65 Fed. Reg. 18,440 (Apr. 7, 2000).

meet the definition of a hospital outpatient at the time the service is furnished.[3]

As outlined above, the AlloMap test does not use a stored or archived specimen. Further the specimen is collected from a non-patient. Under this situation, the patient is a non-hospital patient because the beneficiary is not registered at the time of blood draw as an outpatient. According to Medicare Claims Processing Manual 50.3.2 a non-hospital patient is a person who is neither an inpatient nor an outpatient. A hospital outpatient is defined as a person who has not been admitted as an inpatient, but who is registered on the hospital records as an outpatient and receives services directly from the hospital. 42 C.F.R. § 410.2.

This is consistent with the Medicare Benefit Policy Manual, that states, *"[w]here a . . . blood sample . . . is taken by personnel that are neither employed nor arranged for by the hospital . . . . , the tests are not outpatient hospital services since the patient does not directly receive services from the hospital."*[4]

Requested Clarification

XDx would like CMS to confirm in the 2008 Physician Fee Schedule final rule that clinical laboratories can bill for tests when the blood is drawn outside the hospital outpatient setting and by non-hospital personnel on the same date as an outpatient visit. XDx respectfully requests that CMS make the following clarifications in the Final Rule:

A. If a clinical laboratory test specimen is collected outside of the hospital by non-hospital personnel, the beneficiary qualifies a non-patient; and

B. Independent clinical laboratories may bill for tests with the same Date of Service as a hospital outpatient visit if the beneficiary is a non-patient when the sample is collected.

These suggested clarifications are consistent with the Medicare Benefit Policy Manual and the underlying intent of the hospital bundling rule.

We note that the exception established in the 2007 Physician Fee Schedule Final Rule, modified the DoS for certain samples because of concerns about the unintended implications of the DoS rules on billing requirements. Like the tests addressed by that Rule, when the blood draw for the AlloMap test is performed by a non-hospital entity, the test is not "appropriately associated with hospital treatment."[5]

Implementation

Based on our discussions with billing and claims adjudication experts, we believe that this interpretation can be implemented within the current claims processing system on the Form 1500. In line 20 the Form notes whether the test is performed by an "Outside laboratory? Y/N." For all AlloMap tests the answer would be "Y'. Line 24 refers to the Date of Service and 24B specifically requests information on "Place of Service." For AlloMap tests the Form 1500

[3] *Id.* at 18441-42.

[4] Medicare Benefit Policy Manual § 20.1

[5] 71 Fed. Reg. 69706 (Dec. 1, 2006).

would indicate that the blood was drawn by a non-hospital entity (i.e. neither owned or operated by hospital personnel).[6]

XDx sincerely appreciates your attention to this issue. We hope to continue working collaboratively with CMS to create an appropriate billing structure for breakthrough clinical laboratory tests that were not anticipated by the current outpatient model. Please do not hesitate to contact us if you have any further questions about our comments.

Sincerely,

Tammy Reilly
Vice President of Commercial Operations
XDx, Inc

cc: John Warren
Glenn Kendall

[6] The place of service codes are a listed at http://www.cms.hhs.gov/PlaceofServiceCodes/Downloads/POSDataBase.pdf. The blood draw for AlloMap testing could take place at an office (POS code 11), home (12), mobile unit (15), independent clinic (49), ESRD Treatment Facility (65), or independent lab (81). The hospital bundling rule would apply to blood draws performed at the hospital (e.g. 21, 22, 23).

Richard B. Clark, MD
#27 N. Sherrill Road
Little Rock AR 72202

July 18, 2007

Leslie Norwalk, ESQ.
Centers for Medicare & Medicaid Services
Baltimore, MD

Dear Ms. Norwalk,

I urge you to do whatever you can to increase anesthesia fee payments under the Fee Schedule. This way, older patients will be sure of having the service of an anesthesiologist.

Sincerely,

Richard Clark, MD

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ACE
ANESTHESIOLOGY
CONSULTANTS EXCHANGE, P.C.

Department of Anesthesiology
975 E. Third Street
Chattanooga, TN 37403
Office 423-778-7608
Billing 423-892-5602

July 24, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P

To: Leslie V. Norwalk:

I am writing to express my strongest support for the proposal, CMS-1385-P, to increase anesthesia payments under the 2008 Physician Fee Schedule. I appreciate the work that the American Medical Society and the Specialty Society Relative Value Update Committee, (RUC), have done to raise awareness of the anesthesia services, and I am glad to see that CMS is addressing this issue.

Anesthesia services are undervalued in the current work value. It is my concern that this undervaluation will trickle down to the patients and create limited access to anesthesia for Medicare/Medicaid patients.

It has been recommended that CMS increase the anesthesia conversion factor to address the undervaluation of anesthesia services. I support implementation of the RUC's recommendation.

I would like to continue to offer my patients my skilled anesthesia services and I would like to see CMS accept the conversion factor increase as recommended by the RUC.

Thank you for considering my opinion and concerns regarding the future of anesthesia health care services.

Sincerely,

Haresh Patel, MD, Medical Director of Anesthesia Services, Grandview Medical Center
Anesthesiology Consultants Exchange, P.C.

ACE
ANESTHESIOLOGY
CONSULTANTS EXCHANGE, P.C.

Department of Anesthesiology
975 E. Third Street
Chattanooga, TN 37403
Office 423-778-7608
Billing 423-892-5602

July 27, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P

Leslie V. Norwalk:

I am writing to express my strongest support to increase anesthesia payments under the 2008 Physician Fee Schedule. I highly value the American Medical Society and the Specialty Society Relative Value Update Committee, (RUC), for raising awareness of the undervaluation of anesthesia services, and I am grateful that CMS is addressing this issue.

Under the rate schedule that took effect January 1, 2007, CMS cut Medicare payments for anesthesia services by 8.9%, even though Congress froze across- the- board sustainable growth rate formula reductions for the year. Since Medicare changed its payment system in 1992, anesthesia services have been undervalued. The dollar conversion factor is lower now than it was in 1990. I would encourage and support a review and change in the current sustainable growth rate formula.

The RUC recommended that CMS increase the anesthesia conversion factor. I support full implementation of the RUC's recommendation.

To continue to offer my patients anesthesia services, it is important to me that CMS follow through with the proposal in the Federal Register by fully accepting the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your time and attention.

Sincerely,

Sudhakar Reddy, MD, Vice President,
Anesthesiology Consultants Exchange, P.C.

27

UNIVERSITY OF
PENNSYLVANIA
HEALTH SYSTEM

Garry L. Scheib
Chief Operating Officer

August 8, 2007

Leslie Norwalk
Acting Administrator
Centers for Medicare and Medicaid Services
United States Department of Health and Human Services
Attention: CMS-1385-P, Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: (CMS-1385-P) Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule; CODING—MULTIPLE PROCEDURE PAYMENT REDUCTION FOR MOHS SURGERY, (Vol. 72, No. 133), July 12, 2007.

Dear Ms. Norwalk:

Thank you for the opportunity to comment on the proposed change in Medicare reimbursement policy by the Centers for Medicare and Medicaid Services (CMS) that seeks to remove Mohs surgery from a longstanding exemption from the multiple surgery reduction rule (MSRR< CPT modifier-51). Finalizing this change would have a significant negative impact on the health care of U.S. citizens and potentially add unnecessary cost to the delivery of health care in this country.

As you are probably aware, over a million Americans per year are diagnosed with skin cancer and over the last ten years the rate of new skin cancer diagnoses is growing at what many would call epidemic proportions. Mohs micrographic surgery is a common way of treating some of these cancers and is considered the industry standard among treatments for skin cancer, allowing the physician to examine 100% of the cancer margin to insure complete removal of the cancer with loss of as little normal skin as possible. Mohs surgery is an outpatient procedure with utilized onsite laboratory analysis of excised tissue while the patient waits for the results. The critical component of Mohs surgery includes meticulous removal and microscopic examination of the entire edge and deep margin of the cancer, in which the same physician serves as both surgeon and pathologist. The procedure is particularly valuable in the treatment of skin cancers in cosmetically or functionally important areas such as the face, neck, hands, feet and genitalia. It is also valuable for large aggressive, or ill-defined cancers and for those that have recurred after other previous treatments. After the cancer is removed, most patients undergo subsequent reconstructive surgery by the same doctor on the same day as the cancer removal.

Penn Tower Suite 102 • 1 Convention Avenue • Philadelphia, PA 19104 • 215-662-3227 • Fax: 215-614-0028

The Department of Dermatology at the University of Pennsylvania Health System (UPHS) offers Mohs micrographic surgery at two locations: the Hospital of the University of Pennsylvania and Penn Medicine at Radnor. At both sites combined, we treat approximately 1500 patients per year with Mohs surgery. As a quaternary care center, we attract patients with aggressive and/or multiple skin cancers. As part of an institution with thriving organ transplant clinics, we care for an inordinate number of organ transplant recipients, who because of their immunosuppressed status, frequently have numerous aggressive skin cancers, sometimes exceeding 30-50 per year.

In 2006, CMS reviewed the American Medical Associations' Current Procedural Terminology (CPT) codes 17304 – 17310 (Mohs micrographic surgery) and requested that new site-specific codes be developed similar to those used for other excisional surgery. The American Academy of Dermatology, the American Society for Dermatologic Surgery, and the American College of Mohs Micrographic Surgery and Cutaneous Oncology participated in last year's review of the Mohs CPT codes, and the new codes were adopted (17311-17315) addressing CMS' concerns without adversely affecting the delivery of these services to patients in need.

On July 12, 2007, CMS proposed a change in the payment policy that has the potential to negatively impact the care of our patients and could add significant cost to an already stressed health care budget. This planned change would remove Mohs surgery from a longstanding exemption from the multiple surgery reduction rule (MSRR, indicated by CPT modifier -51). This is a departure from a longstanding exemption agreed to by CMS and virtually all private insurance carriers since 1991. The change proposed would eliminate the exemption and decrease reimbursement by 50% for either the Mohs excision or for the associated repair, and for Mohs excision of any additional cancers treated on the same day; such a decrease in reimbursement would not cover the cost of providing the service.

In its review of the Mohs codes in 1991, CMS agreed that Mohs excisions are "separate staged procedures; they will be paid separately with no multiple surgery reductions." This rule was placed in the Federal Register at that time (Federal Register, November 25, 1991, volume 56, #227, pg 59602). In 2004, the Mohs codes were added to the CPT Appendix E list of codes exempt from the -51 modifier and the multiple surgery reduction rule, to eliminate the occasional carrier misunderstanding when the multiple surgery reduction was applied to these codes. The July 2004 CPT Assistant article reviewed the rationale: "The rationale for this policy is that for many surgical procedures some of the work of a procedure is not repeated when two or more procedures are performed. For these procedures the intra-service work is only 50% of the total work, while the other 50% represents pre- and post-service work that overlaps when multiple procedures are performed on the same patient on the same date of service. For Mohs surgery, however, greater than 80% of the work is intra-service work that does not overlap when two or more procedures are performed. The pathology portion of Mohs surgery constitutes a large portion of this total and also is not reduced with multiple procedures. The pre-service and post-service work values are small because there is a zero-day global period. Together there is very little overlap or reduction in work when two or more tumors are treated on the same patient on the same day. Therefore, Mohs surgery codes are exempt from the use of modifier 51."

The exemption of the Mohs codes form the MSRR has been maintained by CMS since 1992 and was not questioned during the CMS mandated five-year review of the Mohs codes undertaken last fall or during presentation of the new Mohs codes to the AMA Relative Value Update Committee (RUC) in October, 2006.

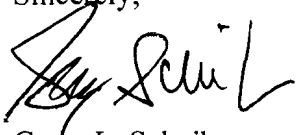
Two very important aspects of care for our patient population at UPHS are same day reconstruction of Mohs defects and same-day treatment of multiple tumors, whenever possible. Inclusion of Mohs micrographic surgery in the multiple surgical reduction rule will make our current practice of care untenable. More importantly, delays in treatment will further increase the risk of fatal metastases for high-risk patients such as organ transplant patients with multiple squamous cell carcinomas, and the risk of larger surgical defects requiring more expensive repair techniques for patients with syndromes such as basal cell nevus syndrome.

In addition to its application to multiple cancers treated on the same day, the MSRR would apply to repairs performed on the same day as Mohs surgery. According to this new proposal, when Mohs surgery is reimbursed less than a reconstructive procedure on the same day, even the first Mohs code will be subject to the multiple surgery reduction rule. Since costs would not be covered, this may require patients to have their Mohs surgery and their reconstruction done on separate days, or to be referred to other physicians for reconstruction, usually plastic, facial plastic, or occuloplastic surgeons, who work primarily in hospitals or ambulatory care centers where costs of care are higher. The result would be that health care costs will be higher than they are under the current policy of payment.

At UPHS, the consequence of applying the multiple surgery reduction rule to Mohs surgery would be to reduce reimbursement potential for Medicare services by over $130,000 per year. Additionally, it is likely that other payers will follow Medicare's lead with regard to this policy change. Assuming a similar reduction in revenue, UPHS could face an additional reduction in reimbursement for Mohs services of approximately $300,000 annually. This reduction would translate into to a reimbursement value less than the cost of providing the service, meaning providers would no longer be able to perform more than one Mohs procedure on any patient on a single day. Many of our patients travel great distances to seek our care. In addition, many of our patients are elderly and require assistance from family and friends to travel to our facilities. Understanding the great effort that patients make to seek our care, we work hard to make our services as convenient as possible.

Our primary goal is to continue to provide the most medically optimal, cost-effective care for our patients; if this unexpected change is allowed to take effect that will no longer be possible. We urge the Agency to rescind this provision of the proposed rule.

Sincerely,



Garry L. Scheib

28-1

ACE
ANESTHESIOLOGY
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July 24, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I appreciate the work that the American Medical Society and the Specialty Society Relative Value Update Committee, (RUC), have done to raise awareness of the undervaluation of anesthesia services, and I am grateful that CMS is addressing this issue.

Because the current payment is under the market rate, my concern is that this will create a threat to the availability of anesthesia care to Medicare patients. Without some regulatory and legislative relief, Medicare populations will be under served. Continued cuts will create an unsustainable system in which anesthesiologists will be forced away from areas with disproportionately high Medicare populations. The area I practice in has a large number of Medicare participants and my services to them are highly valued in this community among our physicians, healthcare facilities, and patients. I have concerns for the future in this area as the ability to recruit anesthesiologists and nurse anesthetist may become difficult if the current system is not amended.

In an effort to rectify this situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation—a move that would result in an increase per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I support full implementation of the RUC's recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC. Thank you for your consideration of this serious matter.

Sincerely,

J. Frank Adkins, MD, Chief of Anesthesia Services, Erlanger Health Systems
Anesthesiology Consultants Exchange, P.C.

Things I Need:

24 July 07

DEAR CMS

I appreciate the hard work and dedication CMS does in controlling health care costs, with fair and equitable treatment of all health care providers

As an anesthesiologist in a primarily urban - inner city practice - our payor mix is almost exclusively Medicare & Medicaid

Our Medicare reimbursement at $17/unit = 7 15 minutes really is undervalued.

I STRONGLY REQUEST YOU ~~APPROVE~~ A SIGNIFICANT ~~INCREASE~~ IN THE MEDICARE PAYMENT

Please vote to increase the conversion factor

Thank you

Brad Bent MD

30

August 2, 2007

The Honorable Herbert Kuhn
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Washington, DC 20201
Phone: 202-690-6726
E-mail: herb.kuhn@cms.hhs.gov

Re: CMS 1385-P: 2008 Medicare Fee Schedule
Coding - Multiple Procedure Payment Reduction for Mohs Surgery

Dear Acting Administrator Kuhn:

As President of the American College of Mohs Surgery, I represent over eight hundred fellowship-trained Mohs surgeons in the United States, whose primary practice is the treatment of skin cancer. The College and I are deeply concerned regarding this proposed rule for multiple reasons. We appreciate this opportunity to offer comment on section II.E.2 (P-122) of the 2008 Medicare Fee Schedule Proposed Rule.

This proposal represents a dramatic reversal of sixteen years of the Centers for Medicare and Medicaid Services'(CMS) own determination that the Mohs codes are and should be exempt from the Multiple Procedure Reduction Rule (MPRR). Furthermore, because of the dual components of surgery and pathology associated with each Mohs surgery procedure, there is no gain in efficiencies when multiple, separate procedures are performed on the same date, making application of the reduction inappropriate. Third, this proposal is contrary to the Relative Value Update Committee's (RUC) own policy regarding procedures qualifying for exemption from this rule. Fourth, this proposal will negatively impact Medicare beneficiaries' access to timely and quality care. Fifth, application of this proposal will not likely generate significant cost savings and may paradoxically increase costs of providing care to these patients. Finally, we are concerned that the Proposed Rule reflects an alteration in the traditional role of the RUC in CMS policy formulation.

First, the Mohs surgery codes have had a longstanding and appropriate exemption from the Multiple Procedure Reduction Rule since 1991. In its Final Rule for the 1992 Medicare Fee Schedule (Federal Register November 25, 1991, volume 56, #227, p. 59602- copy enclosed), the CMS (then HCFA) included specific comment regarding Mohs micrographic surgery. CMS

agreed at that time that the Mohs procedures "are a series of surgeries which, while done on the same day, are done at different operative sessions and are clearly separate procedures in a series of procedures....They will be paid separately with no multiple surgery reductions." This conclusion is still correct and applicable today.

At the request of CMS in 2005, the College, together with the American Academy of Dermatology, the American Society for Dermatologic Surgery, and the American Society for Mohs Surgery, worked through the AMA CPT/AMA RUC five-year review process and the AMA CPT/AMA RUC Modifier -51 Workgroup to develop site-specific codes for the Mohs procedure. Two new site-specific codes, 17311 and 17313, were accepted by AMA CPT/AMA RUC to differentiate Mohs excision of cancers in different anatomic areas.. However, there has been NO CHANGE in the procedure or in the separate and distinct nature of the Mohs procedure from any other procedure which might be performed on the same day. We believe the revised code descriptors to differentiate anatomic sites, in the absence of a change in work associated with the procedure, does not support the change in the multiple procedure exemption status of the new Mohs codes.

Second, as noted in the Proposed Rule, "RVUs were developed for each Mohs surgery base code based on an assumption that each code is performed separately." This assumption is correct. Mohs micrographic surgery uniquely includes two distinct components, surgery and pathology, both of which are performed wholly by the Mohs surgeon, with the pathology component comprising half of the service. The nature of Mohs surgery requires that the entire procedure, including processing and interpretation of the histopathology slides, be completed before any consideration is given to the excision of additional tissue or to repair of the resulting defect. The intra-service work for 17311 was acknowledged by RUC to be 80% of the total physician work of the procedure (78% for 17313), including both the surgery and pathology. Even when two Mohs excisions are performed for a patient on the same date, there is no overlap in work for treatment of the second site, which requires all the same components of excision and tissue processing/interpretation as the first site. There are marginal gains in "efficiencies" when treating more than one tumor at the same time.

Likewise, there is no overlap between a Mohs procedure to remove a skin cancer and a subsequent, separate repair procedure that might be used to address the skin defect created by the Mohs procedure. The time required for the pathology component of the procedure results in an onsite waiting period for the patient. If a repair is performed, it requires return to an operating room, repositioning, re-anesthetizing, re-prepping, etc. It is performed with new instrumentation. It is typically performed in the same room as the prior Mohs procedure. There is no overlap of work or practice expense for clinical labor time, medical supplies, or medical equipment between the Mohs procedure and a repair procedure.

Therefore, it is inappropriate to subject 17311 and 17313 to the multiple procedure reduction rule for repairs performed on the same day as the Mohs procedure or for multiple Mohs lesion excisions performed on the same day.

Third, the RUC -51 Research Subcommittee identified seven criteria to determine whether a code should be included on the Modifier -51 Exemption List: 1, RUC rationale supporting placement on the list; 2, Exemption from the CMS Multiple Surgery Reduction; 3, Limited amount of pre- and post-service time and limited number of visits; 4, No add-on codes; 5, No codes where payment logic would not reduce payment when performed with another procedure; 6, Service is typically adjunctive to another service but can be performed as stand-alone procedure; and 7, Service is performed with multiple other procedures that are so extensive that it is difficult to maintain a "Report With" list typically included in CPT.

Considering the arguments we present above, the Mohs codes meet three of the AMA CPT/AMA RUC Modifier -51 Workgroup criteria for procedures qualifying for exemption.

1. Mohs micrographic surgery was declared exempt by CMS in 1991. The procedure remains unchanged since then except for the new CPT code numbers described above.
2. The Mohs codes have very little pre- and post-service time and have a limited number of visits. As above, 78 - 80% of the total physician work of the Mohs codes is intra-service work. The pre- and post-service time for the Mohs codes is less on a percentage basis than that of the other codes remaining on the list of exemptions. The Mohs codes also have zero post-op visits embedded in the value of the codes.
3. The Mohs codes are typically adjunctive to a repair service but are often performed as stand-alone procedures, in cases when wounds are allowed to heal secondarily. Second-intention healing is typical for tumors in certain areas, especially the medial canthus, conchal bowl, and posterior ear, among others.

Meeting three of the seven RUC-developed criteria for exemption, any one of which merits consideration for inclusion on the list, appropriately justifies retaining the longstanding exempt status of the Mohs codes.

Furthermore, since the pathology component of Mohs surgery comprises half of the procedure, it is appropriate that the Mohs codes be treated similarly to other pathology codes, which are not subject to the multiple procedure reduction rule, since there is no overlap in work from reviewing one slide to another. To apply the reduction to the Mohs codes would be inconsistent with the exemption of application of this rule to other pathology codes.

Fourth, removing the exempt status of the Mohs codes will negatively impact Medicare beneficiaries' access to timely and quality care. Currently, 10% of patients undergoing Mohs micrographic surgery have more than one tumor treated with Mohs on the same day.

Application of the proposed rule to a second tumor treated on the same day will mean that reimbursement for the second procedure does not cover the cost of providing the service. This will affect Medicare beneficiaries disproportionately, since the incidence of skin cancers peaks in Medicare-age patients, who are most likely to have multiple tumors. Additionally, patients who are immunosuppressed from organ transplantation, cancer chemotherapy, infection or other diseases are at significantly higher risk for skin cancers and often have multiple tumors; many of these patients are also Medicare beneficiaries. These immunosuppressed patients are not only at higher risk for cancers but also at higher risk for potential metastases and possibly death from skin cancers, especially squamous cell carcinoma.

Fifth, although perhaps intended as a cost-saving measure, application of this rule will not likely generate significant cost savings and may paradoxically increase cost of providing care to these patients. When Mohs procedures are performed with higher-valued repairs such as flaps or grafts, application of the MPRR to the Mohs codes will result in reduced reimbursement for Mohs that doesn't cover the cost of the procedure. Likewise, for lower-valued repairs such as intermediate and complex layered closures, which are the most commonly performed repairs, reduced reimbursement will not cover the cost of the repair.

Finally, we support the RUC process and recognize the value it brings to the annual physician fee schedule development. As initially charged, the RUC has done an exceptional job over the years in expressing opinions regarding relative values for procedures. In doing this the RUC defied the predictions of critics who claimed that agreement would not be possible among the various stakeholders. The RUC and CMS also prevailed against the legal challenge that the RUC amounted to a Federal Advisory Committee. In defending against that allegation it was persuasive to the court that the RUC only provides opinions on relative values and that CMS retains the authority to make policy decisions. The RUC, it was noted, is independent and is only one source of CMS input on relative values. All policy decisions have undergone full development by CMS in the public notice and comment process.

The policies adopted by CMS such as multiple surgical reductions, bundled services, and prohibition against operating surgeons from separately billing for anesthesia and assistant at surgery restrictions are all examples of policy decisions by CMS. They do no strictly represent issues of relative value but rather they represent policy formulations that guide payment and medical practice. To have the RUC engaged in these policy formulations in a forum which is not open or accessible to the public is unfair to the Medicare beneficiaries affected and threatens the RUC process.

We disagree with using the RUC for this purpose but if CMS believes the RUC role should be expanded it should only be done by giving the RUC a public and well-articulated charge to take on this task.

In light of the concerns raised above, the American College of Mohs Surgery respectfully requests reconsideration of the proposed rule. We provide the above rationale in support of the Mohs procedure base codes, 17311 and 17313, as appropriately exempt from the multiple procedure reduction rule, as are the other add-on Mohs codes. We therefore request permanent exemption from the MPRR.

We would appreciate the opportunity to meet with CMS to discuss this issue as soon as possible. Please feel free to contact me at 412/466-9400.

Respectfully,

David G. Brodland, M.D.
President, American College of Mohs Surgery

cc: Terrence Kay, Director, Hospital and Ambulatory Policy Group
Amy Bassano, Director, Practitioner Services Division
Diane Baker, MD, President, American Academy of Dermatology
Alastair Carruthers, FRCPC, President, American Society of Dermatologic Surgery
Sharon Tiefenbrunn, MD, President, American Society for Mohs Surgery

Enclosures -1992 Medicare Fee Schedule: Final Rule (Federal Register, November 25, 1991, vol. 56, #227, pg 59602)
CPT Assistant, July, 2004
CPT Assistant, November, 2006

of the global fee for the second highest valued procedure, and at 25 percent of the global fee for each succeeding procedure. Each procedure after the fifth procedure will be paid by special report. Our medical consultants advise us that cases with more than five procedures should be extremely rare. We believe that the added documentation requirement along with physician comparative performance reports and our intra-operative computer edits will prevent abuse of the multiple surgery policy through excessive "unbundling".

For certain dermatology services, there are separate CPT codes for multiple surgical procedures (for example, CPT codes 11201, 17001, and 17002). For these procedures, the multiple procedure rules will not apply. Rather, we are presenting RVUs for these codes. For other dermatologic procedures, we believe a 50 percent reduction in the value is appropriate for the second procedure since pre- and post-work and practice expenses will be diminished. However, beyond the second procedure, since there may not be the same reductions in work effort that is associated with multiple surgery through the same incision, a physician may submit a "by report" bill when three or more lesions are removed.

[Mohs Micrographic Surgery]

Comment: Some commenters stated that Mohs micrographic surgery, CPT codes 17303 through 17310, should be exempt from the multiple surgery reductions. These are a series of surgeries which, while done on the same day, are done at different operative sessions and are clearly separate procedures in a series of procedures.

Response: We agree that these surgical procedures are contemplated to be separate staged procedures; they will be paid separately with no multiple surgery reductions.

[Multiple Surgery Policy for Multiple Trauma]

Comment: Some commenters expressed concern that the multiple surgery policy would result in inadequate payment when a number of different surgeons are operating on different body parts at the same time, such as in the case of a multiple trauma patient.

Response: These cases will not be subject to the multiple surgery policy. The multiple surgery policy will apply to multiple surgery done by the same surgeon on the same day. Each physician will be paid separately for his or her services.

c. *Bilateral surgery (CPT modifier 50).* The bilateral modifier is used to indicate cases in which a procedure was performed on both sides of the body. The CPT identifies surgical procedures that are typically bilateral in nature. For these codes, the bilateral modifier would not result in increased payment.

In the absence of any evidence with respect to the actual difference in work for bilateral procedures, we proposed to continue the historic practice of paying 150 percent of the global fee.

[Bilateral Surgery Code Applying to Ophthalmic Procedures]

Comment: The CPT code for bilateral surgery (CPT modifier 50) should not apply to ophthalmic procedures or to the extremities (hands, feet, knees) as it requires the same amount of work for each eye, foot, etc. This policy would merely encourage physicians to bring the patient in on two separate occasions and do each eye, foot, etc., separately.

Response: Harvard did not have data on the resources involved in miscellaneous bilateral surgery and surveyed very few procedures that were bilateral. Like the multiple surgery policy, the use of a bilateral modifier and payment by carriers at 150 percent of the global fee in bilateral cases is a long accepted practice. Until resource data are available, we plan to continue the 150 percent policy. While the actual intra-operative services may be the same for each eye or extremity, we believe the pre-operative and post-operative services are reduced.

d. *Providers furnishing less than the global fee package (CPT modifiers 54, 55, and 56).* Under the current reasonable charge policy, the sum of all allowances for all practitioners who furnished parts of the services included in a global fee (and who billed using one or more of these modifiers) must not exceed the total amount of the allowance that would have been paid to a single practitioner under the global fee for the procedure. We proposed to continue to pay the same amount for surgical services when they are furnished by several physicians as we would pay if only one physician furnished all of the services in the global package. However, we proposed to pay each physician directly for the services furnished to the beneficiary based on the RVUs of the component furnished.

[Physicians Other Than Surgeons Should be Paid Without Regard to Global Fee]

Comment: Commenters objected to the policy that the sum of payments to multiple physicians furnishing services within a global package (CPT modifiers 54, 55, and 56) may not exceed the value of the global fee for the procedure. They stated that since only the pre- and post-operative services of the surgeon were studied by Harvard in setting the global RVUs (not the services of other physicians such as cardiologists, internists, anesthesiologists, intensivists, or other physicians who may furnish this care), a physician other than the surgeon who furnish follow-up care should be paid without regard to the total global fee.

Response: We disagree. The concept of a global fee for a surgery for which the surgeon charges a single global fee and furnishes all usual and necessary services associated with a surgery and follow-up recovery is a long established concept. To ensure equitable payment under the fee schedule, it is necessary to establish a uniform national global package for each surgery. Since the surgeon usually can be expected to furnish the complete package of services, it is entirely appropriate that the value of the package be established on the basis of the value of the surgeon's services. When someone other than the surgeon furnishes services that the surgeon would normally furnish, he or she is merely substituting for the surgeon. The value of the package does not change.

However, there appears to be some misunderstanding concerning the services of other physicians—for example, a nephrologist, an infectious disease specialist for severe infection—furnishing services in addition to those normally furnished by the surgeon when a patient develops renal insufficiency. As discussed in the section of the proposed rule on global surgery, if the services of these other physicians are required in addition to the normal pre- and post-operative services of the surgeon, they will be paid outside of the global fee.

[Apportioning Payment for Post-Operative Care Furnished by Different Physicians]

Comment: A commenter suggested that, if normal post-operative care is furnished by more than one physician, the payment should not be apportioned according to the number of days in the portion of the 90-day period furnished by each physician since the number of visits and intensity of care required during different times in the period varies. The commenter stated that as an example, under the proposal in the proposed rule, a physician furnishing the first 30 days of post-operative care would receive 33 percent of the value of the care, while the physician furnishing the last 60 days of care would receive 66 percent. The commenter noted that, in

AMA
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Your Practical Guide to Current Coding

November 2006 / Volume 16, Issue 11

At Issue This Month

Mohs Micrographic Surgery

CPT 2007 contains revisions to the Mohs surgery codes. These revisions result from the Five-Year Review of the Medicare Physician Fee Schedule. Through the Five-Year Review process, the recommendation was made to differentiate the physician work of the Mohs surgeon according to site, such as the head, neck, and hands from the trunk, arms, and legs. The word *complete* was removed from the code descriptor for Mohs surgery before "histopathologic preparation including routine stains" to indicate that when special staining is used with Mohs surgery, such special stains are to be reported separately.

Simply, for *CPT 2007*, code 17304 has been deleted and separated into two new codes, 17311 and 17313, depending on tumor location. Codes 17305, 17306, and 17307 were replaced with 17312 and 17314, depending on tumor location. Code 17310 was replaced with 17315. The word *specimen* was replaced with the phrase *tissue block* to reflect more accurately the unit of service. CPT codes 17312, 17314, and 17315 are designated as add-on codes.

Mohs micrographic surgery is a technique for the excision of skin cancer. The Mohs surgery family of codes, 17311-17315, is unique because it includes CPT codes that describe procedures that involve surgery and pathology services performed together by the same physician acting as both surgeon and pathologist. This dual responsibility requires policies that differ from other surgical codes and has led to confusion among those unfamiliar with the use of these codes. This discusssion explains the codes, the policy for their use, and the rationale for this policy so that providers, coders, and payers can understand coding for Mohs surgery. This is an update of the July 2004 *CPT Assistant*.

What is of Mohs Micrographic Surgery?

Mohs micrographic surgery is a technique for the removal of complex or ill-defined skin cancer with histologic examination of 100% of the surgical margins. It is a combination of surgical excision and surgical pathology that requires a single physician to act in two integrated but separate and distinct capacities: surgeon and pathologist. If either of these responsibilities is delegated to another physician who reports the services separately, these codes should not be reported. The Mohs surgeon removes the tumor tissue and maps and divides the tumor specimen into pieces, and each piece is embedded into an individual tissue block for histopathologic examination. Thus a tissue block in Mohs surgery is defined as an individual tissue piece embedded in a mounting medium for sectioning.

If repair is performed, separate repair, flap, or graft codes are used. If a biopsy of a suspected skin cancer is performed on the same day as Mohs surgery because there was no prior pathology confirmation of a diagnosis, then diagnostic skin biopsy (11100, 11101) and frozen section pathology (88331) with modifier 59 appended are reported to distinguish from the subsequent definitive surgical procedure of Mohs surgery.

Following are the new Mohs Micrographic Surgery codes for *CPT 2007*:

17311 Mohs micrographic technique, including removal of all gross tumor, surgical excision of tissue specimens, mapping, color coding of specimens, microscopic examination of specimens by the surgeon, and histopathologic preparation including routine stain(s) (eg, hematoxylin and eosin, toluidine blue), head, neck, hands, feet, genitalia or any location with surgery directly involving muscle, cartilage, bone, tendon, major nerves, or vessels; first stage, up to 5 tissue blocks

17312 each additional stage after the first stage, up to 5 tissue blocks (List separately in addition to code for primary procedure)

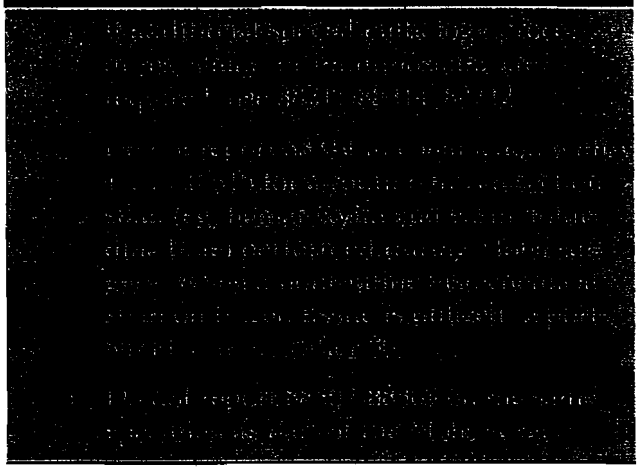
17313 Mohs micrographic technique, including removal of all gross tumor, surgical excision of tissue specimens, mapping, color coding of specimens, microscopic examination of specimens by the surgeon, and histopathologic preparation including routine stain(s) (eg, hematoxylin and eosin, toluidine blue), of the trunk, arms or legs; first stage, up to 5 tissue blocks

17314 each additional stage after the first stage, up to 5 tissue blocks (List separately in addition to code for primary procedure)

17315 Mohs micrographic technique, including removal of all gross

tumor, surgical excision of tissue specimens, mapping, color coding of specimens, microscopic examination of specimens by the surgeon, and histopathologic preparation including routine stain(s) (eg, hematoxylin and eosin, toluidine blue), each additional block after the first 5 tissue blocks, any stage (List separately in addition to code for primary procedure)

Parenthetical Notes Per CPT Guidelines



General Description

Typically, Mohs surgery is an outpatient procedure performed under local anesthesia. The basic tenet is excision followed by complete surgical margin examination by the Mohs surgeon and precise mapping of tumor-containing margins so that the surgeon can re-excise positive margins.

The details of the procedure require that the visible cancer commonly be removed first (debulked) without attempting to remove a margin of normal tissue. After the bulk of the tissue is removed, the first layer or stage is excised as a thin continuous wafer of tissue, typically 1 to 3 mm thick, around the sides and base of the wound or apparent cancer margin. Hemostasis is achieved, and the patient is bandaged and discharged to the waiting room.

This thin cup or saucer-shaped wafer of tissue is flattened by cutting it into pieces or making radial incisions to flatten the tissue. The smallest number of tissue blocks that will allow the performance of sectioning in the cryostat is created. The edges of the tissue are color coded with dyes that persist through histologic tissue processing. Once the wafer is cut into pieces and color coded, a drawing or map of this tissue and its pieces is made so that it corresponds to the surgical wound. These tissue pieces, disassembled like a puzzle, are processed by frozen section pathology. One or more flattened tissue piece is positioned on a single frozen tissue specimen disk ("block"), embedded, frozen, sectioned horizontally in a cryostat onto a microscope slide, and stained. These frozen sections create an image of 100% of the surgical margin. Microscopic examination of this image allows the Mohs surgeon, whose dual role is to function as both surgeon and pathologist, to precisely identify the location of any remaining tumor. The location of the remaining tumor as seen through the microscope is marked on the map of the surgical wound.

If the frozen sections indicate residual tumor, the patient is called back from the waiting room, reanesthetized, prepped, and draped for the next Mohs surgical stage. The Mohs surgeon, using the marked map of the wound, excises any remaining tumor as in the previous stage(s). This process of excision of remaining tumor, mapping, and histologic exam is repeated until all of the tumor is excised completely.

This Mohs method of margin examination differs significantly from traditional frozen sections used during routine surgery for margin exam. Traditional techniques use bread-loafed surgical specimens, providing an image that includes a vertical cut through the tissue. This offers a view of the center of the specimen and the lateral and deep margins, but it only samples these tissue pieces every few millimeters or centimeters. Such a sampling technique typically examines far less than 0.1% of the total margin of excision. Because traditional pathologic examination of surgical margins is only a sampling and may miss true positive margins, wider surgical margins are usually used for non-Mohs skin cancer surgery. Conversely, Mohs surgery—using 100% examination of the margin—allows excision with very narrow margins. This results in narrower surgical margins overall, less complicated reconstruction of smaller operative wounds, and higher cure rates.

Coding for Mohs Surgery (17311 and 17313)

Codes 17311 or 17313 are used for the first layer (stage) of Mohs surgery depending on the location of the tumor(s). Roughly 50%-55% of Mohs cases require only a single layer. Codes 17311 and 17313 include the *preservice* work of explaining the procedure, obtaining informed consent, and preparing the patient for surgery. The *intraservice* work includes local anesthesia, debulking of the visible tumor, excision of the first Mohs layer, color coding of the specimens, and mapping. It also includes the pathology services of tissue preparation, microscopic examination, and mapping of positive margins. The *intraservice* work also includes the final evaluation of the tumor-free wound to determine wound management. The *postservice* work includes the discussion of postoperative wound management. It is important to understand these components of physician work and their relation to relative value units (RVUs) because they determine the coding and reimbursement policies.

The use of these codes is restricted to situations where one physician acts as both surgeon and pathologist. Performance of the entire procedure by one physician increases the accuracy of the technique as the risk of mapping errors is minimized. The codes are not appropriate for use when a surgeon excises tissue interpreted separately by a pathologist, even if the histologic exam is done by enface or horizontal techniques and a map is made by a pathologist for the surgeon. In those cases-sometimes erroneously described as "modified" Mohs-the surgeon should code the appropriate excision and/or repair codes and the pathologist should report the appropriate codes for his or her service.

Codes 17311 and 17313 are used for the first layer (stage) only and include the work of excision and pathology of up to five specimens. If the tissue layer is large enough that it must be cut into six or more specimens producing six or more blocks of tissue in order to examine the entire surgical margin, then code 17315 should be used for each additional block beyond the first five included in 17311 or 17313. As the number of tissue blocks increases, the potential for false positive or false negative results rises, so efforts are made to evaluate each layer in as few blocks as possible. In certain circumstances, more than one slide may be prepared from the tissue block. The additional slides, regardless of the number of sections cut from the block, still count as a single block. Add-on code 17315 is reportable in conjunction with the entire range of 17311-17314 Mohs codes.

Pathology Services: Bundled Services and Those That Are Separately Reportable

The unit of service previously described by codes 17304-17310 was the number of specimens. However, the specimen that is taken during surgery is used to create tissue blocks. In the context of Mohs Surgery, a *tissue block* is defined as tissue placed upon a single frozen section specimen disk and embedded in a mounting medium for sectioning. This tissue block more accurately describes the unit of service. To more accurately reflect the unit of service, codes 17311-17315 describe the unit of service as blocks rather than specimens.

The work of processing and interpreting one routine stain is included in the procedure 17311-17315. This stain is usually hematoxylin and eosin, or toluidine blue. If other special stains are necessary after one routine stain, then the code for special stains may be used (88314) as well as immunoperoxidase stains (88342) or decalcification procedures (88311). Special stains are not typically used and in most Mohs practices are of low frequency. Each stain is reported only once per block, not per slide or per layer (stage).

Surgical pathology codes 88302-88309 should not be used for reporting histopathology of Mohs surgical specimen. This instructional parenthetical note has been added preceeding code 17311.

CMS Reporting Guidelines

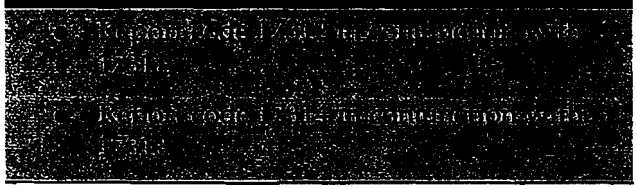
Because a high complexity histology laboratory in close proximity is a necessary part of this procedure, the presence of such as designated by a current Clinical Laboratory Improvement Amendments (CLIA) number is now a necessary part of the claim when reporting Mohs micrographic surgery codes to the Centers for Medicare and Medicaid Services (CMS).

Codes 17312 and 17314

Codes 17312 and 17314 describe the second and subsequent stages of Mohs surgery to remove positive surgical margins. These two codes replace 17305-17307. The RVUs already reflect any reduction in work done for these repeat procedures compared to codes 17311 or 17313. No debulking procedure is done on these add-on codes; they represent only the additional surgical work for re-excision of positive margins and the additional pathology work for interpretation of the specimens. When two or more stages are performed in one day, code 17312 or 17314 should be used with an appropriate number of units for each additional stage. For example, if a tumor was excised with a total of five layers (stages) on the head, then code 17311 would be reported one time and code 17312 would be reported with 4 units for the additional four stages. Likewise, if a tumor was excised with a total of five layers (stages) on the trunk without muscle involvement, then codes 17313 would be reported one time and code 17314 would be reported with 4 units for the additional four stages.

When Mohs surgery is performed on a single tumor but is carried over to a second day, the first layer (stage) on the next day should continue with the next code in the series. For example, if the surgery after the first (initial) layer was postponed until the second day, then coding the second day's surgery starts with code 17312 or 17314 but not code 17311 or 17313 because no debulking is necessary on the second day. Each layer (stage) represented by 17312 and 17314 includes up to five specimens in each layer (stage). Note that 17312 and 17314 are add-on codes and not typically reported without a primary code on the same day. For any individual stage that has more than five blocks, code 17315 should be used. It is recommended to report the two-day Mohs surgery on the same claim form.

Parenthetical Notes Per CPT Guidelines



Code 17315

Code 17315 is used for unusually large tumors requiring more than five tissue blocks in any layer. It is used for fewer than 10% of tumors excised with Mohs surgery. This code represents the incremental increase in work for both surgery and pathology for these larger tumors. Code 17315 is reported once with the appropriate number of units for each additional tissue block after the first five blocks in any stage. That is, 17315 represents one piece of the puzzle of the Mohs surgery map; it does not represent the number of slices of tissue from the block on the glass slides or the total number of slides.

Code 17315 is an add-on code and cannot be reported without codes 17311, 17312, 17313, or 17314. When two or more tumors are treated in one day, code 17315 is reported for each piece of tissue beyond five for any one layer (stage). It is not appropriate to add and average all pieces from all layers. For example, if the first tumor layer was divided into seven pieces that generated seven separate blocks of tissue and the second tumor excision layer had three pieces, then code 17315 would be submitted once each (ie, twice in the units box) for the sixth and seventh specimen in the first tumor layer while the appropriate base code would be submitted for the Mohs surgery performed in each site.

Historically, the Mohs micrographic surgery codes have been exempted from multiple procedure reduction.

Parenthetical Notes Per CPT Guidelines

General Issues: Skin Biopsy Before Mohs Surgery

It is generally recognized that a skin biopsy and histologic diagnosis is necessary before beginning Mohs surgery. If a definitive diagnosis of the tumor is not available, the Mohs surgeon may perform a biopsy to confirm a diagnosis of skin cancer before the decision to initiate Mohs surgery. In this instance, biopsy codes 11100 and 11101 and frozen section surgical pathology code 88331 may be reported separately in addition to Mohs surgery.

11100	Biopsy of skin, subcutaneous tissue and/or mucous membrane (including simple closure), unless otherwise listed; single lesion
11101	Biopsy of skin, subcutaneous tissue and/or mucous membrane (including simple closure), unless otherwise listed; each separate/additional lesion (List separately in addition to code for primary procedure)
88331	Pathology consultation during surgery; first tissue block, with frozen section(s), single specimen

A biopsy may also be required if:

- A biopsy report is not available with reasonable effort.
- A biopsy has been done more than 90 days before surgery.
- The original biopsy diagnosis is ambiguous.

Modifier 59 should be appended to the biopsy codes (eg, 11100 with modifier 59) and pathology (eg, 88331 with modifier 59) to document that these are separate services that are not components of Mohs surgery and that may be bundled erroneously into Mohs surgery if the modifier is not used. It is not appropriate to report a biopsy or frozen section with Mohs surgery for routinely reviewing the histopathologic features of the tumor being treated.

Code 11100 is reported for the first biopsy and code 11101 for a biopsy of second or subsequent skin lesions in different locations. Code 88331 is reported for the pathology interpretation of each skin biopsy specimen. Code 88332 is reported *only* if a single surgical specimen is cut into separate tissue blocks for separate examination.

Reconstruction

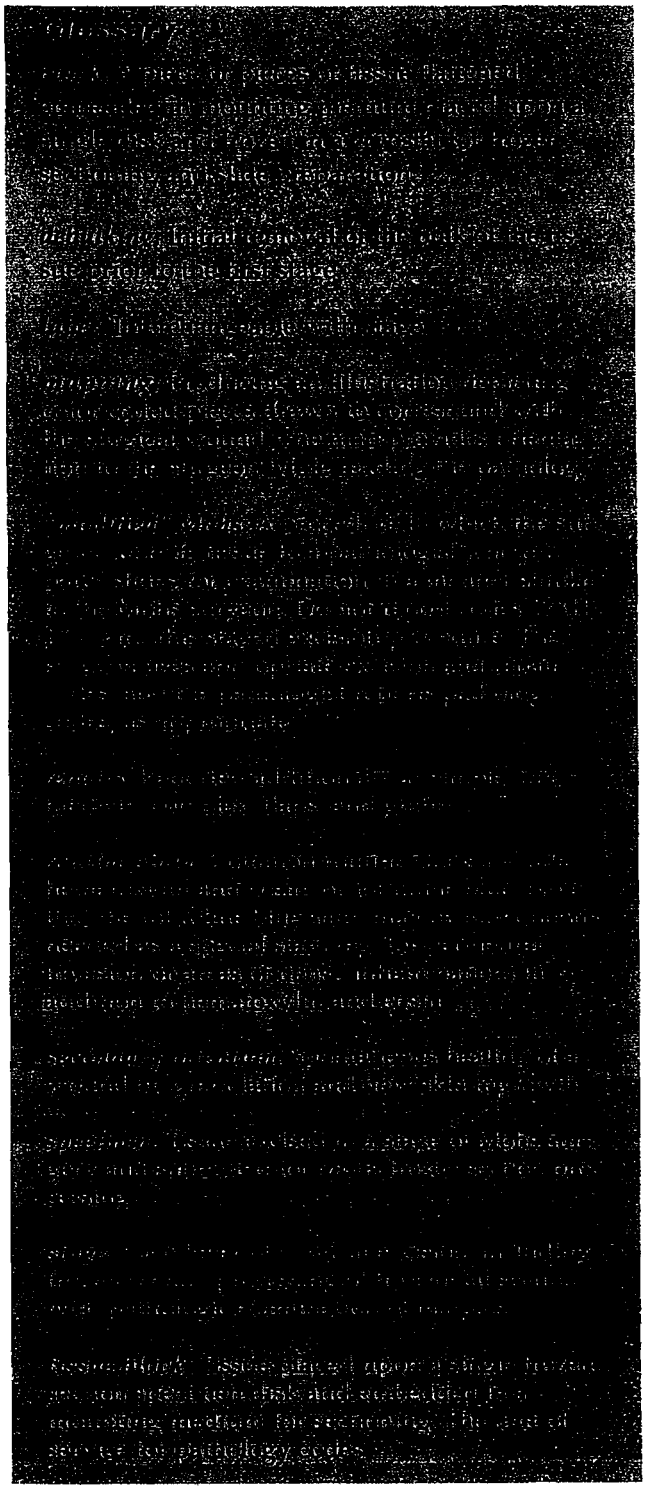
Some wounds after Mohs micrographic surgery are allowed to heal spontaneously by secondary intention without reconstruction of the wound; therefore, no RVUs are included in the Mohs family of codes for surgical repair. *Secondary intention* is the spontaneous healing of a wound by granulation and new skin regrowth. If surgical repair is necessary, then the repair codes (simple, intermediate, complex, flaps, and grafts) should be reported separately.

Evaluation and Management Services

Evaluation and management (E/M) services provided on the same date of service as Mohs micrographic surgery may be reported if a significant separately identifiable service is performed and documented. A separately identifiable service may include an initial evaluation of a new patient, an initial consultation, or other E/M service, or it may include the decision to perform surgery. Modifier 57 is used for the E/M service to indicate the decision to perform surgery. If an E/M service is performed with Mohs micrographic surgery alone, or when a repair code with a global period less than 90 days is performed, the E/M service should be reported with modifier 25 appended.

CMS Reporting Guidelines

If an E/M service is performed on the same date of service as a surgical reconstruction with a 90-day global period (ie, flap or graft), CMS policy requires modifier 57, *Decision for surgery* be appended to the E/M service. A separate



diagnosis for the E/M service and for the Mohs micrographic surgery is not required per CPT coding guidelines (see modifier 25 in Appendix A of the CPT codebook).

E/M services following Mohs micrographic surgery may be reported depending on the global period of any surgical reconstruction services done with Mohs surgery. If the wound was allowed to heal by secondary intention and no other service other than Mohs surgery was performed, a zero global postoperative period applies, and any E/M services provided after Mohs are reported without modifiers. If reconstruction is performed with Mohs surgery, the 10- or 90-day global period of the reconstruction applies and no E/M service related to the reconstruction procedure is allowable during the global period. However, an E/M service may be reported if it is for an unrelated service, in which case modifier *24, Unrelated evaluation and management service by the same physician during a postoperative period,* would be appended.

Complications

Sometimes complications such as wound infection, bleeding, hematoma, or wound dehiscence may require a return to the operating room. It is important to note that CMS defines an operating room as a room that is equipped specifically and staffed for the sole purpose of performing procedures. Such a room is not a minor treatment room or recovery room. In this instance, modifier *78, Return to the operating room for a related procedure during the postoperative period,* would be appended to the appropriate procedure (eg, incision and drainage of hematoma). This would only be appropriate if a repair with a global period of zero days was performed as Mohs surgery. ■

References

American Medical Association. *Medicare RBRVS: The Physicians' Guide.* Chicago, Ill: AMA; 2005:78-81.

Physician fee schedule (2000 CY); payment policies and relative value unit adjustments. *Federal Register.* November 2, 1999;64:59410-59411, 59428.

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Your Practical Guide to Current Coding

At Issue This Month

Mohs Micrographic Surgery

Mohs surgery is a technique for the excision of skin cancer. It is a combination of surgical excision and microscopic pathology. The Mohs surgery family of codes – CPT codes 17304-17310 – is unique because it includes the only CPT codes that describe procedures that involve surgery and pathology services performed together by the same surgeon or pathologist. This dual responsibility requires policies that differ from other surgical codes and has led to confusion among those unfamiliar with the use of these codes. This discussion explains the codes, the policy for their use, and the

rationale for this policy so that providers, coders, and payers can all understand coding for Mohs surgery. This is an update of the Winter 1994 *CPT Assistant*.

General Description

Typically, Mohs surgery is an outpatient procedure usually done under local anesthesia. The basic tenet is excision followed by complete surgical margin exam by the Mohs surgeon and precise mapping of tumor containing margins so that the surgeon can re-excise positive margins.

The details of the procedure require that the visible cancer be removed first (debulking) without attempting to remove a margin of normal tissue. After the bulk of the tissue is removed, the first layer or stage is excised as a thin continuous wafer of tissue, typically 1 to 3 mm thick, around the sides and base of the wound. Hemostasis is achieved, and the patient is bandaged and discharged to the waiting room.

This thin cup or saucer shaped wafer of tissue is flattened by cutting it into pieces (blocks) or making radial incisions to flatten the tissue. The smallest number of tissue blocks are created that will allow the performance of sectioning in the cryostat. The edges of the tissue are color coded with dyes that persist through histologic tissue processing. Once the wafer is cut into pieces and color-coded, a drawing or map of this tissue and its pieces is made so that it corresponds to the surgical wound. These tissue pieces, disassembled like a puzzle, are processed by frozen section pathology. Each flattened piece (or tissue block) is mounted, frozen, and sectioned horizontally. These frozen sections create an image of 100% of the surgical margin. Microscopic examination of this image allows the Mohs surgeon, who also functions as the pathologist, to identify the location of any remaining tumor. Its location as seen through the microscope is marked on the map of the surgical wound.

If the frozen sections indicate residual tumor, the patient is called back from the waiting room, reanesthetized, prepped, and draped for the next Mohs surgical stage. The Mohs surgeon, using the marked map of the wound, excises any remaining tumor as in the previous stage(s). This process of excision of remaining tumor, mapping, and histologic exam is repeated until all of the tumor is completely excised.

This Mohs method of margin exam differs significantly from traditional frozen sections used during routine surgery for margin exam. Traditional techniques use bread loaf surgical specimens, providing an image that includes a vertical cut through the tissue. This offers a view of the center of the specimen, and the lateral and deep margins, but it only samples these images every few millimeters or centimeters. This sampling technique typically examines far less than 1% of the margin. Because traditional pathology examination of surgical margins is only a sampling and may miss true positive margins, wider surgical margins are usually used for non-Mohs skin cancer surgery. Conversely, Mohs surgery using 100% examination of the margin allows excision with very narrow margins. This results in both narrower surgical margins overall, easier reconstruction of smaller operative wounds, and higher cure rates.

Coding for Mohs Surgery

17304	Chemosurgery (Mohs' micrographic technique), including removal of all gross tumor, surgical excision of tissue specimens, mapping, color coding of specimens, microscopic examination of specimens by the surgeon, and complete histopathologic preparation including the first routine stain; first stage, fresh tissue technique, up to 5 specimens

Code 17304 is used for the first layer of Mohs surgery. Roughly 60% of Mohs cases require only a single layer. Code 17304 includes the *preservice* work of explanation of the procedure, informed consent, and preparation of the patient for surgery. The *intraservice* work includes local anesthesia, debulking of the visible tumor, excision of the first Mohs layer, color-coding of the specimens, and mapping. It also includes the pathology services of tissue preparation, microscopic examination, and mapping of positive margins. Finally, the intraservice work includes final evaluation of the tumor-free wound to determine wound management. The *postservice* work

includes the discussion of postoperative wound management. It is important to understand these components of physician work and their relation to relative value units (RVUs) because they determine the coding and reimbursement policies.

The use of these codes is restricted to situations where one physician acts as both surgeon and pathologist. Performance of the entire procedure by one physician increases the accuracy of the technique as the risk of mapping errors is minimized. The codes are not appropriate for use when a surgeon excises tissue interpreted separately by a pathologist, even if the histologic exam is done by enface or horizontal techniques and a map is made by a pathologist for the surgeon. In those cases – something erroneously described as "modified" Mohs – the surgeon should code the appropriate excision and/or repair codes and the pathologist should report the appropriate codes for his or her service.

Code 17304 is used for the first layer only and includes the work of excision and pathology of up to five specimens. If the tissue layer is large enough that it must be cut into six or more specimens in order to examine the entire surgical margin, then code 17310 (each additional specimen, after the first 5 specimens, fixed or fresh tissue, any stage) should be used for each additional one specimen beyond the first five included in 17304. As the number of tissue blocks increases, the potential for false positive or false negative results rises, so efforts are made to evaluate each layer in as few blocks as possible. In certain circumstances, more than one slide may be prepared from the tissue block. The additional slides, regardless of the number of sections cut from the block, still count as a single specimen.

The work of processing and interpretation of one routine stain is included in the reimbursement for codes 17304 through 17310. This stain is usually hematoxylin and eosin, or toluidine blue. If other special stains are necessary after one routine stain, then the code for special stains may be used (88314), as well as immunoperoxidase stains (88342), or decalcification procedures (88311). Special stains are not typically used and in most practices are of low frequency.

Multiple Surgery: Modifier 51, Exempt

Under most circumstances, when two or more services are performed on the same patient at the same operative session on the same date of service, modifier 51 is appended. This identifies a secondary service associated with less physician work and practice expense than if it were a primary service and, therefore, is usually reimbursed less than the primary service. Some carriers refer to this as the multiple surgery reduction rule. The Mohs surgery family of codes is exempt from the need to append modifier 51. For example, when two or more separate tumors are treated on the same day, CPT code 17304 is reported for the first stage of each tumor. This does not require the use of modifier 51 because code 17304 is exempt from Medicare's multiple surgery reduction rule. (CPT Appendices list codes exempt from the use of modifier 51. Appendix E lists 17304, 17305, 17306, and 17307 and; Appendix D lists 17310 as an add-on code. All Mohs codes are exempt from the use of modifier 51.)

The rationale for this policy is that for many surgical procedures some of the work of a procedure is not repeated when two or more procedures are performed. For these procedures the intraservice work is only 50% of the total work, while the other 50% represents pre- and postservice work that overlaps when multiple procedures are performed on the same patient on the same date of service. For Mohs surgery, however, greater than 80% of the work is intraservice work that does not overlap when two or more procedures are performed. The pathology portion of Mohs surgery constitutes a large portion of this total and also is not reduced with multiple procedures. The preservice and postservice work values are small because there is a zero day global period. Together there is very little overlap or reduction in work when two or more tumors are treated on the same patient on the same day. Therefore, codes 17304-17310 are exempt from the use of modifier 51.

Codes 17305-17307

17305 Chemosurgery (Mohs micrographic technique), including removal of all

gross tumor, surgical excision of tissue specimens, mapping, color coding of specimens, microscopic examination of specimens by the surgeon, and complete histopathologic preparation including the first routine stain; second stage, fixed or fresh tissue, up to 5 specimens

17306 Chemosurgery (Mohs micrographic technique), including removal of all gross tumor, surgical excision of tissue specimens, mapping, color coding of specimens, microscopic examination of specimens by the surgeon, and complete histopathologic preparation including the first routine stain; third stage, fixed or fresh tissue, up to 5 specimens

17307 Chemosurgery (Mohs micrographic technique), including removal of all gross tumor, surgical excision of tissue specimens, mapping, color coding of specimens, microscopic examination of specimens by the surgeon, and complete histopathologic preparation including the first routine stain; additional stage(s), up to 5 specimens, each stage

Codes 17305-17307 describe the second and subsequent stages of Mohs surgery to remove positive surgical margins. The RVUs already reflect any reduction in work done for these repeat procedures compared to code 17304 (see Appendix E, *CPT 2004*). No debulking procedure is done for these codes; they represent only the additional surgical work for re-excision of positive margins and the additional pathology work for interpretation of the specimens. Like code 17304, these codes are exempt from the multiple surgery reduction rule and do not require modifier 51. When four or more stages are performed in one day, code 17307 should be used with an appropriate number of units for each additional stage. For example, if a tumor was excised with a total of five layers (stages), then codes 17304, 17305, and 17306 would each be reported one time, and code 17307 would be reported with 2 units for the additional two stages.

When Mohs surgery is performed on a single tumor but is carried over to a second day, the first layer on the next day should continue with the next code in the series. For example, the second day starts with code 17305, 17306, or 17307 but not code 17304 because no debulking is necessary. Each layer represented by 17305, 17306, or 17307 includes up to five specimens in each layer. For any individual stage that has more than five specimens, code 17310 should be used.

Code 17310

17310 Chemosurgery (Mohs micrographic technique), including removal of all gross tumor, surgical excision of tissue specimens, mapping, color coding of specimens, microscopic examination of specimens by the surgeon, and complete histopathologic preparation including the first routine stain; each additional specimen, after the first 5 specimens, fixed or fresh tissue, any stage (List separately in addition to code for primary procedure)

Code 17310 is used for unusually large tumors requiring more than five tissue blocks in any layer. It is used for less than 10% of tumors excised by Mohs surgery. This code represents the incremental increase in work for both surgery and pathology for these larger tumors. Code 17310 is reported once with the appropriate number of units for each additional specimen, after the first five specimens in any stage. A *specimen* is defined as a piece of tissue from the layer that must be examined individually and is similar to a tissue block. That is, it represents one piece of the puzzle of the Mohs surgery map. It does not represent the number of slices of tissue from the block on the glass slides or the total number of slides.

Code 17310 is an add-on code and cannot be reported without codes 17304, 17305, 17306, or 17307. Reimbursement is typically not reduced when submitted more than once (see Appendix D, *CPT 2004*). When two or more tumors are treated in one day, code 17310 is reported for each piece of tissue beyond five for any one layer. It is not appropriate to add and average

all pieces from all layers. For example, if the first tumor layer was divided into six pieces, and the second tumor layer had three pieces then code 17310 would be submitted once for the sixth specimen in the first tumor layer.

General Issues: Skin Biopsy Before Mohs Surgery

It is generally recognized that a skin biopsy and histologic diagnosis is necessary before beginning Mohs surgery. If a definitive diagnosis of the tumor is not available, the Mohs surgeon may perform a biopsy to confirm a diagnosis of skin cancer before the decision to initiate Mohs surgery. In this instance, the biopsy codes *11100, Biopsy of skin, subcutaneous tissue and/or mucous membrane (including simple closure), unless otherwise listed; single lesion,* and *11101, Biopsy of skin, subcutaneous tissue and/or mucous membrane (including simple closure), unless otherwise listed; each separate/additional lesion (List separately in addition to code for primary procedure),* and frozen section surgical pathology code 88331 may be reported separately in addition to Mohs surgery. A biopsy may also be required if:

- A biopsy report is not available with reasonable effort
- A biopsy has been done more than 90 days before surgery
- The original biopsy is ambiguous

Modifier 59 should be used with the biopsy (eg, 11100 with modifier 59) and pathology (eg, 88331 with modifier 59) codes to document that these are separate services that are not components of Mohs surgery and that may be bundled erroneously into Mohs surgery if the modifier is not used. It is not appropriate to report a biopsy or frozen section with Mohs surgery for routinely reviewing the histopathologic features of the tumor being treated.

Code 11100 is reported for the first biopsy and code 11101 for a biopsy of second or subsequent skin cancers in different locations. Code 88331 is used for the pathology interpretation of each skin biopsy specimen. Code 88332 is used only if a single surgical specimen is cut into separate tissue blocks for separate examination and usually is not billed with Mohs surgery.

Reconstruction

Some wounds after Mohs surgery are allowed to heal spontaneously by secondary intention without reconstruction of the wound; and, therefore, no RVUs are included in the Mohs family of codes for surgical repair. *Secondary intention* is the spontaneous healing of a wound by granulation and new skin regrowth. If surgical repair is necessary, then the repair codes (simple, intermediate, complex, flaps, and grafts) should be submitted separately. If another procedure is performed on the same day as Mohs surgery, such as reconstruction, typically both procedures should be reimbursed in full since Mohs surgery, is exempt from the multiple surgery reduction rule, and the repair is performed at a separate operative session. If two Mohs surgeries are performed on the same day with both involving reconstruction, the second reconstruction procedure only is subject to the 50% multiple surgery reduction rule.

Evaluation and Management Services

Evaluation and management (E/M) services provided on the same day as Mohs surgery may be reported if a significant separately identifiable service is documented. A separately identifiable service may include an initial evaluation of a new patient, an initial consultation, or other E/M service, or it may include the decision to perform surgery. Modifier 57 is utilized for the E/M service to indicate the decision to perform surgery. If an E/M service is performed with Mohs surgery alone, or when a repair code with a global period less than 90 days is done, the E/M service should be submitted with modifier 25 appended. If an E/M service is performed on the same day as a surgical reconstruction with a 90-day global period (ie, flap or graft), the E/M service should be submitted with modifier 57 according to Medicare guidelines. A separate diagnosis for the E/M service and for the Mohs surgery is not required per CPT guidelines (see modifier 25 in CPT Appendix A).

E/M services following Mohs surgery may be reported depending on the global period of any surgical reconstruction services done with Mohs

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Coding Communication: Proper Use and Reporting of Needle Electromyography: CPT Codes 95860-95870

Reporting needle electromyography (EMG) services has prompted many questions. One commonly asked question about needle EMG studies concerns the number of muscles required to be studied per limb in order to use the limb EMG codes 95860-95864. Another frequent question concerns the use of CPT codes 95869 and 95870. Codes 95869 and 95870 should be reported for limited needle EMG studies of specific muscles in the limbs and trunk musculature.

CPT Codes

95860 Needle electromyography; one extremity with or without related paraspinal areas

95861 two extremities with or without related paraspinal areas

95863 three extremities with or without related paraspinal areas

95864 four extremities with or without related paraspinal areas

95869 Needle electromyography; thoracic paraspinal muscles (excluding T1 or T12)

95870 Needle electromyography; limited study of muscles in one extremity or non-limb (axial) muscles (unilateral or bilateral), other than thoracic paraspinal, cranial nerve supplied muscles, or sphincters

CPT codes 95860, 95861, 95863, and 95864 are the most commonly used needle EMG codes. To report these codes, extremity muscles innervated by three nerves (eg, radial, ulnar, median, tibial, peroneal, or femoral; not sub-branches) or four spinal levels, must be evaluated with a minimum of five muscles studied per limb. One cannot report paraspinal muscles separately with these codes.

CPT code *95869, Needle electromyography; thoracic paraspinal muscles (excluding T1 or T12)*, should be used when exclusively studying thoracic paraspinal muscles T2-T11. Code 95869 should be reported once, or one unit can be reported, regardless of the number of levels studied or whether the study is unilateral or bilateral. CPT code 95869 cannot be reported with CPT codes 95860, 95861, 95863, nor 95864 if only T1 and/or T2 paraspinal muscles are studied and when upper extremity muscles are also studied. In that case, the thoracic paraspinal muscles are "related paraspinal areas" and are covered under the limb EMG codes.

CPT code *95870, Needle electromyography; limited study of muscles in one extremity or non-limb (axial) muscles (unilateral or bilateral), other than thoracic paraspinal, cranial nerve supplied muscles, or sphincters*, was created to include the following three different kinds of limited needle EMG studies:

- Needle EMG study of a limb or limbs that does not meet the criteria that allow use of CPT codes 95860, 95861, 95863, nor 95864 (eg, study of fewer than five muscles per limb). This code is reported once, or one unit per each extremity studied can be reported. The modifier 59 should be appended to the second, third, and fourth unit or code to indicate that separate limbs were tested.
- Needle EMG of muscles on the thorax or abdomen. This is reported once, or one unit can be reported, regardless of whether it is a unilateral or bilateral study.
- Needle EMG study of cervical or lumbar paraspinal muscles. This is reported once, or one unit may be reported, regardless of the number of levels tested or whether it is a

continued on back page

Proper Use, continued from page 6

unilateral or bilateral study. This code cannot be used when paraspinal muscles corresponding to an extremity are tested and the limb needle EMG codes 95860, 95861, 95863, or 95864 are also reported. In that case, the cervical or lumbar paraspinal muscles are "related paraspinal areas" and are covered under the limb EMG codes.

Codes 95860-95864, 95869, and 95870 can be reported together in various combinations. For example, to report for an extensive needle EMG study of one limb and a limited comparison study of the contralateral asymptomatic limb, one would report codes 95860 and 95870 together. Modifier 59 may be appended to code 95870 to indicate that it is separate and distinct from code 95860, which refers to another limb.

For example, a 45-year-old man presents for electrodiagnostic evaluation of arm pain. He reports similar pain in both arms, although the right arm is more severe than the left. The clinical concern is possible bilateral cervical radiculopathies. In order to evaluate multiple possibly involved myotomes, needle examination was performed in the following muscles on the right: first dorsal interosseus, pronator teres, triceps, deltoid, and cervical paraspinals. Findings were consistent with a C6 radiculopathy. In the left arm only, the pronator teres, triceps, and deltoid were examined to screen for a left C6-7 radiculopathy; results were normal.

In this scenario, code 95860 (since *five* muscles supplied by at least three nerves or four spinal segments were evaluated in the right arm) and code 95870 (only three muscles were examined in the left arm) should be reported.

It should be noted that in order to clarify the proper use of these codes, the Centers for Medicare and Medicaid Services formulated the following policies for Medicare patients. These policies were outlined on page 59090 in the October 31, 1997, *Federal Register* (Vol. 62, No. 211). Other carriers may also follow these guidelines. ■

AC29:04-P-024:7/04

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7/26/07

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Baltimore, MD

Dear Sirs: I have been a practicing (academic) anesthesiologist since 1969. This letter is being sent to urge CMS to analyze "the underfunding of Medicare payments for anesthesia services - and to raise fees it pays to anesthesia providers in 2008. Because the current rates are far below the mkt. rate we are concerned that this inequity creates a threat to access to anesthesia care for Medicare patients. Without some regulatory legislative relief the ability to practice is totally unsustainable & will hurt all Americans especially the elderly who are most in need of our services & expertise. Thank you for your consideration

Marilyn E O'Connor MD

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7/26/07

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Dept of Human Srv
Baltimore, MD.

Dear Sirs: I am writing to urge CMS to analyze "the underfunding" of Medicare payments for anesthesia services and to raise fees it pays to anesthesia providers in 2008. Because the current rates are far below the market rate we are concerned that this inequity creates a threat to access to anesthesia care for Medicare patients. Without some regulatory legislative relief the ability to practice is totally unsustainable. I will hurt all Americans especially the elderly who are most in need of our services & expertise.
Thank you for your consideration & time

William J Brosnan
MD

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Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my support for the proposal to increase anesthesia Medicare payments as part of the 2008 Physician Fee Schedule. As an anesthesiologist practicing for more than twenty years I am appreciative of CMS finally realizing the undervaluation of my services compared to other specialists. While this increase will benefit me somewhat in my final years of practice (I'm currently fifty-eight years old) it will have its'greatest effect by attracting medical students to this specialty as they would more easily be able to pay off their burgeoning educational debts. It would also shore up the bottom line of anesthesia practices with high Medicare populations making them more attractive to all practitioners.

I hope you will vigorously support the RUC's recommendation.

Sincerely,

Patrick J. Donahue, M.D.
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Jeffrey K. Broussard, M.D.
Richard L. Armfield, M.D.
Brian R. Conroy, M.D.

July 24, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

This letter is written to state support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. On behalf of our group of anesthesiologists, we strongly support the proposal.

Anesthesia services are currently undervalued by Medicare. The payment for an anesthesiologist's time is currently approximately $62 per hour. If an anesthesiologist is supervising a Certified Registered Nurse Anesthetists (CRNAs) – the CRNA's hourly cost, not considering the fact that they are salaried, exceeds Medicare's hourly reimbursement. Recently, I had a lawnmower serviced. The hourly repair bill, for 1.5 hours of work, was approximately the same as the total payment, including all factors of base and time units, for an average risk Medicare anesthetic that would last the same amount of time. This situation is untenable.

Some specialties may argue that their worth is greater or that an anesthesiologist or CRNA should be low on the priority of payment – and that any increase to anesthesiologists is a decrease to someone else. Please understand that we have difficulty recruiting for our specialty – we cannot continue to provide the services that are expected of us at our current reimbursement from Medicare.

In the face of rising costs and aging demographics, the reimbursement for anesthesia has fallen behind the cost of providing the service to the nation's senior population. The new RUC recommendation to increase one component of the formula calculation would result in a nearly $4.00 per unit increase for anesthesia. This step would be critical in beginning to reverse our misfortune.

We appreciate your consideration in the matter of correcting the anesthesia reimbursement system. I urge CMS to follow the recommendation by the RUC and implement the modification as soon as possible

Sincerely,

Greg Broyles
Administrator

mayo

Mayo Clinic Hospital
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July 26, 2007

Leslie V. Norwalk, Esp.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

RE: CMS-1385-P, Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I strongly support the RUC's recommendation to increase anesthesia payments in 2008.

Current Medicare payments for anesthesia services do not cover the cost of providing care to America's seniors. The advanced age and complex medical conditions of Medicare beneficiaries makes advanced skills, training, and technology necessary in order to provide safe anesthesia care.

Thank you for considering the problem of undervaluation of anesthesiology services. I urge you to fully implement the RUC's recommended anesthesia conversion factor increase at soon as possible.

Respectfully,

Kent P. Weinmeister, M.D.

Re: CMS—1385—P; Proposed Physician Fee Schedule and other Part B Payment Policies for CY 2008.
CODING --ADDITIONAL CODES FROM 5-YEAR REVIEW.

Dear Mr. Kuhn:

As a **cardiac sonographer** who provides echocardiography services to Medicare patients and others in Batesville, IN, I am writing to object to CMS's proposal to "bundle" Medicare payment for color flow Doppler (CPT Code 93325) into all echocardiography "base" services. This proposal would discontinue separate Medicare payment for color flow Doppler effective on January 1, 2008, on the grounds that color flow Doppler has become "intrinsic to the performance" of all echocardiography procedures.

In conjunction with two-dimensional echocardiography, color Doppler typically is used for identifying cardiac malfunction (such as valvular regurgitation and intra-cardiac shunting), and for quantitating the severity of these lesions. In particular, color Doppler information is critical to the decision making process in patients with suspicion of heart valve disease and appropriate selection of patients for valve surgery or medical management. In addition, color flow Doppler is important in the accurate diagnosis of many other cardiac conditions.

CMS's proposal to "bundle" (and thereby eliminate payment for) color flow Doppler completely ignores the practice expenses and physician work involved in performance and interpretation of these studies. While color flow Doppler can be performed concurrently or in concert with the imaging component of echocardiographic studies, the performance of color flow Doppler increases the sonographer time and equipment time that are required for a study; in fact, the physician and sonographer time and resources involved have, if anything, increased, as color flow Doppler's role in the evaluation of valve disease and other conditions has become more complex. The sonographer and equipment time and the associated overhead required for the performance of color flow Doppler are not included in the relative value units for any other echocardiography "base" procedure. Thus, with the stroke of a pen, the CMS proposal simply eliminates Medicare payment for a service that (as CMS itself acknowledges) is important for accurate diagnosis and that is not reimbursed under any other CPT code.

Moreover, CMS is incorrect in assuming that color flow Doppler is "intrinsic" to the provision of all echocardiography procedures. I understand that data gathered by an independent consultant and submitted by the American College of Cardiology and the American Society of Echocardiography confirm that color flow Doppler is routinely performed in conjunction with CPT code 93307. However, these data, which were previously submitted to CMS, also indicate that an estimated 400,000 color flow Doppler claims each year are provided in conjunction with 10 echocardiography imaging codes other than CPT Code 93307, including fetal echo, transesophageal echo, congenital echo and stress echo. For many of these echocardiography "base" codes, the proportion of claims that include Doppler color flow approximates or is less than 50%. More recent data submitted by the ASE in response to the Proposed Rule confirms that this practice pattern has not changed over the past several years. **[Include additional examples from your practice of CPT codes that are rarely billed with color flow Doppler.]**

For these reasons, I urge you to refrain from finalizing the proposed "bundling" of color flow Doppler into other echocardiography procedures, and to work closely with the American Society of Echocardiography to address this issue in a manner that takes into account the very real resources involved in the provision of this important service.

Sincerely yours,

Patrick McClanahan, BS, RDCS
Echo Lab Coordinator
Margaret Mary Community Hospital

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27 July 2007

Leslie V Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P

Dear Ms. Norwalk:

I would like to express my support and gratitude for CMS considering and hopefully instituting a long overdue increase to anesthesia payments under the 2008 Physician Fee Schedule. I understand how complicated an issue this is when considering all of the interest groups and budgetary issues involved however, there is no question that anesthesia services have been greatly undervalued since the RBRVS was instituted.

With the current Medicare payment for anesthesia services standing at only $16.19 per unit anesthesia groups in this country are essentially subsidizing, a situation which is untenable. It would be a sad day indeed if senior citizens in this country were unable to have access to the anesthesiology care they deserve. The current RUC recommendation that CMS increase the anesthesia conversion factor by 32% would go a long way to correct the undervaluation of anesthesia services. My understanding is that this recommendation was accepted by CMS, which I consider to be a fair and wise decision. I hope to see this finalized for the coming year.

Thank you for your consideration in this matter.

Sincerely,

Jeffrey Gordon, MD
President

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July 30, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1385–P
P.O. Box 8018
Baltimore, MD 21244–8018

Re: CMS—1385—P; Proposed Physician Fee Schedule and other Part B Payment Policies for CY 2008. **CODING --ADDITIONAL CODES FROM 5-YEAR REVIEW.**

To Whom It May Concern:

I am writing this letter on behalf of Children's Healthcare of Atlanta Sibley Heart Center, a 34-physician practice. As a major provider of pediatric cardiology diagnosis and treatment services in the state of Georgia, our doctors would like to express their earnest opposition to the proposed bundling of color flow Doppler (CPT Code 93325) into all echocardiography "base" services.

Echocardiography in infants, children and young adults, with or without congenital heart disease, is an extremely skilled and time-consuming activity. The concept that the inclusion of color flow Doppler velocity is intrinsic with the routine two dimensional exam and does not require any increased sonographer work time, physician examination time, or interpretive skill, is sadly erroneous.

Certainly, perhaps contrary to popular belief, we judiciously decide which patients do not need color flow Doppler, such as checking for pericardial effusion or measuring ventricular contractility. However, when used, the complexity of the application of flow Doppler in our patients is significant. We carefully review each vessel, valve, chamber and septum for subtle evidence of congenital anomalies even to the point of demonstrating the direction of flow in the coronary arteries. This is also often performed in the setting of an uncooperative child. Additionally, due to the different flow velocities in children, often more than one frequency of transducer has to be used, repeating examinations of previously scanned regions, in a single patient to avoid artifactual signals and incorrect interpretation. The work for both sonographer and physician, to optimize the color flow Doppler, is therefore a very significant addition to the routine two-dimensional exam. Also, because of the multiple sizes of our patients, which may range from 500-gram premature infants to 300-pound high school athletes, we have to equip all our machines with multiple transducers at additional expense primarily for the Doppler examination.

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Sibley Heart Center
CARDIOLOGY

It is important that we prevent this decrease in the reimbursement amounts available to our profession, and the subsequent effect on our ability to provide quality patient care.

It is our hope that these comments clarify the inequities of bundling Echo and Doppler codes and we again strenuously urge you to cancel this erroneous proposal.

Sincerely,

Robert M. Campbell, MD
CMO, Children's Healthcare of Atlanta Sibley Heart Center
Director, Sibley Heart Center Cardiology
Division Director of Cardiology, Department of Pediatrics,
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July 30, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services,
Attention: CMS-1385-P,
P.O. Box 8018,
Baltimore, MD 21244-8018

Re: File Code CMS-1385-P; Comments to Proposed Rules contained therein relating to Independent Diagnostic Testing Facilities

Ladies and Gentlemen:

On July 2, 2007, the Centers for Medicare and Medicaid Services ("CMS") posted on its website the proposed updates to the Medicare Physician Fee Schedule for 2008, which includes significant revisions to the IDTF performance standards. This posting was officially published July 12, 2007 in the *Federal Register* (72 Fed. Reg. 38121). As set forth in the proposed rules, the public has been afforded the opportunity to respond and provide comments thereto. This correspondence is intended to proffer such comments to those particular sections set forth herein that relate to revisions of those performance standards for Independent Diagnostic Testing Facilities.

The following are the current rules for which the text has been marked to show the proposed rules, together with comments on certain sections that cause concern from a legal and business standpoint:

IDTF ISSUES

Liability Insurance --410.33(2)(6)

§ 410.33(g) ***Application certification standards.***

6) Have a comprehensive liability insurance policy of at least $300,000 per location that covers both the place of business and all customers and employees of the IDTF. The policy must be carried by a nonrelative-owned company ~~and list the serial numbers of any and all diagnostic equipment used by the IDTF, whether the equipment is stationary, in a mobile unit, or at the beneficiary's residence~~. Failure to maintain required insurance at all times will result in revocation of the IDTF's billing privileges retroactive to the date the insurance lapsed. IDTF

suppliers are responsible for providing the contact information for the issuing insurance agent and the underwriter. In addition, the IDTF must -

(i) Ensure that the insurance policy must remain in force at all times and provide coverage of at least $300,000 per incident:

(ii) Notify the CMS designated contractor in writing of any policy changes or cancellations; and

(iii) List the CMS designated contractor as a Certificate Holder on the policy.

The stated rationale for requiring that IDTFs add the CMS designated contractor as a Certificate Holder on the policy is to enable the designated contractor to, at any time, directly verify with the IDTF's insurance underwriter and agent that the IDTF is maintaining the required liability insurance. From a business standpoint, this does not appear to cause any concern among IDTFs. However, it remains to be seen whether insurance underwriters will be open to this idea of adding the government as certificate holder on an insurance policy since that could, theoretically, provide the government with contractual rights to indemnification or payment that it would not otherwise have. We anticipate there could be some resistance regarding this requirement. Prior to making this formal requirement, we would suggest a survey of some of the major insurance carriers which provide this type of coverage to IDTFs to determine if this performance standard is achievable.

Supervising Physician - § 410.33(b)(1)

§ 410.33(b) ***Supervising physician.*** *(1)*Each supervising physician must be limited to providing supervision to no more than three IDTF sites.This applies to both fixed sites and mobile units where three concurrent operations are capable of performing tests. ~~The IDTF supervisingphysician is responsible for the overall operation and administration of the IDTFs, including the employmentof personnel who are competent to perform test procedures, record and reporttest results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations.~~

Although the text of the proposed regulation does not specifically state this, the preamble discussion clarifies that the three IDTF supervision limit is intended to apply to those physicians *providing general supervision services* (rather than direct or personal supervision services). In addition, the definition of "sites" must be considered in light of whether the IDTF is in a fixed location (one permanent site, whether it is in a physician office or other continuous location) or conducts business on a mobile basis as allowed by CMS. This rule may be practical for those fixed locations since the site of services does not change, but not necessarily for those operating on a mobile basis, unless clarified.

The nature of an IDTF's business is to go to the physician's office when a diagnostic test is necessary based upon the determination of the patient by the physician. It is not out of the ordinary for a mobile IDTF technician to provide services to a single physician's office once during a week, and not to provide services again at that location for some time. In fact, a mobile IDTF technician may provide services to any number of different office locations during a week. From a business standpoint, it would not be feasible or appropriate to require a mobile IDTF to have a different supervising physician for every three (3) of those multiple office locations serviced as this change would require. The volume of tests would be so low, it would be impossible in many cases to reach a financial agreement with enough supervising physicians for a mobile IDTF to be financially viable. In fact, this proposed rule may have the contrary effect and instead encourage mobile IDTFs to enter into financial arrangements that do not comply with various fraud and abuse laws in order to avoid such financial hardships. In light of the difference in the business models of fixed versus mobile IDTFs, the requirement for a set maximum of supervising physicians for a mobile IDTF should be based upon its home office, which is normally its only fixed location.

The problems resulting from this proposed rule were recently experienced by one mobile IDTF. In the period immediately following initial publication of the CY 2007 PFS final rule, one carrier's enrollment manager insisted on a site visit prior to the rule being revoked. The enrollment manager and staff informed the IDTF that the general supervising doctor could only supervise technicians performing tests at *three (3) locations*. The mobile IDTF never sees patients in its home office and while it may service a large number of clients, the supervising physicians is actually supervising a limited number of technicians and expensive mobile equipment. Language was located in the CFR that caused the carrier to revisit its position but there clearly was intent to improperly enforce the wording which would have forced the IDTF out of business. Therefore, it is critical to properly differentiate between fixed and mobile IDTFs business models and the differences in the means by which IDTFs using these models provide services and furthermore, to clarify the definition of "site" versus "testing locations" distincttion.

Enrollment Date -, 410.33(i)

§ 410.33 (i) ***Effective date of billing privileges.*** The effective date of billing privileges for a newly enrolled IDTF is the later of the following:

(1) The filing date of the Medicare enrollment application that was subsequently approved by a fee-for-service contractor; or

(2) The date the IDTF first furnished services at its new practice location;

(3) The filing date of the Medicare enrollment application is the date that the Medicare fee-for-service contractor receives a signed provider enrollment application that is able to process for approval.

While this new rule would not entirely preclude IDTFs from retroactively billing for services, it would limit the period of time for retroactive billing. Unfortunately, under this new rule, an IDTF could be subject to a delayed enrollment date if the initial application is rejected, for any reason, by the CMS designated contractor. While we have no issue with the purpose of the rule, it must be tied to a requirement that the CMS designated contractor process the application in a timely fashion. One IDTF's experience with multiple carriers is that it is taking six (6) or more months to get an application processed. In one case, a mandamus action had to be filed in federal court in order to compel the CMS designated contractor to process the application. Once this extraordinary action was initiated, the CMS designated contractor was then able to immediately process the application without explanation.

An inherent problem with this rule pertains to the economic effect on small and medium-sized businesses in complying with the requirements for filing an application and having it processed. For the IDTF application to be processed, the IDTF must list the credentialed employee on the application itself in order for it to be processed. This is inappropriate and has the effect of rendereing impractical new IDTF applications by small and medium-sized businesses if they have to hire expensive, properly credentialed technicians, but cannot use them or bill for them during this often extended time period. Furthermore, there is no benefit to the patient nor the Medicare Trust Fund in forcing the IDTF to hire a technician and have them perform few (or no) tests for six (6) months to a year. This also is clearly not the best way to ensure the quality of testing by the technician as they are unable to routinely deliver services to maintain their skills. The net effect is that only large organizations with significant funding which can afford to lose money for many months can become Medicare providers. We do not believe this is the intent of Congress.

Prohibition on Sharing - § 410.33(g)(15)

§ 41033(g) Application certification standards.

(15) Does not share space, equipment, or staff or sublease its operations to another individual or organization.

It is understood that the purpose of this standard is supposedly to ensure that an IDTF's operations are separate and distinct from the operations of other entities, so that CMS can confirm that the IDTF is operating in compliance with the Medicare conditions of participation. In addition, CMS noted that shared facility arrangements raise concerns under the physician self-referral prohibition and the federal anti-kickback statute. There are instances where this proposed rule would prohibit arrangements that fall outside of the purpose of this rule. While it is agreed that this arrangement would not be appropriate for a home-based office, an example currently common within the health care marketplace that would be prohibited under this proposed rule would be where a IDTF utilizes hotel or motel rooms for sleep lab studies. In this example, the IDTF contracts directly with a hotel or motel to rent a room for studies, and there is no issue regarding any arrangement with a physician that would be a concern under the intent of

the rule. If the proposed rule is allowed to be finalized, it should be amended to allow for the sharing of locations as long as the arrangements are of such a nature not to trigger the concerns regarding Medicare conditions of participation. In order to regulate a proper setting for such a shared facility relationship, there could be requirements as to size, cleanliness or quality in order to ensure a proper location to perform the study.

CMS is proposing that the above standard apply only to fixed-base IDTF locations, but has requested public comment on whether this standard should also apply to mobile IDTFs. In its discussion of the proposed standard, CMS notes that it intends for the prohibition on sharing of office space to apply to shared waiting rooms, and for the prohibition on shared staff to apply to *supervising physicians.* With regard to sharing of space and staff with mobile IDTFs, if the rule is too restrictive, it will effectively put many of these entities out of business. The mobile IDTF typically rents space and staff from existing offices to perform their services. They use the front desk staff to sign in and move the patient to the exam/treatment room.

We are unclear at this time as to how this prohibition on sharing supervising physicians could possibly be implemented since, in many cases, the supervising physician of an IDTF is, in fact, an individual whose services are "shared" by an IDTF and that physician's own group practice. If this standard is adopted, it would clearly eliminate the ability of an IDTF to enter into any type of sublease arrangement with a physician practice, a hospital (including "under arrangement" agreements), or any other individual or entity - regardless of whether the sublease was "per click," "block time," or any variation thereof.

Where direct supervision is required, if the mobile IDTF can not rent space from an existing office, it would have no choice by to hire physicians to sit in an office while the testing was done. This would, in effect, require personal supervision because the doctor would not be seeing patients in this location unless it was established as a bona-fide office, and then they would pay rent, meaning the space would become commingled. It becomes a circular problem. It is likely that CMS will need to further refine this standard in order to permit or address the sharing of supervising physicians.

One method of satisfying the concern and also allowing for mobile IDTFs to continue to operate in this setting would be to make the OIG guidelines on the proper payment of rent for staff and space be a part of the 855b, or an addition to the new "14 Points" guidelines that have been proposed. A standard form or a separate lease agreement could be required and made available in the same manner as patient medical records for examination by the carrier. This would give the carrier clear enforcement ability to determine if the IDTF was promoting a business model that was inadvertently or intentionally leading the doctor to violate the self referral rule.

We thank you for the opportunity to tender our comments on the proposed rules relating to IDTFs.

Very truly yours,

Patrick D. Souter

PDS;tr

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of Medical Specialties
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Key Certifying Boards and Medicare's Physician Quality Reporting Initiative (PQRI):

Comments on CMS Rulemaking (CMS-1385-P)

August 3, 2007

Issue Identifier: "T" Division B of the Tax Relief and Health Care Act – Medicare Improvements and Extension Act of 2006

The American Board of Medical Specialties (ABMS) and the Centers for Medicare and Medicaid Services (CMS) share a common set of challenges and goals as it relates to enhancing physician quality, efficiency, and appropriateness of care. The certifying boards propose working with CMS on this set of challenges to support their efforts to drive improvement through the Physician Quality Reporting Initiative (PQRI). The following are comments for CMS consideration as the agency finalizes rulemaking for the 2008 PQRI program.

Our common challenges include:

- Numerous and redundant (wasteful) physician-level measurement requirements;
- Evaluations of physicians that are largely based on condition-specific measures and, therefore, lack the breadth and scope of more comprehensive assessment;
- Insufficient physician engagement in quality improvement and potentially in the PQRI program;
- Expensive and time-consuming collection/reporting of clinical data, particularly for smaller practices; and
- The scarcity of demonstrated, valid, and meaningful physician-level performance measures suitable for public reporting to drive improvement.

Our proposed solution to these challenges is for CMS to recognize *specific* specialty boards' Maintenance of Certification (MOC) programs as a "composite structural" measure that would entirely fulfill the PQRI requirements for 2008 for physicians who select this pathway. Further, these certifying boards are prepared to report the PQRI measures and other NQF endorsed measures to CMS or meaningful participation in an approved successful QI initiative, with the authorization of the physician, as soon as the agency is prepared to "catch" such data. It is our understanding that they are not yet prepared to do so in 2008.

ABMS proposes that CMS recognize these Maintenance of Certification programs as a "composite structural" measure because they are a well thought out combination of measures: practice performance, knowledge and judgment, patient experience of care, and structure of practice. For a description of ABMS maintenance of certification programs and evidence related to certification, please see Addendum "A."

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This proposal would expand the number of CMS structural measures, adding to those listed in table 19 of the draft rules (p.427). The certifying boards – defined as "standard bearing" boards – that are prepared to move forward for 2008 include several that are key to the Medicare program: the American Boards of Family Medicine (ABFM), Internal Medicine (ABIM), Ophthalmology (ABO), Pediatrics (ABP), and Surgery (ABS). Collectively, 22,602 physicians maintain their certificates in these clinical specialties in any given year; CMS's acceptance of our proposed approach could raise this number substantially. ABMS fully expects that additional member boards will seek to participate in PQRI in subsequent years.

To make this composite structural measure as meaningful as possible, these boards have agreed to the following commitments and program changes:

- Publicly commit to report to CMS two options for physician quality: a) all NQF-endorsed measures that these boards collect as part of Maintenance of Certification, when an individual physician authorizes such reporting and the agency is prepared to receive such data; or b) evidence of meaningful physician participation in an ABMS board approved quality measurement effort that demonstrates significant improvement in quality of care. Moving forward, these boards are committed to engaging with patients and payers to ensure that Maintenance of Certification – and the scientifically valid, meaningful data that it provides – is relevant to informing choice of physician and to driving improvements in performance;

- Work with the agency on a "registry pilot" (p. 433 of draft rulemaking) to help in facilitating the reporting of clinical data and to facilitate the use of registries to improve care;

- Put their entire Maintenance of Certification programs through an NQF review process in order to obtain endorsement as a valid structural composite measure per the draft rules (p. 427) and to simultaneously pursue AQA adoption of this measure by November 15, 2007;

- Require that any physician wishing to participate in the CMS program through a recognized Maintenance of Certification pathway be enrolled in Maintenance of Certification and complete a self-assessment of practice performance within the measurement year, based on NQF endorsed measures. This change would greatly increase the periodicity of physician self assessment, which currently ranges from once every 3 years to once every10 years;

- Include NQF-endorsed measures in their practice assessment programs, or measures that have received "time-limited" NQF endorsement with the agreement that they will be taken through the NQF process within 12-18 months. Such measures include clinical measures and the Clinician and Group CAHPS Survey (CG-CAHPS). Boards will use registries and modules that use additional measures that are on the cutting edge of quality measurement and will be a source of future endorsed measures of quality;

- In programs where medical record sampling is used, the sampling strategy will be brought into line with national guidelines for physician-level performance measurement, while maintaining an approach that is less burdensome and more meaningful than administrative data collection;

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- MOC programs will describe the explicit process for assuring data quality, validity, and a review or audit process for both the data collection and reporting and the quality improvement process. This will require boards to modify existing policy to allow for an audit of a sample of physician reports, perhaps performed by the QIOs (a possible validation pathway, per p. 439 of the draft rules); and

- Make clear to physicians that any falsification of reporting will result in loss of certification.

The summary of the specifications for the proposed composite structural measure are in Addendum B.

ABMS's rationale for this approach includes the following:

- **Reducing Wasteful Redundancy.** The five standard bearing boards' practice performance assessment modules strive to use NQF measures (including CG-CAHPS) – the same measures required by CMS's PQRI program and many more – and the boards have agreed to put other measures that are appropriate for public reporting through the NQF endorsement process within the next 12-18 months;

- **Explicitly Linking Measurement and Practice-Based Quality Improvement.** Maintenance of Certification requires a self-assessment of performance, offers a rapid comparison to national guidelines (and where available to national benchmarks) and requires implementation of a QI plan to address areas of weakness including participation in an approved successful ongoing QI initiative. Alignment with the boards would make data collection and reporting to CMS the front-end of a professionally led effort to identify and capitalize on opportunities to improve care, in small practices as well as larger ones;

- **Aligning with Existing Private Payer Approaches.** The Boards of Internal Medicine and Family Medicine have already aligned Maintenance of Certification with numerous health plan reward/recognition programs – whose programs now cover more than half of all insured Americans. Other boards are actively engaged in consummating similar agreements. CMS's adoption of this approach would bring the professional, private payer and public payer sectors into alignment, thereby driving more physicians to measure and improve their performance;

- **Encouraging Efficient and Meaningful Use of Practice Performance Measures.** With many of the boards' Maintenance of Certification programs, physicians themselves collect the data from their records which are used to calculate measures – giving them firsthand observation of what they are – and are not– doing to care for their patients. Physicians collect data from their patients, through the CG-CAHPS survey, which gives them the opportunity to listen to their patients and make improvements based on what those patients tell them. These clinical and patient experience data—and the practice infrastructure data collected by some of the boards—are actionable, engaging and uniquely motivational; and practices of all sizes can readily participate in examining their own performance.

American Board of Medical Specialties
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- **Promoting a Multi-Dimensional Approach.** Certification is a multi-dimensional evaluation of physicians that includes performance, knowledge and judgment, diagnostic acumen, clinical and communications skills, professional behavior, and capacity to improve care and to function in complex systems – allowing for a more comprehensive assessment than do condition specific measures;

- **Encouraging Engagement of More Experienced Physicians.** Linkage with CMS would provide an important incentive for physicians certified prior to time-limited certification to go through the Maintenance of Certification process;

- **Working Closely with CMS to Operationalize Board Reporting of Clinical Data and Successful Performance in Improving Care.** In the absence of widespread adoption of EHRs that could facilitate the reporting of valid and meaningful performance measures that are based on clinical data, the boards can act as very effective intermediaries to report clinical data and/or successful improvement of care to CMS at the request of individual physicians. The standard bearing boards are very motivated to work with CMS to operationalize registry reporting under Option 3 of the proposed rules (p.433); initial ideas are captured in Addendum C.

ABMS and the standard bearing boards believe that this approach will allow CMS to collaborate with medical boards to more effectively engage physicians – critical partners in our collective efforts to enhance the performance of our nation's healthcare system. Further, CMS's recognition of specific MOC programs as completely fulfilling PQRI requirements will provide an important incentive for physicians with time- unlimited certification to engage in quality assessment, reporting and improvement through maintenance of certification. Given evidence that skills and knowledge deteriorate over time without dedicated effort to main competence,[1] this is a critical segment of the physician population to reach.

In addition, qualifying for additional payment from CMS for participating in the PQRI-eligible Maintenance of Certification programs will provide an important incentive to boards which must make substantive modifications to their current programs (detailed above) and related investment. Finally, and most importantly, we believe that Maintenance of Certification as a composite structural measure is as, or more, robust than the PQRI measurement requirements proposed in the draft rules (CMS-1385-P).

Consumer and purchaser organizations also support our approach, including leading national organizations such as the **National Partnership for Women and Families,** the **National Business Coalition on Health**, and the **Pacific Business Group on Health**. We look forward to working with CMS to advance quality – leveraging professional and payer approaches – and together reaching a broader array of physicians, whether they are working in solo practice or large multi-specialty groups. All patients – including those covered by Medicare – would be the beneficiaries of such a partnership, as would our entire healthcare system. We sincerely hope that you agree with our proposed approach.

[1] Choudhry NK, Fletcher RH, Soumeria SB. Systematic Review: The Relationship between Clinical Experience and Quality of Health Care. Annals of Internal Medicine. 2005; 142: 260-273.

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Respectfully submitted on August 3, 2007:

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Addendum A

I. Standard Bearing Boards Maintenance of Certification Programs

A. ABMS MOC Framework
MOC focuses on the six general competencies which have been deemed necessary for physician specialists:

- Patient care
- Medical knowledge
- Practice-based learning and improvement
- Interpersonal and communications skills
- Professionalism
- Systems-based practice

The six competencies are incorporated into four component categories and adopted by all ABMS Member Boards as the model for recertifying their physician specialists.

Part I: Professional Standing
Physicians must hold a valid, unrestricted medical license in at least one state or jurisdiction in the United States, its territories or Canada.

Part II: Lifelong Learning and Self-Assessment
Physicians are required to participate in educational and self-assessment programs that meet specialty specific standards set by the Member Boards for its physician diplomates to provide quality care in that specialty.

Part III: Cognitive Expertise
Physicians must prove, through formalized examination, that they have the fundamental, practice related and practice environment
related knowledge to provide quality care in a particular specialty.

Part IV: Practice Performance Assessment
Physicians are evaluated in their clinical practice according to specialty-specific standards for patient care. They are asked to demonstrate that they can assess the quality of care they provide compared to peers and national benchmarks and then apply the best evidence or consensus recommendations to improve that care using follow-up assessments. The aim of MOC is career long professional development around the six core competencies correlated with delivering high quality care around the six IOM dimensions.

II. Standard Bearing Boards Practice Performance Assessment Programs

A. ABFM Practice Performance Module (PPM)
PPMs are web-based, quality improvement modules in health areas which generally correspond to the Self-Assessment Modules. Each physician will assess his or her care of patients using evidence-based

quality indicators. After a physician enters data from ten patients into the ABFM website, feedback is provided for each of these quality indicators. The performance data is used by the physician to choose an indicator for which a quality improvement plan will be designed. Using a menu of interventions available from various online sources, the physician designs a plan of improvement, submits the plan, and implements the plan in practice. After a minimum of three months, the physician assesses the care provided to ten patients in the chosen health area and inputs the data to the ABFM website. The physician then is able to compare pre- and post-intervention performance, and compare their results to those of their peers. Evidence of improvement is not required to satisfy this requirement.

B. ABIM Practice Improvement Module (PIM)

PIMs are web-based self-evaluation tools that guide physicians through chart abstraction (25 charts), patient survey (25 surveys) and practice system inventory to establish a robust multi-dimensional practice performance assessment for a chronic condition or preventive service. The interactive report guides physician reflection on detailed performance data, selection of areas for improvement, and creation of an improvement plan with goals and strategies. Once the plan has been tried and its effect measured, the physician reports the results to ABIM.

C. ABP

ABP's Practice Performance Assessment consists of two components designed to address quality improvement in the general pediatrician's practice.

Component A, which will be available by 2008 or 2009, uses patient surveys to solicit information about a participant's interpersonal and communication skills and professionalism. Once during the seven-year life span of a certificate, physicians will circulate patient surveys provided by the ABP. Patients will submit anonymous responses directly to the ABP. Feedback will provide comparisons of ratings on key competencies relative to other pediatricians who are participating in the Pediatric Maintenance of Certification Program. There will be no minimum score for this activity.

Component B, the Practice Performance component, is designed to help physicians learn about quality improvement strategies, collect and analyze practice data over time, and document improved quality of care. This component is satisfied by successful participation in an ABP-approved program. The Education in Quality Improvement for Pediatric Practice (eQIPP) program developed and administered by the American Academy of Pediatrics through its PediaLink™ program is the only approved web-based program for this requirement. eQIPP involves the use of anonymous patient chart information from one's own practice and may include the use of simulated chart information supplied by the eQIPP program. Several other web-based products will be available by the end of 2008 including an ABMS developed patient safety module. The ABP has also developed standards for valid ongoing Quality Improvement efforts and standards for meaningful physician participation in these efforts for credit for Part 4 Practice Performance. Approved QI efforts must show improvement in care. Several QI projects have been approved in neonatology and applications are under review in general pediatrics and other subspecialty areas.

D. ABO Office Record Review

The ORR is an on-line self review of clinical practice utilizing 15 current patient records. The ORR consists of 37 modules that encompass practice patterns related to different ophthalmic diagnoses (ORR modules). To complete the ORR, physicians review 15 of their patient records according to three ORR modules of choice (five records for each module). This self-review assesses the quality of practice via documentation of appropriate measurements, diagnosis, management, treatment and follow-up.

ORR module selection should be based on a physician's clinical practice because for each of the three ORR modules chosen, physicians will select five records of patients they have seen with that diagnosis within the timeframe specified. To register for each module, the physician is required to provide the following information about each patient record they will review:

- Year of birth, initial visit date, most-recent visit date, and a unique record identifier that will enable the physician to identify the records selected. Physicians should use an internal chart referencing number; this identifier is for the physician's use in identifying the patient records that will be used for the review.
- Attestation of direct patient care responsibility for each patient record selected for the review. Please note that direct patient care is required. If a physician is in a group-partnership or teaching position, exclusive care of the patient is not mandatory for selection of patient charts for the ORR, but he/she must be actively involved in the patient's care.

Physicians receive immediate feedback upon completion of the ORR.

E. ABS

To satisfy the requirements for practice performance assessment, physicians maintaining their American Board of Surgery Certification must participate in a national, regional or local surgical outcomes database or quality assessment program. Some acceptable programs:

- Bariatric Surgery Database (ACS or ASBS)
- Burn Registry (NTRACS or Other)
- CMS Physician Quality Reporting Initiative (PQRI - formerly PVRP)
- National Surgical Quality Improvement Project (NSQIP)
- National Trauma Data Bank (NTDB)
- Society of American Gastrointestinal Endoscopic Surgeons (SAGES) Outcomes Initiative
- Society of Thoracic Surgeons (STS) National Database
- Surgical Care Improvement Project (SCIP)
- United Network for Organ Sharing (UNOS)
- VSB-Defined Outcomes Report - for vascular surgery only

In cases where no such program is available, the ABS will consider the use of individual practice data.

Periodic communication skills assessment based on patient feedback will also be required as part of the practice assessment component, but this is not yet finalized.

III. Certification and Quality – The Evidence

Summary of Studies Examining the Relationship Between Physician Certification and Quality

Author	Specialty(ies) Studied	Quality Measures	Results
Kelly & Hellinger (1986) (57)	Surgery (1241 subjects)	In-hospital: 1. Mortality: peptic ulcer surgery 2. Mortality: stomach cancer 3. Mortality: abdominal aneurysm	1. Certified Surgery better (2% lower mortality) 2. No difference 3. No difference
Kelly and Hellinger (1987) (58)	Internal Medicine (IM) and Family Medicine (FM) (1170 subjects)	1. Mortality for cardiac catheterization (IM) 2. Mortality for AMI* (IM) 3. Mortality for AMI* (FM)	1. No difference 2. Certified IM better (3.1% lower mortality) 3. Certified FM better (4.2% lower mortality)
Ramsey et al. (1989) (59)	Internal Medicine (IM) (259 subjects)	1. Preventive care 2. Hemoglobin A1c for diabetics 3. Blood pressure control 4. Patient satisfaction	1. Certified IM better 2. Certified IM better (lower hgb A1c levels) 3. No difference 4. No difference
Tussing & Wojtowycz (1993) (47)	Obstetrics and Gynecology (Ob-Gyn) (1740 subjects)	1. Cesarean rates	1. Certified Ob-Gyn worse (higher rates)
Haas et al (1995) (60)	Obstetrics and Gynecology Family Medicine (924 subjects)	1. Prenatal visits 2. Low birth-weight babies	1. Certified Ob-Gyn and FM better (more prenatal visits) 2. Certified Ob-Gyn better (less low weight babies)
Rutledge et al (1996) (61)	Surgery (sample size not provided)	1. Mortality rate for ruptured abdominal aortic aneurysm	1. Certified Surgeons better (8.9% difference in rate)
Heck et al. (1998) (62)	Orthopedics (48 subjects)	Total knee replacement: 1. Postoperative pain 2. Physical function 3. Mental function 4. Knee function 5. Complications	1. No difference 2. No difference 3. No difference 4. No difference 5. No difference

Pearce et al. (1999) (49)	Vascular Surgery (Comparison group: general surgeons no certified in vascular surgery) (531-734 subjects depending on year and procedure)	1. Mortality/complications post carotid endarterectomy 2. Mortality/complications post abdominal aneurysm repair 3. Mortality/complications post lower leg bypass graft	1. Certified Vascular Surgeon better (15% lower rate) 2. Certified Vascular Surgeon better (24% lower rate) 3. No difference
Hanson et al. (2001) (63)	Pediatrics (60 subjects)	1. Childhood immunization rates for poor children	1. Certified pediatricians better (9% absolute difference in rate)
Silber et al (2002) (64)	Anesthesia (mid career providers) (541 subjects)	1. Mortality 2. Failure to rescue	1. Certified Anesthesiologist better (OR† 1.13 for non-certified) 2. Certified Anesthesiologist better (OR† 1.13 for non-certified)
Prystowsky et al (2002) (65)	Surgery (514 subjects)	1. Mortality for colorectal surgery 2. Complications for colorectal surgery	1. Certified Surgeons better (OR† 1.4 for non-certified) 2. Certified Surgeons better (OR† 1.2 for non-certified)
Norcini et al (2002) (51-52)	Internal Medicine Family Medicine Cardiology (4,546 subjects)	1. Mortality for AMI*	1. Certified physicians better (15% lower mortality)
Masoudi et al (2005) (66)	Internal Medicine Cardiology (not provided; involved 19,226 patients in US)	1. Inappropriate use of Spironolactone in Congestive Heart Failure	1. Certified physicians better (OR† 0.7 for lower inappropriate use)
Pham et al (2005) (50)	Internal Medicine Family Medicine (3,660 subjects)	1. Hemoglobin A1C measurement for diabetics 2. Eye exam for diabetic 3. Mammography 4. Colon cancer screening 5. Influenza vaccine 6. Pneumovax vaccine	1. No difference 2. No difference 3. Certified physician better (OR† 1.34) 4. Certified physicians better (OR† 1.27) 5. No difference 6. No difference 7.

Chen et al (2006) (53)	Internal Medicine Family Medicine Cardiology (IM = 34,578 subjects; FM = 21,390 subjects; Cardiology = 45,283 subjects)	Acute Myocardial infarction care 1. Aspirin on admission 2. Beta-blocker on admission 3. Aspirin on discharge 4. Beta-blocker on discharge 5. 30-day mortality	1. Certified IM and Cardiologist better 2. Certified IM and Cardiologist better 3. Certified IM and Cardiologist better 4. Certified Cardiologist better 5. No difference for IM Cardiologist Note: No significant difference in all FM comparisons

* AMI = Acute myocardial infarction † OR = Odds ratio.

Addendum B

MAINTENCE OF CERTIFICATION "COMPOSITE STRUCTURAL" MEASURE OF PHYSICIAN QUALITY:

PROPOSED FOR CMS PQRI PROGRAM

Approved by the ABMS Board of Directors

July 9, 2007

1. Enrolled in the ABMS Board's Maintenance of Certification program

a. Passing an examination of knowledge within the past 10 years; or if greater than 10 years within 3 years after enrolling in the Maintenance of Certification program
b. Unrestricted license to practice medicine and other appropriate volume or credentials criteria
c. Has met milestone for Part-2, self-assessment of knowledge.

2. Completion of an Assessment of Practice Performance and Improvement within the reporting period (e.g. 12 months)

Completion of this requirement means meaningful participation by the physician in the measurement and improvement of processes, outcomes, or structures of the practice where care is provided. Two approaches may be used:

a. Participation in a solo or small group self-assessment of performance measurement and improvement in the physician's practice.
    i. At least three of the measures will have been endorsed by NQF, are in the process of review; or will be taken through NQF in the next 12-18 months.
    ii. The sampling strategy used to calculate measures will meet national guidelines (BTE, NCQA) such as 35 charts in a retrospective analysis.
    iii. Boards will assure the veracity of the measures reported by physician through a random audit of 2-3% of physician reports. Falsification will result in withdrawal of certification.
b. Documented, valid participation in an ABMS Board approved multi-center systematic improvement effort that demonstrates positive outcomes for a defined population.[1] Criteria for approval will include meeting the CMS standards for multi-center registry use in PQRI.[2]

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[1] For example, but not exclusively Northern New England Cardiovascular Study Group, Cystic Fibrosis Foundation Improvement Program, Vermont Oxford Neonatal Network Improvement Projects, California Perinatal Quality Care Collaborative, NACHRI Blood Stream Infection Collaborative

[2] For example, but not exclusively the STS registry or the NSQIP registry

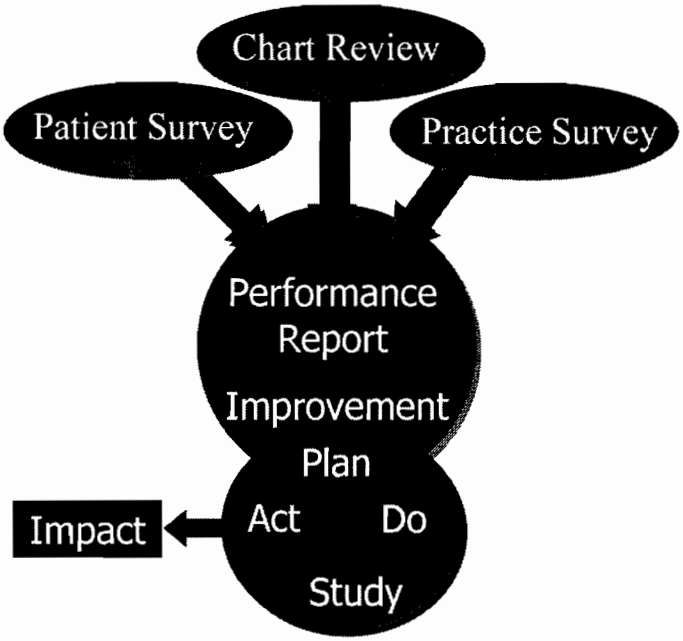
Addendum C

Most of the standard-bearing certifying boards have operational technology for the submission of clinical data, calculation of results and generation of performance reports. This technology permits physicians participating in Maintenance of Certification to abstract clinical data and deliver it to the Board via the web, the board then calculates performance measures and provides the participating physician with a summarized report (also via the web). These data collection and reporting processes are robust and reliable, and offer participating physicians a broad range of information about patients with selected (and in most cases Medicare-relevant) conditions, including performance results on measures that are among the PQRI/proposed 2008 sets.

Over 80% of the physician practices in the United States use paper medical records for recording clinical data. It is impossible to use important clinical data for calculating performance measures without adding a step to the work flow, either through additional codes added to the billing process, or through abstraction of data from a sample of medical records. The Boards apply the second process in recognition of the inherent errors in using codes to translate clinical states. The evidence substantiates that a scientific valid sample of medical records can provide as accurate an estimate of the practice performance on measures as can a limited set of codes used to translate clinical data into billing data. Therefore boards will use a prospective sample of 25 to 35 patient with the condition being measured and abstract the data recorded in the medical record for calculation of performance measures. The number of patients selected will be based on the best scientific evidence available from the statistical analysis of the use of measures in practice.

These data collection and reporting technologies are linked to the collection of data about patient experience (CG-CAHPS survey), practice systems (for some boards), and to a quality improvement planning tool. With CG-CAHPS, physicians can make improvements in their practices based on valid, objective feedback from patients that was relatively inexpensive to collect. For boards that offer practice infrastructure surveys, physicians can examine the relationship between their clinical results and their practice infrastructure. In all cases, performance results immediately launch a

quality improvement process.



A schematic that describes certifying board practice assessment technology. Note the broad array of data inputs; the generation of performance reports from those data; and the explicit link between performance reporting and a PDSA (quality improvement) cycle

As a result, the boards believe that these technologies act as "enhanced registries;" that is, they include important enhancements that extend registry functionality in areas that are critical to CMS: the explicit link to systems capability communicates (at a "teachable moment") the relationship between weaknesses in practice infrastructure and suboptimal performance; the link to patient experience, such as the patient's lack of understanding the physician's instructions, may help physicians understand why they are (or are not) performing well in terms of clinical results; and the explicit link to quality improvement planning turns a static performance report into the front end of a dynamic performance improvement activity.

We believe that these links create both energy for improvement, and the insights that are needed to translate that energy into effective and sustainable change. And, clearly, they do so in the context of a professional commitment to excellence that is very meaningful to physicians, and in a manner that creates highly valued efficiencies with respect to data collection and use.

Some boards (ABS) use national and regional registries that have adopted NQF endorsed measures and standards of data collection and reporting that permit public reporting of comparison of performance of participants. Numerous studies have demonstrated that registries developed to share data improve care, while public reporting of a few physician-level measures remains to be proven as an effective strategy for improving care.

Some boards do not themselves collect individual physician clinical performance data but require physicians to collect and submit this data to registries and shared databases as part of individual practice or multicenter improvement efforts. These registries usually collect aggregate practice or group data and not individual physician data and the ABP will accept group data for individual MOC. The use of these registries must show significant improvement in care and be approved by the ABP for physicians to receive credit for Maintenance of Certification

With respect to the rulemaking, CMS offers an option ("option 3") through which such technology could support its PRQI program. The certifying board web-based quality improvement registries are currently able to provide the functional elements required under option 3. In particular, some of the standard-bearing boards are able to "calculate the reporting and performance rates for Medicare beneficiaries only, and submit these rates to CMS...including completed numerator/denominators for both reporting and performance rates," as the draft rules describe (p.435). This capacity is not present in all the standard bearing boards but most are willing to implement the necessary program modifications to make it possible.

CMS- 1385-P

Dear CMS Officials:
Thank you for inviting comments on the proposed rules which would dismantle the pod system now entrenched in the practice of pathology. While many arguments against pods have been well-articulated, there is one that has perhaps been under-emphasized.

Surgical pathology began as a sub-specialty of surgery in the 1800's as surgical techniques improved. Surgeons would perform the biopsies, interpret the biopsies, perform the surgeries, and then compare the final pathology with the pre-operative pathologic diagnoses. As surgery and surgical pathology grew in complexity, it was no longer possible for one individual to perform all of these functions. Surgery and surgical pathology became separate disciplines but stayed in very close contact within academic and community hospitals. This close interaction was essential for patient care and for the advancement of knowledge in both fields.

The practice of surgical pathology in a pod laboratory strays from these historical roots. The pod pathologist has little or no interaction with surgeons and other clinicians. More importantly, the pod pathologist does not obtain follow-up on his biopsy diagnoses. In point of fact, in my nearly 15 years of practice, I have never been asked to send follow-up slides to a pod or commercial lab so that the primary pathologist can learn from his cases. In contrast, the hospital-based pathologist is constantly comparing biopsy and subsequent surgical material and honing his diagnostic skills from this exercise. The hospital-based pathologist also meets on a regular basis (both formally and informally) with surgeons and other clinicians to share insights and perspectives on cases, sometimes with immeasurable patient benefit.

Pods have flourished because of the commoditization of the biopsy. They undercut the mission of our specialty and diminish the practice of medicine in general. The pod pathologist practices in the proverbial "vacuum", not only to his detriment, but sadly, to the detriment of patients. Confined to a study carroll thousands of miles from the patient and clinician, how can the pod pathologist experience true professional growth?

Thank you for your continued interest in this matter.

Sincerely,

Paul Fiedler, MD

42

Reg

ACMS American College of Mohs Surgery

Fellowship trained skin cancer and reconstructive surgeons

Fax

To: MR. HERBERT KUHN From: DR. D. BRODLAND

Fax: 202-690-6262 Pages: 21

Phone: Date:

Re: CC:

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2007 AUG -3 PM 5:07

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August 2, 2007

The Honorable Herbert Kuhn
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Washington, DC 20201
Phone: 202-690-6726
E-mail: herb.kuhn@cms.hhs.gov

Re: CMS 1385-P: 2008 Medicare Fee Schedule
Coding – Multiple Procedure Payment Reduction for Mohs Surgery

Dear Acting Administrator Kuhn:

As President of the American College of Mohs Surgery, I represent over eight hundred fellow-ship-trained Mohs surgeons in the United States, whose primary practice is the treatment of skin cancer. The College and I are deeply concerned regarding this proposed rule for multiple reasons. We appreciate this opportunity to offer comment on section II.E.2 (P-122) of the 2008 Medicare Fee Schedule Proposed Rule.

This proposal represents a dramatic reversal of sixteen years of the Centers for Medicare and Medicaid Services'(CMS) own determination that the Mohs codes are and should be exempt from the Multiple Procedure Reduction Rule (MPRR). Furthermore, because of the dual components of surgery and pathology associated with each Mohs surgery procedure, there is no gain in efficiencies when multiple, separate procedures are performed on the same date, making application of the reduction inappropriate. Third, this proposal is contrary to the Relative Value Update Committee's (RUC) own policy regarding procedures qualifying for exemption from this rule. Fourth, this proposal will negatively impact Medicare beneficiaries' access to timely and quality care. Fifth, application of this proposal will not likely generate significant cost savings and may paradoxically increase costs of providing care to these patients. Finally, we are concerned that the Proposed Rule reflects an alteration in the traditional role of the RUC in CMS policy formulation.

First, the Mohs surgery codes have had a longstanding and appropriate exemption from the Multiple Procedure Reduction Rule since 1991. In its Final Rule for the 1992 Medicare Fee Schedule (Federal Register November 25, 1991, volume 56, #227, p. 59602- copy enclosed), the CMS (then HCFA) included specific comment regarding Mohs micrographic surgery. CMS

agreed at that time that the Mohs procedures "are a series of surgeries which, while done on the same day, are done at different operative sessions and are clearly separate procedures in a series of procedures....They will be paid separately with no multiple surgery reductions." This conclusion is still correct and applicable today.

At the request of CMS in 2005, the College, together with the American Academy of Dermatology, the American Society for Dermatologic Surgery, and the American Society for Mohs Surgery, worked through the AMA CPT/AMA RUC five-year review process and the AMA CPT/AMA RUC Modifier -51 Workgroup to develop site-specific codes for the Mohs procedure. Two new site-specific codes, 17311 and 17313, were accepted by AMA CPT/AMA RUC to differentiate Mohs excision of cancers in different anatomic areas.. However, there has been NO CHANGE in the procedure or in the separate and distinct nature of the Mohs procedure from any other procedure which might be performed on the same day. We believe the revised code descriptors to differentiate anatomic sites, in the absence of a change in work associated with the procedure, does not support the change in the multiple procedure exemption status of the new Mohs codes.

Second, as noted in the Proposed Rule, "RVUs were developed for each Mohs surgery base code based on an assumption that each code is performed separately." This assumption is correct. Mohs micrographic surgery uniquely includes two distinct components, surgery and pathology, both of which are performed wholly by the Mohs surgeon, with the pathology component comprising half of the service. The nature of Mohs surgery requires that the entire procedure, including processing and interpretation of the histopathology slides, be completed before any consideration is given to the excision of additional tissue or to repair of the resulting defect. The intra-service work for 17311 was acknowledged by RUC to be 80% of the total physician work of the procedure (78% for 17313), including both the surgery and pathology. Even when two Mohs excisions are performed for a patient on the same date, there is no overlap in work for treatment of the second site, which requires all the same components of excision and tissue processing/interpretation as the first site. There are marginal gains in "efficiencies" when treating more than one tumor at the same time.

Likewise, there is no overlap between a Mohs procedure to remove a skin cancer and a subsequent, separate repair procedure that might be used to address the skin defect created by the Mohs procedure. The time required for the pathology component of the procedure results in an onsite waiting period for the patient. If a repair is performed, it requires return to an operating room, repositioning, re-anesthetizing, re-prepping, etc. It is performed with new instrumentation. It is typically performed in the same room as the prior Mohs procedure. There is no overlap of work or practice expense for clinical labor time, medical supplies, or medical equipment between the Mohs procedure and a repair procedure.

Therefore, it is inappropriate to subject 17311 and 17313 to the multiple procedure reduction rule for repairs performed on the same day as the Mohs procedure or for multiple Mohs lesion excisions performed on the same day.

Third, the RUC -51 Research Subcommittee identified seven criteria to determine whether a code should be included on the Modifier –51 Exemption List: 1, RUC rationale supporting placement on the list; 2, Exemption from the CMS Multiple Surgery Reduction; 3, Limited amount of pre- and post-service time and limited number of visits; 4, No add-on codes; 5, No codes where payment logic would not reduce payment when performed with another procedure; 6, Service is typically adjunctive to another service but can be performed as stand-alone procedure; and 7, Service is performed with multiple other procedures that are so extensive that it is difficult to maintain a "Report With" list typically included in CPT.

Considering the arguments we present above, the Mohs codes meet three of the AMA CPT/AMA RUC Modifier -51 Workgroup criteria for procedures qualifying for exemption.

1. Mohs micrographic surgery was declared exempt by CMS in 1991. The procedure remains unchanged since then except for the new CPT code numbers described above.
2. The Mohs codes have very little pre- and post-service time and have a limited number of visits. As above, 78 - 80% of the total physician work of the Mohs codes is intra-service work. The pre- and post-service time for the Mohs codes is less on a percentage basis than that of the other codes remaining on the list of exemptions. The Mohs codes also have zero post-op visits embedded in the value of the codes.
3. The Mohs codes are typically adjunctive to a repair service but are often performed as stand-alone procedures, in cases when wounds are allowed to heal secondarily. Second-intention healing is typical for tumors in certain areas, especially the medial canthus, conchal bowl, and posterior ear, among others.

Meeting three of the seven RUC-developed criteria for exemption, any one of which merits consideration for inclusion on the list, appropriately justifies retaining the longstanding exempt status of the Mohs codes.

Furthermore, since the pathology component of Mohs surgery comprises half of the procedure, it is appropriate that the Mohs codes be treated similarly to other pathology codes, which are not subject to the multiple procedure reduction rule, since there is no overlap in work from reviewing one slide to another. To apply the reduction to the Mohs codes would be inconsistent with the exemption of application of this rule to other pathology codes.

Fourth, removing the exempt status of the Mohs codes will negatively impact Medicare beneficiaries' access to timely and quality care. Currently, 10% of patients undergoing Mohs micrographic surgery have more than one tumor treated with Mohs on the same day.

Application of the proposed rule to a second tumor treated on the same day will mean that reimbursement for the second procedure does not cover the cost of providing the service. This will affect Medicare beneficiaries disproportionately, since the incidence of skin cancers peaks in Medicare-age patients, who are most likely to have multiple tumors. Additionally, patients who are immunosuppressed from organ transplantation, cancer chemotherapy, infection or other diseases are at significantly higher risk for skin cancers and often have multiple tumors; many of these patients are also Medicare beneficiaries. These immunosuppressed patients are not only at higher risk for cancers but also at higher risk for potential metastases and possibly death from skin cancers, especially squamous cell carcinoma.

Fifth, although perhaps intended as a cost-saving measure, application of this rule will not likely generate significant cost savings and may paradoxically increase cost of providing care to these patients. When Mohs procedures are performed with higher-valued repairs such as flaps or grafts, application of the MPRR to the Mohs codes will result in reduced reimbursement for Mohs that doesn't cover the cost of the procedure. Likewise, for lower-valued repairs such as intermediate and complex layered closures, which are the most commonly performed repairs, reduced reimbursement will not cover the cost of the repair.

Finally, we support the RUC process and recognize the value it brings to the annual physician fee schedule development. As initially charged, the RUC has done an exceptional job over the years in expressing opinions regarding relative values for procedures. In doing this the RUC defied the predictions of critics who claimed that agreement would not be possible among the various stakeholders. The RUC and CMS also prevailed against the legal challenge that the RUC amounted to a Federal Advisory Committee. In defending against that allegation it was persuasive to the court that the RUC only provides opinions on relative values and that CMS retains the authority to make policy decisions. The RUC, it was noted, is independent and is only one source of CMS input on relative values. All policy decisions have undergone full development by CMS in the public notice and comment process.

The policies adopted by CMS such as multiple surgical reductions, bundled services, and prohibition against operating surgeons from separately billing for anesthesia and assistant at surgery restrictions are all examples of policy decisions by CMS. They do no strictly represent issues of relative value but rather they represent policy formulations that guide payment and medical practice. To have the RUC engaged in these policy formulations in a forum which is not open or accessible to the public is unfair to the Medicare beneficiaries affected and threatens the RUC process.

We disagree with using the RUC for this purpose but if CMS believes the RUC role should be expanded it should only be done by giving the RUC a public and well-articulated charge to take on this task.

In light of the concerns raised above, the American College of Mohs Surgery respectfully requests reconsideration of the proposed rule. We provide the above rationale in support of the Mohs procedure base codes, 17311 and 17313, as appropriately exempt from the multiple procedure reduction rule, as are the other add-on Mohs codes. We therefore request permanent exemption from the MPRR.

We would appreciate the opportunity to meet with CMS to discuss this issue as soon as possible. Please feel free to contact me at 412/466-9400.

Respectfully,

David G. Brodland, M.D.
President, American College of Mohs Surgery

cc: Terrence Kay, Director, Hospital and Ambulatory Policy Group
Amy Bassano, Director, Practitioner Services Division
Diane Baker, MD, President, American Academy of Dermatology
Alastair Carruthers, FRCPC, President, American Society of Dermatologic Surgery
Sharon Tiefenbrunn, MD, President, American Society for Mohs Surgery

Enclosures -1992 Medicare Fee Schedule: Final Rule (Federal Register, November 25, 1991, vol. 56, #227, pg 59602)
CPT Assistant, July, 2004
CPT Assistant, November, 2006

of the global fee for the second highest valued procedure, and at 25 percent of the global fee for each succeeding procedure. Each procedure after the fifth procedure will be paid by special report. Our medical consultants advise us that cases with more than five procedures should be extremely rare. We believe that the added documentation requirement along with physician comparative performance reports and our intra-operative computer edits will prevent abuse of the multiple surgery policy through excessive "unbundling".

For certain dermatology services, there are separate CPT codes for multiple surgical procedures (for example, CPT codes 11201, 17001, and 17002). For these procedures, the multiple procedure rules will not apply. Rather, we are presenting RVUs for these codes. For other dermatologic procedures, we believe a 50 percent reduction in the value is appropriate for the second procedure since pre- and post-work and practice expenses will be diminished. However, beyond the second procedure, since there may not be the same reductions in work effort that is associated with multiple surgery through the same incision, a physician may submit a "by report" bill when three or more lesions are removed.

[Mohs Micrographic Surgery]

Comment: Some commenters stated that Mohs micrographic surgery, CPT codes 17303 through 17310, should be exempt from the multiple surgery reductions. These are a series of surgeries which, while done on the same day, are done at different operative sessions and are clearly separate procedures in a series of procedures.

Response: We agree that these surgical procedures are contemplated to be separate staged procedures; they will be paid separately with no multiple surgery reductions.

[Multiple Surgery Policy for Multiple Trauma]

Comment: Some commenters expressed concern that the multiple surgery policy would result in inadequate payment when a number of different surgeons are operating on different body parts at the same time, such as in the case of a multiple trauma patient.

Response: These cases will not be subject to the multiple surgery policy. The multiple surgery policy will apply to multiple surgery done by the same surgeon on the same day. Each physician will be paid separately for his or her services.

c. *Bilateral surgery (CPT modifier 50).* The bilateral modifier is used to indicate cases in which a procedure was performed on both sides of the body. The CPT identifies surgical procedures that are typically bilateral in nature. For these codes, the bilateral modifier would not result in increased payment.

In the absence of any evidence with respect to the actual difference in work for bilateral procedures, we proposed to continue the historic practice of paying 150 percent of the global fee.

[Bilateral Surgery Code Applying to Ophthalmic Procedures]

Comment: The CPT code for bilateral surgery (CPT modifier 50) should not apply to ophthalmic procedures or to the extremities (hands, feet, knees) as it requires the same amount of work for each eye, foot, etc. This policy would merely encourage physicians to bring the patient in on two separate occasions and do each eye, foot, etc., separately.

Response: Harvard did not have data on the resources involved in miscellaneous bilateral surgery and surveyed very few procedures that were bilateral. Like the multiple surgery policy, the use of a bilateral modifier and payment by carriers at 150 percent of the global fee in bilateral cases is a long accepted practice. Until resource data are available, we plan to continue the 150 percent policy. While the actual intra-operative services may be the same for each eye or extremity, we believe the pre-operative and post-operative services are reduced.

d. *Providers furnishing less than the global fee package (CPT modifiers 54, 55, and 56).* Under the current reasonable charge policy, the sum of all allowances for all practitioners who furnished parts of the services included in a global fee (and who billed using one or more of these modifiers) must not exceed the total amount of the allowance that would have been paid to a single practitioner under the global fee for the procedure. We proposed to continue to pay the same amount for surgical services when they are furnished by several physicians as we would pay if only one physician furnished all of the services in the global package. However, we proposed to pay each physician directly for the services furnished to the beneficiary based on the RVUs of the component furnished.

[Physicians Other Than Surgeons Should be Paid Without Regard to Global Fee]

Comment: Commenters objected to the policy that the sum of payments to multiple physicians furnishing services within a global package (CPT modifiers 54, 55, and 56) may not exceed the value of the global fee for the procedure. They stated that since only the pre- and post-operative services of the surgeon were studied by Harvard in setting the global RVUs (not the services of other physicians such as cardiologists, internists, anesthesiologists, intensivists, or other physicians who may furnish this care), a physician other than the surgeon who furnish follow-up care should be paid without regard to the total global fee.

Response: We disagree. The concept of a global fee for a surgery for which the surgeon charges a single global fee and furnishes all usual and necessary services associated with a surgery and follow-up recovery is a long established concept. To ensure equitable payment under the fee schedule, it is necessary to establish a uniform national global package for each surgery. Since the surgeon usually can be expected to furnish the complete package of services, it is entirely appropriate that the value of the package be established on the basis of the value of the surgeon's services. When someone other than the surgeon furnishes services that the surgeon would normally furnish, he or she is merely substituting for the surgeon. The value of the package does not change.

However, there appears to be some misunderstanding concerning the services of other physicians—for example, a nephrologist, an infectious disease specialist for severe infection—furnishing services in addition to those normally furnished by the surgeon when a patient develops renal insufficiency. As discussed in the section of the proposed rule on global surgery, if the services of these other physicians are required in addition to the normal pre- and post-operative services of the surgeon, they will be paid outside of the global fee.

[Apportioning Payment for Post-Operative Care Furnished by Different Physicians]

Comment: A commenter suggested that, if normal post-operative care is furnished by more than one physician, the payment should not be apportioned according to the number of days in the portion of the 90-day period furnished by each physician since the number of visits and intensity of care required during different times in the period varies. The commenter stated that as an example, under the proposal in the proposed rule, a physician furnishing the first 30 days of post-operative care would receive 33 percent of the value of the care, while the physician furnishing the last 60 days of care would receive 66 percent. The commenter noted that, in

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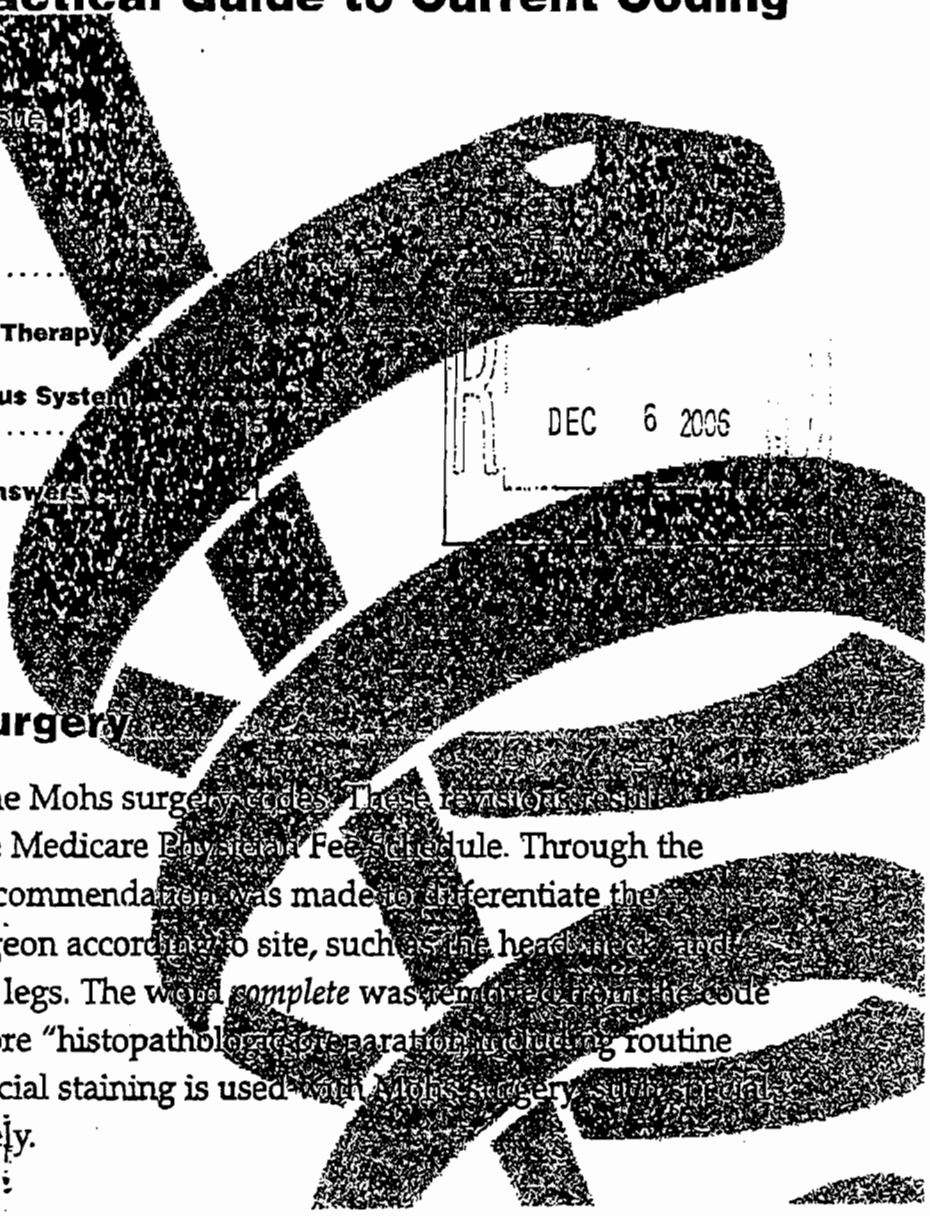


Mohs Micrographic Surgery

CPT 2007 contains revisions to the Mohs surgery codes. These revisions result from the Five-Year Review of the Medicare Physician Fee Schedule. Through the Five-Year Review process, the recommendation was made to differentiate the physician work of the Mohs surgeon according to site, such as the head, neck, and hands from the trunk, arms, and legs. The word *complete* was removed from the code descriptor for Mohs surgery before "histopathologic preparation, including routine stains" to indicate that when special staining is used with Mohs surgery, special stains are to be reported separately.

Simply, for *CPT 2007*, code 17304 has been deleted and separated into two new codes, 17311 and 17313, depending on tumor location. Codes 17305, 17306, and 17307 were replaced with 17312 and 17314, depending on tumor location. Code 17310 was replaced with 17315. The word *specimen* was replaced with the phrase *tissue block* to reflect more accurately the unit of service. CPT codes 17312, 17314, and 17315 are designated as add-on codes.

Mohs micrographic surgery is a technique for the excision of skin cancer. The Mohs surgery family of codes, 17311-17315, is unique because it includes CPT codes that describe procedures that involve surgery and pathology services performed together by the same physician acting as both surgeon and pathologist. This dual responsibility requires policies that differ from other surgical codes and has led to confusion among those unfamiliar with the use of these codes. This discusssion explains the codes, the policy for their use, and the rationale for this policy so that providers, coders, and payers can understand coding for Mohs surgery. This is an update of the July 2004 *CPT Assistant*.

What is of Mohs Micrographic Surgery?

Mohs micrographic surgery is a technique for the removal of complex or ill-defined skin cancer with histologic examination of 100% of the surgical margins. It is a combination of surgical excision and surgical pathology that requires a single physician to act in two integrated but separate and distinct capacities: surgeon and pathologist. If either of these responsibilities is delegated to another physician who reports the services separately, these codes should not be reported. The Mohs surgeon removes the tumor tissue and maps and divides the tumor specimen into pieces, and each piece is embedded into an individual tissue block for histopathologic examination. Thus a tissue block in Mohs surgery is defined as an individual tissue piece embedded in a mounting medium for sectioning.

If repair is performed, separate repair, flap, or graft codes are used. If a biopsy of a suspected skin cancer is performed on the same day as Mohs surgery because there was no prior pathology confirmation of a diagnosis, then diagnostic skin biopsy (11100, 11101) and frozen section pathology (88331) with modifier 59 appended are reported to distinguish from the subsequent definitive surgical procedure of Mohs surgery.

Following are the new Mohs Micrographic Surgery codes for *CPT 2007*:

17311 Mohs micrographic technique, including removal of all gross tumor, surgical excision of tissue specimens, mapping, color coding of specimens, microscopic examination of specimens by the surgeon, and histopathologic preparation including routine stain(s) (eg, hematoxylin and eosin, toluidine blue), head, neck, hands, feet, genitalia or any location with surgery directly involving muscle, cartilage, bone, tendon, major nerves, or vessels; first stage, up to 5 tissue blocks

17312 each additional stage after the first stage, up to 5 tissue blocks (List separately in addition to code for primary procedure)

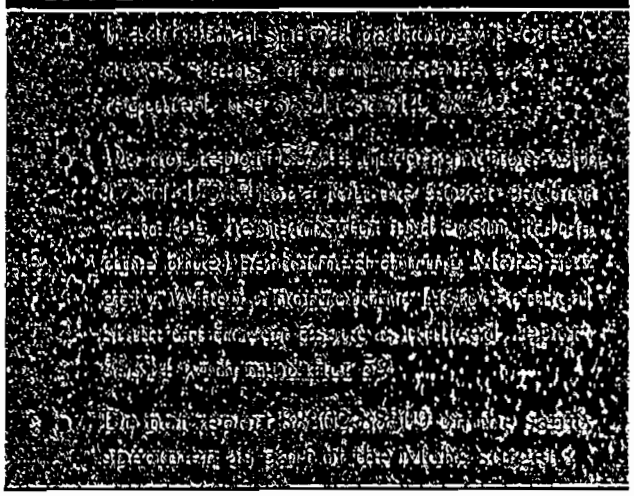
17313 Mohs micrographic technique, including removal of all gross tumor, surgical excision of tissue specimens, mapping, color coding of specimens, microscopic examination of specimens by the surgeon, and histopathologic preparation including routine stain(s) (eg, hematoxylin and eosin, toluidine blue), of the trunk, arms or legs; first stage, up to 5 tissue blocks

17314 each additional stage after the first stage, up to 5 tissue blocks (List separately in addition to code for primary procedure)

17315 Mohs micrographic technique, including removal of all gross

tumor, surgical excision of tissue specimens, mapping, color coding of specimens, microscopic examination of specimens by the surgeon, and histopathologic preparation including routine stain(s) (eg, hematoxylin and eosin, toluidine blue), each additional block after the first 5 tissue blocks, any stage (List separately in addition to code for primary procedure)

Parenthetical Notes Per CPT Guidelines



General Description

Typically, Mohs surgery is an outpatient procedure performed under local anesthesia. The basic tenet is excision followed by complete surgical margin examination by the Mohs surgeon and precise mapping of tumor-containing margins so that the surgeon can re-excise positive margins.

The details of the procedure require that the visible cancer commonly be removed first (debulked) without attempting to remove a margin of normal tissue. After the bulk of the tissue is removed, the first layer or stage is excised as a thin continuous wafer of tissue, typically 1 to 3 mm thick, around the sides and base of the wound or apparent cancer margin. Hemostasis is achieved, and the patient is bandaged and discharged to the waiting room.

This thin cup or saucer-shaped wafer of tissue is flattened by cutting it into pieces or making radial incisions to flatten the tissue. The smallest number of tissue blocks that will allow the performance of sectioning in the cryostat is created. The edges of the tissue are color coded with dyes that persist through histologic tissue processing. Once the wafer is cut into pieces and color coded, a drawing or map of this tissue and its pieces is made so that it corresponds to the surgical wound. These tissue pieces, disassembled like a puzzle, are processed by frozen section pathology. One or more flattened tissue piece is positioned on a single frozen tissue specimen disk ("block"), embedded, frozen, sectioned horizontally in a cryostat onto a microscope slide, and stained. These frozen sections create an image of 100% of the surgical margin. Microscopic examination of this image allows the Mohs surgeon, whose dual role is to function as both surgeon and pathologist, to precisely identify the location of any remaining tumor. The location of the remaining tumor as seen through the microscope is marked on the map of the surgical wound.

If the frozen sections indicate residual tumor, the patient is called back from the waiting room, reanesthetized, prepped, and draped for the next Mohs surgical stage. The Mohs surgeon, using the marked map of the wound, excises any remaining tumor as in the previous stage(s). This process of excision of remaining tumor, mapping, and histologic exam is repeated until all of the tumor is excised completely.

This Mohs method of margin examination differs significantly from traditional frozen sections used during routine surgery for margin exam. Traditional techniques use bread-loafed surgical specimens, providing an image that includes a vertical cut through the tissue. This offers a view of the center of the specimen and the lateral and deep margins, but it only samples these tissue pieces every few millimeters or centimeters. Such a sampling technique typically examines far less than 0.1% of the total margin of excision. Because traditional pathologic examination of surgical margins is only a sampling and may miss true positive margins, wider surgical margins are usually used for non-Mohs skin cancer surgery. Conversely, Mohs surgery—using 100% examination of the margin—allows excision with very narrow margins. This results in narrower surgical margins overall, less complicated reconstruction of smaller operative wounds, and higher cure rates.

Coding for Mohs Surgery (17311 and 17313)

Codes 17311 or 17313 are used for the first layer (stage) of Mohs surgery depending on the location of the tumor(s). Roughly 50%-55% of Mohs cases require only a single layer. Codes 17311 and 17313 include the *preservice* work of explaining the procedure, obtaining informed consent, and preparing the patient for surgery. The *intraservice* work includes local anesthesia, debulking of the visible tumor, excision of the first Mohs layer, color coding of the specimens, and mapping. It also includes the pathology services of tissue preparation, microscopic examination, and mapping of positive margins. The *intraservice* work also includes the final evaluation of the tumor-free wound to determine wound management. The *postservice* work includes the discussion of postoperative wound management. It is important to understand these components of physician work and their relation to relative value units (RVUs) because they determine the coding and reimbursement policies.

The use of these codes is restricted to situations where one physician acts as both surgeon and pathologist. Performance of the entire procedure by one physician increases the accuracy of the technique as the risk of mapping errors is minimized. The codes are not appropriate for use when a surgeon excises tissue interpreted separately by a pathologist, even if the histologic exam is done by enface or horizontal techniques and a map is made by a pathologist for the surgeon. In those cases-sometimes erroneously described as "modified" Mohs-the surgeon should code the appropriate excision and/or repair codes and the pathologist should report the appropriate codes for his or her service.

Codes 17311 and 17313 are used for the first layer (stage) only and include the work of excision and pathology of up to five specimens. If the tissue layer is large enough that it must be cut into six or more specimens producing six or more blocks of tissue in order to examine the entire surgical margin, then code 17315 should be used for each additional block beyond the first five included in 17311 or 17313. As the number of tissue blocks increases, the potential for false positive or false negative results rises, so efforts are made to evaluate each layer in as few blocks as possible. In certain circumstances, more than one slide may be prepared from the tissue block. The additional slides, regardless of the number of sections cut from the block, still count as a single block. Add-on code 17315 is reportable in conjunction with the entire range of 17311-17314 Mohs codes.

Pathology Services: Bundled Services and Those That Are Separately Reportable

The unit of service previously described by codes 17304-17310 was the number of specimens. However, the specimen that is taken during surgery is used to create tissue blocks. In the context of Mohs Surgery, a *tissue block* is defined as tissue placed upon a single frozen section specimen disk and embedded in a mounting medium for sectioning. This tissue block more accurately describes the unit of service. To more accurately reflect the unit of service, codes 17311-17315 describe the unit of service as blocks rather than specimens.

The work of processing and interpreting one routine stain is included in the procedure 17311-17315. This stain is usually hematoxylin and eosin, or toluidine blue. If other special stains are necessary after one routine stain, then the code for special stains may be used (88314) as well as immunoperoxidase stains (88342) or decalcification procedures (88311). Special stains are not typically used and in most Mohs practices are of low frequency. Each stain is reported only once per block, not per slide or per layer (stage).

Surgical pathology codes 88302-88309 should not be used for reporting histopathology of Mohs surgical specimen. This instructional parenthetical note has been added preceeding code 17311.

CMS Reporting Guidelines

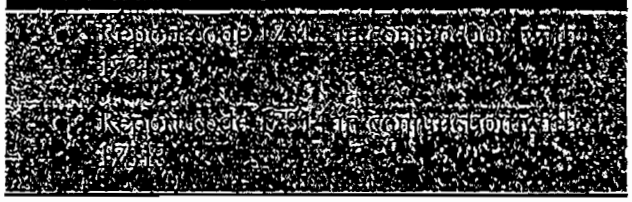
Because a high complexity histology laboratory in close proximity is a necessary part of this procedure, the presence of such as designated by a current Clinical Laboratory Improvement Amendments (CLIA) number is now a necessary part of the claim when reporting Mohs micrographic surgery codes to the Centers for Medicare and Medicaid Services (CMS).

Codes 17312 and 17314

Codes 17312 and 17314 describe the second and subsequent stages of Mohs surgery to remove positive surgical margins. These two codes replace 17305-17307. The RVUs already reflect any reduction in work done for these repeat procedures compared to codes 17311 or 17313. No debulking procedure is done on these add-on codes; they represent only the additional surgical work for re-excision of positive margins and the additional pathology work for interpretation of the specimens. When two or more stages are performed in one day, code 17312 or 17314 should be used with an appropriate number of units for each additional stage. For example, if a tumor was excised with a total of five layers (stages) on the head, then code 17311 would be reported one time and code 17312 would be reported with 4 units for the additional four stages. Likewise, if a tumor was excised with a total of five layers (stages) on the trunk without muscle involvement, then codes 17313 would be reported one time and code 17314 would be reported with 4 units for the additional four stages.

When Mohs surgery is performed on a single tumor but is carried over to a second day, the first layer (stage) on the next day should continue with the next code in the series. For example, if the surgery after the first (initial) layer was postponed until the second day, then coding the second day's surgery starts with code 17312 or 17314 but not code 17311 or 17313 because no debulking is necessary on the second day. Each layer (stage) represented by 17312 and 17314 includes up to five specimens in each layer (stage). Note that 17312 and 17314 are add-on codes and not typically reported without a primary code on the same day. For any individual stage that has more than five blocks, code 17315 should be used. It is recommended to report the two-day Mohs surgery on the same claim form.

Parenthetical Notes Per CPT Guidelines



Code 17315

Code 17315 is used for unusually large tumors requiring more than five tissue blocks in any layer. It is used for fewer than 10% of tumors excised with Mohs surgery. This code represents the incremental increase in work for both surgery and pathology for these larger tumors. Code 17315 is reported once with the appropriate number of units for each additional tissue block after the first five blocks in any stage. That is, 17315 represents one piece of the puzzle of the Mohs surgery map; it does not represent the number of slices of tissue from the block on the glass slides or the total number of slides.

Code 17315 is an add-on code and cannot be reported without codes 17311, 17312, 17313, or 17314. When two or more tumors are treated in one day, code 17315 is reported for each piece of tissue beyond five for any one layer (stage). It is not appropriate to add and average all pieces from all layers. For example, if the first tumor layer was divided into seven pieces that generated seven separate blocks of tissue and the second tumor excision layer had three pieces, then code 17315 would be submitted once each (ie, twice in the units box) for the sixth and seventh specimen in the first tumor layer while the appropriate base code would be submitted for the Mohs surgery performed in each site.

Historically, the Mohs micrographic surgery codes have been exempted from multiple procedure reduction.

Parenthetical Notes Per CPT Guidelines

Report 11311 in addition to 11312, 11313

General Issues: Skin Biopsy Before Mohs Surgery

It is generally recognized that a skin biopsy and histologic diagnosis is necessary before beginning Mohs surgery. If a definitive diagnosis of the tumor is not available, the Mohs surgeon may perform a biopsy to confirm a diagnosis of skin cancer before the decision to initiate Mohs surgery. In this instance, biopsy codes 11100 and 11101 and frozen section surgical pathology code 88331 may be reported separately in addition to Mohs surgery.

11100	Biopsy of skin, subcutaneous tissue and/or mucous membrane (including simple closure), unless otherwise listed; single lesion
11101	Biopsy of skin, subcutaneous tissue and/or mucous membrane (including simple closure), unless otherwise listed; each separate/additional lesion (List separately in addition to code for primary procedure)
88331	Pathology consultation during surgery; first tissue block, with frozen section(s), single specimen

A biopsy may also be required if:

- A biopsy report is not available with reasonable effort.
- A biopsy has been done more than 90 days before surgery.
- The original biopsy diagnosis is ambiguous.

Modifier 59 should be appended to the biopsy codes (eg, 11100 with modifier 59) and pathology (eg, 88331 with modifier 59) to document that these are separate services that are not components of Mohs surgery and that may be bundled erroneously into Mohs surgery if the modifier is not used. It is not appropriate to report a biopsy or frozen section with Mohs surgery for routinely reviewing the histopathologic features of the tumor being treated.

Code 11100 is reported for the first biopsy and code 11101 for a biopsy of second or subsequent skin lesions in different locations. Code 88331 is reported for the pathology interpretation of each skin biopsy specimen. Code 88332 is reported *only* if a single surgical specimen is cut into separate tissue blocks for separate examination.

Reconstruction

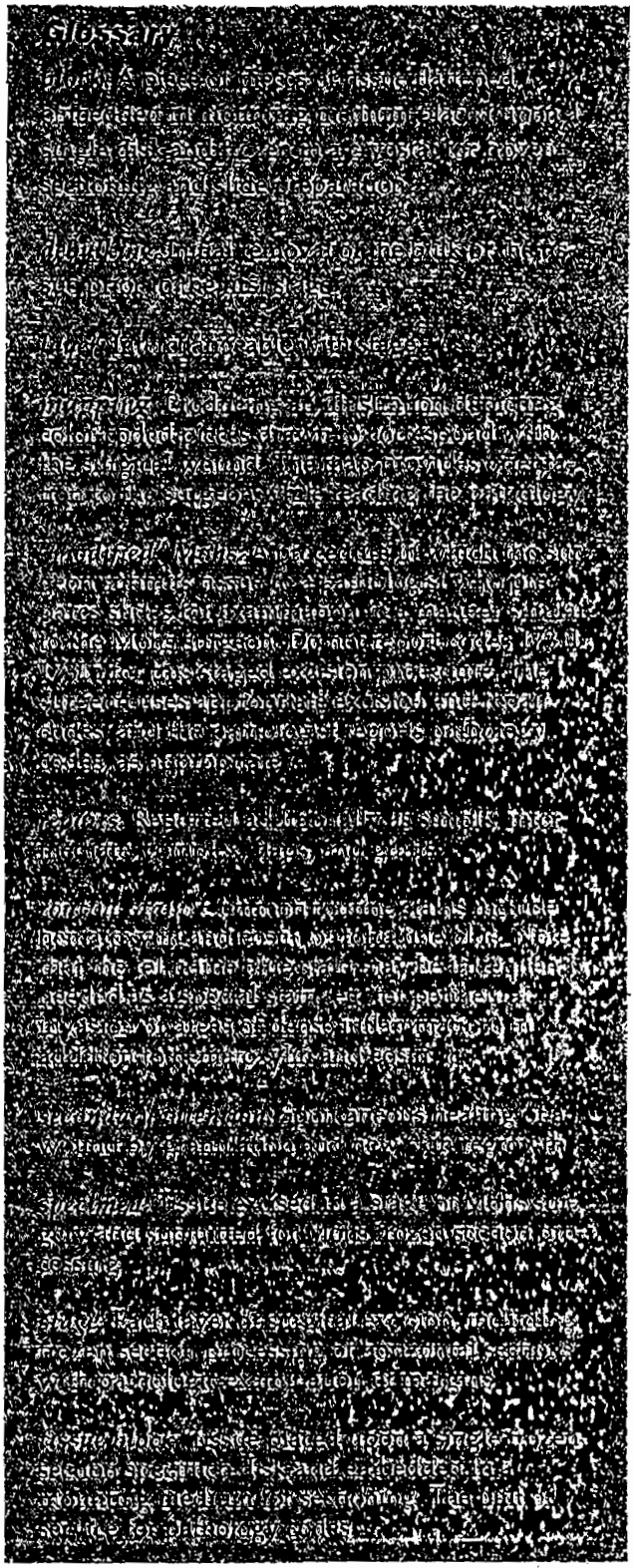
Some wounds after Mohs micrographic surgery are allowed to heal spontaneously by secondary intention without reconstruction of the wound; therefore, no RVUs are included in the Mohs family of codes for surgical repair. *Secondary intention* is the spontaneous healing of a wound by granulation and new skin regrowth. If surgical repair is necessary, then the repair codes (simple, intermediate, complex, flaps, and grafts) should be reported separately.

Evaluation and Management Services

Evaluation and management (E/M) services provided on the same date of service as Mohs micrographic surgery may be reported if a significant separately identifiable service is performed and documented. A separately identifiable service may include an initial evaluation of a new patient, an initial consultation, or other E/M service, or it may include the decision to perform surgery. Modifier 57 is used for the E/M service to indicate the decision to perform surgery. If an E/M service is performed with Mohs micrographic surgery alone, or when a repair code with a global period less than 90 days is performed, the E/M service should be reported with modifier 25 appended.

CMS Reporting Guidelines

If an E/M service is performed on the same date of service as a surgical reconstruction with a 90-day global period (ie, flap or graft), CMS policy requires modifier 57, *Decision for surgery* be appended to the E/M service. A separate



diagnosis for the E/M service and for the Mohs micrographic surgery is not required per CPT coding guidelines (see modifier 25 in Appendix A of the CPT codebook).

E/M services following Mohs micrographic surgery may be reported depending on the global period of any surgical reconstruction services done with Mohs surgery. If the wound was allowed to heal by secondary intention and no other service other than Mohs surgery was performed, a zero global postoperative period applies, and any E/M services provided after Mohs are reported without modifiers. If reconstruction is performed with Mohs surgery, the 10- or 90-day global period of the reconstruction applies and no E/M service related to the reconstruction procedure is allowable during the global period. However, an E/M service may be reported if it is for an unrelated service, in which case modifier *24, Unrelated evaluation and management service by the same physician during a postoperative period,* would be appended.

Complications

Sometimes complications such as wound infection, bleeding, hematoma, or wound dehiscence may require a return to the operating room. It is important to note that CMS defines an operating room as a room that is equipped specifically and staffed for the sole purpose of performing procedures. Such a room is not a minor treatment room or recovery room. In this instance, modifier *78, Return to the operating room for a related procedure during the postoperative period,* would be appended to the appropriate procedure (eg, incision and drainage of hematoma). This would only be appropriate if a repair with a global period of zero days was performed as Mohs surgery. ■

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AMA press

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American Medical Association

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Your Practical Guide to Current Coding

At Issue This Month

Mohs Micrographic Surgery

Mohs surgery is a technique for the excision of skin cancer. It is a combination of surgical excision and surgical pathology. The Mohs surgery family of codes – CPT codes 17304-17311 – is unique because it includes the only CPT codes that describe procedures that involve surgery and pathology services performed together by the same surgeon or pathologist. This dual responsibility requires policies that differ from other surgical codes and has led to confusion among those unfamiliar with the use of these codes. This discussion explains the codes, the policy for their use, and the

rationale for this policy so that providers, coders, and payers can all understand coding for Mohs surgery. This is an update of the Winter 1994 *CPT Assistant*.

General Description

Typically, Mohs surgery is an outpatient procedure usually done under local anesthesia. The basic tenet is excision followed by complete surgical margin exam by the Mohs surgeon and precise mapping of tumor containing margins so that the surgeon can re-excise positive margins.

The details of the procedure require that the visible cancer be removed first (debulking) without attempting to remove a margin of normal tissue. After the bulk of the tissue is removed, the first layer or stage is excised as a thin continuous wafer of tissue, typically 1 to 3 mm thick, around the sides and base of the wound. Hemostasis is achieved, and the patient is bandaged and discharged to the waiting room.

This thin cup or saucer shaped wafer of tissue is flattened by cutting it into pieces (blocks) or making radial incisions to flatten the tissue. The smallest number of tissue blocks are created that will allow the performance of sectioning in the cryostat. The edges of the tissue are color coded with dyes that persist through histologic tissue processing. Once the wafer is cut into pieces and color-coded, a drawing or map of this tissue and its pieces is made so that it corresponds to the surgical wound. These tissue pieces, disassembled like a puzzle, are processed by frozen section pathology. Each flattened piece (or tissue block) is mounted, frozen, and sectioned horizontally. These frozen sections create an image of 100% of the surgical margin. Microscopic examination of this image allows the Mohs surgeon, who also functions as the pathologist, to identify the location of any remaining tumor. Its location as seen through the microscope is marked on the map of the surgical wound.

If the frozen sections indicate residual tumor, the patient is called back from the waiting room, reanesthetized, prepped, and draped for the next Mohs surgical stage. The Mohs surgeon, using the marked map of the wound, excises any remaining tumor as in the previous stage(s). This process of excision of remaining tumor, mapping, and histologic exam is repeated until all of the tumor is completely excised.

This Mohs method of margin exam differs significantly from traditional frozen sections used during routine surgery for margin exam. Traditional techniques use bread loaf surgical specimens, providing an image that includes a vertical cut through the tissue. This offers a view of the center of the specimen, and the lateral and deep margins, but it only samples these images every few millimeters or centimeters. This sampling technique typically examines far less than 1% of the margin. Because traditional pathology examination of surgical margins is only a sampling and may miss true positive margins, wider surgical margins are usually used for non-Mohs skin cancer surgery. Conversely, Mohs surgery using 100% examination of the margin allows excision with very narrow margins. This results in both narrower surgical margins overall, easier reconstruction of smaller operative wounds, and higher cure rates.

Coding for Mohs Surgery

17304 Chemosurgery (Mohs' micrographic technique), including removal of all gross tumor, surgical excision of tissue specimens, mapping, color coding of specimens, microscopic examination of specimens by the surgeon, and complete histopathologic preparation including the first routine stain; first stage, fresh tissue technique, up to 5 specimens

Code 17304 is used for the first layer of Mohs surgery. Roughly 60% of Mohs cases require only a single layer. Code 17304 includes the *preservice* work of explanation of the procedure, informed consent, and preparation of the patient for surgery. The *intraservice* work includes local anesthesia, debulking of the visible tumor, excision of the first Mohs layer, color-coding of the specimens, and mapping. It also includes the pathology services of tissue preparation, microscopic examination, and mapping of positive margins. Finally, the intraservice work includes final evaluation of the tumor-free wound to determine wound management. The *postservice* work

includes the discussion of postoperative wound management. It is important to understand these components of physician work and their relation to relative value units (RVUs) because they determine the coding and reimbursement policies.

The use of these codes is restricted to situations where one physician acts as both surgeon and pathologist. Performance of the entire procedure by one physician increases the accuracy of the technique as the risk of mapping errors is minimized. The codes are not appropriate for use when a surgeon excises tissue interpreted separately by a pathologist, even if the histologic exam is done by enface or horizontal techniques and a map is made by a pathologist for the surgeon. In those cases – something erroneously described as "modified" Mohs – the surgeon should code the appropriate excision and/or repair codes and the pathologist should report the appropriate codes for his or her service.

Code 17304 is used for the first layer only and includes the work of excision and pathology of up to five specimens. If the tissue layer is large enough that it must be cut into six or more specimens in order to examine the entire surgical margin, then code 17310 (each additional specimen, after the first 5 specimens, fixed or fresh tissue, any stage) should be used for each additional one specimen beyond the first five included in 17304. As the number of tissue blocks increases, the potential for false positive or false negative results rises, so efforts are made to evaluate each layer in as few blocks as possible. In certain circumstances, more than one slide may be prepared from the tissue block. The additional slides, regardless of the number of sections cut from the block, still count as a single specimen.

The work of processing and interpretation of one routine stain is included in the reimbursement for codes 17304 through 17310. This stain is usually hematoxylin and eosin, or toluidine blue. If other special stains are necessary after one routine stain, then the code for special stains may be used (88314), as well as immunoperoxidase stains (88342), or decalcification procedures (88311). Special stains are not typically used and in most practices are of low frequency.

Multiple Surgery: Modifier 51, Exempt

Under most circumstances, when two or more services are performed on the same patient at the same operative session on the same date of service, modifier 51 is appended. This identifies a secondary service associated with less physician work and practice expense than if it were a primary service and, therefore, is usually reimbursed less than the primary service. Some carriers refer to this as the multiple surgery reduction rule. The Mohs surgery family of codes is exempt from the need to append modifier 51. For example, when two or more separate tumors are treated on the same day, CPT code 17304 is reported for the first stage of each tumor. This does not require the use of modifier 51 because code 17304 is exempt from Medicare's multiple surgery reduction rule. (CPT Appendices list codes exempt from the use of modifier 51. Appendix E lists 17304, 17305, 17306, and 17307 and; Appendix D lists 17310 as an add-on code. All Mohs codes are exempt from the use of modifier 51.)

The rationale for this policy is that for many surgical procedures some of the work of a procedure is not repeated when two or more procedures are performed. For these procedures the intraservice work is only 50% of the total work, while the other 50% represents pre- and postservice work that overlaps when multiple procedures are performed on the same patient on the same date of service. For Mohs surgery, however, greater than 80% of the work is intraservice work that does not overlap when two or more procedures are performed. The pathology portion of Mohs surgery constitutes a large portion of this total and also is not reduced with multiple procedures. The preservice and postservice work values are small because there is a zero day global period. Together there is very little overlap or reduction in work when two or more tumors are treated on the same patient on the same day. Therefore, codes 17304-17310 are exempt from the use of modifier 51.

Codes 17305-17307

17305 Chemosurgery (Mohs micrographic technique), including removal of all

gross tumor, surgical excision of tissue specimens, mapping, color coding of specimens, microscopic examination of specimens by the surgeon, and complete histopathologic preparation including the first routine stain; second stage, fixed or fresh tissue, up to 5 specimens

17306 Chemosurgery (Mohs micrographic technique), including removal of all gross tumor, surgical excision of tissue specimens, mapping, color coding of specimens, microscopic examination of specimens by the surgeon, and complete histopathologic preparation including the first routine stain; third stage, fixed or fresh tissue, up to 5 specimens

17307 Chemosurgery (Mohs micrographic technique), including removal of all gross tumor, surgical excision of tissue specimens, mapping, color coding of specimens, microscopic examination of specimens by the surgeon, and complete histopathologic preparation including the first routine stain; additional stage(s), up to 5 specimens, each stage

Codes 17305-17307 describe the second and subsequent stages of Mohs surgery to remove positive surgical margins. The RVUs already reflect any reduction in work done for these repeat procedures compared to code 17304 (see Appendix E, *CPT 2004*). No debulking procedure is done for these codes; they represent only the additional surgical work for re-excision of positive margins and the additional pathology work for interpretation of the specimens. Like code 17304, these codes are exempt from the multiple surgery reduction rule and do not require modifier 51. When four or more stages are performed in one day, code 17307 should be used with an appropriate number of units for each additional stage. For example, if a tumor was excised with a total of five layers (stages), then codes 17304, 17305, and 17306 would each be reported one time, and code 17307 would be reported with 2 units for the additional two stages.

When Mohs surgery is performed on a single tumor but is carried over to a second day, the first layer on the next day should continue with the next code in the series. For example, the second day starts with code 17305, 17306, or 17307 but not code 17304 because no debulking is necessary. Each layer represented by 17305, 17306, or 17307 includes up to five specimens in each layer. For any individual stage that has more than five specimens, code 17310 should be used.

Code 17310

17310 Chemosurgery (Mohs micrographic technique), including removal of all gross tumor, surgical excision of tissue specimens, mapping, color coding of specimens, microscopic examination of specimens by the surgeon, and complete histopathologic preparation including the first routine stain; each additional specimen, after the first 5 specimens, fixed or fresh tissue, any stage (List separately in addition to code for primary procedure)

Code 17310 is used for unusually large tumors requiring more than five tissue blocks in any layer. It is used for less than 10% of tumors excised by Mohs surgery. This code represents the incremental increase in work for both surgery and pathology for these larger tumors. Code 17310 is reported once with the appropriate number of units for each additional specimen, after the first five specimens in any stage. A *specimen* is defined as a piece of tissue from the layer that must be examined individually and is similar to a tissue block. That is, it represents one piece of the puzzle of the Mohs surgery map. It does not represent the number of slices of tissue from the block on the glass slides or the total number of slides.

Code 17310 is an add-on code and cannot be reported without codes 17304, 17305, 17306, or 17307. Reimbursement is typically not reduced when submitted more than once (see Appendix D, *CPT 2004*). When two or more tumors are treated in one day, code 17310 is reported for each piece of tissue beyond five for any one layer. It is not appropriate to add and average

all pieces from all layers. For example, if the first tumor layer was divided into six pieces, and the second tumor layer had three pieces then code 17310 would be submitted once for the sixth specimen in the first tumor layer.

General Issues: Skin Biopsy Before Mohs Surgery

It is generally recognized that a skin biopsy and histologic diagnosis is necessary before beginning Mohs surgery. If a definitive diagnosis of the tumor is not available, the Mohs surgeon may perform a biopsy to confirm a diagnosis of skin cancer before the decision to initiate Mohs surgery. In this instance, the biopsy codes *11100, Biopsy of skin, subcutaneous tissue and/or mucous membrane (including simple closure), unless otherwise listed; single lesion,* and *11101, Biopsy of skin, subcutaneous tissue and/or mucous membrane (including simple closure), unless otherwise listed; each separate/additional lesion (List separately in addition to code for primary procedure),* and frozen section surgical pathology code 88331 may be reported separately in addition to Mohs surgery. A biopsy may also be required if:

- A biopsy report is not available with reasonable effort
- A biopsy has been done more than 90 days before surgery
- The original biopsy is ambiguous

Modifier 59 should be used with the biopsy (eg, 11100 with modifier 59) and pathology (eg, 88331 with modifier 59) codes to document that these are separate services that are not components of Mohs surgery and that may be bundled erroneously into Mohs surgery if the modifier is not used. It is not appropriate to report a biopsy or frozen section with Mohs surgery for routinely reviewing the histopathologic features of the tumor being treated.

Code 11100 is reported for the first biopsy and code 11101 for a biopsy of second or subsequent skin cancers in different locations. Code 88331 is used for the pathology interpretation of each skin biopsy specimen. Code 88332 is used only if a single surgical specimen is cut into separate tissue blocks for separate examination and usually is not billed with Mohs surgery.

Reconstruction

Some wounds after Mohs surgery are allowed to heal spontaneously by secondary intention without reconstruction of the wound; and, therefore, no RVUs are included in the Mohs family of codes for surgical repair. *Secondary intention* is the spontaneous healing of a wound by granulation and new skin regrowth. If surgical repair is necessary, then the repair codes (simple, intermediate, complex, flaps, and grafts) should be submitted separately. If another procedure is performed on the same day as Mohs surgery, such as reconstruction, typically both procedures should be reimbursed in full since Mohs surgery, is exempt from the multiple surgery reduction rule, and the repair is performed at a separate operative session. If two Mohs surgeries are performed on the same day with both involving reconstruction, the second reconstruction procedure only is subject to the 50% multiple surgery reduction rule.

Evaluation and Management Services

Evaluation and management (E/M) services provided on the same day as Mohs surgery may be reported if a significant separately identifiable service is documented. A separately identifiable service may include an initial evaluation of a new patient, an initial consultation, or other E/M service, or it may include the decision to perform surgery. Modifier 57 is utilized for the E/M service to indicate the decision to perform surgery. If an E/M service is performed with Mohs surgery alone, or when a repair code with a global period less than 90 days is done, the E/M service should be submitted with modifier 25 appended. If an E/M service is performed on the same day as a surgical reconstruction with a 90-day global period (ie, flap or graft), the E/M service should be submitted with modifier 57 according to Medicare guidelines. A separate diagnosis for the E/M service and for the Mohs surgery is not required per CPT guidelines (see modifier 25 in CPT Appendix A).

E/M services following Mohs surgery may be reported depending on the global period of any surgical reconstruction services done with Mohs

continued on bottom of page 14

Coding Communication: Proper Use and Reporting of Needle Electromyography: CPT Codes 95860-95870

Reporting needle electromyography (EMG) services has prompted many questions. One commonly asked question about needle EMG studies concerns the number of muscles required to be studied per limb in order to use the limb EMG codes 95860-95864. Another frequent question concerns the use of CPT codes 95869 and 95870. Codes 95869 and 95870 should be reported for limited needle EMG studies of specific muscles in the limbs and trunk musculature.

CPT Codes

95860	Needle electromyography; one extremity with or without related paraspinal areas
95861	two extremities with or without related paraspinal areas
95863	three extremities with or without related paraspinal areas
95864	four extremities with or without related paraspinal areas
95869	Needle electromyography; thoracic paraspinal muscles (excluding T1 or T12)
95870	Needle electromyography; limited study of muscles in one extremity or non-limb (axial) muscles (unilateral or bilateral), other than thoracic paraspinal, cranial nerve supplied muscles, or sphincters

CPT codes 95860, 95861, 95863, and 95864 are the most commonly used needle EMG codes. To report these codes, extremity muscles innervated by three nerves (eg, radial, ulnar, median, tibial, peroneal, or femoral; not sub-branches) or four spinal levels, must be evaluated with a minimum of five muscles studied per limb. One cannot report paraspinal muscles separately with these codes.

CPT code *95869, Needle electromyography; thoracic paraspinal muscles (excluding T1 or T12)*, should be used when exclusively studying thoracic paraspinal muscles T2-T11. Code 95869 should be reported once, or one unit can be reported, regardless of the number of levels studied or whether the study is unilateral or bilateral. CPT code 95869 cannot be reported with CPT codes 95860, 95861, 95863, nor 95864 if only T1 and/or T2 paraspinal muscles are studied and when upper extremity muscles are also studied. In that case, the thoracic paraspinal muscles are "related paraspinal areas" and are covered under the limb EMG codes.

CPT code *95870, Needle electromyography; limited study of muscles in one extremity or non-limb (axial) muscles (unilateral or bilateral), other than thoracic paraspinal, cranial nerve supplied muscles, or sphincters*, was created to include the following three different kinds of limited needle EMG studies:

- Needle EMG study of a limb or limbs that does not meet the criteria that allow use of CPT codes 95860, 95861, 95863, nor 95864 (eg, study of fewer than five muscles per limb). This code is reported once, or one unit per each extremity studied can be reported. The modifier 59 should be appended to the second, third, and fourth unit or code to indicate that separate limbs were tested.
- Needle EMG of muscles on the thorax or abdomen. This is reported once, or one unit can be reported, regardless of whether it is a unilateral or bilateral study.
- Needle EMG study of cervical or lumbar paraspinal muscles. This is reported once, or one unit may be reported, regardless of the number of levels tested or whether it is a

continued on back page

Proper Use, continued from page 6

unilateral or bilateral study. This code cannot be used when paraspinal muscles corresponding to an extremity are tested and the limb needle EMG codes 95860, 95861, 95863, or 95864 are also reported. In that case, the cervical or lumbar paraspinal muscles are "related paraspinal areas" and are covered under the limb EMG codes.

Codes 95860-95864, 95869, and 95870 can be reported together in various combinations. For example, to report for an extensive needle EMG study of one limb and a limited comparison study of the contralateral asymptomatic limb, one would report codes 95860 and 95870 together. Modifier 59 may be appended to code 95870 to indicate that it is separate and distinct from code 95860, which refers to another limb.

For example, a 45-year-old man presents for electrodiagnostic evaluation of arm pain. He reports similar pain in both arms, although the right arm is more severe than the left. The clinical concern is possible bilateral cervical radiculopathies. In order to evaluate multiple possibly involved myotomes, needle examination was performed in the following muscles on the right: first dorsal interosseus, pronator teres, triceps, deltoid, and cervical paraspinals. Findings were consistent with a C6 radiculopathy. In the left arm only, the pronator teres, triceps, and deltoid were examined to screen for a left C6-7 radiculopathy; results were normal.

In this scenario, code 95860 (since *five* muscles supplied by at least three nerves or four spinal segments were evaluated in the right arm) and code 95870 (only three muscles were examined in the left arm) should be reported.

It should be noted that in order to clarify the proper use of these codes, the Centers for Medicare and Medicaid Services formulated the following policies for Medicare patients. These policies were outlined on page 59090 in the October 31, 1997, *Federal Register* (Vol. 62, No. 211). Other carriers may also follow these guidelines. ■

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August 2, 2007

Herb Kuhn, Acting Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Mail Stop C5-01-14
Room 313 HHH
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Deputy Administrator Kuhn:

The American College of Cardiology (ACC) is a 34,000 member non-profit professional medical society and teaching institution whose mission is to advocate for quality cardiovascular care—through education, research promotion, development and application of standards and guidelines—and to influence health care policy. The College represents more than 90 percent of the cardiologists practicing in the United States.

The ACC has reviewed the notice of proposed rulemaking entitled **Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions(CMS 1385-P)** web posted on July 2, 2007. Our goal in reviewing proposed Medicare policy changes is determine whether those that affect cardiovascular specialists and their patients are rational and consistent with methods that have been established over the past 15 years. The College believes that rational and fair physician payment policies are essential if CMS is to retain credibility with providers and the public.

This letter will focus on CMS's proposal to bundle CPT 93325 into other echocardiography procedures. We will address other provisions of the NPRM in a separate letter.

CODING--ADDITIONAL CODES FROM 5-YEAR REVIEW

CMS proposes to bundle CPT 93325 into all other CPT codes for echocardiography services codes76825, 76826,76827, 76828, 93303, 93304, 93307, 93308, 93312, 93314, 93315, 93317, 93320, 93321, 93350, asserting that color flow Doppler is "intrinsic" to all echocardiography procedures. The ACC strongly disagrees with the approach CMS has proposed and we urge that the proposal be retracted. In evaluating CMS's proposal we considered three primary issues:

- Is color flow Doppler intrinsic to all echocardiography services?
- Do the RVUs for the existing echocardiography codes (other than CPT 93325) account for the distinct physician work and practice expense associated with 93325?
- Can the already-scheduled changes to CPT codes for echocardiography address CMS's concerns?

Is color flow Doppler intrinsic to all echocardiography services?

The ACC does not agree with CMS' assertion that color flow Doppler is "intrinsic" to all echocardiography services. Historically, 1-dimensional echo (M-mode) was developed in the 1970's, 2-dimensional echo became common in the early 1980's, spectral Doppler (93320) grew in the late 1980's, and color flow Doppler (93325) became common in the early 1990's. Each new technology required new transducers and new equipment. Over time it has become common to perform routine 2-dimensional echocardiography (93307) with spectral Doppler (93320) and color flow Doppler (93325), but the Doppler services have not become an intrinsic part of any echo service. Every echo case does not require Doppler. In every echo case where Doppler is used, there is a conscious decision to adjust the imaging mode and acquire a different type of information with very different clinical implications. Examples of its use include the assessment of heart murmurs and the assessment of timing and magnitude of systolic and diastolic left ventricular contraction. Color Doppler is critical for differentiating mild degrees of valve regurgitation that do not require surgical intervention from more significant degrees of valve regurgitation that are treated by valve repair or replacement.

If, as CMS asserts, color flow Doppler is intrinsic to all echocardiography services, it would be reasonable to expect that it would be utilized uniformly across all echocardiography base procedures. The attached table, which shows 2005 Medicare claims data from the Medicare 5% sample file, demonstrates that there is significant variation in the use of color flow Doppler across the family of echocardiography codes. The data indicate that 95% of the Medicare claims for 93307 also include a claim for 93325 performed on the same day. In 2005, the 93307/93325 combination accounted for approximately 93% of all Medicare claims for 93325. Color flow Doppler is performed in conjunction with the remaining base echocardiography procedures 76825, 76826, 76827, 76828, 93303, 93304, 93307, 93308, 93312, 93314, 93315, 93317, 93350 less frequently, ranging from 23% for 93317 to 68% of claims for 93312.

The claims data from the 5% sample file also show varying frequency of use of color flow Doppler with the codes for fetal echocardiography CPT codes 76825, 76826, 76827 and 76828 and echocardiography for congenital anomalies. It is critical to note, though, that Medicare claims data for these procedures are scant and do not form an adequate basis upon which conclude that color flow Doppler is an intrinsic part of any of these procedures.

Based on analysis of the data shown in the table the ACC believes that Medicare claims data do not support CMS's contention that color flow Doppler is intrinsic to all echocardiography services. *We therefore strongly urge CMS to maintain 93325 as a separately payable service for all other echocardiography codes in 2008.*

Do the RVUs for the existing echocardiography codes (other than CPT 93325) account for the distinct physician work and practice expense associated with 93325?

CMS's proposal to bundle 93325 into all other echocardiography procedures does not address the issue of compensation for the additional physician work and practice expense associated with performing color flow Doppler. When color flow Doppler is performed in conjunction with another echocardiography service, the sonographer must spend additional time to acquire the color flow images and the physician must spend additional time and work to interpret and report on those images. The RVUs for CPT codes 76825, 76826, 76827, 76828, 93303, 93304, 93307, 93308, 93312, 93314, 93315,

93317, 93350 do not include this physician work and practice expense. We have recommended that CMS not bundle 93325 into any other echo codes. However, if CMS decides to proceed with any part of its bundling proposal for 93325, we believe that RVUs for those codes should be adjusted to reflect the additional physician work and practice expense required to perform 93325.

Can the already-scheduled changes to CPT codes for echocardiography address CMS's concerns?

The ACC and the American Society of Echocardiography have been in communication with CMS and the RUC concerning appropriate action to take with respect to 93325 since the code was first addressed during the five year review in 2005. As a result of this ongoing dialogue and the ACC/ASE response to concerns expressed by both CMS and the RUC, separate reporting of 93325 will decline sharply beginning in 2009 even if CMS withdraws its bundling proposal. During its June 2007 meeting the AMA CPT Editorial Panel approved a proposal from the ACC and the American Society of Echocardiography for a new CPT code combining 93307, 93320, and 93325. The new code will be implemented in January 2009. As noted above, Medicare claims data show that 93325 is used most often in conjunction with 93307 and this combination accounts for more than 90% of all claims for 93325. Similarly, claims for CPT 93320 can also be expected to decline precipitously in 2009 because 94% of the claims for 93320 are submitted in conjunction with a claim for 93307.

The ACC and ASE will present physician work and practice expense recommendations for the new combined echocardiography code at the September 2007 meeting of the RUC. We believe that implementation of the new combined echocardiography code -- with RVUs reflecting the RUC's evaluation of the physician work and practice expense associated with the code-- will largely address CMS's concerns about separate reporting of 93325.

We urge CMS to defer any decisions about bundling of 93325 until the RUC has made its recommendations for the new echocardiography code.

The ACC is eager to work collaboratively with CMS to determine a rational and fair solution to concerns about utilization of 93325. We believe a face-to-face meeting between representatives of cardiology and key CMS staff would be helpful. ACC's Regulatory Affairs staff will contact CMS to try to arrange a meeting in the very near future.

As always, the ACC commends CMS for its willingness to work in partnership with the physician community to strengthen the Medicare program. Please feel free to contact Denise Garris, Associate Director, Coding and Reimbursement at 202-375-6496 or dgarris@acc.org with any questions.

Sincerely,

James T. Dove, M.D., F.A.C.C.
President

cc: Thomas Ryan, M.D., President, American Society of Echocardiography
James Blankenship, M.D., Chair, CV-RUC
Jack Lewin, M.D., Chief Executive Officer, American College of Cardiology
Robin Wiegerink, Executive Director, American Society of Echocardiography

Medicare 5% Sample LDS SAF Physician/Supplier File 2005.
All Claims Lines with the Indicated CPT Codes -- Crosstab Showing Add-on Codes Appearing With Base Codes

		Count of Claims With Add-on Codes					Percent of Base Code Claims Having Add-On Code				
Base Codes	All Claims	93320	93321	93325	92978	92979	93320	93321	93325	92978	92979
Total all claims	422,018	379,204	4,280	376,567	1,587	178					
No base code on claim	10,454	4,678	252	6,936	1,576	176					
76825	40	-	-	18	-	-	0%	0%	45%	0%	0%
76826	5	-	-	3	-	-	0%	0%	60%	0%	0%
76827	31	-	-	6	-	-	0%	0%	19%	0%	0%
76828	22	-	-	6	-	-	0%	0%	27%	0%	0%
93303	293	249		253	-	-	85%	0%	86%	0%	0%
93304	44		16	28	-	-	0%	36%	64%	0%	0%
93307	369,139	357,750	669	349,376	11		97%	0%	95%	0%	0%
93308	5,327	654	2,262	2,115	-	-	12%	42%	40%	0%	0%
93312	10,997	6,469	292	7,423	-	-	59%	3%	68%	0%	0%
93314	1,008	431	65	531	-	-	43%	6%	53%	0%	0%
93315	102	58		61	-	-	57%	0%	60%	0%	0%
93317	64	48	-	15	-	-	75%	0%	23%	0%	0%
93350	24,492	8,861	716	9,796	-	-	36%	3%	40%	0%	0%

Note: Totals reflect 5% sample data. Multiply by 20 to get estimated US totals. Data blanked if fewer than ten claims.

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AUGUST 02 2007

Centers for Medicare & Medical Services
Department of Health and Human Services
Attention: CMS-1385-P
P.O. BOX 8018
Baltimore, MD 21244-8018

Dear CMS,

I am an anesthesiologist practicing in Southern California. I ask you to increase the Medicare anesthesia conversion factor. Certainly, it needs an update.

Our most difficult challenge in my practice is physician retention. We are able to recruit with difficulty, but find it a challenge to retain long-term.

This absolutely risks access to care. An increase in the Medicare anesthesia conversion factor will give us something to attract new recruits.

My area desperately needs your support.

An increase of what we are asking will help patients, attitudes and outlook for the future.

Thank you sincerely,

James A. McDonald, MD.
21820 Balantree Cr
Yorba Linda, CA. 92887
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J. GRESHAM BARRETT
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45

August 3, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my support for the Medicare payment levels for anesthesia services under the recently released 2008 Physician Fee Schedule rule.

I have heard from a number of practicing anesthesiologists in the 3rd Congressional District of South Carolina who have expressed strong concerns about the current level of payments for anesthesia services under Medicare. These physicians contend that 2007 Medicare payment rates represent between only 30 to 40 percent of commercial insurance payment rates. Specifically, these physicians point out that insurers in South Carolina pay in the $55 to $75 per unit range while the South Carolina Medicare payment rate is currently $15.02 per unit. This significant under-funding of payments for anesthesia services is problematic for practices seeking to cover the cost of providing services to Medicare beneficiaries.

I am pleased that CMS has sought to address this under-funding as part of the 2008 physician payment rule by proposing an increase in anesthesia payments. I urge CMS to finalize this proposal.

Sincerely,

J. Gresham Barrett
Member of Congress

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2 August 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
ATTENTION: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8918.

Dear Members of The Center:

The American Society of Anesthesiologists (ASA) has requested that every ASA member write to you regarding "Support of the CMS proposed increase to anesthesia CF". I am an ASA member, albeit "retired", but am also a senior citizen interested in quality medical care. I therefore submit the following to you.

Before you make any decision in this matter, I urge each and every one of you who vote on this matter to go within, deeply within yourself and answer this question:

If your wife or husband, your son, your daughter, your mother, your father or any person dear to your heart needs surgery to save or prolong their life to preserve their full and natural talents and capacities, who are you willing to approve of and endorse at that time to administer, manage or completely supervise that beloved's anesthesia which will make that a reality?

- an anesthesiologist certified by The American Board of Anesthesiology with years of experience
- an experienced certified registered nurse anesthetist
- a person either physician or nurse, in an anesthesia training program
- a genereal practitioner (MD or DO) with no specialized training
- a nurse with no specialized training, or
- a janitor (an environmental engineer) - don't laugh. It has happened, though not recently.

Please ponder quietly and seriously, that question before you even think of the matter at hand. Would you want the very best, most most highly qualified and skillful soul at the head of the table to bring all their knowledge, expertise, experience and intuition to take care of the very life of your own wife or husband or child?

After you have completed that deliberation, keeping in mind the old saw that "you get what you pay for" ,<u>THEN</u> make the decision you are here to consider.

I urge you to:

1) Approve the proposed increase for anesthesia which the Medicare program has announced it is considering, and further to:

2) grant Board certified anesthesiolgists the same supervisory compensatory regulations as granted to Board certified surgeons for their reponsible supervision of multiple, simultaneous proceedures.

I have no personal stake in either or these matters, except as a possible patient. I retired from anesthesiology practice in June 1990. But I still have strong feelings as the "surgical patients' last advocate" for thirty-one years. I know that untold numbers of surgical patients to be in the future need your help.

My curriculum vitae is attached.

Respectfully yours,

Allen E. Yeakel

Allen E. Yeakel, M.D.

581 Blossom Trail,
Mount Joy, PA 17552-3140

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American Society of Echocardiography

1500 Sunday Drive, Suite 102 • Raleigh, North Carolina 27607 • (919) 861-5574 • Fax: (919) 787-4916
E-mail: ase@asecho.org • Web site: www.asecho.org

August 6, 2007

Herb Kuhn, Acting Administrator
Centers for Medicare and Medicaid Administration
Department of Health and Human Services
CMS 1385-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD. 21244-1850

Re: CMS-1385-P; Proposed Physician Fee Schedule and other Part B Payment Policies for CY 2008. **CODING – ADDITIONAL CODES FROM 5-YEAR REVIEW.**

Dear Mr. Kuhn:

On behalf of the American Society of Echocardiography (ASE), I am writing to comment on the proposed changes in the Physician Fee Schedule (PFS) for CY 2008, published in the July 12, 2007 *Federal Register* (the "CY 2008 PFS Proposed Rule").

The ASE strenuously objects to CMS's proposal to "bundle" Medicare payment for color Doppler (CPT Code 93325) into all echocardiography ("echo") "base" services, effective January 1, 2008. This proposal:

- Is inconsistent with the approach to the "bundling" of color Doppler taken by the Relative Value Update Committee (RUC) – an approach that was taken at the urging of CMS;

- Is based on the faulty assumption that color Doppler is "intrinsic" to the performance of all echo services – an assumption that CMS has made despite ASE's prior transmittal of an analysis of Medicare claims that demonstrates that this assertion is incorrect; and

- Ignores the very real physician work and intra-service practice expenses associated with color Doppler – neither of which are reflected in any echo "base" services.

I. Background

A. Background: The Clinical Utility of Color Doppler

Color Doppler is performed in conjunction with one of the echo "base" imaging codes (transthoracic (TTE), transesophageal, congenital, fetal, or stress) to identify and quantify the severity of valvular malfunction, congenital lesions, myocardial dysfunction and other structural abnormalities. It is used to evaluate hemodynamic status, to select therapy, and to follow the results of treatment. Interpretation of the findings requires a systematic analysis of the color Doppler images, quantitation and integration of the data, and incorporation of this information into the echocardiographic report.

Careful review of color Doppler information is essential for decision making and patient management in a variety of clinical situations. This modality is typically the primary diagnostic technique used in determining optimum therapy for many conditions. For example, color Doppler provides quantitative diagnostic information on the severity of valve regurgitation and, therefore, is essential to identify patients with mitral or aortic regurgitation (in whom murmurs are not always audible and may be unimpressive) to optimize their treatment, and especially to identify those who are candidates for surgical repair.

In similar fashion, color Doppler is necessary for evaluating patients with more common clinical conditions, such as heart failure and acute myocardial infarction, to assess valvular, myocardial and hemodynamic status quantitatively. Color Doppler information is critical to the decision-making process in determining appropriate treatment and following up on the results of treatment. For example in these patients it is used to select patients for medical management versus surgical repair/replacement of valves and is used to assess myocardial synchrony to determine who does and does not need cardiac resynchronization therapy for heart failure.

B. Background: Valuation and "Bundling" of Color Doppler

CMS initially requested inclusion of CPT code 93325 in the five-year review because this service had not been subject to RUC review previously. Accordingly, in 2005 the ACC conducted a survey of the physician work associated with this code in accordance with established RUC survey procedures. Instead of considering the survey results, and based primarily on the fact that the number of claims for color Doppler approximated the number of claims for TTE, the RUC requested ACC to consider submitting a CPT code request that "bundled" color Doppler (but not spectral Doppler) into CPT code 93307.

Shortly thereafter, the ACC and ASE attempted to engage CMS in a dialogue on the issue, and sent an in-depth analysis to CMS setting forth numerous reasons to maintain current coding for color Doppler (the "2005 Position Paper") (Attachment A), including an independent consultant's study detailing the distribution of color Doppler services across echo base codes (the

"2005 Direct Research Analysis) [1] CMS did not respond until March 2, 2006, shortly before the Editorial Panel meeting.. At that time, CMS indicated in e-mail correspondence that: ***"If we decide to review this code {93325}, it will be as part of our usual rule-making process."*** (Emphasis added.) However, CMS did not convey to the CPT Editorial Panel any plan to handle the color Doppler issue in the context of the 2007 PFS, and the Editorial Panel referred the color Doppler back to the RUC "for valuation."

Prior to the next RUC meeting, attempts were made to confirm with the RUC and with CMS that the meeting would address color Doppler valuation – not bundling – and oral assurances were received from RUC sources. Despite these assurances, the RUC meeting once again focused on "bundling" of color Doppler. Subsequently, at the urging of the RUC and CMS, ACC submitted a request for a NEW CPT code for TTEs performed with **both** color and spectral Doppler (i.e., the combination of CPT codes 93307, 93325, and 93320). RUC staff confirmed in writing that this approach was consistent with the RUC's directive. The code request was approved by the Editorial Panel on June 7-10, 2007 and is scheduled for valuation by the RUC at its upcoming September meeting.

II. Comments

A. CMS's Color Doppler Proposal Is Inconsistent with the RUC Process

As discussed above, the RUC, with the full participation of CMS and based in part on what was understood as CMS's position, has already approved a new comprehensive transthoracic CPT code that bundles color Doppler (along with spectral Doppler) into a new CPT code for TTE (933xx). The new CPT code, which is slated for valuation by the RUC in September, 2007 and for implementation in 2009, addresses both spectral and color Doppler, and bundles Doppler services only with TTEs currently reported using CPT code 93307 – since 93% of color Doppler and 94% of spectral Doppler services are performed in conjunction with this base code. An estimated 400,000 Medicare claims (based on the 2005 Direct Research Report) and a substantial number of spectral Doppler services performed in conjunction with other echo "base" procedures remain separately reportable and separately payable. By contrast, CMS's proposal (a) bundles color Doppler with **all** echo base codes; and (b) does not address spectral Doppler.

It is unclear to us why CMS modified its view on this issue at this late date. However, we respectfully urge CMS to refrain from pre-empting all of the time and effort put into this matter by affected professional groups, the RUC, and the Editorial Panel by now adopting a completely different bundling policy which (as discussed below) does not reflect clinical practice insofar as it "bundles" color Doppler into "base" echo services with which color Doppler is not routinely performed.

[1] As discussed below, the 2005 Direct Research is analysis, which was also provided to the CPT Editorial Panel and the RUC (both of which include CMS representation), demonstrates that color Doppler is not an "intrinsic part" of all echo base codes.

B. Color Doppler Is Not "Intrinsic" to the Performance of **all** Echo "Base" Codes

Contrary to CMS's assumption (and as supported by the 2005 Direct Research Analysis), color Doppler is not "intrinsic" to the performance of all echo base services. In fact, the 2005 Direct Research Analysis that accompanied the 2005 Position Statement – which was provided previously to the RUC and Editorial Panel (including CMS) – demonstrates that the only echo "base" code with which color Doppler is billed more than 57% of the time (other than CPT code 93307) is the code for congenital echo (CPT 93303), which generally is not performed for Medicare beneficiaries. More recent data (Attachment C) drawn from the 5% Physician/Supplier Standard Analytic File for 2005 and analyzed by Direct Research (the 2007 Direct Research Report) confirms that this pattern has remained essentially unchanged: Of the 13 echo "base" codes, seven include color Doppler less than 50% of the time. Thus, CMS's own data demonstrate that the performance of color Doppler is not, in fact, "intrinsic" to all echocardiography services.

C. CMS's Color Doppler Proposal Ignores the Physician Work and Practice Expenses Involved in Color Doppler

CMS's proposal to "bundle" (and thereby eliminate payment for) color Doppler completely ignores the practice expenses and physician work involved in performance and interpretation of color Doppler studies. Thus the proposal ignores RUC valuations that were previously accepted, without providing any explanation.

Preliminarily, please note that, as the result of CMS's recent modifications of its Practice Expense Relative Value Unit (PE-RVU) methodology, Medicare payment for color Doppler is already slated to decline by **over 60%.** Therefore, if CMS's interest in bundling color Doppler arises from the unstated assumption that this service is overpriced, significant reductions are already scheduled to occur.

Regardless of the value assigned to color Doppler, providing this service unquestionably does involve real work. While the current work-RVUs associated with color Doppler are minimal, the physician work is real – and growing. (Currently, .07 work RVUs are assigned to this service, which equates to approximately $2.66, assuming the current conversion factor.) The ASE's Guideline entitled, "Recommendations for Evaluation of the Severity of Native Valvular Regurgitation with Two-dimensional and Doppler echocardiography," (www.asecho.org/freepdf/vavularregurg.pdf) details the physician work involved in color Doppler for the assessment of valvular disease:

> This technique [color Doppler] provides visualization of the origin of the regurgitation jet and its width (vena contracta), the spatial orientation of the regurgitant jet area in the receiving chamber and, in cases of significant regurgitation, flow convergence into the regurgitant orifice. The size of the regurgitation jet by color Doppler and its temporal resolution however, are

> significantly affected by transducer frequency and instrument settings such as gain, output power, Nyquist limit, size and depth of the image sector. Thus, full knowledge by the sonographer and interpreting echocardiographer of these issues is necessary for optimal image acquisition and accuracy of interpretation.

This document requires the interpreting physician to perform a number of measurements. Yet, CMS's proposal ignores the physician work involved, assuming (without basis or explanation) that the additional value of this work is 0.

Likewise, CMS's proposal utterly ignores the practice expenses involved in performing color Doppler studies. It appears that CMS believes that because echo equipment now universally incorporates color Doppler capability, and because color Doppler is often performed concurrently with the imaging and spectral Doppler components of echo studies, there are no practice expenses involved. In fact, however, the provision of color Doppler adds sonographer and equipment time to the study, both of which are recognized under CMS's PE methodology.

More specifically, the practice expenses recognized by the PEAC when this code was valued set forth in detail the resources required, and establish quite clearly that there was no "double counting" of the color Doppler and the base code practice expenses. Attachment E. To the contrary, the **total** practice expenses involved in color Doppler (CPT code 93325), spectral Doppler (CPT 93320) and transthoracic echo (CPT 93307) were valued **together,** in reference to two other ultrasound codes – Duplex scan of extracranial arteries; complete bilateral study (CPT 93880) and Duplex scan of arterial inflow and venous outflow of abdominal, pelvic, scrotal contents and/or retroperitoneal organs; complete study (CPT 93975). The presenter argued, and the PEAC agreed, that the total clinical labor time involved in the provision of 93307, 93325, and 93320 (93 minutes), considered together, was greater than the clinical labor time for a duplex scan (82 minutes) and less than the clinical labor time for an abdominal arterial and venous study (108 minutes). Of the total combined 93 minutes of clinical labor time, 13 minutes was accorded to color Doppler (11 minutes of intraservice time was approved for data acquisition, and two minutes for processing, analyzing, and recording the results). Because color Doppler is always performed in the same session as an echo "base" code, no pre- or post service time was requested by the presenter or approved by the PEAC: To avoid double counting, all pre and post-service time – which should be allowed only once for the entire session – was associated with the "base" code.

The direct practice expense data published on the CMS website appears to reflect only 11 (rather than 13) minutes of staff time, and presumably direct expenses for the necessary echo equipment were estimated on the basis of staff time. There are no supply costs associated with color Doppler.

The sonographer time and skill involved in providing color Doppler is not insubstantial. The protocol for data acquisition for color Doppler requires the cardiac sonographer to perform numerous tasks and obtain a number of measurements, as reflected in the ASE standard entitled,

"Recommendations for Quantification of Doppler Echocardiography" at www.asecho.org/freepdf/RecommendationsforQuantificationofDopplerEcho.pdf , as well as in the vavular regurgitation standard at www.asecho.org/freepdf/vavularregurg.pdf). Thus, allocating 11 minutes of time for the cardiac sonographer to acquire, process, and record the preliminary results of a color Doppler study is, if anything, conservative. CMS's proposal to pay nothing for the cardiac sonographer's time, the equipment time, and associated overhead is entirely unsupportable. In fact, if CMS's proposal were adopted, the practice expenses involved in the performance of a complete TTE examination, including spectral and color Doppler services, would be less than the practice expenses involved in performing a duplex study, which clearly was not the intent of the PEAC.[2]

Moreover, the Hospital Outpatient Prospective Payment System (HOPPS) Proposed Rule for CY 2008 includes an entirely different proposal for "bundling" color Doppler into echo base codes. Under this proposal, the practice expenses associated with **both color and spectral** Doppler are bundled: However, the Ambulatory Payment Classification (APC) rates of the associated "base" echo services are increased to account for the additional costs. While we have not yet fully analyzed the HOPPS color Doppler "bundling" proposal and we clearly disagree with the "bundling" rationale used in the HOPPS Proposed Rule for both spectral and color Doppler, the HOPPS "bundling" proposal at least does recognize the very real resources involved in the provision of color Doppler.

III. Our Request.

At this stage, the cardiology community is faced with no fewer than three proposals for "bundling" color Doppler into base echo codes:

- **Proposed PFS Approach**. This approach singles out *color Doppler* and "bundles" it into all echo codes, *without providing additional payment* on the grounds that color Doppler is an "inherent" part of echo. We disagree strongly with this approach and the underlying rationale.

- **Proposed HOPPS Approach**. This approach bundles Medicare payment for numerous add-on codes and other "ancillary support" services into the APC payment amounts for the associated principal procedures, and *increases APC rates* applicable to principal procedures proportionately. Under this proposal, *both spectral and Doppler* are bundled into all echo base codes, the former on the grounds that it is an "intra-operative procedure" and the latter on the grounds that it is an "image processing" service. In point of fact, neither of these rationales reflects an accurate understanding of cardiac Doppler services

[2] In fact, if this proposal is adopted, we believe that it would be appropriate to re-value the practice expenses accorded to both the carotid duplex and the AAA reference codes.

- **RUC Approach**. The RUC approach (taken with the apparent concurrence of CMS) would create a *new code* for the commonly performed combination of (resting) TTE (93307) with *color Doppler and spectral Doppler*, without bundling either spectral or color Doppler into any other echo base code. *Recommended valuation under the PFS would be provided by the RUC*, and payment under HOPPS for the new code would be determined in the interim final HOPPS rule for CY 2009.

Under these circumstances, we cannot help but conclude that CMS's approach to "bundling" of echo and other services is in need of additional study and coordination. **For this reason, we request a meeting that includes not only CMS personnel with authority over the CY 2008 PFS Proposed Rule but also those with authority over the CY 2008 HOPPS Proposed Rule, as soon as practicable.**

We appreciate the opportunity to comment on this proposal, and look forward to meeting with you to discuss the possibility of a more unified and well-reasoned approach to this issue.

Sincerely yours,

Thomas Ryan, MD

Thomas Ryan, MD
President
ASE

Summary of Accreditation Provisions in Section 309 of H.R.

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ACE
ANESTHESIOLOGY
CONSULTANTS EXCHANGE, P.C.

Department of Anesthesiology
975 E. Third Street
Chattanooga, TN 37403
Office 423-778-7608
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July 26, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P

Dear Ms. Leslie V. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I join the fifty eight House members from both parties, who have signed support urging you to analyze the under funding of Medicare payments for anesthesia services.

I provide anesthesia services to many Medicare/Medicaid patients. My services are highly valued in the hospital and the community. I feel that the undervaluation that CMS has placed on my specialty service is unjustified. My services continue to be a unique and necessary part of patient's care and yet CMS continues to reduce their value with the sustainable growth rate formula.

I am grateful that the Anesthesia Society of America's Committee on Economics recommended a payment update and has urged CMS to reconsider how little they have paid for anesthesia services. While there was some success at the 1996 Five Year Review, I believe it did not go far enough to correcting the inequality in anesthesia payments.I am pleased that the Specialty Society Relative Value Update Committee was convinced that anesthesia was significantly undervalued in the Medicare Physician Fee Schedule. I fully support CMSs proposal to increase the work value of anesthesia services by about $3.30 per unit.

In order to continue offering quality anesthesia services to my area it is important to me that CMS follow through with the proposal and implement the increase in the anesthesia conversion factor. I appreciate you addressing my concerns and I thank you for your consideration.

Sincerely,

Gerald Brocker, MD, Coordinator of Anesthesia Services, T.C. Thompson Children's Hospital
Anesthesiology Consultants Exchange, P.C.

MCAA MEDICAL CENTER ANESTHESIOLOGY OF ATHENS, P.C.

Hospital Telephone (706) 475-3666
Business Office (706) 543-3449
Facsimile (706) 543-5744

July 27, 2007

To Whom It May Concern:

I am writing to request that the Centers for Medicare and Medicade Services (CMS) analyze the under-funding of Medicare payments for anesthesia services and consider possible changes to these payments as part of the 2008 fee schedule rulemaking process. Because the current rates are far below the market rate, we are concerned that this inequity creates a threat to access to anesthesia care for Medicare recipients.

Despite a longstanding under-funding for anesthesia services, CMS instituted a significant payment reduction to anesthesia services this year. Effective January 1, 2007, even with Congress acting to temporarily freeze on the physician-wide SGR payment reductions, CMS reduced Medicare anesthesia payments 8.9% -- a reduction that exceeded payment changes for every other specialty for the year. The reductions resulted from the unfair impact on anesthesia services of the Medicare "budget neutrality adjustment", and the implementation of a new measure of physician overhead or practice expense costs which CMS has subsequently acknowledged requires refinement.

Medicare's payments for anesthesia services already lag significantly behind the level of the program's payments for other services. The average 2007 Medicare anesthesia conversion factor is actually lower than it was in 1990 and is less than 36% of the commercial insurance conversion factor. In contrast, MedPAC, the Congressional advisory commission reports that Medicare payments to other providers average 80% of commercial insurance payments.

We urge CMS to address the under-funding of this important medical specialty by considering changes for anesthesia services as part of the 2008 physician fee schedule rule. Such an effort would be an important step in assuring appropriate payment levels for these critical services.

Thank you for your consideration.

Peter Kelley, M.D.

2425 WEST BROAD ST. • ATHENS, GEORGIA 30606

CAMBRIDGE HEART

August 2, 2007

Amy Bassano
Director, Division of Practitioner Services
Centers for Medicare & Medicaid Services
7500 Security Boulevard, C4-01-26
Baltimore, MD 21244

Re **Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008 CMS-1285-P Practice Expense -- Equipment Usage Percentage**

Dear Ms. Bassano

We appreciate the opportunity to comment on the 2008 Physician Fee Schedule Proposed Rule as published in Federal Register on July 12, 2007. Cambridge Heart, Inc. is the manufacturer of the Microvolt T-Wave Alternans (MTWA) non-invasive diagnostic test for the assessment of the risk of sudden cardiac death. This letter primarily addresses the negative impact of the equipment usage percentage in the practice expense calculation on the physician payment rate for MTWA. We would like to meet with the agency during the comment period to review these issues.

Summary

The application of a standard equipment usage assumption of 50% in calculating the PE component of the PFS payment for medical equipment vastly overstates MTWA's actual utilization rate. As a result, over the next four years physicians will be subject to a reduction of more than 40% in the Medicare payment rate for MTWA. This is contrary to the purpose of the revised PFS PE methodology, and threatens to compromise patient access to this breakthrough diagnostic technology.

For the reasons set forth below, Cambridge Heart respectfully requests that CMS employ the actual equipment usage for MTWA.

- CMS's issuance of a National Coverage Determination (NCD) for MTWA testing reflects the agency's view that MTWA is an effective risk stratifier for patients under consideration for costly Implantable Cardioverter Defibrillator (ICD) placement.
- The dramatic overstatement of MTWA equipment utilization under CMS's standard utilization assumption inappropriately understates physician costs, and thereby deters physicians from using this non-invasive and inexpensive life-saving risk stratification tool.

[illegible] • Boston, MA 02[illegible] • Phone: (8[illegible] • Fax: (9[illegible]
• www.cambridgeheart.com

- Because Cambridge Heart is the sole supplier of the single-use disposable sensors required for MTWA testing, the company can determine with great accuracy the actual usage of MTWA equipment

Background on MTWA

MTWA is a noninvasive diagnostic test that assesses the risk of sudden cardiac arrest and sudden cardiac death resulting from ventricular arrhythmias. Sudden cardiac death from ventricular arrhythmias claims the lives of 400,000 Americans each year, a large proportion of who are Medicare beneficiaries. Cambridge Heart developed and manufactures the only MTWA test recognized and covered by Medicare.

Cambridge Heart's MTWA test uses propriety algorithms and specialized alternans sensors to detect minute beat-to-beat fluctuations in the T-wave portion of a patient's electrocardiogram. MTWA testing has been evaluated in numerous prospective clinical trials. These trials have shown that patients, who are potentially at risk of life threatening arrhythmias due to the presence of cardiac disease, who have a normal (negative) MTWA test bear only minimal risk for a sudden cardiac event while those with an abnormal test bear a substantially higher risk. MTWA testing enables physicians to guide truly at-risk patients to life saving ICD therapy, while allowing patients who are at minimal risk and unlikely to benefit from ICD therapy to avoid an expensive and invasive procedure associated with its own risk of morbidity and mortality.

In March 2006, CMS issued a National Coverage Decision to expand coverage of MTWA for the evaluation of patients at risk of sudden cardiac death. This expansion of Medicare coverage provided physicians and beneficiaries with a non-invasive and inexpensive means of assessing the risk of sudden cardiac death in individuals who are candidates for ICD implantation.

The majority of the usage of the MTWA testing is in cardiology based physician offices. In a typical office based examination, a patient at risk for sudden cardiac death due to underlying structural heart disease would undergo MTWA testing in addition to a battery of other non invasive tests directed towards evaluating his/her underlying heart disease. It is not common practice for a cardiologist to refer a patient to a hospital for an MTWA test.

CMS Should Use the Actual Usage Rate

In the proposed rule CMS indicated its desire to assign appropriate usage rates to different types of equipment. CMS states:

> *We are interested in receiving comments relating to alternative percentages and approaches that differentially classify equipment into mutually exclusive categories with category specific usage rate assumptions. We are committed to continuing our work with the physician community to examine equipment usage rate assumptions that ensure appropriate payments and encourage appropriate utilization of equipment. Additionally, we would welcome any empirical data that would assist us in these efforts.*

[illegible] One Main Street • Medford, MA 01720 • Phone: [illegible] • Fax: [illegible]
[illegible]

Cambridge Heart believes that CMS should base the PE RVU for MTWA testing on its actual usage rate. For many types of equipment, it is exceedingly difficult to determine accurately actual usage rate. In order to accommodate this common informational deficiency, CMS has applied an equipment usage assumption of 50%, that is, equipment required to furnish a service is assumed to be used for one-half of the maximum possible minutes per year.

While the application of a standard equipment usage assumption may be reasonable for categories of equipment for which it is difficult to determine accurately actual usage, it is inappropriate with respect to equipment for which actual usage is well documented.

In the case of MTWA testing, the standard 50% usage assumption is significantly greater than the actual utilization rate.

We understand that MedPAC has already begun to investigate the possibility of updating the PE RVU methodology by accounting for utilization rates that are substantially ***higher*** than the standard 50% assumption. In its June 2006 report to CMS, MedPAC noted that some categories of high priced equipment have utilization rates between 70% and 90%, and proposed that CMS could "improve the accuracy of input prices" by revisiting "the assumptions it uses to estimate the per service cost of medical equipment, particularly the assumption that equipment is operated 50 percent of the time." Additionally, Congress is considering legislation that would increase equipment usage assumption from 50% to 75% for imaging technologies.

Cambridge Heart is encouraged by these efforts to incorporate actual utilization rates, and is committed to working with CMS and others to establish a more accurate equipment usage rate for MTWA testing.

Cambridge Heart believes that in the final rule CMS should create a category for those items for which the actual utilization is accurately known and documented. Cambridge Heart is prepared to work with CMS on an ongoing basis to provide actual equipment utilization data for MTWA testing to document any future changes in utilization.

MTWA Testing Equipment Actual Utilization Rate

The actual utilization rate for MTWA testing equipment is precisely known and very well documented. MTWA tests require a single-use disposable sensor, of which Cambridge Heart is the sole supplier. Cambridge Heart has conducted a review of all fielded MTWA units to determine their actual usage.

The Table below presents the calculation of the MTWA equipment utilization based on an MTWA equipment utilization time per test of 15 minutes which is the current CMS input for this data element. The Cambridge Heart MTWA systems utilize a single-use disposable set of Micro-V™ sensors for which Cambridge Heart is the sole supplier. Cambridge Heart knows how many of its MTWA systems are fielded and the precise number of sensor sets shipped each year. Using the number of sensor sets shipped allows us to calculate an upper limit for the actual equipment utilization (actual utilization would be a bit less if some of the shipped sensor sets end up not being used).

Table: 2006 Microvolt T-Wave Alternans Equipment Utilization

Fielded MTWA Systems (US - year end)	**687**
Micro-V Alternans Sensor™ sets shipped in US	**30,900**
Tests per MTWA System per Year (30,900 Sensor Sets / 687 Fielded Systems)	**44.98**
Minutes Used per MTWA System per Year (44.98 tests/yr x 15 min/test)	**675**
Actual Utilization Rate (675 min/yr) /(150,000 min/yr max)	**0.45%**

Current Utilization Rate for MTWA is Low

CMS has raised questions regarding the low utilization of MTWA. The current utilization is reflective of the patient populations in which the technology is used and current limitations of reimbursement and coverage and also, as discussed below, the artificially low CMS time input for MTWA equipment utilization. Utilization is expected to increase over the next several years but the equipment utilization will always be substantially below the 50% usage assumption. We should also mention that if CMS adopts the correction to the time input for MTWA equipment usage recommended below the current utilization rate would be 1.59% instead of 0.45% - still very substantially below the 50% assumption.

The current primary target population for MTWA testing are those patients with left ventricular ejection fraction (LVEF) less than or equal to 35% with no prior history of cardiac arrest (CA). These patients are generally covered by Medicare and most private carriers for implantable cardioverter/defibrillator (ICD) therapy to prevent future CA and sudden cardiac death (SCD). MTWA identifies approximately one-third of this population as being at very low risk of SCD and unlikely to benefit from ICD therapy. ICD therapy while very effective in reducing mortality from SCD is associated with its own significant mortality and morbidity risk and is also a costly therapy. MTWA testing is used by physicians to help guide ICD therapy in this population. It is estimated that approximately 100,000 ICDs per year are implanted in the United States in this primary prevention population. In 2006, Cambridge Heart, Inc shipped 30,900 sensor sets in the United States the majority of which we believe were used in this primary prevention population. Thus even though MTWA is early in its adoption phase, the number of MTWA tests performed per year in the United States is already equal to a significant fraction of the number of primary prevention patients who receive ICD therapy each year in the United States.

MTWA was approved by the FDA in 2001. In the initial years, Medicare coverage and private payer coverage for MTWA varied by region. This patch work of coverage policies limited utilization. In 2005, Medicare expanded coverage of ICD therapy. In March 2006, CMS expanded coverage of MTWA for sudden cardiac death through a National Coverage Decision (NCD) and this has led to increased coverage by a number of the large private payers. Cambridge Heart therefore expects that there will be increased levels of MTWA testing in future years, however, Cambridge Heart also expects that there will an increased number of fielded MTWA systems. Cambridge Heart, Inc. hopes that utilization per system (currently 3.75 tests

per month per US fielded system) will increase. However, even if that rate were to double the equipment utilization would remain a very small fraction of the current 50% utilization assumption.

Despite the fact that the total number of tests performed is modest, the medical/clinical impact of the test for an individual Medicare beneficiary is enormous. If the MTWA test indicates that ICD therapy is necessary, the result of an MTWA test may quite literally be life-saving for that patient. Conversely, if the MTWA test indicates that the patient is at very low risk, that patient may avoid a costly invasive procedure which carries the risk of device-related mortality and morbidity.

Complications of ICD therapy include infection, perforation, inappropriate shocks, lead breakage and device recall. In the absence of MTWA testing, a large number of ICDs (estimated at 15-20) must be implanted in the primary prevention population in order to save one life for some period of time. MTWA testing is inexpensive, but ICD therapy is quite costly. MTWA testing has the potential of substantially reducing Medicare expenditures for un-needed ICDs while helping to ensure that ICDs are received by Medicare beneficiaries who actually will benefit from this therapy.

CMS Time and Data PE Inputs for MTWA Testing CPT Code

A realistic clinical scenario is that all the MTWA associated equipment is located in a room in a physician's office and that this room can be used at most for one patient at a time to perform MTWA testing or for stress testing. We believe therefore that it is accurate to estimate that all the MTWA associated equipment is used for at least the 53 minutes although we would argue (after consulting with MTWA clinical experts) should be 60 minutes or one hour per test and that the associated nurse time (staff type should be at least the same level as stress test but currently is not – an MTWA test requires more skill and training to perform than a standard stress test) to conduct the stress test is also at least 53 minutes or our estimate as one hour. Cambridge Heart requests that CMS make the following specific adjustments to their PE data inputs.

- Change Staff type from L037D RN/LPN/MTA to L051A RN this is the same personnel input as for a Stress Test see CPT 93015 and CPT 93017
- Change Table Time from EF023 at 23 minutes to 53 minutes
- Change the cardiac monitor w-treadmill (12-lead PC-based ECG) EQ078 from 15 minutes to 53 minutes
- Change the cardiac monitor w-treadmill (microvolt CH2000) from EQ079 15 minutes to 53 minutes

At present a physician may not bill for the practice expense of an MTWA test and a stress test on the same date of service. Cambridge Heart believes the reason for this is that it was believed that the data collected during an MTWA test could also be used for purposes of stress testing. In fact this is not the case. The exercise protocols for the two tests are entirely different. If a physician wanted to perform a maximum capacity stress test at the same time as an MTWA test, typically the physician would perform the MTWA test, let the patient rest for at least 15 minutes and then perform a standard stress test protocol.

Cambridge Heart will be requesting through the CMS CCI edit contractor a change from 0 to 1 to allow for the limited and appropriate times a maximum capacity stress test would be performed on the same day as an MTWA study

Conclusion

CMS greatly expanded Medicare coverage for and beneficiary access to, MTWA testing through development of an NCD. Because the 50% equipment usage assumption inappropriately understates physician payments, it deters physicians from using MTWA and thus limits beneficiary access to this non-invasive and inexpensive life-saving risk stratification tool.

We are available to work with and assist CMS in implementing the most appropriate and accurate method of calculating practice expense costs for MTWA.

We appreciate your attention to this issue.

Sincerely,

Robert P. Khederian
CFO, Cambridge Heart, Inc.

PHYSICIANS
LABORATORY

focused on excellence

51

8 August 2007

Department of Health and Human Services
P.O. Box 8018
Baltimore, MD 21244-8018
Attention: CMS-1385-P

RE: Physician Self-Referral Provisions

Gentlemen:

The following comments are submitted regarding Physician Self-Referral Provisions of CMS-1385-P entitled "Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2008." My practice in Sioux Falls, South Dakota, includes 10 other pathologists, all of whom are board-certified and members of the College of American Pathologists. We provide professional services to four hospitals in Sioux Falls, Yankton and Mitchell South Dakota as well as Spencer, Iowa as well as to numerous clinics in South Dakota, Minnesota, Iowa and Nebraska.

For years it has been the practice of large clinics to coerce pathology laboratories into "client billing" where clinics paid a flat fee for pathology services, then marked the fee to patients up and pocketed the "profit". The coercion was based on the threat of loss of referrals. Over the years, this practice has been refined to levels I could not have imagined. We are continuously under pressure from some of our clients to support these kinds of arrangements. Regardless of the variations, the outcomes are the same: providers billing for work performed by others for which they take no professional responsibility. I believe these arrangements are an abuse of the Stark law prohibition against physician self-referrals and I support revisions to close the loopholes that allow physicians to profit from pathology services.

I am pleased that CMS has initiated a process to end self-referral abuses in the billing and payment for pathology services. Expansion of the anti-markup rule to purchased pathology

1000 E. 21st Street • Suite 4100 • Sioux Falls, SD 57117-5050
605-322-7200 • 800-658-5474 • FAX 605-322-7222
www.PLPATH.com

interpretations and the exclusion of anatomic pathology from the in-office ancillary services exception to the Stark law are specific revisions I particularly strongly support. I believe that physicians should not be able to profit from the provision of pathology services unless the physician is capable of personally performing or supervising the service. In the absence of this capability, financial self-interest too often becomes an important element in clinical decision-making rather than the interest of the patient.

The proposed changes impact neither the availability or delivery of pathology services. They are designed only to remove the financial conflict of interest that compromises the integrity of the Medicare program. While opponents to the proposed changes suggest that existing self-referral arrangements enhance patient care, they exist for another purpose entirely and that is to maximize physician practice income. The Medicare program should ensure that providers furnish care in the best interests of their patients, and, restrictions on physician self-referrals are an imperative program safeguard to ensure that clinical decisions are determined solely on the basis of quality.

Please accept my compliments on a well-written proposal which I fully support.

Sincerely yours,

Henry Travers, M.D., F.A.C.P.
Pathologist

August 13, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-year review)

Dear Ms. Norwalk:

As a practicing anesthesiologist, I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. This is long overdue and I am grateful the CMS has recognized the gross undervaluation of anesthesia services. It is ironic that plumbers and auto mechanics earn more per hour than anesthesiologists who care for medicare patients. The current medicare reimbursement is so inadequate that it doesn't even cover our costs. Some of my colleagues moved out of areas of high medicare populations because it was not economically viable to practice in these areas.

Thank you for your consideration of this crucial issue.

Sincerely

Curtis Winters, M.D.

Submitter : Dr. **Date:** 07/19/2007

Organization : Dr.

Category : Physician

Issue Areas/Comments

Conversion Factor

Conversion Factor

The method by which Medicare physician s fees are determined from year to year is completely and undeniably flawed. Practice expenses are outstriping reimbursements for Medicare patients creating an untenable situation. Lowering the conversion factor from 37.8975 to 34.1350 will most definitely cause physicians to close their practices to Medicare patients, drop out of the program altogether or retire from practice. The collective effect of these three options will create huge ACCESS TO CARE issues in our practice at Welborn Clinic as it will across the country.

Furthermore, as we all know reimbursements from Medicare are heaviy weighed to subspecialty care and/or higher technology, incentivizing the providers of such services to do more in such a way that they may cover the costs of the rest of their practice. This is classic cost shifting which has become a core conundrum to the entire health care reimbursement system. It is time to stop this ludicrous cycle and CMS holds the leadership key. Congress will listen to you - please present a concept for office practice reimbursements that is more than simple brute price reduction. You can do better.

McLeod Pediatric Cardiology
305 E. Cheves St. Suite 220
Florence, SC 29506
843-777-7300, Fax 843-777-7311

To: CMS
Re: File Code: CMS–1385–P, Coding—Additional codes from 5-year review

08/07/2007

Dear Sir or madam,

I am writing in regards to the proposed change to bundle CPT 93325 into the other echocardiographic codes. I could say that echocardiography is the backbone of cardiac diagnostic testing and the three components of the study (the 2D, Color and Doppler) are still separate studies with different uses in different patients but you already know all that. Everyone knows what's going on: you want the same high quality, professional service for less and less money, but cutting payments to cardiologists is not the answer.

If you want to save millions of dollars and improve quality, the answer is abundantly clear: stop paying for incompetent care.

What's that? You don't pay for incompetence?

Of course you do; worst still, you encourage and enable incompetence every time you pay a family practitioner or an internist for "reading" an echo. Let's examine the facts: cardiologists spend years performing and reading echo's in heavily supervised training programs. Internists and family doctors spend zero time in formal echo training during residency. Attending cardiologists spend a significant part of their CME time on echo. Internists and family doctors: nearly zero. Where do noncardiologists learn echo interpretation? Some take a weekend course, some learn from other noncardiologists: In other words, the blind leading the blind. What if an internist has been reading studies for 20 years? Doesn't that imply quality? Well, if he was never properly trained and does not keep up, then he can't know what he's doing. To put it bluntly, he's been doing it wrong for 20 years, but don't take my word for it; where is the data on the diagnostic accuracy of non-specialists reading echo's? One study (Diagnostic accuracy of pediatric echocardiograms performed in adult laboratories. Am J Cardiol. 1999 Mar 15;83(6):908-14) found an accuracy rate of 50%. Flip a coin and anyone can read pediatric echocardiograms with the same level of competence.

Is this what you want? If you want to save millions and promote quality, only pay experts for expert care and stop talking about "saving money" by slashing payments to the people who actually know what they are doing.

Sincerely,

Charles A. Trant, Jr. MD, F. A. C. C.

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore< MD 21244-8018

Forrest Krause M.D.
1910 South Ave
La Crosse, WI 54601

August 11, 2007

Dear Sir,

I am writing to you today to urge you to support a very positive payment change. Earlier this year, the AMA/Specialty Society Relative Value Update Committee (RUC) submitted to CMS a recommendation to boost the anesthesia conversion factor to account for a calculated 32-percent work under valuation. This change is needed for fair compensation of anesthesia providers who participate in Medicare and Medicaid programs. Thank you.

Sincerely,

Forrest Krause

Forrest Krause, M.D.

August 8, 2007

Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8017
Baltimore, MD 21244-8018

Re: CMS 1512-PN; PRACTICE EXPENSE

Dear Dr. McClellan:
I am a cardiac sonographer, in a mobile service serving the elderly in nursing homes, and I am delighted to have the opportunity to comment on the Proposed Notice published by CMS in the *Federal Register* of June 29, 2006, which sets forth proposed changes to the relative value units used to establish payment for services to Medicare patients under the Physician Fee Schedule.

I am extremely concerned about the possible impact of these changes on Medicare payment for cardiac ultrasound and other cardiac imaging services performed in the mobile setting. While the Proposed Notice would result in increases in Medicare payment for some of the services that we provide—most notably evaluation and management services –we are concerned that, by the end of the transition period, the Proposed Notice would result in payment reductions in the range of 25% for the most common combination of echocardiography procedures (transthoracic echocardiogram with spectral and color flow Doppler (CPT codes 93325, 93320 and 93325). This part of an exam requires a great deal of time in my patients. Elderly patients have a difficult time lying still to allow doppler window to be placed properly. **These changes would essentially put me out of business. We could no longer offer this procedure in the mobile setting.**
Echocardiography is a crucial tool in the diagnosis of a broad range of cardiac disease, including congestive heart failure, congenital heart disease, valve disorders, and coronary artery disease. The performance of echocardiography requires the acquisition and maintenance of costly medical equipment and the retention of highly trained cardiac sonographers who are in increasingly short supply. We are concerned that payment reductions of the magnitude outlined in the Proposed Notice may have an adverse impact on the overall quality of the echocardiography services provided to our patients at the very time that the federal government is seeking to improve quality through pay for performance and similar quality-related initiatives.
While I am not in a position to provide a complete technical analysis of the Proposed Notice, I understand that the American Society of Echocardiography (ASE) is conducting such an analysis and will be submitting comprehensive comments. I support those comments, and strongly urge you to consider making the changes suggested by ASE in the Final Rule.
Thank you for your attention to this most important matter.

Sincerely yours,

Ronald D. Fox R.T.(R)(CV)
410 Grant St. Galion Ohio 44833
419-468-6023
President
Mobile Echo & Imaging, Inc.

59-1

ROWAN REGIONAL PATHOLOGY ASSOCIATES, P.A.
612 Mocksville Ave.
Salisbury, N.C. 28144

August 7, 2007

Dear CMS,

Thank you for the opportunity to submit comments on the Physician Self-Referral Provisions of CMS-1385-P entitled "Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2008."

I am a board-certified pathologist and a long time member of the College of American Pathologists. I have practiced in Salisbury, North Carolina as part of a four person group in a hospital for the past 23 years. We receive our work both from the surgeries performed in the hospital and the biopsies performed in doctor's offices.

I commend CMS for undertaking this important initiative to end self-referral abuses in the billing and payment for pathology services. I am aware of arrangements in my practice area that give physician groups a share of the revenues from the pathology services ordered and performed for the group's patients. This is particularly a problem in Dermatology practices but also is used by primary care groups that perform many skin biopsies and surgeons that perform needle biopsies of the breast and prostate. These doctors select Pathologists that are willing to bill them at a small fraction of what I bill to allow them to mark-up this fee and make huge profits. I believe these arrangements are an abuse of the Stark law prohibition against physician self-referrals and I support revisions to close the loopholes that allow physicians to profit from pathology services. Profit should not be the motive behind the *selection* of a physician who determines if you have a Melanoma or Breast Cancer!

Specifically I support the expansion of the anti-markup rule to purchased pathology interpretations and the exclusion of anatomic pathology from the in-office ancillary services exception to the Stark law. These revisions to the Medicare reassignment rule and physician self-referral provisions are necessary to eliminate financial self-interest in clinical decision-making. I believe that physicians should not be able to profit from the provision of pathology services unless the physician is capable of personally performing or supervising the service.

Opponents to these proposed changes assert that their captive pathology arrangements enhance patient care. I agree that the Medicare program should ensure that providers furnish care in the best interests of their patients, and, restrictions on physician self-referrals are an imperative program safeguard to ensure that clinical decisions are determined solely on the basis of quality. The proposed changes do not impact the availability or delivery of pathology services and are designed only to remove the financial conflict of interest that compromises the integrity of the Medicare program and American health.

Thank you for your kind attention to this matter.

Sincerely,

Rachel H. Ross

Rachel H. Ross, MD

Rachel H. Ross MD, Leslie Sierra-Renten MD, Jim Cervin MD, Joel Weber MD

60-1

ASHLAND
PHYSICAL THERAPY

MICHAEL J. SIEGL, PT, MTC

August 10, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244

Re: CMS-1385-P

Dear CMS Representative:

I am writing this letter to express my concern regarding the proposed Medicare Physician Fee Schedule (MPFS) revision that will dramatically affect the reimbursement of Physical and Occupational Therapy services provided to elderly patients in my community.

This proposed method for reduction in payment will undoubtedly result in lack of patient access to necessary medical rehabilitation that prevents higher cost interventions, such as surgery and/or long term inpatient care.

I understand that the AMA, the American Physical Therapy Association and the American Occupational Therapy Association, as well as other organizations are preparing an alternative solution to present to Congress. Please give this information much consideration and preserve these patients' right to adequate and necessary medical care.

Sincerely,

MICHAEL SIEGL, PT MTC

275 Lithia Way :: Ashland, Or 97520
Phone 541.482.6743 :: Fax 541.482.6758

Submitter : Dr. Naji Tawfik **Date:** 07/20/2007

Organization : Welborn Clinic

Category : Physician

Issue Areas/Comments

Conversion Factor

Conversion Factor

I am a physician who practised in Canada for a number of years. I worked under a national health system. In that system fees were constantly down-adjusted. This approach will, and definitely, affcct access to care. Canadian health care system offers excellent quality of care, but quality is meaningless if it can not be accessed by patients in a timely fashion. I do not want to see access curtailed here. What is being proposed is conducive to such an untoward outcome.
Thank you for allowing this feedback.

Fletcher Allen HEALTH CARE | The UNIVERSITY of VERMONT

Vermont's Academic Health Center

Filed electronically at http://www.cms.hhs.gov/eRulemaking

August 10, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Att: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS 1385-P: 2008 Medicare Fee Schedule
Coding – Multiple Procedure Payment Reduction for Mohs Surgery

Dear Sir/Madam:

I am writing to offer my comments on section II.E.2 (P-122) of the 2008 Medicare Fee Schedule Proposed Rule, which proposes to change how Mohs surgery is reimbursed by Medicare.

I am a dermatologic surgeon at Fletcher Allen Health Care and an associate professor at the University of Vermont. I am also the immediate past Chair of the Scientific Advisory Committee of the American College of Mohs Surgeons. I have been performing dermatologic surgery in Vermont for 12 years at Fletcher Allen Health Care – the University of Vermont College of Medicine.

As a dermatologic surgeon I focus mainly on skin cancer removal. Over a million Americans per year are diagnosed with skin cancer, and over the last ten years the rate of new skin cancer diagnoses has increased dramatically. Substantial morbidity and mortality is associated with skin cancer.

Mohs micrographic surgery (MMS) is a common way of treating nonmelanoma and some melanoma skin cancers and is considered the gold standard among treatments for nonmelanoma skin cancer, allowing the physician to examine 100% of the cancer margin to insure complete removal of the cancer with loss of as little normal skin as possible. It provides the patient with the highest cure rate of any treatment for skin cancer. Mohs surgery is an outpatient procedure that utilizes onsite laboratory analysis of excised tissue while the patient waits for the results. In my 12 years as a Mohs surgeon at Fletcher Allen Health Care I have removed approximately 7500 skin cancers using MMS. During this time I have accomplished a cure rate of well over 99%, despite the fact that some were very challenging, with prior treatment having failed on multiple occasions.

The Issue:

The issue involves the application of the "multiple procedure rule" (MPR) to surgical procedures. The MPR is used by CMS when two surgical procedures are performed on the same day. With the MPR, the higher-value procedure is paid in full, and the lower-valued procedure paid at 50%. The rationale for the MPR is that face-to-face time for two procedures on one patient is generally less than that for two procedures on two patients.

There are a number of procedures that have always been exempt from the MPR, most notably those procedures for which the majority of the work effort does not involve time spent with the patient face-to-face. **MMS was exempted from the MPR in 1991 based on the fact that most of the work associated with the MMS procedure is laboratory work that does not involve face-to-face time with a patient.** As a result, since 1991, when two MMS procedures are done on the same day both are paid in full at the CMS rate. Similarly, once a tumor has been completely removed by MMS, the repair has been considered a separate encounter, since the patient actually leaves the operating suite while awaiting the results of pathology. This decision had been affirmed on several prior reviews of the code 17304, most recently in 2004.

Over the last ten years there has been a marked increase in the utilization of MMS. As a whole, the increased utilization of MMS has had a tremendous positive impact on skin cancer care. When I arrived in Vermont, there were many cases of recurrent skin cancers resulting in marked disfigurement. Now that MMS is available, these cases are much rarer, and most tumors are removed with cure.

Last year the Mohs codes were up for review by the Specialty Society Relative Value Update Committee (RUC), an American Medical Association committee designated to assign relative values to given procedures. The implicit goal of this review was to establish two sets of codes, one for MMS on the face, hands, genitalia, and feet, and the other for other locations, where MMS should rarely be utilized. With input from my professional organization, the American College of Mohs Surgery (ACMS), the RUC proposed new site-specific codes for Mohs surgery, namely CPT codes 17311, 17312, and 17313. These recommendations and associated Relative Value Units (RVUs) were proposed and accepted by CMS for MMS. At the same time, however, the RUC recommended and then CMS elected to apply the MPR to Mohs surgery for the first time. No explanation for this shift was made available. The ACMS protested this decision, which had been made without notice, in violation of CMS's policies. CMS agreed and temporarily restored the MPR exemption.

As of July 1st of this year, CMS again announced a planned change in payment policy. (The proposed payment revisions were published in the Federal Register on July 12; *see* 72 Fed. Reg. 38122, 38146.) The planned change would remove Mohs surgery from the longstanding exemption from the MPR. The change would decrease reimbursement by

50% for either the Mohs excision or for the associated repair, as well as for Mohs excision or repair of any additional cancers treated on the same day.

The implications of this decision:

This decision, if implemented, will negatively affect skin-cancer patients who need MMS procedures, as well as substantially reducing the revenues Mohs-trained dermatologists need to cover the cost of these services. In addition, if the intent of the change is to save Medicare money, the result will likely be the opposite – more money will be spent on more procedures, without the efficiency, cost-effectiveness, and patient-centeredness of today's practices.

To illustrate, at present the Mohs surgeon who removes a lesion and repairs the wound on the same day is paid at the Medicare rate for both procedures. MMS and repair tend to be done in an outpatient setting, and facility fees are not usually applied. If the repair (often a very challenging part of the surgery) is only paid at ½ value due to the MPR, many Mohs surgeons will refer the repair to a colleague in plastic surgery or ENT. This practice is already reasonably common in dealing with difficult cases as a collaborative effort, but it will become widespread if MMS and repair cannot be billed in full on the same day. Since both plastic surgeons and otorhinolaryngologists work exclusively in the operating room, an unintended result will be that the cost per lesion per patient will include not only the full repair amount but also the operating room costs along with anesthesia. This will actually result in an overall higher expenditure per given lesion. In addition, whereas Mohs surgeons will frequently remove two or more lesions on the same day, if they are only paid 50% for the second lesion, they will have no choice but to request that the patient come back on a second day. Although this is inefficient and not patient-care friendly, it will become the standard practice in order for Mohs surgeons to cover their costs.

Let me give you a real-life example of how it works now, and what will likely happen should this new rule take effect. I recently treated a woman with four skin cancers on her face. I was able to remove all four in a single session, and repaired the wounds appropriately. From the patient's perspective, she was happy to have all four spots taken care of in one sitting. She needed to make only one trip to the hospital, was able to minimize the disruption to her life, and was able to know that all four cancers had been taken care of simultaneously.

In terms of the actual procedure, four removals were done, and four pathology specimens were mounted, cut, stained, and analyzed. The patient was then returned to the operative suite and all four sites were repaired surgically. The patient was allotted a substantial time allocation and spent the majority of the morning in the outpatient suite.

Medicare reimbursement for all of this work was $4,281.49. This reflected payment in full for all four Mohs surgery removals (17311 – 4 units), payment for the largest repair in full, and – because the MPR is already applied to the other three repairs – 50% payment for each of them.

If the MPR were implemented for the Mohs code 17311, the reimbursement would have been $2,960.89 – a reduction of $1,320.60, or 31%. This amount would not have covered the cost of running my lab, paying my technician, my nurse, my medical assistant, the room time, the surgical instruments and supplies, and the remainder of my staff expenses.

If on the other hand the MPR were applied and we performed surgery for her four lesions on four separate days, Medicare would reimburse $3,879.95 – an overall savings to Medicare of only $401.54 from how it would be reimbursed today, but an increase to the physician of $919.06. Despite the enormous imposition on patients to treat them in this inefficient manner, the difference in payment to the physician will likely mean that lesions would start to be treated one at a time in order to ensure that the costs of the services are covered.

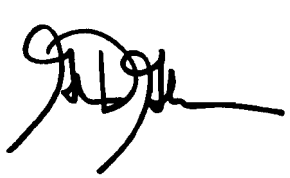
Furthermore, if these procedures were to be performed by plastic or general surgeons in the hospital, the costs would be even higher, since the pathology fees and facility fees would be multiple times that of the MMS and repairs as listed.

Similarly, if the MMS were done by an individual physician and the repair by a separate reconstructive surgeon, the overall cost would also be higher.

For the reasons stated above, I urge you not to adopt the proposal in section II.E.2 (P-122) of the 2008 Medicare Fee Schedule Proposed Rule, but instead to continue the longstanding exemption of MMS procedures from the MPR rule. The planned change in Medicare reimbursement policy will have a significant negative impact on the skin cancer care of U.S. citizens, and will likely end up increasing – rather than decreasing – overall expenditures for this health care service.

Thank you for the opportunity to express my concern. I would be happy to answer any questions you may have.

Sincerely,



Glenn D. Goldman, MD
Fletcher Allen Health Care – University of Vermont College of Medicine
111 Colchester Avenue – WP5
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(Home) 802 872 0805
(Pager) 802 842 2700 – Provider access service
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glenn.goldman@vtmednet.org

cc: Centers for Medicare and Medicaid Services (by mail, original and two copies)
The Honorable Patrick J. Leahy
The Honorable Bernard Sanders
The Honorable Peter Welch

Submitter : **Date: 07/22/2007**

Organization :

Category : **Physician**

Issue Areas/Comments

Conversion Factor

Conversion Factor

You have already pushed doctors to the edge with inadequate payment that doesn't keep up with costs. The proposed payment cuts will push us over the edge. I'm tired of working with the most complicated patients for the lowest compensation not counting medicaide. I am not a public servant. I won't work for nothing. You have used up all my compassion. I don't take new medicare patients. I am sure access for medicare patients to medical care will drop dramatically if this rule is implemented. I think it will be very clear to the people of America who is responsible for this disaster.

NORTH SHORE
SPORTS & PHYSICAL THERAPY
Rehabilitation For All Ages And Activities
7419 Granby Street • Norfolk, Virginia 23505 • Tel: (757) 489-5820 • Fax: (757) 489-5822
email: northshore@cavtel.net

August 13, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1385-P
P. O. Box 8018
Baltimore, MD 21244

RE: CMS-1385-P

Dear CMS Representative:

North Shore Sports & Physical Therapy is an outpatient physical therapy clinic centrally located in one of the oldest established neighborhoods of Norfolk, Virginia. In fact, we are within walking distance of many of the Medicare patients we serve. A number of our patients reside in assisted living facilities across the street from our clinic; others are retirees who live in the neighborhood homes where they've lived their entire lives.

On behalf of our patients, we are asking you to please *reconsider* the proposed reduction in Medicare reimbursement rates for physical and occupational therapy. We have little to no financial "wiggle room," and if we cannot continue to provide outpatient services to our community, the alternative will be costly surgery and/or long-term inpatient care. Please do not impose this alternative on our neighborhood patients and their physicians.

We are asking you to take an objective look at the proposals being drafted by the AMA, the American Physical Therapy Association, and the American Occupational Therapy Association. Surely a solution can be reached which will allow our clinic, our patients, and their physicians to continue the outpatient physical therapy services so vital to this community.

Sincerely,

Laura Thom

Laura Thom
Office Manager

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attn: CMS-1385-P
PO Box 8018
Baltimore, MD 21244-8018

August 9, 2007

Re: CMS-1385-P
Anesthesia Coding (Part of 5-year review)

Dear Ms. Norwalk,

I am writing to support the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am please that CMS is moving to correct the significant undervaluation of anesthesia services.

I urge you to accept the RUC recommendation that CMS increase the anesthesia conversion factor as a means of correcting the long-standing undervaluation of anesthesia services. This will help ensure that Medicare patients have access to quality anesthesia care, especially in areas with high Medicare populations like Montana.

Sincerely,

Michael D. Sterbis, MD

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July 31, 2007

The Honorable Herb Kuhn
Acting Deputy Administrator
Centers for Medicare and Medicaid Services
RE: Docket # CMS1385P
Department of Health and Human Services
Washington, D.C. 20201

Dear Mr. Kuhn:

I am writing this letter to reinstate the Multiple Surgery Reduction Rule (MSRR) exemption for the Mohs stage one procedures as referenced in Docket # CMS1385P. I believe that this proposed change will have a significant negative impact on the healthcare of U.S. citizens and potentially add unnecessary cost to the delivery of healthcare in this country.

As you are probably aware, over a million Americans per year are diagnosed with skin cancer and over the last ten years the rate of new skin cancer diagnoses is growing at what many would call epidemic proportions. Mohs micrographic surgery is a common way of treating some of these cancers and is considered the gold standard among treatments for skin cancer, allowing the physician to examine 100% of the cancer margin to insure complete removal of the cancer with loss of as little normal skin as possible. Mohs surgery is an outpatient procedure that utilizes onsite laboratory analysis of excised tissue while the patient waits for the results. The critical component of Mohs surgery includes meticulous removal and microscopic examination of the entire edge and deep margin of the cancer, in which the same physician serves as both surgeon and pathologist. The procedure is particularly valuable in the treatment of skin cancers in cosmetically or functionally important areas such as the face, neck, hands, feet and genitalia. It is also valuable for large, aggressive, or ill-defined cancers and for those that have recurred

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after other previous treatment. After the cancer is removed, most patients undergo subsequent reconstructive surgery by the same doctor on the same day as the cancer removal.

In 2006, CMS reviewed the American Medical Association's Current Procedural Terminology (CPT) codes 17304 – 17310 (Mohs micrographic surgery) and requested that new site-specific codes be developed similar to those used for other excisional surgery. The American Academy of Dermatology, the American Society for Dermatologic Surgery, and the American College of Mohs Micrographic Surgery and Cutaneous Oncology participated in last year's review of the Mohs CPT codes, and new codes were adopted (17311-17315) addressing CMS' concerns without adversely affecting the delivery of these services to patients in need.

However, as of July 1st of this year, we were notified by CMS of a planned change in payment policy that in our opinion has the potential to negatively impact the care of our patients and could add significant cost to an already stressed healthcare budget. This planned change would remove Mohs surgery from a longstanding exemption from the multiple surgery reduction rule (MSRR, indicated by CPT modifier –51). This is a departure from a longstanding exemption agreed to by CMS and virtually all private insurance carriers since 1991. The change proposed would eliminate the exemption and decrease reimbursement by 50% for either the Mohs excision or for the associated repair, and for Mohs excision of any additional cancers treated on the same day; such a decrease in reimbursement would not cover the cost of providing the service.

If this proposed change is enacted, we will no longer be able to provide the same kind of high-quality, cost-effective services for our patients in need. We will be forced to change the way we deliver care in order to cover our costs or providing this service. The following paragraphs attempt to explain the rationale behind the need to exempt Mohs surgery from the multiple surgery reduction rule and the consequences of not doing so.

In its review of the Mohs codes in 1991, CMS agreed that Mohs excisions are "separate staged procedures; they will be paid separately with no multiple surgery reductions." This rule was placed in the Federal Register at that time (Federal Register, November 25, 1991, volume 56, #227, pg 59602). In 2004, the Mohs codes were added to the CPT Appendix E list of codes exempt from the –51 modifier and the multiple surgery reduction rule, to eliminate the occasional carrier misunderstanding when the multiple surgery reduction was applied to these codes. The July 2004 CPT Assistant article reviewed the rationale: "The rationale for this policy is that for many surgical procedures some of the work of a procedure is not repeated when two or more procedures are performed. For these procedures the intraservice work is only 50% of the total work, while the other 50% represents pre- and post-service work that overlaps when multiple procedures are performed on the same patient on the same date of service. For Mohs

surgery, however, greater than 80% of the work is intraservice work that does not overlap when two or more procedures are performed. The pathology portion of Mohs surgery constitutes a large portion of this total and also is not reduced with multiple procedures. The preservice and postservice work values are small because there is a zero-day global period. Together there is very little overlap or reduction in work when two or more tumors are treated on the same patient on the same day. Therefore, Mohs surgery codes are exempt from the use of modifier 51."

The exemption of the Mohs codes from the MSRR has been maintained by CMS since 1992 and was not questioned during the CMS mandated five-year review of the Mohs codes undertaken last fall or during presentation of the new Mohs codes to the AMA Relative Value Update Committee (RUC) in October, 2006.

The consequence of applying the multiple surgery reduction rule to the Mohs codes would be a reimbursement reduction to a value less than the cost of providing the service. Therefore, providers will no longer be able to perform more than one Mohs procedure on any patient on a single day. Multiple tumors are commonly diagnosed on one visit, occurring in 10% of my referral practice population. Treatment of only one tumor per day will inconvenience many patients and their friends and families who accompany them for treatment. It will also inconvenience employers when workers are absent from work more frequently for multiple treatments. More importantly, delays in treatment will further increase risk for high-risk patients such as organ transplant patients with multiple squamous cell carcinomas, and for patients with syndromes such as basal cell nevus syndrome. In addition to its application to multiple cancers treated on the same day, the MSRR would apply to repairs performed on the same day as Mohs surgery. According to this new proposal, when Mohs surgery is reimbursed less than a reconstructive procedure on the same day, even the first Mohs code will be subject to the multiple surgery reduction rule. Sine costs would not be covered, this may require patients to have their Mohs surgery and their reconstruction done on separate days, or to be referred to other physicians for reconstruction, usually plastic, facial plastic, or oculoplastic surgeons, who work primarily in hospitals or ambulatory care centers where costs of care are higher. The result would be that healthcare costs will be higher than they are under the current policy of payment.

I am asking that you consider the above information. Please feel free to contact me with questions and further clarification of this very important issue.

Thank you for your help.

Sincerely,

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July 25, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P

Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule

I have followed the attempts by the Relative Value Update Committee and the ASA in to make recommendations to CMS for an increase in the value of anesthesia services. I am pleased to see that CMS is considering this and I urge you to accept and implement their recommendations. I am concerned with the trend in cutting reimbursement to anesthesia providers for Medicare/Medicaid services. As the population in this country grows older more of Medicare services will be utilized and I fear that the quality and availability of anesthesia services will decline if it is not recognized by your organization.

While I have concerns for the patients in my state and the future of anesthesiology as a whole if the current trends continue, I am positive in my outlook that you will address these concerns and make the necessary changes to restore the value of anesthesia services in our health care system.

I appreciate you taking the time to listen to my concerns and I count on your support of CMS-1385-P.

Sincerely,

Monica Jones, MD, Medical Director of Anesthesia Services, Erlanger East Hospital
Anesthesiology Consultants Exchange, P.C.

Larry Nestor MD Inc

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Friday, August 10, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention CMS 1385-P
PO Box 8018
Baltimore MD 21244-8018

Re: File Code: CMS 1385-P coding

Dear Sirs,

I understand you are considering revising reimbursement for CPT 93325 (Doppler echocardiography blood flow velocity mapping), including it with other related similar codes with which 93325 is frequently billed. To a pediatric cardiologist, this is the most important part of a pediatric ultrasound study. This surely will hurt the quality of the echoes being performed.

Please reconsider this proposal. It is likely to do more harm than good for the population I serve.

Cordially yours,

Larry Nestor MD

Larry Nestor MD

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposed increase in anesthesiology payments under the 2008 Physician Fee Schedule. I appreciate that CMS now recognizes their gross undervaluation of anesthesiology services and that the Agency is considering some incremental redress for this long-standing under-compensation for our physician services.

When the RBRVS was initially proposed in 1990, it created a huge payment disparity for compensating anesthesiology care. Professor Hsiao inflicted a simplistic linear conversion between the existing ASA Relative Value time units and the new RBRVS time units. This calculation ignored the fact that a major component of workload measurement in the traditional ASA Relative Value system is not derived solely from time units. This simplistic RBRVS calculation resulted in anesthesiology services being grossly undervalued compared to other physician services. I used public-source CMS data to calculate the effect of the RBRVS on anesthesiology payments. In a letter to the ASA Newsletter in October 2004, I showed that **anesthesiology was <u>DEAD LAST</u> amongst all medical specialties** in the "CMS allowed/billed services" ratio. (Table and Letter attached) A cynic might say that we "just bill too much," but even CMS now recognizes that our services have been markedly undervalued since the implementation of the RBRVS. At $16.19 per unit, current CMS compensation for anesthesiology services is less than 33% of the fair market value for our services.

How did this travesty occur? In 1990, our professional society (the ASA) was too busy building a new headquarters building and squabbling with other providers to effectively counter the computational errors inflicted within the initial RBRVS. The rest of "organized medicine" hardly rushed to our specialty's defense! Frankly, our leadership "dropped the ball" accepting the initial calculations for RBRVS. Consequently, our specialty has endured this compensation inequity for well over a decade. The RUC has recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation, or about $4.00 per unit. It is a partial redress for this long-standing undervaluation of anesthesiology a services. I am pleased that the Agency accepted this recommendation in its proposed rulemaking and I support the immediate and full implementation of the RUC's recommendation. It is about time!

To ensure that all our patients have access to expert anesthesiology medical care, it is imperative that CMS immediately implement the anesthesia conversion factor increase as recommended by the RUC. The substantial historical and current inequities in CMS professional anesthesiology compensation contribute to medical care cost-shifting, the high cost of private health insurance, and the lack of affordable or even available private insurance for many citizens. It is bad public policy to create a market-inefficiency that denies patients full access the good healthcare. As an aside, this systematic underpayment for anesthesiology services has particularly devastating effects on our GME training programs. In all, your efforts to rectify this small part of over-all healthcare reform are most appreciated.

Thank you for your consideration of this serious matter.

Sincerely,

Carlton Brown, MD

October 2004

Dear (ASA Newsletter) Editor -

I was amused by your recent missives in our April 2004 NEWSLETTER touting the merits of "AMA membership for ASA members." Notwithstanding some interesting distant history and your invocation an ancient guilt-trip, it is hard to see the contemporary AMA as a stalwart defender of the interests of anesthesiologists. While many other examples abound, I offer the following information:

The Medicare "allowable/charged" ratio is absolutely the lowest for anesthesiologists amongst all medical specialties. Simply restated, Medicare pays a higher percentage of the bills from every other specialty compared to anesthesiologists. That hardly sounds to me like the AMA has been looking out for our specialty's best interests. In fact, we are remarkably lower than many other specialties, receiving only about half the average for all specialties! In the current zero-sum game of Medicare funding, the AMA and other specialties are balancing their budgets on our backs! Some allies!

The data supporting my disturbing statement come from *Physician Practice* magazine in their April 2004 edition. They lifted the data from the public records of Medicare. *Physician Practice* assembled these data to complain about the high incidence of "rejected claims" across all specialties. However, by simply taking a ratio of "allowed charges per billed charges" one can see where we stand as anesthesiologists in the Medicare food chain. **Dead last.** I have attached the data table from *Physician Practice*. The last column is my additional analysis. If these numbers are wrong, please offer me a better source of data.

To my ear, these data hardly speak well for the advocacy of our interests by the AMA. Frankly, it speaks poorly for any of our advocacy groups! Thoughts?

Carlton Q. Brown, MD
Great Falls, Virginia

Editor's Note: Dr. Brown, I agree with your data. Why would the AMA want to look out for a specialty that doesn't participate? If we are not in the forefront of AMA politics, and to get there we need members, for AMA representation is based upon the number of AMA members within a specialty, we will be forgotten. Now that there is an anesthesiologist within the highest councils of the AMA, hopefully some of these past wrongs will be righted. .....
— D.R.B.

Denial Rate by Specialty for Medicare

Description	Total Services Count	Submitted Charges Amount	Allowed Charges Amount	Denied Services Count	Denied Amount	% Services denied by number	%Services denied by dollars	Percent charges allowed
General Surgery	16,455,972	$5,476,041,184	$2,016,563,881	2,052,754	$708,136,889	12.47%	12.93%	36.83%
Allergy/Immunology	12,145,754	$214,519,321	$150,915,160	876,398	$17,668,749	7.22%	6.24%	70.35%
Otolaryngology	13,446,355	$1,468,574,736	$682,206,957	1,168,922	$180,254,623	8.69%	12.27%	46.45%
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	9.92%	[redacted]
Cardiology	93,895,104	$13,191,526,672	$5,502,118,226	7,801,560	$1,199,128,552	8.31%	9.09%	41.71%
Dermatology	31,829,198	$2,211,495,838	$1,526,563,021	1,750,417	$147,893,254	5.50%	6.69%	69.03%
Family Practice	113,363,376	$5,861,254,702	$3,689,344,091	11,305,447	$506,225,467	9.97%	8.64%	62.94%
Gastroenterology	15,550,306	$3,612,998,480	$1,440,111,521	1,214,928	$277,807,276	7.81%	7.69%	39.86%
Internal Medicine	197,285,898	$13,012,823,359	$7,732,597,609	16,908,585	$1,090,569,129	8.57%	8.38%	59.42%
Neurology	19,390,448	$1,800,138,053	$999,973,429	2,153,164	$166,510,619	11.10%	9.25%	55.55%
Neurosurgery	2,555,839	$1,633,567,290	$417,596,009	367,754	$277,581,363	14.39%	18.99%	25.56%
Obstetrics/Gynecology	9,198,383	$1,091,432,455	$486,016,914	2,062,531	$178,244,086	22.42%	16.33%	42.70%
Ophthalmology	38,608,242	$8,698,232,651	$4,303,140,741	3,061,920	$648,241,288	7.93%	7.45%	49.47%
Orthopedic Surgery	30,228,221	$6,923,214,800	$2,635,392,707	3,825,514	$785,348,405	12.66%	11.34%	38.07%
Clinical Pathology	19,157,707	$1,943,701,998	$720,519,000	2,038,064	$152,900,618	10.64%	7.87%	37.07%
Peripheral Vascular Disease	2,048,885	$741,866,470	$251,311,583	322,237	$126,209,905	15.73%	17.02%	33.88%
Plastic and Reconstructive Surgery	13,768,799	$1,008,954,297	$543,799,951	1,854,142	$112,007,192	13.47%	11.12%	54.00%
Physical Medicine and Rehabilitation	16,936,574	$1,596,836,535	$1,032,690,456	1,510,923	$129,840,144	8.92%	8.13%	64.67%
Psychiatry, Neurology	667,848	$230,557,666	$91,525,327	71,399	$24,174,678	10.69%	10.49%	39.70%
Colorectal Surgery	22,015,383	$2,014,574,426	$1,207,174,698	1,758,227	$147,369,406	7.99%	7.32%	59.92%
Pulmonary Disease	96,652,153	$11,129,337,576	$3,884,229,331	11,439,363	$1,269,866,055	11.84%	11.41%	34.90%
Radiation Therapy	1,726,663	$1,443,613,633	$472,813,677	191,709	$132,412,837	11.09%	9.17%	32.75%
Thoracic Surgery	29,079,627	$4,452,715,232	$2,502,102,970	2,551,869	$370,126,685	8.78%	8.31%	56.19%
Urology	3,084,974	$116,813,875	$60,371,021	479,828	$18,309,813	15.66%	15.67%	51.68%
Pediatric Medicine	1,879,128	$126,373,564	$85,325,106	116,945	$7,013,492	6.22%	5.55%	67.52%
Geriatric Medicine	24,117,945	$2,029,724,800	$1,106,431,752	1,701,487	$136,930,737	7.05%	6.75%	54.51%
Nephrology Nephrology	501,025	$108,307,766	$40,513,901	86,692	$18,609,298	17.30%	15.34%	37.41%
Hand Surgery	7,558,560	$546,959,194	$323,970,116	735,343	$37,998,858	9.73%	6.95%	59.23%
Infectious Disease	6,593,229	$399,078,939	$248,797,962	482,563	$28,028,814	7.32%	7.02%	62.34%
Endocrinology	5,488,331	$1,349,660,035	$582,837,210	1,038,952	184140355	18.93%	13.64%	43.18%
Rheumatology	13,696,430	$778,536,800	$508,487,510	969,863	$56,830,156	7.08%	7.30%	65.31%
Vascular Surgery	2,716,397	$1,052,838,874	$369,994,663	322,267	$131,391,514	11.86%	12.48%	35.14%
Cardiac Surgery	812,296	$920,565,488	$295,679,069	115551	$74,929,711	14.23%	8.14%	32.12%
Hematology	4,839,009	$227,648,147	$117,393,495	441,683	$20,901,166	9.13%	9.18%	51.57%
Hematology/Oncology	111,527,946	$4,811,302,878	$2,563,235,650	9,960,850	$405,009,510	8.93%	8.42%	53.28%
Emergency Medicine	17,335,282	$3,077,280,323	$1,261,432,866	2,195,921	$265,240,795	12.67%	8.62%	40.99%
Interventional Radiology	3,166,258	$505,427,955	$148,592,158	402,448	$66,491,857	12.71%	13.16%	29.40%

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UroCare
Practice Limited to Urology
and Urological Surgery

August _10_, 2007

James W. Faulkner, III, M.D.
David A. Guthman, M.D., F.A.C.S.
Jerrold H. Seckler, M.D., F.A.C.S.
Helen C. Ahn, M.D.

Centers For Medicare and Medicaid Services
Dept of Health and Human Services
Attention: CMS-1385-P
PO Box 8018
Baltimore, MD 21244-8018

RE: PHYSICIAN SELF-REFERRAL PROVISIONS

Ladies and Gentlemen:

I am writing to you as a practicing physician with an office in Arlington Heights,IL. I am deeply concerned about certain proposals made by CMS regarding Medicare, as I believe they will unduly and unnecessarily harm patients and physicians and have a detrimental affect on the healthcare system. I believe that CMS could address its concerns in a much less intrusive manner. Frankly, some of the proposals strike me as trying to kill a flea with a sledgehammer.

As a urologist, I have been involved with providing my patients lithotripsy and other cutting edge therapies for urological disease: services that would not have been widely available to my patients, including Medicare beneficiaries, unless physician joint ventures had provided the services. Urology joint ventures greatly expanded patient access to these technologies. These joint ventures took the risk of providing costly services when hospitals were unwilling to do so. Yet in the July 2, 2007 released 2008 Physician Professional Fee Schedule proposal, CMS attacks the substance of the very joint ventures that by all accounts have saved Medicare millions of dollars. I will address the various CMS proposals that I believe are anti-physician ownership.

1. **Services Furnished Under Arrangements**

It appears to me that the purpose of the proposed changes to Stark regulations regarding services furnished under arrangements is to ban physician joint ventures from contracting with hospitals to provide therapeutic services that are designated health services (DHS). Unfortunately, the proposals are so broad that they would ban legitimate arrangements for therapeutic services that are not otherwise designated health services *only* because they are performed in a hospital setting. These therapeutic services include a variety of laser procedures for benign prostate disease and cryotherapy for cancer of the prostate. CMS takes the view that physicians who invest in these ventures do so at the expense of good patient care. My experience is quite the opposite. I believe that, at least for the urological joint ventures, the primary purpose of physician investment is to improve patient care.

In the mid 1980s, hospitals refused to purchase lithotripters, preferring to populate their operating rooms with surgeons performing invasive surgical procedures to remove

kidney and ureteral stones that were too large for a patient to pass naturally. Physicians formed joint ventures to buy lithotripters because hospitals did not want to make a large capital investment and at the same time cut off a revenue stream for their operating rooms. Physicians wanted a better and non-invasive treatment for their patients and were fought at every turn by the hospitals.

Hospital recalcitrance continues. Hospitals balk at buying state of the art technology, such as the new laser for the treatment of benign prostate disease, even if it is clinically superior, because of expense and the fact that rapidly changing technology makes today's "best", tomorrow's "obsolete". Through urology joint ventures, we have been able to improve clinical care and take that risk of obsolescence, when our institutions would not. Hospitals complain that they have closets full of lasers that physicians said they wanted and no longer will use. The problem is that these lasers and other technologies soon become outdated as newer models become available. The newer models frequently provide a better treatment outcome. Physicians want to have new technology available for their patients. And, just as with lithotripsy, sometimes hospitals will not invest in new capital because it will result in lesser use of other services that they currently provide. As other new technology becomes available, hospitals refuse to purchase it. They don't want to make a capital investment and lose an existing revenue source.

Moreover, a single hospital by itself often does not have enough volume to justify the expense of purchasing technology. As I noted above, physicians who want to have up to date treatment for their patients are willing to invest in a joint venture with other physicians who practice at other hospitals to purchase technology and bring it to their various hospitals on a rotating basis. This way usage can be spread among several hospitals. The healthcare system, including CMS, benefits because otherwise unavailable technology is brought to both urban and rural settings, the cost is spread among several providers, and overall capital costs are reduced.

Several years ago, the American Lithotripsy Society, won a lawsuit against CMS. In that case, ALS v. Thompson the court held that extracorporeal shockwave lithotripsy is not a DHS even though it is provided under arrangements with a hospital. It would be highly beneficial to patients and providers if CMS also exempted procedures that are not otherwise DHS from the proposed prohibitions to under arrangements.

It appears to me that the reason CMS wants to ban services under arrangements where there is physician ownership is because it has heard of questionable diagnostic imaging arrangements, as noted in your commentary. Diagnostic imaging is a DHS in any setting as the result of overutilization and improper referrals identified in bona fide studies. CMS does not identify any overuse or improper referrals for other services such as laser services and other urological procedures. Simple fairness and common sense should prevail and under arrangements should not be prohibited for services that would not otherwise be DHS but for being furnished in a hospital.

When urologists refer patients for therapeutic procedures that the urologists perform, the professional fee the urologist receives is greater than the incremental increase in the urologist's distributions from his investment interest in the joint venture. The incremental increase in the distribution is not likely to induce referring physician to refer the patient for the procedure CMS should not prohibit services under arrangements where the investor physician performs the professional portion of the procedure.

2. **Per Click Fee**

In the preamble to the proposed regulations, CMS notes that Congress did not explicitly prohibit per click arrangements. In fact, I am advised that the legislative history states that per procedure and other similar compensation arrangements are permitted. CMS should not prohibit a compensation arrangement that Congress intended to permit.

Further, the preamble indicates that what raises CMS' concern is the per click arrangements for DHS. Yet the proposed rule suggests that it will be more broadly applied and no per click arrangements would be permitted if physicians have ownership in the service. I believe that per click payments should be permitted. But, at the very least, the ban should not apply to services that are not DHS, or if provided in a hospital, would not be DHS if not provided for or in the hospital.

Hospitals generally do not want to take risks. When physicians bring new technology to the hospitals, the hospitals do not want to sign flat rate contracts, fearing that there will be insufficient volume. The physicians who invest in joint ventures to bring new, innovative therapeutic technology to my community are willing to take the risk of failure. The hospitals are comfortable with the doctor group bearing the risk of low volume and welcome per click arrangements in order to protect themselves from low or no volume. The per click fee arrangement is essential to bringing new, improved treatments to many places in America, by allowing cash strapped hospitals to pay the risk taking doctor joint venture to bring the new treatment to them, without the hospital having any financial risk for less than projected use or adoption.

In addition, sometimes a patient will need a procedure that is less often performed and it is difficult to calculate this into the compensation arrangement. For example, in some cases a patient who receives a lithotripsy procedure also needs to have a stent inserted or removed. Or, the patient may need a ureturoscopy or cystoscopy. The venture furnishing the service and the hospital cannot determine in advance how often this will occur or which procedures will be required. Per click fees are the most accurate and fair way to determine compensation.

3. **Percentage Fee Reimbursement**

Percentage compensation arrangements are also reasonable and fair. The driving force for these payment methods to doctor joint ventures is apportionment of the risk of failure of adoption or low volume of new therapeutic modalities. Some insurers pay low amounts and others higher. Why should not the entity that brings the service to the hospital, be compensated in proportion to the payments? Generally, commercial

payments are higher than Medicare payments. It is hard to understand why CMS cares. But, as new therapies are developed in the future, the Medicare patient will be harmed by denial of access to these procedures, unless CMS understands the utility of the past.

4. Stand in the Shoes

On the one hand CMS seems to prefer that as many procedures as possible are performed in the ambulatory surgical center (ASC) setting where the reimbursement will be lower, saving Medicare funds. But, many ASCs are owned partially or entirely by a local hospital. If a referral to an ASC owned or controlled by a hospital is viewed as a referral to the hospital, it will become difficult for legitimate physician joint ventures to provide services at those ASCs. The likely result would be for physicians to withdraw from hospital-owned ASCs and build additional ASCs to provide service to their patients, with the attendant costs and very likely the demise of the efficiencies of the current methodology.

5. Burden of Proof

Finally, and of great concern, is the CMS proposal that, if CMS or the OIG decides that a referral is made contrary to Stark requirements, it is the provider that would have to prove that referrals were not made in violation of Stark. The government would not have to prove that the referral was made in violation. This is indeed troubling. I believe that this would make CMS the judge and jury. In addition, because Stark penalties extend to anyone who "causes a claim to be submitted in violation of the regulations," CMS could take the view that any party to a contract that CMS believes is in violation could be subject to huge fines. Most Stark exceptions require payments to be made at fair market value and that those payments not reflect the volume or value of referrals or other business between the parties. It would be impossible for providers and physicians to prove the negative – that compensation does not reflect the volume or value of referrals or other business between the parties. Moreover, valuation experts often disagree on what is fair market value. If a better example of predatory behavior or abuse of power can be shown, I would like to see it. Not only do I take care of the health problems of the Medicare beneficiary at a price set arbitrarily by CMS, I now face the undeclared burden of a hidden tax in which I must prove my actions were legal, rather than the governmental agency which writes the law proving that my action was illegal.

In sum, I ask CMS to separate those beneficial <u>therapeutic</u> joint ventures which are not of themselves DHS from the abusive and questionable <u>diagnostic</u> ventures that physicians and hospitals may have propagated. Without a doubt, it should be clear to CMS that the urology community's therapeutic joint ventures have broadened access to new technology for Medicare patients, brought needed efficiency to the market, and simultaneously saved CMS hundreds of millions of dollars. As CMS tries to stop abusive arrangements, it would be a great mistake to jeopardize such a time tested and proven model.

Sincerely,

David A Guthman,MD FACS

NATIONAL BOARD FOR CERTIFICATION IN OCCUPATIONAL THERAPY, INC.

Serving the Public Interest

August 10, 2007

Centers For Medicare and Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS – 1385 – P
Dorothy Shannon, PhD
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS Proposed Rules, Federal Register, Vol. 72, No. 133
Therapy Standards and Requirements
Thursday July 12, 2007

Dear Dr. Shannon:

I am writing to submit comment on the CMS DRAFT Rules regarding *Therapy Standards and Requirements*. I hope the following background information and rationale is useful in an effort to address our organization's position.

The National Board for Certification in Occupational Therapy, Inc. (NBCOT®) is the independent credentialing agency that certifies eligible individuals as OCCUPATIONAL THERAPIST REGISTERED OTR (OTR®) or CERTIFIED OCCUPATIONAL THERAPY ASSISTANT COTA (COTA®). Our organization's mission is to serve the public interest. NBCOT is accredited by the American National Standards Institute (ANSI) as being in conformity with the international personnel certification standard ISO/IEC 17024 as well as the National Commission For Certifying Agencies, the accreditation commission of the National Organization for Competency Assurance (NOCA).

As the national certification agency in the field of occupational therapy, NBCOT administers certification examinations for the OTR and COTA candidate populations. Eligible exam candidates complete accredited occupational therapy education programs the standards of which comply with the U.S. Department of Education. These standards are used to guide occupational therapy curriculum.

Revisions to Personnel Qualification Standards for Therapy Services

- This rule should only apply to internationally educated occupational therapists not occupational therapy assistants. It is important to clarify that there are no internationally educated occupational therapy assistants thus, language

proposing to adopt similar standards for OTAs should be stricken from the proposed rules. Specific references are found on page 38192, 2nd column, 2nd paragraph and page 38193 1st column, 1st paragraph.

- Individuals trained by the United States military are required to complete occupational therapy programs accredited by the Accreditation Council for Occupational Therapy Education, (ACOTE). It is important to clarify that these individuals are not required to complete occupational therapy programs accredited by the World Federation of Occupational Therapists (WFOT) as the proposed rules site. Such references in the proposed rules should be amended accordingly.

  Specific references are found on page 38192, 2nd column, 2nd paragraph (general language linking therapists who obtain occupational therapy education outside the Unites States and therapists who obtain their education through a U.S. military program), page 38192 3rd column, 4th paragraph and page 38230 2nd column, (B) ii.

- Related to internationally educated occupational therapists, we support the position of the CMS to implement standards which are comparable to that of an occupational therapist educated in the United States. As the proposed rules indicate on page 38192, 2nd column, 2nd paragraph, the NBCOT has and continues to conduct this eligibility determination review process. (Based on clarification sited above, individuals educated through U.S. military occupational therapy education programs are not required to complete the eligibility comparability determination review process because these programs are accredited by the Accreditation Council for Occupational Therapy Education, ACOTE - just as all other U.S. based programs are).

- On page 38193, 1st column, 1st paragraph of the proposed rules, we recommend that eligibility criteria number three (3) for the internationally educated occupational therapist be amended as follows: 'have successfully completed the certification examination for Occupational Therapist Registered' as opposed to the current language which reads as 'Registered Occupational Therapist.'

- We support the position of CMS to stipulate and require that the personnel qualifications for occupational therapists and occupational therapy assistants be applicable to and consistent throughout all treatment settings. This proposed requirement is sited on page 38193, 2nd column, 2nd paragraph.

- Regarding the grandfathering and personnel qualifications provisions relating to qualifications of occupational therapists and occupational therapy assistants, we recommend that draft language setting forth individuals who began work in the field prior to 1977, those who worked in the field between 1977 and January 1, 2008 and those who will begin work after January 1, 2008 be stricken from the rules. References to such date frames is found on page 38192, 1st and 2nd columns and page 38230, 2nd and 3rd columns. Instead, we propose that the personnel qualifications language read as follows:

Occupational therapist: A person who meets all practice requirements as set forth by the State in which occupational therapy services are provided and who is certified and in good standing with the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

Occupational therapy assistant: A person who meets all practice requirements as set forth by the State in which occupational therapy services are provided and who is certified and in good standing with the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

Rationale: It is to be understood that in the case of these regulations, eligibility requirements for an occupational therapist or occupational therapy assistant have changed over time and that the entities involved in accreditation or certification, by national examination, have changed over time as well. Rather than complicating the qualifications outlined in the rules, we are suggesting that one set of qualifications be applied to all sections of the rules, no matter when the individual entered into professional practice. We suggest this with the understanding that an occupational therapist or occupational therapy assistant must meet all practice requirements set forth by the state in which occupational therapy services are furnished and that the occupational therapist or occupational therapy assistant comply with and meet national certification requirements established by NBCOT.

Case Example: If an occupational therapy employer, state regulatory board administrator or consumer contacts the NBCOT for verification of certification for an occupational therapist or occupational therapy assistant, the certification status is consistently verified as current or non-renewed. Further, the initial date of certification and reissue date are confirmed irrespective of when the individual entered the field or what the name of the accrediting or certification entity was at the time of initial certification.

In this spirit, it may be helpful to clarify that the national certification examination requirement for occupational therapists and occupational therapy assistants used to be administered by the American Occupational Therapy Association, Inc. (AOTA) prior to 1986. In 1986, AOTA determined that the examination process be separated away from the auspices of the Association. A new entity was created and initially named the American Occupational Therapy Certification Board, (AOTCB). The AOTCB became incorporated in 1988 and changed its name in 1995 to the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

I hope these comments are helpful and that you will consider our position. I appreciate the opportunity to comment on the proposed rules and invite you to contact me at (301) 990-7979 ext. 3130 or paul.grace@nbcot.org if you have questions.

Sincerely,

Paul Grace

Paul Grace, MS, CAE
President and Chief Executive Officer

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ALLIED UROLOGICAL SERVICES, LLC

Metropolitan Lithotriptor Associates, PC

August 9, 2007

Centers For Medicare and Medicaid Services
Dept of Health and Human Services
Attention: CMS-1385-P
PO Box 8018
Baltimore, MD 21244-8018

RE: PHYSICIAN SELF-REFERRAL PROVISIONS

Ladies and Gentlemen:

As a physician practicing in New York City, I am acutely aware of both the clinical and cost issues that are important to the Medicare beneficiary and CMS. As a urologist, I have been involved with providing my patients lithotripsy and other cutting edge therapies for urological disease -- *services that would not have been widely available to the Medicare beneficiary without the involvement of urology joint ventures* that dramatically expanded patient access by taking the risk of providing costly services. Yet in the July 2, 2007 released 2008 Physician Professional Fee Schedule proposal, CMS attacks the substance of the very joint ventures that by all accounts have saved Medicare millions of dollars. Let me address the different anti-physician ownership proposals separately and as they were enumerated in the proposal.

1. **Under Arrangements**

The substance of the CMS proposal is to ban legitimate physician joint ventures from contracting with hospitals to provide therapeutic services that are designated health services (DHS) *only* because they are performed in a hospital setting. These therapeutic services include a variety of laser procedures for benign prostate disease and cryotherapy for cancer of the prostate. CMS takes the view that physicians who invest in these ventures do so at the expense of good patient care. *My experience is quite the opposite.*

Indeed, hospitals balk at buying state of the art technology, such as the new laser, even if it is clinically superior, because of expense and the fact that rapidly changing technology makes today's "best", tomorrow's "obsolete." Through urology joint ventures, we have been able to improve clinical care and take that risk of obsolescence, when our institutions would not. Sometimes hospitals will not invest in

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new capital because it will result in lesser use of other services that they currently provide. They do not want to make a capital investment and lose an existing revenue source. Lithotripsy is a good example of this. Physicians formed joint ventures to buy lithotripters because hospitals did not want to make a large capital investment and at the same time cut off a revenue stream for their operating rooms. Physicians wanted a better and less invasive treatment for their patients and were fought at every turn by the hospitals.

In addition, a single hospital often does not have enough volume to justify the expense of a large capital investment. Physicians who want to have up-to-date treatment for their patients are willing to invest with other physicians who practice at other hospitals. Joint ventures involve physicians so that usage can be spread among several hospitals. The healthcare system, including CMS, benefits because our ventures mobilize technology and take it far and wide, to both urban and rural settings, and spread the cost among several providers, reducing overall capital costs.

As the court in ALS v. Thompson noted, extracorporeal shockwave lithotripsy is not a DHS, and common sense would dictate that the other therapeutic services that urologists join together to bring to their communities through the hospital would fall in the same category.

Most important, it appears that the reason CMS wants to ban services under arrangements where there is physician ownership is it has heard of questionable diagnostic imaging arrangements that are referenced in your commentary. Diagnostic imaging is a DHS in any setting as the result of overutilization and improper referrals identified in bona fide studies. CMS does not identify any overuse or improper referrals for other services such as laser services and other urological procedures. Simple fairness would dictate that under arrangements should not be banned for services that are not otherwise DHS (if not furnished in a hospital).

Where urologists perform therapeutic procedures, the professional fee is far greater than the return on equity the physician receives for that referred procedure. In this case the referring physician is not likely to be induced to refer based on the portion of the technical fee that he will earn in distributions from the investment. CMS should prohibit services under arrangements *where the investor physician performs the professional portion of the procedure.*

2. **Per Click Fee**

CMS's proposal to ban per click fees flies directly in the face of Congressional intent, as you note in your commentary. CMS should not ban a compensation method that Congress stated is permitted.

Further, the commentary indicates that CMS is concerned with per click arrangements for DHS, yet the proposed rule suggests that it is to be more broadly applied and no per click arrangements would be permitted if physicians have

ownership in the service. I believe that per click payments should be permitted. But, at the very least, the ban should not apply to services that are not DHS.

Sometimes a patient will need a procedure that is less often performed and it is difficult to calculate this into the compensation arrangement. For example, in some cases a patient who receives a lithotripsy procedure also needs to have a stent inserted or removed. Or, the patient may need a ureteroscopy or cystoscopy. The company furnishing the service and the hospital receiving the service cannot calculate in advance how often this will occur or which procedures will be required. Per click fees balance the risk.

As mentioned above, physician joint ventures have brought new, innovative therapeutic technology to my community because the doctors were willing to bear the risk of failure. Our hospitals are risk averse and, thus, wanted physician groups to bear the risk of low volume. As a consequence, hospitals would only enter into per click arrangements in order to protect themselves from low or no volume. Thus, the per click fee arrangement is essential to bringing new, improved treatments to many places in America, by allowing cash strapped hospitals to pay the risk-taking doctor joint venture to bring the new treatment to them, without the hospital having any financial risk for less than projected use or adoption.

3. Percentage Fee Reimbursement

The same entrepreneurial spirit that created value for the per click fee arrangement did the same for the percentage fee arrangement. Again, the driving force for the origin of these payment methods to doctor joint ventures was apportionment of the risk of failure of adoption or low volume of new therapeutic modalities. As new therapies are developed in the future, the Medicare patient will be harmed by denial of access to these procedures, unless CMS understands the utility of the past.

4. Stand in the Shoes

CMS's goal seems to be to push as many procedures as possible into the ambulatory surgical center (ASC) setting where the reimbursement will be lower, and thus save Medicare money. But many community ASCs are owned partially or entirely by a local hospital. If referral to an ASC owned or controlled by a hospital is viewed as a referral to the hospital, it would make it impossible for legitimate physician joint ventures to provide services at those ASCs. The likely result would be for physicians to withdraw from hospital-owned ASCs and build additional ASCs to provide service to their patients, with the attendant costs and very likely the demise of the efficiencies of the current methodology.

5. Burden of Proof

CMS proposes in any action involving Stark regulations it is the provider that would have to prove that referrals were not made in violation of Stark. Further, Stark penalties extend to anyone who "causes a claim to be submitted in violation of

the regulations." That could be interpreted to mean that any party to a contract that CMS believes is in violation could be subject to huge fines. Most Stark exceptions require payments to be made at fair market value and in a manner that does not reflect the volume or value of referrals or other business generated between the parties. How are providers and physicians going to prove the negative – that compensation does not reflect the volume or value of referrals or other business generated between the parties? Moreover, valuation experts often disagree on what is fair market value. If a better example of predatory behavior or abuse of power can be shown, I would like to see it. Not only do I take care of the health problems of the Medicare beneficiary at a price set arbitrarily by CMS, I now face the undeclared burden of a hidden tax in which I must prove my actions were legal, rather than the governmental agency which writes the law proving that my action was illegal. CMS will sit as judge and jury.

In conclusion, I would ask CMS to consider the distinction between beneficial therapeutic joint ventures which are not of themselves DHS from the questionable diagnostic ventures that physicians and hospitals may have propagated. With certainty both CMS and the urology community can say that our therapy joint ventures have broadened access to new technology for Medicare patients, brought needed efficiency to the market, and simultaneously saved CMS hundreds of millions of dollars. To jeopardize such a time tested and proven model would seem foolhardy, even in CMS's rational attempt to eliminate some bad behavior.

Sincerely,

Jon Owen Marks, MD

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OAG

The Quality Team

OREGON ANESTHESIOLOGY GROUP, P.C.

July 25, 2007

Victor Takla, M.D.
4136 NW Thunder Crest Dr
Portland, OR 97229

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

As an OAG anesthesiologist, I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation's seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation—a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC's recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Yours truly,

V. Takla MD

Victor Takla, M.D.
Oregon Anesthesiology Group, P.C.

PS. Ms. Norwalk: Oregon has been notoriously low for medicare reimbursement because we are actually more efficient/focuse in giving cost effective care, thus medicare thinks we need less. Those states that have waste and spend more, actually get more My reimbursiment is about half the

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www.oagpc.com

... change would help tremendously. Furthermore, I never turn a patient down or away b/c insurance or ability to pay. I do a very large % of non-pay, low-pay, medicare, medicaid, & oregon health plan clients. Any $ from " would help defray some of the loss I incur from working in an inner city hospital. Thank you for your time. Victor Tan

Center for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1385-P
P.O. Box 8018
Baltimore, Maryland 21244-8018

Re: Technical Corrections

Dear Staff:

I understand that you are considering eliminating the provision whereby a beneficiary can be reimbursed by Medicare when x-rays are taken by a non-treating provider and used by a Doctor of Chiropractic. For years, Medicare has deliberately not paid for x-rays in a chiropractor's office while demanding that x-rays be taken to demonstrate the presence of spinal subluxations. Now, you are considering a provision in which we can't get x-rays covered even outside our office.

X-rays are covered under virtually every other insurance policy. Chiropractors are listed as physicians under your Medicare regulations. We need proper examinations and diagnostic procedures to safely treat our patients and we should be paid for those services. We should be covered for our x-rays and our patients should have coverage as beneficiaries when x-rays are taken on our patients by non-treating providers.

Surely your goal is cost savings. Therefore, why not provide for full x-ray benefits for chiropractic patients? This would save our patients from incurring the cost of another office visit with another provider and the end result will be the same – the patient will get x-rays to justify and document proper care.

X-rays should be reimbursed when taken by medical and osteopathic doctors and chiropractors? Otherwise, this is either political discrimination or a decision based on some flawed bureaucratic decision? It is time to correct your policies and provide FULL COVERAGE FOR CHIROPRACTIC X-RAYS! Please feel free to contact me for additional assistance as you consider your policy changes.

Signed

W. Keith Parrish DC, DABCO, CCRD

W. Keith Parrish, D.C., D.A.B.C.O., C.C.R.D.
New Hampshire Representative
Medicare Carrier Advisory Committee

W. Keith Parrish, D.C., D.A.B.C.O.
Diplomate in Chiropractic Orthopedics
Village West One, Building Four • 25 Country Club Road
P.O. Box 7566 • Gilford, New Hampshire 03247 • 603-528-4466

Sutter West
Medical Group

Affiliated with the Sutter Medical Foundation

Administration

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(530) 750 7210
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August 1, 2007

Department of Health and Human Services
Attention CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: Proposed reconfiguration of CA physician payment localities

We appreciate the opportunity to comment on the three options outlined in the proposed physician payment rule for 2008 with respect to reconfiguration of physician payment localities in California.

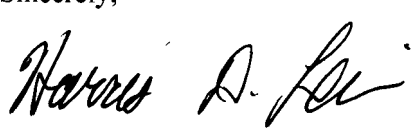
CMS has not updated the physician localities in any state since 1997. CMS is well aware that payment inaccuracies have increased substantially during that time. The GAO has called for a national reform of the payment localities. CMS has expressed concerns that increasing the number of physician payment localities which would clearly improve payment accuracy to physicians carries with it an unacceptable administrative burden for CMS. Our comments are limited to these points.

1) The three options proposed are insufficient. None of the proposed options are based on the iterative reconfiguration process that CMS used in 1996. The GAO recommends using an iterative approach in two of the five proposed methods to reform the payment localities. Two the other GAO recommendations (1 - create statewide localities for all states and 2 -move to county-specific localities for all US counties) are not viable options. Therefore, two of three proposed GAO options use iterative methods for reform. We are concerned that CMS did not include this method in any of the three options in the proposed rule. The preferred option for CA would be to use the 1996 5% iterative methodology that CMS previously used applying to the existing nine physician payment localities in CA.
2) If CMS will not apply its pre-existing methodology to the reconfiguration of CA counties, we would recommend the choice of Option 3 in the proposed rule. However, the following are requested to be distributed publicly over the CMS website for our review:
    a. Source data for all US counties for GPCIs, RVUs and all input components of the GPCIs by county;
    b. A thorough explanation for the unexpected and marked decreases of the practice expense GPCIs for several CA counties, including Santa Clara, San Mateo, Alameda and San Francisco.
3) CMS published GAF data for all CA counties in the proposed rule. CMS applied, in its Option 3, a 5% non-iterative grouping of all 58 CA counties into six new proposed localities. We have applied the stated methodology to the published GAFs for CA and would like to respectfully point out that CMS erred in the application of the proposed methodology. Santa Clara County should be placed into Locality 01 as its GAF is greater than 95% of the GAF of the highest county GAF in this grouping, San Mateo. Santa Cruz County should be placed into Locality 02 as its GAF is greater than 95% of the GAF of the highest county in this grouping, Contra Costa. Sacramento and El Dorado should be placed into Locality 03 as their GAFs are greater than the highest county in this grouping, Monterey. There are similar errors within Locality 04 and 05.

We believe that adding additional physician payment localities as would occur using the iterative methods proposed by the GAO would not produce significant administrative burdens on CMS. CMS currently pays physicians based on the zip code in which the care to Medicare beneficiaries is provided. CMS could easily improve payment accuracy to physicians by creating sufficient localities to eliminate the marked variations between cost and payment levels existing today in many CA counties.

Proposed CMS Option 3	Corrected CMS Option 3
Locality 01	Locality 01
San Mateo	San Mateo
San Francisco	San Francisco
Marin	Marin
	Santa Clara
Locality 02	Locality 02
Santa Clara	Contra Costa
Contra Costa	Alameda
Alameda	Orange
Orange	Ventura
Ventura	Los Angeles
Los Angeles	Santa Cruz
Locality 03	Locality 03
Santa Cruz	Monterey
Monterey	Napa
Sonoma	Sonoma
San Diego	San Diego
Santa Barbara	Santa Barbara
Napa	Solano
Solano	Sacramento
	El Dorado
Locality 04	Locality 04
Sacramento	San Bernardino
El Dorado	Placer
San Bernardino	Riverside
Placer	San Luis Obispo
Riverside	San Joaquin
San Luis Obispo	Yolo
San Joaquin	Stanislaus
	Mono
	Nevada
	Kern

Sincerely,



Harris D. Levin, M.D.
President
Sutter West Medical Group

76-1

EASTMAN CHIROPRACTIC CLINIC

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337-436-3145 FAX 377-436-5435

KENNETH R. EASTMAN, DC LORRAINE EASTMAN, DC DANIEL N. WICKISER, DC

August 6, 2007

Center for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1385-P
P. O. Box 8018
Baltimore, MD 21244-8018

Re: TECHNICAL CORRECTIONS CMS-1385-P

To whom it may concern:

I am writing to oppose CMS's effort to abolish provisions "which permit a physician who is not a treating physician to order and receive payment' for an x-ray that is used by a chiropractor." [Please see Item 4 on page 38190 of the July 12,2007, Federal Register.]

The rationale for doing away with this provision is that since CMS no longer requires a chiropractor to prove the existence of a subluxation through use of x-rays, then medical physicians should no longer be paid to provide the x-rays. However, such reasoning fails to take into account those instances in which an x-ray is needed by the chiropractor to confirm the presence of a subluxation and/or determine treatment options, which may include referral to an appropriate specialist.

With fixed incomes and limited resources, Medicare patients, who will now be obligated to pay out-of-pocket for these x-rays, may choose, instead, to forgo the cost and, subsequently, appropriate treatment. Such delays in delivery of appropriate care may result in the increased severity of the patient's condition, ultimately leading to greater costs on the part Medicare to treat the advanced conditions.

In the interest of the hundreds of thousands of Medicare recipients that benefit from chiropractic care, I urge you to reconsider this proposal.

Sincerely,

Lorraine Eastman, D.C.

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LAKEWOOD CONSULTING GROUP

1340 Lakewood Drive
Lake Forest, Illinois 60045
TEL (847) 840-3077

DATE: July 23, 2007

TO: Centers for Medicare & Medicaid Services

FROM: Joe Plandowski, President, Lakewood Consulting Group

SUBJECT: Comments to File Code CMS-1385-P
"PHYSICIAN SELF-REFERRAL PROVISIONS"

I am responding to your solicitation of comments on this subject and wish to begin with a broader scope of comments and then move on to some specific, narrower comments.

Broader Scope Comments

After years of witnessing the evolution of rules and regulations regarding pathology and laboratories, it is apparent to me that treating parties unequally has led to many of the contortions in the rules today. In addition, it appears CMS suffers from some incorrect impressions. I cite these particular items:

- Rules prohibiting markup should apply equally to all parties. Otherwise, we get exemptions in the current rules that make little sense. Examples:
    - A hospital-based pathologist who provides pathology services for tissues derived from a private practice physician's office and charges Medicare full global fees, although the pathologist purchased the technical services associated with those tissues from the hospital at highly discounted fees.
    - A pathologist provides pathology services for tissues from Medicare patients and charges Medicare full global fees, although the pathologist purchased the technical services associated with those tissues from another pathology laboratory at highly discounted fees.

- The notion that pathologists do not order tests is one of the oldest myths in the laboratory industry. Examples:
    - While the Pap smear/test is on the laboratory fee schedule, the review of by a pathologist of abnormal Pap smear/test slides is on the physician's fee schedule. The criteria for which Pap slides are to be reviewed is set by a pathologist. And, the same pathologist bills the reviewed slides to Medicare. The percentage of reviews varies greatly among pathologists.

- When a clinician sends tissue from a Medicare patient to a pathologist for diagnosis, rarely does the clinician know that a pathologist may directly order one or more stains on that tissue and charge those to Medicare at global fees. Those fees are then paid directly to the pathologist or the laboratory for which he is employed. The stains in question are 88312, 88313 and 88342, among others. Furthermore, the percentage of tissue slides that are ordered by a pathologist to be stained varies dramatically across pathology practices and across the country, even when adjusted for types of tissue being diagnosed.

- The reference to "profits" being made at the expense of the Medicare program is incessant and does not serve any purpose. Examples:

  - CMS must recognize that unless a profit can be achieved, no one will perform services needed by the Medicare or any other program. CMS is in a unique position with a published fee schedule whereby pathology and laboratory services are paid. Who collects those fees and makes that profit, whether an individual pathologist or a commercial laboratory or a specialty practice, should not be a focus of CMS (other than assuring timeliness and quality of services to Medicare patients) because someone will make a profit or the service will not be provided.

  - CMS should be involved in assuring that Medicare patients actually do receive the services for which payment was made. CMS should not get involved in determining whether a pathologist, a specialty physician laboratory, a commercial laboratory or a hospital outreach program or some other party is receiving the payment and, hence, the profits. If a pathologist's professional service is billed to Medicare, whether the bill comes directly from the pathologist, or the commercial laboratory that employs the pathologist, or the specialty practice that contracts for pathologist services, CMS should be neutral in terms of payment. Not one cent more gets paid to any of these parties, yet all of them provide the pathology services necessary for the Medicare patient.

- Reference to "abuse" in the form of overutilization is similar to the profits issue in terms of incessancy and is a diversionary tactic. Examples:

  - CMS should review the current standards of care and hold providers to those standards. A good example of this is the number of cores that are to be performed on a patient undergoing prostate biopsy. The National Comprehensive Cancer Coalition (NCCN) has developed standards for a patient with early prostate cancer (attached). For a long time this number was 6 cores. With additional research, the number increased to 10 cores and the recommendation was recently further increased to 12 cores.

  - CMS should actively pursue those practitioners who do not follow the accepted and published standards of care. By doing so, overutilization will become a non-issue and, importantly, Medicare patients will receive the standard of care and quality they deserve.

The above issues should give some pause to those at CMS considering the next steps. Not needed are further complications to an already complicated set of existing rules.

Narrower Scope Comments

To respond to your request for comments on specific issues, I offer these:

- Should certain services not be exempted?
    - All pathology services, including anatomic and clinical, should remain exempted whether provided directly by a solo pathologist, a pathologist in a group practice or employed or contracted to a commercial laboratory or employed by a specialty practice in-office pathology laboratory. The focus of CMS should be quality of services to Medicare patients, not the route taken by the provision of the pathologist's professional service.
    - The organized pathology community prefers to split clinical from anatomic pathology and allow only clinical pathology in specialty practice in-office pathology laboratories. The rationale given is anatomic pathology results are not needed immediately for patient treatment. Pathologists do not seem concerned that a PSA test may be performed in specialty physician laboratories and there is no concerted organized pathology effort to stop it. A clue for this stance may be found in the fact that Medicare does not pay professional component fees for clinical pathology services, such as PSA. However, this is not the case with anatomic pathology work.
    - CMS needs to recognize that the structure of practices has changed over the years into significantly larger-sized groups than ever existed before. Urologists and gastroenterologists have led the way, driven by higher cost and lower reimbursement pressures, partly caused by lower Medicare fees. These physicians are seeking ancillary services, such as full clinical and anatomic laboratories, to accompany their much larger investments in new physical facilities encompassing sophisticated urology procedure suites and endoscopy centers, respectively.

- Should changes impact the definition of same/centralized building?
    - When the building issue was raised last year, so were many eyebrows in wonderment. CMS should be out of the definition of laboratory size or staffing levels. Whether the space should be 350 sq. ft. or 10 sq. ft. larger or smaller and whether there should be 0.35 or 0.75 FTEs is a moot point and not a place for CMS to exert itself. The real issue is whether owners of the laboratory have oversight of their laboratory. This means, is it in the neighborhood. A laboratory in Florida owned by a practice in Kansas is not in the neighborhood. A laboratory in Kansas City (KS) owned by a practice in Kansas City (MO) is in the neighborhood. The neighborhood oversight issue is one that does make sense.

- In a similar vein, requiring a full-time employed pathologist at a specialty practice in-office or other such laboratory is a burden that serves no one except organized pathology. This becomes an issue when the laboratory needs only 0.75 of a pathologist to operate efficiently, or if they need 1.3 pathologists. Requiring full-time pathologists in these examples adds to the inefficiency in the US healthcare system and will cause major problems for pathologists who service smaller laboratories with fractional FTE efforts. The proposed rule is no different than the arbitrary square footage issue for pod/condo laboratories.

Other Comments

- CMS also needs to recognize that specialty practices and other pathology laboratories must retain a pathologist to diagnose the Medicare patient's tissue. There is no shortage of very competent and well-trained pathologists willing and able to do the work. They do that work at less than the full Medicare professional component fee because they are bright enough to recognize that the professional fee includes a practice expense which they do not incur when working in a laboratory where no investment has come from their pocket. Organized pathology prefers that CMS rein in these renegade pathologists. It is the typical Teamster reaction; if it's a truck, a Teamster at union rates should be driving it. CMS should not be in an enforcer role for organized pathology. It has been shown time and again that a free-market economy does best for all parties.

- No one should be surprised about pathologists performing professional work for less than Medicare's professional component fee. This happens whenever a pathologist takes employment with a commercial laboratory or a pathology practice. These entities bill the professional fee and pay the pathologist a salary and benefit package that are less than the total professional fees generated by the pathologist. The same occurs when a pathologist is contracted by a specialty practice to provide pathology services in their in-office laboratory. The owners of these laboratories must earn a return on their investment by billing and collecting more dollars than they are spending.

- CMS appears to be pained when a pathologist does not receive full professional component fees. Although a pathologist may work part-time at a discounted fee for a specialty practice in-office laboratory or other such laboratory, an important question may be how many of these pathologists charge Medicare a discounted professional fee when they do work at a hospital for a Medicare patient. The answer is none or very close to none. CMS should not lose sight of this point and focus on properly setting professional fees, not on whether a solo pathologist, commercial laboratory or any other such entity receives those fees. The market will efficiently take care of fee distribution. CMS' concern should be to assure that proper pathology professional services are delivered to Medicare patients.

I appreciate the opportunity to contribute my comments to CMS' understanding of many issues facing pathology and laboratories in our changing healthcare environment.

NCCN National Comprehensive Cancer Network®

NCCN Clinical Practice Guidelines in Oncology™

Prostate Cancer Early Detection

V.1.2006

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ω Urology
Þ Internal Medicine
≠ Pathology
& Epidemiology
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Prostate Cancer Early Detection

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Clinical Trials: The NCCN believes that the best management for any cancer patient is in a clinical trial. Participation in clinical trials is especially encouraged.

To find clinical trials online at NCCN member institutions, click here: nccn.org/clinical_trials/physician.html

NCCN Categories of Consensus: All recommendations are Category 2A unless otherwise specified.

See NCCN Categories of Consensus

Summary of Guidelines Updates

Prostate Cancer Early Detection

INTRODUCTION

It is neither the intent nor the suggestion of the panel that all men diagnosed with prostate cancer require treatment. It is inherent that as we maximize the detection of early prostate cancer we will increase the detection of both non-aggressive (slow growing) and aggressive (faster growing) prostate cancers. The challenge is to identify the biology of the cancer that is detected, and thus identify cancers that, if treated effectively, will result in a significant decrease in morbidity and mortality.

This variability in prostate tumor behavior is unlike any other cancer and, consequently, causes major concern with the problem of over treatment resulting in potentially significant adverse implications on quality of life issues (eg, urinary, bowel and erectile dysfunction). The natural history of prostate cancer is that it will progress over time, but the unanswerable question is over what period of time.

The Prostate Cancer Early Detection guidelines do not address the treatment of prostate cancer. It is the majority opinion of the Prostate Cancer Early Detection panel members that there is a growing population of men currently being diagnosed with prostate cancer who can, and should, be monitored for their disease as presented in the Prostate Cancer Treatment Guidelines. The guidelines for a baseline PSA and lowering the PSA thresholds for biopsy were recommended by most panel members, but a consensus was not reached.

The guidelines are continuously in a state of evolution and the panel will incorporate changes based on new evidence and expert opinion and provide a rating of consensus with respect to each recommendation.

See Suggested "talking points" to cover in a discussion with a potential screenee about the pros and cons of PSA testing (PROSD-A).

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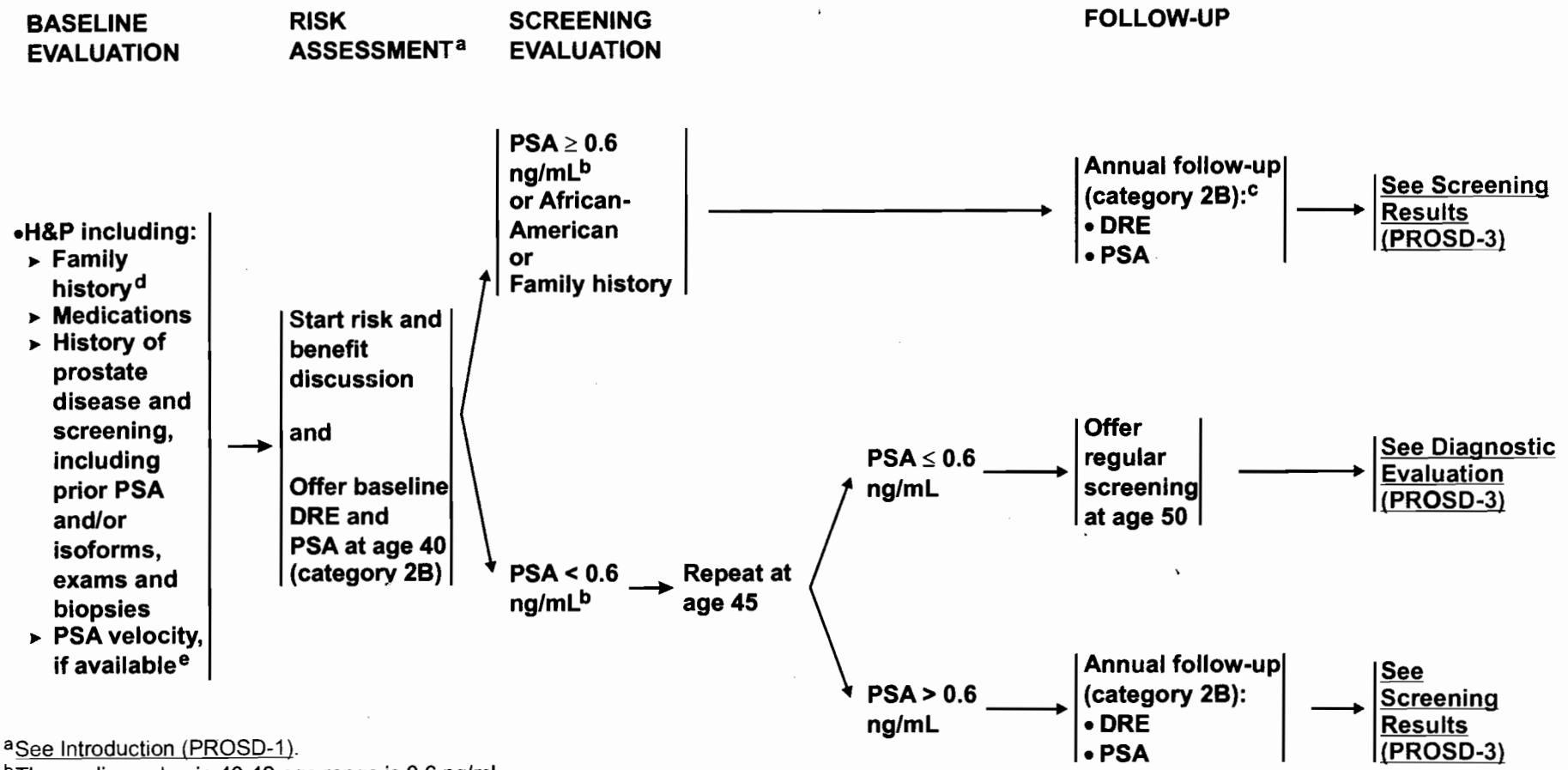
See Baseline Evaluation (PROSD-2)

Prostate Cancer Early Detection



[a] See Introduction (PROSD-1).

[b] The median value in 40-49 age range is 0.6 ng/mL.

[c] There is no evidence in the literature to support the follow-up recommendations listed; they represent the consensus-based opinions of the panel based upon their clinical experience.

[d] Family history may affect a decision to biopsy. The closer the relative, the earlier the onset and the more affected family members, the higher the risk.

[e] PSA Velocity: For men with PSA < 4 ng/mL, data suggest that a PSA velocity of ≥ 0.5 ng/mL/yr is suspicious for the presence of cancer (this could change with further data), and biopsy is recommended; for men with PSA 4-10 ng/mL, a PSA velocity of ≥ 0.75 ng/mL/yr is suspicious for cancer. PSA velocity in men with PSA > 10 ng/mL is not available. Measurement should be made on at least three consecutive specimens drawn over at least an 18-24 mo interval. There is variability. Longer time periods increase reliability, but, as calculation of PSA velocity over longer prior time intervals usually decreases the PSA velocity estimate, it might decrease predictive power. The same assay should be used. It is also important to remember that biologic variability may be a confounding factor in determining PSA velocity.

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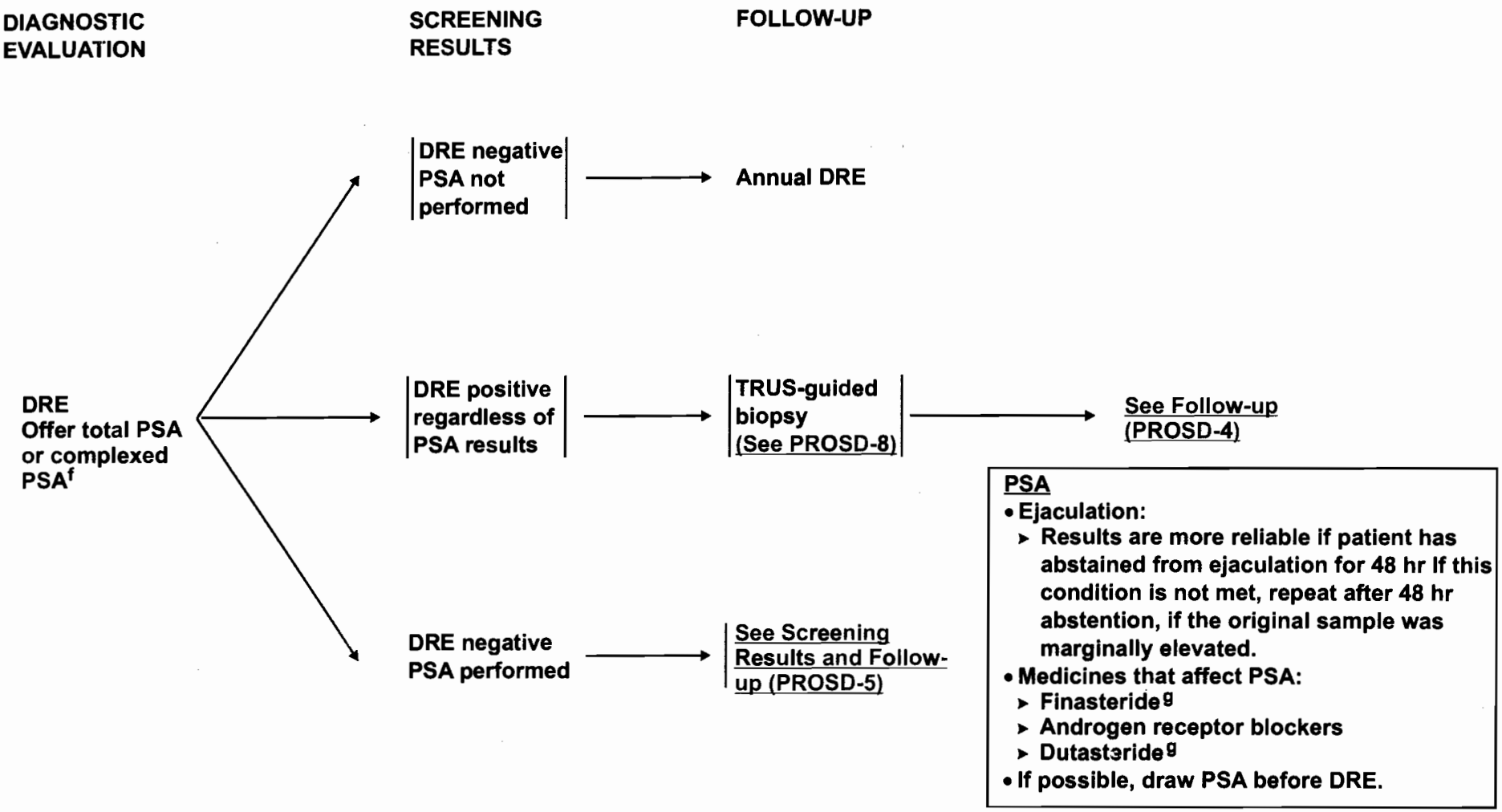
Prostate Cancer Early Detection



[f]Complexe l PSA can be used in place of total PSA, but the two assays are not interchangeable and one cannot be calculated from the other. Consider the following threshold values as equivalent for decision making: 1. Complexed PSA 2.2 and total PSA 2.5; 2. Complexed PSA 3.4 and total PSA 4.0; 3. Percent complexed PSA can be substituted for percent free PSA. The same assay should be used over time.

[g]In patients using finasteride or dutasteride, failure to have a substantial decrease in PSA or an increase while on medication can be associated with an increased risk of prostate cancer.

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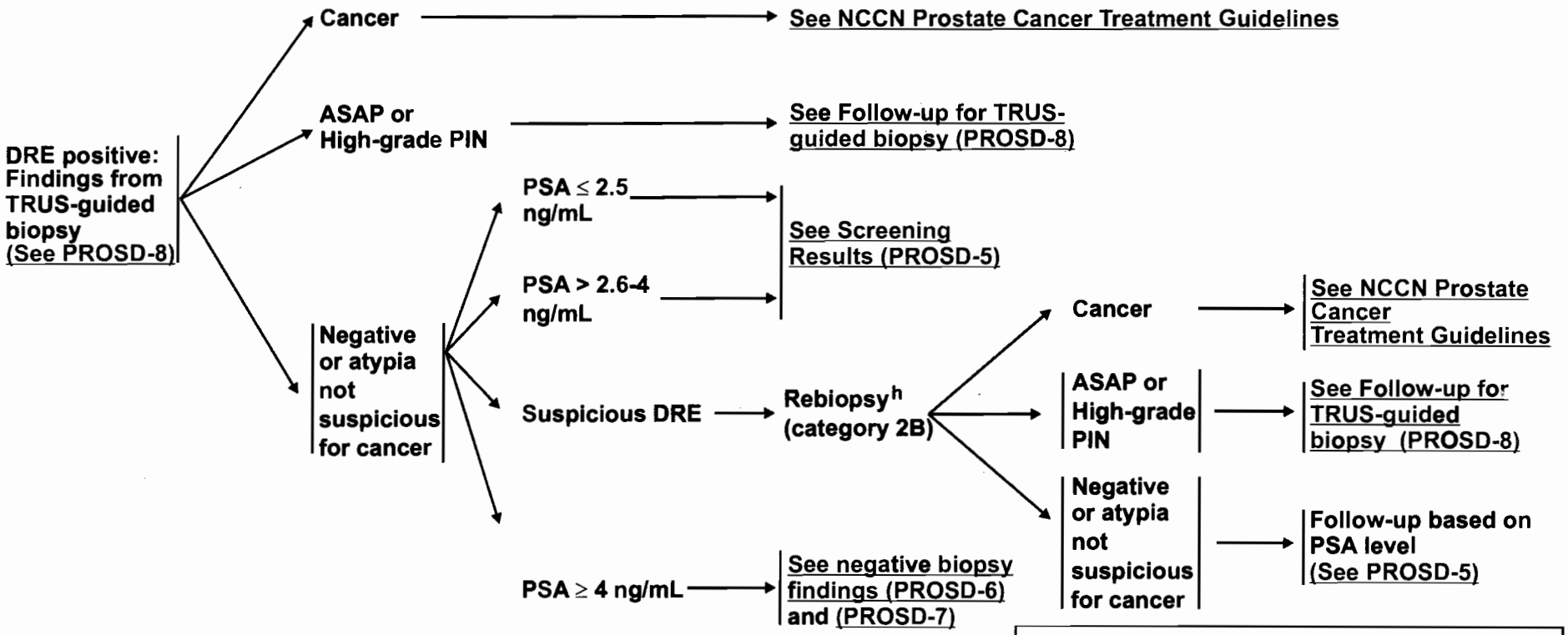
Prostate Cancer Early Detection

FOLLOW-UP



PSA

- **Ejaculation:**
  - **Results are more reliable if patient has abstained from ejaculation for 48 hr. If this condition is not met, repeat after 48 hr abstention, if the original sample was marginally elevated.**
- **Medicines that affect PSA:**
  - **Finasteride[g]**
  - **Androgen receptor blockers**
  - **Dutasteride[g]**

[g] In patients using finasteride or dutasteride, failure to have a substantial decrease in PSA or an increase while on medication can be associated with an increased risk of prostate cancer.

[h] Rebiopsy any abnormal DRE finding if it does not correspond to an ultrasound finding which has already been biopsied.

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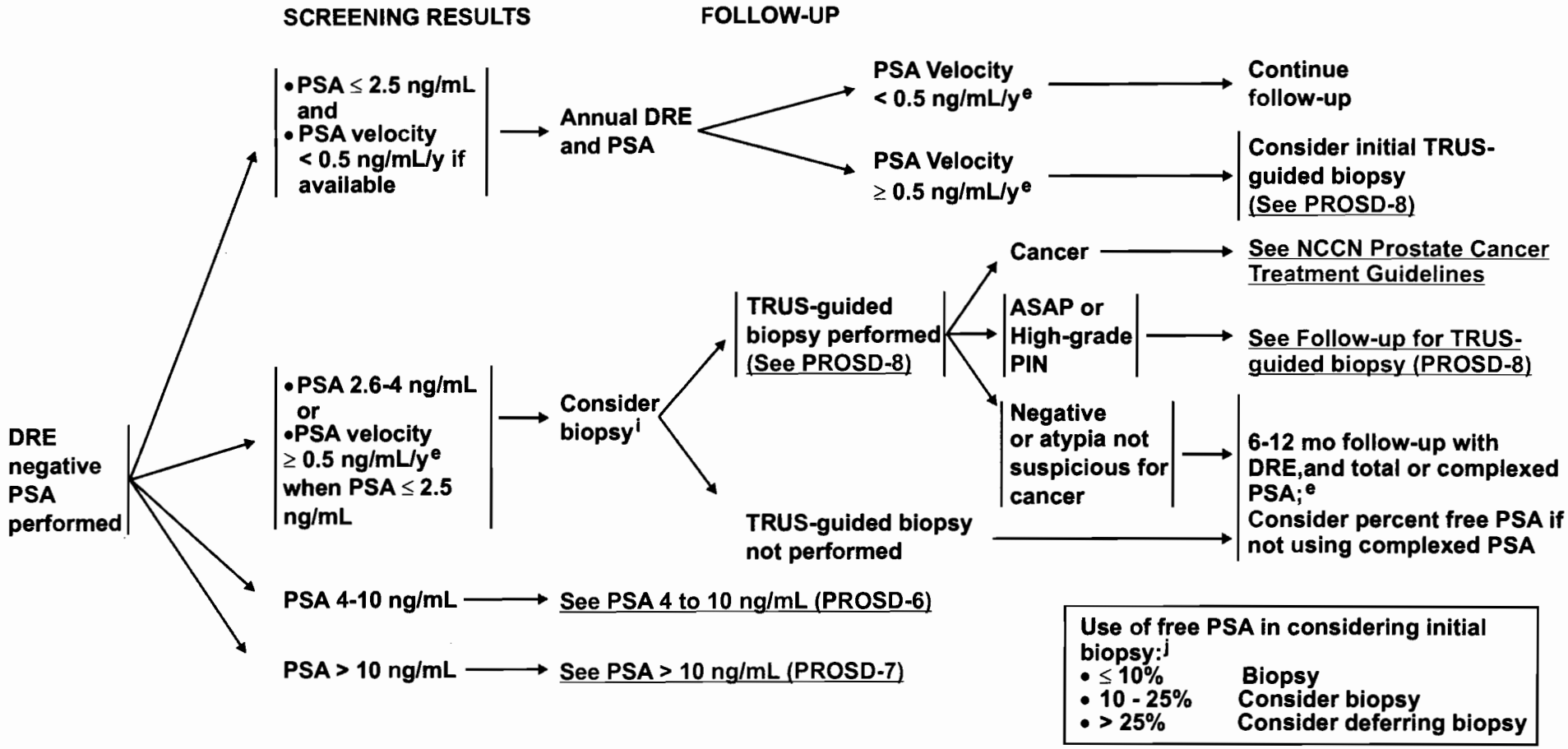
Prostate Cancer Early Detection



Use of free PSA in considering initial biopsy:[j]

- ≤ 10% — Biopsy
- 10 - 25% — Consider biopsy
- > 25% — Consider deferring biopsy

[e] PSA Velocity: For men with PSA < 4 ng/mL, data suggest that a PSA velocity of ≥ 0.5 ng/mL/yr is suspicious for the presence of cancer (this could change with further data), and biopsy is recommended; for men with PSA 4-10 ng/mL, a PSA velocity of ≥ 0.75 ng/mL/yr is suspicious for cancer. PSA velocity in men with PSA > 10 ng/mL is not available. Measurement should be made on at least three consecutive specimens drawn over at least an 18-24 mo interval. There is variability. Longer time periods increase reliability, but, as calculation of PSA velocity over longer prior time intervals usually decreases the PSA velocity estimate, it might decrease predictive power. The same assay should be used. It is also important to remember that biologic variability may be a confounding factor in determining PSA velocity.

[i] Factors to consider: age, comorbid conditions, percent free PSA, prostate exam/size, strength of family history, African-American.

[j] Free PSA is not generally used in deciding whether or not to perform an initial biopsy. However, in selected circumstances, it may be considered employing the following recommendations: > 25%, no biopsy; ≤ 10% biopsy; > 10% ≤ 25% indeterminate, consider biopsy.

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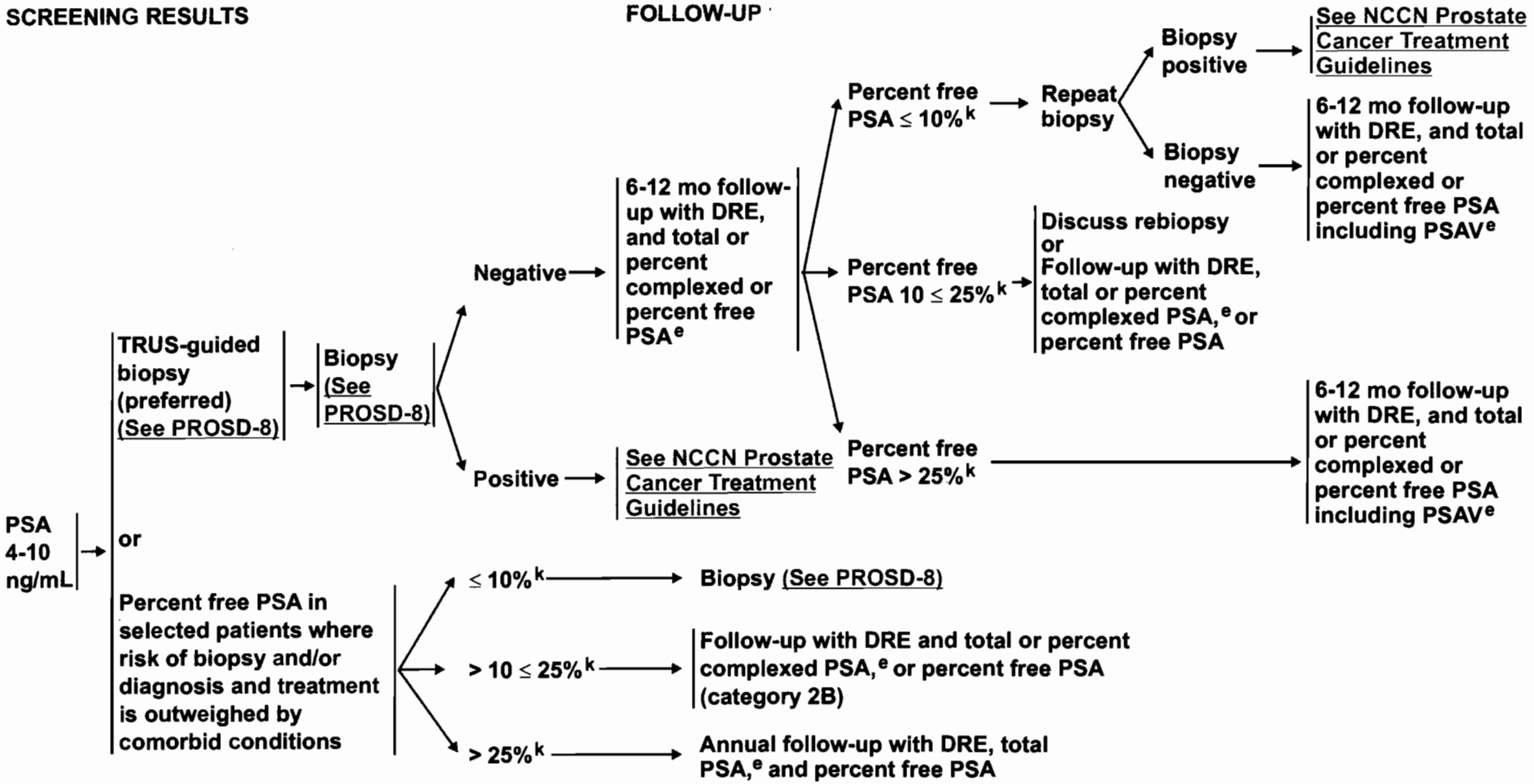

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[k] Percent free PSA cut-off levels based on data from Catalona WJ, Partin AW, Slawin KM et al. Use of percentage of free prostate-specific antigen to enhance differentiation of prostate cancer and benign prostatic disease: a prospective multicenter trial. JAMA 1998; 279: 1542-7.

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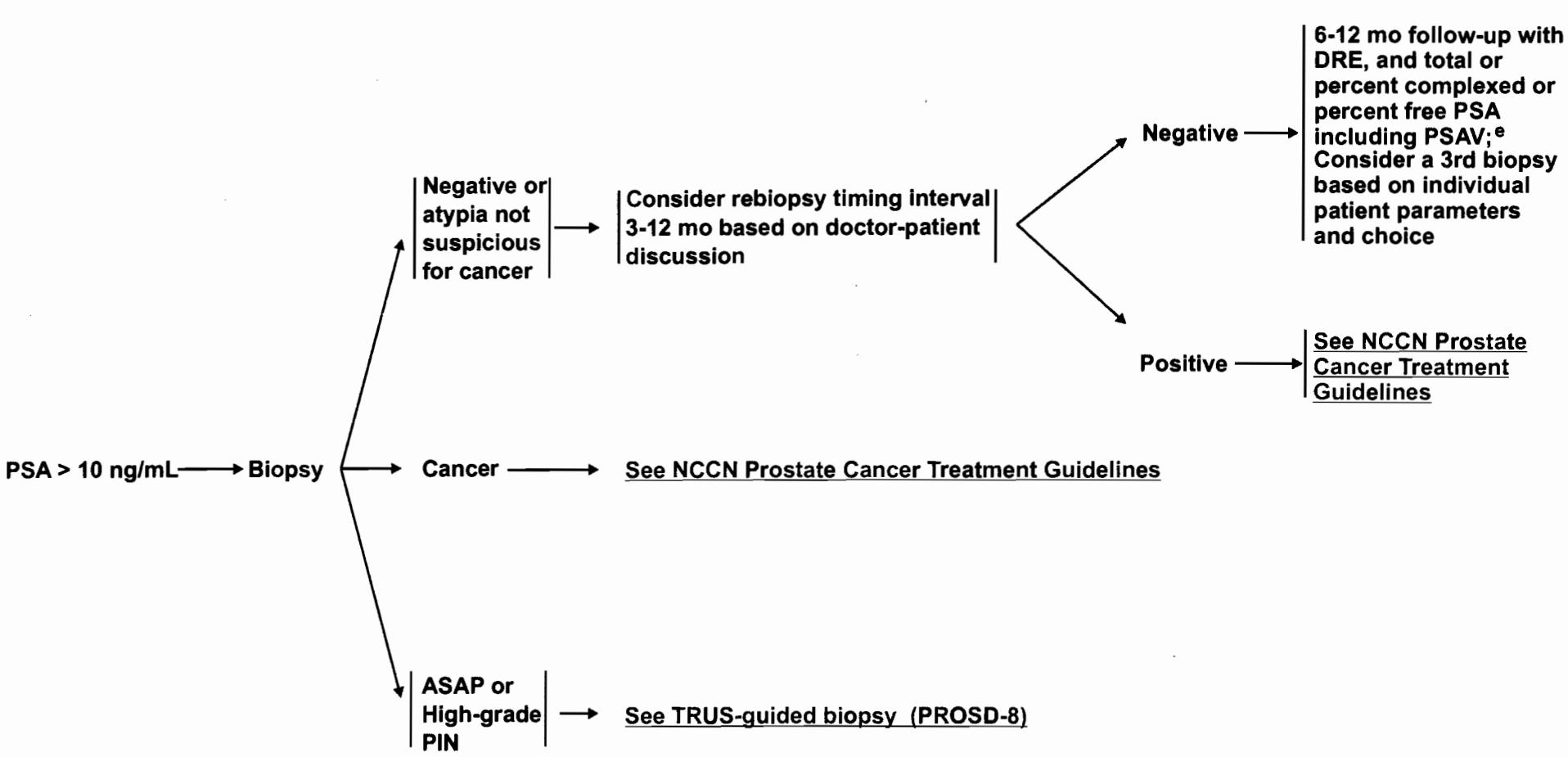
Prostate Cancer Early Detection



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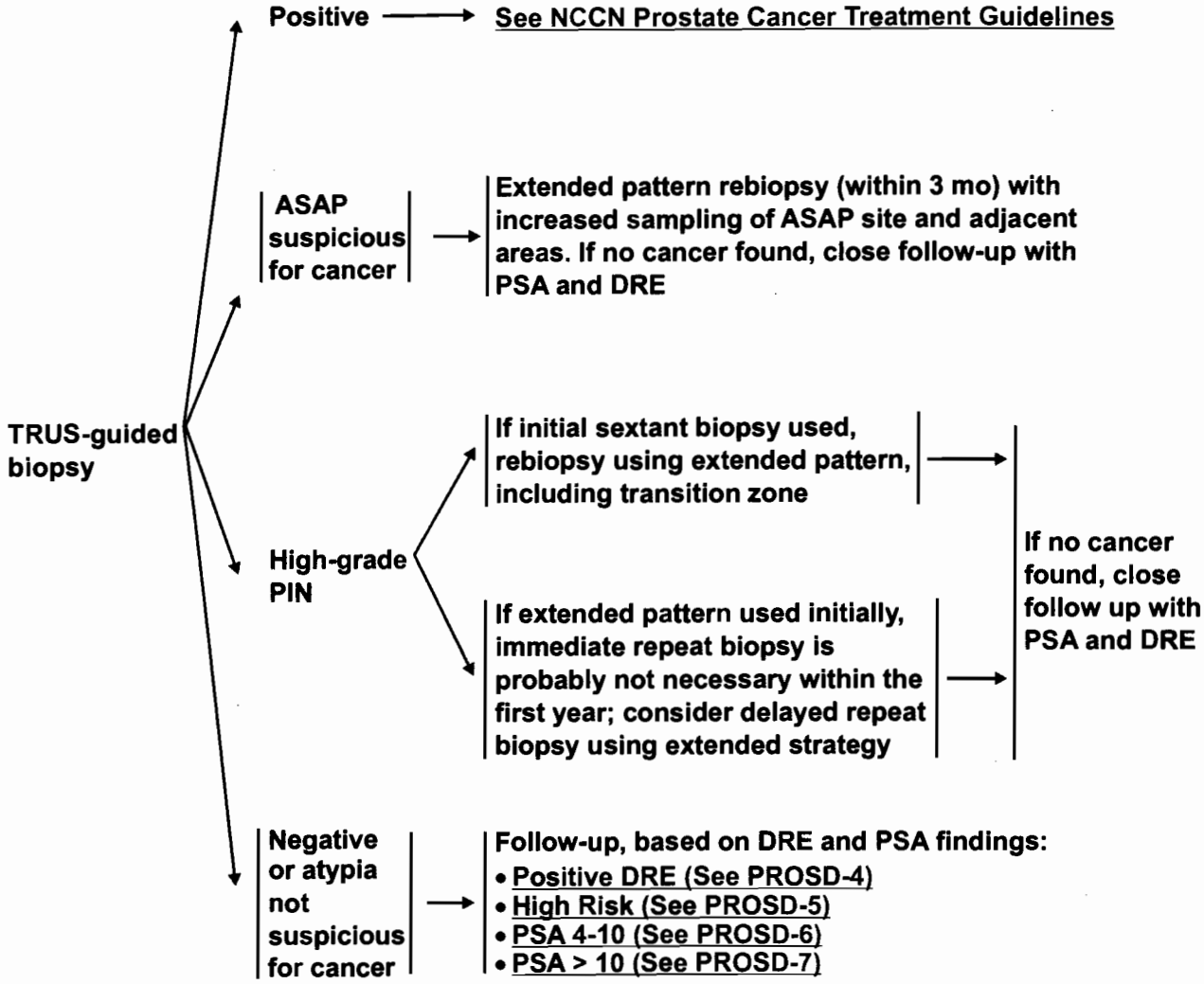
Prostate Cancer Early Detection

FOLLOW-UP FOR TRUS BIOPSIES



TRUS-GUIDED BIOPSY

Initial and Repeat
Extended-pattern biopsy (12 cores)

- **Number of Cores:**
  - **Sextant (6) and,**
  - **Lateral peripheral zone (6) and,**
  - **Lesion-directed at palpable nodule or suspicious image**
- **Transition zone biopsy is not supported in routine biopsy. However, the addition of a transition zone biopsy to an extended biopsy protocol may be considered in a repeat biopsy if PSA is persistently elevated.**
- **After 2 negative extended TRUS biopsies, prostate cancer is not commonly found at repeat biopsy.**
- **For high risk men with multiple negative biopsies, consideration can be given to a saturation biopsy strategy.**
- **Local anesthesia can decrease pain/discomfort associated with prostate biopsy.**

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SUGGESTED "TALKING POINTS" TO COVER IN A DISCUSSION WITH A POTENTIAL SCREENEE ABOUT THE PROS AND CONS OF PSA TESTING

- Prostate cancer is the most common cancer found in older men, other than skin cancer.[1] Men in the United States have about 1 chance in 6 of eventually finding out they have prostate cancer.[2] Men who have regular PSA tests have a higher chance of finding out they have prostate cancer; men who do not have PSA tests have a lower chance but a higher probability of having more advanced cancer when ultimately diagnosed. The PSA test can detect the majority of prostate cancers earlier than a digital rectal examination when a man has no symptoms.

- African-American men and men with a father, brother, or son with prostate cancer (especially if it was found a younger age) have a higher risk of prostate cancer. Latino men have a slightly lower risk, while Native American, and Asian-American men have a substantially lower risk.[2]

- American men also have about 1 chance in 30 of eventually dying from prostate cancer. However this would be higher, if no men opted for early detection and treatment. About 30,000 men die from prostate cancer each year in the United States. Only about 1 in 100 prostate cancer deaths occur in men under age 55. About 1 in 20 prostate cancer deaths occur in men age 55-64, 2 in 10 in men age 65-74, and 7 in 10 in men age 75 and older.[2] However, these deaths usually occur after some period of suffering from metastatic disease.

- Many prostate cancers grow very slowly. Consequently, many men with prostate cancer may die of something else before their prostate cancer causes any symptoms. However prostate cancers that grow more rapidly can potentially impact overall survival and quality of life. Whether a man will die of something else or prostate cancer depends on how aggressive the cancer is, how early it is detected, how effectively it is treated, as well as a man's age and his other medical problems. Most experts believe that in general men over age 75, or even younger men with serious medical problems, have little to gain from a PSA test.

- Doctors disagree about what level of PSA is high enough to do further testing, such as a prostate biopsy, to look for prostate cancer. Most doctors feel men with PSA levels greater than 4 should have a biopsy, while others feel men with levels greater than 2.5 should have a biopsy. There is an increasing tendency to focus less on absolute PSA values and to consider changes in PSA over time. There is accumulating evidence that men who have a steady rise in their PSA level are more likely to have cancer, and if the rise is rapid, the cancer is more likely to be life threatening. Other factors such as patient age and prostate volume (how large the gland is) are also important to consider when deciding who needs a prostate biopsy.

- A prostate biopsy is usually performed using local anesthesia through a probe placed into the rectum through which a needle is placed. This needle is used to take samples of the prostate tissue. Usually 10 to 12 samples are taken. The prostate biopsy, not the PSA test, tells whether or not a man has prostate cancer. A prostate biopsy is usually well tolerated and infrequently causes serious problems such as pain, infection or bleeding in the urine, semen, or stool. Long-term complications almost never occur.

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Talking Points continued on next page

SUGGESTED "TALKING POINTS" TO COVER IN A DISCUSSION WITH A POTENTIAL SCREENEE ABOUT THE PROS AND CONS OF PSA TESTING (Continued)

- A PSA test can be abnormal even when a man does not have prostate cancer. This is called a "false positive" test. These false positive PSA tests can come from other prostate conditions that are not important to find (unless a man has bothersome urinary symptoms). About 1 out of 3 men with a high PSA level have prostate cancer, which means that 2 out of 3 do not. The higher the PSA level, the more likely a man will be found to have prostate cancer if a biopsy is performed.[3]

- A PSA test can also be normal even when a man does have prostate cancer. This is called a "false negative" test. About 1 out of 7 men with PSA levels less than 4 have prostate cancer, which means 6 out of 7 do not.[4] The higher a man's PSA level is across all PSA ranges from zero on up, the more likely a man is to have prostate cancer. This is true even within the so-called "normal" range below 4.

- Prostate biopsies aren't perfect tests, either. Prostate biopsies sometimes miss cancer when it's there. Some doctors recommend a second set of biopsies if the first set is negative. Others will follow the PSA level and suggest more biopsies only if the level continues to go up.

- If prostate cancer is found after a PSA test and a biopsy, common treatments are surgery to remove the prostate or radiation treatment to the prostate. Surgery has a very small risk of death. Both radiation and surgery can cause problems with urinary leakage in some men, but the risk of urinary leakage is higher with surgery. Both radiation and surgery cause problems with getting and keeping an erection in many men. The risk of problems with erections is higher with surgery in the short run, but over the long run, the risk is about the same with the two treatments.[3] Radiation, though, also has a risk of causing bowel problems in some men. Some men, especially older men with slower-growing cancers, may not need treatments like surgery or radiation for their prostate cancer and can be followed with periodic PSA tests and physical exams, a process known as watchful waiting or active surveillance.

- It is not clear if screening a man with the PSA test lowers his chances of eventually dying of prostate cancer or helps him live longer. It is also not clear if screening a man with the PSA test lowers a man's chances of eventually having to deal with complications of prostate cancer, such as painful spread of prostate cancer to the bones, but the lower rates of advanced-stage disease at the time of diagnosis and the lower rates of prostate cancer deaths suggest that fewer men may suffer from advanced disease. As a result, doctors disagree over the value of screening men with the PSA test. However it is well established that screening has been associated with an unprecedented shift in the stages of prostate cancer at the time of diagnosis. More than 75 % of cancers are now detected when they are confined to the prostate gland, when current therapies are most effective. The actual relationship to PSA testing however remains unknown, but available evidence suggests that the lower mortality rates may be due, at least in part, to PSA testing. Special studies called randomized trials are the best way to determine how PSA testing affects the death rate from prostate cancer. Two of these long-term studies are underway in the US and Europe. Results are not expected for at least several years.[5-7]

Note: All recommendations are category 2A unless otherwise indicated.
Clinical Trials: NCCN believes that the best management of any cancer patient is in a clinical trial. Participation in clinical trials is especially encouraged.

Talking Points continued on next page

SUGGESTED "TALKING POINTS" TO COVER IN A DISCUSSION WITH A POTENTIAL SCREENEE ABOUT THE PROS AND CONS OF PSA TESTING (Continued)

- **In summary, there are advantages and disadvantages to having a PSA test, and there is no "right" answer about PSA testing for everyone. Each man should make an informed decision about whether the PSA test is right for him.**

- **Frequency of biopsy complications with 10 core biopsy:**
  - **hematuria greater than 1 day - 14.5%**
  - **hematospermia - 37.4%**
  - **rectal bleeding < 2 days - 2.2%**
  - **prostatitis- 1.0%**
  - **epididymitis- 0.7%**
  - **fever > 38.5°C (101.3°F)- 0.3%**
  - **urinary retention - 0.2%**
  - **rectal bleeding > 2 days ± requiring surgical intervention- 0.7%**
  - **other complications requiring hospitalization- 0.3%**

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[4]Thompson IM, et al. Operating characteristics of prostate-specific antigen in men with an initial PSA level of 3.0 ng/mL or lower. JAMA 2005;294:66-70.
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[6]de Koning HJ, Auvinen A, Berenguer Sanchez A, et al. Large-scale randomized prostate cancer screening trials: program performances in the European Randomized Screening for Prostate Cancer trial and the Prostate, Lung, Colorectal and Ovary cancer trial. Int J Cancer. 2002;97(2):237-244.
[7]Prorok PC, Andriole GL, Bresalier RS, et al. Design of the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial. Control Clin Trials. 2000;21(6 suppl):273S-309S.

Note: All recommendations are category 2A unless otherwise indicated.
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Summary of the Guidelines updates

Highlights of major changes in the v.1.2006 version of the Prostate Cancer Early Detection guideline from the v.1.2005 version include:

- The wording to the Introduction was updated and a link to the Risks and Benefits talking points was added (PROSD-1).
- Baseline evaluation including H&P was added as the first heading (PROSD-2).
- A risk assessment category was added before the screening evaluation (PROSD-2).
- Family history and African-American descent were added as parameters for screening evaluation (PROSD-2).
- A positive DRE regardless of PSA results in the Screening Results section, goes directly to TRUS-guided biopsy (PROSD-3).
- Footnote 'g' discussing the use of finasteride and dutasteride was clarified (PROSD-3).
- Atypia was replaced by ASAP throughout the guideline and atypia not suspicious for cancer was added to the negative branch througout the guideline.
- The PSA velocity threshold was changed from 0.75 ng/mL/y to 0.5 ng/mL/y (PROSD-5).
- The box concerning the use of free PSA and initial biopsy was updated (PROSD-5).
- Complexed PSA was changed to percent complexed PSA throughout the guideline.
- Percent free PSA is also recommended in selected patients where the diagnosis and treatment is outweighed by comorbid conditions (PROSD-6).
- Percent free PSA is also included as an option in follow-up (PROSD-6).
- Rebiopsy is a consideration for patients with screening PSA > 10 ng/mL and negative biopsy; it is no longer a category 2B (PROSD-7).
- A rebiopsy for ASAP suspicious for cancer is specified as an extended pattern biopsy (PROSD-8).
- Immediate repeat biopsy is no longer mandatory in the first year for High-grade PIN (PROSD-8).
- Extended pattern biopsy was clarified to be 12 cores (PROSD-8).
- The statement regarding the decreased probability of finding cancer after a second negative extended pattern biopsy was removed (PROSD-8).
- The Risk and Benefit Discussion has been completely re-worked to include talking points (PROSD-A).

Manuscript

NCCN Categories of Consensus

Category 1: There is uniform NCCN consensus, based on high-level evidence, that the recommendation is appropriate.

Category 2A: There is uniform NCCN consensus, based on lower-level evidence including clinical experience, that the recommendation is appropriate.

Category 2B: There is nonuniform NCCN consensus (but no major disagreement), based on lower-level evidence including clinical experience, that the recommendation is appropriate.

Category 3: There is major NCCN disagreement that the recommendation is appropriate.

All recommendations are category 2A unless otherwise noted.

The NCCN Prostate Cancer Early Detection Clinical Practice Guidelines in Oncology provide a set of sequential recommendations detailing a screening and subsequent work-up strategy for maximizing the detection of prostate cancer in an organ-confined state and attempting to minimize unnecessary procedures. These guidelines were developed for men who have elected to participate in prostate cancer screening; the controversy over whether to screen is not addressed.

Overview

Prostate cancer is the most commonly diagnosed cancer in American men and the third leading cause of cancer deaths. More than 234,460 men will be diagnosed with prostate cancer in 2006, and an estimated 27,350 patients will die of this disease.[1]

During the same period, nearly 20 million men in the United States will be confronted with important decisions regarding early detection for prostate cancer. Men in the United States have about one chance in six of eventually being diagnosed with this malignancy and about one chance in 30 of eventually dying of it. Those who undergo regular prostate-specific antigen (PSA) tests have a higher chance of undergoing prostate biopsy and of finding out if they have prostate cancer compared with men who do not undergo PSA tests. African-American men and men with a first-degree relative with prostate cancer (especially cancer found at a younger age) have a higher risk of having prostate cancer. About one in 10 prostate cancer deaths occur in men under age 65, two in 10 men between the ages of 65 and 74, and seven in 10 men age 75 and older.

The decision about whether to pursue early detection of prostate cancer is complex. In brief, the dilemma is that because not all men with prostate cancer will die of this disease, treatment is not necessary for some patients. Conversely, prostate cancer remains the third most common cause of male cancer deaths. To meet this challenge, a laboratory test must have maximum sensitivity for detecting clinically significant disease and maximum specificity and positive predictive value to eliminate as many unnecessary biopsies as possible.

Historical Perspective

The intense controversy surrounding early detection recommendations has prompted many medical organizations to develop prostate cancer detection guidelines. The American Cancer Society (ACS) and the American Urological Association (AUA) were the first groups to make definitive recommendations for the early detection of prostate cancer, advising men to obtain an annual digital rectal examination (DRE) and serum PSA test beginning at

age 50 in the absence of specific risk factors and earlier for those in high-risk groups. If the PSA level is above a designated threshold, indicating an increased risk, further testing, usually including a prostate biopsy, is indicated because a prostate biopsy is the only way to diagnose prostate cancer.

Opponents of systematic early detection programs for prostate cancer note that prospective, randomized trials have not yet matured to show an unequivocal benefit (decrease in disease-specific mortality) for early detection and definitive therapy. For this reason, the US Preventive Services Task Force and the American College of Physicians do not recommend performing routine PSA examinations as a screening procedure for prostate cancer. Low-grade prostate cancer typically progresses slowly. Mortality related to prostate cancer depends on how aggressive the cancer is and the patient's age and comorbidities. Most experts believe that men over age 75 have little to gain from PSA testing, unless they have an aggressive tumor, in which case they may have substantial benefits.

Many would agree, however, that the introduction of early detection methods such as DRE and the serum PSA test has played a critical role in the downward migration of prostate cancer stage seen over the past decade. There has been a 75% decrease in the rate of metastatic disease at the time of diagnosis between 1992 and 2002. Currently, 70% to 80% of prostate cancers are pathologically organ-confined at diagnosis. Multiple studies have unequivocally shown that prostate cancer cases detected through PSA screening are more often confined to the prostate than those detected solely by DRE.

In addition, recent declines in prostate cancer mortality among white and African-American men within the United States may be attributable, in part, to early detection efforts which became popular in the early 1990s. Both the ACS and the AUA have recommended that men who are at high risk for developing prostate cancer (eg, men with a strong family history of prostate cancer and all African-American men) should begin an early detection program before age 50. The AUA recommends starting an early detection program for these men at age 40, and the ACS advocates beginning testing at age 45. However, recent studies have shown that men whose PSA level is higher than the median for their age group are also at a higher risk for having prostate cancer, higher risk that the prostate cancer is aggressive, and a higher risk for recurrence after local treatment.[2] In fact, the baseline PSA value is a far stronger risk factor than a positive family history or being of African-American heritage.

Since the introduction of the ACS and AUA guidelines, many new derivatives of the PSA test have been introduced to try to improve the ability to detect prostate cancer and decrease the number of unnecessary biopsies performed. In addition, much research over the past decade has been directed toward the selection of appropriate early detection intervals to help make these efforts more cost-effective.

PSA Test and Its Derivatives

After a patient and physician decide to undertake an early detection program for prostate cancer, understanding the complex nature of diagnostic tests and their appropriate use is imperative. When the first recommendations for early detection programs for prostate cancer were made, serum total PSA was the only PSA-based test available. Subsequent years have seen the development of an exciting series of PSA derivatives that are possibly useful in increasing specificity and decreasing unnecessary biopsies.

The panel carefully evaluated the available literature regarding these PSA derivatives and, when appropriate, introduced them into the NCCN guidelines. Before discussing the guidelines, therefore, a brief description of PSA and its derivatives is warranted.

Prostate Specific Antigen

Total PSA (tPSA)

The development of PSA testing is arguably the most important advance that has been made in detecting prostate cancer at an early stage. PSA is a glycoprotein secreted by prostatic epithelial cells, and its protease activity lyses the clotted ejaculate to enhance sperm motility. Although primarily confined to the seminal plasma, PSA "leaks" into the circulation by means of an unknown mechanism. Many commercially available sources of PSA antibodies for serum tests are now available worldwide. With the exception of minor differences in the calibration of these assays, they perform comparably when used appropriately. However, the levels are not interchangeable since they are standardized against two different standards.

Besides prostate cancer, ejaculation and prostate manipulation can raise serum PSA levels as well, so the test should be performed at least 48 hours after these events. Additionally, the test should be repeated if increased levels are noted, particularly if the value is close to the threshold.

Effect of medication and herbal supplements on total PSA. The effect of the 5-alpha reductase inhibitor finasteride on serum PSA levels has been well documented in several studies. This class of drug results in an average decrease in serum PSA levels (30 80%) after 6 to 12 months. However, this effect is tremendously variable. For example, one study showed that at 1 year, only 35% of men had the expected 40% to 60% decrease in PSA and another 30% had greater than a 60% decrease in serum PSA levels.[3] Thus, not only should care be taken to elicit the use and duration of use of 5-alpha reductase inhibitors during history taking, but the commonly employed "rule of thumb" to simply double the measured PSA value may result in unreliable cancer detection.

A recent health questionnaire showed that well over 40% of men in the United States over age 50 take over-the-counter herbal supplements for lower urinary tract symptoms. Several of these herbal supplements, such as saw palmetto, may contain phytoestrogenic compounds that may affect serum PSA levels. Very little is known about the exact makeup of these herbal supplements and their specific effects on serum PSA levels. In a recent double-blinded study (NCT00037154), saw palmetto did not improve lower urinary tract symptoms caused by benign prostatic hyperplasia as measured by changes in either the Urological Association Symptom Index (AUASI) scores or peak urinary flow rates.[4] 225 men over the age of 49 years who had moderate to severe symptoms were randomized to receive either 160 mg of saw palmetto extract or a placebo for one year. No significant difference was observed between the two groups, for the primary outcome measures; changes in the American Urological Association Symptom Index (AUASI) scores (mean difference, 0.04 point, 95% confidence interval) and peak urinary flow rate (mean difference, 0.43 ml per minute, 95% confidence interval). Side effects were also similar in the two groups. Nevertheless, patients should be asked specifically about their use of supplements such as saw palmetto.

Total PSA thresholds. Numerous studies have shown that a PSA level above 4 ng/mL increases the chance of detecting prostate

cancer at prostate biopsy to nearly 30% to 35%. Large programs for the early detection of prostate cancer have shown that nearly 70% of cancer cases can be detected using a PSA cutoff level of 4 ng/mL.[5] Overall, appropriate use of PSA alone can provide a diagnostic lead time of nearly 5 to 10 years compared with DRE. Historically, more than 90% of PSA-detected cancers are biologically significant based on tumor volume and tumor grade criteria. Detection of prostate cancer by PSA examination results in the detection of earlier organ-confined disease.[6] Recent studies have investigated the predictive value of evaluating men with PSA values in the 2.5 to 4.0 ng/mL range (see subsequent sections).

PSA Velocity

The rate of change in PSA over time is called the PSA velocity (PSAV). This parameter was first introduced by Carter et al. This important study showed for the first time that the "rate of change" of serum PSA over time provides useful information and increases the specificity of PSA for cancer detection. These authors showed that a cutoff of 0.75 ng/mL/y had a sensitivity of 72% among men with cancer and a specificity of more than 90% among those without cancer when PSA levels were between 4-10ng/ml. When PSA levels were less than 4ng/ml, sensitivity using a cutoff of 0.75ng/ml was only 11%. It has been shown that lower PSAV cutoffs (0.2-0.4ng/ml per year) are necessary to maintain sensitivity and specificity when PSA levels are below 4ng/ml. Current recommendations for the use of PSA velocity include collection of PSA levels over a period of no less than 18 months and the use of multiple values (minimum of 3) to perform the calculation. However, recent studies have shown that the prognostic information contained in PSA velocity measurements for predicting the aggressiveness of the prostate cancer is contained in the PSA velocity during the year prior to the diagnosis of prostate cancer.[7] Also, PSA velocity measurements can be confounded by prostatitis, a condition that can cause dramatic increases in PSA levels. In fact, men with very high PSA velocities are more likely to have prostatitis than prostate cancer. Therefore, it is helpful to try to rule out prostatitis by diagnostic evaluation and empiric antibiotic therapy.[8]

Currently, PSA velocity has been best used in younger men who have elected to begin early detection programs before age 50. These men have predominantly lower (normal) serum PSA levels and no prostate enlargement to confound the interpretation of PSA. Even minimal rises in PSA (0.2-0.4ng/ml per year) should raise the suspicion of prostate cancer in these men and prompt closer monitoring of PSA levels at shorter intervals (eg. yearly) in order to detect prostate cancer at a localized stage. Patients and physicians electing to monitor prostate disease by measuring PSA velocity should be cautioned that fluctuations between measurements can occur as a result of either laboratory variability related to inter-assay variability from the use of different commercially available sources or from individual biologic variability. Consequently, both of these causes may confuse the interpretation of PSA velocity measurements.

At present, PSA velocity provides a useful longitudinal or serial test for following up the millions of men with "normal" serum PSA levels that are now embarking on early detection programs for prostate cancer. When PSA velocity is chosen as a method for monitoring men in an early detection program, the physician should carefully discuss with these men the risks and benefits associated with such a longitudinal monitoring program.

Age- and Race-Specific PSA Reference Ranges

Age-specific PSA reference ranges were introduced by Oesterling and colleagues as a method to increase cancer detection (increase

sensitivity) in younger men by lowering PSA cutoff values and to decrease unnecessary biopsies (improve specificity) in older men by increasing the PSA cutoffs. These age-specific ranges have been investigated by several groups with controversial results.[9] Race-specific reference ranges have also been suggested.[10] However, the exact roles of these age- and race-specific PSA cutoffs in the early detection of prostate cancer remain unclear and continue to be the source of debate. The panel, therefore, chose not to incorporate these variables into the current prostate cancer early detection guidelines.

Percent-free PSA (fPSA)

A flurry of exciting work over the past decade has characterized a family of molecular forms of PSA and their possible clinical roles. Free PSA expressed as a ratio with total PSA has emerged as a clinically useful molecular form of PSA, with the potential to provide improvements in early detection, staging, and monitoring of prostate cancer. Several molecular forms of PSA are known to circulate in the blood. In most men, the majority (60% to 90%) of circulating PSA is covalently bound to endogenous protease inhibitors. Most immunoreactive PSA is bound to a protease inhibitor called alpha-1-antichymotrypsin. Other immunoreactive PSA-protease inhibitor complexes, such as alpha-1-antitrypsin and protease C inhibitor, exist at such low serum concentrations that their clinical significance has not been determined. In addition, a large proportion of PSA is complexed with alpha-2-macroglobulin (AMG). Unfortunately, this PSA-AMG complex cannot be measured by conventional assays because of the shielding (or "caging") of PSA antigenic epitopes by AMG.

Most clinical work investigating the use of the molecular forms of PSA for early detection of prostate cancer has focused on the percentage of PSA found circulating in the free or unbound form. Numerous studies have shown that the percentage of free PSA is significantly lower in men who have prostate cancer compared with men who do not.

Recently, the US Food and Drug Administration (FDA) approved the use of percent-free PSA for the early detection of prostate cancer in men with PSA levels between 4 and 10 ng/mL. The multi-institution study that characterized the clinical utility of this assay showed that a 25% free PSA cutoff detected 95% of prostate cancers while avoiding 20% of unnecessary prostate biopsies.[11] Since its approval by the FDA, testing for percent-free PSA has gained widespread clinical acceptance in the United States, specifically for patients with normal DREs who have previously undergone prostate biopsy because they had a total PSA level within the "diagnostic gray zone" (ie, between 4 and 10 ng/mL).

Complexed PSA (cPSA)

As noted previously, PSA exists in both free and several complexed forms. Direct measurement of the complexed form with alpha-1-antichymotrypsin is now available and has been found to be equivalent to the determination of total PSA in detecting prostate cancer, that is, the sensitivity was similar. For practical purposes, total PSA consists essentially of free PSA and the alpha-1-antichymotrypsin complexed form. The threshold levels are therefore not equivalent: cPSA levels of 2.2 and 3.4 ng/mL are equivalent to tPSA levels of 2.5 and 4.0 ng/mL, respectively. In a multicenter trial of 831 men, of whom 313 had prostate cancer, researchers found that cPSA offered an advantage compared with tPSA.[12] In the range of 80% to 95% sensitivity thresholds, cPSA increased specificity compared with tPSA, which would result in 13.8% fewer biopsies if a cutoff of 2.2 ng/mL is used. Results were similar for percent cPSA and percent fPSA. Therefore, the ratio of complexed to total PSA should

provide comparable information as the free to total PSA ratio. Other studies specifically evaluating the utility of cPSA in men with a tPSA in the range of 2 to 4.0 ng/mL confirmed the increased specificity of cPSA.[13,14] The results of recent study in Japanese men support the observation that a low cPSA (α-antichymotrypsin) (>1.7 -4.0) had a greater area under the ROC than tPSA confirming the increased specificity of the complex PSA compared to the total PSA in this reference range. In this range there was also an indication it performed better than the free/total PSA. However, the number of patients with prostate cancer in this PSA range is small and there are differences in patient populations, PSA methodology, biopsy number and study design in the various studies. There is a conspicuous absence of confidence intervals. In a recent study, Babaian et al reported that a 2.2 ng/mL cPSA cutoff point decreases the number of unnecessary biopsies in the tPSA range of 2.5-6.0 ng/mL, demonstrating the potential value of cPSA as a first-line diagnostic test for the early detection of prostate cancer.[15] An advantage of cPSA compared with percent fPSA is that the latter requires two laboratory measurements, whereas the cPSA is a single test.

PSA Density

Prostate-specific antigen density requires measurement of prostate volume by transrectal ultrasound (TRUS) and is expressed as the PSA value (in nanograms per milliliter) divided by the prostate volume (in cubic centimeters). Benson and coworkers[16] first proposed the use of PSA density as a means of discriminating prostate cancer from the most frequent cause of PSA elevation, benign prostatic hypertrophy. Initially, PSA density was used to differentiate high PSA levels in men with large prostates who did not have prostate cancer. A PSA density cutoff of 0.15 mg/mL/cc was recommended in earlier studies, which spared as many as 50% of these patients from undergoing unnecessary biopsies. Some subsequent studies have reported that the 0.15 cutoff has insufficient sensitivity and have recommended the use of a cutoff of 0.10 instead.[17]

More recent studies have tried to improve upon the performance of PSA density by using complexed[18] or free PSA[19] in the numerator or correcting the denominator for transition zone volume[20]. The lack of precision of measurement of both PSA and prostate volume has prevented the widespread clinical acceptance of PSA density. PSA density may explain an elevated PSA value considered after negative biopsies, but the panel did not incorporate it into early detection guidelines.

The need for accurate prostate volume determination using TRUS has prevented the widespread clinical acceptance of PSA density. In many recent studies, percent-free PSA has outperformed PSA density in early-detection algorithms[21]. Thus, the panel, although recognizing the clinical utility of PSA density, did not incorporate it into the early detection guidelines, because PSA density offers little benefit for cancer detection over that provided by the use of PSA velocity and PSA isoforms (free and complexed). However, PSA density has been clinically under utilized and should be considered in evaluating patients, especially those who have had prior ultrasound-determined measurements of prostate volume. PSA density has been shown to correlate with prostate cancer presence, aggressiveness, pathologic tumor stage and progression-free survival after treatment.[22]

Age at Onset of Screening and Thresholds for Annual Screening

Although age 50 has traditionally been the age for starting to consider PSA screening, researchers have recognized that high-risk

groups such as African-Americans and men with family histories of prostate cancer may benefit from beginning screening at an earlier age.

The Baltimore Longitudinal Study on Aging identified median PSA levels as a function of age with a median PSA for men in their 40s of 0.6 ng/mL and a median value for men in their 50s of 0.7 ng/mL. Significantly, they found a threefold higher risk of prostate cancer within 10 to 25 years if PSA was greater than the median for the patient's age group.[23] Catalona et al. evaluated the probability of finding cancer within 5 years of screening men in their 40s and found that for men with a PSA less than 0.7 ng/mL, the cancer rate was 0.5%. This is compared with a 7.3% rate for men with a PSA of 0.7 ng/mL or higher (*P*=.0002). For patients screened in their 50s, those with a PSA of less than 0.9 ng/mL had a cancer rate of 0.7%, and those with a PSA value of 0.9 or higher had an 8.1% cancer rate (*P*=.0001).[2] Recent unpublished studies have demonstrated that the median PSA value for men in their 40s is approximately 0.6-0.7 ng/ml, in men in their 50s it is approximately 0.7-0.9 ng/ml, and in men older than 60, it is 1.4 ng/ml. Furthermore, these studies have also demonstrated that the risk for subsequent cancer detection is very low, if the PSA level is less than the median for the age group; however, the risk increases with increases in PSA level above the median, particularly in younger patients. These studies have shown a correlation between the baseline PSA level and PSA velocity, aggressive prostate cancer features, pathologic tumor stage and progression-free survival rate after radical prostatectomy. Autopsy studies have shown that histologic evidence of prostate cancer is present in approximately 25% of men in the fourth decade of life, and the US SEER Database shows that prostate cancer deaths begin to appear in men in their 30s. Accordingly, to prevent these tragic, untimely deaths, screening for prostate cancer should begin earlier. It seems reasonable to obtain a baseline PSA test at age 40 to assess the risk for subsequent prostate cancer detection. This risk assessment might be useful in determining the most appropriate surveillance strategy for the individual, as well as whether or when a prostate biopsy should be recommended. For this reason, the NCCN guidelines now recommend that for men who choose to begin PSA screening, they should consider obtaining a baseline value at age 40.

Threshold for Prostatic Biopsy

A level of total PSA of 4.0 ng/mL has traditionally been used as the threshold for consideration of a prostate biopsy, recognizing that 30% to 35% of men in the 4 to 10 ng/mL range will be found to have cancer. Subsequent studies of the incidence of cancer in men whose PSA is in the range of 2.5 to 4.0 ng/mL have shown that a substantial number of men in this group will have cancer. A study of 332 screened men with PSA in this range revealed that 22% incidence of prostate cancer.[24] A prospective study of 151 subjects with PSA values in this range showed an incidence of 24.5%.[25] What is significant is that the cancers found in this population have been determined to be clinically significant based on the volume and Gleason score and are organ-confined in a larger percentage of cases.[26,27] An over diagnosis of clinically insignificant or unimportant tumors did not occur. Researchers have estimated that lowering the threshold to 2.6 ng/mL would double the rate of detecting cancer in men younger than 60 years old with little loss of specificity.[28]

Recently, the Prostate Cancer Prevention Trial demonstrated that 15% of men with a PSA level of 4 ng/ml or less and a normal DRE had prostate cancer diagnosed on end-of-study biopsies[29]. There was a direct correlation between the PSA level and the prostate cancer detection rate, ranging up to 26.9% in patients whose PSA

was 3.1 to 4.0 ng/ml. High-grade prostate cancers (defined by a Gleason score of 7 or greater) was prevalent in 25% of patients with a PSA level of 3.1 4.0 ng/mL. Based on the results of this trial, high-grade prostate cancers detected by biopsy is not rare among men with PSA levels of 4.0 ng/mL or less.

Based on this and other supportive data, it now appears that the use of a PSA threshold of 4.0 ng/mL will miss a significant number of potentially curable tumors. The NCCN guidelines therefore recommend consideration of biopsies for men with PSAs in the range of 2.5 to 4.0 ng/mL. The caveat remains, of course, that the definitive demonstration of improvement in mortality from PSA screening still awaits the results of ongoing, large randomized trials and considerations of quality of life. Economic consequences must also be factored into policy-making.[30]

NCCN Guidelines

General Considerations

The decision to participate in an early detection program for prostate cancer is complex for both the patient and physician. Important factors that must be considered when beginning an early-detection program include patient age, life expectancy, family history, race, and previous early detection test results. Most importantly, the patient and physician need to understand the risks and benefits associated with the early detection and treatment of prostate cancer. Several general principles for early detection should be clearly understood before using the NCCN guidelines:

- No portion of these early detection guidelines is designed to replace an accurate history and complete physical examination conducted by a physician.
- The general health, medical comorbidities, and life expectancy of the patient are paramount when recommending or designing an early detection program.
- Prostate cancer risk factors, such as family history and race (i.e., African-American), should be considered before decisions concerning the initiation of an early detection program are made.
- Prostate cancer in its early stages has no identifiable symptoms. In advanced disease, symptoms may include urinary obstruction, prostatic bleeding, hematospermia, and bone pain. Although most men wishing to take part in early detection programs have no symptoms of prostate cancer, they may have mild to severe symptoms of lower urinary tract disease because of benign prostatic enlargement. Care should be taken to educate patients about the distinction between these two diseases when discussing the risks and benefits associated with early detection.
- A patient's history of prior testing, including DRE, PSA, PSA derivatives, and prostate biopsy, must be considered when designing an early detection program for that patient. Patients who have had numerous serial PSA values should make the information available to the physician. In addition, previous negative prostate biopsy results and the actual histologic findings should also be made available. Although a clear understanding of the approach to early detection in men who have a long history of abnormal PSA values has not been completely documented, these earlier test results should be considered when testing intervals are chosen.
- Numerous large, community-based early detection programs have clearly documented the synergy of DRE and PSA testing in increasing the sensitivity for the detection of prostate cancer over the use of either test alone. Serum PSA testing is not a substitute for a thorough DRE.
- Total PSA levels greater than 10 ng/mL confer a greater than 67%

likelihood of harboring prostate cancer. Thus, men with serum PSA values over this level (regardless of their DRE results, percent-free PSA, or PSA velocity values) should undergo a TRUS-guided biopsy of the prostate. False-negative findings should be discussed clearly with the patient and a repeat biopsy considered if total PSA values continue to remain in the high-risk category.

Specific Considerations

Prostate Biopsy Technique

Initial Biopsy Technique: Systematic prostate biopsy under transrectal ultrasound guidance is the recommended technique for prostate biopsy. Initially described as a sextant technique sampling both right and left sides from the apex, mid-gland and base in the mid-parasagittal plane, more recently extended biopsy schemes have demonstrated improved cancer detection rates. Although no one scheme is considered optimal for all prostate shapes and sizes, most emphasize better sampling of the lateral aspect of the peripheral zone. One commonly used scheme is the 12-core biopsy scheme that includes a standard sextant as well as a lateral sextant scheme (lateral apex, lateral mid-gland, lateral base). This scheme has been validated in a large study of 2299 patients involving 167 community-based Urologists.[31] Moreover, a randomized trial found that increasing the number of cores taken from 6 to 12 did not substantially increase complications or delay return to normal activities.[32] The overall cancer detection rate in this referral-based population was 44%. If only a sextant scheme was performed, approximately 20% of the cancers in the series would have been missed. Lesion-directed biopsies (hypoechoic lesions seen on TRUS) rarely contribute to unique cancer identification not detected by extended systematic biopsy. The utility of transition zone biopsies in initial biopsy patients is low and is not recommended.[33,34] The panel recommends an extended-pattern 12-core biopsy [sextant (6) and lateral peripheral zone (6) and lesion directed palpable nodule or suspicious image]. Transition zone biopsy is not supported in routine biopsy. However, this can be added to an extended biopsy protocol in a repeat biopsy if PSA is persistently elevated.

Repeat Biopsy Technique: Patients with prior negative biopsies, yet persistently rising PSA values should undergo repeat biopsy. Important factors in predicting chance of cancer on repeat biopsy include PSA velocity and the adequacy of initial biopsy (number of cores, prostate size). Cancer detection rates are higher in men with prior negative sextant biopsies compared to those with prior negative extended biopsies. Yields are highest in the laterally directed cores and the apical cores.[35] Particular attention should be given to apical sampling including the anterior apical horn, which is comprised of peripheral zone.[36] Transition zone biopsies can be considered in repeat biopsy patients. In patients with two negative extended biopsies, yet persistently rising PSA values, a saturation biopsy may be considered.[37]

Use of anesthesia: Historically, up to 90% of men undergoing a prostate biopsy have reported some discomfort during the procedure.[38] Both topical lidocaine gel and an injectable nerve block have been shown to be safe and efficacious in reducing discomfort.[39] Topical lidocaine was more efficacious in reducing pain during probe insertion, whereas periprostatic injection reduced pain during the biopsy itself. These minor anesthetic techniques greatly enhance the acceptability of the procedure, particularly with extended templates and saturation techniques but should be considered in all patients.[40] For exceptional cases such as men with anal strictures or patients who have been inadequately blocked with a periprostatic injection, intravenous sedation or general anesthetic may be advantageous

Percent-free PSA. The NCCN guidelines recommend the use of the percent-free or complexed PSA as an alternative in the management of patients with normal DREs and total PSA levels between 4 and 10 ng/mL if there is a contraindication to biopsy. Physicians and patients electing to use percent-free PSA should be cautioned that this assay and the multi-institution study performed to obtain its FDA approval were designed with the intention of avoiding unnecessary biopsies in men with a high likelihood of not having prostate cancer. If an anticoagulated patient presents with a negative DRE, total PSA value of 4-10 ng/mL, and percent-free PSA levels greater than 25% annual follow-up with DRE, tPSA, and percent free PSA can be considered. This strategy met with less-consensus (category 2B) if the percent free PSA is 25% or less, where biopsy is preferred.

Percent-free PSA levels less than 10% are clearly associated with a high risk of having prostate cancer, and patients should be encouraged to undergo a biopsy if percent-free PSA values fall below this level. There is a negative linear relationship between the likelihood of having prostate cancer and having percent-free PSA values between the levels of 10% and 25%. The risks associated with these values should be carefully discussed with the patient before electing to forego prostate biopsy. In general, percent-free PSA is used in the decision process when an individual has had an initial negative biopsy.

In addition, physicians should consult the clinical chemistry laboratory to determine manufacturer's recommendations regarding sample collection and sample handling. It should also be noted that "mixing and matching" free and total PSA assays from different manufacturers is not recommended and may lead to spurious results.

PSA velocity. Studies of PSA velocity have determined that an increase in the serum PSA levels ≥ 0.5 ng/mL/y indicates a high likelihood of having prostate cancer. The PSA values used to calculate PSA velocity should be performed by similar assay techniques in the same clinical laboratory. Prostate-specific antigen velocity should be calculated from at least three consecutive PSA values obtained over at least an 18-24 month period. Longer time periods increase reliability. In patients using finasteride or dutasteride, failure to have a substantial decrease in PSA or an increase indicates that they are at increased risk for prostate cancer.

Carter and colleagues have described the technique for calculating PSA velocity in detail. The research that went into the determination of PSA velocity cutoff points was collected primarily in men with PSA levels below 10 ng/mL. Evidence is lacking regarding the usefulness of this measurement for men with PSA levels greater than 10 ng/mL. However, guideline panel members universally endorse performing a prostate biopsy in all men with a PSA value greater than 10 ng/mL who also fulfill other screening criteria.

Management of Negative or Suspicious Biopsies

Increasingly, pathologists have recognized the importance of reporting non malignant but pathologically atypical findings. High grade prostatic intraepithelial neoplasia and atypical small acinar proliferation are noted in up to 14% and 5% of biopsies, respectively.[41] Such diagnoses are often confirmed through the use of immunohistochemical staining for basal cell markers and other markers of neoplasia such as Alpha Methyl-Acyl CoA Racemase (AMACR).[42,43]

High-grade Prostatic Intraepithelial Neoplasia (HGPIN). Cytologically, the nuclear features of HGPIN resemble that of cancer, however the presence of a basal layer on the acini distinguishes this entity from cancer. Extended biopsy schemes

have dramatically resulted in a decline in the positive rebiopsy rate in patients initially found to have HGPIN. While reports in the sextant biopsy scheme era demonstrated positive rebiopsy rates of approximately 50%, contemporary series using extended biopsy schemes report positive rebiopsy rates of approximately 10-20%.[44,45]

Atypical Small Acinar Proliferation (ASAP). Distinct from HGPIN in which a basal cell layer is present, ASAP, or atypia, is characterized by small singlecell layer acini. However, because so few glands are present on the biopsy specimen, an unequivocal diagnosis of cancer cannot be established. Even in the era of extended biopsy schemes, positive rebiopsy rates in patients with ASAP are 40-50% and the most likely area of finding cancer resides in the prostate area demonstrating ASAP.[46] Hence a repeat extended biopsy scheme is warranted with additional cores being obtained from the prior region demonstrating ASAP.

If the biopsy result for a man with PSA level greater than 10 ng/mL reveals histologic evidence of atypical small acinar proliferation (ASAP) or high-grade PIN (prostate intraepithelial neoplasia) TRUS-guided biopsy is indicated. The NCCN guidelines therefore recommend that if high-grade PIN is found on TRUS-guided biopsy, of less than 10 cores, repeat biopsy using an extended pattern, including transition zone, is indicated if an extended biopsy strategy was not used. If extended biopsies were used, a delayed strategy may be considered, as suggested by Lefkowitz et al.[47] For findings of ASAP suspicious of cancer, extended pattern rebiopsy (within 3 months) with increased sampling of ASAP site and adjacent areas is recommended.

Negative biopsy in the absence of suspicious lesions.[48] Men with a PSA of 4 to 10 ng/mL with a percent-free PSA level less than 10% should undergo a repeat biopsy. If the free PSA level is between 10% and 25%, repeat biopsy or close follow-up with total PSA or one of its derivatives can be considered. If the free PSA is greater than 25%, the surveillance strategy (6-12 month follow-up with DRE and total or percent complexed PSA including PSA velocity) can be used. If a biopsy returns as negative in a man with a serum PSA level greater than 10 ng/mL, a repeat prostate biopsy should likewise be considered at 3-12 month interval based on the discussion with the patient. Given the importance of technique, issues discussed above regarding the use of extended or saturation techniques for a repeat prostate biopsy should be considered.

Summary

Since guidelines for the early detection of prostate cancer were developed by the ACS in the early 1990s, many variants of the total PSA assay have been introduced in attempts to increase the sensitivity of screening programs (cancer detection) while maintaining specificity (elimination of unnecessary biopsies). Again, it is important to note that the NCCN guidelines recommend a method by which individuals and their physicians can use these new methods rationally for the early detection of prostate cancer. These guidelines are not designed to provide an argument for the use of early detection programs for prostate cancer. Rather, they are meant to provide a vehicle by which early detection efforts can be practiced in an evidence-based, systematic fashion in patients who choose to participate in such programs.[49]

The NCCN guidelines incorporate many new validated findings in addition to the DRE and tPSA test. These new factors include percent-free PSA, PSA velocity, complexed PSA, biopsy pathology, and TRUS-guided biopsy techniques. The panel will re-examine the

clinical utility of these new modalities annually, and the guidelines will be modified accordingly. In addition, future iterations of these guidelines may incorporate new serum markers currently undergoing clinical investigation.

The goal of the NCCN and this guideline panel in updating these algorithms is that they will assist men and clinicians choose a program of early detection for prostate cancer to make decisions regarding the need for prostate biopsy. Any clinician who uses these guidelines is expected to exercise independent medical judgment in the context of the individual clinical circumstances to determine the patient's need for prostate biopsy. These guidelines will continue to evolve as the field of prostate cancer advances.

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American Society of Echocardiography

September 21, 2005

Via E-mail and U.S. Mail

Kenneth Simon, MD
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Dear Dr. Simon:

As Presidents of the American College of Cardiology (ACC) and the American Society of Echocardiography (ASE), we are writing to you to follow up on recent discussions regarding the potential modification of the CPT codes for echocardiography services, which were discussed during the August 25th Five Year Review meeting of RUC Workgroup 4. As you will recall, some Workgroup members suggested bundling the CPT code for color flow Doppler (CPT code 93325) into the CPT code for transthoracic echocardiography (CPT code 93307).

We understand that this suggestion was based on the observation that the RUC data base for 2003 reflected nearly equal numbers of CPT 93307 and CPT 93325 services and the subsequent conclusion that color Doppler was "always used with transthoracic echocardiographic imaging (CPT code 93307)." It was also observed that the echocardiography family of codes includes separate codes for color Doppler and spectral Doppler, while these services are bundled with the imaging component of extracranial vascular ultrasound services.

Both ACC and ASE strongly believe that the current CPT code for color flow Doppler services should not be bundled into CPT code 93307. Moreover, we do not believe that any other CPT changes are needed for the echocardiography code "family." The current echocardiography procedure nomenclature and codes are longstanding and have attained widespread acceptance among both payers and the physician community. This "building block" nomenclature enables physicians to describe precisely what services have been performed and enables payers to provide payment only for those services that actually were provided—no more, no less. The history and use of these codes are different from that of vascular ultrasound and general ultrasound services, and each set of codes serves the unique needs of those physicians who use them for accurate and consistent reporting.

I. The "Building Block" Approach to Flexible and Accurate Reporting

Echocardiography codes, like the codes for many other kinds of physicians' services, are characterized by a "building block" approach that enables the physician to bill for precisely those services that are provided. In the case of the echocardiography code "family," there are a number of "base" codes and

three primary "add-on" codes—two for spectral Doppler (CPT Code 93320 (complete) and 93321 (limited)) and one for color flow Doppler (CPT Code 93325).

The descriptor for CPT code 93325 explicitly recognizes that this service is performed in conjunction with many different echocardiography imaging procedures. Specifically, the CPT description explicitly indicates that CPT code 93325 may be used in conjunction with any of the following "base" codes:

CPT code 76825—fetal echocardiographic imaging, complete study
CPT code 76826—fetal echocardiographic imaging, followup study
CPT code 93303—transthoracic echo imaging, complete, congenital heart disease
CPT code 93304—transthoracic echo imaging, limited, congenital heart disease
CPT code 93307—transthoracic echo imaging, complete, adult (aquired heart disease)
CPT code 93308---transthoracic echo imaging, limited, adult (acquired heart disease)
CPT code 93312—transesophageal echo imaging, (complete)
CPT code 93314—transesophageal echo imaging, image acquisition and reporting only
CPT code 93315—transesophageal echo imaging for congenital abnormalities,(complete)
CPT code 93317—transesophageal echo image acquisition and reporting, congenital
CPT code 93350—stress echo imaging

In addition, color flow Doppler CPT 93325) may be billed either with or without spectral Doppler for both fetal (CPT codes 76827 and 76828) and adult applications (CPT codes 93320 and 93321). Either complete or limited spectral Doppler applications may be appropriate depending on the clinical issues being addressed.

This building block approach enables physicians to bill accurately for all the services—and only those services—that are actually provided. Using the building block approach, physicians are able to bill for nearly 70 different combinations and permutations of various echocardiography services, as necessary to accurately describe their services.

Not surprisingly, the "building block" approach to ultrasound coding appears to be the rule, rather than the exception. The CPT section relating to Diagnostic Ultrasound indicates that Doppler evaluation of vascular structures is separately reportable and directs users to report using CPT codes 93875-93990.[1] In addition, the codes available to report obstetrical ultrasound parallel those available to report cardiac ultrasound: CPT code 76815 is used to report general fetal ultrasound imaging, while CPT codes 76820 and 76821 can be used in addition (when appropriate clinically) to report Doppler velocimetry of the umbilical and middle cerebral arteries, respectively. While these services are not generally provided to Medicare patients, the "building block" approach to coding is identical.

II. The Current "Building Block" Approach to Billing for Echocardiography and Other Ultrasound Services Should Be Retained.

We strongly believe that the current "building block" approach to echocardiography and other ultrasound service billing should be retained for a number of reasons:

[1] While color flow "used only for anatomic structure identification" does not appear to be separately reportable, we note that color flow Doppler used in conjunction with echocardiography is typically used not for "structure identification", but rather for identification of pathologic cardiac function (such as intracardiac shunting and valvular regurgitation), and for quantitation of the severity of these lesions.

1. We note that the CPT Editorial Panel considered and rejected the idea of "bundling" the echocardiography "add-on" codes into the echocardiography "base imaging" codes at least twice over the past ten years—once in 1994 and once in 1996.[2] On both occasions, CMS decided not to "bundle" the echocardiography add-on codes into the base codes. Since practice patterns with respect to the use of the add-on codes do not appear to have changed substantially since the mid-1990's, it would be inappropriate for the RUC to recommend now that the CPT Editorial Panel again revisit the issue.

2. There are sound reasons why the vascular ultrasound codes include color and spectral Doppler while the echocardiography "base" codes do not. Historically, each set of codes was developed in a different manner to meet different clinical needs. Although the first clinical applications of color Doppler were described in congenital heart disease in 1978, soon thereafter the first commercial color Doppler instrument was produced for use with carotid ultrasound. This technology complemented early work by Strandness and colleagues using alterations of spectral Doppler waveforms as a marker of arterial stenosis severity. Rapidly, two dimensional imaging of the carotid arteries was combined with color Doppler imaging to localize regions of turbulence, and spectral Doppler to quantitate changes in flow velocity and turbulence in order to determine lesion severity. Hence, all three modalities (structure imaging, color Doppler flow localization, and spectral Doppler velocimetry) were "married" early on in what became termed "duplex" technology, with each modality serving a distinct clinical role in the diagnostic regimen. It was sensible to construct codes that bundled all three of these modalities since that is how they were used.

By contrast, cardiac ultrasound evolved in a different manner. Two-dimensional imaging became rapidly used for demonstrating cardiac structure and dynamics in the mid-1970's. Spectral Doppler was initially used for evaluating stenotic valve lesions in the late 1970's and early 1980's; additional uses of spectral Doppler for determining volume flow rate, for evaluating valvular regurgitation, and for assessing diastolic function were developed later on and incorporated gradually into clinical practice. Color Doppler flow imaging became commercially available in the mid-1980's, and new applications have continued to evolve over the last 20 years. Construction of a "building block" coding system was logical and practical since it allowed the clinician to describe accurately and precisely those services that he/she needed to use to answer the clinical question(s).

3. In fact, the coding nomenclature differs for vascular, cardiac, ophthalmic, gynecological and other ultrasound applications, and the codes for each have been developed based on the clinical needs of the various specialties involved. In the case of general ultrasound, there are separate codes based primarily on the anatomical site that is examined (e.g. separate codes for abdominal ultrasound (CPT codes 76700-76705), ultrasound of the bladder (CPT codes 51798), ultrasound of the colon (CPT codes 45391-45392 and 45341-45342), etc.) In the case of vascular ultrasound, separate codes have been developed based on whether the study is extracranial (CPT codes 93880-93882) or intracranial (CPT code 93886-93893); bilateral or unilateral (CPT code 93880 vs. 93882), and contrast- enhanced or unenhanced (CPT codes 93892-93893). Ophthalmic ultrasound (CPT codes 76506-76536) is based on whether an A-scan or B-scan is provided; whether the scan is performed to localize a foreign body or to determine intraocular lens power, whether the corneal or anterior segment is examined, and other factors. Cardiac

[2]On April 19, 1996, the then-President of the ASE, Dr. Alan Pearlman, wrote to Drs. Grant V. Rodkey (Chair, RUC) and T. Reginald Harris (Chair, CPT Editorial Panel) arguing against a proposal to bundle the echocardiography add-on codes into the base codes. An April 17, 1996 letter from Dr. James Blankenship (Chair, ACC Coding and Nomenclature Committee) to Dr. Harris also offers ACC's recommendation against bundling, as does another letter of the same date from Dr. Anthony DeMaria writing as chair of the ACC's Economics of Health Care Delivery Committee.

ultrasound coding is similarly tailored to clinical needs. In view of the robust nature of cardiac ultrasound, with evidence-based utility in virtually every different form of heart disease[3]. An echocardiography coding system that included a separate code for each structure examined or for each clinical entity of concern would be highly unwieldy at best. Thus, echocardiography coding is based primarily on which techniques are needed to address the clinical concerns.

4. The "building block" approach remains extremely useful in light of the breadth of echocardiography applications. For example, consider the use of add-on codes in conjunction with stress echocardiography (CPT 93350). This service would be provided alone to assess a patient with symptoms of exertional chest pain if coronary artery disease were suspected. However if the patient also had a systolic murmur or if a thickened and immobile aortic valve were noted on echocardiographic imaging prior to the stress test, then spectral Doppler (93320) would be mandatory to evaluate the severity of aortic stenosis, and color Doppler flow imaging (93325) would be necessary to help assess for and determine the severity of associated aortic and mitral regurgitation. As another example, consider a patient with shortness of breath and a systolic heart murmur sent by his primary care provider to determine the cause and significance of the murmur and the cause of dyspnea. If mitral valve redundancy and obvious prolapse were evident on 2-dimensional echo imaging (CPT 93307), then the use of spectral Doppler (CPT 93320) and color Doppler flow imaging (CPT 93325) would be mandatory in order to determine the severity of mitral regurgitation and to document the presence and degree of pulmonary hypertension. On the other hand, if the echocardiographic imaging study demonstrated a large pericardial effusion with right heart chamber compression (as a cause for the patient's symptoms) with normal valve morphology and mobility, it might be more appropriate to do a limited spectral Doppler (93321) evaluation to help document the presence of tamponade and the need for pericardiocentesis; a complete spectral Doppler or a color Doppler flow imaging evaluation might not be necessary. We would be delighted to provide additional examples for other echocardiography "base" codes.

5. As a practical matter, CPT 93325 is often (although clearly not always) done with virtually every base imaging code in the echocardiography family. [4] Attachment A sets forth an analysis of data from the CY 2003 Medicare 5% Physician/Supplier Standard Analytic File, prepared by Chris Hogan of Direct Research (the "Hogan Analysis"). While most color flow Doppler services are provided in conjunction with two dimensional transthoracic echo (CPT code 93307), an estimated 388,230 color flow Doppler claims each year are provided in conjunction with other echocardiography services,[5] including fetal echo, transesophageal echo, congenital echo and stress echo. The proportion of claims for each of these types of echocardiography services that include color flow Doppler varies substantially. For example, the Hogan Analysis indicates that approximately 36% of stress echo claims include color flow Doppler, while approximately 80% of congenital echo (complete) claims include the color flow Doppler code. For many of the echocardiography imaging codes, the proportion of claims that include color flow Doppler hovers in the 50% range. Therefore, any effort to "bundle" color flow Doppler into the base codes and to

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[3] See Cheitlin MD, Armstrong WF, Aurigemma, GP, Beller GA, Bierman FZ, Davis JL, Douglas PS, Faxon DP, Gillam LD, Kimball TR, Kussmaul WG, Pearlman AS, Philbrick JT, Rakowski H, Thys,DM. ACC/AHA/ASE 2003 guideline update for the clinical application of echocardiography: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (ACC/AHA/ASE Committee to Update the 1997 Guidelines for the Clinical Application of Echocardiography). 2003. American College of Cardiology Web Site. Available at: www.acc.org/clinical/guidelines/echo/index.pdf.

[4] As the number of CPT 93307 services is quite large, it is not surprising that the majority of CPT 93325 services are performed in conjunction with CPT 93307 as the base imaging code

[5] The Hogan Analysis indicates that approximately 5.3% of the 336,255 color flow Doppler claims in the 5% file are provided in conjunction with CPT base codes other than CPT code 93307.

provide payment on the basis of services provided to the "typical" patient would be extremely difficult and would necessarily result in less accurate payment for a substantial number of claims.

6. The Hogan Analysis makes it clear that bundling the color flow or spectral Doppler codes into the echocardiography base codes would not simplify billing. On the contrary, bundling would necessarily result in either (a) less accurate coding and billing, or (b) a considerably more complex coding and billing structure for echocardiography services. Color flow Doppler services not only are commonly billed with a wide range of echocardiography "base" codes, but also may be billed either with or without spectral Doppler. And, as illustrated above, either complete or limited spectral Doppler may be appropriate in different clinical circumstances. Therefore, if bundling were mandated, a series of "permutations" would be necessary to describe the range of clinical scenarios accurately. For example, to preserve accuracy in the face of "bundling", CPT code 93307, which is currently used to report the most common echocardiographic imaging procedure, would explode to include separate codes for:

*Transthoracic echo alone—CPT 93307.
*Transthoracic echo with spectral Doppler (complete)—CPT 93307 and CPT 93320.
*Transthoracic echo (complete) with spectral Doppler (limited)—CPT 93307 and CPT 93321
*Transthoracic echo with color flow Doppler—CPT code 93307 and 93325.
*Transthoracic echo with spectral Doppler (complete) and color flow —CPT 93307, 93320 and 93325
*Transthoracic echo (complete) with spectral Doppler (limited) and color flow -- CPT 93307, 93321 and 93325.

Similar multiple permutations also would be required for all of the other echocardiography imaging services—limited transthoracic, fetal, congenital transthoracic echo, transesophageal echo, congenital transesophageal echo, and stress echo. In order to bill with accuracy equivalent to what is now possible using the "building block" approach, the physician community would need nearly 70 different codes, rather than the 11 imaging and 5 "add on" codes that currently comprise the echocardiography code "family." This is certainly not a "coding simplification". Moreover, we note that changes to the CPT codes used to describe echocardiography services would also necessitate changes in the APC categories used to code and bill for these services in the Hospital Outpatient setting. Since for many base imaging codes, the use of spectral and color Doppler "add on" codes hovers around 50%, determining appropriate hospital charge data for new APC's would be extremely challenging.

7. The "building block" approach to ultrasound codes also facilitates efficient addition of new codes without requiring the revaluation of existing codes. For example, if and when new codes are developed for three dimensional echocardiography, these can be added to the echocardiography code "family" without requiring revaluation of any existing code. The same is true for other new technologies, such as tissue Doppler and Left Ventricular Synchrony. If the building block approach is abandoned and the codes combined, the addition of new codes to reflect advances in echocardiography will further complicate the echocardiography coding scheme and require frequent revaluation of existing codes. We note as well that a "building block" approach also has been used in many other sections of CPT precisely because it preserves flexibility and accuracy in describing combinations of specific services, without requiring users to employ "modifiers" for "reduced" or "prolonged" services, and because it reduces the need for manual review of claims.

Summarizing, then, in light of ultrasound's broad utility in the diagnosis of various illnesses, it is neither surprising that there is considerable variation in the applicable coding conventions--nor is it clear that consistency in coding format ought to prevail over descriptive accuracy. Making all ultrasound CPT codes consistent would require a major undertaking involving a broad array of specialties and a substantial commitment of time and resources by both the CPT Editorial Panel and the RUC. This is

especially true insofar as the use of building block codes for services such as Doppler appears to be the rule, rather than the exception in the CPT.

The physician work involved in all of the major echocardiography "base" codes have been valued by RUC, and almost all of the "high volume" echocardiography services have undergone review through the Five Year Review process. The practice expense inputs of all of the current echo codes have been reviewed by the PEAC. The various echocardiographic imaging, spectral Doppler, and color Doppler codes have been written and valued in a manner that avoids duplication of work and/or time, and so represent "independent" services the combination of which accurately reflects both physician work and practice expense. Both the Editorial Panel and the RUC already have expended considerable energy and resources in developing and valuing the current echocardiography and other ultrasound codes, and we do not think it makes sense to overhaul the current system (which is well understood, flexible enough to meet clinical needs, and allows users to describe exactly those services they have provided) in order to develop a new CPT coding system for cardiac ultrasound that likely would be either less accurate or substantially more complex than the current "building block" approach.

We appreciate your consideration of this issue, and urge you to contact Rebecca Kelly, Director of Regulatory Affairs for the American College of Cardiology (RKelly@acc.org) or Diane Millman, Washington Counsel for the American Society of Echocardiography (DMillman@ppsv.com) if you have any questions or concerns.

Sincerely yours,

Pamela S. Douglas, MD, FACC, President
American College of Cardiology

Bijoy Khandheria, MD, FASE, President
American Society of Echocardiography

Cc. Edith Hambrick, MD
Robert Zwolak, MD
James Blankenship, MD
Alan Pearlman, MD
Michael Picard, MD
Rebecca Kelly
Denise Garris
Diane Millman
Janice Brannon

Attachment B

CY 2003 Medicare 5% Physician/Supplier Standard Analytic File, All Claims Lines
For all claims with these base codes, what fraction of claims also had each of the add-on codes?
Note: Percentages on a line may sum to more than 100% if claims typically had multiple add-on codes.

Base Code	Description	Number of claims, 5	93320 Spectral (complete)	93321 Spectral (ltd)	93325 Color flow	No Add'l service None of the add-on codes on the claim
76825	Echo exam of fetal heart	36	0.00%	0.00%	47.20%	52.80%
76826	Echo exam of fetal heart	2	0.00%	0.00%	0.00%	100.00%
76827	Echo exam of fetal heart	36	0.00%	0.00%	50.00%	50.00%
76828	Echo exam of fetal heart	20	0.00%	0.00%	20.00%	80.00%
93303	Echo transthoracic	277	78.30%	1.80%	80.10%	17.70%
93304	Echo transthoracic	52	26.90%	38.50%	67.30%	28.80%
93307	Echo exam of heart	336,036	95.50%	0.20%	92.10%	3.40%
93308	Echo exam of heart	4,442	18.80%	37.90%	42.20%	40.10%
93312	Echo transesophageal	11,007	57.00%	2.30%	65.50%	31.90%
93314	Echo transesophageal	1,235	41.40%	4.50%	52.20%	46.20%
93315	Echo transesophageal	117	41.00%	1.70%	40.20%	53.80%
93317	Echo transesophageal	65	29.20%	0.00%	29.20%	70.80%
93350	Echo transthoracic	26,043	34.20%	1.60%	36.10%	61.30%

*Excludes spectral and color flow claims that did not include base code.

Medicare 5% Sample LDS SAF Physician/Supplier File 2005.
All Claims Lines with the Indicated CPT Codes -- Crosstab Showing Add-on Codes Appearing With Base Codes

		Count of Claims With Add-on Codes					Percent of Base Code Claims Having Add-On Code					Percent of all Add-On Code Occurrences				
Base Codes	All Claims	93320	93321	93325	92978	92979	93320	93321	93325	92978	92979	93320	93321	93325	92978	92979
Total all claims	422,018	379,204	4,280	376,567	1,587	178						100%	100%	100%	100%	100%
No base code on claim	10,454	4,678	252	6,936	1,576	176						2%	1%	6%	2%	99%
76825	40	-	-	18	-	-	0%	0%	45%	0%	0%	0%	0%	0%	0%	0%
76826	5	-	-	3	-	-	0%	0%	60%	0%	0%	0%	0%	0%	0%	0%
76827	31	-	-	6	-	-	0%	0%	19%	0%	0%	0%	0%	0%	0%	0%
76828	22	-	-	6	-	-	0%	0%	27%	0%	0%	0%	0%	0%	0%	0%
93303	293	249		253	-	-	85%	0%	86%	0%	0%	0%	0%	0%	0%	0%
93304	44		16	28	-	-	0%	36%	64%	0%	0%	0%	0%	0%	0%	0%
93307	369,139	357,750	669	349,376	11		97%	0%	95%	0%	0%	87%	94%	16%	93%	1%
93308	5,327	654	2,262	2,115	-	-	12%	42%	40%	0%	0%	1%	0%	53%	1%	0%
93312	10,997	6,469	292	7,423	-	-	59%	3%	68%	0%	0%	3%	2%	7%	2%	0%
93314	1,008	431	65	531	-	-	43%	6%	53%	0%	0%	0%	0%	2%	0%	0%
93315	102	58		61	-	-	57%	0%	60%	0%	0%	0%	0%	0%	0%	0%
93317	64	48	-	15	-	-	75%	0%	23%	0%	0%	0%	0%	0%	0%	0%
93350	24,492	8,861	716	9,796	-	-	36%	3%	40%	0%	0%	6%	2%	17%	3%	0%

Note: Totals reflect 5% sample data. Multiply by 20 to get estimated US totals. Data blanked if fewer than ten claims.

Attachment C

	CMS STAFF TYPE, MEDICAL SUPPLY, OR EQUIPMENT CODE			93880 Reference Duplex scan of extracranial arteries; complete bilateral study		93975 - Reference Duplex scan of arterial inflow and venous outflow of abdominal, pelvic, scrotal contents and/or retroperitoneal organs; complete study		TTE Total - Reference 93307 + 93320 + 93325		99307 - Reference Echocardiography, transthoracic, real-time with image documentation (2D) with or without M-mode recording; complete		93 Doppler echo pulsed w continuou spectral d separately l code echocard imaging);
LOCATION				**In Office**	**Out Office**	**In Office**	**Out Office**	**In Office**	**Out Office**	**In Office**	**Out Office**	**In Office**
GLOBAL PERIOD				XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
TOTAL CLINICAL LABOR TIME	CS - 13004			82	0	108	0	93	0	59	0	21
PRE-SERVICE				3	0	3	0	3	0	3	0	0
Start: Following visit when decision for surgery or procedure made												
Other Clinical Activity (please specify) Review prior echo studies*				3		3		3		3		
End: When patient enters office for surgery/procedure												
SERVICE PERIOD				71	0	97	0	84	0	50	0	21
Start: When patient enters office for surgery/procedure												
Pre-service services												
Review charts												
Greet patient and provide gowning				3		3		3		3		
Obtain vital signs				3		3		3		3		
Provide pre-service education/obtain consent												
Prepare room, equipment, supplies				3		3		3		3		
Prepare and position patient/ monitor patient/ set up IV (incl. attach electrodes)				3		3		3		3		
Document clinical elements (" patient history")*				1		1		1		1		
Sedate/apply anesthesia												
Intra-service												
Assist physician in performing procedure (acquire ultrasound data)*				42		67		52		25		16
Process data, measure, record preliminary findings				10		9		13		6		5
Post-Service												
Monitor pt. following service/check tubes, monitors, drains												
Clean room/equipment by physician staff				3		3		3		3		
Complete diagnostic forms, lab & X-ray requisitions												
Review/read X-ray, lab, and pathology reports												
Check dressings & wound/ home care instructions /coordinate office visits /prescriptions												
Other Clinical Activity (please specify) Patient education, instruction, counseling*				3		5		3		3		
End: Patient leaves office												
POST-SERVICE Period				8	0	8	0	6	0	6	0	0
Start: Patient leaves office												
Conduct phone calls/call in prescriptions (Communication with ordering physician/ patient/ family)*				4		4		2		2		
Total Office Visit Time												
Conduct phone calls between office visits												
Other Activity (please specify) (QA documentation required for accreditation)*				4		4		4		4		
End: with last office visit before end of global period												
MEDICAL SUPPLIES	**Code**	**Unit**	**Unit Cost**									
patient gown, disposable	11107	item	$ 0.570	1		1		1		1		
exam table paper	11111	foot	$ 0.015	7		7		7		7		
pillow case, disposable	11112	item	$ 0.320	1		1		1		1		
paper towel	11118	item	$ 0.010	1		1		5		5		
drape, sheet	11106	item	$ 0.260	1		1		1		1		
patient ed. booklet (50% of the time)	11140	item	$ 0.460	1		1		1		1		
gloves, non-sterile	11302	pair	$ 0.120	1		1		1		1		
Transducer wipe (echo ultrasound)	11520	wipe	$ 0.094	2		2		3		3		
aquasonic gel	71001	10 ml	$ 0.270	60		60		6		6		
film, 14x17	73402	sheet	$ 2.800	2		2						
tape, VHS	73408	item	$ 3.000	1		1		0.200		0.200		
recording paper	73414	sheet	$ 0.150	0		0						
film, 8x10 color	73403	item	$ 0.850	3		3						
Enviroside Cleanser	52302	10 ml	$ 0.340	1		1		1		1		
ECG electrodes	71006	item	$ 0.080					3		3		
pillow case, disposable	11112	item	$ 0.320					1		1		
drape, sheet	11106	item	$ 0.260					1		1		
pt education booklet	11115	item	$ 0.920					1		1		
PROCEDURE SPECIFIC EQUIPMENT												
Vascular Lab Room (=Ultrasound Room) Prices to be updated	E52018		$ 272.000									
Stretcher	E11002		$2,664					84		50		21
Computer	E52003		$2,800									
Processor	E51080											
Viewbox, 2 panes	E51001											
Sony Video Color Printer	E52010							84		50		21
SVHS Video Recorder	E53012							84		50		21
Computer	E52003		$ 2,800									
Processor	E51080		$ 55,100									
Viewbox, 2 panes	E51001		$ 909									
Sony Video Color Printer	E52010		$ 10,500					84		50		21
Review Station:AG7300SVHS 17 in. (VCR)	E52013		$ 900					84		50		21
Digital Acquisition unit (Nova Microsonics Image Vue DCR or ...)	E52007		$ 29,900					84		50		21
Sony Color Monitor	7		7					84		50		21

	CMS STAFF TYPE, MEDICAL SUPPLY, OR EQUIPMENT CODE			120 cardiography, ve and/or wave with splay (List addition to s for lographic complete	93325 Doppler echocardiography, color flow velocity mapping (List separately in addition to codes for echocardiography)		93308 Echocardiography, transthoracic, real-time with image documentation (2D) with or without M-mode recording; follow up or limited study		93321 Doppler echocardiography, pulsed wave and/or continuous wave with spectral display (List separately in addition to codes for echocardiographic imaging); follow-up or limited study (List separately in addition to codes for	
LOCATION				Out Office	In Office	Out Office	In Office	Out Office	In Office	Out Office
GLOBAL PERIOD				XXX	XXX	XXX	XXX	XXX	XXX	XXX
TOTAL CLINICAL LABOR TIME	CS - 13004			0	13	0	44	0	11	0
PRE-SERVICE				0	0	0	3	0	0	0
Start: Following visit when decision for surgery or procedure made										
Other Clinical Activity (please specify) Review prior echo studies*							3			
End: When patient enters office for surgery/procedure										
SERVICE PERIOD				0	13	0	35	0	11	0
Start: When patient enters office for surgery/procedure										
Pre-service services										
Review charts										
Greet patient and provide gowning							3			
Obtain vital signs							3			
Provide pre-service education/obtain consent										
Prepare room, equipment, supplies							3			
Prepare and position patient/ monitor patient/ set up IV (incl. attach electrodes)							3			
Document clinical elements (" patient history")*							1			
Sedate/apply anesthesia										
Intra-service										
Assist physician in performing procedure (acquire ultrasound data)*					11		13		8	
Process data, measure, record preliminary findings					2		3		3	
Post-Service										
Monitor pt. following service/check tubes, monitors, drains										
Clean room/equipment by physician staff							3			
Complete diagnostic forms, lab & X-ray requisitions										
Review/read X-ray, lab, and pathology reports										
Check dressings & wound/ home care instructions /coordinate office visits /prescriptions										
Other Clinical Activity (please specify) Patient education, instruction, counseling*							3			
End: Patient leaves office										
POST-SERVICE Period				0	0	0	6	0	0	0
Start: Patient leaves office										
Conduct phone calls/call in prescriptions (Communication with ordering physician/ patient/ family)*							2			
Total Office Visit Time										
Conduct phone calls between office visits										
Other Activity (please specify) (QA documentation required for accreditation)*							4			
End: with last office visit before end of global period										
MEDICAL SUPPLIES	**Code**	**Unit**	**Unit Cost**							
patient gown, disposable	11107	item	$ 0.570				1			
exam table paper	11111	foot	$ 0.015				7			
pillow case, disposable	11112	item	$ 0.320				1			
paper towel	11118	item	$ 0.010				5			
drape, sheet	11106	item	$ 0.260				1			
patient ed. booklet (50% of the time)	11140	item	$ 0.460				1			
gloves, non-sterile	11302	pair	$ 0.120				1			
Transducer wipe (echo ultrasound)	11520	wipe	$ 0.094				3			
aquasonic gel	71001	10 ml	$ 0.270				3			
film, 14x17	73402	sheet	$ 2.800				0.200			
tape, VHS	73408	item	$ 3.000							
recording paper	73414	sheet	$ 0.150							
film, 8x10 color	73403	item	$ 0.850							
Enviroside Cleanser	52302	10 ml	$ 0.340				1			
ECG electrodes	71006	item	$ 0.080				3			
pillow case, disposable	11112	item	$ 0.320				1			
drape, sheet	11106	item	$ 0.260				1			
pt education booklet	11115	item	$ 0.920				1			
PROCEDURE SPECIFIC EQUIPMENT										
Vascular Lab Room (=Ultrasound Room) Prices to be updated	E52018		$ 272,000							
Stretcher	E11002		$2,664		13		35		11	
Computer	E52003		$2,800							
Processor	E51080									
Viewbox, 2 panes	E51001									
Sony Video Color Printer	E52010				13		35		11	
SVHS Video Recorder	E53012				13		35		11	
Computer	E52003		$ 2,800							
Processor	E51080		$ 55,100							
Viewbox, 2 panes	E51001		$ 909							
Sony Video Color Printer	E52010		$ 10,500		13		35		11	
Review Station:AG7300SVHS 17 in. (VCR)	E52013		$ 900		13		35		11	
Digital Acquisition unit (Nova Microsonics Image Vue DCR or ...)	E52007		$ 29,900		13		35			
Sony Color Monitor	?		?		13		35		11	

79-1

CMS- Department of Health and Human Services
Attention: CMS-1385-P
PO Box 8018
Baltimore, Maryland 21244-8018

Re: "TECHNICAL CORRECTIONS"

The proposed rule dated July 12th contained an item under the technical corrections section calling for the current regulation that permits a beneficiary to be reimbursed by Medicare for an X-ray taken by a MD or DO and used by a Doctor of Chiropractic to determine a subluxation, be eliminated. I am writing in strong opposition to this proposal.

The costs for patient care will go up significantly due to the necessity of a referral to another provider (orthopedist or rheumatologist, etc.) for duplicative evaluation prior to referral to the radiologist. As it is now, these duplicative services and expenses are not required. With fixed incomes and limited resources, I may choose to forgo X-rays and thus needed treatment. If treatment is delayed illnesses that could be life threatening may not be discovered. Simply put, it is the patients that will suffer as a result of this proposal.

I strongly urge you to table this proposal. These X-rays, if needed, are integral to the overall treatment plan of a Medicare patient like me. It is ultimately the patients that will suffer should this proposal become standing regulation.

Sincerely,

Adwina Jarvis
(Signature)

ADWINA JARVIS
(Printed Name)

P.O. Box 84-328-GREEN MEADOW DR.
(Street Address)

WAUTOMA, WI 54982
(City, State, Zip)

August 13, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Att: CMS-1385-P
P.O. Box XXXX
Baltimore, MD 21244-XXXX

Re: CMS 1385-P: 2008 Medicare Fee Schedule
Coding – Multiple Procedure Payment Reduction for Mohs Surgery

Dear Sirs;

As Chairman of the American Academy of Dermatology's Health Care Finance Committee and Senior RUC advisor for Dermatology, I would like to comment on section II.E.2 (P-122) of the 2008 Medicare Fee Schedule Proposed Rule. I would like to point out one passage in particular. (Bold italics are mine).

Section II.E.2 (P-122) proposes that:

> ***Because the RVUs for these services do not take into account the efficiencies that occur when multiple procedures are performed in one session, we do not believe that these codes should continue to be exempt from the multiple procedure payment reduction***. Therefore, we are proposing to eliminate the modifier -51 exemption and apply the multiple procedure payment reduction rules to these codes."

I understand the RUC recommended that the Mohs codes multiple procedure payment reduction rule exemption be removed based on the concern that there was overlapping work when multiple tumors were treated the same day. This is consistent with your rationale.

However, the American Academy of Dermatology has recently conducted research from the CMS Part B Extract and Summary System (BESS) database, which demonstrates that only 10% of the time are multiple Mohs surgeries performed at the same operative session. This information was not available at the time of the RUC meeting.

I believe that application of the multiple procedure reduction rule (MPRR) is too draconian a correction measure. The multiple procedure reduction rule not only cuts additional Mohs surgeries done at the same operative session by 50% but also cuts the original Mohs surgery first stage or the repair 50% even if a repair is done at a ***separate operative session later on the same***

day. Such a reduction on a repair done at a separate session is not consistent with the CMS rationale provided.

As CMS is aware, 80% of the physician work time in the Mohs procedure codes is intraservice time. This allows for little or no efficiency gains when surgically addressing multiple cancerous lesion sites. There is no overlapping intra operative work and there are no redundant post operative visits since the Mohs stage one codes (CPT 17311 and 17313) have zero day global periods.

In addition, the practice expense RVUs for performing Mohs surgery is over half of the total RVU value, since each of these surgeries includes a pathology component and are performed in a physician's office not in a hospital or ASC. Cutting reimbursement of the code in half with application of the multiple procedure reduction rule results in actual loss of either the surgical component or the pathology component RVUs for the Mohs surgeon operating on more than one lesion site.

May I suggest that a more reasonable reduction for Mohs performed on more than one lesion site done at the same operative session on the same patient would be, at most, a 20% reduction on the additional Mohs base procedure for these sites and no reduction on the first repair. Additional repairs would be subject to the multiple procedure reduction rule as they are now.

Unfortunately, there is currently no AMA CPT modifier that would accurately identify this, so a 2% adjustment to the Mohs procedure base code physician work RVUs, (20% percent correction for multiple Mohs sites which occurs 10% of the time) with reinstatement of the multiple procedure reduction rule exemption might be a solution.

Many Mohs patients with multiple tumors are also organ transplant patients with a higher risk of metastatic disease. Certainly, it is not fair for these patients to have the treatment of their tumors delayed because of Medicare payment policy, but neither is it fair to insist that the Mohs surgeon be forced to remove these tumors at a loss.

The Mohs codes are unique since they are performed at separate operative sessions for each lesion being removed and for each subsequent stage of that lesion's removal. These cases are long and tedious. In current practice, tired patients are sometimes sent home to resume surgery the next day.

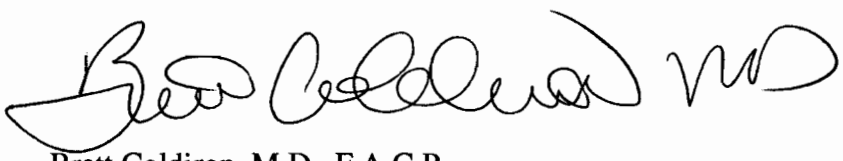
A Mohs surgeon might reasonably start sending more patients home at the end of the day instead of staying late to accomplish a wound reconstruction in the office. Alternatively, the patient could be sent to a plastic or reconstructive surgeon who will repair the wound in the hospital or ambulatory surgery center at much greater cost to CMS than the Mohs surgeon's office setting.

With the application of multiple procedure reduction rule, the Mohs surgeon will be performing a same day repair for about what it costs him in overhead, that is, for free.

Thus, I sincerely believe that CMS application of the multiple procedure reduction rule to the staged Mohs procedures are unlikely to result in significant savings but will result in significant disruption of care with attendant negative patient feedback.

I feel a reasonable compromise can be reached by pursuing additional discussions with the appropriate specialty societies on this complicated and contentious issue.

Sincerely,



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513-221-2828
bcoldiron@gmail.com

81-1

Babu V Surya, M.D.
Certified, American Board of Urology

August 13, 2007

Centers For Medicare and Medicaid Services
Dept of Health and Human Services
Attention: CMS-1385-P
PO Box 8018
Baltimore, MD 21244-8018

RE: PHYSICIAN SELF-REFERRAL PROVISIONS

Dear Sir or Madam,

I am writing to express my concerns regarding certain proposals in the recently released 2008 Proposed Physician Fee Schedule. As a physician practicing in Aberdeen, NJ , I fear that several of the proposed changes to the physician self-referral rules will needlessly and unjustifiably harm Medicare patients and providers. Although I understand and support the efforts by CMS to prevent abusive practices, I believe the current proposals will extend beyond this worthy goal to hamper valuable and legitimate joint venture arrangements. I believe that CMS could address its concerns in a much less intrusive manner.

As a urologist, I have seen firsthand the beneficial effects that joint ventures have had for the healthcare system. I have been involved with providing my patients lithotripsy and other cutting edge therapies for urological disease that would not have been widely available to my patients, including Medicare beneficiaries, unless physician joint ventures had provided the services. By accepting the risk of providing these costly services when hospitals refused to do so, urology joint ventures have greatly expanded patient access to worthwhile and effective treatments. Yet the proposals in your 2008 Physician Professional Fee Schedule attack the substance of the very joint ventures that by all accounts have saved Medicare millions of dollars and increased beneficiary access to effective treatments.

I will discuss below the various anti-physician ownership proposals that I believe will have a negative effect on the healthcare system, if adopted, in the order in which they were presented in the proposed rule.

1. Burden of Proof

CMS proposes that a provider should bear the burden of proving that referrals were not made in violation of Stark in any appeal of a denial of payment on this basis. This appears to me to require providers to prove a negative (that a prohibited arrangement leading to a referral did not exist), which would be difficult if not impossible to accomplish. Complicating matters is that most Stark exceptions require payments to be

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made at fair market value and in a manner that does not reflect the volume or value of referrals or other business between the parties. Valuation experts often disagree on what is fair market value and I am unable to think of an efficient and effective method of proving that a payment does not reflect the volume or value of referrals.

This proposal will mean that CMS or its contractors will sit as judge and jury over complex matters in which experts themselves may have varying opinions – with the burden of proof on the provider. If a better example of abuse of power can be shown, I would like to see it. Not only do I take care of the health problems of my Medicare beneficiary patients at a price set arbitrarily by CMS, I now face the burden of a hidden tax in which I must prove my actions were legal, rather than the governmental agency which writes the law proving that my actions were illegal.

2. Per Click Payments

As I understand, it was the intent of Congress, as recognized by CMS in its Phase I rulemaking, to permit time-based or unit-of-service-based payments for space and equipment leases. The proposal to prohibit these arrangements, therefore, directly contradicts Congressional intent. CMS should not prohibit an arrangement that Congress expressly intended to permit.

Moreover, CMS indicates that it is concerned with per click lease arrangements involving designated health services (DHS). Yet the proposed rule suggests that the prohibition will be applied to all lease arrangements in which physicians have ownership in the service, not only those involving DHS. Although I am unconvinced that per click arrangements are, by definition, abusive, at the very least the ban should not apply to services that are not DHS (and, if provided in a hospital, to those services that would not be DHS if provided in another setting).

Hospitals are generally unwilling to take risks and are often operating on razor-thin margins. They are averse to bearing the risk of low volume usage for new and innovative technologies and services. When physician joint ventures bring these beneficial technologies to hospitals, the hospitals may require per click arrangements to protect themselves from the risk of low volume. The physicians who invest in these joint ventures, however, are willing to take the risk of failure. Thus, per click arrangements are essential to bringing new, improved treatments to many places in America, by allowing cash-strapped hospitals to pay risk taking joint ventures to bring new treatments and technologies to them, without the hospitals having any financial risk for less than projected use or adoption. By banning per click lease arrangements, CMS may inadvertently preclude beneficiary access to innovative treatments.

Further, per click arrangements are vital to the provision of certain services such as lithotripsy. Not infrequently, patients scheduled for lithotripsy services will require unexpected additional or separate services. These services may include insertion or removal of a stent; ureteroscopy; or cystoscopy. The hospital and the company that provides the service are unable to determine in advance how often a procedure will be

needed or which procedures will be required. Per click fees are the most accurate and fair way to determine compensation.

3. "Set in Advance" and Percentage-Based Fee Arrangements

I also believe that percentage-based compensation arrangements enable new treatments and technologies to be offered to more beneficiaries and are not, inherently, abusive, as CMS seems to believe. Like per click arrangements, percentage-based arrangements allow the apportionment of the risk of low or no volume for new or costly therapeutic modalities. It is unclear to me why a person or entity that brings a service to a hospital should not be compensated in proportion to the payments. Such arrangements may, in fact, more accurately reflect the value of the efforts provided by the entities than would a flat fee arrangement. I believe it would be unwise for CMS to adopt a blanket prohibition of percentage-based fee arrangements, which may result in unintended consequences.

4. Stand in the Shoes

Medicare reimbursement for ambulatory surgical centers (ASCs) is lower than for hospitals, causing CMS to, I believe, encourage more procedures to be performed in ASCs. Many ASCs, however, are owned or controlled partially or entirely by a local hospital. If a referral to one of these ASCs is viewed by CMS as a referral to the hospital, it will become impossible for legitimate physician joint ventures to provide services at those ASCs. The likely result would be for physicians to withdraw from hospital-owned ASCs and build additional ASCs to provide services to their patients, with the attendant costs and very likely the demise of the efficiencies of the current methodology.

5. Services Furnished Under Arrangements

The goal of the proposed changes to the Stark regulations regarding services furnished under arrangements is, it appears, to prohibit physician joint ventures from contracting with hospitals to provide diagnostic DHS. Unfortunately, the proposals are so broad that they would ban legitimate, non-abusive arrangements for therapeutic services that are not otherwise DHS except for the fact that they are performed in a hospital setting. The therapeutic services that will be affected include (from a urology perspective) a variety of laser procedures for benign prostate disease and cryotherapy for cancer of the prostate. Based on the commentary in the proposed rule, CMS seems to view that physicians who invest in these joint ventures do so at the expense of good patient care. My experience is quite the opposite. I believe that, at least for the urological joint ventures, the primary purpose of physician investment is to improve patient care.

New technologies and innovations to prior technologies are constantly being introduced into the healthcare system. Maintaining the most current, state of the art technologies, such as the new laser for the treatment of benign prostate disease, is expensive. Hospitals are reluctant to undertake the expense and the risk that today's

"best" technology will be obsolete tomorrow. Urology joint ventures, on the other hand, are willing and have undertaken that risk. Lithotripsy is a useful illustration of this dynamic. In the mid-1980s, hospitals refused to purchase lithotripters because they did not want to make a large capital expenditure and lose an existing revenue source (invasive surgical procedures to remove kidney and ureteral stones that were too large for a patient to pass naturally). Physicians, wanting a better treatment for their patients, formed joint ventures to buy lithotripters and were fought at every turn by the hospitals. This refusal by hospitals to undertake the risk of innovative and effective new technologies continues. Physicians want to have new technology available for their patients in order to provide the best patient care.

In addition, a single hospital often does not have enough volume to justify the expense of purchasing certain technology. Physicians who want to have up-to-date treatment for their patients are willing to invest in a joint venture with other physicians practicing at other hospitals to purchase the technology. This way usage can be spread among several hospitals on a rotating basis. The healthcare system, including CMS, benefits from these arrangements because otherwise unavailable technology is brought to both urban and rural settings, and the cost is spread among several providers, reducing overall capital costs.

As the court in ALS v. Thompson noted, extracorporeal shockwave lithotripsy is not a DHS even though it is provided under arrangement with a hospital. It would be highly beneficial to patients and providers if CMS also exempted procedures that are not otherwise DHS from the proposed prohibitions to under arrangements.

Finally, it appears to me that the reason CMS wants to ban services under arrangements where there is physician ownership is because it has heard of questionable diagnostic imaging arrangements. CMS does not identify any overuse or improper referrals for therapeutic services such as laser services and other urological procedures. Simple fairness would dictate that under arrangements should not be prohibited for services that would not otherwise be DHS but for being furnished in a hospital.

The incentive to overutilize present in diagnostic imaging services is not present for most other services furnished under arrangements where the referring physician also performs the professional portion of the referred procedure. Where urologists perform therapeutic procedures, the referring physician receives a professional fee and the professional fee is greater than the distributions for any particular referred procedure that the physician will earn from his investment interest in the joint venture. The portion of the technical fee that he will earn in distributions from his investment in the venture is not likely to create an inducement to refer for the procedure. CMS should not prohibit services under arrangements where the investor physician performs the professional portion of the procedure.

In conclusion, I ask CMS to separate those beneficial therapeutic joint ventures which are not of themselves DHS from the abusive and questionable diagnostic ventures that physicians and hospitals may have propagated. Without a doubt, it should be clear to

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Babu V Surya, M.D.
Certified, American Board of Urology

CMS that the urology community's therapeutic joint ventures have broadened access to new technology for Medicare patients, brought needed efficiency to the market, and simultaneously saved CMS hundreds of millions of dollars. As CMS tries to stop abusive arrangements, it would be a great mistake to jeopardize such time tested and proven models.

Sincerely,

Babu V Surya MD

Babu V. Surya, M.D.
301 Church Street,
Aberdeen, NJ 07747

August 14, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
P. O. Box 8013
Baltimore, Maryland 21244-8018

Re: Technical Corrections

The proposed ruled change dated 7/12/07 called for the elimination of the reimbursement to a beneficiary for an x-ray taken by a non-treating provider and used by a chiropractic physician to determine the presence of a subluxation will be an additional financial burden for the Medicare patient. With this rule change, Medicare patients with limited resources may choose to forego spinal x-ray examinations that would severely limit the chiropractic doctor in determining the presence of a subluxation and any other concerns in determining a diagnosis, treatment options, or referral to another provider. It is already incomprehensible that a Medicare patient cannot be reimbursed when a Doctor of Chiropractic performs the often necessary x-ray examination.

This type of "technical correction" appears to be just another impediment for a Medicare patient to obtain competent care from a chiropractic physician. I urge you to table this proposed change.

Sincerely,

James A. Mertz, D.C.
A Medicare Patient and Provider
3101 Camino de La Sierra, NE
Albuquerque, NM 87111

>>>>
>>>>Dear Administrator Kuhn:
>>>>
>>>>Thank you for the opportunity to submit comments on the Physician
>>>>Self-Referral Provisions of CMS-1385-P entitled "Medicare Program;
>>>>Proposed Revisions to Payment Policies Under the Physician Fee
>>>>Schedule for Calendar Year 2008." I am a board-certified pathologist
>>>>and a member of the College of American Pathologists. I practice in
>>>>[include city, state of your primary practice area] as part of
>>>>[include a description of your pathology practice, whether you are a
>>>>solo practitioner or part of a 5-member pathology group and whether
>>>>you operate an independent laboratory or practice in a hospital or
>>>>other setting.]
>>>>
>>>>I applaud CMS for undertaking this important initiative to end
>>>>self-referral abuses in the billing and payment for pathology
>>>>services. I am aware of arrangements in my practice area that give
>>>>physician groups a share of the revenues from the pathology services
>>>>ordered and performed for the group's patients. I believe these
>>>>arrangements are an abuse of the Stark law prohibition against
>>>>physician self-referrals and I support revisions to close the
>>>>loopholes that allow physicians to profit from pathology services.
>>>>
>>>>Specifically I support the expansion of the anti-markup rule to
>>>>purchased pathology interpretations and the exclusion of anatomic
>>>>pathology from the in-office ancillary services exception to
>>the Stark
>>>>law. These revisions to the Medicare reassignment rule and physician
>>>>self-referral provisions are necessary to eliminate financial
>>>>self-interest in clinical decision-making. I believe that physicians
>>>>should not be able to profit from the provision of pathology
>>services
>>>>unless the physician is capable of personally performing or
>>supervising the service.
>>>>
>>>>Opponents to these proposed changes assert that their captive
>>>>pathology arrangements enhance patient care. I agree that
>>the Medicare
>>>>program should ensure that providers furnish care in the best
>>>>interests of their patients, and, restrictions on physician
>>>>self-referrals are an imperative program safeguard to ensure that
>>>>clinical decisions are determined solely on the basis of
>>quality. The
>>>>proposed changes do not impact the availability or delivery of
>>>>pathology services and are designed only to remove the financial
>>>>conflict of interest that compromises the integrity of the
>>Medicare program.
>>>>
>>>>Sincerely,
>>>>
>>>>
>>>>Gabriel Chamyan, M.D.
>>>>305 663 6841
>>>>
>>>>
>>
>>

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August 16, 2007

Center for Medicare & Medicaid Services
Department of Health and Human Services
ATTN: CMS-1385-P
Mailstop: C4-26-05
Y500 Security Boulevard
Baltimore, MD 21244-1850

RE: Geographic Practice Cost Indices (GPCIs)

Dear Sirs:

I am writing to you in support of CMS's proposed reconfiguration to California's payment localities for the Medicare physician fee schedule. My understanding is that CMS is contemplating three possible options for reconfiguration of payment localities to better align physician reimbursement with actual practice input costs.

I am writing in support of CMS finally addressing this issue. I commend CMS for tackling what may admittedly be a politically controversial subject. It is imperative for CMS to quickly and definitively address the current reimbursement inequities that exist in California. As a community hospital serving approximately 160,000 individuals on the Monterey Peninsula, we have seen significant erosion in the number of physicians who are able to continue to see Medicare patients. We have seen the worst erosion among our primary care physicians, while specialty physicians continue to cross-subsidize their Medicare patients through commercial payors. Here on the Monterey Peninsula alone, we have a shortage of over 16 primary care physicians. When physicians retire, they are unable to recruit any replacement physicians to our area as a result of high practice expenses and disproportionately low Medicare reimbursement. It is particularly discouraging when physician candidates visit our area and learn that their CMS reimbursement will be 10-15% below that provided to their colleagues a mere 25 miles up the road in Santa Clara County. Certainly, I am sure that you are aware that the cost of living and genuine expenses associated with the practice of medicine are no less on the Monterey Peninsula than they are in San Jose.

On behalf of the 250 active medical staff members of Community Hospital of the Monterey Peninsula and our 2200 employees, I strongly request that Medicare enact either Option 1 or Option 2 for reconfiguring the GPCI payment system in California.

Thank you for your attention and assistance in this matter.

Sincerely,

Steven Packer, M.D.
President/CEO

SP/kcs

JONATHAN D. REICH, M.D.
PEDIATRIC CARDIOLOGY AND ADULT
CONGENITAL HEART DISEASE

August 13, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018
Re: File Code: CMS-1385-P,Coding-Additional Codes from 5 year review

Dear Sir or Madam:

Allow me to express my opposition to the bundling of CPT code 93325 into CPT codes 76825, 76826, 76827, 76828, 93303, 93304, 93307, 93308, 93312, 93314, 93315, 93317, 93320, 93321, and 93350.

First, the proper time frame was not allowed. The allowed time frame of 2 months for comments is abnormally brief, as these changes are usually addressed in multi-year processes. Furthermore, the changes are not reflective of changes in technology as well as the costs incurred by such changes. The responsibilities of diagnosis and treatment continue to expand, requiring increasing time in both diagnosis, decision making, and counseling. This increased demand would be contrary to a reduction in reimbursement.

The changes made in 1997 to the echocardiographic CPT codes were made in conjunction with the CPT panel of the American College of Cardiology. Specific effort was made to address the different services involed in assessing and performing echocardiography on infants and children with congenital anomalies. Further changes to the CPT code should address these issues as well.

The 93325 code (Doppler color flow mapping) is used differently in children than in adults. It is a distinct diagnostic tool especially in infants. Its need for a separate CPT code is critical.

Thank you for your attention to this matter.

Sincerely,

Jonathan D. Reich, M.D., M.Sc., FAAP, FACC
Pediatric Cardiology

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PHONE: 863-680-7316 • FAX: 863-680-7434

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

Thank you and your agency for addressing the marked undervaluation of anesthesia services. I am very pleased to learn of the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule.

The present undervaluation of 32% is imperiling the care of patients in areas with high Medicare populations, as it does not cover the cost of caring for these generally sicker and more complex patients. By enabling access to expert anesthesiology medical care via fair valuation of anesthesiology services, this patient population will certainly reap the benefits of high quality perioperative care.

It is extremely important that CMS follow through with the proposal to increase the anesthesia conversion factor as recommended by the RUC immediately and fully.

I appreciate your consideration of this vital matter.

Sincerely,

James T. Byland, MD
9535 Butler Dr.
Brentwood, TN 37027
byland@comcast.net

87

Submitter: Concerned Physician 7/12/2007

Organization: Private Practice

Category: Physician

Issue Area/Comments: **PHYSICIAN SELF-REFERRAL PROVISIONS CMS 1385-P**

Changes to Reassignment and Physician Self-Referral Rules Relating to Diagnostic Tests

Anti-Markup Rule

In-Office Ancillary Services (IOAS) Exemption

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

The **Anti-Markup Rules** may stop "condo" or "pod" lab proliferation, as well as the proliferation of Designated Health Services (DHS) imaging companies with the attendant inappropriate physician self-referrals and patient abuse that these schemes encourage. A liberal interpretation of the in-office ancillary services (IOAS) exemption, created the "turn-key" pathology or imaging solution. Faced with rising practice expenses coupled with diminishing practice reimbursement by Medicaid and third party payers, family physicians, internists, and others have sought additional revenue sources to maintain their incomes.

"Condo" labs are flourishing and diagnostic imaging is growing by 20% per year because of a liberal interpretation of the IOAS exemption that effectively allows any doctor to perform any test. Finalizing the proposed **Anti-Markup Rules** would be effective at ceasing some of these more abusive arrangements only if the **Anti-Markup Rule** applies **to all arrangements not involving a reassignment from a full time employee of the billing entity.** This must pertain to all arrangements, most importantly to the IOAS exemption. The **Rule** does not effect the IOAS exemption as it is written.

Clarifying and restating existing rules would accomplish a similar goal without the potential legal or political backlash of creating new rules. I will explain.

The portion of the document cited in **bold** are quotes from the **Federal Register** or other identified government sources. Normal font will be my narrative and my suggestions for diminishing over utilization.

The "in-office" exemption for self-referral was intended to allow physicians to bill and collect for services that are an extension of their care.

The **"Federal Register / Vol. 72, No. 133 / Thursday, July 12, 2007"** states
At the time of enactment, a typical in-office ancillary services arrangement might have involved a clinical laboratory owned by physicians located on one floor of a small medical office building. Under such an arrangement, a staff member would take a urine or blood sample to the clinical laboratory, create a slide, perform the test, and obtain the results for the physician while the patient waited. However, services furnished today purportedly under the in-office ancillary services exception are often not as closely connected to the physician practice.

In the above example, the physician ordering the urinalysis is qualified to perform the test, interpret the findings as well as treat any abnormal results. This improves the quality of medical care and improves convenience for the Medicare patient. However, as the rules are presently being interpreted, physicians are performing a large number of tests in their offices that they are not qualified to perform, interpret, or to treat the abnormal studies. Physicians are billing and collecting for these studies at fiscally unsustainable rates. For example, primary care physicians (PCPs) routinely perform DHS including ultrasound, echocardiography, and nuclear cardiology testing in their offices. To determine if these services should be allowed I will look back through the **Federal Register** to establish the definitions of several terms with which liberties have been taken.

1.) Do these studies fit the "incident-to a Physicians Professional Services" provision, if the physician is unable to interpret the study?

The Medicare Carriers Manual Section 2050 Part 3 Chapter 1-3 defines **Incident to Physician Professional Services**. The last revision was August 28, 2002 reads:

"Incident to a physician's professional service means that the service of supplies are furnished as an integral, although incidental , part of the physician's personal professional services in the course of diagnosis or treatment of an injury of illness."

So are these services truly **"ancillary"** to the physician's **"core" medical practice**?

Comments on the **Final Rule in the Federal Register vol. 66 page 885** define **"ancillary" and "core medical practice".**

The Congress sought to establish a nexus between the referring physician and the individual performing the ancillary service in order to limit the exception to services that are truly "ancillary" to the referring physician's medical practice. [The statute provides that] **physicians "in the group practice" may supervise the furnishing of ancillary services to patients of a referring physician who is a member of the group practice.** Independent contractors may be "in the group practice", but may not be

"members of the group practice". For referral of ancillary services, this distinction becomes crucial, since under **section 1877(b) (2) (A) (ii) (I) of the Act, services qualify for the in-office ancillary services exemption if they are furnished "in a building in which the referring physician (or another physician who is a member of the same group practice) furnishes services ...We believe the underlying intent is to allow physicians to furnish DHS that are ancillary to the physician's core medical practice in the locations where the core medical services are routinely delivered. ...Simply stated, the DHS should be ancillary to physician services that are not DHS, and not the other way around. The exception was intended as an accommodation to physician's customary practice of medicine and not as a loophole for physicians and group practices to operate DHS enterprises that are unconnected –or only marginally connected—to their medical practice.** As independent contractors are not "members" of the practice, their services do not count for the "Full range of services test". A referring physician should not be able to self-refer a study which neither he/she nor any "member" of the group is able to interpret, since an inability to interpret a study clearly identifies a study which is not core to that physicians' or group's medical practice.

A strongly worded clarification of "ancillary services", "members of a group", and "incident to" services must be composed. This statement should be completely drawn from language in previous final rules. The **Federal Register/Vol. 66, No. 3/Thursday, January 4, 2001 (pages 889-890)** states the following:

[1]**"We regard the building requirement of the in-office ancillary services exemption in combination with the supervision and billing requirements, as the Congress' attempt to circumscribe the exception so that it applies only to services provided within the referring physician's actual sphere of practice. Without these requirements, physicians could refer to, and profit form, almost any entity, with the claim that somehow the referred services are "in-office" services that are being supervised from some remote place...."**

[2]**"Because of the increased risk of abuse we do not intend to protect DHS provided by mobile vans or other mobile facilities under the in-office services exemption except in very limited circumstances described in section VI.B.3 of this preamble. Thus, we wish to make clear that for purposes of this rule, a "building" does not include exterior spaces such as courtyards and parking lots...."**

[3]**"In light of the changes we are making in the supervision standard, we believe it is necessary to revisit the building standards in order to limit the scope of the in-office services exemption to the services that are truly ancillary to physician services and are not the primary business of the practice. Thus, we are revising the "same building" requirements to more definitely tie in-office ancillary services to the referring physician's core medical practice. Simply stated, to ensure that services covered by the exception are, in fact, furnished "in office." Under section 1877(b)(2)(A)(ii)(I) of the Act, services qualify for the in-office exemption if they are furnished "in a building in which the referring physician (or another physician who is a member of the same group practice) furnishes physicians' services unrelated to**

the furnishing of DHS." We believe the underlying intent of this provision is to allow physicians to furnish DHS that are ancillary to physician's core medical practice in the location where the core medical practice occurs. We believe the Congress did not intend to permit the wholesale provision of DHS in locations in which physicians perform only token services unrelated to the furnishing of DHS. Thus we are interpreting the "same building requirements as follows:

[4] **The referring physician (who is a member of the same group practice) must furnish in the same building substantial physician services unrelated to the furnishing of DHS. In addition, we are requiring that the unrelated physician services furnished in the building represent substantially the full range of services unrelated to the furnishing of DHS that the physician routinely provides (or, in the case of a member of the group practice, the full range of physician services that the physician routinely provides for the group practice). Independent contractors are not members of a group practice for the purposes of compliance with the substantial physician services test under the "same building" requirements, unless they are the referring physician...."**

[5]**"For the purposes of this exception, we are defining the phrase "services unrelated to the furnishing of DHS" to mean physician services that are neither Federal nor private pay DHS, even if the services might generate orders or referrals of DHS. Thus, for example, a cardiologist who examines a patient and thereafter orders a diagnostic radiology test has performed a service unrelated to the furnishing of DHS. On the other hand, a cardiologist who reads the results of a diagnostic radiology test (such as, for example, a transthoracic echocardiography for congenital heart disease anomalies, CPT code 93303) (whether for a Federal or private pay patient) has performed a service that is related to the furnishing of DHS."**

[6]**"The DHS furnished in the building are furnished to patients whose primary nexus with the referring physicians is the receipt of physicians services unrelated to the furnishing of DHS."**

It is clear from the preceding discussion that Congress' intent was to make DHS services available and convenient to patients in their physicians' offices. However, Congress intent was to limit these services to those services core to a physician's actual "sphere of practice". The **Federal Register** provides an example of an acceptable and unacceptable DHS self-referral in paragraph 5. The acceptable DHS referral is appropriate if the physician (in the example given a cardiologist) possesses the skills and training to interpret the study. In other words, being properly trained to interpret the study makes it an appropriate DHS self-referral because it is core to the ordering physician's sphere of practice. However, merely ordering a test that the ordering physician does not interpret because it is not integral or core to the physician's sphere of practice makes this DHS referral inappropriate.

Paragraph 4 distinguishes between "members of the group" and "physicians in the group." The "members of the group" define the full range of services and the scope of service. The skill set of an independent contractor, who is a "physician in the group" does not count for purposes of compliance with the substantial services test, as the independent contractor is not a "members of the group."

Physicians who are performing diagnostic imaging services in their offices, and who do not have cardiologists or radiologists as "members" of their groups, are hiring interpreting specialists as independent contractors to prevaricate. However, these interpreting physicians, as independent contractors, are only claiming to be "physicians in the group" and as such their services do not quality for the exemption. These independent contractors read studies remotely and for the most part, never enter the physicians' office where the DHS is performed. Per **Sec 411.351 a "physician in the group practice" means a member of the group practice, as well as an independent contractor physician, during the time the independent contractor is furnishing patient care services to the group practice under a contractual arrangement with the group practice's patients in the group practice's facilities.** As the independent contractor usually does not enter the practice where the DHS occurs, the independent contractor is not meeting the definition of being a "physician in the group" since the independent contractor is not interpreting the DHS in the group practice's facility. Since the independent contractor is not a "member of the group" by the definition in **Section 411.351,** then his/her skill set or "sphere of practice" cannot be included in the "sphere of practice" of the group. Even if he was present at the practice site when he was interpreting (and then qualified as a "physician in the group"), his/her "sphere of practice" could not be included in the "sphere of practice" of the group, as the interpreting physician is not a "member of the group". The DHS should not be allowable under current Medicare rules.

The above-described transgression from the rules is facilitated by **Transmittal 111,** which is vaguely written. Its use in this case is contrary to its original intent. Physicians operating improper DHS facilities may cite its language as support. **Transmittal 111** reads, **"A carrier may make payment to an entity (i.e., a person, group , or facility) enrolled in the Medicare Program that submits claims for services provided by a physician or other person under a contractual arrangement with that entity, regardless of where the service is furnished. Thus, the service may be furnished on or off the premises of the entity submitting the bill."** It is not stated that **Transmittal 111** supersedes the requirements of the self-referral law, the definitions of "physician in the group" or "member of the group", or "incident to" referral as set out in **Section 411.351,** and in particular the "in-office ancillary service" exemption.

Nonetheless, as the rule is presently being interpreted throughout the United States, PCPs are performing a large number of ultrasounds, echocardiograms, and nuclear cardiac tests in their offices that they are not qualified to interpret. They are billing and collecting for these studies using **Medicare Claims Processing Manual Rule 30.2.9.1-Payment to Supplier of Diagnostic Tests for Purchased Interpretations** to obtain interpretations purchased through an independent contractor.

However, there is no section of **Rule 30.2.9.1** which states that the services rendered do not need to meet the requirement of being "ancillary" meaning that the service is "core" to the physician group's medical sphere of practice. Moreover, if an independent contractor skill set were allowed to contribute to the hiring medical group's "sphere of practice", then the group could engage in practices that would be "all encompassing" if the appropriate mix of independent contractors were hired.

Quoting the **Federal Register / Vol. 66, No. 3 / Thursday, January 4, 2001 (page 889), "We regard the building requirement of the in-office ancillary services exemption, in combination with the supervision and billing requirements, as the Congress's attempt to circumscribe the exception so that it applies only to services provided within the referring physician's actual sphere of practice. Without these requirements, physicians could refer to, and profit from, almost any entity, with the claim that somehow the referred services are "in-office" services that are being supervised from some remote place."**

Certainly, this scenario was not Congress' intent and should not be allowed. Simply put, a referring physician should not be able to self-refer a study which no "member" of their group is able to interpret, since the inability to interpret a study clearly identifies a study which is not "core" to that physician's or that physician's group "sphere of practice". Explicit clarification—along with publicizing that clarification—would greatly reduce the high rate of inappropriate self-referrals for diagnostic imaging tests and pathology specimens. Most physicians participating in these arrangements do so with the reassurance of legal counsel from imaging companies. Most are ignorant of the specifics of the intricacies of medical law.

Such a clarification of the definition of the appropriate use of the IOAS exemption would immediately curtail the use of "condo" labs and the proliferation of diagnostic imaging schemes. The clarification would require no new rules as the verbiage above is already in the **Federal Register** and part of prior rules. The **Anti-Markup Rule** would be impotent if the joint ventures with "Condo" labs and imaging companies were exempted due to incorrect usage of the IOAS exemption. Crafty imaging companies often will set up weekly or bi-weekly service calls on a specified yearlong contract in order to obfuscate the anti-kickback rules and Stark Law by seeming to comply with the IOAS exemption. (See Attachment 1: An Overview of Current Diagnostic Imaging Abuses). On the other hand, if the **Rule** applied to **all arrangements** including lease arrangements billed under "in-office ancillary services", it would be potent indeed. There is no greater manner to obtain the attention of participants in a joint venture than to deny them payment!

Submitter: Physician

Organization: Private Practice

Category: Physician

Issue Area/Comments: **PHYSICIAN SELF-REFERRAL PROVISIONS CMS 1385-P**

Changes to Reassignment and Physician Self-Referral Rules Relating to Diagnostic Tests

In-Office Ancillary Services Exemption

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

I shall now comment on questions from the **Federal Register / Vol. 72, No. 133 / Thursday, July 12, 2007, page 38181.**

(1) Whether certain services should not qualify for the exception (for example, any therapy services that are not provided on an incident to basis, and services that are not needed at the time of the office visit in order to assist the physician in his or her diagnosis or plan of treatment, or complex laboratory services);

As explained above (see my comments on the **Anti-Markup Rule**), any services which are not "core" to or "integral to" a physicians' practice should not be allowed to be billed as an "incident-to" service. The **Anti-Markup Rule** would effectively end the practice of non "core" services from being billed, as few compliant practices would have a full time employee to satisfy the requirements. The calculation of the "net" charge would be problematic in many ventures, as the contracted services are for one year in duration to try to satisfy the anti-kickback and Stark exemptions. Of course, this would only be effective if the **Anti-Markup Rule** applied to the IOAS exemption (which it presently does not.)

(2) whether and, if so, how we should make changes to our definitions of same building and centralized building;

I believe a change in the "centralized" building exemption would be unnecessary if the **Anti-Markup Rule** applies to the IOAS exemption.

If the **Anti-Markup Rule** does not apply to IOAS, then the definition of centralized building should be "the place where the diagnostic testing is both performed and interpreted and at the same location where the practice physicians also treat patients for their medical conditions". I recommend that for a physician or medical group to bill the TC or PC of a diagnostic test, the physician or medical group must interpret the study within the same building that the test was performed and use the same group billing number for the TC and PC. This would more strictly define premises and make it much more likely that the interpreting physician has a relationship with and direct access to the Medicare patient receiving outpatient diagnostic testing.

(3) whether non-specialist physicians should be able to use the exception to refer patients for specialized services involving the use of equipment owned by the non-specialists;

The IOAS exemption once again should be used as it was intended. It should be permitted only for services that are "core" to a physicians' practice. One obvious test is if the referring physician bills the PC of the test. If the physician or practice routinely uses the **Purchase Interpretation Rule, 30.2.9.1,** there is evidence that the service is not "core" to the physicians' practice. It should be disallowed.

Notably, this test would allow services such as teleradiology "Nighthawk" services, because a radiology practice would not be referring out substantially all of its radiology interpretation. Instead, the purchased interpretations would be a minority. A cut off of 75% of services could be used. I f greater than 25% of the interpretations are obtained through **30.2.9.1** then one could assume that these services are not "core" to the physicians' practice. Allowing a "cut-off" would also allow a provision for "over-reads".

(4) any other restrictions on the ownership or investment in services that would curtail program or patient abuse.

A) **§ 414.50 Physician billing for purchased diagnostic tests.** If this rule pertains to in-office ancillary services, this too would be an effective deterrent to abusive imaging joint ventures and "condo" labs, and should be implemented.

B) Medicare should require direct supervision of patients by the interpreting doctor (or a similarly qualified member of the same group) who is on the premises (i.e. within the building) at the time of testing; A "supervising physician" should be a physician with the expertise in an imaging modality to indeed supervise the mid-level provider (MLP), that is to, improve the quality of the studies of the MLP by providing feedback and critiquing his/her work. This would therefore require the "supervisor" to indeed be an expert in the field, someone who is able to interpret the study independently. He/she would have credentials from a nationally recognized board, which would have tested and acknowledged his/her expertise.

The loose interpretation of "general supervision" today allows any physician to "supervise" any procedure. A dermatologist could "supervise" a cardiac ultrasound, a procedure he/she may never have seen. He/she would then be able to bill Medicare using the "in-office ancillary services" exemption, having the interpreting physician being 100 or more miles away, and having never met the patient.

C) Medicare should mandate that only doctors who have completed qualified training at accredited program and who are board-certified or board-eligible in the designated specialty could bill the TC or PC for sonograms, echocardiograms, and nuclear cardiology testing. Qualified physicians for interpretation of sonograms are radiologists. Additionally, vascular surgeons and cardiologists who have completed vascular training programs are qualified to interpret carotid ultrasounds. Cardiologists are qualified to interpret echocardiograms. Radiologists, nuclear medicine physicians and cardiologists with nuclear licenses are qualified to interpret nuclear cardiology testing. This standard should go into effect on January 1, 2008. Medicare should explore limiting payment of the TC to certified laboratories with "permanent placement of the equipment used in the provision of substantially all of the designated health services" as proposed, and PC to doctors with expertise demonstrated by certification in echocardiography, nuclear cardiology, and vascular medicine as part of its pay for performance program.

D) Medicare should amend **Section 1842(b)(6) of the Social Security Act** to prohibit a physician from reassigning payment for Medicare covered services to any entity that provides diagnostic imaging services.

E) Medicare should explicitly define "**incident to**", "**ancillary services**" and "**supervising physician**". If general supervision is maintained as the standard for non-stress diagnostic testing services, and if the "incident to" physician lacks the expertise to interpret the test, and if the interpreting physician is not on site and has never met the patient to establish an "incident to" diagnostic procedure, then who is supervising the technician or Midlevel Provider (MLP)? If the interpreting physician is the "incident to" physician, are STARK laws violated because the interpreting physician has never met the patient establishing the required relationship needed to order the diagnostic study? If the technician is operating under the "supervision" of the ordering physician, who does not have the knowledge and qualifications to "supervise" the technician or MLP, how disingenuous is this? Rules need to be changed to explicitly state who may qualify as a "supervising physician" and which DHS services may be "ancillary" to a physician's practice.

F) CMS should reverse its 2002 Fee Schedule which liberalized the "incident to" rules so that ancillary personnel (the technologists, or MLP performing the diagnostic tests) no longer had to be a W-2 employee of the group billing for TC. Requiring the technologist or MLP performing the test to be a W-2 employee of the medical group billing the TC and/or PC will curb the proliferation of the for-profit imaging companies and "pod" labs.

Attachment 1

An Overview of Current Diagnostic Imaging Abuse

Recent articles in the New York Times *(Nerve test, A Moneymaker, Divides Doctors)* and the Wall Street Journal *(U.S. Seeks to More Tightly Restrict Doctors' Billing for Medical Tests)* have highlighted legal loopholes that have been exploited by healthcare companies and physicians using the "in-office ancillary services" exemption. The business models generated are the unintended consequences of how low reimbursement for physicians' evaluation and management skills motivates them to augment their revenues in non-traditional ways. I would like to provide you with an in depth look at how and why the "in office ancillary services" exemption for imaging technologies is presently being abused. These abusive imaging arrangements cost Medicare at least hundreds of millions of dollars annually in poorly performed or unnecessary tests, prompt the performance of further non-invasive diagnostic imaging tests, and sometimes potentially harmful invasive procedures.

The current Medicare rules, combined with the "perfect storm" of diminishing reimbursement for primary care physicians (PCPs) rapid improvements in digital imaging technologies, and aggressive marketing by imaging companies are currently causing tremendous over-utilization of diagnostic tests. The cost of imaging studies is one of the fastest growing health care services and accounts for 10-15% of health care payments. Imaging costs are growing at an annual average exceeding 20%.

In the face of rising practice expenses and diminishing practice reimbursement by Medicaid and third party payers, family physicians, internists, and others have sought additional revenue sources to maintain their incomes. Creating another "service line" by imaging patients seen in their offices is a lucrative, no-risk way to augment incomes. For years these PCPs have referred patients for diagnostic testing (ultrasonography, echocardiography, and nuclear cardiac testing) to hospitals or specialists' offices. PCP's billing and collecting the technical component (TC) and sometimes the professional component (PC) of diagnostic tests substantially increases their revenues.

For example, one recently hired internist's billings were lower than what his group expected and to remedy the situation, he began ordering more diagnostic tests to be performed by his practice. Current practices, if left unchecked, will cost Medicare hundreds of millions or even billions of dollars annually. Follow-up care of these suboptimal tests also exposes elderly patients to suboptimal studies and additional non-invasive testing or invasive procedures. The abusive testing occurs by one of two basic methods.

In a less common and more extreme scenario, a PCP will purchase used, old ultrasound or echocardiography equipment and then attend a two day CME course to learn how to

interpret studies (http://www.empiremedicaltraining.com/workshop_detail.cfm?dateID=99). It is noteworthy the courses target "Those looking to significantly increase their in-office earning potential". These courses are not a substitute for the years of training that a radiologist or cardiologist spends to learn to interpret studies.

Medicare does not have written requirements demanding that a doctor be board certified in the field that he/she are interpreting, nor does Medicare demand that the equipment be modern. Untrained physicians using outdated equipment will be paid for performing the study at the same rate as an expert who performs the study at a first-rate, certified imaging center. In the most egregious examples that I have seen, the physician's interpretation is merely signing the technologist's report! This allows any physician to bill and collect for any Medicare patient. I have been asked where is the cheapest place to purchase imaging equipment by a primary care physician who is interested in entering this lucrative business.

In a very common scenario, an imaging company markets and recruits PCPs to provide them a "turn-key" imaging solution. The imaging company contracts with specialists to provide interpretation of imaging studies at a pre-set, heavily discounted reimbursement rate that the PCP pays the specialist. The imaging company hires technologists. They rent imaging equipment and motor vans to move the technologists and equipment to widely dispersed PCP offices throughout the state or region. Their contracts with PCPs to rent professional services are probably legal due to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108-173 Section 952. The Revisions to Reassignment Provisions "allows physicians to reassign payment for Medicare covered services to entities with which they have an independent contractor arrangement, such as a medical group, a physician management organization or staffing company." This rule has spawned a rapidly growing imaging industry (see www.mobilepui.com, www.cardiacimaging-sound.com/reasons.html, www.ultrascaninc.com, www.digirad.com).

In one variation of this insidious arrangement between the medical group and the imaging company, the medical group signs an annual leasing agreement with the imaging company to rent a $1/10^{th}$ or $1/5^{th}$ interest in imaging equipment and a technologist who becomes an independent contractor of the medical group. The group pays the imaging company about $500 for one-half day of service each week or about $1000 for a full day of service each week. The technologist will perform as many echocardiography and ultrasonography studies as possible in that allotted time. As part of the "turn key" approach, the group receives a printed interpretation of the study with the group's name on it interpreted by a specialist. Medicare patients are billed for the technical component by the medical group and the professional component is billed by the interpreting physician who will occasionally suggest that patients with abnormal studies be seen by them in consultation. Privately insured patients are billed globally by the medical group with the interpreting doctor compensated by the imaging company at a very low rate. The cunning imaging company, which recruited the PCPs and the interpreting specialists (who are "independently" hired by the primary care physician) and created the "turn-key" operation is not violating Medicare law as it never bills Medicare patients. Its revenues

are from the PCP customers. Without such companies the over utilization would be much less. These companies are providing a valued service to the PCPs; however, Medicare is paying for a large portion of the tab.

For an annual payment of $25,000 or $50,000 to the imaging company, the medical group receives four or eight hours of imaging time with the reports included in the price. The PCP must order 2 or 4 studies to pay for the contract and any additional studies represent profit. In this perverse but widespread practice, physicians are better paid to order studies than to treat patients. Incredibly, these PCPs would be financially penalized if they do not order enough studies to cover the extra expense of money owed to the imaging company! Ordering additional studies means more revenue and under current Medicare rules, the ordering doctor does not need to know how to interpret the study, how to judge if the equipment or study is technically adequate, or how to treat patients with abnormal studies. Faced with declining payments for the evaluation and management services that the PCP spent years acquiring, this deal is too good—and too legal—to pass up.

These arrangements are facilitated because of technological advancements with the digitalization of imaging equipment. Five to ten years ago, sonograms and echocardiograms were recorded onto video tape. The difficulty of transporting video tapes slowed the growth of the industry. Current machines allow for digital capturing of imaging and transmission to a server. The readers of the studies interpret the images and generate the reports by logging on the server, and thus the readers can be based in distant locations. Readers do not have the benefit of seeing the patients, obtaining medical histories, or reviewing prior studies before rendering their interpretations.

Nuclear cardiology is undergoing a similar rapid evolution into a "service line" for PCPs due to technological advances and outdated reimbursement rules. Until recently, nuclear cardiology testing required the purchase of an expensive gamma camera which weighed thousands of pounds and needed to be kept at a constant temperature. Therefore, leased arrangements for nuclear cardiology testing (exercise or pharmacological nuclear testing) were virtually non-existent. Technological advances have created mobile nuclear cameras that are easily transported from van to office thus qualifying for the "in-office ancillary service" exemption. Digitalized nuclear cardiac images can be read remotely by independent contractors utilizing the reassignment provision allowed by the Medicare Modernization Act of 2003. Aggressive marketing by "turn key" imaging companies showing small practices how to generate "greater revenues" at "no cost to your practice" is contributing to the rapid growth of outpatient nuclear cardiology services. Mobile nuclear testing is now being done in primary care physicians' offices, and expectedly there will be a great increase in the utilization of these studies. Digirad, a company manufacturing mobile nuclear imaging equipment and providing mobile ultrasound and mobile nuclear imaging services discussed their reliance of marketing studies to PCPs by imaging companies as being vital in their annual report.

Patients with an abnormal sonogram or echocardiogram performed by the PCP are referred to a specialist who must often repeat the study as the images that the written

report is made from are not available. The study is repeated with additional cost but without risk to the patient. Unfortunately, when a patient with an abnormal nuclear cardiology study is referred for evaluation, the very expensive test cannot be repeated and so the patient frequently undergoes invasive cardiac catheterization. Other problems with the treating specialist reviewing a test such as an echocardiogram or nuclear cardiology study done elsewhere and the test being unavailable include: not knowing the qualification of the readers, liability of not pursuing abnormal studies, not having access to accompanying diagnostic data, and the disconnection of the patient being told that a study is abnormal by one interpreting physician that he/she never meets and subsequently being told that a follow-up study is normal.

The problem has become so widespread that several private payers have begun addressing the problem. Highmark Blue Cross of Pennsylvania is not allowing some diagnostic testing to be performed in non-specialist offices. Highmark Blue Cross, Aetna, and other Blue Cross subsidiaries also reacted in 2005 by contracting with National Imaging Associates (NIA) to manage imaging services. Some insurance companies adopted a new credentialing criterion for participation in their managed care network. Highmark Blue Cross expects a 25% decrease in utilization of imaging services as a result of eliminating duplication of services or elimination of unnecessary services. TUFTS HealthPlan in Massachusetts similarly uses NIA, as well as a strict service specific credentialing process for outpatient facilities, to promote reasonable and consistent quality of imaging services.

The August 26, 2006 Federal Register requested comments regarding proposed rules on physician self-referral relating to diagnostic tests and I submitted my ideas of how to change the rules so that doctors can not profit more by ordering tests, which they are not trained to interpret, than evaluating and managing patients. Medicare's unfunded obligations are in the tens of trillions of dollars and we need not be spending money on tests that do not need to be performed.

88-1

Ms. Stacey Linck
189 Rutherglen
Valley Park, MO 63088

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-year review)

Dear Ms. Norwalk:

I am pleased that CMS has accepted the recommendation of the RUC in its proposed rule, and I fully support such action to correct anesthesia reimbursement.

When RBRVS was implemented it greatly undervalued anesthesia services compared to other medical services. This reimbursement is about 30 – 35% of private insurance reimbursement. This amount does not cover the cost of caring for our nation's seniors and has caused problematic staffing issues for high Medicare population areas. The almost $4.00 increase would help offset the 32% undervalued work of anesthesia services compared to Medicare reimbursement for other specialties and ensure seniors have access to anesthesia care.

Again, it was imperative that the Agency accept this recommendation in the proposed rule, and I support full implementation of the RUC's recommendation.

Sincerely,

Stacey L. Linck, CRNA

89-1

intermountain
physical therapy &
hand rehabilitation

August 14, 2007

Re: CMS-1385-P

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Dear CMS Representative:

I am writing in regards to the proposed Medicare Physician Fee Schedule (MPFS) and the negative impact the drastic decrease in reimbursement for both Physical Therapy and Occupational Therapy will have on most communities.

I currently take care of the billing for a small clinic and can tell you that with the current fee schedule it would be very difficult to remain in business if the only clients we had were Medicare patients. This problem will be inflated with the proposed reduction.

This reduction will most certainly result in a lack of access to rehabilitation services for Medicare patients for the simple reason Medicare will not pay enough to cover the cost of seeing their patients. This will in turn result in more high cost interventions such as surgeries and long term inpatient care that could have been prevented if patients would have had access to the proper care in the first place.

To come to the point, this proposed reduction in the fee schedule will result in fewer available services for our elderly citizens. Please quit picking on the little old people they deserve better.

Thank you for your time,

Laura Kelly

Laura Kelly,BOM

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90 - 1

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JOHNS HOPKINS
MEDICINE

JOHNS HOPKINS
BAYVIEW MEDICAL CENTER

Herb Kuhn,
Acting Administrator
CMS Department of Health and Human Services
Attention CMS 1385--P
P.O. Box 8018
Baltimore, MD 21244-8018

RE: CMS- 1385-P; Proposed Physician Fee Schedule and other Part B Payment Policies for CY 2008.
CODING—ADDITIONAL CODES FROM 5-YEAR REVIEW.

Dear Mr. Kuhn,

As a physician who provides echocardiography services to adult patients, including Medicare patients, in Baltimore at Johns Hopkins Bayview Medical Center. I am writing to you to express my objection of the CMS's proposal to "bundle" Medicare payment for color flow Doppler (CPT Code 93325) into all echocardiography "base" services. Based on this proposal, payment would be discontinued for color flow Doppler, effective on January 1, 2008 on the grounds that color flow Doppler is "intrinsic to the performance" of all echocardiography procedures.

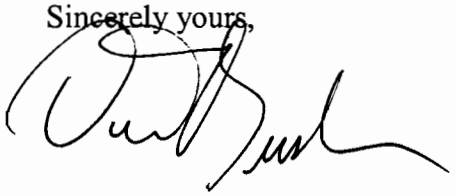
In addition to two-dimensional echocardiography, color Doppler is important in identification, assessment, and quantitation of the severity of cardiac abnormalities in many disease processes, including valvular heart disease, shunts, and congenital and acquired defects. In many instances, color flow Doppler helps diagnose disease processes which could not be detected by two-dimensional echocardiography alone. More over, color Doppler provides useful information which helps guide the management of these patients, whether it is medical or surgical management.

CMS's proposal to "bundle" (and therefore eliminate payment for) color flow Doppler does not take into account the time and expense involved in the performance and interpretation of a quality study. Performance of color Doppler by the sonographer increases the time of the study and the equipment used in the echo laboratory. As technology has advanced, color Doppler is playing a pivotal role in valvular heart disease and shunts which has increased the time needed for performance of these complex disease processes. The sonographer and equipment time and associated overhead required for the performance of color flow Doppler are not included in the relative value units for any other echocardiography "base" procedure. However, the CMS proposal eliminates Medicare payment for a service that (as CMS itself acknowledges) is important for accurate diagnosis and that is not reimbursed under any other CPT code.

Moreover, CMS is incorrect in assuming that color flow Doppler is "intrinsic" to the provision of all echocardiography procedures. I understand that data gathered by an independent consultant and submitted by the American College of Cardiology and the American Society of Echocardiography confirms that color flow Doppler is routinely performed in conjunction with CPT code 93307. However, data was previously submitted to CMS which indicated that an estimated 400,000 color flow Doppler claims each year are provided in conjunction with 10 echocardiography imaging codes other than CPT code 93307, including fetal, transesophageal, congenital, and stress echo. For many of these echocardiography "base" codes, the proportion of claims that include Doppler color flow approximates or is less than 50%. More recent data submitted by the ASE in response to the Proposed Rule confirms that this practice pattern has not changed over the past several years. In our practice, CPT code 93350 is rarely billed with color flow Doppler.

For these reasons, I urge you to refrain from finalizing the proposed "bundling" of color flow Doppler into other echocardiography procedures, and to work closely with the American Society of Echocardiography to address this important issue in a manner that takes into account the resources involved in the provision of this important service.

Sincerely yours,



91-1

Michael Hensien, M.D.
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12 July 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Center for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-1385-P
PO Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P

Dear Ms. Norwalk:

It has been brought to my attention that AMA/Specialty Society Relative Value Update Committee (RUC) has recommended an increase in the anesthesia conversion factor. This increase, I understand, would result in close to a $4.00 increase in the anesthesia unit. I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

The current fee schedule grossly undervalues anesthesia services. This amount does not cover the cost of caring for our nation's seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

The specialty of anesthesiology in recent years has enjoyed a welcome increase in entrants from medical school. As such we are seeing some of the best and brightest medical school graduates consider becoming anesthesiologists. This will continue to add to the increasing safety of patients, including an aging population, in the perioperative period. An increase in the fee schedule will assist in bringing safe anesthesia services to all aspects of the population, urban and rural, young and senior.

Thank you for your consideration of this matter.

Respectfully,

Michael Hensien, M.D.

92

PREMIER
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August 28, 2007

VIA FEDERAL EXPRESS

Mr. Herb Kuhn
Acting Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-1385-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1385-P

Dear Mr. Kuhn:

I. INTRODUCTION

Premier Health Care Management, Inc. ("Premier") appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services ("CMS") Proposed Rule, CMS-1385-P, entitled *Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008* ("the Proposed Rule") that was published in the Federal Register on July 12, 2007.[1] Premier is a mid-size health care company with facilities located in Southeastern Michigan. Premier affiliates include skilled nursing facilities, home health agencies, therapy providers and management companies.

As requested, our comments are linked to the issue "Therapy Standards and Requirements" identified in the Proposed Rule, and relate primarily to the proposed revisions to the qualification for physical therapist assistants ("PTAs").

II. DISCUSSION OF "THERAPY STANDARDS AND REQUIREMENTS"

A. There is a Clear and Compelling Need to Update the Qualification Requirements for PTAs

The Proposed Rule includes a discussion and proposed language intended to update the personnel qualifications currently contained in 42 C.F.R 484.4 and various other regulations related to physical therapists ("PTs"), PTAs, occupational therapists ("OTs"), occupational therapist assistants ("OTAs") and speech language pathologists ("SLPs"), (collectively referred to as "therapists"). CMS specifically notes the need to make changes to the regulations

[1] *See* 72 Fed. Reg. 38,121 *et seq.* (Jul. 12, 2007).

governing therapists' qualifications because: (i) the current regulations contain outdated terminology; (ii) therapy standards have changed since many of the CMS regulations were promulgated; and (iii) some of the current regulations do not address individuals trained outside the US and/or refer to outdated requirements.[2]

We strongly support CMS efforts to update Medicare's qualifications for therapists for the reasons CMS describes. Further, as a practical matter, the current regulations have made it difficult to provide high quality therapy services to patients because the pool of therapists, particularly PTAs, considered to be "qualified" under these outdated standards is extremely, and unnecessarily, limited. In particular, as CMS no doubt is aware, as a result of the aging of the baby boom generation and certain other clinical advances, there is a tremendous and increasing need for qualified PTs and PTAs. As noted in a state government report,

> In Michigan, as throughout other parts of the nation, there is a shortage of physical therapists. This shortage, along with continued medical cost containment measures, is expected to prolong an increased demand for qualified Physical Therapist Assistants and Therapy Aides. Projections indicate the demand will remain as the large baby boom generation approaches the prime age for heart attacks and strokes, thus requiring cardiac and physical rehabilitation.[3]

Further, an article published earlier this summer in the HOUSTON CHRONICLE noted that, "the worst shortage [in health care services for seniors] is in all types of therapy, especially physical therapy and occupational therapy. ... Physical therapist assistants are helping ease the shortage of physical therapists."[4]

Accordingly, we are in complete agreement that Medicare's qualifications for PTAs need to be updated, and in particular, those requirements applicable to individuals educated overseas. We are writing because the regulatory language that is being proposed will not resolve significant parts of the problem for the reasons described below.

B. Consistent Standards for PTAs are Necessary and Should be Fully Implemented across All Sites of Service

In the preamble to the Proposed Rule, CMS states that "the [proposed] revisions would have the benefit of establishing consistent standards across provider/supplier lines."[5] We agree with CMS that consistency in this area is a worthwhile, and long overdue, objective. We are not aware of, and CMS has not advanced, any clinical reason to require therapists to have different qualifications depending on the type of facility in which they practice, and in particular, to differentiate PTAs in the home health agency ("HHA") and hospice settings from all other sites of service. Nevertheless, under the Proposed Rule, PTAs in most settings who began their practice before January 1, 2008, may qualify to participate in Medicare under a newly created

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[2] *Id.* at 38,191.

[3] *See, e.g.*, Health Careers in Michigan, #414 – Physical Therapist Assistant & Aide, *available at* http://www.michigan.gov/healthcareers/0,1607,7-221-39742-64699--,00.html.

[4] *See* David Wahome, *Allied Health Services Help Keep Seniors Healthier*, HOUSTON CHRONICLE, (Jun. 17, 2007).

[5] 72 Fed. Reg. at 38,191.

grandfather clause. PTAs who seek to practice in HHAs or hospices, however, have no such grandfather clause available. The only reason CMS suggests for continuing this historical distinction is that the current regulations at 42 C.F.R 484.4 have applied in the home health and hospice setting for almost 20 years and CMS does not "expect that there are therapists furnishing services in a HHA or hospice that do not meet either the current or proposed revised qualifications."[6] While this statement may be true in a number of jurisdictions, it is not true in Michigan (and likely in certain other states where foreign-trained PTAs are neither licensed nor otherwise recognized under state law).

Moreover, having different standards for PTAs depending on the setting in which they practice creates substantial inefficiencies and additional costs. Specifically, under the Proposed Rule, a therapist who satisfies the new grandfather clause may be "qualified" to provide therapy services in a skilled nursing facility ("SNF"), but not in a HHA. Many companies, such as Premier, are affiliated with different types of health care providers, and also employ therapists to work in their various subsidiaries, on an as-needed basis. Certain companies also employ therapists who are leased to independent providers that operate various types of facilities, such as HHAs and SNFs. In either case, this distinction based on settings creates an unnecessary and costly administrative burden to have to differentiate among PTA assignments based on historical distinctions between provider types. More important, such unnecessary distinctions could have a negative impact on quality of care and patient access to care if there is a need for a PTA(s) at a hospice, but the only PTA(s) available satisfy the SNF grandfather clause, but not the hospice PTA requirements.

Further, as we will describe in more detail in section C(1) below, the current HHA/hospice regulations with regard to PTAs in particular, are outdated, ambiguous and subject to improper interpretation, at best. We encourage CMS to take this opportunity to fully implement the policy it proposes, and make PTA standards consistent across all provider types. There is no reason to put PTAs who provide services in HHAs and hospices in a separate, more restrictive category. Moreover, since CMS correctly notes that qualifications for PTAs, in particular, vary widely among States, it makes sense to include a broad grandfather clause. However, this grandfather clause should apply to PTAs in all settings and should not discriminate against PTAs who happen to practice in a state, like Michigan, which does not license or otherwise officially recognize foreign-trained PTAs.

C. Foreign-Trained Individuals with Comparable Credentials Should be Allowed to Serve as PTAs

The preamble specifically states that one of the primary reasons behind the revisions contained in the Proposed Rule is to address individuals who have been trained outside of the United States.[7] CMS states, and we agree, that the standards for individuals trained outside of the US should be comparable to those standards applicable to PTAs trained within the US. However, the Proposed Rule fails to adequately address this issue in a number of ways.

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[6] *Id.* at 38,192.
[7] *Id.*

1. Foreign-Trained PTAs Beginning Their Practice Before 2008

a. In the HHA/Hospice Setting

While we do not believe that CMS intended this result, the Proposed Rule could be read to prohibit virtually all foreign-trained individuals from serving as PTAs if they began their practice before January 1, 2008, particularly in the HHA/hospice context. This conundrum arises because the language in proposed 42 C.F.R 484.4 describing the requisite qualifications for PTAs who began their practice before Jan. 1, 2008 is virtually identical to the language in the current regulations. Under these regulations, a PTA must be licensed in the state where practicing, if applicable, and must either:

> (i) have "graduated from a 2-year college-level program approved by the American Physical Therapy Association [APTA]" or (ii) have "2 years of appropriate experience as a physical therapist assistant, and [have] achieved a satisfactory grade on a proficiency examination conducted, approved or sponsored by the U.S. Public Health Service, except that these determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking initial qualification as a physical therapist assistant after December 31, 1977."

42 C.F.R 484.4 (emphasis added). Foreign trained therapists cannot qualify under the first standard since the APTA has not approved any overseas PTA programs.[8]

With regard to the second standard, it would appear that a foreign trained PTA could qualify if they have "2 years of appropriate experience" as a PTA. Based on the plain language of the regulations, the requirement to achieve a satisfactory grade on a US Public Health Service ("PHS") proficiency exam does not apply to "persons initially licensed by a State or seeking initial qualification as a physical therapist assistant after December 31, 1977." Nevertheless, despite the plain language of the regulation and the physical impossibility of taking the PHS exam for many years,[9] at least one jurisdiction has interpreted these regulations as prohibiting foreign-trained PTAs from satisfying Medicare standards, no matter how many years of appropriate experience they have, simply because they did not take the PHS exam.

As a result, if CMS decides to continue using the regulatory language in 42 C.F.R 484.4 as a basis for PTA qualification, it is imperative that the language be modified to make it very clear that a PTA who has 2 years of appropriate experience and who sought initial qualification as a PTA at any time after December 31, 1977 is not required to pass a PHS exam that no longer exists.

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[8] *See* CAPTE Accredited Physical Therapist Assistant Education Programs, *available at* http://www.apta.orgAM/Template.cfm?section=PT_aptaapps/accreditedschools/acc_schools_map.cfm&process=3&type=PTA.

[9] The PHS proficiency examination was discontinued so long ago that we have not been able to find anyone at CMS who could tell us the date it was last offered.

(b) *PTAs Outside the HHA/Hospice Setting*

The grandfather clause that CMS proposes to use in all contexts, besides hospice and home health, for PTAs who began their practice before January 1, 2008, is a step in the right direction but fails to address the situation affecting a foreign-trained PTA in a state, such as Michigan, that does not currently license, certify, register or otherwise recognize such PTAs. As a result, the grandfather clause will not apply to PTAs who practiced in Michigan before January 1, 2008. These PTAs theoretically may take advantage of the PTA qualifications requirements in 42 C.F.R 484.4 (although the problems with this provision have been described in detail above). However, it seems arbitrary and unfair to penalize PTAs in the few states that did not officially recognize foreign-trained PTAs in the past by prohibiting them from using the grandfather clause applicable to all other PTAs in other jurisdictions.

2. Foreign-Trained PTAs Beginning Their Practice after January 1, 2008

The Proposed Rule would allow foreign-trained individuals, beginning their PTA practice after January 1, 2008, to qualify as PTAs under Medicare if, *inter alia*, they have "graduated after successful completion of an education program that by a credentials evaluation process approved by the [APTA], is determined to be comparable with [PTA] entry level education in the United States."[10] We believe this proposed language strikes an appropriate balance; allowing qualified individuals to serve as PTAs, when the education they received in another country is comparable to what they would have received in this county. However, there are a few points of clarification that should be addressed.

First, the currently proposed regulatory language refers to PTA "entry level education." In our experience, many foreign-educated individuals seeking work as PTAs in the United States were trained overseas as PTs. The additional level of expertise that they bring will enable them to furnish high quality care to Medicare beneficiaries and thus should not prohibit them from qualifying to provide PTA services. Similarly, where CMS states in the preamble to the Proposed Rule that it does not intend to "recognize as qualified therapists or therapy assistants, individuals trained in other disciplines for purposes of furnishing [physical therapy] ...services to Medicare beneficiaries,[11] it would be very helpful for CMS to make it clear that training as a PT would be considered "in the same discipline" as PTA training. Towards this end, CMS may want to revise the language slightly in proposed 484.4(1)(ii) under the definition of "physical therapist assistant" to read:

> If educated outside the United States or trained in the United States military, graduated after successful completion of an education program that by a credentials evaluation process approved by the American Physical Therapy Association or accredited by a national accreditation agency approved by the appropriate state agency, is determined to be, at a minimum, comparable to physical therapist assistant entry level education in the United States.

[10] 72 Fed. Reg. at 38,231.
[11] *Id.* at 38,192.

These complex issues may be clarified with the following hypothetical: Assume an individual received a degree in Physical Therapy from a 4 year school in France in 1995 and practiced as a therapist there for 7 years. He or she came to the United States in 2002 and was recognized as a PTA by State X where he or she practiced for 3 years until 2005. Despite the 4 years of education and 7 years of experience as a PT (albeit in a different country), and 3 years of experience in another U.S. jurisdiction as a PTA, this individual would have been unable to provide PTA services to Medicare patients in a state like Michigan because some CMS regions have interpreted 42 C.F.R 484.4 as essentially requiring a PTA to have completed an APTA accredited curriculum, period. Aside from the fact that this interpretation contravenes the plain language of the regulations, the situation is particularly ironic since existing CMS regulations provide various other options for a foreign trained individual to qualify as a PT, which requires a higher level of training and expertise.

Nevertheless, despite the plain language in 42 CFR 484.4, certain jurisdictions have not allowed individuals with 2 years of appropriate experience to participate in Medicare as a PTA (unless they were old enough and began their practice long enough ago) to have taken the PHS exam. This result contravenes the regulatory language, common sense and good policy. In an era where the American public needs an increasing number of qualified PTAs, it is irrational to prohibit qualified individuals from providing services to Medicare beneficiaries simply because they were educated overseas.

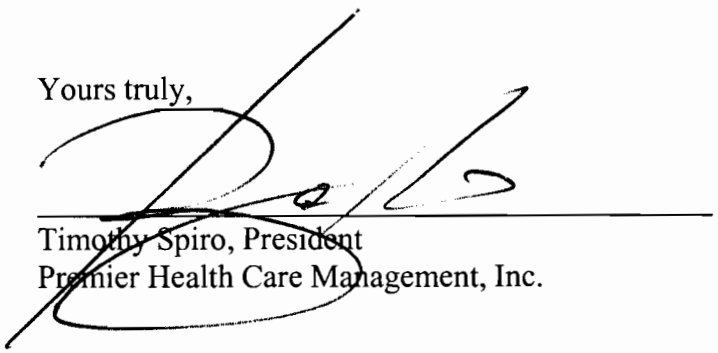
III. CONCLUSION

We commend CMS for its efforts to update the requirements for Medicare therapists, including PTAs. We are particularly appreciative of CMS efforts to address the situation of foreign-trained individuals. However, the Proposed Rule will not solve the problem with regard to foreign-trained individuals who began their practice before January 1, 2008. The proposed grandfather clause, which does not even apply in the HHA/hospice context, would be ineffective in a state, like Michigan, which does not currently recognize foreign-trained individuals as PTAs. Moreover the proposed HHA/hospice provisions related to PTAs do not solve the problem since the Proposed Rule retains the current language in 42 C.F.R 484.4 which has been improperly interpreted in some jurisdictions, so as to virtually prohibit foreign-trained individuals from working as Medicare PTAs. Therefore, at a minimum, 42 CFR 484.4 should be modified so as to clearly state that a foreign-trained individual can qualify as a Medicare PTA if they are licensed by the State, if applicable, and have two years of appropriate experience.

We realize that these are complicated issues, in large part because of the wide range of state regulations on this subject. Nevertheless, we believe that CMS should set a minimum floor of qualifications that can be fairly applied to PTAs in all states. The standards CMS develops should ensure high quality care for Medicare beneficiaries. However, in light of the steadily increasing need for therapy services, the existing shortage of PTAs, and the cost efficiencies inherent in using PTAs whenever appropriate and possible, CMS standards should allow all available and qualified individuals to provide PTA services to Medicare beneficiaries.

Premier appreciates the opportunity to comment on the important proposals on therapist qualifications developed by CMS. We value the ongoing opportunity for cooperation with CMS on various policy issues and looks forward to continuing this productive relationship. If you have any questions, or require clarification or additional information related to our comments, please feel free to contact me.

Yours truly,



Timothy Spiro, President
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Centers for Medicare and Medicaid Services
Dept of Health and Human Services
Attention: CMS-1385-P
PO Box 8018
Baltimore, MD 21244-8018

RE: PHYSICIAN SELF-REFERRAL PROVISIONS

Ladies and Gentlemen:

I am writing on behalf of several entities in the business of providing lithotripsy and other therapeutic services to Medicare patients through a urology partnership. We represent approximately 75 Urologists in Georgia, Alabama and Houston, Texas.

In particular, we are concerned with CMS's proposals regarding the following: Under Arrangements, Per Click Fee, Percentage Fee Arrangements, Stand in the Shoes, and Burden of Proof. I'll address each separately.

1. Under Arrangements:

In the ALS v. Thompson case the court held that extracorporeal shockwave lithotripsy is not a designated health service even though it is provided under arrangement with a hospital. Thus the proposed changes to "under arrangements" should not affect lithotripsy. PLEASE CLARIFY. It would be highly beneficial to patients and providers if CMS also exempted procedures that are not otherwise DHS from the proposed prohibitions to under arrangements.

- CMS should limit the reach of Stark to only those arrangements that are known to be abusive and that Congress intended to reach.
    - No one has ever shown any evidence of abuse by urology joint ventures that provide therapeutic services, but CMS has nevertheless attacked them in their effort to eliminate abusive imaging arrangements between physician groups and hospitals and imaging centers.
    - Joint ventures that offer services such as laser prostate ablation and cryotherapy are providing a valuable service to the community and should not be prohibited

- just because they are done at the hospital, especially in the absence of evidence that they are abusive.

- For the urological joint ventures, the primary purpose of physician investment is to improve patient care.

    - Hospitals refuse to purchase state of the art technology, such as the new laser for the treatment of benign prostate disease, even if it is clinically superior, because of the expense and the fact that rapidly changing technology makes today's "best", tomorrow's "obsolete". Hospitals also frequently refuse to invest in technology if it will replace a procedure already done in the hospital using existing machinery or operating room space.

    - Lithotripsy is a good example of this. Physicians wanted a better and less invasive treatment for their patients and were fought at every turn by the hospitals. Physicians formed joint ventures to buy lithotripters because hospitals did not want to make a large capital investment and at the same time cut off a revenue stream from the services they had been providing.

    - Through urology joint ventures, we have been able to improve clinical care and take that risk of obsolescence, when our institutions would not. Physicians want to have new technology available for their patients.

- In many instances a hospital does not have enough volume to justify the expense of purchasing technology.

    - Physicians who want to have state of the art treatment for their patients are willing to invest in a joint venture with other physicians who practice at other hospitals to purchase technology and bring it to their various hospitals on a rotating basis. Usage can be spread among several hospitals and locations that would not otherwise have the service such as rural areas or at hospitals with little volume.

    - Spreading the use of costly equipment also reduces overall capital costs.

2. <u>Per Click Fee Ban</u>:

    - hospitals are generally risk averse and do not want to spend capital for new equipment that may become obsolete fairly quickly. But, doctors want their patients to have access to the best therapy, and are willing to join together to purchase new equipment and take the risk of failure.

    - To accommodate hospitals' fear of failure, urology joint ventures have accepted per click fee contracts. By doing so, the urology joint ventures take the entrepreneurial risks and the hospitals are able to avoid the risk that the volume will be lower than projected.

3. Percentage Fee Prohibition:

   - Another way that a hospital avoids risk is to create arrangements where compensation is set as a percentage of reimbursement for the procedure.

   - Certain third party payors provide low reimbursement while others reimburse more generously.

   - Percentage compensation arrangements permit the physician joint venture to shoulder some of the risk, but at the same time receive a fair payment. Physicians are willing to take this risk.

4. Stand in the Shoes:

   - The proposed rules would provide that if a DHS entity, such as a hospital, owns or controls another entity, a referral by a physician to the entity owned or controlled by the hospital would be deemed for Stark purposes as a referral to the hospital.

   - ASCs rarely furnish designated health services. Thus, when a physician is invested in a joint venture that contracts with an ASC, the physician's referrals to ASCs rarely are prohibited by Stark.

   - The CMS proposal to have a hospital stand in the shoes of an ASC that it owns or controls would have the effect of turning hundreds if not thousands of procedures that are not of themselves DHS into DHS.

   - An ASC with hospital ownership would not be able to contract on a per click basis or on a percentage basis. CMS should not be able to reach further than Congress intended when it enacted Stark.

   - If the proposal is finalized, physicians would likely withdraw from ownership in ASCs where hospitals are investors.

5. Burden of Proof:

   - Incredibly, CMS wants the burden to be on the provider to prove that he did not violate the Stark laws, even though CMS is the accuser in that situation and the one that wrote the rules that the doctor must follow.

   - Such an effort to shift the burden from you/CMS to the providers who are taking care of Medicare patients is unfair and outrageous and flies in the face of the very definition of justice. **What ever happened to innocent until proven guilty??**

   - The most contentious issues under Stark are whether the DHS entity had knowledge of physician ownership, fair market value, and whether compensation

takes into account the volume or value of referrals or other business between the parties.

- Requiring a DHS entity or a physician to prove lack of knowledge would create the impossible situation of having to prove a negative.
- The same would be true for whether compensation takes into account the volume or value of referrals or other business between the parties.
- Fair market value is often viewed differently by valuation experts. If CMS obtains a valuation that is different from that obtained by the joint venture, CMS, as judge and jury, would always win, but not necessarily because it is right.

- Moreover, there are many relationships between physicians and DHS entities where the contract is not sufficiently large enough to warrant obtaining an outside valuation, such as hourly payments for certain physician services. This may cause a hospital, in fear, or in an effort to save money, to reduce physician compensation to an amount so low that it would never be questioned. That would be highly unfair to physicians.

In closing, I would ask you to:

- Accept the burden of proof that the law has historically placed upon the one creating the rules, and not try to shirk responsibility,
- Clarify that as a result of the ruling in ALS v. Thompson lithotripsy would not be subject to the proposed under arrangements restrictions,
- Clarify the proposed "under arrangements" provision to make certain that therapeutic services provided by urology joint ventures are not DHS services if they would be so only because of the site where they are delivered,
- Drop any prohibition of per click or percentage fees as related to these same therapeutic joint ventures in order to preserve the access and cost savings that the shared service model has created, and
- Clarify the stand in the shoes provision to except hospital ownership or control in an ASC to clarify that legitimate joint ventures are not forced to abandon all ASCs with any hospital participation.

Thank you for allowing me to comment on these proposed rules.

Sincerely,

Tracy M Stolarski

Tracy M Stolarski
President

Alaska Children's Heart Center LLC

Scott A. Wellmann MD
Pediatric Cardiologist

August 8, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: File Code: CMS-1385-P, CODING- ADDITIONAL CODES FROM 5-YEAR REVIEW

Esteemed Representative of the Centers for Medicare & Medicaid Services:

I recently learned of a proposed change in CPT codes which pertain to my practice specialty. Specifically, the change proposed would bundle CPT 93325, Doppler echocardiography color flow velocity mapping, with CPT codes 76825, 76826, 76827, 76828, 93303, 93304, 93307, 93308, 93312, 93314, 93315, 93317, 93320, 93321 and 93350 when the services described under these codes are provided at the same time.

I urge you to reconsider this issue and do not implement this change. These codes were initially created because these services are distinctly different. I agree with the conclusion that color flow velocity and spectral analysis are complementary components of Doppler imaging and they are generally used to maximal efficacy when used in concert, as stated in the proposal for this change. However, the specific utility of Doppler color flow velocity mapping is even more pronounced now than it had been when the original CPT codes were created. The rationale to bundle these codes is based on outdated information gathered ten years ago. This proposed change also seems to have been rushed without allowing customary review by the specialty societies of the impacted providers. I urge you to employ another more thorough evaluation of this issue before any modifications are implemented. If bundling is still felt to be appropriate after this review, please adjust the associated RVUs accordingly to reflect the more extensive services which would then be covered by these codes. If you want fries and a drink with your sandwich, you expect to pay a little more for the combo meal than you would for the sandwich alone. This may seem a little oversimplified, but it is an apt comparison. Doppler color flow velocity mapping is a significant component of Doppler echocardiography and this should be reflected in the compensation.

I appreciate your attention to this matter.

Sincerely,

Scott A. Wellmann, M.D.
Medical Director, Alaska Children's Heart Center, LLC.

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NORTH CONWAY AMBULANCE & VALLEY TRANSFER, INC.

P.O. Box 2787 • North Conway, NH 03860 • (603) 356-5248 • FAX: (603) 356-8738
Kenneth (Tinker) Kiesman - *President*

August 15, 2007

Leslie Norwalk, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-1541-P
P.O. Box 8012
Baltimore, Maryland 21244-8012

Re: CMS-1385-P; Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions.

Dear Ms. Norwalk:

North Conway Ambulance Inc. provides emergency and non-emergency ambulance services to the communities which we serve. The proposed rule would have a direct impact on our operation and the high quality health care we provide to Medicare beneficiaries. We therefore greatly appreciate this opportunity to submit comments on the proposed rule.

BENEFICIARY SIGNATURE

Our organization commends CMS for recognizing that providers and suppliers of emergency ambulance transportation face significant hardships in seeking to comply with the beneficiary signature requirements. Ambulance services are atypical among Medicare covered services to the extent that, for a large percentage of encounters, the beneficiary is not in a condition to sign a claims authorization during the entire time the supplier is treating and/or transporting the beneficiary. Many beneficiaries are in physical distress, unconscious, or of diminished mental capacity due to age or illness. The very reason they need ambulance transportation often contraindicates the appropriateness of attempting to obtain a signature from the beneficiary.

We believe strongly, however, that the relief being proposed by CMS would have the unintended effect of increasing the administrative and compliance burden on ambulance services and on the hospitals. Accordingly, we urge CMS to abandon this approach and instead eliminate entirely the beneficiary signature requirement for ambulance services.

Current Requirement

When the beneficiary is physically or mentally incapable of signing, the industry has been following the requirements listed in the CMS Internet Only Manual, Pub. 100-02, Chapter 10, Section 20.1.2 and Pub. 100-04, Chapter 1, Section 50.1.6(A)(3)(c). These sections require the ambulance provider or supplier to document that the beneficiary was unable to sign, the reason and that no one could sign for the beneficiary.

Summary of New Exception Contained in Proposed Rule

While the intent of the proposed exception is to give ambulance providers explicit relief from the beneficiary signature requirements where certain conditions are met, we note that the proposed exception does not grant ambulance providers any greater flexibility than that currently offered by existing regulations. Specifically, 42 C.F.R. §424.36(b)(5) currently permits an ambulance provider to submit a claim signed by its own representative, when the beneficiary is physically or mentally incapable of signing and no other authorized person is available or willing to sign on the beneficiary's behalf. If "provider" in this context was intended to mean a facility or entity that bills a Part A Intermediary, the language should be changed to also include "ambulance supplier". The proposed exception essentially mirrors the existing requirements that the beneficiary be unable to sign and that no authorized person was available or willing to sign on their behalf, while adding additional documentation requirements. Therefore, we believe that the new exception for emergency ambulance services set forth in proposed 42 C.F.R. §424.36(b)(6) should be amended to include only subsection (i), i.e. that no authorized person is available or willing to sign on the beneficiary's behalf.

It is important for CMS to realize that the first two requirements in the proposed sub-division (ii) are always met, as the ambulance crew will always complete a trip report that lists the condition of the beneficiary, the time and date of the transport and the destination where the beneficiary was transported. For this reason, we do not object to the requirements that an ambulance provider obtain (1) a contemporaneous statement by the ambulance employee or (2) documentation of the date, time and destination of the transport. Nor do we object to the requirement that these items be maintained for 4 years from the date of service. However, we do not see any reason to include these in the Regulation, as they are already required and standard practice.

The Proposed Rule would add a requirement that an employee of the facility, i.e. hospital, sign a form at the time of transport, documenting the name of the patient and the time and date the patient was received by the facility. Our organization **strongly objects** to this new requirement as:

- Instead of alleviating the burden on ambulance providers and suppliers, an additional form would have to be signed by hospital personnel.
- Hospital personnel will often refuse to sign any forms when receiving a patient.
- If the hospital refuses to sign the form, it will be the beneficiary that will be responsible for the claim.

- The ambulance provider or supplier would in every situation now have the additional burden in trying to communicate to the beneficiary or their family, at a later date, that a signature form needs to be signed or the beneficiary will be responsible for the ambulance transportation.
- Every hospital already has the information on file that would be required by this Proposed Rule in their existing paperwork, e.g. in the Face Sheet, ER Admitting Record, etc.

We also strongly object to the requirement that ambulance providers or suppliers obtain this statement from a representative of the receiving facility *at the time of transport.* Since the proposed rule makes no allowances for the inevitable situations where the ambulance provider makes a good faith effort to comply, but is ultimately unable to obtain the statement, we believe this requirement imposes an excessive compliance burden on ambulance providers and on the receiving hospitals. Consider what this rule requires—the ambulance has just taken an emergency patient to the ER, often overcrowded with patients, and would have to ask the receiving hospital to take precious time away from patient care to sign or provide a form. Forms such as an admission record will become available at a later time, if CMS wants them for auditing purposes.

Institute of Medicine Report on Hospital Emergency Department Overcrowding

The Institute of Medicine Committee on the Future of Emergency Care recently released a report citing hospital emergency department overcrowding as one of the biggest issues in emergency health care. According to that report, demand on hospital emergency departments (EDs) increased by 26% between 1993 and 2003. During that same period, the number of EDs fell by 425. Combined with a similar decrease in the number of inpatient hospital beds, this has resulted in serious overcrowding of our nation's ED. A further consequence has been a marked increase in the number of ambulance diversions, with 50% of all hospitals—and nearly 70% of urban hospitals—reporting that they diverted ambulances carrying emergency patients to a more distant hospital at some point during 2003.

The report recommended that hospitals find ways to improve efficiency in order to reduce ED overcrowding. However, the requirement that ambulance providers or suppliers obtain a statement from a representative of the receiving hospital at the time of transport would only compound the existing problem, by adding an additional paperwork burden. To meet this requirement, ambulance crews would be forced to tie up already overtaxed ED staff with requests for this statement. The Institute of Medicine report makes clear that this time would be more efficiently spent moving patients through the patient care continuum.

Purpose of Beneficiary Signature

a. Assignment of Benefits – The signature of the beneficiary is required for two reasons. The first purpose of the beneficiary signature is to authorize the assignment of Medicare benefits to the health care provider or supplier. However, assignment of

covered ambulance services has been mandatory since April 2002. Furthermore, 42 C.F.R. §424.55(c), adopted November 15, 2004 as part of the Final Rule on the Physician Fee Schedule (67 Fed. Reg. 6236), eliminated the requirement that beneficiaries assign claims to the health care provider or supplier in those situations where payment can only be made on an assignment-related basis. Therefore, the beneficiary's signature is no longer required to effect an assignment of benefits to the ambulance provider or supplier.

CMS recognized this in the Internet Only Manual via Transmittal 643, by adding Section 30.3.2 to Pub. 100-04, Chapter 1. As a result, the beneficiary signature is no longer needed to assign benefits of covered ambulance services.

b. Authorization to Release Records – The second purpose of the beneficiary signature is to authorize the release of medical records to CMS and its contractors. However, the regulations implementing the HIPAA Privacy Rule, specifically 45 C.F.R. §164.506(c)(3), permit a covered entity (e.g. an ambulance provider or supplier) to use or disclose a patient's protected health information for the covered entity's payment purposes, without a patient's consent (i.e. his or her signature). Therefore, federal law already permits the disclosure of medical records to CMS or its contractors, regardless of whether or not the beneficiary's signature has been obtained.

Signature Already on File

Almost every covered ambulance transport is to or from a facility, i.e. a hospital or a skilled nursing facility. In the case of emergency ambulance transports, the ultimate destination will always be a hospital. These facilities typically obtain the beneficiary's signature at the time of admission, authorizing the release of medical records for their services *or any related services*. The term "related services", when used by hospitals and SNFs, can mean more than only entities owned by or part of the facility. We believe that ambulance transport to a facility, for the purpose of receiving treatment or care at that facility, constitutes a "related service", since the ambulance transports the patient to or from that facility for treatment or admission. Therefore, we believe a valid signature will be on file with the facility. Additionally, for those transports provided to patients eligible for both Medicare and Medicaid, a valid signature is on file at the State Medicaid Office as a product of the beneficiary enrollment process.

Electronic Claims

It is also important to note that, as a result of section 3 of the Administrative Simplification Compliance Act and the implementing regulations at 42 C.F.R. §424.32, with very limited exceptions (e.g. providers or suppliers with less than 10 claims per month), ambulance suppliers must submit claims electronically. Thus, the beneficiary does not even sign a claim form. When submitting claims electronically, the choices for beneficiary signature are "Y" or "N". An "N" response could result in a denial, from some Carriers. That would require appeals to show that, while the signature has not been obtained, an alternative is accepted. As a result, many Carriers allow a "Y", even though the signature was not actually obtained, if one of the exceptions is met.

While this may be a claims processing issue, since you are now looking at the regulation, this would be a good time to add language indicating that the signature requirement will be deemed to be met if one of the exceptions to the requirement exists.

Program Integrity

It is important for CMS to realize that, for every transport of a Medicare beneficiary, the ambulance crew completes a trip report listing the condition of the patient, treatment, origin/destination, etc. AND the origin and destination facilities complete their own records documenting the patient was sent or arrived via ambulance, with the date. Thus, the issue of the beneficiary signature should not be a program integrity issue.

Conclusion

Based on the above comments, it is respectfully requested that CMS:

- Amend 42 C.F.R. §424.36 and/or Pub. 100-02, Chapter 10, Section 20.1.1 and Pub. 100-04, Chapter 1, Section 50.1.6 to state that "good cause for ambulance services is demonstrated where paragraph (b) has been met and the ambulance provider or supplier has documented that the beneficiary could not sign and no one could sign for them OR the signature is on file at the facility to or from which the beneficiary is transported".
- Amend 42 C.F.R. §424.36 to add an exception stating that ambulance providers and suppliers do not need to obtain the signature of the beneficiary as long as it is on file at the hospital or nursing home to or from where the beneficiary was transported. In the case of a dual eligible patient (Medicare and Medicaid), the exception should apply in connection to a signature being on file with the State Medicaid Office.
- Amend 42 C.F.R. §424.36(b) (5) to add "or ambulance provider or supplier" after "provider".

In light of the foregoing, we urge CMS to forego creating a limited exception to the beneficiary signature requirement for emergency ambulance transports, especially as proposed, and instead eliminate the beneficiary signature requirement for ambulance services entirely if one of the exceptions listed above is met.

AMBULANCE SERVICES – AMBULANCE INFLATION FACTOR

Our organization has no objection to revising 42 C.F.R §414.620 to eliminate the requirement that annual updates to the Ambulance Inflation Factor be published in the Federal Register, and to thereafter provide for the release of the Ambulance Inflation Factor via CMS instruction and the CMS website.

Thank you for your consideration of these comments.

Sincerely,

William Riley
Operations Manager
North Conway Ambulance, Inc.

Cascade
Urological
Services

August 14, 2007

Centers For Medicare and Medicaid Services
Dept of Health and Human Services
Attention: CMS-1385-P
PO Box 8018
Baltimore, MD 21244-8018

Ladies and Gentlemen:

I am a practicing Urologist in the Northwest. I have provided quality lithotripsy and therapeutic devices to Medicare and Medicaid patients through urology joint ventures for over ten years. I am concerned for patients' welfare if CMS carries out an apparent attack on legitimate physician joint ventures.

I understand CMS'S concern about abusive therapeutic and radiologic Services. I understand that these are aimed mostly at radiology (per click) imaging centers. I find however, no clarification for legitimate lithotripsy services, which have no abuses as patients either have kidney stones or they do not.

Let it be known that these technologies are extremely expensive and that hospitals refuse to purchase them as they may become obsolete in the near future. Lithotripsy is a good example of this. Through these urology joint ventures, we have been able to continue to take the very best care of all patients no matter of their insurance status. Some of the services in concern are so-called designated health services, and it should have been made clear to CMS in ALS vs. Thompson that the court held that extra corporeal shock wave lithotripsy is not a designated health service thus any proposed changes in the "under arrangement" should not affect lithotripsy.

In the proposed per click fee ban CMS should understand that hospitals are adverse to risk capital in new equipment that may become obsolete. Urology ventures have accepted the risk in these per click contracts.

In the proposed stand in the shoes regulations, CMS would affect the turning of hundreds if not thousands of procedures into DHS. This would interfere with many legitimate ambulatory surgical centers where hospitals and physicians are co-investors.

In the burden of proof, provisions of the proposed rules CMS attempts to shift the burden from itself to the providers. This is an offense of justice and should not be allowed to happen.

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Urology joint ventures have enabled expensive capital technology to be shared with many hospitals who cannot afford to purchase them. This has worked well in rural communities and in small communities in which I practice. Therapeutic joint ventures have brought clinical benefits to thousands of Medicare beneficiaries and this might end if the proposed rules are written as indicated.

I ask CMS to accept the burden of proof that the law has historically placed upon CMS, and not to shrink from its responsibilities. I ask CMS to clarify that ALS vs. Thompson suit should not be subject to the proposed under arrangement restrictions. I ask CMS that the proposed "under arrangement" provision are not DHS services and would only be so because of the site where they are delivered. I ask CMS to drop any prohibition of per click or percentage fees. I ask CMS to clarify the stand in the shoes provision to accept hospital ownership or control in an ASC, and to clarify that legitimate joint ventures are not forced to abandon all ASC'S with any hospital participation.

Without these changes CMS will limit the availability of expensive technologies to Medicare and Medicaid patients. This is obviously not their intent, but may happen if these proposed rules take affect.

Sincerely yours,

Thomas P. Cooper MD

97

ReedSmith

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August 16, 2007

VIA OVERNIGHT COURIER

Hon. Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: *Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008 (CMS-1385-P)*

Dear Ms. Norwalk:

Please find attached the comments of Bio-Tissue, Inc. concerning the Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008. We have included two additional copies for your convenience.

Very truly yours,

Paul W. Pitts

PWP:ckn

Enclosures

cc (w/encl.): Pam West, CMS
Cherie McNett, Director of Health Policy, American Academy of Ophthalmology
Gail Daubert, Esq.
Paul Pitts, Esq.

August 16, 2008

Hon. Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Mail Stop C4–26–05,
7500 Security Boulevard
Baltimore, MD 21244–1850

Re: Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008 (CMS-1385-P)

Dear Ms. Norwalk:

Bio-Tissue, Inc. ("Bio-Tissue") is pleased to submit the following comments on the Proposed Revisions to Payment Policies Under the Physician Fee Schedule ("PFS") for Calendar Year ("CY") 2008 (the "Proposed Rule"), 72 Fed. Reg. 38122 (July 12, 2007).

Bio-Tissue is a bio-tech company specializing in the discovery and manufacture of high quality amnion-based tissue and cell products that provide healing and regeneration of ocular surface tissue including the cornea and the conjunctiva. Bio-Tissue's current products, AMNIOGRAFT® and PROKERA™, are used worldwide to help ophthalmologists treat conditions with ocular surface damage such as pterygium, corneal defects/ulcers, tumors/scars, viral infections, leaking glaucoma blebs, chemical burns, Stevens-Johnson Syndrome, high-risk corneal transplants, conjunctivochalasis, and many other conditions.

The Proposed Rule does not list preserved human amniotic membrane tissue (HCPCS Level II Code V2790) as a separately payable code. The medical products represented by code V2790, and in particular PROKERA™, are well suited for use in a physician's office and have been so used to successfully treat a number of ocular injuries and diseases as discussed more fully below. When PROKERA™ is used in an office setting it would typically be billed with an E&M code for office related visits/treatments or possibly CPT 65780, the code for amniotic membrane transplantation. In either case, the cost of providing the amniotic membrane is not covered by existing codes. By failing to list V2790 in the PFS, the Centers for Medicare & Medicaid Services ("CMS") will create a significant disincentive for the use of amniotic membrane tissue in the treatment of ocular surface injury and disease. Furthermore, failure to list V2790 as a separately payable code in the PFS will cause providers and beneficiaries to seek

alternative treatments that are often more expensive to the Medicare program, such as corneal transplant, and resort to surgical treatments in a more intensive settings, such as a hospital outpatient department or an ambulatory surgery center ("ASC").

In summary, we request that HCPCS Level II Code V2790 be included in the CY 2008 PFS with a status indicator of "C" to permit payment for this code on an individual basis following a review of applicable documentation.

Preserved Human Amniotic Membrane Tissue

Amniotic membrane is a safe, effective and therapeutic treatment option for corneal and conjunctival epithelial damage resulting from trauma or disease. Amniotic membrane is the inner most lining of the placenta which has been FDA recognized for the use in ocular surface wound repair and wound healing since 2001. The clinical efficacy of amniotic membrane transplantation for ocular surface reconstruction is well established in peer-reviewed scientific journals.

Clinical Office Use of Amniotic Membrane

Unlike eye shields, bandage contact lenses, patches and other eye protection options available for use in the office, amniotic membrane protects the ocular surface while simultaneously delivering therapeutic biologic actions that aid in ocular surface wound repair and wound healing. An ocular surface protected by amniotic membrane is simultaneously receiving amniotic membrane's FDA confirmed biologic actions which reduce inflammation, minimize scarring, facilitate epithelial wound healing, and aid in the migration of limbal stem cells.

The use of amniotic membrane in the office can prevent the need for a hospital or ASC procedure. Non-healing corneal defects that often lead to the need for corneal transplantation can be healed in the office using PROKERA™. Patients that have had corneal transplants and run the risk of rejecting the transplant can be treated with PROKERA™ to help save the transplanted cornea. In addition, patients with acute chemical or thermal burns affecting their eyes can be treated immediately in the office with PROKERA™ and often do not require additional surgical procedures.

PROKERA™ Amniotic Membrane Device

PROKERA™ is an ophthalmic conformer containing amniotic membrane that is used to assist in ocular surface corneal and limbal wound repair and wound healing. PROKERA™ is constructed with two polycarbonate rings clipped together with a piece of amniotic membrane

The leader in ocular surface tissue therapies

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BIO-TISSUE

fastened in between. PROKERA™ can be easily inserted between the eyeball and the eyelid in the office.

The natural biologic actions of the amniotic membrane in PROKERA™ facilitate the healing process for the corneal and limbal surfaces. The polycarbonate rings are removed in the office once the ocular surface healing has taken place. No other commercially available product provides the same therapeutic actions as PROKERA in the office setting.

In October of 2006, CMS extended the supply code for preserved human amniotic membrane tissue, V2790, to include PROKERA™. Without reimbursement for this device in the office setting, physicians will treat patients with corneal epithelial defects in the hospital or ASC where this device is reimbursed. These alternative settings needlessly increase the cost of treatment and inconvenience the patient.

Given the substantial benefits offered by PROKERA™ when applied in an office setting, we ask that you carefully consider the significant applications of preserved amniotic membrane tissue, as well as the considerable impact amniotic membrane tissue can have on Medicare beneficiaries who exhibit the appropriate indications for its use.

Sincerely,

Amy Tseng, MBA
President

cc: Pam West, CMS
Cherie McNett, Director of Health Policy, American Academy of Ophthalmology
Gail Daubert, Esq.
Paul Pitts, Esq.

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amcno
THE ACADEMY OF MEDICINE OF CLEVELAND & NORTHERN OHIO
formerly known as AMC/NOMA

AUG 17 2007

August 14, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

Re: Proposed Rule CMS-1385-P

As Vice President of Legislative Affairs of the Academy of Medicine of Cleveland & Northern Ohio (AMCNO), an organization representing more than 4,400 physicians in Northeastern Ohio I am writing on behalf of the organization and the physicians we represent to comment on the Medicare Program; Revisions to payment policies under the physician fee schedule for calendar year 2008; proposed rule – CMS-1385-P.

Physician Payment Updates

Physician payment updates are driven by a flawed formula called the Sustainable Growth Rate (SGR). The underlying flaw of the SGR formula is the link between the performance of the overall economy and the actual cost of providing physician services. The medical needs of individual patients are not related to the overall economy.

By 2015, the 2006 Medicare Trustees report predicts that Medicare physician payment rates will be cut by 37% due to the flawed payment update formula, starting with a cut of nearly 5% in 2007. From 2007-2015, Medicare payments in Ohio will be cut by $7.43 billion. In Ohio, the cuts over this period will average $27,000 per year for each physician in the state. All patients will be adversely affected by these proposed payment changes because Medicaid and private insurers use Medicare rates as a resource for their reimbursement rates.

The AMCNO realizes that ultimately the administration and Congress will have to act in order to replace the SGR, however, CMS and its' administrators have the ability to review comments from physicians, physician organizations and other healthcare providers regarding the proposed payment and policy changes and try to find ways to improve physician payment without adding to overall Medicare costs.

Geographic Practice Cost Indices

It is our understanding that CMS adjusts Medicare physician fees for geographic differences in the costs of operating a medical practice. At this time, CMS uses 89 physician payment localities among which fees are adjusted. However, it is our belief that the boundaries of these payment localities do not accurately address variations in physicians' costs.

As noted in the proposed rule, CMS recognizes that changing demographics and local economic conditions may lead to increased variations in practice costs in certain payment locality boundaries. The AMCNO strongly believes that Medicare's geographic payment adjustment formula does not accurately reflect practice costs in Northern Ohio. Currently, the state of Ohio is designated as a statewide locality. This is problematic for our physician members practicing in Northern Ohio because CMS has not revised the geographic boundaries of the physician payment localities since the 1997 revision. Also, since that year, CMS has indicated that the only mechanism the agency has set forth to modify the payment localities is for the state medical associations to petition for change by demonstrating that the change has the overwhelming support of the physician community. This mechanism for change in the payment localities seems biased since the state medical association does not represent all of the physicians in the state of Ohio. In addition, CMS has not required medical associations in the

states that are now consolidated to continue to demonstrate that there is "overwhelming" support from the physician community for a statewide payment locality.

A recent Government Accounting Office report (GAO-07-466 - Medicare Payment for Physician Services) indicated that more than half of the physician payment localities analyzed had a least one county within them with a large payment difference. We believe that the counties located in Northern Ohio should be reevaluated due to the fact that the urban area where our physician members are located would definitely qualify as an area receiving a "large payment difference" due to the statewide payment locality applied in Ohio.

As noted in the GAO report, "adjusting Medicare payments for the costs physicians incur operating a private medical practice in different parts of the country is important to ensure that Medicare accurately accounts for variations in physicians' costs of providing care, and that beneficiaries have sufficient access to physician care. Without a new approach to revising payment localities there will continue to be substantial cost variations among the localities." The AMCNO wholeheartedly concurs with this statement and we believe that a new approach must be implemented in Ohio to adequately reflect the differences across the state.

It is also the opinion of the AMCNO that CMS must find a new methodology for collecting and reviewing malpractice premium data from the states since there is verifiable data that the Northern Ohio area pays some of the highest medical liability rates in not only the state but the nation. While malpractice rates account for only a small portion of the GPCI calculation, this clearly has an impact on physicians in our area.

The CMS proposed rule lays out three options for a pilot program concept, which would be implemented in California with no plans to implement the program in any other state at this time. The AMCNO is of the opinion that option 3 as outlined in the proposed rule could, in fact, assist the physicians in Northern Ohio if this option were implemented in our state as well.

In fact, option 3 in the proposed rule appears to mirror one of the options suggested in the recent GAO report which calls for county-based geographic adjustment factor (GAF) ranges, which provides for a methodology which would result in Ohio becoming two separate localities, if it were implemented in our state.

However, the AMCNO would prefer the option outlined in the GAO report which calls for a metropolitan statistical area (MSA) iterative which would result in Ohio becoming five (5) separate localities an option which would clearly delineate the Northern Ohio area into two separate localities with the remaining three localities located in other parts of the state.

For the sake of our patients and profession, the members of the AMCNO ask that the proposed payment changes as well as the payment methodologies used by CMS be carefully reviewed and evaluated to assure fairness and accuracy. As it is, Medicare payments already lag behind increases in practice costs and unless the above referenced items in the proposed rule are adequately addressed additional problems will arise. The AMCNO believes that the CMS proposed payment and payment methodology changes for 2008 would adversely affect how Medicare patients will be cared for in the future.

If you have any questions regarding our comments please feel free to contact me through the AMCNO offices at 216-520-1000.

Sincerely,

John A. Bastulli, MD
Vice President of Legislative Affairs
The Academy of Medicine of Cleveland & Northern Ohio (AMCNO)

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- ADULT AND PEDIATRIC ORTHOPAEDICS
- SPORTS MEDICINE
- TOTAL JOINT REPLACEMENT
- ARTHROSCOPIC SURGERY

July 30, 2007

AUG 17 2007

Via Courier and Electronic Mail

Leslie Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
Attn: CMS-1385-P
P.O. Box 8018
7500 Security Boulevard
Baltimore, MD 21244-8018

Re: CMS-1385-P
Support Establishment of Non-Facility PE RVUs for Arthroscopy Procedures

Dear Ms. Norwalk:

Thank you for this opportunity to comment on the proposed 2008 Medicare Physician Fee Schedule Rule. As an orthopedic surgeon in private practice who works in both hospital and office settings, I was pleased to see that the Centers for Medicare & Medicaid Services (CMS) may establish Practice Expense (PE) Relative Value Units (RVUs) for arthroscopy procedures performed in a physician's office. I am writing to express my support for this proposal and recommend that you finalize and implement non-facility PE RVUs, effective January 1, 2008.

By way of background, until 1992 I served as an orthopedic surgeon in the United States Air Force where I had a large volume sports medicine practice. Today, I practice privately in the Louisville, Kentucky area and also serve as an Associate Clinical Professor of Surgery at the University of Louisville. I am a member of the American Academy of Orthopaedic Surgeons (AAOS) and the Arthroscopy Association of North America (AANA)

For a number of years, modern arthroscopic technology has allowed physicians to perform diagnostic arthroscopy procedures in the office setting safely and effectively. By using this technology we can immediately assess a patient's condition and can often forego ordering more expensive tests such as MRI scans. There are a number of scenarios where MRIs are inconclusive or can not be used. Arthroscopy, particularly in office, can help with these difficult cases. As a result, we can determine more expeditiously how to best manage a particular patient's condition. Since no conscious sedation is used, patients can walk out of the office after the procedure with minimal discomfort.

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- ARTHROSCOPIC SURGERY

However, physicians can not afford to provide diagnostic arthroscopies in the office setting unless CMS establishes non-facility/office PE RVUs that take into account the cost of our supplies and the cost of the device used for this procedure. As a result, many arthroscopies are needlessly performed in the hospital, which consumes additional resources, or are replaced with MRI scans.

On behalf of my patients and many of my colleagues, I therefore recommend that CMS establish non facility RVUs for diagnostic arthroscopy procedures in the final 2008 Physician Fee Schedule Rule. Doing so, will allow physicians to make medical decisions solely according to the patient's need and to perform diagnostic arthroscopy in whatever setting is most appropriate.

Sincerely,

Frank Bonnarens

Frank Bonnarens, M.D.

cc: Pamela West, CMS (via email)
Ken Simon, MD, CMS (via email)
William Rogers, MD, CMS (via email)
Brad Henley, MD, AAOS (via email)
Bob Fine, AAOS (via email)
Matt Tweeten, AAOS (via email)

/00

SOCIETY FOR MATERNAL-FETAL MEDICINE
409 12th Street, SW
Washington, DC 20024
202/863-2476
www.smfm.org

August 15, 2007

Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
P. O. Box 8018
Baltimore, MD 21244-8018

RE: CMS-1385P: CODING – ADDITIONAL CODES FROM 5-YEAR REVIEW

On behalf of the Society for Maternal-Fetal Medicine (SMFM), we appreciate the opportunity to comment on CMS' proposed rule "Proposed Revisions to Payment Policies under the Physician Fee Schedule, and other Part B Payment Policies for CY 2008" [CMS-1385-P]. Our comments address the proposed coding change to bundle CPT 93325 (Color Flow Doppler Echocardiography) into codes 76825, 76826, 76827, 76828, and focus on those aspects of direct concern to Maternal-Fetal Medicine (MFM) physicians and their patients: namely the lack of administrative due process followed in this instance, the negative impact this regulatory action would have on MFM practices, and the potential impact on patient access to care.

First, with regard to the administrative process, we believe it is important to note that the CPT Editorial Panel already recommended earlier this year that a new code be established that would combine 93325 with 93307, for implementation in 2009. The RUC is scheduled to evaluate the recommended relevant work and practice expense for this new code at its next upcoming meeting. Importantly, the CPT editorial panel did not recommend bundling 93325 with other echocardiography base codes, other than 93307.

This new code is fully expected to address any outstanding issues relative to current Medicare utilization of 93307, predominantly used in older populations. Furthermore, this new code has been developed after extensive research and involvement by appropriate national medical societies, the CPT Editorial Panel, and the RUC.

However, as a result of this proposed rule to bundle 93325 into CPT codes other than those recommended by RUC/CPT Editorial Panel, the 93325 bundling issue now directly impacts a distinctly non-Medicare population – namely, high risk pregnant mothers and their fetuses. Further, because the proposed regulation runs contrary to the normal administrative process followed for such changes, specialty societies have not been able to evaluate the proposed change and its impact on Maternal-Fetal Medicine in order to develop appropriate new Work and Practice Expense proposals for consideration by the RUC.

Our second concern focuses on this issue: namely, the adverse impact this proposal will have on Maternal-Fetal Medicine. The surveys performed to set the work RVUs for almost all of the echo codes utilized specifically by Maternal-Fetal Medicine physicians and affected by this proposed change were performed more than 10 years ago. As a result, particularly with respect to 93325, the RVUs are reflective of a focus

on the cost of the technology and not the advances in care that have been developed as a result of the technology. Particularly among Maternal-Fetal Medicine physicians, new surveys are needed which we believe would show that the work and risk components of the procedures that involve Doppler Color Flow Mapping have shifted to a significantly greater work component and a lesser technology component.

On behalf of the Society for Maternal-Fetal Medicine and its 2000 members, we respectfully urge CMS to withdraw the proposed change with respect to bundling 93325 with other echocardiography codes until such time as an appropriate review of all related issues can be completely analyzed. Once this review is completed an appropriate solution can be developed.

Thank you for your consideration of this serious matter.

Sincerely,

Daniel L. O'Keeffe, MD

Daniel F. O'Keeffe, MD
Chair, SMFM Coding Committee
Phoenix, AZ
602.256.4628 ext. 606

K.D. Wenstrom, MD

Katharine D. Wenstrom, MD
President Society for Maternal-Fetal Medicine

August 15, 2004
915 E Eagle Lake Dr.
Kalamazoo, MI 49009

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O.Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P

Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I want to express my strongest agreement with the proposed increase for anesthesia payments under the 2008 Physician Fee Schedule. I am thankful that CMS has recognized the gross undervaluation of anesthesia services and has taken steps to begin to correct this problem.

Since its creation more than a decade ago the RBRVS has created a large under-payment for the services anesthesiologists provide compared to other physicians. The current $16.19/unit Medicare payment does not cover the costs of providing anesthesia services to Medicare beneficiaries and has created an unsustainable situation to provide unrestricted care to Medicare populations.

The recommendation by the RUC that CMS increase the anesthesia conversion factor by nearly $.00/unit to begin to correct the 32 percent anesthesia work undervaluation is a major move in the proper direction toward correcting this too long practiced undervaluation of anesthesia services. I am pleased to see the Agency accepted this recommendation by the RUC in its proposed rule. Full immediate implementation by CMS of this proposal will help to assure Medicare populations of unrestricted access to anesthesiology medical care.

Thank you for your consideration of this matter which is important to both providers and recipients of anesthesiology medical care.

Sincerely,

Richard A Stark, M.D.

AMERICAN AMBULANCE ASSOCIATION

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"The American Ambulance Association promotes health care policies that ensure excellence in the ambulance services industry and provides research, education, and communications programs to enable members to effectively address the needs of the communities they serve."

August 13, 2007

Leslie Norwalk, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-1541-P
P.O. Box 8012
Baltimore, Maryland 21244-8012

Re: CMS-1385-P; Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions.

Dear Ms. Norwalk:

The American Ambulance Association (AAA) welcomes this opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) Proposed Rule entitled "Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions" (the "Proposed Rule"), 72 Fed. Reg. 38122 (July 12, 2007).

The American Ambulance Association is the primary trade association representing ambulance service providers that participate in serving communities with emergency and non-emergency ambulance services. The AAA is composed of more than 600 ambulance operations and has members in every state. AAA members include private, public and fire and hospital-based providers covering urban, suburban and rural areas. The AAA was formed in 1979 in response to the need for improvements in medical transportation and emergency medical services. The Association serves as a voice and clearinghouse for ambulance service providers who view pre-hospital care not only as a public service but also as an essential part of the total public heath care system. The comments submitted herein are on behalf of our members.

BENEFICIARY SIGNATURE

The AAA commends CMS for recognizing that providers and suppliers of emergency ambulance transportation face significant hardships in seeking to comply with the beneficiary signature requirements of 42 C.F.R. §424.36. Ambulance services are atypical among Medicare covered services to the extent that, for a large percentage of encounters, the beneficiary is not in a condition to sign a claims authorization during the entire time the supplier is treating and/or transporting the beneficiary. Many beneficiaries are in physical distress, unconscious, or of diminished mental capacity due to age or illness. The very reason they need ambulance transportation often contraindicates the appropriateness of attempting to obtain a signature from the beneficiary.

However, the AAA believes strongly that the relief being proposed by CMS would have the unintended effect of increasing the administrative and compliance burden on ambulance services and on the hospitals. Accordingly, we urge CMS to abandon this approach, and to instead eliminate the beneficiary signature requirement for ambulance services entirely.

Current Requirement

When the beneficiary is physically or mentally incapable of signing, the industry has been following the requirements listed in the CMS Internet Only Manual, Pub. 100-02, Chapter 10, Section 20.1.2 and Pub. 100-04, Chapter 1, Section 50.1.6(A)(3)(c). These sections require the ambulance provider or supplier to document that the beneficiary was unable to sign, the reason and that no one could sign for the beneficiary.

Summary of New Exception Contained in Proposed Rule

The Proposed Rule would create a new exception to the beneficiary signature requirements for emergency ambulance transport services. Under this exception, an ambulance provider would be permitted to submit a claim to Medicare for payment without the beneficiary's signature provided each of the following conditions was met:

1. The beneficiary was physically or mentally incapable of signing the claim at the time of service;
2. None of the individuals listed in 42 C.F.R. §424.36(b)(1) – (5) was available or willing to sign the claim on the beneficiary's behalf at the time the service was provided; and
3. The ambulance provider maintains specific information and documentation for at least 4 years from the date of service. The required information and documentation includes:
    a. A contemporaneous statement from an ambulance employee present during the transport, stating that the beneficiary was physically or mentally incapable of signing, and that no other authorized person was available or willing to sign the claim on the beneficiary's behalf.

b. Documentation providing the date and time of the transport, and the name and location of the receiving facility.
c. A contemporaneous statement from a representative of the receiving facility, which documents the name of the beneficiary and the date and time the beneficiary was received by that facility.

While the intent of the proposed exception is to give ambulance providers explicit relief from the beneficiary signature requirements where certain conditions are met, we note that the proposed exception does not grant ambulance providers any greater flexibility than that currently offered by existing regulations. Specifically, 42 C.F.R. §424.36(b)(5) currently permits an ambulance provider to submit a claim signed by its own representative, when the beneficiary is physically or mentally incapable of signing and no other authorized person is available or willing to sign on the beneficiary's behalf. If "provider" in this context was intended to mean a facility or entity that bills a Part A Intermediary, the language should be changed to also include "ambulance supplier". The proposed exception essentially mirrors the existing requirements that the beneficiary be unable to sign and that no authorized person was available or willing to sign on their behalf, while adding additional documentation requirements.

Therefore, we believe that the new exception for emergency ambulance services set forth in proposed 42 C.F.R. §424.36(b)(6) should be amended to include only subsection (i), i.e. that no authorized person is available or willing to sign on the beneficiary's behalf.

It is important for CMS to realize that the first two requirements in the proposed sub-division (ii) are always met, as the ambulance crew will always complete a trip report that lists the condition of the beneficiary, the time and date of the transport and the destination where the beneficiary was transported. For this reason, the AAA does not object to the requirements that an ambulance provider obtain (1) a contemporaneous statement by the ambulance employee or (2) documentation of the date, time and destination of the transport. Nor do we object to the requirement that these items be maintained for 4 years from the date of service. However, we do not see any reason to include these in the Regulation, as they are already required and standard practice.

The Proposed Rule would add a requirement that an employee of the facility, i.e. hospital, sign a form at the time of transport, documenting the name of the patient and the time and date the patient was received by the facility. The American Ambulance Association **strongly objects** to this new requirement as:

- Instead of alleviating the burden on ambulance providers and suppliers, an additional form would have to be signed by hospital personnel.
- Hospital personnel will often refuse to sign <u>any</u> forms when receiving a patient.
- If the hospital refuses to sign the form, it will be the beneficiary that will be responsible for the claim.
- The ambulance provider or supplier would in every situation now have the additional burden in trying to communicate to the beneficiary or their family,

at a later date, that a signature form needs to be signed or the beneficiary will be responsible for the ambulance transportation.

- Every hospital already has the information on file that would be required by this Proposed Rule in their existing paperwork, e.g. in the Face Sheet, ER Admitting Record, etc.

The AAA also strongly objects to the requirement that ambulance providers or suppliers obtain this statement from a representative of the receiving facility *at the time of transport*. Since the proposed rule makes no allowances for the inevitable situations where the ambulance provider makes a good faith effort to comply, but is ultimately unable to obtain the statement, we believe this requirement imposes an excessive compliance burden on ambulance providers and on the receiving hospitals. Consider what this rule requires—the ambulance has just taken an emergency patient to the ER, often overcrowded with patients, and would have to ask the receiving hospital to take precious time away from patient care to sign or provide a form. Forms such as an admission record will become available at a later time, if CMS wants them for auditing purposes.

Institute of Medicine Report on Hospital Emergency Department Overcrowding

The Institute of Medicine Committee on the Future of Emergency Care recently released a report citing hospital emergency department overcrowding as one of the biggest issues in emergency health care. According to that report, demand on hospital emergency departments (EDs) increased by 26% between 1993 and 2003. During that same period, the number of EDs fell by 425. Combined with a similar decrease in the number of inpatient hospital beds, this has resulted in serious overcrowding of our nation's ED. A further consequence has been a marked increase in the number of ambulance diversions, with 50% of all hospitals—and nearly 70% of urban hospitals—reporting that they diverted ambulances carrying emergency patients to a more distant hospital at some point during 2003.

The report recommended that hospitals find ways to improve efficiency in order to reduce ED overcrowding. However, the requirement that ambulance providers or suppliers obtain a statement from a representative of the receiving hospital at the time of transport would only compound the existing problem, by adding an additional paperwork burden. To meet this requirement, ambulance crews would be forced to tie up already overtaxed ED staff with requests for this statement. The Institute of Medicine report makes clear that this time would be more efficiently spent moving patients through the patient care continuum.

Difficulty in Obtaining Hospital Records

The PCS requirement is an excellent analogy for the difficulty ambulance providers and suppliers have in obtaining forms signed by facilities, and how CMS has adopted acceptable alternatives.

Medicare requires ambulance providers and suppliers to obtain a physician certification statement (PCS) from the facility for most non-emergency transports. CMS understood the problem experienced in trying to obtain PCS forms – and that was for non-emergencies. For non-repetitive patients, Medicare regulations provide the ambulance provider with up to 21 days *after* the date of transport to obtain this PCS. Where the ambulance provider is unable to obtain the PCS within this extended period of time, the regulations still permit a claim to be submitted, provided the ambulance provider documented its attempts to obtain the PCS and uses the alternative permitted, i.e. proof of the attempt to obtain the PCS, e.g. by Certified Mail or Proof of Mailing.

In other words, Medicare regulations recognize that obtaining the PCS is, to some extent, outside the control of the ambulance provider, and, accordingly, permit claims to be submitted so long as the ambulance provider takes reasonable steps to comply with the PCS requirement. We believe that, at a minimum, a similar exception should apply to medical emergencies. Treatment and care of the beneficiary should be the overriding focus of all parties, not another form signed by already overburdened ER personnel.

Purpose of Beneficiary Signature

a. Assignment of Benefits – The signature of the beneficiary is required for two reasons. The first purpose of the beneficiary signature is to authorize the assignment of Medicare benefits to the health care provider or supplier. However, assignment of covered ambulance services has been mandatory since April 2002. Furthermore, 42 C.F.R. §424.55(c), adopted November 15, 2004 as part of the Final Rule on the Physician Fee Schedule (67 Fed. Reg. 6236), eliminated the requirement that beneficiaries assign claims to the health care provider or supplier in those situations where payment can only be made on an assignment-related basis. Therefore, the beneficiary's signature is no longer required to effect an assignment of benefits to the ambulance provider or supplier.

CMS recognized this in the Internet Only Manual via Transmittal 643, by adding Section 30.3.2 to Pub. 100-04, Chapter 1. As a result, the beneficiary signature is no longer needed to assign benefits of covered ambulance services.

b. Authorization to Release Records – The second purpose of the beneficiary signature is to authorize the release of medical records to CMS and its contractors. However, the regulations implementing the HIPAA Privacy Rule, specifically 45 C.F.R. §164.506(c)(3), permit a covered entity (e.g. an ambulance provider or supplier) to use or disclose a patient's protected health information for the covered entity's payment purposes, without a patient's consent (i.e. his or her signature). Therefore, federal law already permits the disclosure of medical records to CMS or its contractors, regardless of whether or not the beneficiary's signature has been obtained.

Signature Already on File

Almost every covered ambulance transport is to or from a facility, i.e. a hospital or a skilled nursing facility. In the case of emergency ambulance transports, the ultimate

destination will always be a hospital. These facilities typically obtain the beneficiary's signature at the time of admission, authorizing the release of medical records for their services *or any related services*. The term "related services", when used by hospitals and SNFs, can mean more than only entities owned by or part of the facility. We believe that ambulance transport to a facility, for the purpose of receiving treatment or care at that facility, constitutes a "related service", since the ambulance transports the patient to or from that facility for treatment or admission. Therefore, we believe a valid signature will be on file with the facility. Additionally, for those transports provided to patients eligible for both Medicare and Medicaid, a valid signature is on file at the State Medicaid Office as a product of the beneficiary enrollment process.

Electronic Claims

It is also important to note that, as a result of section 3 of the Administrative Simplification Compliance Act and the implementing regulations at 42 C.F.R. §424.32, with very limited exceptions (e.g. providers or suppliers with less than 10 claims per month), ambulance suppliers must submit claims electronically. Thus, the beneficiary does not even sign a claim form. When submitting claims electronically, the choices for beneficiary signature are "Y" or "N". An "N" response could result in a denial, from some Carriers. That would require appeals to show that, while the signature has not been obtained, an alternative is accepted. As a result, many Carriers allow a "Y", even though the signature was not actually obtained, if one of the exceptions is met.

While this may be a claims processing issue, since you are now looking at the regulation, this would be a good time to add language indicating that the signature requirement will be deemed to be met if one of the exceptions to the requirement exists.

Program Integrity

It is important for CMS to realize that, for every transport of a Medicare beneficiary, the ambulance crew completes a trip report listing the condition of the patient, treatment, origin/destination, etc. AND the origin and destination facilities complete their own records documenting the patient was sent via ambulance or arrived via ambulance, with the date.

Thus, the issue of the beneficiary signature should not be a program integrity issue.

Conclusion

Based on the above comments, it is respectfully requested that CMS:

- Amend 42 C.F.R. §424.36 and/or Pub. 100-02, Chapter 10, Section 20.1.1 and Pub. 100-04, Chapter 1, Section 50.1.6 to state that "good cause for ambulance services is demonstrated where paragraph (b) has been met and the ambulance provider or supplier has documented that the beneficiary could not

sign and no one could sign for them OR the signature is on file at the facility to or from which the beneficiary is transported".

- Amend 42 C.F.R. §424.36 to add an exception stating that ambulance providers and suppliers do not need to obtain the signature of the beneficiary as long as it is on file at the hospital or nursing home to or from where the beneficiary was transported. In the case of a dual eligible patient (Medicare and Medicaid), the exception should apply in connection to a signature being on file with the State Medicaid Office.
- Amend 42 C.F.R. §424.36(b) (5) to add "or ambulance provider or supplier" after "provider".

In light of the foregoing, we urge CMS to forego creating a limited exception to the beneficiary signature requirement for emergency ambulance transports, especially as proposed, and instead eliminate the beneficiary signature requirement for ambulance services entirely if one of the exceptions listed above is met.

AMBULANCE SERVICES – AMBULANCE INFLATION FACTOR

The AAA has no objection to CMS' proposal to revise 42 C.F.R §414.620 to eliminate the requirement that annual updates to the Ambulance Inflation Factor be published in the Federal Register, and to thereafter provide for the release of the Ambulance Inflation Factor via CMS instruction and the CMS website.

Thank you for your consideration of these comments. If you or your staff should have any questions regarding our comments, please contact myself or Tristan North, AAA Senior Vice President of Government Affairs, at 703-610-9018.

Sincerely,

Jim McPartlon
President

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TwinCrest Group
"Bringing specialty physicians together with pathologists for financial opportunities"

DATE: July 20, 2007

TO: Centers for Medicare & Medicaid Services

FROM: Doug Cunningham, Co-Founder, TwinCrest Group

SUBJECT: Comments to File Code CMS-1385-P
"REASSIGNMENT AND PHYSICIAN SELF REFERRAL"

My objective in commenting on the subject proposed rules is to assure that in-office pathology laboratories owned and operated by specialty practices for their patients are not disadvantaged relative to pathology laboratories owned and operated by pathologists. I am not requesting any special considerations for in-office pathology laboratories other than continuation of fair and equal treatment which I believe exists today.

I support many of the proposals to restrict "pod" or "condo" laboratories and a variety of technical / professional fee ("TC / PC") schemes because they are not the intent or spirit of CMS' regulations. These also happen to be issues dear to the pathologist community, although that community's agenda is one of protectionism.

In any revisions to CMS' regulations, I want to be certain that in-office pathology laboratories found in specialty group practices such as dermatology, urology and gastroenterology do not suffer any harm. Some pathologists are not particularly happy about in-office laboratories because they are draining testing volume from the laboratories owned by these pathologists. If that isn't enough of self-interest, the battle cry from these pathologists is now shifting from pod/condo laboratories, in which they feel they have won, to the in-office specialty group practice pathology laboratories. That battle cry includes claims of over-utilization, poor quality of pathology diagnosis and high pricing. Nothing could be further from the truth.

Allow me to explain TwinCrest Group's approach to in-office pathology laboratories so you can have a balanced view in which to gauge the anticipated comments to this File Code from pathology organizations that are working themselves into a heated frenzy to ban in-office pathology laboratories. I have these points to make:

- An in-office pathology laboratory provides better patient service. For example, patient specimens do not leave the practice. There are no lost specimens due to shipment to an off-site reference laboratory. Turnaround time to obtain a test result is far better. There is no searching for reports sent by a reference laboratory. Instead, results are entered directly into the practice's records. And, best of all, the patient can meet with the practice's pathologist to review any adverse test results. In the manner pathology is practiced today, it is a rarity for a pathologist to meet with a patient.

- Pricing in any laboratory is a non-issue. Today it does not matter what a specialty physician or a pathologist wishes to charge because virtually all payers, including Medicare, have a fee schedule they use to reimburse for pathology services. In a number of cases, the fees paid by many carriers are substantially less than fees paid by Medicare.

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- Over-utilization is an over-used excuse. It appears that most pathologists have never heard of the National Comprehensive Cancer Network (NCCN) and the standards they publish for the treatment of an extensive list of virtually all known cancers. That is not the case with specialty practice physicians who pay close attention to these standards. For example, NCCN's Clinical Practice Guidelines in Oncology has a 33 page document titled "Prostate Cancer Early Detection" (version1.2006 issued on 5/17/06) which states on page MS-9: "The panel recommends an extended-pattern 12-core biopsy." TwinCrest supports all of NCCN's standards and encourages specialty practices with in-office pathology laboratories to do the same. The reason for following the standards is two-fold. First, doing less than the standard, unless there is a clear documented medical reason for doing so, subjects the specialty physician to a lawsuit if something goes wrong because the patient was not provided standard of care treatment. Second, doing more than the standard, unless there is a clear documented medical reason for doing so, may cause an unpleasant OIG audit.

- Quality of diagnosis by a pathologist in an in-office pathology laboratory is a non-issue. In most cases, the pathologist who is diagnosing the patient's tissue at the in-office pathology laboratory is generally the same pathologist who would have been diagnosing that same tissue in his/her own pathology laboratory or in a hospital laboratory prior to the existence of the in-office laboratory. Because the pathologist is from a local pathology group, he or she also has access to others in the group to assist in difficult cases. TwinCrest does not recruit, nor does it subscribe to retaining sub-standard pathologists.The pathology organizations who are strongly against in-office laboratories like to use the story of retired pathologists being hired into in-office laboratories with the implication these pathologists do not have the skills to provided quality diagnosis. TwinCrest avoids that argument by assuring the specialty practice only retains pathologists with sub-specialty training in the cases they are to diagnosis.

Also, allow me to explain what TwinCrest Group is and what it does. TwinCrest was formed by three individuals with extensive experience in the laboratory industry. I am one of those individuals. TwinCrest assists specialty practices in providing the full gamut of pathology services to their patients. Here are important points regarding TwinCrest:

- TwinCrest is directly compensated for the services it offers. It does not have any ownership in any in-office laboratory, it does not lease equipment to the specialty practice or its in-office laboratory and it does not lease employees to the specialty practice or its in-office laboratory. In short, there is a contractual relationship with the specialty practice that is clearly arms-length. There are no joint ventures or other questionable arrangements that might infringe on OIG's "safe harbors."

- Laboratory construction is contracted directly by the specialty practice with a contractor selected by TwinCrest.

- Laboratory equipment is selected by TwinCrest but purchased directly by the specialty practice from a very large national distributor.

- TwinCrest recruits histotechnicians candidates for the in-office laboratory and the specialty practice selects the final candidate(s), determines compensation and directly hires the individual(s).

- TwinCrest recruits pathology groups for the in-office laboratory through a formal Request for Proposal (RFP) process and the specialty practice selects the pathology group and negotiates compensation.

- Pathology billing services are contracted directly by the specialty practice with a contractor selected by TwinCrest.

- In the end, the specialty practice owns the built and fully equipped in-office laboratory, has one or more histotechnician employees, has a contract with a local pathology group and an outside pathology billing company. TwinCrest provides consulting services for a period determined by the specialty practice and is paid by the specialty practice for those services.

- TwinCrest provides operating guidelines to the specialty practice in that the in-office specialty practice pathology laboratory must be located within the practice, can only serve the patients of the practice, all pathology professional services must be provided at the in-office laboratory and the laboratory must be inspected and accredited by COLA.

The bottom line is there is a proper way to operate an in-office pathology laboratory for the benefit of patients. TwinCrest is very attentive to CMS' rules and regulations for physician office laboratories (POLs). There are over 106,000 POLs today that are CLIA-registered. And, TwinCrest will abide by any future new or revised rules and regulations promulgated by CMS regarding POLs.

Again, all I ask of CMS on behalf of TwinCrest is that in-office pathology laboratories be treated the same as pathology laboratories owned and operated by pathologists. I ask for no advantage against pathologist-owned laboratories nor is it fair to disadvantage in-office pathology laboratories as some pathologists and pathology organizations wish might occur via a CMS rules and regulations route.

Thank you for accepting these comments. Please contact me if you have any questions regarding TwinCrest Group.

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August 10, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008

Issue Identifier: Medical Nutrition Therapy ("MNT") Services, CPT 97802-4, G0270-1

Dear Sir or Madam:

Midtown Nutrition Care is a single-specialty nutrition group practice with 7 registered dietitians. We have been providing MNT services since 1994 to patients referred to us by their physicians. We have been frequent commenters to Proposed Rules and respectfully submit the following Comment to this year's Proposed Rule:

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Summary of Points

In the 2007 Physician Fee Schedule Final Rule, 71 FR 69645 (Attachment A), work values for CPT 97802-4 were established in the amounts recommended by RUC/HCPAC in July 2000 (Attachment B, the "Interim Recommendations"). These recommendations are based on serious flaws, among the most important of which is that these codes were never surveyed. We submit that CMS should modify the 2007 MNT work values (increasing some and decreasing others), as recommended below.

The two flaws that warrant immediate attention from CMS are:

First, the work values in the Interim Recommendations are based on the work value of a registered dietitian rather than on the work value of a physician. This does not appear to comply with Section 1833(a)(1)(T) of the Social Security Act, as added by PL 106-544, Appendix F, Section 105 (Attachment C), which requires that payment to non-physician nutrition specialists be 85% of the amount that a physician would be paid for providing the same service.

Second, as a result of a methodological error contained in the Interim Recommendations, the work value for the follow-up visit 15-minute time-increment is 27% lower than the work value for the initial visit 15-minute time-increment.

Our Recommendations:

To remedy these flaws, CMS should request that RUC survey the MNT codes and then make work recommendations that may be considered by CMS for the Calendar Year 2009 Physician Fee Schedule.

In the meantime, for Calendar Year 2008, CMS should add 15% to the work values of the MNT codes, as recommended by RUC/HCPAC in their 2001 Amended Recommendation, which superceded their July 2000 Interim Recommendations. Alternatively, CMS could crosswalk the work value for MNT services to an appropriate physician service.

In addition, for Calendar Year 2008, CMS should assign the same work value to both the initial visit 15-minute time-increment (CPT 97802) and to the follow-up visit 15-minute time-increment (CPT 97803 and G0270). CMS should also adopt work values for the group visit 30-minute time-increment (CPT 97804 and G0271) that would generate an hourly equivalent to the individual visit 15-minute time-increment.

The resulting new interim RVUs should be included in the to be published "Codes with Interim RVUs" Addendum to the 2008 Physician Fee Schedule Final Rule with Notice (which was Addendum C to the Final Rules the past 2 years).

History of the Creation and Valuation of the MNT Codes

Prior to 2000 there were neither CPT codes for MNT services provided by non-physician nutrition specialists, nor was there a Medicare benefit that allowed payment to be made to non-physician nutrition specialists for the provision of MNT services. On the other hand, physicians could and did provide MNT services to Medicare beneficiaries under Section 1861(s)(1) of the Social Security Act. According to the Institute of Medicine report, "The Role of Nutrition in Maintaining Health in the Nation's Elderly", released on January 1, 2000, page 267: "The physician is responsible for prescribing nutrition therapy and may also provide and bill for this service under Part B of Medicare." Attachment D hereto contains three scenarios of physicians providing MNT services to Medicare beneficiaries.

In July 2000 the CPT Editorial Panel adopted 3 codes for MNT services, CPT 97802-4, effective for the 2001 CPT edition. The Editorial Panel also placed a note beneath the codes that directed physicians who perform the service to use other CPT codes, namely, E/M codes when the visit is for the purpose of disease management. Attachment E hereto contains the full text of the 3 codes and the commentary text following, as it has appeared in the CPT 2001 edition through the CPT 2007 edition.

On August 1, 2000, RUC/HCPAC transmitted their July 2000 Interim Recommendations to CMS (Attachment B). Since the codes were meant to be used by registered dietitians, the codes were valued as services performed by registered dietitians, not by physicians: "New code 97802 Medical nutrition therapy; initial assessment and intervention, individual, face-to-face with the patient, each 15 minutes, was created to describe both the assessment as well as intervention which regularly includes behavior components requiring advanced skills and knowledge by a registered dietitian."

Five months later, on December 21, 2000, Congress passed Public Law 106-554, Appendix F, Section 105 (Attachment C), which made MNT services provided by non-physician nutrition specialists a covered Medicare benefit for patients with diabetes or renal disease, beginning January 1, 2002. The law defined MNT services as nutritional diagnostic, therapy and counseling services for the purpose of disease management, provided upon physician referral, and fixed reimbursement for non-physician nutrition specialists at 85% of the amount that would be paid to physicians for providing the same service. Sections 1861(vv)(1) and 1833(a)(1)(T) of the Social Security Act, see Attachment C.

In the 2007 Physician Fee Schedule Final Rule (Attachment A) CMS adopted as work values for the codes the registered dietitian's values contained in the Interim Recommendations (Attachment B), so registered dietitians and nutrition professionals are now being paid 85% of their own value, instead of 85% of what a physician would be paid.

The published legislative history regarding compensation is very brief. The Statement of the Manager for Section 105 (see last page of Attachment C) has only one sentence devoted to compensation: "The provision would specify that the amount paid for medical nutrition therapy services would equal the lesser of the actual charge for the service or 85% of the amount that would be paid under the physician fee schedule if such services were performed by a physician."

Because the published legislative history does not specifically address the issue of whether the registered dietitian's own value may be used as the basis for the statutory 85% discount, we met with and had a series of communications with the staff of Congressman Jose Serrano, the original House sponsor of the MNT benefit. We asked whether the use of the registered dietitian's work values in the Interim Recommendations as the basis for the statutory 85% discount was in the opinion of the Congressman compliance with the statute. Congressman Serrano did not think so and wrote a June 15, 2007 letter to CMS (Attachment F) in which he stated: "The law is premised on the work value of the service when provided by a physician being higher than the work value of the service when provided by a non-physician. Therefore, the work value should always be linked to a physician work value instead of being used as a replacement, as in the current interpretation of the law." Because there is no published legislative history that addresses this specific issue, we believe it would be appropriate for CMS to give deference to the written opinion of Congressman Serrano, the original House sponsor of the legislation.

Point 1: CMS Should Enable a RUC Survey

Since the adopted codes CPT 97802-4 were never surveyed, CMS should enable a RUC survey. RUC recommendations based upon a survey will provide CMS with better information with which to value these codes for Calendar Year 2009.

Point 2: In the Meantime, for Calendar Year 2008, CMS Should Modify the RUC/HCPAC July 2000 Interim Recommendations By Adding Back 15% Pursuant to the RUC/HCPAC 2001 Amended Recommendation

For Calendar Year 2008 CMS should modify the RVUs in the July 2000 Interim Recommendations by adding 15% to those RVUs as recommended by RUC/HCPAC in 2001 (their "Amended Recommendation"): In 2001 RUC/HCPAC amended their July 2000 Interim Recommendations stating that "the 15% reduction should not apply" (i.e., should not be applied twice). 66 FR 55278, middle column, near bottom

If CMS is going to base work values on RUC/HCPAC recommendations pending a survey, we submit that CMS should use RUC/HCPAC's most up-to-date recommendation; that is, the 2001 Amended Recommendation.

To implement the 2001 Amended Recommendation, CMS would divide the work values in the Interim Recommendations by .85; for example, the CPT 97802 work RVU of **0.45** divided by .85 = **0.53**.

Point 3: In the Alternative, for Calendar Year 2008, CMS Could Modify the July 2000 Interim Recommendations By Cross-Walking to an Appropriate Physician Code

The requirements for performing an MNT service are set forth in "Evidence Based Nutrition Practice Guidelines" (http://www.adaevidencelibrary.com) and "CPT Reference of Clinical Examples: Official Scenarios for Correct Coding 2007", pages 352-354.

The requirements include:

- Taking a problem focused or expanded problem focused medical history by reviewing labs and other reports from the referring physician and interviewing the patient;
- Performing a problem focused examination, which will include an anthropometric examination, and could also include additional examination such as taking blood pressure or examining affected body areas such as the skin for diabetic acanthosis nigricans or the extremities for pressure ulcers that may be connected with protein-calorie malnutrition (all of which lower level physical examination the non-physician nutrition specialist is trained to do, see the Institute of Medicine report, "The Role of Nutrition in Maintaining Health in the Nation's Elderly", released on January 1, 2000, Appendix E: The American Dietetic Association Foundation Knowledge and Skills and Competency Requirements for Entry-Level Dietitians); and
- Engaging in straightforward or low complexity medical decision making, which will include prescribing or modifying nutrient and/or micronutrient intake and/or supplementation, and could include additional medical decision making such as

matching carbohydrate to insulin dose or using carbohydrate counting/insulin ratios.

MNT services are ambulatory services in which more than 50% of the face-to-face time of the visit is spent counseling. MNT services are thus comparable to E/M services in which 50% or more of the time is spent counseling, where time may be the controlling factor. Using time, there are two 15-minute E/M codes that could describe the value of the physician's 15-minute time increment when providing MNT services, CPT 99241 Office Consultation and CPT 99213 Office Visit.

Because the levels of history taking, physical examination and decision making in the MNT visit are comparable to CPT 99241 we believe it would be appropriate for CMS to crosswalk the work RVU of 99241 (**0.64**). CPT 99213 does not have comparable levels of history taking, physical examination, and decision making, so a crosswalk to CPT 99213 does not seem as appropriate. CPT 99241 appears especially appropriate because it is a consultation code, and the law requires that the MNT visit be upon physician referral, to whom a report is written after the visit.

One may question, however, whether the problem focused examination (a limited examination of the affected body area or organ system) required by CPT 99241 can be met by the anthropometric examination that occurs in an MNT consultation. We believe it does, but submit that physicians would in any event report MNT using codes where at least two of the three components are performed. However, if CMS prefers to crosswalk MNT to a code where there is no physical examination, it could look to CPT 90804, the 20 to 30 minute Insight Oriented, Behavior Modifying and/or Supportive Psychotherapy service. The heart of MNT is counseling, and CPT 90804 is a physician's non-E/M counseling code. (If E/M services are also involved CPT 90805 would be reported.) The CPT 90804 work value would be **0.73** for 15 minutes of physician time (**1.21** work value X 2.4 = 2.904 per hour ÷ 4 = 0.726 for 15 minutes), which is slightly higher than the CPT 99241 work RVU of **0.64**.

Point 4: In Addition, for Calendar Year 2008, CMS Should Use the Same Work Values for the Individual Codes and an Hourly Equivalent for the Group Codes

The Interim Recommendations set the work value of the initial visit 15-minute time-increment (CPT 97802) at **0.45** and set the work value of the follow-up 15-minute time-increment (CPT 97803) at **0.37**, a 27% reduction.

Most time-based services do not distinguish between initial and follow-up visits, so all time increments, whenever provided, are paid the same. Examples include (a) the psychotherapy codes CPT 97804 and 97805, (b) the psychological testing and exam codes CPT 96101, 96116 and 96118, (c) the health and behavioral intervention code CPT 96152, (d) the physical and occupational therapy codes CPT 97110, 97352, 97535, 97750 and 97755, and (e) the orthotic and prosthetic codes, CPT 97760 and 97761.

There is only one time-based service in the CPT that has separate codes for initial and follow-up visits, the health and behavior assessment codes CPT 96150 (initial assessment) and CPT 96151 (re-assessment). The work value for the initial assessment is **0.50** and the work value for the follow-up assessment is **0.48**, a reduction of only 4%.

How did the follow-up MNT time-increment come to be valued at 27% less than the initial visit MNT time-increment? To understand this, we must look again at the history of the creation and valuation process of these codes.

When MNT codes were first proposed by the CPT Editorial Panel, there were 7, complexity-based, not time-based, codes that were provisionally approved and surveyed in March, 2000:

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

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

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

978X4 Medical nutrition therapy reassessment and intervention, low complexity

978X5 Medical nutrition therapy reassessment and intervention, moderate complexity

978X6 Medical nutrition therapy reassessment and intervention, high complexity

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

However, as previously mentioned, the codes actually adopted were never surveyed. These are the existing codes:

97802 Medical nutrition therapy; initial assessment and intervention, individual, face-to face with the patient, each 15 minutes

97803 re-assessment and intervention, individual, face-to-face with the patient, each 15 minutes

97804 group (2 or more individuals), each 30 minutes

(For medical nutrition therapy assessment and/or intervention performed by a physician, see **Evaluation and Management** or **Preventive Medicine** service codes)

The survey values of the complexity-based codes were not used by RUC/HCPAC to generate work values for the time-based codes, see Attachment B. Instead the **0.45** work value of the physical therapy 15-minute time-increment of CPT 97110 (used for

both initial and follow-up physical therapy visits) was cross-walked to the MNT initial visit 15-minute time-increment.

However, the survey time data was used. It showed initial visits would average a total time of 75 minutes while follow-up visits would average a total time of 55 minutes, or 27% less time. Based on this, RUC/HCPAC reduced the work value of the follow-up visit 15-minute time-increment by 27% to "maintain relativity" as between the codes, see the second page of the Summary of Recommendations, Attachment B.

This was inappropriate. The complexity-based codes had been replaced by time-based codes so there was no need to reduce the work value of the follow-up time-increment by 27%, a follow-up visit would take less time so would have fewer time-increments and generate a lower payment. Reducing the work value of the follow-up 15-minute time-increment results in an unintended double reduction of the fee, first for fewer time increments, then for a lower value of the time-increment. CMS recognized this and used its authority to correct the 27% reduction error for Calendar Years 2002-2006, and should do so again:

"A commenter representing dietitians asked us to review the relativity of payment across the three medical nutrition CPT codes. The commenter indicated that payment for CPT code 97803 was set at 72.9 percent of proposed RVUs for CPT 97802 and 97804 was set at 31 percent of CPT code 97802. The commenter argues that, because reassessments are shorter than initial assessments, the proposed RVUs are actually discounted twice (that is, less payment per 15 minutes of time as well as less total time). They believe the value of CPT codes 97802 and 97803 should be identical.... We have reviewed the payments for CPT codes 97802 and 97803 and agree with the commenter that these two codes should have the same values. The essential difference between an initial and follow up medical nutrition therapy service is the time spent performing the service. Initial visits will be longer than follow-up visits and will likely involve Medicare payment for more increments of service. We will pay less for follow up visits because they will typically involve fewer 15-minute increments of time than an initial visit. The payment rate we are establishing in this final rule for CPT code 97803 will be the same as the proposed rate for CPT code 97802. We have also changed the payment rate for CPT code 97804 assuming that the code will normally be billed for 4 to 6 patients with the average of 5. Using the revised values, the payment rate for group medical nutrition therapy would approximate the hourly rate paid for other medical nutrition therapy services." 68 FR 55280, first-second columns

The MNT code values for Calendar Years 2002-2006 did not include work values, but instead included dietitian clinical labor time in the Practice Expenses. In Calendar Year 2007 clinical labor time has been replaced by time-based work values, but this substitution should not cause CMS to change its previous reasoning. RUC/HCPAC found that the only difference between initial and follow-up MNT services is the length of the visit. Therefore, until these codes are surveyed, CMS should correct the methodological error and establish the same work values for CPT 97802 and CPT 97803 (and G0270), just as it had established the same clinical labor values prior to 2007.

Under the 2007 valuation, follow-up time-increments are treated as if they are less intense than initial time-increments. However, since the codes are time-based, not intensity based, a lower work value should be established only if a survey shows that the respondents believe follow-up visits are less intense. In the meantime, CMS should not adopt RUC/HCPAC's flawed methodology, which itself was not based on a difference in intensity – it was based on an (erroneous) difference in time. RUC/HCPAC simply applied an (erroneous) methodological formula to the average total time of the initial and follow-up visits. If the average times had been 75 minutes and 45 minutes the flawed methodology would have created a discount of 40%; if 75 minutes and 65 minutes, the flawed methodology would have created a discount of 13%. We request that CMS correct this error and, pending survey results, assign the same work RVUs to CPT 97802 and CPT 97803 (and G0270). CMS should do this regardless of whether it increases the work RVUs for Calendar Year 2008 (either by 15% or by a crosswalk).

To avoid a rank order anomaly in these codes, if CMS agrees that the 15-minute time-increment work values should be the same pending a survey, CMS should also follow its prior reasoning with regard to the 30-minute time increment work values in the group codes CPT 97804 and G0271, giving them hourly equivalent values by multiplying by 2 to go from 15 to 30 minutes, then dividing by 5, the average number of patients in a group. This will cause a reduction in the current group work RVU of **0.25**, but will establish a more consistent value pending the completion of a survey.

Sincerely yours,

Robert Howard, RD, JD
Managing Partner

Attachment A

Federal Register / Vol. 71, No. 231 / Friday, December 1, 2006 / Rules and Regulations **69645**

c. Medical Nutrition Therapy Services

In 2000, the Health Care Professional Advisory Committee (HCPAC) recommended that we assign work RVUs to three new medical nutrition therapy (MNT) CPT codes: 97802, *Medical nutrition therapy; initial assessment and intervention, individual, face-to-face with the patient, each 15 minutes* at 0.45 RVUs; 97803, *Medical nutrition therapy; reassessment and intervention, individual, face-to-face with the patient, each 15 minutes* at 0.37 RVUs; and 97804, *Medical nutrition therapy; group (two or more individuals), each 30 minutes* at 0.25 RVUs. However, during rulemaking for the CY 2001 PFS final rule, we indicated that MNT was not covered because there was no statutory benefit category that would allow medical nutritionists to bill these services. We also did not accept the HCPAC recommendations for work RVUs for these MNT services because

the codes were designed for use only by nonphysicians. The following year, section 105(c) of the Medicare, Medicaid, and State Child Health Insurance Program Benefits Improvement Protection Act of 2000 (BIPA) (Pub. L. 106–554) provided for the coverage of MNT services when furnished by registered dietitians or nutritional professionals at 85 percent of the amount that a physician would be paid for the same services. As a result, we established values for these MNT services for the CY 2002 PFS. In keeping with our earlier decision, we did not assign the HCPAC-recommended work values. However, the associated work value for each code was utilized in the conversion of work to clinical labor time for MNTs as part of the PE component. At that time we received several comments, including one from the American Dietetic Association (ADA), urging us to adopt the work values recommended by the HCPAC.

More recently, the ADA has requested us to reconsider our decision not to accept the HCPAC recommended work RVUs. The ADA contends that the payment rate established by section 105(c) of BIPA, 85 percent of the PFS

amount that would be paid for the same service if furnished by a physician, is based on the premise that work values are inherent to these MNT services. The ADA believes that without work RVUs, the payment for these services does not reflect 85 percent of what a physician would be paid for performing the same service. Because these MNT codes were created specifically for MNT professionals, the ADA compared the work associated with their services to physician E/M services of CPT codes 99203 and 99213, which have respective work RVUs of 1.34 and 0.67.

After reviewing the issues and relevant arguments raised by the ADA, we are persuaded that it would be appropriate to include work RVUs for the MNT services. Consequently, we proposed to establish work RVUs for each code at the level previously recommended by the HCPAC, as follows:

- CPT code 97802 = 0.45 RVUs.
- CPT code 97803 = 0.37 RVUs.
- CPT code 97804 = 0.25 RVUs.

Because we proposed to add the work RVUs to these services, the MNT clinical labor time in the direct input database will be removed. Additionally,

two HCPCS codes, G0270, *MNT subs tx for change dx* and G0271, *Group MNT 2 or more 30 mins* were created to track MNT services following the second referral in the same year and these HCPCS codes correspond to CPT codes 97803 and 97804, respectively. Therefore, we also proposed to add the same work RVUs to these HCPCS codes and to delete the MNT clinical labor inputs from the PE database upon adoption of this policy. We encouraged specialty societies and other professional groups to comment on this proposal.

Comment: We received comments from the ADA, several MNT providers, one drug company, the National Kidney Foundation and one Congressional member all supporting our decision to establish work RVUs for the MNT services. Further, several commenters joined the ADA in requesting an increase in the proposed work RVUs. In justification of their request, the ADA and other commenters compared these services to CPT codes 99213 (mid-level E/M service) and 90804 (individual psychotherapy service). These commenters also requested that the total work RVUs for 97802, 97803, and G0270

be equal and the total work RVUs for CPT code 97804 and HCPCS code G0271 also be equal. In addition, the ADA provided specific supplies and equipment to be added to the PE database in order to facilitate correct PE calculations for these codes.

Response: We appreciate that the commenters acknowledge and support our decision to establish work RVUs for the 5 MNT services. However, we do not believe it would be appropriate to accommodate the request to increase these work RVUs. We believe that the HCPAC work recommendations best represent the MNT services and encourage the ADA to utilize the established RUC or HCPAC processes to further assess valuation of their services. For this reason, we will maintain the proposed work values for all MNT CPT/ HCPCS codes. However, we have added the supplies and equipment to the PE database as requested.

Attachment B

Memo to: Paul Rudolf, MD, JD

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

Date: August 1, 2000

Subject: HCPAC Review Board Recommendations for Medicare Fee Schedule 2001

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

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

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

cc: Rick Ensor
Carolyn Mullen
Terry Kay

RUC HEALTH CARE PROFESSIONALS ADVISORY COMMITTEE REVIEW BOARD SUUMARY OF RECOMMENDATIONS

July 2000
Medical Nutrition Therapy

CPT Code 97802

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

Practice Expense Recommendations
The HCPAC agrees to the attached list of practice expenses for CPT 97802.

CPT Code 97803

Work Relative Value Recommendation

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

Practice Expense Recommendations

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

CPT Code 97804

Work Relative Value Recommendation

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

Practice Expense Recommendations

The HCPAC agrees that the attached list of in office direct inputs represent the practice cost to perform this procedure.

Attachment C

PUBLIC LAW 106–554—-DEC. 21, 2000

* * *

APPENDIX F — H.R. 5661

SECTION 1. SHORT TITLE; AMENDMENTS TO SOCIAL SECURITY ACT; REFERENCES TO OTHER ACTS; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000".

(b) AMENDMENTS TO SOCIAL SECURITY ACT.—Except as otherwise specifically provided, whenever in this Act an amendment is expressed in terms of an amendment to or repeal of a section or other provision, the reference shall be considered to be made to that section or other provision of the Social Security Act.

(c) REFERENCES TO OTHER ACTS.—In this Act:

(1) BALANCED BUDGET ACT OF 1997.—The term "BBA" means the Balanced Budget Act of 1997 (Public Law 105–33; 111 Stat. 251).

(2) MEDICARE, MEDICAID, AND SCHIP BALANCED BUDGET REFINEMENT ACT OF 1999.—The term "BBRA" means the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (Appendix F, 113 Stat. 1501A–321), as enacted into law by section 1000(a)(6) of Public Law 106–113.

(d) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

Sec. 101. Coverage of biennial screening pap smear and pelvic exams.

Sec. 102. Coverage of screening for glaucoma.

Sec. 103. Coverage of screening colonoscopy for average risk individuals.

Sec. 104. Modernization of screening mammography benefit.

Sec. 105. Coverage of medical nutrition therapy services for beneficiaries with diabetes or a renal disease.

* * *

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

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

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

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

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

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

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

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

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

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

"Medical Nutrition Therapy Services; Registered Dietitian or Nutrition Professional

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

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

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

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

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

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

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

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

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

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

(d) APPLICATION OF LIMITS ON BILLING.—Section 1842(b)(18)(C) (42 U.S.C.1395u(b)(18)(C)) is amended by adding at the end the following new clause:

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

(e) EFFECTIVE DATE.—The amendments made by this section shall apply to services furnished on or after January 1, 2002.

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

Statement of the Manager For Section 105

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

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

Attachment D

Three Scenarios of Medical Nutrition Therapy Provided By Physicians

According to the Centers for Disease Control and Prevention June 23, 2006 National Ambulatory Care Survey: 2004 Summary, in 12.8% of office visits physicians ordered or provided nutrition counseling, education, or therapeutic services. Three scenarios are given below of physician services that would be considered Medical Nutrition Therapy services for Medicare beneficiaries.

Medical Nutrition Therapy services are defined by Section 1861(vv)(1) of the Social Security Act, as nutritional diagnostic, therapy, and counseling services for the purpose of disease management provided upon physician referral. Section 1861(s)(2)(V) of the Social Security Act, limits Medicare coverage of Medical Nutrition Therapy services to patients with diabetes or renal disease, about 10 million out of approximately 40 million Medicare beneficiaries. Because the statute requires the service to be for the purpose of disease management and limits coverage to patients with diabetes or renal disease, the scenarios given below will not include preventive medicine counseling services or morbidities other than diabetes or renal disease.

The first scenario is an office consultation in which nutritional diagnostic, therapy, and counseling services for the purpose of disease management are a part of the consultation, which includes other services. The second two scenarios are of office consultations which consist solely of nutritional diagnostic, therapy, and counseling services for the purpose of disease management--the first because the services of a non-physician nutrition specialist are not readily available, the second because a physician is chosen

to perform the services despite the availability of a non-physician nutrition specialist.

Scenario 1--Part of an Office Consultation That Includes Other Services

Patient A, a 72 year-old male, is referred to Dr. X, a nephrologist, because recent tests show a decline in Patient A's GFR. Patient A has hypertension, for which he has been taking blood pressure-lowering medication for several years.

Dr. X diagnoses Patient A with chronic renal failure; increases Patient A's blood pressure-lowering medication; and spends 30 minutes of the visit in which Dr. X: performs an anthropometric examination; reviews Patient A's food and medication history; assesses that Patient A consumes a high protein, high sodium diet; prescribes as nutrition therapy a low protein, low sodium diet; informs Patient A orally and with written materials which foods and seasonings should be consumed and which should be avoided; and counsels Patient A as to ways for achieving the prescribed dietary changes. After the visit Dr. X prepares and sends a report to the referring physician.

Scenario 2--Consultation Solely Medical Nutrition Therapy; Non-Physician Nutrition Specialist Not Available

Patient B, a 70 year-old female, is referred to Dr. Y, a bariatric physician, because Patient B has been gaining weight for about 10 years, was diagnosed with Type 2 diabetes 3 years ago, is taking appropriate doses of oral hypoglycemic medication, but is not achieving good blood glucose control. In her small town there are no non-physician nutrition specialists so Patient B has been referred to Dr. Y.

Dr. Y tells Patient B to keep a food journal prior to the visit and schedules a 45-minute visit, at which Dr. Y: performs an anthropometric examination; reviews Patient B's diet history; assesses that her diet is high in simple carbohydrate and calories; prescribes a lower simple carbohydrate, lower calorie meal plan; and counsels Patient B as to how to achieve the changes required by the prescribed meal plan. After the visit Dr. Y prepares and sends a report to the referring physician.

Scenario 3--Consultation Solely Medical Nutrition Therapy; Non-Physician Nutrition Specialist Available But Physician Chosen to Perform the Service

Patient C, a 23 year-old disabled male, is referred to Dr. Z, an endocrinologist, because Patient C has had Type 1 insulin-dependent diabetes since he was 16 (not the cause of his disability), but is not achieving good blood glucose control despite having been started on intensive insulin therapy, which involves taking 1 or 2 injections per day of long acting basal insulin and 3 to 4 injections per day of fast acting insulin to control the blood glucose rise caused by meals.

Dr. Z tells Patient C to keep a 3-day timed history of Patient C's food, insulin doses and blood glucose readings, and schedules a 45-minute visit in which Dr Z: performs an anthropometric examination; determines how well Patient C is matching the carbohydrate grams he consumes to his adjustable insulin unit dosage (called the carbohydrate counting and insulin ratio method of determining mealtime dosage), adjusts the ratios, as appropriate, and counsels Patient C on ways to improve his skill in counting carbohydrate grams. After the visit Dr. Z prepares and sends a report to the referring physician.

Attachment E

Medical Nutrition Therapy CPT Codes (Effective January 1, 2001-present)

Medical Nutrition Therapy

97802 Medical nutrition therapy; initial assessment and intervention, individual, face-to face with the patient, each 15 minutes

97803 re-assessment and intervention, individual, face-to-face with the patient, each 15 minutes

97804 group (2 or more individuals), each 30 minutes

(For medical nutrition therapy assessment and/or intervention performed by a physician, see **Evaluation and Management** or **Preventive Medicine** service codes)

Attachment F

JOSE E. SERRANO
[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

COMMITTEE:
APPROPRIATIONS

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

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

June 15, 2007

Leslie Norwalk, Esq.
CMS Acting Administrator
200 Independence Avenue, SW--Room 314G
Washington, DC 20201

Dear Ms. Norwalk:

As sponsor of the original medical nutrition therapy benefit bills in the mid 90s and cosponsor of the 1999 bill that eventually became law, as Section 105 of PL 106-544, I am concerned that CMS has misinterpreted Congress' intent with regard to reimbursement rates for nutritional therapists.

As you prepare the Calendar Year 2008 Physician Fee Schedule rule pertaining to medical nutrition therapy benefits, please be aware that the law provides that payment to registered dietitians and nutrition professionals be 85% of the amount that would be paid to physicians for providing the service. The current interpretation of the law pays registered dietitians and nutrition professionals 85% of their own value.

This interpretation subverts the intent of the law, which is that physicians would continue to provide the service as they had prior to the statute and that the work value of the service be the work value of a physician providing the service. The law is premised on the work value of the service when provided by a physician being higher than the work value of the service when provided by a non-physician. Therefore, the work value of a registered dietician should always be linked to a physician's work value instead of being used as a replacement, as in the current interpretation of the law.

I have reviewed the attached request of Midtown Nutrition Care and ask that it be given every consideration as the rule in question is formulated.

Sincerely,

Jose E. Serrano
Member of Congress

Appalachian Physical Therapy, Inc.

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August 15, 2007

Mr. Kerry N. Weems
Administrator-Designate
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

RE: Medicare Program; Proposed Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Rule.

Dear Mr. Weems:

I am a practicing physical therapist and have practiced now for 31 years. 21 of those years have been in my own private practice and I have practiced in several states across this great nation. I am very fortunate to be able to use the skills I have to help many individuals reach their full potential and remain active, especially aging adults.

It remains a mystery to me how we can afford the practice of self referral with physicians employing physical therapist to "serve" their patients. We know from many examples that this practice is detrimental to the public and recently have a very disturbing report from the OIG dated May 1, 2006 outlining this very same practice.

I could fill up an entire library with examples of increased cost, reports of extremely poor and costly care that could and should have been avoided. Preventing this from happening and covering this loophole in the Stark law would save millions alone in benefits paid that are proven to be bogus, unregulated and often performed with unlicensed individuals. This does not even take into consideration the loss of time and function that our seniors are experiencing due to this growing business.

I would urge CMS to take a stance and say enough! Help protect our citizens against less than optimum health care. Help us as a country in providing good stewardship of our hard earned money in taking control of an ever growing problem that is way out of control. **Remove physical therapy from the "in-office ancillary services" exception to the federal physician self-referral laws.**

Thank you for your time with this matter and if I can be of help, please feel free to contact me.

Sincerely,

Bill Whiteford, PT
Appalachian Physical Therapy, *President*

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Jeff Giulietti, MPT, ATC, OCS, CSCS, COMT, FAAOMPT
Christy Karcher, PT, OCS, Cert. MDT, CSFA
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Neisha Lundberg, MSPT, CSCS
Todd Covington, PT, CWS

August 16, 2007

"....Excellence as a Standard of Care...."

Mr. Kerry N. Weems
Administrator - Designate
Centers for Medicare and Medicaid Services
U S. Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

RE: Medicare Program; Proposed Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Rule

EMPHASIS: **Physician Self-Referral Issues**.

Dear Mr. Weens:

I wish to comment on the proposed 2008 July 12 Physician Fee Schedule Rule, specifically the issue surrounding **Physician self-referral and the "in-office ancillary services" exception.**

I am a Physical Therapist in private practice in Eugene, Oregon. I have been an active clinician for 18 years, and have seen much change in both medical and physical therapy practice in those 2 decades.

Despite Stark I & Stark II Anti-trust legislation, their continues to be rampant ABUSE of Physicians who are self-referring to Physical Therapy services they HOLD OWNERSHIP or financial interest in. In my 2 decades of practice, I have seen no change in this Physician behavior.

Despite the Oregon Medical Association having strict guidelines that say "it is illegal for a Physician to force a patient to see a specific Physical Therapist", this occurs quite frequently. They are failing to take any action. We have patients that continue to tell us that their physician (in large company based practices), advised them "they had to see 'their Physical Therapist'". How did we see these patients? We are completely independent, have no financial relationships with any medical company, and have a "Reputation for Clinical Excellence" in our community, and have clinical staff with nationally recognized advanced credentials of distinction. ***Quality of care should dictate referrals, not financial incentives for profit.***

Nationally, Physicians are presently owning and controlling Physical Therapy Departments and services by cloaking themselves in "company ownership." I have "inside knowledge" of such practices here locally. I previously worked for a company as a Director of a private out-patient clinic (it had no Physician ownership). My former company chose to take a contract to Manage a Physical Therapy clinic "in-house" and still holds a contract to provide Physical Therapy services to one of our larger Physician groups. This Physician group has strict recommendations that all physicians refer "in-house" (although they can't force the physician), with the Physicians receiving a higher profit from the contract if more patients are referred. This is still "Referral for Profit" and is considered unethical use of ancillary services. And yet it continues.

I no longer associate with this company. Locally, another large Physician Company Group, which has over 5 PT clinics "in-office", has the same problem, although we hear less similar complaints from their patients.

I urge you to tighten RULES that simply put, removes all possible potential for increased profits distributed to a physician, based on services rendered by a Physical Therapist.

Jeff Giulietti, MPT, OCS, FAAOMPT
Private Practice Co-Owner
Physical Therapist, Masters degree (MPT)
Board Certified Orthopaedic Clinical Specialist (OCS)
Fellow, American Academy of Orthopaedic Manual Physical Therapy (FAAOMPT)
Member, American Physical Therapy Association (APTA)

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LIFELINE
SPECIALTY OUTPATIENT CENTERS
PHYSICAL THERAPY & PULMONARY REHAB

August 17, 2007

Mr. Kerry N. Weems
Administrator – Designate
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Subject: Medicare Program; Proposed Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Rule

Purpose: **Physician Self-Referral Issues**

I have been a physical therapist since 1995. I am currently practicing in a private practice located in Forest Hills, Pennsylvania where I have been for the last two years. I am enrolled in Chatham University's Transitional Doctoral of Physical Therapy program with the goal of protecting the ability to practice autonomously.

I wish to comment on the July 12 proposed 2008 physician fee schedule rule, specifically the issue surrounding physician self-referral and the "in-office ancillary services" exception.

In the case of physician-owned physical therapy services, there is potential for fraud and abuse. When physicians are able to refer Medicare beneficiaries to entities in which they have a financial interest, there is an inherent incentive to do so/overutilize services. This financial incentive can outweigh regard to the best interest of the Medicare beneficiary.

The "in-office ancillary services" exception is defined so broadly in the regulations that it facilitates the creation of abusive referral arrangements. By eliminating physical therapy as a designated health service furnished under the in-office ancillary services exception, CMS would reduce a significant amount of the aforementioned fraud and abuse.

Due to the repetitive nature of physical therapy services, it is no more convenient for patients to receive services in the physician's office than in any independent physical therapy clinic.

Lastly, physician direct supervision is not needed to administer physical therapy services.

I thank you for your consideration of my comments.

Sincerely,

Jeanette Kochman, MPT

Forest Hills
412-829-2450
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McMurray, PA 15317

Warrendale
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Fax: 724-933-3288
Suite 300
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Warrendale, PA 15086

108

NORTH HILLS
ORTHOPEDIC AND SPORTS
PHYSICAL THERAPY

DIRECTOR
Steven A. Hoffman, PT, ATC, SCS
Board Certified Sports Physical Therapist

THERAPISTS
Christopher J. Hughes, PT, Ph.D., OCS
Gordon Riddle, PT, ATC
Omar A. Ross, PT, ATC

August 16, 2007

Mr. Kerry N. Weems
Administrator-Designate
Centers for Medicare and Medicaid Services
U. S. Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Subject: Medicare Program; Proposed Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Rule

Dear Mr. Weems:

I am a Physical Therapist in Pittsburgh, Pennsylvania and I have been in private practice for 14 years. The purpose of my letter is to bring to your attention the concern I have regarding physician self-referral and the "in-office ancillary services" exception for the proposed 2008 physician fee schedule rule. The purpose of my letter is to relay my concerns regarding the potential abusive nature of Physician Owned Physical Therapy Services (POPTS) and request that physical therapy services be **removed** from those permitted services under the in-office ancillary exception.

I have been a Physical Therapist for 29 years. Early in my career, the concept of Physician Owned Physical Therapy Services (referral for profit entities) was quite common. In the early 1990's, Representative Pete Stark introduced a bill to ban physician self-referral, as it was shown through extensive study that abusive billing practices existed, patients were coerced to receiving services at the facilities the physicians owned, and freedom of choice was essentially squelched. "Loopholes" in the Stark II legislation created an avenue for physicians to open up their own physical therapy practices once again, and as a result, individuals such as myself are seeing a significant drop in patient referrals, income, and many have been forced to lay off employees or close their practices. In addition, patients are being funneled into the practices the physicians own, completely eliminating their freedom of choice and the potential for better services.

I have personal relationships with many physicians, particularly orthopedic surgeons in the Pittsburgh area. When I questioned them as to why they were opening up their own physical therapy practices, one told me that his practice was "forced" into this venture because of the drop in reimbursement they were experiencing for their own medical services. Another told me that the passive income derived from owning a physical therapy practice would help to pay for his child's college education. Others have told me that self-referral is a way for them to derive a significant increase in their annual income.

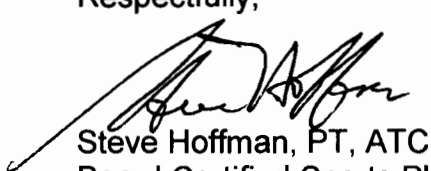
I have heard from patients who have been referred to physician owned practices. They were not given a choice as to where they may receive physical therapy. They also said they were encouraged to attend physical therapy for as long as possible until their insurance benefits expired. I also lost 3 employees to a physician owned practice.

The purpose of my letter is to request that CMS **remove** physical therapy as a designated health service under the in-office ancillary exception of the federal physician self-referral law. When physicians refer patients to their own physical therapy practice, there is a conflict of interest and when a referral causes them to earn profits, the physicians are no longer objective. It is my opinion that the physical therapy may not be any better than what the patients can receive if they went to an independent practitioner.

The concept of referral for profit is deemed by the American Physical Therapy Association (APTA) as not being in the best interest of the public. Based on my own personal experience, I agree. I request that CMS not allow physical therapy services to be included in the in-office ancillary services exception, and help facilitate removal of these self-referral entities so that patients have freedom of choice and Physical Therapists can compete fairly.

Thank you for your time and consideration. If you wish to discuss any of the above matters with me, I can be reached at the number on this letterhead.

Respectfully,



Steve Hoffman, PT, ATC, SCS
Board Certified Sports Physical Therapist

SH/jat

EASTSIDE
PATHOLOGY
INCORPORATED P.S.

August 10, 2007

I appreciate having the opportunity to comment on the Physician Self-Referral Provisions of CMS-1385-P entitled "Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2008." I am a board-certified pathologist and a member of both the College of American Pathologists and the American Society of Clinical Pathologists. I am a member of Eastside Pathology, Inc., a 16-member pathology group with an independent laboratory in Bellevue, WA. I provide pathology services, including Medical Directorship of the Clinical Laboratory, for Valley Medical Center in Renton, WA.

I fully support the efforts of the CMS to end self-referral abuses in the billing and payment for pathology services. I am personally aware of specific arrangements that provide the opportunity for certain physician groups (for example, gastroenterologists) to increase their revenue through self-referrals of pathology specimens, attempting to circumvent the Stark law prohibition against physician self-referrals. These groups are entering into arrangements with Pathology laboratories under an agreement that allows the referring physician group to bill for the technical component of the pathology service.

I want to be very clear about what is happening. Here is my real-life example. The gastroenterology group which had sent their biopsies to our pathology group for over two decades decided to follow the recent national trend of pursuing an arrangement by which they could bill for the technical component of pathology services. They expressed a desire to continue a relationship with our group, but we decided not to participate because of the Stark Law prohibition and the obvious incentives for the gastroenterology group to perform more biopsies than medically necessary. The gastroenterology group then entered into an arrangement with another pathology group, such that the gastroenterologists could bill for the pathology technical component. **Our pathology group was told that the quality of our work, and our service levels, were not a factor. This was, in the words of one of the gastroenterologists, purely a "business decision", a way for them to capture additional revenue in an environment of shrinking reimbursement.**

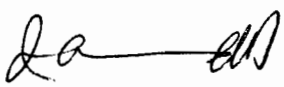
Please don't be fooled by those who oppose the CMS' proposed revisions with the argument that arrangements like the one described above provide better care for patients. This is simply not true. In the above situation, 1) both the timeliness of pathology services and the direct access to pathologists is not improved (the new pathology group is many miles away and cannot directly review slides with the gastroenterologists, which our group had done routinely), and 2) the quality of interpretation is likely to be diminished since the new group does not have a fellowship-trained gastrointestinal pathologist (our group does). With regard to the in-office ancillary services exception to the Stark law, it is important to remember that the interpretation of tissue biopsies is very different from blood/urine tests. Some of the latter, if performed in a physician's in-

EASTSIDE
PATHOLOGY
INCORPORATED P.S.

office laboratory, may provide more timely medical care to the patient. However, tissue biopsies in these settings do not require rapid interpretation and must be evaluated by a pathologist.

In conclusion, physicians should not be able to bill for any pathology services unless they personally perform or supervise such services. I support the exclusion of anatomic pathology from the in-office ancillary services exception to the Stark law. I also support the expansion of the anti-markup rule to purchased pathology interpretations. The revisions to the Medicare reassignment rule and physician self-referral provisions are necessary to eliminate financial self-interest in clinical decision-making.

Sincerely,



Ira Allen, MD
Pathologist, Eastside Pathology, Inc.
Medical Director, Valley Medical Center Clinical Laboratory

salient
HEALTH VENTURES

August 15, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, Maryland 21244-8018

To Whom It May Concern:

These comments are being submitted in response to file code **CMS-1385-P** and Proposed Regulations regarding **Physician Self Referral Provisions: Services Furnished "Under Arrangements".**

The Proposed Regulations go too far in addressing stated concerns. If implemented, the Regulations will have a far reaching impact on many existing business relationships between physicians and hospitals. These relationships were formed in reliance on previous Regulations adopted by the government.

CMS regulators state they are concerned with "Under Arrangements" agreements between physicians and hospitals, but fail to provide justification for such concerns - apparently relying on "anecdotal reports". Our actual experience with "Under Arrangements" agreements has, in fact, been completely opposite of the general concerns stated in the Proposed Regulations.

Each specific "Under Arrangements" agreement with which we are familiar was and is subject to significant review by healthcare attorneys representing their hospital client and by healthcare attorneys representing the physician group. In addition, all agreements and the associated compensation have been subjected to an initial and periodic Fair Market Value analysis conducted by an independent accounting firm. Once operational, the service overseen by the "Under Arrangements" entity is subject to the utilization review, credentialing, and quality assurance oversight of the hospital partner.

To be direct, our primary concern is the application of the Proposed Regulations to "Under Arrangements" agreements associated with outpatient surgical centers.

CMS believes that "Under Arrangements" agreements are "causing a claim to be presented" to the Medicare and Medicaid programs, presumably on the basis that "they may be little more than a method to share hospital revenues with referring physicians".

When applied to an outpatient surgery center "Under Arrangements" agreement, the Federal government is establishing contradictory positions. The legislative intent has been to support surgeon ownership of Ambulatory Surgery Centers (ASC's) based on evidence that ***surgical cases are by nature not subject to unnecessary referrals and therefore over-utilization.***

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If this is true for surgeon ownership of an ASC, then the same principle applies to surgeon participation in an "Under Arrangements" company responsible for oversight of a hospital-based surgery center.

The ASC industry has been increasingly vocal about the 'dangers' of "Under Arrangements" models. We recently attended a conference sponsored by several ASC companies and witnessed first hand the frontal attack. We strongly suspect that this industry and key attorneys representing ASC's are the original source for most of the "anecdotal reports". If this is the case, such "anecdotal reports" of abuse must be investigated further or summarily dismissed, as the reporting party is conflicted.

The ASC industry is in competition with hospitals, and generally discourages physicians from partnering with hospitals. When surgeons and hospitals agree to partner, it is the loss of clients and additional profits that is of concern to the ASC's, as opposed to the perceived shortcomings of the legal model adopted. ASC's have generally been good for healthcare, and hospitals have learned many difficult lessons from these formidable competitors. However, hospitals and surgeons working together is not part of their business plan!

The stability of community hospitals should, in general, be a societal concern. Many hospitals quietly serve as a safety net for the medically indigent. The number one key to community hospital stability is the growth and support of its medical staff. Technology has pushed many clinical services into the outpatient arena. The outpatient nature of many clinical services creates business opportunities for physicians. They can pursue these opportunities with or without the hospital, in most situations. If pursued independent of the hospital, existing resources and infrastructure are abandoned, further undermining the hospital's financial stability.

Surgery Centers developed by hospitals and physicians, structured as an "Under Arrangements" model, do not "cause a claim to be presented" to the government. Rather than surgeons aligning interests with proprietary ASC development companies, "Under Arrangements" and other models provide a mechanism for surgeons and hospitals to formally work together.

CMS should not eliminate mechanisms for hospitals and surgeons to collaborate, such as "Under Arrangements" models; only further refine the guidelines and operating parameters.

Sincerely,

Jesse O. Weatherly
Principal

1117

August 13, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-year review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. This is long overdue and I am grateful the CMS has recognized the gross undervaluation of anesthesia services. It is ironic that plumbers and auto mechanics earn more per hour than anesthesiologists who care for medicare patients. The current medicare reimbursement is so inadequate that it doesn't even cover the anesthesiologists' costs. Anesthesiologists are moving out of areas of high medicare populations because it is not economically viable to practice in these areas.

Thank you for your consideration of this crucial issue.

Sincerely

Donna Mae Vollstedt

Donna Mae Vollstedt

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Rehabilitation Services

August 16, 2008

Mr. Kerry N. Weems
Administrator - Designate
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018.

Re: Physician Self-Referral Issues.
Proposed Revisions to Medicare Payment Policies under the Physician Fee Schedule

Dear Mr. Weems:

My name is Leslie Kesler and I have been a Physical Therapist for almost 25 years. I have been a member of the American Physical Therapy Association since my student days at the University of North Carolina at Chapel Hill. I have worked at New Hanover Regional Medical Center (Wilmington, NC) for more than 16 years, recently becoming the Director for Rehabilitation Services. In my various roles, which have included providing patient care in the outpatient setting, it has become clearly obvious to me that physician-owned physical therapy services (POPTS) are not in the best interest of patients and the community. I therefore wish to comment on some of my experiences that relate to the proposed 2008 physician fee schedule rule, specifically the issue surrounding physician self-referral and the "in-office ancillary services" exception.

When I first began working for NHRMC in 1991, there were no POPTS in the Wilmington community. Within the past few years, three of the major orthopedic physician groups in town and one major internal medicine/specialty medicine facility have established their own PT practices in their offices, for a town of less than 100,000 people; there are multiple independent physical therapy practices also in the community. The direct impact of the proliferation of POPTS has been that NHRMC's outpatient therapy programs have seen a shift in the payor mix of the patients that these

physician groups send to us. If we get a referral from these physician groups, the patients almost always have Medicaid or are uninsured. For referrals of patients with Medicare, the patients have often received services already at the POPTS but are at risk for denial for further services so are sent to our facility for additional care. The result of this 'cherry-picking' is that our community's not-for-profit medical center is providing care without covering our costs. As our facility is not supported by local taxes, there is no off-setting income. At some point, the long-term viability of hospital-based outpatient services will become questionable, which in my opinion would be a great loss to the community. I have difficulty imagining that if the POPTS were operating at a loss that the physicians would chose to continue providing Physical Therapy just because patients benefit from the service.

In addition, I have personally known of NHRMC employees or their family members, friends, and neighbors (all of whom have payment sources), who have been treated by physicians in the practices which have POPTS. It is implied to these patients that they have no choice but to go to PT clinic in the physician's office if they need rehabilitation. When I have informed the people that they have a choice in providers, they usually respond that they do not want to risk making their doctor mad and fear that the level of physician services they receive would be impacted by choosing another PT provider. I think that it is a disservice to the patients and their caregivers to promote practices that limit choice, convenience, and/or access to care.

I fully support PT services removal as a designated health service (DHS) permissible under the in-office ancillary exception of the federal physician self-referral laws. Physical Therapy referrals should be based on patient needs, not on the financial gain to the referral source.

Thank you for your consideration and for your patient advocacy.

Sincerely,

Leslie P. Kesler, PT, MHA
Director of Rehabilitation Services
New Hanover Regional Medical Center
PO Box 9000
Wilmington, NC 28402-9000
910-815-5619
leslie.kesler@nhhn.org

August 16, 2007

Mr. Kerry N. Weems
Administrator - Designate
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018.

RE: **Physician Self Referral Issues**
July 12 proposed 2008 physician fee schedule rule; physician self-referral and the "in-office ancillary services" exception

Medicare Program; Proposed Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Rule

Dear Mr. Weems:

I am a physical therapist who has been licensed and practicing in the state of Washington for over twenty years. During my career I owned and operated a private practice in Federal Way, Washington, subcontracted a hospital facility in Lakewood, Washington and a skilled nursing facility in Des Moines, Washington at various points in my career. I am currently a physical therapist assistant instructor and work part-time for a private out-patient physical therapy practice (non-physician owned).

My concern with the proposed rule exception centers on the abuse that a landlord-tenant relationship can create in the referral patterns. I have personally seen this play out where I contracted a hospital service because the hospital was about to face accreditation issues when a private PT practice was set up in the building across the street, owned by the key orthopedic surgeons in the area. The surgeons had successfully steered the majority of the referrals to the practice operating in their building, but run by a physical therapist. Although I was not privy to the exact contractual arrangement, word had it that the physicians had a rent plus arrangement where they would charge a base rent and then get an additional amount of rent each month based on the revenue or patient visits generated by their referrals. This arrangement is an option for commercial leasing where a retail operation is concerned, but the landlord does not usually possess the power to actually increase the business by direct referral means. The most the landlord can do is to provide obvious signage and easy physical access. In the retail world, these arrangements allow landlords to take on some of the risk for start-up businesses that they think will eventually do well or to provide an incentive for businesses to move into buildings that might be less desirable otherwise. That is not the case with a referral-for-profit situation.

Sun Lakes Fire District

August 16, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention CMS - 1385 – P
P.O. Box 8018
Baltimore, MD. 21244-8018

Ladies and Gentlemen,

Re: BENEFICIARY SIGNATURE 42 CFR Part 424.36 (b)(1)

The Sun Lakes Arizona Fire District, serving 9-1-1 patients in the metropolitan Phoenix area, is opposed to the proposed change to 42 CFR Part 424.36 (b)(1), ***Beneficiary Signature for Ambulance Transport Services.***

We find the proposed change to paragraph five (5) "*A signed contemporaneous statement, from a representative of the facility that received the beneficiary, which documents the name of the beneficiary and the time and date that the beneficiary was received by that facility*" to be unacceptable to 9-1-1 ambulance services.

The ambulance personnel, in accordance with paragraph one (1), have already complied with Medicare and Medicaid rules by providing a statement that the patient was physically or mentally incapable of signing a claim form.

To now require, under the proposed change in paragraph five (5), ambulance personnel to obtain a receiving facility representative signature and statement places undue delay on the 9-1-1 system ambulances. Ambulances are desperately needed to return to service and transport patients who are awaiting emergency services in their community.

The hospital emergency room is not a location where a receiving facility representative can be easily obtained, to provide the proposed signature, statement, date and time for additional documentation.

The Sun Lakes Arizona Fire District finds the proposed rule would impose a hardship on local government and its ability to provide timely transport services to 9-1-1 patients.

Sincerely,

Paul S. Wilson
Fire Chief

C.c. Board of Directors
Mediclaim Data Services, Inc.
EMS Coordinator

115

Rami M. Akel, MD
Phillip G. Apprill, MD, FACC
Gregory W. Botteron, MD
Charles F. Carey, MD, FACC
Duck Sung Chun, MD, FACC
Dennis L. Disch, MD, FACC
David J. Dobmeyer, MD, FACC
Manoj K. Eapen, MD, FACC
Darlene L. Eyster, MD, FACC
Leonard F. Fagan, MD, FACC

METRO HEART GROUP OF ST. LOUIS, INC.

M. Carolyn Gamache, MD, FACC
Michael G. Goldmeier, MD, FACC
Rajiv R. Handa, MD

M. Kiran Kancherla, MD, FACC
David J. Kardesch, MD, FACC
John W. Kilgore, MD, FACC
David J. Morton, MD, FACC
Jeffrey T. Reese, MD, FACC
Bassam A. Roukoz, MD, FACC
David J. Sewall, MD, FACC
Michael L. Shapiro, MD, FACC
Robert Snitzer, MD, FACC
Richard B. Whiting, MD, FACC

August 20, 2007

Herb B. Kuhn, Deputy Administrator (Acting)
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P / Mail Stop: C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Proposed Revisions to Payment Policies Under the Physicians Fee Schedule, and Other Part B Payment Policies for CY 2008

Dear Mr. Kuhn:

On behalf of Metro Heart Group of St. Louis and our 23 individual, independent practicing cardiologists, we appreciate the opportunity to submit comments to the Centers for Medicare & Medicaid Services ("CMS") regarding the ***"Resource-Based PE RVU's"*** section of the above referenced July 2, 2007 Proposed Rule. We are specifically concerned with the 2008-2010 PE RVU's established for non-facility outpatient cardiac catheterization procedure codes and the significant negative impact that could result for our practice and our patients if these values are finalized for the 2008 Physicians Fee Schedule.

Metro Heart Group of St. Louis (MHG) and predecessor organizations has a 50+ year history of providing quality cardiovascular services to the people of St. Louis and the larger metropolitan area. MHG employs 203 individuals including the 23 physicians, 5 nurse practitioners, 29 RN's, 11 sonographers, 7 nuclear technologists, and other professional and clerical support staff. We operate a central business office and maintain 7 clinical office locations throughout our service area. MHG physicians have privileges with all the major hospital systems in St. Louis in addition to several of the community hospitals. As an indication of the volume of care provided, our physicians have nearly 50,000 in-office patient encounters and diagnostic testing visits and perform over 4,500 diagnostic catheterizations each year. Our physicians provide essential diagnostic services in outpatient catheterization labs at various locations including Midwest Cardiovascular Center (an IDTF facility) and Premier Heart Care among others. As evidences of quality services, MHG physicians are all board certified or board eligible. In addition, MHG has secured ICAEL and ICANL accreditations at all offices and achieved NCQA recognitions for quality cardiovascular and stroke care.

MHG is a member of the Cardiovascular Outpatient Center Alliance (COCA) and as such we have actively been involved in the work that COCA has accomplished this year to collect and submit direct and indirect cost data to the AMA's Practice Expense Review Committee (PERC) of the Relative Value Scale Update Committee (RUC). Unfortunately, this process did not allow all of COCA's data to be considered and resulted in PE RVU recommendations to CMS that severely

undervalued the direct and indirect costs associated with providing these procedures to our patients.

It is apparent from the July 2, 2007 Proposed Rule that CMS has accepted the RUC recommendations without considering the detailed direct cost information that COCA provided to CMS in May 2007. The PE-RVU values set out in the July 2 Proposed Rule would result in a draconian cut in reimbursement for cardiac catheterizations performed in practice or IDTF locations. For example, if the 2007 conversion factor is applied to the technical component of the primary three CPT codes for a Left Heart Cath (93510TC, 93555TC, and 93556TC) the reimbursement in 2008 would be cut by **32%** and when fully implemented the total reimbursement would be reduced by **49%**. These reductions would undoubtedly result in the closing of the majority of non-facility outpatient cardiac catheterization labs in the country forcing all patients who now benefit from improved access and lower costs into more acute hospital settings.

We request that CMS review the additional cost data provided by COCA and establish PE RVU's for outpatient cardiac catheterization procedures that more reasonably reflect the direct and indirect costs of providing these procedures. If the proposed RVU's are allowed to stand, the outcome will inevitably that will cost the Medicare program more in direct APC payments **and** Medicare patients more in higher deductibles and co-insurance.

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

Sincerely,

David J. Morton, MD
President

N Rock Erekson, MBA, CMPE
Executive Director

116

CONTI CHIROPRACTIC CENTER

15 Warren Street, Suite 27 • Hackensack, NJ 07601 • (201) 343-8717 • Fax (201) 343-1517

DR. ROBERT CONTI
CHIROPRACTIC PHYSICIAN

August 15, 2007

Centers for Medicare and Medicaid Services
Dept.of Health and Human Services
Attn:CMS-1385-P
P.O. Box 8018
Baltimore, Maryland 21244-8018
Re: Technical Corrections

To Whom It May Concern:

I am writing this letter on behalf of myself and the over 5000 patients that I care for. I am writing to urge you in the strongest possible way that you abolish the recommendation that patients no longer be reimbursed for X-rays taken by an MD or DO and used by a chiropractor to determine a subluxation.

The use of x-ray especially in the older segment of our society to properly diagnose spinal subluxations and more serious pathologies that often appear on the x-rays of these patients is critical in providing responsible, safe and medically prudent care to our patients. Without the ability to do so would greatly put our patients at higher risk and also put the chiropractic profession as a whole at greater risk for providing the wrong type of care. We not only need these x-rays to properly diagnose subluxations but also need the information on them to know when to refer to other specialists when pathologies are identified.

I am sure you can understand the necessity of taking immediate action to rectify this troubling situation.

Sincerely,

Robert Conti, D.C., C.C.I.C., ABDA
Certified Independent Medical Examiner
Certified in Peer Review
Certified in Ancillary Diagnostic Testing Essentials
Certified in Whiplash Traumatology
Certified in Motor Vehicle Crash Forensic Risk Analysis
Certified Chiropractic Insurance Consultant
Board Certified-American Board of Disability Analysts

117

ACE
ANESTHESIOLOGY
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Department of Anesthesiology
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July 26, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P

Dear Ms. Norwalk:

I am writing to support an increase anesthesia payment under the 2008 Physician Fee Schedule. This is one attempt to reverse the 15 year erosion of revenue that anesthesiologists and nurse anesthetists have received from Medicare. I strongly support the revision of the sustainable growth formula revision. Where other providers receive approximately 80% from Medicare what they would from commercial insurers, anesthesia providers receive only about 36 % of the commercial conversion factor.

The efforts of the American Medical Society and the Specialty Society Relative Value Update Committee, (RUC) to recommend increasing the work value of anesthesia services is a positive step toward addressing the undervaluation of anesthesia services. I am delighted that CMS is considering their recommendations and I fully support the implementation of the increase in the anesthesia conversion factor.

I provide anesthesia services to Medicare beneficiaries, such as the elderly, and I have been concerned for some time that the inequality in anesthesia reimbursements would lead to a decreased availability of anesthesiology services in this region.

Once again, I fully support the positive payment change. I look forward to the recognition of the value of anesthesia services and their benefits to the patients.

Thank you for your time and attention.

Sincerely,

Brian Johnson, MD, Medical Director of Anesthesia Services, Parkridge East Hospital
Anesthesiology Consultants Exchange, P.C.

HOECK PHYSICAL THERAPY, INC.
9404 Genesee Avenue
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La Jolla, CA 92037
858-455-9391 phone • 858-455-7101 fax

August 16, 2007

Mr. Kerry N. Weems
Administrator-Designate
Centers for Medicare and Medicaid Services
U.S. Department of health and Human Services

Re: Physician Self-Referral Issues

I am writing you to express my concern over the continued ability of physicians to own and operate physical therapy offices. As a recent graduate in the field of physical therapy, I see no real benefit to having physician owned practices. The thought is that the patient could benefit from having the physician provide guidance and oversee treatment. We are well educated in our programs and practices to independently evaluate and treat any diagnosis or injury.

Having physician owned clinics could essentially lead to fraud and abuse. A physician who has financial gains through his or her ownership of a physical therapy practice could potentially abuse the number of visits the patient should be seen. This in turn would profit the physician. Also, this could eliminate patients' free will and right to choose which office or physical therapist they wish to see.

To combat and prevent this abuse, it is necessary that we eliminate physical therapy as a designated health service (DHS) where it currently is under the in-office ancillary services exception.

Thank you very much for taking the time to consider my comments.

Sincerely,

Allison Milloy, PT, DPT
Doctor of Physical Therapy

ROBERT W. BLUE, D.C.

DARBOY FAMILY CHIROPRACTIC, S.C

CMS
P.O. Box 8018
Baltimore, MD. 21244-8018

8/15/07

Attn: CMS-1385-P

RE: "Technical Corrections"

Dear Sir/Madam,

I am writing to strongly protest the proposal dated July 12th stating under the technical corrections section that calls for the elimination of the current regulation regarding Medicare reimbursement for x-rays taken by an MD or DO that can be used by Chiropractors.

X-rays can be an essential and critical tool to not only support examination findings, but to accurately diagnose the cause of the patient's complaint. X-rays can especially be helpful in a Medicare patient due to their age and degenerative diseases that often exist. Although x-rays are not essential to diagnose subluxations, they are essential in ruling out "red flags" and contraindications, and also help determine if a referral for other diagnostic testing and/or to another health provider is indicated.

This proposed rule will only increase the cost of care. It makes absolutely no sense for me to do an evaluation on a patient and then refer the patient to another provider who will also have to do an evaluation prior to referring the patient to a radiologist. The way things stand at this time, repetitive evaluations are not needed.

Seniors also have limited income and therefore many may delay getting the treatment they need if their out of pocket expense increases. In the case of seniors, this will likely lead to progression of their illness and therefore require more extensive and costly treatment once they are forced to have their complaint treated. As you know, early detection and intervention is essential in reducing costs and promoting more positive outcomes. This proposal provides no benefit to any Medicare patient and will only induce more suffering and unnecessary costs.

I strongly urge you to trash this proposal. X-rays are an essential tool for those patients who require them. No doctor can make an accurate diagnosis if they are not provided the tools to do so. Misdiagnosing a condition only leads to ineffective treatment, delayed referrals, and a significant increase in health care cost to both the patient and insurance carrier.

The bottom line is that PATIENTS WILL SUFFER.

Sincerely,

Robert W. Blue, D.C.

W2654 Cty. Trk. KK, Appleton, WI 54915 • Phone: (920) 731-8002 • Fax: (920) 731-8006

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August 24, 2007

VIA OVERNIGHT DELIVERY

Centers for Medicare and Medicaid Services
Department of Health and Human Services'
Attention: CMS-1385-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: PHYSICIAN SELF-REFERRAL PROVISIONS

Ladies and Gentlemen:

We represent a physician owned company that has been in the business of providing quality lithotripsy and other urology-related therapies to Medicare patients for over 20 years. We operate primarily in the mid-west and treat in excess of 11,000 patients per year. Needless to say, we are greatly troubled by CMS' attack on legitimate physician joint ventures.

If CMS were to expand Stark by applying it to hospital services billed under arrangements, it should carve out an exception for entities in which there are no fewer than 250 physician investors. When an enterprise achieves this level of physician involvement, it is clear that the ownership of such investors is so dispersed as to leave only the most tenuous connection between any one person's referrals and their resulting profit distributions. As Congress recognized when it exempted ownership interests in publicly traded companies, the more that equity is distributed the less risk that physician ownership will yield any meaningful financial incentives for overutilization. Therefore, even if CMS is unwilling to exempt physician owned ventures altogether from the new rules, it should protect those with 250 or more physician investors. This would enable CMS to curb what it views as potentially abusive while preserving effective vehicles for spreading the cost of new technology.

The following outlines our problems with the proposed regulations.

Under Arrangements

It is our understanding from a reading of the proposed regulations that CMS would prohibit a hospital from billing Medicare for any referrals made by a physician for a designated health service provided by the hospital if the service was provided to the hospital "under arrangements" by the physician or any entity in which the physician is an investor. We believe that CMS should limit the reach of Stark to only those arrangements that are known to be abusive and that Congress intended to reach.

CMS' primary concern is about physician joint ventures that provide radiology equipment in which such joint ventures are circumventions of the Stark prohibitions on physician referrals to imaging centers. In such a situation, the physician investors get the same benefit as if they owned the imaging center by leasing the equipment on a "per click" basis to the imaging center. This is vastly different from that of urologists. In fact, no one has ever shown any evidence of abuse by urology joint ventures that provide

therapeutic services, but CMS has nevertheless attacked them in their effort to eliminate abusive imaging arrangements between physician groups and hospitals and imaging centers. Moreover, joint ventures that offer services such as laser prostate ablation are providing a valuable service to the community and should not be prohibited just because they are done at the hospital, especially in the absence of evidence that they are abusive.

Unlike diagnostic procedures, therapeutic procedures, such as urological procedures, where the referring physician performs the professional portion of the procedure, the professional fee is greater than the profit distribution payment for the technical fee that the referring physician would earn from his investment interest in the joint venture. Thus, the ability to derive a portion of the technical fee does not constitute a significant inducement to make referrals. The prohibition on services furnished under arrangements should not apply to services where the investor physician performs the professional portion of the procedure.

Furthermore, for the urological joint ventures, the primary purpose of physician investment is to improve patient care. For example, many hospitals oftentimes refuse to purchase state of the art technology, such as the new laser for the treatment of benign prostate disease, even if it is clinically superior, because of the expense and the fact that rapidly changing technology makes today's "best", tomorrow's "obsolete". Hospitals also frequently refuse to invest in technology if it will replace a procedure already done in the hospital using existing machinery or operating room space. Lithotripsy is an excellent example of this. Physicians wanted a better and less invasive treatment for their patients and were fought at every turn by the hospitals. Physicians formed joint ventures to buy lithotripters because hospitals did not want to make a large capital investment and at the same time cut off a revenue stream from the services they had been providing. Through urology joint ventures, doctors (and the companies they formed) have been able to improve clinical care and take that risk of obsolescence, when their institutions would not. Physicians want to have new technology available for their patients.

Physician-owned companies or joint ventures make sense economically because they allocate resources more efficiently and effectively. In many instances a hospital does not have enough volume to justify the expense of purchasing technology. Physicians who want to have state of the art treatment for their patients are willing to invest in a joint venture with other physicians who practice at other hospitals to purchase technology and bring it to their various hospitals on a rotating basis. Usage can be spread among several hospitals and locations that would not otherwise have the service such as rural areas or at hospitals with little volume. Spreading the use of costly equipment also reduces overall capital costs.

As we are sure you must know, in the ALS v. Thompson case the court held that extracorporeal shockwave lithotripsy is not a designated health service even though it is provided under arrangements with a hospital. Thus the proposed changes to "under arrangements" would not affect lithotripsy. It would be highly beneficial to patients and providers if CMS also exempted procedures that are not otherwise DHS from the proposed prohibitions to under arrangements.

Per Click Fee Ban

Given that hospitals are risk averse and do not want to spend capital for new equipment that may become obsolete fairly quickly, doctor-owned ventures are a way to bring state-of-the-art capital equipment to hospitals and their patients. Doctors want their patients to have access to the best therapy, and are willing to join together to purchase new equipment and take the risk of failure. To accommodate hospitals' fear of failure and expense, urology joint ventures have accepted per click fee contracts. By doing so, the urology joint ventures take the entrepreneurial risks and the hospitals are able to avoid the risk that the volume will be lower than projected. Frequently, the patient will need a procedure that is less often performed and it is difficult to calculate this in to the compensation arrangement. Many examples come to mind, including a lithotripsy that requires insertion or removal of a stent.

Percentage Fee Prohibition

Another way that a hospital avoids risk is to create arrangements where compensation is set as a percentage of reimbursement for the procedure. There is no doubt that certain third party payors provide low reimbursement while others reimburse more generously. The hospital or other health care entity does not want to pay its vendor more for a procedure than the reimbursement provided because it cannot predict how many procedures will be paid for by any particular insurer. But, if compensation is based on the lowest payor the service company likely will not be fairly compensated for its investment, efforts and risk. Consequently, percentage compensation arrangements permit the physician joint venture to shoulder some of the risk, but at the same time receive a fair payment. Physicians are willing to take this risk.

Stand in the Shoes

The proposed rules would provide that if a DHS entity, such as a hospital, owns or controls another entity, a referral by a physician to the entity owned or controlled by the hospital would be deemed for Stark purposes as a referral to the hospital. Ambulatory Surgery Centers ("ASCs") rarely furnish designated health services. Thus, when a physician is invested in a joint venture that contracts with an ASC, the physician's referrals to ASCs rarely are prohibited by Stark. However, the CMS proposal to have a hospital stand in the shoes of an ASC that it owns or controls would have the effect of turning hundreds if not thousands of procedures that are not of themselves DHS into DHS. An ASC with hospital ownership would not be able to contract on a per click basis or on a percentage basis. CMS should not be able to reach further than Congress intended when it enacted Stark. If the proposal is finalized, physicians would likely withdraw from ownership in ASCs where hospitals are investors.

Burden of Proof

Oddly enough, CMS wants the burden to be on the provider to prove that he did not violate the Stark laws, even though CMS is the accuser in that situation and the one that wrote the rules that the doctor must follow. The effort by CMS to shift the burden from itself to the providers who are taking care of Medicare patients is unfair and outrageous and offends any reasonable person's sense of justice.

The most contentious issues under Stark are whether the DHS entity had knowledge of physician ownership, fair market value, and whether compensation takes into account the volume or value of referrals or other business between the parties. Requiring a DHS entity or a physician to prove lack of knowledge would create the impossible situation of having to prove a negative. The same would be true for whether compensation takes into account the volume or value of referrals or other business between the parties. Fair market value is often viewed differently by valuation experts. If CMS obtains a valuation that is different from that obtained by the joint venture, CMS, as judge and jury, would always win, but not necessarily because it is right. Moreover, there are many relationships between physicians and DHS entities where the contract is not sufficiently large enough to warrant obtaining an outside valuation, such as hourly payments for certain physician services. This may cause a hospital, in fear, or in an effort to save money, to reduce physician compensation to an amount so low that it would never be questioned. That would be highly unfair to physicians.

Urology joint ventures enable the sharing of an expensive capital technology, like lithotripsy, between many hospitals that cannot afford to purchase a lithotripter by themselves or cannot justify such a purchase due to their case volume. Many rural areas are also served by this same shared service concept that urology joint ventures have fostered. Moreover, urology therapeutic joint ventures have brought clinical benefits to thousands of Medicare beneficiaries while saving CMS millions of dollars through the efficiency of the shared service model.

We ask that you (i) accept the burden of proof that the law has historically placed upon the one creating the rules, and not shirk your responsibility, (ii) clarify that as a result of the ruling in ALS v. Thompson lithotripsy would not be subject to the proposed under arrangements restrictions, (iii) clarify the proposed "under arrangements" provision to make certain that therapeutic services provided by urology joint ventures are not DHS services if they would be so only because of the site where they are delivered, (iv) drop any prohibition of per click or percentage fees as related to these same therapeutic joint ventures in order to preserve the access and cost savings that the shared service model has created, and (vi) clarify the stand in the shoes provision to except hospital ownership or control in an ASC to clarify that legitimate joint ventures are not forced to abandon all ASCs with any hospital participation.

Lastly, if CMS is to expand Stark, we would ask that CMS carve out exception for entities in which there are no fewer than 250 physician investors. When an enterprise achieves this level of physician investment, not only is it clearly tapping into the physician community as a source of investment capital, but the ownership of such investors is so dispersed as to leave only the most tenuous connection between any one person's referrals and resulting profit distributions. As Congress recognized when it exempted ownership interests in publicly traded companies, the more that equity is distributed the less risk that physician ownership will yield any meaningful financial incentives for overutilization. Therefore, even if CMS is unwilling to exempt physician owned ventures altogether from the new rules, it should protect those with 250 or more physician investors. By wielding a scalpel, not a saw, CMS could curb what it views as potentially abusive, closely-held enterprises while preserving effective vehicles for spreading the cost of new technology.

Thank you for your consideration in this matter. If you have any questions or concerns please do not hesitate to contact me.

Very truly yours,

F. Bruce Cohen
Chief Financial Officer

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AdvaMed
Advanced Medical Technology Association

August 24, 2007

Via Electronic and U.S. Mail

Herb Kuhn, Acting Deputy Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Revisions to the Payment Policies for Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions (CMS-1385-P)

Dear Mr. Kuhn:

The Advanced Medical Technology Association (AdvaMed) welcomes the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Revisions to the Payment Policies for Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions (CMS-1385-P, *Federal Register*, Vol. 72, No. 133, Thursday, July 12, 2007, p. 38122). AdvaMed member companies produce the medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. Our members produce nearly 90 percent of the health care technology purchased annually in the United States and more than 50 percent purchased annually around the world. AdvaMed members range from the largest to the smallest medical technology innovators and companies.

AdvaMed appreciates the considerable effort you and your staff have put into the development of the proposed Medicare Physician Fee Schedule rule (PFS). While we are pleased with some of the proposed changes announced in the rule we remain concerned with others. AdvaMed supports the establishment of payment rates under the physician

fee schedule that are adequate and ensure access to advanced medical technologies by Medicare beneficiaries. We will comment on the following issues raised in the proposed 2008 PFS Rule:

1. Resource Based PE RVUS
   a. Discussion of Equipment Usage Percentage
   b. Equipment Interest Rate (Discussion)
   c. PE Proposals for CY 2008
   d. RUC Recommendations for Direct PE Inputs and Other PE Input Issues
      Transcatheter Placement of Stent(s)
      Arthroscopic Procedure Non-facility Inputs
2. Coding- Reduction in TC for Imaging Services
3. Clinical Laboratory Issues
4. TRHCA—Section 101(b): PQRI
5. Physician Self-Referral Provisions

PROVISIONS

I. Resource Based PE RVUS

AdvaMed supports CMS's decision to leave equipment utilization and interest rate assumptions unchanged for CY 2008. AdvaMed also encourages CMS to establish non-facility PE inputs for arthroscopic procedures done under local/regional anesthesia and furnished in the office setting. Our comments on these issues are discussed in more detail below.

a. Discussion of Equipment Usage Percentage

CMS acknowledges that it does not have sufficient empirical evidence to justify a change from its current assumption of a 50 percent utilization rate for imaging equipment. Some analysts cite a Medicare Payment Advisory Commission (MedPAC) survey of CT and MRI services provided by select physician offices and independent diagnostic testing facilities (IDTFs) as evidence for the need to change the CMS assumption about equipment use rates. When describing this survey during a public MedPAC meeting on April 19, 2006, a MedPAC professional staff member noted the following:

> "This survey is a first step in examining the use of imaging equipment. It was not nationally representative and it was not designed to determine equipment use rates. Its intent was to assess the feasibility of getting use rate data from the survey. It shows that a the [sic] short survey instrument can be used to collect information on how frequently equipment is operating while achieving a high response rate," and "I do want to caution that this survey is not representative [of] anything." (See MedPAC meeting transcript, pages 237, 242.)

Despite the limitations of the survey, the results formed the basis for MedPAC's discussion of equipment use rates in its June 2006 report.

At AdvaMed's request, United BioSource Corp (UBC) prepared an analysis of the MedPAC survey on imaging equipment utilization rates performed by the National Opinion Research Center (NORC) and Georgetown University.[1] The survey examined MRI and CT equipment use rates in physician offices and Independent Diagnostic Testing Facilities (IDTFs). UBC concluded that the survey results should not form the basis for evidence-based decision making due to limitations in the survey, which included:

- Low response rate;
- Lack of geographical representation in sample selection;
- Responses from physician offices and IDTFs that may not reflect the distribution of imaging service providers in many parts of the nation;
- Inclusion of only MR and CT equipment in the survey, which may not be representative of all imaging modalities.

As part of its analysis, UBC canvassed the literature for information about imaging equipment use rates. Like CMS, UBC found insufficient empirical evidence to inform evidence-based decision making about utilization rates.

AdvaMed supports CMS's decision to maintain the imaging equipment usage assumption at 50 percent until such a time as sufficient empirical evidence justifies an alternative proposal.

b. Equipment Interest Rate (Discussion)

In the proposed rule, CMS states its intention to maintain the interest rate on equipment at 11 percent , following their analysis of revised Small Business Administration data. AdvaMed concurs with the use of this data for verifying assumptions about the actual interest rates paid by physician offices and IDTFs and supports CMS's decision to retain the interest rate assumption used in the calculation of equipment costs at 11 percent.

c. PE Proposals for CY 2008

AdvaMed has some concerns regarding the potential impact of significant reductions in practice expense values on access to care, particularly in the case of some radiation therapy procedures (for example partial breast and High Dose Rate (HDR) brachytherapy). We ask that CMS consider the issue of beneficiary access to procedures in making any final determinations regarding practice expense reductions that impact the

1 Donald E. Stull and Craig A. Hunter, United BioSource Corporation, "Final Report: Evaluation and Critique of MedPAC's Survey on MRI/CT Utilization Included as Part of MedPAC's June 2006 Report to Congress" June 2007. National Opinion Research Center, "Survey of Imaging Centers: Use of MRI and CT Equipment in Five Markets," May 2006.

ability of physicians to offer certain treatment options to their patients.

d. RUC Recommendations for Direct PE Inputs and Other PE Input Issues

Transcatheter Placement of Stent(s)

In the proposed rule, CMS states that the PERC considered and approved direct PE inputs for the non-facility setting for transcatheter placement of stent(s) (CPT codes, 37205, 37206, and 75960). In the 2007 Final HOPPS/Ambulatory Surgical Centers Rule, CMS did not move forward with its proposal to add CPT codes 37205 and 37206 to the list of Ambulatory Surgical Center (ASC) approved procedures stating that,

> "Our medical advisors reconsidered our proposal to add CPT codes 37205 and 37206 to the ASC list and determined that it would be in the best interests of Medicare beneficiaries to continue to deny payment for them in ASC facilities. Our medical advisors believe that the procedures would require more than 4 hours of recovery time and would most often require an overnight stay in the facility. For these reasons, we are not finalizing our proposal to add CPT codes 37205 and 37206 to the ASC list for CY 2007."[2]

In the 2008 Proposed HOPPS/ASC Rule, CMS reiterated their safety concerns related to performing these transcatheter placement of stent procedures in ASCs.[3] AdvaMed urges CMS to consider these safety issues in making a determination regarding the appropriateness of developing direct PE inputs for the use of peripheral stent procedures in the non-facility setting.

Arthroscopic Procedure Non-facility Inputs

AdvaMed urges CMS to establish non-facility PE inputs for arthroscopic procedures done under local/regional anesthesia and furnished in the office setting. AdvaMed recommends that CMS work with physicians and manufacturers and use available data, including data received from manufacturers, in establishing new, interim non-facility PE RVUs. Establishing non-facility PE RVUs will help to ensure that patients have access to all physician services in the most appropriate setting.

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2 Federal Register, Vol. 71, No. 226, 68168 (Friday, November 24, 2006).

3 Federal Register, Vol. 72, No. 148, 42488 (Thursday, August 2, 2007).

II. Coding- Reduction in TC for Imaging Services

The proposed rule contains recommendations related to the technical component (TC) for imaging services under the physician fee schedule, which are currently subject to the DRA imaging cap. AdvaMed would like CMS to clarify that when an imaging service is packaged under the hospital outpatient prospective payment system, the cap will not apply to the TC of that service under the physician fee schedule.

III. Clinical Laboratory Issues

In this section, we offer comments relating to the pricing of clinical diagnostic laboratory tests. In contrast to several other payment systems, which have been significantly revised in the last several years, the procedures for operating the clinical laboratory fee schedule have remained relatively static. The applicable statute provides the Secretary opportunities to improve the system regarding specific details and to implement reasonable processes relating to new tests. Below we offer comments specific to the various aspects of the reconsideration proposal and suggest further improvements.

Reconsideration – Process

We commend CMS for proposing a reconsideration process for use in future new test payment determinations. Implementation of a reconsideration process would be a significant step in helping assure reasonable pricing decisions for new tests. At present, once CMS has established the payment amount for a new test, the decision is largely unchangeable. If significant questions arise later about either the basis for a decision to cross-walk or to gap fill a new test code, or a decision concerning the payment amount for the new test code, CMS and affected parties lack a regular process by which the decision can be revisited and revised.

We have a few questions and comments on the proposed reconsideration process:

- *Frequency of Public Meetings; Effective Date of Reconsidered Determinations.* We note that the Secretary has the authority under section 1833(h)(8)(D) to convene public meetings as the Secretary deems appropriate in order to receive public comments on payment amounts. However, the reconsideration process that is set forth in the proposed rule references the use of only the public meeting that is held typically in July to discuss new test payment for the following calendar year. We also note that the explanation of the proposed reconsideration process in the Preamble to the regulation appears to reference only the July public meeting to discuss comments regarding reconsidered determinations. This would mean that reconsiderations would only take place on an annual basis. Some reconsiderations may merit a speedier process. Because an improper payment rate could impact beneficiary access, we recommend that this option be built into the time lines associated with the reconsideration process. We recommend that CMS make public a summary of all recommendations for reconsideration by January 31st using a grid similar to the annual posting in September

which contains the recommendations made at the July public meeting and CMS's preliminary new test payment determinations. CMS could then accept public comments for at least 30 days, and make updates by the end of the first quarter of the calendar year. CMS could also elect to hold another public meeting, in addition to and in advance of the July public meeting, to consider public comment on the matters that are being reconsidered on this faster track. If CMS found that it needed additional time for reconsideration, any remaining codes could go through the July public meeting and be updated by January 1st of the following year.

- *Opportunity to Make Oral Public Comments.* The Preamble discussion of the proposed reconsideration process makes reference to a 60-day public comment period concerning either the basis for a decision (to price a new test code through either the cross-walk or gap fill process) or the amount of payment for the new test code. This discussion states that those members of the public who submit written comments during the 60-day comment period will also have the opportunity to comment orally at the next clinical laboratory public meeting. AdvaMed does not support restricting the comments made during the clinical laboratory public meeting. We recommend that CMS accept comments from entities who submitted written comments, during the 60-day comment period, AND other interested parties during the meeting.

- *CMS Rationale for Initiating a Reconsideration and for Deciding Whether to Change a Prior Determination.* AdvaMed appreciates CMS's clarification that its proposed reconsideration process would involve two steps: (1) deciding whether to reconsider a prior determination; and (2) deciding whether to change a prior determination. We note that the agency has stated that it will post information on the CMS website regarding its decision to reconsider a prior determination, as well as the results of the reconsideration. First, we urge the agency to enhance the transparency of its process by posting summaries of all recommendations to reconsider prior determinations. Second, we recommend that CMS provide information regarding the rationales underlying its decisions to either accept or decline reconsideration requests submitted by external requestors. Third, after a reconsideration has begun, we urge CMS to include information in its web postings regarding the basis or rationale for deciding whether to change a prior determination. In particular, we recommend that the postings provide a succinct explanation for the determination, indicating the information that the agency found persuasive or important. The current tracking sheets used in the national coverage process provide a useful model for presenting the agency's rationale for its decisions.

Pricing New Test Codes by Cross-walking

AdvaMed urges the agency, when cross-walking payment for a new test, to set the payment amount at the national limitation amount (NLA) of the test on the Clinical Laboratory Fee Schedule to which the new test is cross-walked.

When electing to price a new test code by cross-walking it to an existing test code on the

fee schedule, the agency is making a single decision with national applicability, rather than subjecting the test to a fresh assessment by multiple contractors. The decision is presumably based on both the similarity of the tests and the resources needed for their delivery. Under these circumstances, we submit that the choice being made is in effect based on a national rate, the NLA, without significant attention to the local carrier-specific rates that might be below that national value.

Some of these carrier-specific amounts below the NLA are improbably low, and may compromise access to these tests in some carrier jurisdictions. Assigning such inappropriately low rates to new tests would compound any potential access problem. We believe that the statute affords the Secretary the opportunity to set appropriate policy in this area, and we urge the Secretary to exercise this discretion by setting payment amounts at levels sufficient to encourage the ready availability of new tests for beneficiaries throughout the country.

Pricing New Test Codes by Gap Fill

CMS's gap fill proposal, while valuable, could be improved in a number of ways. The proposal appears to confine the gap fill pricing process to a single calendar year. Once a decision is made to gap fill, claims-payment contractors (carriers or Medicare Administrative Contractors (MACs)) would start, as at present, to use carrier-specific amounts on any claims starting January 1. As we understand the proposal, the contractors would establish preliminary carrier-specific amounts by April 1, and CMS would post these amounts for public review by April 30. Final carrier-specific amounts would then be collected by CMS by September 30. After this, CMS would either let the NLA calculated on the basis of these carrier-specific amounts stand or would revise the NLA "based on comments received."

AdvaMed endorses the proposed change that could result in revisions to the otherwise applicable NLAs based on consideration of further information, if the process for doing so adequately allows for transparency and public input. As proposed, the new process deprives the agency of the advantages of fully-informed comments and could lead to questionable results.

Under the proposal, it appears that CMS would have access to comments based on the April 30 preliminary carrier-specific amounts. Contractors would have four months to establish these amounts. The amounts will inevitably be less reliable than those available today. As stated in the proposed rule, "it takes approximately 9 months for our carriers to establish carrier-specific amounts". See 72 FR 38163. Thus the agency will examine the carrier-specific amounts it harvests on September 30 using comments based on preliminary amounts harvested five months earlier. While we appreciate the willingness of the agency to receive and react to comments, we urge creation of an opportunity for comment on the September 30 amounts.

We appreciate the timing difficulties such an opportunity might present in establishing

final gap fill payment amounts by January 1. However, we believe the importance of achieving reasonable pricing decisions outweighs the need to establish a final amount by that date. We urge CMS to consider a revision to the proposed process that would allow gap fill prices to be revised, even if that requires retaining contractor prices for some period of time into the next year, or establishing an interim NLA to be used starting January 1 and permitting revision of that NLA sometime over the ensuing year.

The proposed changes offer a welcome opportunity to revisit payment amounts established by gap fill, but promise no significant effect on the quality of the payment decisions initially made by contractors. If reasonable payment amounts can be established at the start of the process, the need to rework decisions through a reconsideration process could be avoided. We have repeatedly urged CMS to provide clear and detailed instructions and improve the transparency of the process. In addition, we urge CMS to provide the information on which the contractors base their decisions to the public. Specifically, contractors should be directed to consider a number of factors, including: (1) the resources involved in acquiring the equipment and materials needed to perform the new test; (2) the staff expertise and skill required to perform the new test; (3) the time associated with performing the test or method; and (3) the potential value of the test or method. We continue to believe such steps would be valuable, and we urge the agency to update its instructions and make information used in the decision process readily available to the general public. In addition, considering several recent experiences with gap fill pricing of new test codes, we are concerned with several additional aspects of this process.

- First, it appears that contractors have sometimes misunderstood or misinterpreted CMS's existing instructions. In particular, contractors have arrived at carrier-specific amounts for a gap fill test that appear to be cross-walked to the payment amounts for a similar test, even when the agency has explicitly rejected cross-walking in the particular instance.

- Second, contractors are frequently unfamiliar with clinical aspects of new tests. Developing a payment rate using gap-fill is resource-intensive from the contractors' perspective because they need to learn the details about the nature, use, expected outcomes, and needed resources of a new test to price it appropriately. This is a particularly challenging dilemma when some new tests may only be performed in one or a few laboratories nationwide, and thus many contractors may have no claims experience with such tests at all.

- Third, contractors may be unfamiliar with the gap-fill process because it is employed infrequently and represents a very small portion of a given contractor's overall workload.

The first of these problems might be addressed by CMS examining compliance with its instructions or by exclusion of ostensibly cross-walked payment amounts from the NLA

calculations. The agency may wish to consider such steps. We would, however, urge the following changes in the approach to gap fill pricing that could help to address many of these concerns.

CMS should consider limiting the number of contractors involved in the gap-fill process for clinical laboratory services because it will enable greater attention to this process and improve overall quality in gap-fill decision-making. This limitation in the number of contractors should only apply to the gap-fill process, not other aspects of clinical lab services reimbursement. Section 1833(h) of the Social Security Act gives the Secretary the authority to establish regions for laboratory services, and it appears to provide sufficient latitude for this purpose. The resulting payment amounts would prevail for an entire region and would serve as the basis for the NLA in due course. This activity could be added as a specific task to one of the MAC contracts in each region. Having the task explicitly described and funded with appropriate resources would be vital. In turn, the concentration of resources should afford the chosen contractors the ability to develop more sophisticated capacity in making payment decisions. Such resources could be used, for example, to obtain staff knowledgeable in matters related to clinical lab services. Further, the relevant contractors could more easily be held accountable for following CMS's instructions and for the transparency of their activities. We believe that this approach would yield high quality, reliable decisions more consistently than the existing approach where all carriers are called upon to engage in gap fill pricing.

This approach would still cause concern in instances where a new test is performed only in a single location. As more high-technology, molecular tests aimed at genetic characteristics are developed by the industry and become available to Medicare beneficiaries, more instances are likely to arise in which the test is done in only one or a few select locations. In these circumstances, some contractors would, under either the existing arrangement or the alternative discussed above, be required to establish prices for tests whose claims will never be processed in their jurisdictions. The exercise would be abstract for those contractors; whatever advantages might be thought to result from a carrier's familiarity with local circumstances would be missing and the consequences of its decisions would have no immediate impact in its area.

For tests performed in only one location, we recommend having the single contractor with claims experience take the lead role in gap fill pricing. If CMS concludes that the statute does not permit the resulting payment amount to stand as the NLA without further steps, perhaps the lead entity's proposed payment amount and the associated information on which it is based could be shared with the other contractors for their review and consideration.

As a further step, we believe that the entire process could be better informed by making use of an advisory committee of laboratory experts which could advise the agency on molecular (including genetic) tests. Some of the tests, while very valuable and cost-effective in informing clinical decisions regarding use of potentially expensive or risky therapies, are likely to be quite expensive (per test). Failure by Medicare to set

appropriate payment rates could have a chilling effect on the availability of these tests for current and future Medicare beneficiaries. AdvaMed believes that the information needed to fairly assess the uses, resource costs, and value of these tests is often complex and challenging to marshal effectively in brief remarks at a public meeting or even in written comments. Establishing a panel of experts, including clinicians, laboratory experts, and representatives of the public, could help the agency develop and assess relevant information fairly and more reliably. The interaction of knowledgeable experts in such an advisory forum could significantly improve the information base available to CMS and its contractors. Recommendations of such a panel could help inform both the entities making gap fill pricing decisions and also CMS as it considers all of the decisions, including the basis for pricing and the possibility of reconsideration, relating to such tests.

The Secretary clearly has the authority to establish such a committee in accord with the Federal Advisory Committee Act. While we are mindful of the administrative resources needed to operate such a panel, we believe that these costs should be weighed in comparison to the difficulty and significant effect of the decisions the agency will be required to make in this area.

In addition to the above recommendations, we urge CMS to enhance the transparency and openness of the gap-fill process overall. We recommend that CMS make available for public inspection and comment the proposed new gap-filled national payment amount. Additionally, we recommend using informal mechanisms for requesting comment, such as the agency's web site for the following:

- To facilitate meaningful comment, provide the data and methodology upon which the gap-filled amount is based;
- If based on claims data, provide specific information on the number of claims, and the localities from which those claims were filed;
- Provide principles to be employed to ensure that the data used by carriers are statistically significant and alternatives to follow if statistically significant data are unavailable; and
- Provide rationales and any other information or data that was factored into the decision-making.

We also recommend that CMS make open for comment any proposals to switch from gap-fill to cross-walk (or vice versa). After taking into account additional data and comments received, we recommend that CMS publish the final national payment amount for the new test, with a clear explanation of the basis for its determination, again using informal publication mechanisms, such as the web site.

On a separate note, to date, CMS has not clarified how carrier fee-schedule amounts below the NLA will be adjusted as carriers are phased out and their functions are moved to Medicare Administrative Contractors (MACs). Leaving the existing set of carrier fee schedules in place, even as the MAC jurisdictions transcend old carrier localities, appears

to be unnecessarily complicated. In establishing MAC amounts, the agency appears to have the ability to choose an appropriate policy. We believe that in virtually all cases, the majority of carrier-specific amounts in each MAC jurisdiction will be at or above the NLA for each test. In a few cases, amounts will be below the NLA. The NLA for all old tests is set at 74 percent of the median of carrier-specific amounts, already a low figure, and the few instances where tests are paid amounts below the NLA may lead to access problems. We urge CMS to establish the payment amount for the MAC jurisdictions, as the new MACs are implemented, at the NLA.

Finally, as an editorial point, we suggest that CMS may wish to reconsider the use of the term "carrier-specific amount" in the regulation text. Carriers as such are being phased out in favor of MACs, and the retention of the word "carrier" in this section may contribute to confusion in the future.

V. TRHCA—Section 101(b): PQRI

CMS began its Physician Quality Reporting Initiative (PQRI) in 2007, with physicians beginning to report on quality in July for a bonus payment in 2008. CMS proposes to continue its PQRI program in 2008 by allocating $1.35 billion from the Physician Assistance and Quality Initiative Fund.

CMS is required to use measures for 2008 that have been endorsed or adopted by a consensus organization and have been developed through the use of a consensus-based process. CMS identifies the National Quality Forum as a consensus organization but concludes that the AQA Alliance is not a consensus organization. AdvaMed concurs with this interpretation.

We appreciate the efforts of CMS to implement the PQRI. We especially applaud the agency for the extensive discussion in the Proposed Rule of the process and the measures proposed for 2008, as well as for its extensive outreach efforts to help explain this initiative. One area of the PQRI about which AdvaMed would like to comment is the measure development process. The description provided in the Proposed Rule was very helpful in understanding the roles of the National Quality Forum (NQF) and the Ambulatory Quality Alliance (AQA) in the measure endorsement process. Nonetheless, the Proposed Rule also demonstrates the many routes that physician quality measures may take during the measure development process (e.g., the American Medical Association Physicians Consortium for Performance Improvement, Quality Insights of Pennsylvania, etc). This array of sources for new measures makes it very difficult for anyone trying to stay informed about the development and review of new measures.

Therefore, we encourage CMS to actively consider ways to ensure that this critical measure development process is fully transparent. In that regard, we would encourage the agency to consider establishing on its web site an updated listing of measures under formal consideration by the various organizations. To promote further transparency and input from multiple stakeholders, including consumers, CMS could require measure developers

to institute public comment periods on their measures. CMS could post information about the measures and the comment periods on the CMS web site. CMS could consider not including in the PQRI any measure that does not go through a public comment period during its development stage. In addition, CMS could post information about measures under consideration for endorsement by the NQF and AQA.

CMS would be the logical collection point for this information, and it could be a requirement for inclusion in the PQRI that each organization make this information available to CMS for posting on its site. AdvaMed would also encourage CMS to continue managing the PQRI process in a manner that allows input from the public, especially patient advocacy groups and device manufacturers.

AdvaMed applauds CMS for considering the feasibility and utility of accepting clinical quality data submitted from electronic health records (EHRs) as an alternative to claims-based reporting. We believe that using EHRs will reduce reporting costs, reporting errors, and enhance the value of the data reported.

VI. Physician Self-Referral Provisions

AdvaMed would like to respond to the request for comments related to the in-office ancillary services exception. We are concerned that modifications to this exception may hamper ease of access to ancillary care for Medicare beneficiaries. AdvaMed does not support CMS's statement that "these types of arrangements appear to be nothing more than enterprises established for the self-referral of DHS". Instead we view the in-office ancillary services exception as a mechanism for ensuring continuity of care. Therefore, AdvaMed encourages CMS to not limit the services that qualify for the exception.

Providing in office ancillary services greatly facilitates immediate clinical care, patient compliance, and patient convenience by eliminating the need for Medicare beneficiaries to travel long distances or see providers with whom they are not familiar. Better diagnostic and preventive health care is facilitated by allowing access to necessary services in surroundings that are comfortable and familiar to the beneficiary. The early and accurate diagnosis of critical health issues or the ruling out of the need for any additional medical intervention saves the healthcare system the cost of more expensive, unnecessary, and high-risk invasive procedures.

Across the board restrictions on the use of the in-office ancillary services exception to curb abuse and over utilization is not necessary at this time. In fact, limiting use of the exception could in some cases deprive Medicare beneficiaries of convenient access to necessary health care. AdvaMed urges CMS to maintain the in-office ancillary services exception in its current form and to seek alternative means to manage perceived abuses.

Conclusion

AdvaMed urges CMS to carefully consider our comments as well as those submitted by

our member companies, as they provide a unique source of information in developing appropriate PFS and clinical diagnostic lab test payment rates. We appreciate the opportunity to submit comments on the Proposed 2008 PFS rule, and look forward to working with CMS to address our concerns.

Sincerely,

Ann-Marie Lynch
Executive Vice President

cc: Terry Kay
Liz Richter

WICHITA
UROLOGY

David J. Backes, MD
Richard E. Steinberger, MD
Ayham J. Farha, MD
George F. Zakharia, MD
James H. Gilbaugh, MD, FACS
Gerald L. Albert, MD, PhD
Gregory F. Byrd, MD
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August 20, 2007

Center for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

To Whom It May Concern:

My name is Dr. David Backes. I am a urologist practicing in Wichita, KS, and an owner in a joint venture that provides lithotripsy service for central and western Kansas. I am writing because of the proposed changes which would take place in the Stark Laws relative to physician ownership in joint ventures. Since providing the lithotripsy service to this area of our state, we have been able to provide this service to small hospitals and small communities which would otherwise not have this service available. I believe this is a distinct advantage to the patients in these areas and would not exist if the hospitals were required to purchase their own lithotripsy technology. Our corporation has also kept up to date with any changes in technology and the physicians involved in the practice are always interested in upgrading the technology so that we have the best available services for our patients.

It is also my understanding that under prior laws and court decisions lithotripsy is not considered a designated health service and therefore current laws applying to the DHS services do not apply to lithotripsy.

I realize that there may exist in certain settings a number of conflicts of interest in providing services for patients; however, I do not believe that applies with the lithotripsy service.

Patients are seen and evaluated for their stone disease and ordering excessive numbers of procedures is not possible since it is only possible to do these procedures on patients who truly have ureteral or kidney stones in place.

I would ask that you reconsider changing any of the current laws.

Respectfully,

David J. Backes, M.D.

DJB/ler

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Physical Therapy Clinic, Inc.

August 20, 2007

Kerry N. Weems
Administrator - Designate
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Dear Kerry Weems, Administrator - Designate:

RE: Medicare Programs; Proposed revisions to payment policies under the Physicians Fee Schedule and other Part B payment Policies for CY 2008; Proposed Rule

Physician Self-Referral Issues

My name is Chad Gooding, a practicing Physical Therapist in Massillon, Ohio. I obtained by Master's Degree from Walsh University in 2000 and have been practicing for the past seven years, six of which are in private practice. Today, I am writing in regards to the July 12 proposed 2008 Physician Fee Schedule Rule, specifically the issue surrounding physician self-referral and the "in-office ancillary services" exception.

I believe that there is an empirical potential for fraud and abuse whenever physicians are able to refer Medicare beneficiaries to entities in which they have a financial interest, specifically physician owned physical therapy services. In northeast Ohio, physicians who own practices that provide physical therapy services have an inherent financial incentive to refer their patients to their practices, thus opening the door for abuse and over utilization of services for financial gain. There is an opportunity to act now and eliminate this problem by simply ending physical therapy as a designated health service furnished under the in-office ancillary services exception.

As a result, CMS wold reduce a significant amount of programmatic abuse, over utilization of physical therapy services under the Medicare program and most importantly enhance the quality of patient care..

Thank you for your consideration of my comments. If you have any further questions, please feel free to contact me at 330-833-3110. Again, thank you for your time regarding this matter.

Respectfully,

Chad Gooding, M.S., P.T.

CG/nm

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Fax: (727) 441-4540

Quality Providers of Physical and Occupational Therapy

To: Mr. Kerry N. Weems
Administrator - Designate
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018.

August 20, 2007

Subject: Medicare Program; Proposed Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Rule

Physician Self-Referral Issues

I am a physical therapist that practices in Clearwater, FL. I have been in practice for over 10 years now. Physician self-referral is a problem that has become rampant in our community and impacts the ability to provide professional care to patient clientele. Physicians that end up "owning" physical therapy services by employing a physical therapist to treat patients when the physician afterwards reaps the financial profit of his/her own referral (after physical therapist and other business expenses) is wrong. It is counter-intuitive and allows for and perpetuates a "referral for profit" mind set by the physician. I have had patients come to me and tell me that they had to repeatedly ask to be referred back to me for physical therapy services because the physician wanted to send them elsewhere. The fact that they had received quality service from me in the past makes no difference to the physician provider that is blinded to quality results and only cares about putting more money back into his/her pocket. Allowing this loophole for self-referral is wrong for the patient and destructive to my profession. If we close off this loophole, this fraudulent practice goes away and patients should be referred out the way they should be, to quality providers, not to the ones where the physicians are just making extra dollars after they have already charged for physician services.

In regards to the July 12 proposed 2008 physician fee schedule rule, specifically the issue surrounding physician self-referral and the "in-office ancillary services" exception, I support the removal of PT services from permitted services under the in-office ancillary exception. The abusive nature of physician-owned physical therapy services is the reason why. It creates and perpetuates a tremendous conflict of interest. The client's wellbeing is sacrificed for the financial gain of the physician. The physician limits choices to the client and tries to refer only to where the physician makes additional profit.

The financial arrangements that are created by physician-owned physical therapy services severely hamper patient rights and quality care.

Sincerely,

David Brown, PT

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Physical Therapy Clinic, Inc.

August 20, 2007

Kerry Weems
Administrator-Designate
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
P.O. Box 8018
Baltimore, MD. 21244-8018

Physicians Self Referral Issues

My name is Jim Walker and I have been in practice as a Physical Therapist for 35 years of which the last 25 years have been in a private practice. I wish to comment on the July 12 proposed 2008 Physician Fee Scheduled Rule; specifically, the issue of physician self referral and the "in-office ancillary services" exception.

The potential for fraud and abuse exist whenever physicians are able to refer Medicare beneficiaries to entities in which they have a financial interest, especially physicians who own practices that provide physical therapy services . Physicians who own practices that provide physical therapy services have an inherent financial incentive to refer their patients to the practices they have invested in. By eliminating physical therapy as a designated health service (DHS) furnished under the "in-office ancillary services" exception, CMS would reduce a significant amount of programmatic abuse, over utilization of physical therapy services under the Medicare Program and enhance the quality of patient care.

The "in-office ancillary services" exception is defined so broadly in the regulations that it facilitates the creation of abusive referral arrangements.

The "in-office ancillary services" exception has created a loophole that has resulted in the expansion of physician owned arrangements that provide physical therapy services. Because of Medicare referral requirements, physicians have a captive referral base for physical therapy patients in their offices.

Thank you for your consideration of these comments on the important health care issue.

Sincerely,

James Walker, P.T.

JW/nm

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Physical Therapy Clinic, Inc.

August 20, 2007

Kerry N. Weems
Administrator - Designate
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Dear Kerry Weems, Administrator - Designate:

RE: Medicare Programs; Proposed revisions to payment policies under the Physicians Fee Schedule and other Part B payment for CY 2008 proposed rule

Physician Self-Referral Issues

My name is Mark Fernandez, and I am a Physical Therapist in Massillon, Ohio who works in a privately owned out patient physical therapy clinic. I have 34 years of experience and have been working in this particular out patient clinic for 26 years.

I wish to comment on the July 12 proposed 2008 physician fee schedule rule, specifically the issue surrounding physician self referral and the "in-office ancillary services" exception. The potential for fraud and abuse exists whenever physicians are able to refer Medicare beneficiaries to entities in which they have a financial interest, especially in the case of physicians-owned physical therapy services. Physicians who own practices that provide physical therapy services have an inherent financial incentive to refer patients to these practices and over utilize those services for financial reasons.

In our area, physician owned physical therapy services have been increasing rapidly and local independent physical therapy practices have been severely impacted. In our case, several large local groups of orthopaedic surgeons have opened their own physical therapy clinics and we have been personally told that quality of service was not the reason for opening their own physical therapy clinics but rather the desire to increase income. In fact, these groups have attempted to "convert" other groups of surgeons to operating their own physical therapy clinics citing the profitability of these operations. Conversely, the quality of care has declined. Many patients of these physicians have told us that they feel pressured to go to these clinic but that they have been dissatisfied with the level of care and have opted not to return. Unfortunately, many other patients are either afraid to go against their physicians referral or unfamiliar as to what to expect from physical therapy. Additionally, in many instances, patients are traveling greater distances to receive physical therapy than would be necessary if available private out patient physical therapy clinics were a referral option.

Thank you for your consideration of these comments. It is my hope that CMS will recognize the abuses taking place in physician owed physical therapy clinics and that Stark Phase III will correct this situation.

Sincerely,

Mark Fernandez P.T.

Mark Fernandez, P.T.

MF/nm

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The Pediatric Group

Mark B. Levin, MD
John M. Cotton, MD
Timothy J. Patrick-Miller, MD
Louis J. Tesoro, MD
Helen M. Rose, MD

August 13, 2007

CMS
Department of Health and Human Services
Centers for Medicare and Medicaid Services
Jacob K. Javitz Building, Room 3800
26 Federal Plaza
New York, NY 10278-0063

RE: Stark Law Amendments

To Whom It May Concern:

As a primary care provider, I am concerned about the possible revision of the Stark Amendment that would limit in-office ancillary services, and in particular, in-office laboratory facilities. If a physician-office-lab can comply with CLIA, State Health Department regulations, OSHA regulations, et cetera, it should be permitted to operate unfettered for that particular office since it improves patient access to immediate care. Delaying results of lab studies, particularly in situations which might lead to inpatient care, would be a detriment to patient care. For public assistance patients, reimbursement levels are pre-determined by government contract, so cost serves only to assure that expensive tests are referred to a reference lab.

For ill patients, the availability of immediate results can make a huge difference in outcome and I suggest the physicians office lab be permitted to continue to serve that physician's patients.

Sincerely,

Mark B. Levin, M.D.

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August 20, 2007

Ms. Leslie Norwalk, JD
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8018
Baltimore, MD 21244–8018

RE: CMS–1385–P (BACKGROUND, IMPACT)
ANESTHESIA SERVICES

Dear Ms. Norwalk:

I am a CRNA student and am writing to ask for your support of the current proposal to boost the value of anesthesia services for Medicare & Medicaid. Being new to the profession and still in training, I am concerned that future Medicare payments will be decreasing more than a third below 1992 payment levels if not reversed by Congress by the adoption of CMS-1385-P.

The current under-reimbursement for anesthesia services within the Medicare system is not an attractive option for CRNA's who are struggling to repay high cost student loans which have continued to rise year after year. It is my personal desire to work in a rural area; however the laws will have a large impact upon my decision of employment location once I graduate. **Your support of the proposed CMS rule would ensure access to anesthesia services for Medicare beneficiaries.**

I am impressed with the responsibility and liability anesthesia providers undertake when providing anesthesia; likewise the benefit and reward of the profession should adequately reflect that level of responsibility. CRNA's are the predominant anesthesia providers to rural and medically underserved individuals in America. **Medicare patients and healthcare delivery in the US depend on our services.**

Please support this proposal.

Sincerely,

Julie Loper

Julie Loper RN, BSN, SRNA (student registered nurse anesthetist)
2237 Clinton Avenue #C
Alameda, California
94501

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UROLOGY, INC.

JOHN B. KAISER, M.D., F.A.C.S.
JOHN C. CARROLL, M.D., F.A.C.S.
DENNIS R. LAROCK, M.D.
GEORGE JABREN, M.D.

UROLOGICAL SURGERY
ADULTS & PEDIATRIC UROLOGY

ENDOUROLOGY
SHOCK WAVE LITHOTRIPSY

August 20, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
PO BOX 8018
Baltimore, MD. 21244-8018

Dear Sir or Madam:

I am writing to express my concern regarding certain proposals in the recently released 2008 proposed physician fee schedule. As a physician practicing in Fall River, Massachusetts I feel that several of the proposed changes to the physical self referral rules will unjustifiably harm Medicare patients and providers such as myself. I understand that CMS is trying to prevent abusive practices, but I believe the current proposals extend well beyond that and will obstruct legitimate joint ventures that save hospitals and Medicare money and provide state of the art care to patients. I believe the various anti-physician ownership proposals will have a negative impact on the healthcare system if they are adopted in the way they are currently presented in the proposal. In our practice we have been able to offer shock wave lithotripsy with outstanding availability and outcomes and this has also benefited patients in Taunton, Massachusetts, Providence, Rhode Island, and Newport, Rhode Island. The cost of a Lithotripsy machine is in excess of $400,000. 00 and there is not enough need at the various separate local hospitals for a fulltime machine. The improved services and equipment that a group of urologists was able to put together has greatly improved the healthcare of patients with documented kidney stone problems without any evidence of abuse in the Medicare system regarding these type of treatments.

Furthermore, per click arrangements are vital to the provision of these type services as they are infrequent and often require additional treatments. As new technologies improve our group of urologists has continued to purchase updated equipment to provide the best care for our patients with kidney stone problems. I am certain that my patients will suffer if the physician ownership rules regarding kidney stone management are altered with the new CMS proposals. CMS should not prohibit services under arrangements where the investor physician performs the professional portion of the procedure when it clearly is a necessary procedure easily documented with X-rays and with patient information showing the stone being present.

In conclusion I ask CMS to separate those beneficial therapeutic joint ventures, which are not of themselves DHS from the abusive and questionable diagnostic ventures that physicians and hospitals may have entered into. Without a doubt, it should be clear to CMS that the urology community's therapeutic joint ventures have improved access and patient outcome when it would not be possible for local hospitals to support state of the art of equipment due to the high expense and infrequent need at each separate hospital. The therapeutic joint ventures entered into by urologists have saved millions of dollars for CMS with no abuse regarding these therapeutic interventions.

This issue is extremely important to me and my patients in the Fall River, Massachusetts area. Thank you for your consideration regarding my concerns with the 2008 proposed physician fee schedule.

Yours sincerely,

John B. Kaiser, M.D.

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1030 PRESIDENT AVENUE • FALL RIVER, MA 02720 • (508) 646-0066

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N.E.O. Urology Associates, Inc.

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Robert R. Ricchiuti, M.D., F.A.C.S.
Vincent S. Ricchiuti, M.D., F.A.C.S.
Daniel J. Ricchiuti, M.D.
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August 22, 2007

The Center for Medicare & Medicaid Services
Department of Health & Human Services
ATTN: CMS-1385-P
P. O. Box 8018
Baltimore, MD 21244-8018

To Whom It May Concern:

As a Urologist in Youngstown, Ohio for the past 33 years, I have observed numerous changes in the practice of Urology and in the funding of medical treatments. In regard to exploration of new procedures and new techniques of treatment, it has been apparent that hospitals and all insurers are prone to letting the status quo remain. Were it not for joint ventures including physicians, many of the newer and now widely used therapeutic procedures such as lithotripsy, laser prostatectomy and many endoscopic stone procedures would not have become widely available to our patients. I am therefore concerned that the proposed changes to the Physicians' Self-Referral Rules will serve as a significant road block to further advances in therapeutic medical treatments.

Certainly efforts by CMS to prevent abusive practices are worthwhile but not to discourage the development of therapeutic treatments or procedures.

Sincerely,

Robert R. Ricchiuti

Robert R. Ricchiuti, M.D., F.A.C.S.
Youngstown, OH 44510

sdw

American Academy of Home Care Physicians
ACADEMY of HOME CARE PHYSICIANS

July 31, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
P. O. Box 8018
Baltimore, MD 21244-8018

Dear Ms. Norwalk,

Attached are the comments of the American Academy of Home Care Physicians on the Proposed Physician Payment Rule for 2008, including materials requested at our meeting with Amy Bassano and CMS staff on June 25.

The Academy represents physicians and other providers of in-home medical care for seniors too frail to access physician office services. Providers who see patients at home reached a financially workable level of compensation in 2004, but have since lost an average of at least 8.7%, and for some as much as 20% of their compensation value due to multiple concurrent actions by CMS. We believe that this was unintended, but is no less disastrous and will be exacerbated by the added 13% cuts proposed in this payment rule.

Based on member survey results, we believe that as much as 80% of current primary care house call capacity is at risk. The resultant acceleration in loss of access to care for some of Medicare's sickest and most expensive vulnerable seniors can only be stopped if CMS uses its public policy tools to help these beneficiaries. Saving house calls as a form of medical practice is especially important now since the cost-saving potential of house calls is enormous.

We now hear almost weekly from AAHCP members that are closing their practices. We urgently request feedback via another meeting or a conference call with division director Amy Bassano, if possible the week of August 20.

A memorandum is attached outlining the statement of the problem and our proposed solutions all of which we believe to be within the authority of CMS if it chooses to act. Please contact our Executive Director, Constance Row with questions to schedule the conference call or meeting requested above.

Sincerely,

C. Gresham Bayne, MD
President, AAHCP

P.O. Box 1037 ■
Edgewood, MD 21040-0337 ■

Phone: (410) 676-7966
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Email: aahcp@comcast.net
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Department of Health and Human Services
Centers for Medicare & Medicaid Services
Office of Strategic Operations & Regulatory Affairs

The attachment cited in this document is not included because of one of the following:

- The submitter made an error when attaching the document. (We note that the commenter must click the yellow "Attach File" button to forward the attachment.)
- The attachment was received but the document attached was improperly formatted or in provided in a format that we are unable to accept. (We are not are not able to receive attachments that have been prepared in excel or zip files).
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Please direct any questions or comments regarding this attachment to (800) 743-3951.

132-1

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Department of Health and Human Services
Attention: CMS-1385-P
PO Box 8018
Baltimore, MD 21244-8018

Re.: CMS-1385-P

I am a therapist with CarePartners Health Services in Asheville, North Carolina. I am writing to express my support for the proposed amendment to §424.24 regarding outpatient therapy certifications. This change would extend the length of time for updated treatment plans from 30 to 90 days. My patients, colleagues and I will all benefit from this extension, as it will increase the amount of time I can spend in therapy sessions.

Eliminating the need of regular 30 day updated treatment plans will decrease the amount of time therapists need to allocate to documentation. Therefore, by decreasing the amount of time spent documenting, therapists will have more time to dedicate to our patients' treatment and education.

This will also help us to manage our resources better and improve quality. Currently our support staff spend much of their time faxing paperwork for physicians to sign. Often it takes faxing the same document multiple times to the physician's office in order to get a treatment plan signed. If we are able to free up more time of the support staff, they in turn will be able to assist the therapy staff more. Rather than spending time at the fax machine, support staff can perform tasks such as setting up treatment rooms for therapy sessions and making copies of the exercise plans the therapist wants to provide the patient. The therapists will have more time dedicated to providing skilled interventions, which again should improve quality of care.

Therefore, I support the proposal to amend §424.24 to require recertification every 90 days after beginning treatment.

Thank you for your consideration,

Ellen Reynolds PT
Physical Therapy

68 Sweeten Creek Road Asheville, NC 28803 (828) 277-4800 www.carepartners.org

August 4, 2007

885 Charter Oaks Dr.
Charlottesville, VA 22901
(434) 974-6422
jmathes@usa.net

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attn: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

RE: CMS-1385-P Anesthesia Coding (Part of 5-year Review)

Dear Ms. Norwalk,

I appreciate CMS now seriously considering increasing current medicare physician fee reimbursement for anesthesiologists. Anesthesiology as a specialty has been grossly undervalued in reimbursement for medicare patients compared to other medical specialties. I am encouraged to see that CMS is now recognizing that anesthesia services are undervalued. In Virginia, Anesthesia medicare reimbursement is now less than 33 % that of commercial insurance rates in our area. Other medical specialties are paid somewhere between 70 - 80 % of commercial insurance rates. This gross disparity in Anesthesia medicare reimbursement has resulted in Anesthesiologists leaving our hospital to practice in areas with a lower percentage of medicare patients.

The RUC recommended that the CMS increase the anesthesia conversion factor to offset a calculated 32 % work undervaluation. I fully support the full implementation of the RUC's recommendation to increase anesthesia services as a step forward to correct the gross undervaluation of anesthesia services compared to other medical specialties.

I thought it would be helpful to give you an example of our anesthesiology group (Albemarle Anesthesia Associates) and the income we receive from the care of our medicare patients. We provide one anesthesiologist to one medicare patient care in the operating room; believing this practice style provides the best care of our patients. Our anesthesiologists get paid $15.40 a unit for the care of medicare patients. Our full-time anesthesiologists work between 9500- to 10,000 units a year including many hours working at night, weekends and holidays. If we took care of entirely medicare patients our gross income would be between $ 147,000 and $154,000 per year. My overhead including paying for malpractice, health, life, and disability insurance along with billing and office fees and putting money in my own 401K retirement plan is now about $120,000 per year. This would leave a W-2 after overhead costs of somewhere between $27,000 to $34,000 per year if I took care of only medicare patients in our

area. Currently, my hourly take home wage in taking care of medicare patients is less than the local school teachers or nurses in our area.

Many of my colleagues have remained steadfast in their dedication to the care of the elderly. The medicare population in the Charlottesville area is estimated to double by the year 2025 because of an ever increasing number of medicare age people moving to Charlottesville upon retiring from such areas as Washington D.C and New York. It will become increasingly difficult for our group to attract and retain anesthesiologists to stay in Charlottesville in the future with the current medicare reimbursement disparity for anesthesiology. Thus, this is why I support RUC's recommendation for full implementation of increasing the anesthesia unit rate by almost $4.00 a unit.

I appreciate your thoughtful review of the proposed increase in anesthesia medicare reimbursement. Please contact me by phone or e-mail if I can help clarify the current problems with undervalued anesthesia services.

Enclosed, is a copy of medicare reimbursement for the year 2000. Please note that the number has now dropped from 39% there to actually less than 33% of commercial insurance rates.

Sincerely,

Donald D. Mathes

Donald D. Mathes, M.D.
Albermarle Anesthesia Associates

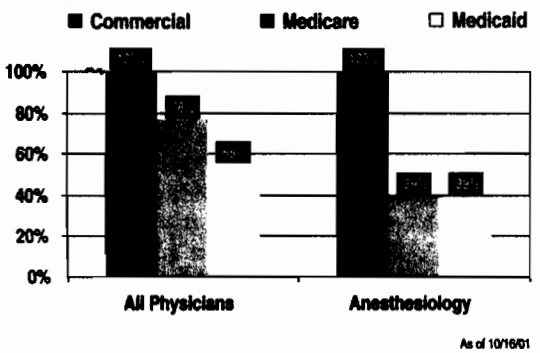
may be violated by discrimination against patients on the basis of their insurance status, the fraud and abuse laws cannot. Anesthesiologists should read between the lines, though and keep in mind the government's general concern with upcoding and billing for "medically unnecessary" services, as well as with Medicare and Medicaid patients' access to care.

How Badly Is Medicare Underpaying You?

Based on data c 2000 year.

Anesthesiologists know all too well that Medicare pays them less, relative to private payers, than it does other physicians. In connection with our ongoing efforts to obtain an increase in the anesthesia conversion factor, Alexander A. Hannenberg, M.D., chair of the Committee on Economics prepared the stark comparison in Figure 1 below:

Figure 1



As of 10/16/01

Data Sources:

ALL PHYSICIANS: 1998 Values

Gallagher PE, Smith SL, eds. Medicare RBRVS: The Physicians Guide. American Medical Association, 2000:119.

Commercial RBRVS CF value raw average of nongovernmental payers cited ($48.02); Medicaid ($26.31); Medicare ($36.68).

See also: Physician Payment Review Commission Annual Report to Congress. 1996:216.

ANESTHESIOLOGISTS

Commercial Anesthesia CF: Bierstein K. Fees paid for anesthesia services: 1999 survey results. *ASA Newsl.* 63(8):23. (Frequency wtd average of 235 payers cited in February 1999 survey = $43.52). Medicaid: 1998 ASA Survey of 29 states' Medicaid CF for programs using Base+Time methodology = $17.19. Medicare 1998 Anesthesia National Avg CF = $16.88.

OIG Special Advisory Bulletin

On the same day as the GAO sent its report to Senator Grassley, the OIG issued its special bulletin regarding "Practices of Business Consultants." The OIG's intent was to warn physicians and other providers about "a small minority of unscrupulous consultants" by listing some of the latters' hallmark marketing practices. The OIG advises providers who engage consultants to be alert to the following:

- *Illegal or Misleading Representations.* Any claim to have "inside access" or some form of approval or certification by Medicare is suspect. Consultants may improperly use Medicare or CMS logos or symbols in their marketing materials, or suggest that attending their programs is a prerequisite for keeping a provider number.
- *Promises and Guarantees.* Promising a prospective client that hiring the consultant will produce a specific percentage increase in collections may lead to the submission of false claims.
- *Encouraging Abusive Practices.* If a consultant recommends that a client use billing codes that could generate higher payment than the correct codes and especially if the consultant discusses ways to avoid detection, the practice should be leery. Anesthesiologists report that some consultants advise them to interpret laws and regulations in ways that are clearly inconsistent with the intent of the Medicare program. There are many, many perplexing questions as to the correct interpretation of anesthesia billing regulations – can you perform pain blocks while medically directing other cases is one of the most frequently asked — but a trustworthy consultant will make sure that you know both the conservative and the practical interpretation (if they differ).
- *Discouraging compliance efforts.* Advice to skip self-audits or refunds of overpayments, as discussed in the GAO report, or not to cooperate with a Medicare audit should raise suspicion.

In the concluding words of the OIG, "In general, if a consultant's advice seems too good to be true, it probably is." It is crucial that the consultant be honest as well as knowledgeable. Given that anesthesia practice management is unique in many respects, it is most important that your consultant have specific and extensive anesthesia experience – which restricts the field of potential consultants considerably. Recommendations from anesthesiolo-

August 20, 2007

Ms. Leslie Norwalk, JD
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8018
Baltimore, MD 21244–8018

RE: CMS–1385–P (BACKGROUND, IMPACT)
ANESTHESIA SERVICES

Dear Ms. Norwalk:

As a member of the American Association of Nurse Anesthetists (AANA), I write to support the Centers for Medicare & Medicaid Services (CMS) proposal to boost the value of anesthesia work by 32%. Under CMS' proposed rule Medicare would increase the anesthesia conversion factor (CF) by 15% in 2008 compared with current levels. (72 FR 38122, 7/12/2007) If adopted, CMS' proposal would help to ensure that Certified Registered Nurse Anesthetists (CRNAs) as Medicare Part B providers can continue to provide Medicare beneficiaries with access to anesthesia services.

This increase in Medicare payment is important for several reasons.

- First, as the AANA has previously stated to CMS, Medicare currently under-reimburses for anesthesia services, putting at risk the availability of anesthesia and other healthcare services for Medicare beneficiaries. Studies by the Medicare Payment Advisory Commission (MedPAC) and others have demonstrated that Medicare Part B reimburses for most services at approximately 80% of private market rates, but reimburses for anesthesia services at approximately 40% of private market rates.
- Second, this proposed rule reviews and adjusts anesthesia services for 2008. Most Part B providers' services had been reviewed and adjusted in previous years, effective January 2007. However, the value of anesthesia work was not adjusted by this process until this proposed rule.
- Third, CMS' proposed change in the relative value of anesthesia work would help to correct the value of anesthesia services which have long slipped behind inflationary adjustments.

Additionally, if CMS' proposed change is not enacted and if Congress fails to reverse the 10% sustainable growth rate (SGR) cut to Medicare payment, an average 12-unit anesthesia service in 2008 will be reimbursed at a rate about 17% below 2006 payment levels, and more than a third below 1992 payment levels (adjusted for inflation).

America's 36,000 CRNAs provide some 27 million anesthetics in the U.S. annually, in every setting requiring anesthesia services, and are the predominant anesthesia providers to rural and medically underserved America. Medicare patients and healthcare delivery in the U.S. depend on our services. The availability of anesthesia services depends in part on fair Medicare payment for them. I support the agency's acknowledgement that anesthesia payments have been undervalued, and its proposal to increase the valuation of anesthesia work in a manner that boosts Medicare anesthesia payment.

Sincerely, William Schroeder, CRNA

William Schroeder, CRNA
Name & Credential
4835 Hornbeam Dr.
Address
Rockville, MD 20853
City, State ZIP

135-

St. Mary's Good Samaritan
Incorporated

Cosponsored by Felician Services, Inc. and SSM Health Care

August 6, 2007

Leslie V. Norwalk, Esq., Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P O Box 8018
Baltimore, MD 21244-8018

Dear Ms Norwalk:

I am writing to express my support for the recent proposal to increase anesthesia payments under the 2008 physician fee schedule. Over the last few years, as the payments for anesthesia have decreased, we as an organization have been required to subsidize the anesthesia department in order to maintain anesthesia in our facilities.

It would be a major help to us if reimbursement to anesthesia was made more appropriate and rational. Such a change would greatly reduce the pressure on hospitals to provide extra funding to maintain an anesthesia staff.

We do not anticipate, given our declining reimbursement, that we can continue to give the support to anesthesia that is required to maintain a quality anesthesia staff.

Sincerely,

James M. Sanger
President & CEO

JMS/nt

400 North Pleasant
Centralia, IL 62801
618.436.8000

605 North 12th Street
Mt. Vernon, IL 62864
618.242.4600

www.smgsi.com

Department of Health and Human Services
P.O. Box 8018
Baltimore, MD 21244-8018
Attention: CMS-1385-P

Re': Physician Self-Referral Provisions

Thank you for soliciting comments on self-referral provisions from the Payment Policies under the Physician Fee Schedule for 2008.

I am a board-certified pathologist, and am Chairman of the Department of Pathology at York Hospital, Pennsylvania, a large community teaching and referral hospital.

The recent proliferation of "pod lab" arrangements and their several permutations violate the Stark law, AMA ethical guidelines, sound medical practice and common sense.

Despite what the apologists and promoters may say, they are constituted solely for financial gain with only lip service to quality and patient care issues. Over time they will inevitably lead to overutilization and abuse, if not outright fraud.

By reducing pathologists to the status of indentured servants of clinicians who "own" the patients and their biopsies, the autonomy and quality of the pathology services provided is fatally eroded. Pathologists will not only be coerced into fee-splitting with the referring clinician to preserve their livelihood, their independent judgment regarding diagnostic substance will be undermined. The dirty little secret rarely mentioned in discussion of this issue is the subtle but constant pressure from clinicians to get the answer they want from the pathologist. The adequacy of a biopsy, the sampling procedure, the need for deeper or additional sections, the severity of a process, the adequacy of margins, the need for re-excision, the appropriateness of special studies, the need for outside expert consultation despite increased expense – all of these issues that are constant parts of daily practice will be decided based ultimately on the maximum economic benefit to the controlling physician. Not the best professional judgment of the pathologist.

The pathologists who will be coerced into these employment arrangements are often vulnerable physicians with large educational debts, geographic hostages based on spousal employment, or who are unable to compete effectively for traditional practice positions. Recruiting (except for a few high-profile expert tenders) will be based on desperation and willingness to work cheap. Hardly harbingers of enhanced quality.

A further indirect impact is the undermining of high-quality community-based multi-specialty practice of pathology. Quality health care is a team effort. Any hospital and community with top quality cancer care, heart care, neurosciences, chronic disease care, etc. needs the support of high caliber pathology services. Our nine member group includes subspecialty expertise in cytopathology, hematopathology, GI pathology, dermatopathology, oncologic pathology, and transfusion medicine. We are seeking to add neuropathology, gyncecologic and breast pathology, and uropathology. How can I as a

Department Chairman -- responsible to my institution, the medical staff, and my patients and my community -- build the kind of pathology program needed to support excellent community based medical care when my very specialty is under assault from corrupt practices?

The erosion of quality will be unrelenting. Collateral damage to patients, and to timely and affordable high-quality pathology services, will unavoidable, and potentially devastating, despite protestations to the contrary.

Thank you for your consideration.

David B. Jones, MD
Chairman, Department of Pathology
York Hospital
York, PA 17403
717-851-5001
djones@wellspan.org

FAX: 410-893-4763
TTY & ASCII: 1-800-735-2258

Mail all correspondence to:
2007 ROCK SPRING ROAD
FOREST HILL, MD 21050

HARNE, SONG AND WOO, M.D., P.A
Board Certified Adult and Pediatric Urology
GARY F. HARNE, M.D., F.A.C.S.
JAMES T. SONG, M.D., F.A.C.S.
KENNETH R. WOO, M.D., F.A.C.S.

August 22, 2007

Centers For Medicare and Medicaid Services
Dept of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

To Whom It May Concern:

I am an urologist practicing in Harford county and providing quality lithotripsy and other therapeutic services to Medicare patients through a urology joint venture. I am very concern regarding the recent CMS's proposals: Under Arrangements, Per Click Fee, Percentage Fee Arrangements, Stand in the Shoes, and Burden of Proof.

In the Under Arrangements proposal, CMS should limit the reach of Stark to only those arrangements that are known to be abusive and that Congress intended to reach. No one has ever shown any evidence of abuse by urology joint ventures that provide therapeutic services. For the urological joint ventures, the primary purpose of physician investment is to improve patient care. Often, hospitals refuse to purchase state of the art technology, such as the new laser for the treatment of benign prostate disease, even if it is clinically superior, because of the expense and the fact that rapidly changing technology makes today's "best", tomorrow's "obsolete". In many instances, a hospital may not have enough volume to justify the expense of purchasing new technology. Physicians who want to have state of the art treatment for their patients are willing to invest in a joint venture with other physicians who practice at other hospitals to purchase technology and bring it to their various hospitals on a rotating basis. Usage can be spread among several hospitals and locations that would not otherwise have the service such as rural areas or at hospitals with little volume. Because the urology joint ventures are taking the risk of failure, the joint ventures should be allowed to accept per click fee and percentage fee contracts. Also, the burden of proof proposal is unfair and outrageous.

Urology joint ventures enable sharing of an expensive capital technology, like lithotripsy, between many hospitals that cannot afford to purchase a lithotripter by themselves or cannot justify such a purchase due to their case volume. Many rural areas are also served by this same shared service concept that urology joint ventures have fostered. These joint ventures have brought clinical benefits to thousands of Medicare beneficiaries while saving CMS millions of dollars through the efficiency of the shared service model.

FAX: 410-893-4763
TTY & ASCII: 1-800-735-2258

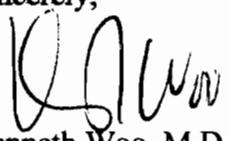
Mail all correspondence to:
2007 ROCK SPRING ROAD
FOREST HILL, MD 21050

HARNE, SONG AND WOO, M.D., P.A
Board Certified Adult and Pediatric Urology
GARY F. HARNE, M.D., F.A.C.S.
JAMES T. SONG, M.D., F.A.C.S.
KENNETH R. WOO, M.D., F.A.C.S.

In conclusion, please 1) do not change the burden of proof that the law has historically placed upon the one creating the rules, 2) do not change lithotripsy to be subjected to the proposed under arrangements restrictions, 3) do not change therapeutic services provided by urology joint ventures to be DHS services, 4) do not prohibit per click or percentage fees in order to preserve the access and cost savings that the shared service model has created, and 5) do not prohibit legitimate joint ventures to continue in all ASCs with any hospital participation.

Thank you for your time and attention.

Sincerely,



Kenneth Woo, M.D.

2007 ROCK SPRING ROAD
FOREST HILL,MD 21050
410- 838-7232
410- 879-4879

464 ALLIANCE STREET
HAVRE de GRACE MD 21078
410-939-9004

August 6, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, Maryland 21244-8018

Dear Sir/Madam:

The American Association for Clinical Chemistry (AACC) welcomes the opportunity to comment on your proposed rule, published in the July 12, 2007 *Federal Register* notice, which outlines the Centers for Medicare and Medicaid Services (CMS) revisions to the physician fee schedule for 2008. Our comments follow:

CLINICAL LABORATORY ISSUES

Reconsideration Process
CMS is proposing to establish a 'reconsideration' process for tests—crosswalked or gap-filled—which are not adequately paid. The Agency states that:

- If it determines that the payment amount for a crosswalked code is not appropriate, it may seek public comments on a more suitable crosswalk for the code. The new payment rate would take effect the following year.

- If after the first year of gap-filling, CMS decides that carrier-specific gap-filled amounts do not sufficiently pay for the test, it may crosswalk the test during the second year in order to establish a more accurate fee. The new payment rate would, once more, take effect the next year.

AACC supports these recommendations. We believe these changes will start to address a number of the flaws in the current payment process, particularly in regards to gap-fill.

We also encourage CMS to take a more proactive approach in preventing the problems that may result in the need to utilize the above mentioned scenarios. AACC recommends that local contractors be required to develop a transparent, formal process for making gap-fill decisions, including a formal appeals process. By creating such a mechanism, CMS may be able to prevent disputes from escalating to the federal level.

By way of background, AACC is the principal association of professional laboratory scientists--including MDs, PhDs and medical technologists. AACC's members develop and use chemical concepts, procedures, techniques and instrumentation in health-related investigations and work in hospitals, independent laboratories and the diagnostics industry worldwide. The AACC provides international leadership in advancing the practice and profession of clinical laboratory science and its application to health care. If you have any questions, please call me at (504) 568-4281, or Vince Stine, PhD, Director, Government Affairs, at (202) 835-8721.

Sincerely,

Larry Broussard, PhD
President-Elect, AACC

SVK

Dear CMS, Mrs. Norwalk, 5 August 2007

I write in strong support of an increase in Medicare payments for Anesthesia services.

Supporting the people who directly care for patients is the right thing to do.

Most sincerely,

Sally Krueger

140-

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1385-P,
P.O. Box 8018,
Baltimore, MD 21244-8018.

Comments regarding: CMS-1385-P: Therapy Standards and Requirements

Dr. Sir/Madam:

We are writing to you regarding the proposed regulatory change outlined in Physician Fee Schedule dated July 12, 2007 that reference grandfathering Physical Therapist Assistants who are licensed by the state that they practice prior to January 1, 2008.

We wholeheartedly support this change as it is currently written, and furthermore ask that this change be put into effect as soon as possible instead of waiting until January 1, 2008 to implement.

We believe that this proposed change would bring the current rules regarding the qualifications of Physical Therapist Assistants to be more consistent with California licensure laws, would relieve hardships by employees, and would provide greater access to therapy services by patients in need of care.

California licenses Physical Therapist Assistants only if they are able to meet strict requirements regarding coursework/relevant work experience, and provided these applicants can pass the same examination that is required for applicants who have completed the APTA approved curriculum.

At Santa Rosa Memorial Hospital (Sonoma County Trauma Center) alone 7 out of the 17 licensed Physical Therapist Assistants have been impacted by the current rule, as well as 2 employees at St. Joseph Homecare. These employees have faced changing work locations/schedules, and most have chosen to go back to school to obtain the required coursework and in the case of homecare PTA's they have lost their jobs. All of these employees are highly skilled, and highly educated (all but 1 have Bachelors Degrees) and have demonstrated high level of competency in performing their jobs exceptionally well.

Thank you for allowing us to advocate for the implementation of the proposed rule regarding grandfathering Physical Therapist Assistants at the earliest possible date.

Thank you,

Rivera

August 1, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re. File Code: CMS-1385-P, CODING-ADDITIONAL CODES FROM 5-YEAR REVIEW

To CMS:

I am writing regarding the proposed change to bundle CPT 93325 into CPT codes 76825, 76826, 76827, 76828, 93303, 93304, 93307, 93308, 93312, 93314, 93315, 93317, 93320, 93321, 93350 when provided together.

As a pediatric cardiologist, this is of particular concern to me because:

1. I do not believe the appropriate process has been followed with respect to this change. After significant interaction and research between the RUC and the appropriate specialty societies (in this case The American College of Cardiology and the American Society of Echocardiography), the CPT editorial panel has recommended that a new code be established that would bundle the 93325 with the 93307 to be implemented on January 1, 2009. The RUC is scheduled to evaluate the recommended relevant work and practice expense for the new code at its upcoming meeting. The CPT editorial panel did not recommend that the list of above echo codes be bundled as well with the 93325.

This new code is fully expected to address any outstanding issues relative to Medicare utilization of 93307, and has been analyzed at length by appropriate national medical societies, the CPT editorial panel, and the RUC. However, as a result of this proposed regulatory action by CMS, we are faced with resolving, in an accelerated timeframe of less than two months, an issue that directly impacts a distinctly non-Medicare population - namely, pediatric cardiology practices - and which is normally addressed over a multi-year period. Further, because the actions of CMS are contrary to the normal process for such changes and the resultant compressed timeframe, the specialty societies have not been able to effectively work with their membership to evaluate the proposed change in a reasoned, methodical manner (something that is in the interests of all parties).

2. The surveys performed to set the work RVUs for almost all of the echo codes utilized specifically by pediatric cardiologists and affected by this proposed change were performed more than 10 years ago. As a result, particularly with respect to the 93325, the RVUs are reflective of a focus on the cost of the technology and not the advances in care that have been developed as a result of the technology. Particularly among pediatric cardiologists, much needed new surveys would provide evidence that the work and risk components of the procedures that involve Doppler Color Flow Mapping have evolved to the point where the relative value of the procedures have shifted to a significantly greater work component and a lesser technology component.

   This shift is reflected in the development of national standards such as those present in the Intersocietal Commission for the Accreditation of Echocardiography Laboratories (ICAEL) initiative to develop and implement an echo lab accreditation process. The focus of this initiative is on process, meaning work performed, and not on the technology associated with the provision of echocardiography services. This echocardiography accreditation initiative will be mandated by many payors within the next year.

In 1997 there were specific echocardiography codes implemented in CPT for congenital cardiac anomalies to complement the existing CPT codes for echocardiography for non congenital heart disease. "The codes were developed by the CPT Editorial Panel in response to the American Academy of Pediatrics and the American College of Cardiology's request to delineate more distinctively the different services involved in *assessing* and *performing* echocardiography on infants and young children with congenital cardiac anomalies." (*CPT Assistant 1997).*

Consistent with this, I have significant concern with the continued approach (of which this bundling proposal is an example) of placing adult and pediatric patients in the same grouping when it comes to evaluation of the work associated with providing care to these significantly different patient populations. Because the adult cardiology population is much larger than the pediatric population, the RVUs for procedures that are common to both are established exclusively using adult patients as the basis. The work and expense associated with providing care to pediatric patients is not considered. The inaccuracies that result from this approach can be linked to anatomical differences between pediatric and adult patients (size, development, etc. - see references from the CPT Assistant below) as well as the basic issue of getting a child to be still while performing complex imaging procedures.

CPT Code 93325 describes Doppler color flow velocity mapping. This service is typically performed in *conjunction* with another echocardiography imaging study to define structural and dynamic abnormalities as a clue to flow aberrations and to provide internal anatomic landmarks necessary for positioning the Doppler cursor to record cardiovascular blood flow velocities.

Pediatric echocardiography is unique in that it is frequently necessary to use Doppler flow velocity mapping (93325) for diagnostic purposes and it forms the basis for subsequent clinical management decisions. CPT Assistant in 1997 references the uniqueness of the 93325 for the pediatric population stating that Doppler color flow velocity is "... even more critical in the neonatal period when

3. I am concerned that this change would adversely impact access to care for pediatric cardiology patients. Pediatric cardiology programs provide care not only to patients with the resources to afford private insurance, but also, to a large extent, to patients covered by Medicaid or with no coverage at all. Because a key impact of this change will be to reduce reimbursement for pediatric cardiology services across all payor groups, the resources available today that allow us to support programs that provide this much-needed care to our patients will not be sufficient to continue to do so should the proposed change to bundle 93325 with other pediatric cardiology echocardiography codes be implemented.

   Thus the effect of this change on pediatric cardiology programs throughout the country will be an increase in the need for subsidies from already resource-challenged children's hospitals and academic programs, or a significant increase in Medicaid reimbursement for the proposed bundled services, in order for pediatric cardiology patients to have the same access to care and resources that they do today.

I strongly urge CMS to withdraw the proposed change with respect to bundling 93325 with other pediatric cardiology echocardiography codes until such time as an appropriate review of all related issues can be performed, working within the prescribed process and timeframe, in order to achieve the most appropriate solution.

Thank you for your consideration of this serious matter.

Sincerely,

Theresa Pryor Roca, M.D.
Nemours Clinic, Pensacola, Florida
Diagnositic Medical Clinic, Mobile, Alabama
1700 Springhill Ave, Suite 100
Mobile, AL 36604

142

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

This letter is in regards to the proposal to the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule.

By way of background, I would like to point out that when the MFS was implemented in 1992, the conversion factor for anesthesia was reduced by 29% from its value in 1991. In 1998, when the Medicare adopted a single conversion factor for all specialties except anesthesiology, the anesthesia conversion factor was set at 46% of the fee schedule conversion factor. This resulted in a national average conversion factor for anesthesia services of $16.88 per unit. When I began practice in 1984, the conversion factor for Medicare was about $34 per unit. The current MFS value is $16.19 which represents a 53% decrease before inflation. The inflation adjusted unit value is closer to $8, which means that anesthesiologists have suffered a 77% decrease in real reimbursement from Medicare in the last 23 years. Unfortunately, as you no doubt realize, living costs, especially that for housing, have gone up sharply in California in the last 15 years. Adding to this burden has been the further downward pressure on reimbursement due to the high penetration of managed care in the state.

To put this further into context, here are examples of the approximate Medicare payment that would result from several common surgical procedures using the current value for the conversion factor.

- Repair of ankle fracture, 1 1/2 hours of time: $140
- Tonsillectomy, 40 minutes of time: $120
- Cholecystectomy, 1 1/2 hours of time: $190

It is important to keep in mind that these are gross income figures and that the time shown is only the intra-operative portion of the time spent with the patient. In terms of the actual time spent taking car of the patient, these figures represent a hourly payment of $70-$90 before taxes, benefits and expenses. When these other factors are considered, the net income is in the range of $35-45 hour. This level of income is far from attractive to new graduates, often burdened with large debt loads, who can earn more and live a far better lifestyle by practicing almost anywhere else in the country. To further put that in perspective please note that nurses in San Francisco make over $50-60/hr for a far easier

and less stressful job that requires only a fraction of time and expense necessary to become a practicing anesthesiologist.

In depth analysis shows that RBRVS results in both a disproportionate decrease in payment for anesthesia services compared to other specialties, and an absolute level of compensation incompatible with the nature and risks of the services provided. A study done in 1995 of the annual reimbursement that would accrue to an anesthesiologist practicing full-time under the MFS resulting in a figure for net income of $53,769 per year. This is less than nurses are paid in my hospital and offends the sensibilities when considering the long and arduous program of training required in anesthesiology. It is noteworthy that a similar analysis of payments to other specialties showed that some fared considerably better than others under an all MFS compensation scheme. Cardiologists would make $276,090/yr; general surgeons $269,285; OB/GYN $131,234; GI $123,748; and psychiatry $96,769. From these figures it is clear that some specialties may find RBRVS payment more "fair" than do others.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation—a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC's recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Sincerely, Steven D. Goldfien, M. D.

DIGIRAD®
Leaders in Solid-State Imaging

August 14, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
CMS-1385-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: File Code CMS-1385-P; Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008

Ladies and Gentlemen:

These comments are submitted on behalf of Digirad Corporation in response to the Proposed Rule published in the Federal Register on July 12, 2007 (72 Fed. Reg. 38122) containing proposed amendments to 42 C.F.R. Part 411, Subpart J, among others ("Proposed Amendments").

PHYSICIAN SELF-REFERRAL PROVISIONS

As part of your discussion regarding your concerns that the in-office ancillary services exception to the Stark rules may have led to potential abuses, you state that "[o]ur review of industry trade articles and discussions with trade associations has heightened our awareness of . . . the migration of sophisticated and expensive imaging or other equipment to physician offices." You requested comments on "(1) Whether certain services should not qualify for the exception (for example, any therapy services that are not provided on an incident to basis, and services that are not needed at the time of the office visit in order to assist the physician in his or her diagnosis or plan of treatment, or complex laboratory services)...."

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We believe that diagnostic medical imaging is particularly suited to be performed in a physician's office, and that this service should not be excluded from the in-office ancillary service exception.

Digirad Corporation ("Digirad") provides diagnostic nuclear and ultrasound imaging systems and leasing services to physicians' offices, hospitals and other medical services providers. Our subsidiary, Digirad Imaging Solutions ("DIS") provides certified personnel and imaging systems for the performance of nuclear and ultrasound imaging procedures under the supervision of our physician clients. The equipment is wheeled directly into the physicians' offices, where the testing is performed. The physicians and we enter into written annual lease contracts for imaging services which set the lease fees in advance, specify the lease period intervals, are consistent with fair market value and do not take into account the volume or value of any referrals otherwise generated between the parties for which payment may be made under federal health care programs. Our services fall within the in-office ancillary service exception to the Stark laws in that the physicians who bill for the services also supervise the testing and perform it directly in the office in which the physicians regularly practice medicine (or another of the specified criteria relating to the building in which the services are performed applies).

We do not believe that the furnishing of nuclear, ultrasound or other diagnostic imaging services in a physician's office, under his or her supervision, lends itself to abuse or raises any of the concerns expressed by CMS. The patients (including Medicare beneficiaries) being imaged are either referred to the physicians leasing our services for consultation and treatment of the very condition for which the imaging is required, or they have directly sought out these physicians for such consultation and treatment. The physicians, their staff, and the leased

imaging technicians all interact directly with one another during the imaging day and while caring for the beneficiary. Plainly, the diagnostic imaging is directly related and incident to the treatment sought by the beneficiaries from the physicians who supervise and bill for the imaging.

Rather than a function of abuse, we believe that growth in the utilization of in-office diagnostic testing is a function of advancement in technology and clinical care, and the consequent general movement of additional services from a hospital to non-hospital setting.

In-office diagnostic imaging also is a cost-effective way to deliver necessary and quality health care. Many physicians lease imaging equipment and personnel because outright ownership of medical imaging devices can be financially prohibitive for physicians whose practices are too small to justify these acquisition costs. The alternative of leasing the equipment on an annual basis enables physicians to provide cost-effective services to Medicare beneficiaries within their own offices.

Restricting the availability of diagnostic imaging services in physician offices would artificially add fragmentation to a health care system that is already difficult for Medicare beneficiaries to manage. Beneficiaries would receive additional bills from third party imaging providers and would be required to travel to an additional imaging provider for testing.

Providing diagnostic imaging in these circumstances greatly facilitates immediate clinical care, patient compliance, and patient convenience as the Medicare beneficiaries are not required to travel long distances or see providers with whom they are not familiar. Better diagnostic and preventive health care is facilitated by allowing access to necessary diagnostic

imaging in surroundings that are comfortable and familiar to the beneficiary. Medical imaging is an extremely helpful diagnostic tool. The early and accurate diagnosis of critical health issues, on the one hand, or the ruling out of the need for any additional medical intervention, on the other, saves the healthcare system the cost of more expensive, often unnecessary and high-risk invasive procedures, such as a trip to the cardiac catheterization lab.

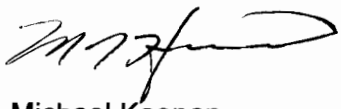
In addition, CMS currently has ample authority to combat any abuses that may exist. The current Stark rules place a number of restrictions on, and apply various standards to, the group practices that can use the in-office ancillary services exception. For example, the current rules do not allow a group practice to distribute reimbursement in a manner that is directly or indirectly based on the volume or value of referrals for diagnostic imaging or other designated health services.

Furthermore, a physician that knowingly bills for medically unnecessary tests is subject to liability under the Federal False Claims Act, 31 U.S.C. § 3729 *et. seq.* And even if the inappropriate billing of diagnostic tests is not done knowingly, CMS has authority to recover any reimbursement paid for medically unnecessary tests. Use of these existing authorities would focus enforcement efforts on those physicians who are inappropriately billing without creating barriers to care for Medicare beneficiaries.

For the reasons stated above, restrictions on the use of this in-office ancillary service are unnecessary to curb abuse or to generate savings in utilization costs; instead, they would only deprive Medicare beneficiaries of convenient access to necessary health care.

We appreciate the opportunity to submit these comments and would be pleased to discuss them with you at your convenience. If you should require additional information, please contact me at (858) 726-1530, or at mkeenan@digirad.com.

Respectfully submitted,



Michael Keenan

President, Digirad Imaging Solutions, Inc.

[redacted]
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Mahendra M. Pujara, M.D.

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August 22, 2007

Centers For Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
PO Box 8018
Baltimore, Maryland 21244-8018

Dear Sir/Madam:

1. Introduction:

My name is Mahendra M. Pujara, MD, a practicing urologist in Pottsville, Schuylkill County, Pennsylvania. I have been in practice since 1981. I have been providing quality urology care to our community, patients who are mainly between 45-50% of the population elderly in the Medicare population. Those patients benefit with our latest technology in urology mainly:
1. Extracorporeal shock wave lithotripsy
2. PVP, photoselective vaporization of prostate done with laser technology
3. Cryotherapy for kidney and prostate cancer
4. Brachytherapy for prostate cancer
All this new technology are very important for cutting down the invasiveness and cutting down the cost for patient care with equally very good results.

I am quite worried that CMS is attacking the legitimate physician joint venture who provide the excellent service to our patients with least amount of dollars. There are various areas I would like to address.

2. Under Arrangements:

CMS is trying to prohibit the hospital from billing the Medicare for any referrals made by a physician for designated health service provided by the hospital if the service was provided by the hospital under arrangements by the physician or any entity for which the physician is an investor.

Let me remind you, CMS is trying to avoid the abusive services but therapeutic urologic care is service not an abusive. No one has any shown evidence of abuse by the urology joint venture that provide therapeutic services, but the CMS has nevertheless attacked them in their effort to eliminate abusive imaging arrangements between physician groups and hospital and imaging centers.

The joint ventures which offer the laser prostate ablation or the above procedures are a very valuable service to our community and should not be prohibited just because they are done at the hospital, especially in the absence of evidence that they are abusive.

To add the point where a urologist performs, one of the above therapeutic procedures, there is a very miniscule amount of payment distributed to the physician as an investing partner compared to what his professional fees is. How would this make this procedure for profit sake only when patient needs the therapeutic procedure either surgery for the stone or surgery for enlarged prostate or surgery for the cancer. All the teachings which are provided to us and with the articles and supporting evidence that all these procedures are the latest in technology, very cost effective and our patient clients can benefit from them.

All these new technologies are quite expensive and in our area we are only four urologists so our total volume may not justify for each individual modality to be purchased by our hospitals. Hospitals are very afraid of an initial capital expenditure when there is always a fear of the technology advancing and the equipment becoming obsolete. It has happened in the past and so it is very highly unlikely that local urologists with a small volume can provide the same benefits to the patient's with current state of the art treatment. In that sense this therapeutic modalities our patient's will be deprived of if we do not have means to provide the care.

If you look at the cost to the insurance carrier for the patient population or in general for health care costs prostate surgery for example with traditional transurethral resection of the prostate is astronomically high compared to a PVP, which is an outpatient procedure. This is done with least amount of nursing care required and least amount of medications required and has the same outcome or result, probably better than the traditional transurethral procedure as no irrigation fluid is required, bleeding is less and a sick patient can tolerate this better than they would with traditional approach.

Kidney stone patients we used to take to Hershey which was an hour and a half one way travel for the doctor and the patient as well. The patient would spend almost a whole day on the road and at Hershey just to have care given for kidney stone. Now we have a mobile lithotripsy unit available which provides a superb service to almost 50 or 60 urologists supporting this equipment with their investment. It is very hard for us to understand that it is for profit. Patient has formed the kidney stone and comes to us for treatment what is wrong in participating with the entity and providing the service at our local hospital when it is so convenient for the patient to come and go home within an hour or two.

With the joint venture the cost is shared by a very large number of urologists and so if the entity or the technology becomes obsolete there is relatively very less risk financially involved. A physician can take responsibility to provide next generation technology for our patients. If it involves the individual hospitals to shoulder the burden of financial cost is will be absolutely impossible. With the 60 urologists participating in the joint venture providing the latest urologist technology care will absolutely not be possible by individual local hospitals to provide the same services. The usage could be spread among several hospitals and locations that would not otherwise have the service such as rural areas or at hospitals with little volume. Spreading the use of costly equipment also reduces the overall capital costs.

3. Per Click Fee Ban:

To accommodate the hospitals' fear of failure because of this new technology treatment which may become obsolete very quickly the urology joint venture have accepted per click fee contracts. By doing so the urology joint ventures take the entrepreneurial risks and the hospitals are able to avoid the risk that the volume will be lower than projected.

Sometimes the patient will need a procedure that is less often performed and it is difficult to calculate this in the compensation arrangement like we put in ureteral stent at the time of lithotripsy. Sometimes patient may require cystoscopy and ureteroscopy.

4. Percentage Fee Prohibition:

Percentage compensation arrangements also permit the physician joint venture to shoulder some of the risk but at the same time receive a fair payment, physicians are willing to take this risk.

5. Stand in the Shoes:

CMS proposal to have a hospital stand in the shoes of an ASC that it owns or controls would have the effect of turning hundreds if not thousands of procedures that are not of themselves DHS into DHS. An ASC with hospital ownership would not be able to contract on a per click basis or on a percentage basis. CMS should not be able to reach further than Congress intended when it enacted Stark.

When a physician is invested in a joint venture that contracts with a ASC physician referral to ASC rarely are prohibited by Stark then why would it prohibit a physicians participation in the hospital providing the service, the joint venture modality?

6. Burden of proof

Burden of proof should not be on the provider who has given the excellent care to the Medicare patients and it is unfair and outrageous. It should be the CMS who should look into this matter themselves. We physicians have not really violated the law rather we are providing excellent care to our patients with least amount of revenue and we are taking the responsibility of financial burden on it if the technology becomes obsolete.

In conclusion I would say the urology joint venture enables sharing of an expensive therapeutic technology like lithotripsy with many hospitals that cannot afford to purchase a lithotripter themselves or cannot justify such a purchase due to their cash volume.

Urology joint ventures brought clinical benefits to thousands of Medicare beneficiaries while saving CMS millions of dollars through the efficiency of shared service.

I thank you for your attention and giving time to share my thoughts.

Sincerely yours,

Mahendra M. Pujara, MD
MMP:bg

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CORE THERAPEUTICS PT
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Mr. Kerry N. Weems
Administrator - Designate
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018.

August 17, 2007

Subject: Physician Self-Referral Issues.
Medicare Program; Proposed Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Rule

Dear Mr. Weems,

I am a physical therapist in practice since 1987 and a physical therapy private practice owner since 2004. My specialty is in orthopedic and pelvic floor dysfunction and I also teach health care providers nationally for the Herman and Wallace Pelvic Rehabilitation Institute. I am indeed fortunate to love my job and feel gratitude to serve my clients and their medical team.

I wish to comment on the July 12 proposed 2008 physician fee schedule rule, specifically the issue surrounding physician self-referral and the "in-office ancillary services" exception. I support PT services removal from permitted services under the in-office ancillary exception. If a physician owns a PT practice, he or she has a vested financial interest in the profitability of that PT practice thereby increasing risk of referral for profit instead of medically justified referral for Physical Therapy treatment.

The clients as well as CMS benefit from a free marketplace where talented and educated Physical Threapists with strong functional outcome data can serve Medicare beneficiaries because of medically justified care, not because the physician will receive financial gain from the client's therapy visits.

Thank you for your consideration and action upon this vital issue.

Kindest regards,

Elizabeth Hampton PT BCIA-PMDB

Elizabeth Hampton PT, BCIA-PMDB

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8/21/07

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1385-P
Mail Stop C4-26-05
7500 Security Blvd
Baltimore, MD 21244-1850

Dear CMS Representative:

I am writing due to my concern regarding the proposed reduction in the Physician Fee Schedule for 2008. This reduction will dramatically reduce the reimbursement for Physical and Occupational Therapy services.

The cost of treating patients has continued to rise while reimbursement continues to decrease. Medicare patients in particular, require a significant amount of time from skilled therapists and this proposed reduction will make it extremely difficult to provide the care that these patients expect and deserve.

As a therapist of 17 years, with advance degrees and certifications , am in full support of the American Physical Therapy Association's recommendation for CMS to reconsider the proposed reduction.

Sincerely,

Doug Galvin, MHS, PT, OCS

155 Northpoint Drive • Mt. Orab, OH 45154 • Tel 937-444-2933 • Fax 937-444-2924

8/21/07

Mr. Kerry N. Weems
Adminstrator- Designate
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services

Re: Physician Self Referral Issue (CMS 1385-p)

Dear Mr. Kerry:

I am writing you with my concerns regarding the ability of Physicians to refer patients for Physical and Occupational Therapy to their own practice. I have been a therapist for 17 years after earning my Bachelors and Masters degree as well as advanced certification. I have seen great changes in heath care with the constant need to adapt to these changes, however the "in-office ancillary service exception is a change that has no place in today's healthcare environment.

The "loophole" in the "in-office ancillary service" exception has created a tremendous conflict in interest between patients and their patients. The exception has created an environment in which physicians feel that they are entitled to determine a patient's provider for Physical and Occupational Therapy.

The Department of Health and Human Services issued a report in May 2006 voicing concerns regarding the "in-office ancillary service" exception and cited a 2002 study from the Office of the Inspector General (OIG) in which 91% of the physical therapy claims billed by physicians did not meet Medicare requirements. Physician practices also were not held to the same standards of licensing for the employees providing this service.

While I am sure there are some instances in which "in-office ancillary service" may be appropriate, the vast majority of this practice is for pure financial benefit of the physicians. Patients have been unfairly and unethically pressured to follow the instructions of their physician and have in many cases have endured hardship due to this practice.

As a therapist, patient advocate, and as a taxpayer, I feel that CMS should recommend that the "in-office ancillary service be banned and empower patients to choose their provider of choice.

Sincerely,

Doug Galvin, MHS, PT, OCS

148

Northern Hills Physical Therapy

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Flanders, New Jersey 07836

August 16, 2007

Mr. Kerry N. Weems
Administrator-Designate
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: SMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Comment Subject: *Medicare Program: July 12 Proposed revisions to payment policies under the physician fee schedule, and other Part B payment policies for CY 2008; proposed rule.*

Dear Mr. Weems,

I am a physical therapist with over 35 years of experience. I treat patients at Northern Hills physical therapy a PT owned practice and also teach in a Doctor of Physical Therapy education program. I have had the opportunity during the past decade to serve on the state licensing board and in that capacity have been exposed to issues of abuse of services. Whether intentionally or not, the opportunity for self-referral in which the referring source may reap financial rewards is an area subject to blatant fraud and abuse.

I am specifically concerned about the "in office ancillary services exception that permits physician owned arrangements that provide "physical therapy services."

It has been my experience that many patients and in particular elderly patients when offered the security of receiving services at the doctors office rather than "someplace else" where there doctor isn't will engage the physician owned service. Unfortunately, services called physical therapy offered in this venue, are not always performed by licensed physical therapists, and unfortunately the trusting patient does not know to look for this, nor do they understand that the modalities they are receiving are only a part of that separate field of medicine called physical therapy. What they often miss in this setting is the patient education for posture, fall prevention, exercise instruction joint protection. This is truly physical therapy and how sad is it that patients never know that because they are being self referred to services that while called physical therapy are not actually physical therapy. As a result I have seen

patients treated ineffectively for months, while their pain increased and their disability increased.

The most egregious situation I can recall is a patient that came to my office on the recommendation of a neighbor, because physical therapy was not working for him. He was receiving PT at his orthopedists office 3x a week for close to a month. We saw him for a consult, recognized that he did not have a musculoskeletal lesion. We referred him back to his oncologist for further work up and sure enough he had METS to the spine. The actual source of his back pain, cancer, was untreated for more than a month, and he was treated by the staff in the doctor's office using ultrasound, a definite contraindication for an individual with cancer. This patient felt confident that the services he was receiving were the right ones, after all they were in his doctors office...but because he was being treated by untrained individuals, and Medicare was paying without question, he did not pursue other treatment options as he continued to get worse.

Physical therapists are well educated and knowledgeable in their specialty area and they should be the practitioner of choice for physical therapy. Because PT services are generally administered 2-3 times per week it is not any more convenient for the patient to go to the doctors office than to a physical therapy office for treatment.

It would appear that the only reason physicians offer PT at their own office is for profit and that type of situation is ripe for abuse. I urge CMS to remove physical therapy services as a designated health service (DHS) permissible under the in office ancillary exception of the federal physician self-referral laws.

Thank you so much for consideration of my comments.

Sincerely,

Nancy R. Kirsch, PT,DPT, PhD
40QA00099100

~~CMS~~ 149

North Florida Radiation Oncology

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FAX 352-331-1558

August 19, 2007

Kerry N. Weems
Administrator Designee
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: Comments to Proposed Rule [File Code: CMS-1385-P]

Dear Administrator Weems:

My name is Mark Perman, MD and I practice CyberKnife image guided radiosurgery and stereotactic body radiation therapy at The CyberKnife Center at North Florida Radiation Oncology. Our facility is a member of the CyberKnife Coalition. As a CyberKnife practitioner I welcome this opportunity to comment on CMS-1385-P RIN 0938-AO65 Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008.

Background

Medical linear accelerators (LINACs) were developed in the 1960's and allowed physicians to deliver isocentric radiation treatments of tumors over several weeks to spare normal tissue. Advancements in computer and linear accelerator technology in the 1980's led to 3-dimensional conformal radiation (3D-CRT) and image-guided radiation therapy (IGRT) which combined CT imaging with LINAC technology to register the location of a lesion before and after a treatment session. In the 1990's, intensity modulated radiation therapy (IMRT) further customized the shape of the radiation field to better conform to the lesion.

In the 1960's, frame-based stereotactic radiosurgery (SRS), was developed to deliver radiation with a high degree of accuracy to the brain and skull base. This intracranial treatment relies on placement and adjustment of an external head frame and manual adjustment of the patient. The accuracy afforded by this technology allows delivery of large, single, ablative doses of radiation. Then, in the late 1990's, image guided robotic stereotactic radiosurgery (r-SRS) proved significantly different from traditional radiosurgery in two ways: 1) no head or

North Florida Radiation Oncology

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body frames are required, and 2) the flexibility of non-isocentric treatments allows for highly conformal treatments throughout the body together with significant decrease in normal tissue radiation.

Addendum B: 2008 Relative Value Units and Related Information Used in Determining Medicare Payments for 2008

In the CY 2007 PFS Final Rule, CMS revised the status indicator of level II HCPCS codes for image guided robotic linear accelerator-based stereotactic radiosurgery (G0339 and G0340) to indicate that they would be Carrier priced. I support CMS in maintaining these HCPCS codes for CY 2008 with the current status indicator so that Medicare beneficiaries may continue to have access to this treatment in the freestanding center setting, and providers may continue to bill for services using the most appropriate codes.

Conclusion

In summary, I appreciate the opportunity to comment, and thank the agency for its decision to continue the use of Carrier-priced level II HCPCS codes for image guided robotic stereotactic radiosurgery in CY 2008.

Sincerely,

Mark Perman, MD

[redacted] 150

Damien Howell Physical Therapy

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August 16, 2007

Mr. Kerry N. Weems
Administrator - Designate
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018.

Subject: Medicare Program; Proposed Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Rule – **Physician Self-Referral Issues**

Dear Mr Weems

I wish to comment on the July 12 proposed 2008 physician fee schedule rule, specifically the issue surrounding *physician self-referral and the "in-office ancillary services"* exception. I am in support of **removing** the permitted services under the "in-office" ancillary exemption.

The loophole in the Stark physicians' self-referral law needs to be eliminated. Allowing a Physician to profit from just providing a referral to ancillary services because it is in his/her office is wrong.

This exemption becomes particularly objectionable because many ancillary services are only accessible upon a physician's referral, such as it required by Medicare in order to obtain Physical Therapy services. This dual role that a Physician is responsible for making the determination of whether services are needed, and allowing the physician to collect money for providing the service a bit of the fox guarding the hen house.

Studies have shown that Physical Therapy services provided in arrangements where the referring physician has an investment interest can result in 10% to 30% higher costs and utilization of Physical Therapy services.

Today a friend shared with me an experience he had. He had a boil in his hand; he went to a hand surgeon, who ordered two radiographs which were performed in his office, referred the patient to the Physical Therapist in his office for treatment for a scar that was forming. The referral called for Physical Therapy 3 times a week for 2 weeks. The patient recognized this was inappropriate treatment for a boil. After seeing the Physical Therapist for one visit and receiving reassurance from the Physical Therapist that Physical Therapy services may not be the most appropriate treatment for a boil he went to his primary care physician who provided appropriate less costly treatment in two office visits. He reported the Physical Therapist was pressuring him to schedule the 5 additional follow up visits prescribed by the surgeon. This friend was very upset, and expressed the opinion, that the Hand Surgeon was gouging the insurance company.

As a Physical Therapist Board Certified in Orthopedic Physical Therapy, practicing in Virginia for 35 years, Physician Owned Physical Therapy practices "in-house" have significantly limited my ability to practice. Until 2001 patients in Virginia could not access Physical Therapy services at all without a physician referral. Because of this limitation, I closed my out patient Physical Therapy practice in 1995 after struggling for 10 years to increases the patient's ability to access my services. My only option for employment was to work in a Physician Owned Physical Therapy Orthopedic practice (in-house) or for a hospital based physical therapy practice. My personal belief is that it is not in the best interest of my patients to provide services in a referral for profit arrangement. I elected to work in a hospital system for 5 years. In 2001 Virginia changed it's statute to allow the public to access Physical Therapy services directly under certain limitations, so I opened an out patient orthopedic Physical Therapy practice again. Unfortunately, I see very few patients who have had orthopedic surgery. Eighty eight percent of the Orthopedic Surgeons in my town (Richmond VA) have a referral for profit arrangement with Physical Therapists. My out patient Orthopedic Physical Therapy practice is all most exclusively non surgical orthopedic type problems. According to Wikipedia a monopoly is characterized by a lack of economic competition for the goods or services that they provide and a lack of viable subsitute. The in-house exemption for ancillary services and the reqirement of physician's referral is very close to causing a government granted monopolistic arrangement for Orthopedic Physical Therapy services in Richmond Virginia. I have difficulty identifying a just reason for Government to grant Orthopedic surgeons the right to have monoplostic control.

According to the American Academy of Orthopedic Surgeons web page Physician owned Physical Therapy services (www.aaos.org/about/papers/position/1166.asp) gives the physician greater role in the Physical Therapy services provided to the patient in office. All of the stated advantages of in-house Physical Therapy identified by the AAOS (quality of care, access to care) can be achieved by having an independent Physical Therapist available in the Physicians office without the Physician financially benefiting just from making a patient referral for Physical Therapy services. Fair business arrangements can be developed so that Physical Therapy services are available in the physician's office without having the physician profit from the referral process. I have made such proposals to two of the large orthopedic surgeons' practices in Richmond, and I was turned down. I can only assume because they eventually, developed a referral for profit Physical Therapy arrangement their motive in providing "in-house" Physical Therapy was financially motivated.

The business of health care should be held to a higher standard than the business of real estate. It is accepted practice that a real estate agent can receive a monetary kick back from a fellow real estate agent for referring a client. The relationship between a health care professional and a patient should not be allowed to be affected by the potential to have a monetary kick back, as this has potential to have medical decisions influenced by monetary rewards rather than what is in the best interest of the patient. I believe the public expects the healthcare industry should be held to a higher ethical standard than the real estate industry.

The "in-office ancillary services" exception result in a conflict of interest and it is unfair for the patient and for Physical Therapist. The inherent potential for a conflict of interest on the part of the Physician making a referral to an "in-house Physical Therapist" needs to be prevented by changing CMS regulations.

Thank you for considering this important issue. I am eager to provide additional information or assistance in this process. Eliminating this loophole is important to my patients, the profession of Physical Therapy, and will decreased Medicare expenditures for Physical Therapy services.

Sincerely

Damien Howell MS PT OCS

Damien Howell MS, PT, OCS

[redacted] 151

Dr J E Scarff Jr
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~~Clinton, North Carolina 28328~~

John E. Scarff, Jr. M.D. F.A.C.S.
Diplomate, The American Board of Urology

18 Aug 07

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Center for Medicare + Medicaid Servs
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Baltimore, MD 21244-8018

re: 2 July MPFS Proposed rules

Sirs:

I am a recently retired urologist whose urology practice was in CLINTON, NC from 1979 - 2000. Currently I am doing part-time work at DAVIDSON MEDICAL MINISTRIES Clinic - a "free clinic" located in LEXINGTON, NC. I became an owner in CAROLINA LITHOTRIPSY - a joint venture LLC. Having the ability to provide Lithotripsy treatment (for Kidney and Ureteral stones) has been a godsend to our patients in rural SAMPSON County - and to my partner and me. This giant leap into technology has allowed urologists in small towns to treat complicated stone cases and not send them off to a major medical center, such as Duke. Lithotripsy is not the magic bullet for all stones. Rather, every patient's stone problem has to be individualized and the urologist evaluates the patient and then decides what is the best treatment for that patient. Before Lithotripsy the urologists had a daily absent Kidney stones: 1st stone AT urologist stone removal
2nd stone AT ER Many was re-operation
3rd stone: removal of the Kidney!

Lithotripsy has saved thousands of Kidneys. What a wonderful thing to have Lithotripsy in one's urological arsenal

August 16, 2007

In reference to **CMS-1385-P**: **"THERAPY STANDARDS AND REQUIREMENTS"**,
Pages 375-387 and 522-523

To those concerned,

I am writing in response to the above proposal allowing grandfathering of existing Physical Therapist Assistants by equivalency by Jan. 2008. I strongly support this proposal and would highly recommend it's passing for all settings.

I received a Bachelors degree in Physical Education and an Associate degree as a Registered Nurse before completing the "Physical Therapist Assistance Equivalency Requirements" as described by the Board of Medical Quality Assurance, Physical Therapy Examining Committee (please refer to the copy of these requirements and instructions I followed included with this letter). Once completed and verification of experience was written by my manager, I received the approval by the Examining Committee to take the written examination (please see copies also included). I did this and passed in 1986. I have been working as a licensed PTA at Santa Rosa Memorial Hospital in inpatient and outpatient settings full time from that time on. I also had two years experience as a PT Aide from 1984-1986.

This demonstrates that even though I acquired a PTA license by "Equivalency" and did not attend an accredited PTA school, I have the education and experience to continue working in any aspect of this field as a PTA with my current license.

Thank you for your serious consideration of this matter and please allow this proposal to pass for all settings as soon as possible.

Sincerely,
Vicki Calamusa, PTA
License # AT 1270

Vicki Calamusa PTA

DEPARTMENT OF Consumer Affairs

BOARD OF MEDICAL QUALITY ASSURANCE
PHYSICAL THERAPY EXAMINING COMMITTEE
1430 HOWE AVENUE, SACRAMENTO, CALIFORNIA 95825
TELEPHONE: (916) 920-6373

PHYSICAL THERAPIST ASSISTANT EQUIVALENCY REQUIREMENTS

Section 1398.47 Equivalent Training or Experience

(a) Training and experience considered equivalent to that obtained in an approved physical therapist assistant school shall be acquired in one of the following ways:

(1) Military training, consisting of satisfactory completion of a basic hospital corpsmember course and of a formal physical therapist assistant course that includes a minimum of 550 hours of technical courses relating to physical therapy, and 350 hours of supervised clinical experience. In addition, the applicant shall complete the general education requirements described in subsection (c).

(2) A combination of training and 36 months of full-time work experience in physical therapy described in subsection (b). Training shall consist of satisfactory completion of 30 semester units or 40 quarter units of instruction in a variety of the following areas:

Human anatomy and physiology, including laboratory experience; kinesiology and topographical anatomy; first aid, basic principles of electromagnetism, mechanics and thermodynamics, biomechanics, and massage; application of therapeutic exercise and modalities for the physically disabled; and survey of pathophysiological conditions resulting from injury or disease. In addition, the applicant shall complete the general education requirements described in subsection (c).

(3) Sixty (60) months of full-time work experience in physical therapy described in subsection (b). In addition, the applicant shall complete the general education requirements described in subsection (c).

(4) Successful completion of professional education described in subdivisions (b)(1), (b)(4), (b)(5) and (b)(8) of Section 2650 of the Code and of the general education requirements described in subsection (c).

(b) Work experience used to satisfy subsections (a)(2) and (a)(3) shall be obtained under the supervision of, 1) a physical therapist licensed by the Board, 2) a physical therapist employed by the United States Government, or 3) an out-of-state licensed physical therapist who has qualifications equivalent to a physical therapist licensed by the Board, and shall consist of assisting the supervising therapist in the treatment of patients of both sexes, varying ages and disabilities. Full-time work experience shall be credited on the basis

of a compensated 40-hour work week, allowing for the usual and customary periods of absence. Work credit shall be given for part-time employment. The work experience shall have been obtained within ten years of the date the application for approval is filed with the committee, provided that one-half of the experience has been obtained within five years of the application.

(c) General education requirements shall consist of satisfactory completion of 15 semester units or 20 quarter units, including at least one course in each of the following areas:

(1) Natural sciences.
(2) Social or behavioral sciences.
(3) Humanities.
(4) English, speech or mathematics.

Completion of a course in English composition which meets the Associate or Bachelor of Arts degree requirement of the college at which the course is taken, is required as part of the general education requirement, except that this subject shall not be required required of those applicants who are foreign trained.

(d) Proof of completion of the general education courses in subsection (c) and of the technical courses in subsection (a)(2) shall be submitted on an official transcript. The courses may be taken at any post-secondary institution that is accredited by an agency recognized by the Council on Post-Secondary Accreditation or the U.S. Department of Education. Credit will be given for academic units given by the educational institution for equivalent experience or education as well well as for the results of equivalency or proficiency examinations.

NOTE: Authority cited: Sections 2615 and 2655.11, Business and Professions Code. Reference: Section 2655.3, Business and Professions Code.

Section 2650 Educational Requirements is attached for reference as mentioned in 1398.47(a)(4) for your information and use in determining educational requirements to be considered for application for examination.

DEPARTMENT OF Consumer Affairs

BOARD OF MEDICAL QUALITY ASSURANCE
PHYSICAL THERAPY EXAMINING COMMITTEE
1430 HOWE AVENUE, SACRAMENTO, CALIFORNIA 95825
TELEPHONE: (916) 920-6373

THIS FORM IS TO BE COMPLETED BY A REGISTERED PHYSICAL THERAPIST

VERIFICATION OF CLINICAL EXPERIENCE
EQUIVALENCY - SECTION 2655.3 (a)

THE APPLICANT:

Name: Vicki Calamusa

Address: 2315 Kipland Dr

City: Santa Rosa

Please have one form completed for each working experience. If additional forms are needed you may xerox this form.

TO THE SUPERVISOR:

The above named applicant is applying for approval as a physical therapist assistant. As a person familiar with his/her previous experience as a physical therapist aide, we would appreciate your providing the Committee with information requested on the form below. It is important that each question be answered throughly.

Name of supervisor: Pat Hall, RPT Telephone No. (707) 525-5220

Facility: Santa Rosa Memorial Hospital

Applicant began employment 6-29-83 → 2-24-85 part time 2-24-85 - present full time

Applicant ended employment Still employed

Was full-time work X or part-time work _____ If part-time, what were the total number of hours a week applicant worked? _____

WORK EXPERIENCE

Work experience should consist of a) basic knowledge and skills (i.e. human anatomy and physiology, applied anatomy, etc) and b) procedures and sills (i.e. patient skills, modalities, massage, functional activities, etc.)

A. TYPES OF DISABILITIES/ DISEASES Vicki has an excellent working knowledge of anatomy & physiology from her nursing experience & training, which she has been able to apply to a wide variety of patient types i.e. Neurological injuries, orthopedics (including total knee & total hip replacements), wounds (diabetic ulcers & burns) and geriatric pts. Her understanding basics of anatomy & physiology makes her assessment the effectiveness of treatment very appropriate for level of training in P.T.

B. PROCEDURES/MODALITIES APPLIED (Specify) Vicki is regularly involved in treatments including the use of various assistive ambulation devices, mat exercises, transfers, application of hot packs, ultrasound, massage, traction, hydrotherapy & wound care. She demonstrates excellent judgment and capability using the above-listed modalities

Total number of work experience hours under the supervision of a Physical Therapist 3824. (Total number of work hours including training hours).

II. DIRECTED CLINICAL EXPERIENCE OR DOCUMENTED TRAINING

Directed clinical experience is expected to include treatment of patients of both sexes, varying levels of chronicity and age, and a range of developmental stages. Experience should also include a range of physical therapy functions and pertinent types of communications. This may include staff lectures or the appropriate hospital courses pertaining to physical therpay. (i.e C.P.R.)

Head Trauma Seminar } Hospital Seminars
Neurosurgical Nursing Seminars }
Vicki has also attended all PT department inservices on such topics as electric stimulation, therapeutic exercise. Vicki has received an extensive (80 hr) one on one orientation to the dept and all its functions as well as individual instruction in the progression of gait training and resistive exercise & various modes of therapy.

Total number of hours of documented training under the supervision of a physical therpaist (exclusive of work experience hours listed on page 2)
178.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Patricia K Hueck PT
Signature

007501
PT License No.

1/29/86
Date

STATE OF CALIFORNIA—STATE AND CONSUMER SERVICES AGENCY GEORGE DEUKMEJIAN, *Governor*

DEPARTMENT OF Consumer Affairs

BOARD OF MEDICAL QUALITY ASSURANCE
PHYSICAL THERAPY EXAMINING COMMITTEE
1430 HOWE AVENUE, SACRAMENTO, CA 95825
TELEPHONE: (916) 920-6373

June 9, 1986

Vicki Calamusa
2315 Kipland Drive
Santa Rosa, CA 95401

Dear Applicant:

We are pleased to notify you that your application for the physical therapy assistant examination has been approved.

This is your ticket to the written examination. Bring this letter with you and keep it afterwards as a permanent record of your examination date and identification number. Your identification number will be issued at the examination.

EXAM DATE: TUESDAY, July 1, 1986

EXAM LOCATION: Los Angeles Convention Center
1201 S. Figueroa - Room 217
Los Angeles, California 90015

The schedule of the written examination is as follows:

Registration 12:45 p.m.

Examination 1:30 p.m. to 5:00 p.m.

NO DICTIONARIES ALLOWED

Sincerely,
PHYSICAL THERAPY EXAMINING COMMITTEE

[redacted] 153

CHIROPRACTIC CENTER
for Pain & Rehabilitation

Dr. Donald R. Thigpen, D.C.

August 17, 2007

Center for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS_1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: TECHNICAL CORRECTIONS
CMS-1385-P

To whom it may concern:

I am writing to oppose CMS's effort to abolish provisions "which permit a physician who is not a treating physician to order and receive payment for an x-ray that is used by a chiropractor." [Please see Item 4 on page 38190 of the July 12, 2007, Federal Register.]

The rationale for doing away with this provision is that since CMS no longer requires a chiropractor to prove the existence of a subluxation through use of x-rays, then medical physicians should no longer be paid to provide the x-rays. However, such reasoning fails to take into account those instances in which an x-ray is needed by the chiropractor to confirm the presence of a subluxation and/or determine treatment options, which may include referral to an appropriate specialist.

With fixed incomes and limited resources, Medicare patients, who will now be obligated to pay out-of-pocket for these x-rays, may choose, instead, to forgo the cost and, subsequently, appropriate treatment. Such delays in delivery of appropriate care may result in the increased severity of the patient's condition, ultimately leading to greater costs on the Medicare to treat the advanced conditions.

In the interest of the hundreds of thousands of Medicare recipients that benefit from chiropractic care, I urge you to reconsider this proposal.

Sincerely,

Dr. Donald Thigpen, D.C.

418 E. College St. Lake Charles, Louisiana 70605
Phone: 337.562.0817 Fax: 337.479.2391 www.ChiropracticCenter.info

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August 17, 2007

Ms. Leslie Norwalk, JD
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8018
Baltimore, MD 21244-8018

Dear Ms. Norwalk:

I am a member of the American Association of Nurse Anesthetists (AANA) and am writing in support of the Centers for Medicare and Medicaid Services (CMS) proposal for a 32% increase in the value of anesthesia work. Under CMS' proposed rule (72 FR 38122l 7/12/07) Medicare would increase the anesthesia conversion factor (CF) by 15% in 2008 compared to current levels. Adoption of the CMS proposed rule would help to ensure that Certified Registered Nurse Anesthetists (CRNAs) as Medicare Part B providers can continue to provide Medicare beneficiaries with access to anesthesia services – particularly in underserved areas.

At present Medicare under reimburses for anesthesia services. Studies by the Medicare Payment Advisory Committee (MedPAC) and others have demonstrated that Medicare Part B reimburses for most services at approximately 80% of private market rates, but reimburses for anesthesia services at approximately 40% of private market rates. This deficiency puts at risk the availability of anesthesia services to Medicare recipients. Most Part B provider's services had been reviewed and adjusted in previous years; however the value of anesthesia services has not been reviewed and adjusted. This proposed rule reviews and adjusts anesthesia services for 2008. In addition, the proposed increase in the relative value of anesthesia work would help correct the value of anesthesia services which have fallen behind inflationary adjustments.

Should the CMS' proposed rule not be enacted and if Congress fails to reverse the 10% sustainable growth rate (SGR) cut to Medicare payment, an average of 12 unit anesthesia service in 2008 will be reimbursed at a rate about 17% below 2006 payment levels, and more than a third below 1992 payment levels (adjusted for inflation).

The United States has 36,000 CRNAs that provide around 27 million anesthetics annually. They are the predominate providers in rural and medically underserved areas of the country. Medicare patients depend on our services. Therefore, I support the CMS' acknowledgement that anesthesia services have been undervalued and its proposal to increase the valuation of anesthesia work in a manner that increases Medicare anesthesia payment.

Respectfully,

Melanie Dillard

Melanie Dillard, CRNA, MS
691 Touchdown Drive
Jackson, MO 63755

AMA
AMERICAN
MEDICAL
ASSOCIATION

August 27, 2007

Herb Kuhn
Acting Director
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Subject: CMS-1385-P Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2008

Dear Mr. Kuhn:

The American Medical Association (AMA)/Specialty Society RVS Update Committee (RUC) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) Proposed Notice on the revisions to Medicare payment policies under the Physician Payment Schedule for calendar year 2008, published in the July 12, 2007 Federal Register.

Resource Based Practice Expense Relative Value Units

CMS proposes a few modifications in its practice expense data for 2008. The RUC will comment on these proposals, as well as a number of discussion items.

Direct Practice Expense Inputs

Nearly 300 codes were reviewed by the Practice Expense Review Committee (PERC) and the RUC at the February and April 2007 meetings, including several issues that were identified by CMS in the *Final Rule* for the 2007 Physician Payment Schedule. CMS has proposed to adopt all of the RUC recommendations submitted in 2007. The RUC, PERC, and specialty societies have contributed significant resources to ensure that the direct practice expense data are fair and relative across all CPT codes. The RUC congratulates CMS for the sincere and extraordinary effort of your staff in reviewing these data and implementing them in a timely fashion each year. The diligence, impeccable attention to detail, and intense level of scrutiny exhibited by the CMS staff members responsible for the upkeep and analysis of these data do not go unnoticed by the RUC. Thank you for your efforts to keep this data reliable.

We are proud of our collaborative effort in this refinement project and strongly encourage the continued utilization of the RUC direct practice expense data.

Equipment Usage Percentage Assumptions – Equipment Utilization Data

When CMS initially proposed the practice expense methodology, the agency utilized data from the Abt Associates to assign an equipment utilization rate (assumed percentage of time the equipment would be in use in an office) of 70%. After the medical profession raised concerns with this assumption, CMS implemented a lower utilization rate of 50%, despite the lack of any actual data to support a 50% rate. The RUC has repeatedly commented that a 50% utilization rate for all equipment is not an accurate measure. However, CMS states in this *Proposed Rule*, "we do not believe that we have sufficient empirical evidence to justify an alterative proposal on this issue" [ie, an equipment utilization rate higher than 50%]. We do not understand the inability to consider an alternative equipment utilization rate, as CMS does not have any data to support the 50% utilization rate either.

The RUC has discussed whether there should be a different rate for all equipment or just for the equipment set by specific cost thresholds. The RUC indicated that the cost of capital may not have a direct linear relationship with equipment utilization. Further, the RUC discussed whether consideration should be given to impacts on rural payment, as utilization rates may not be as high as in urban areas. **The RUC reiterates its recommendation that the existing 50% standard utilization rate for all equipment is not an accurate measure. CMS should consider using a higher rate for all equipment, providing an opportunity to specialty societies to provide data to support lower utilization rates, if appropriate, based on clinical or geographic considerations. An increase in the utilization rate should redistribute practice expense relative values to all services within the RBRVS.**

Equipment Interest Rate Assumptions – Cost of Capital Assumptions

CMS currently utilizes an interest rate of 11% in pricing medical equipment. CMS had previously requested comments regarding the appropriate interest rate. In 2006 and early 2007, the RUC suggested that an 11% interest rate assumption is too high and should be adjusted to market conditions. The RUC appreciates CMS' recent review of the 2007 Small Business Association's (SBA) data on loans and applicable interest rates.

The SBA interest rate rules are as follows:

> Interest rates are negotiated between the borrower and the lender but are subject to SBA maximums, which are tied to the prime rate. Interest rates may be fixed or variable.

- Fixed rate loans of $50,000 or more must not exceed Prime Plus 2.25 percent if the maturity is less than 7 years, and Prime Plus 2.75 percent if the maturity is 7 years or more..
- For loans between $25,000 and $50,000, maximum rates must not exceed Prime Plus 3.25 percent if the maturity is less than 7 years, and Prime Plus 3.75 percent if the maturity is 7 years or more.
- For loans of $25,000 or less, the maximum interest rate must not exceed Prime Plus 4.25 percent if the maturity is less than 7 years, and Prime Plus 4.75 percent, if the maturity is 7 years or more.

CMS utilizes the category of loans between $25,000 and $50,000, with an assumed maturity of 7 years or more. Today, the maximum SBA interest rate for a loan in this category would indeed be in excess of 11% (8.25% prime rate + 3.75% = 12%). However, there are a number of flaws in the assumptions utilized by CMS, including:

1. CMS has failed to incorporate changes in the prime interest rate since the inception of the resource-based practice expenses. According to the *Wall Street Journal,* the prime rate has fluctuated between 4.0% and 9.5% from 1997 – 2007. If CMS does not wish to modify the interest rates on an annual basis, then a rolling average may be appropriate. **Most importantly, CMS must review this data periodically and not use the same interest rate for the next ten years.**

2. The CMS assumption regarding loan cost does not represent the typical equipment cost included in the direct practice cost inputs.

Equipment Cost	Number of Equipment Items Recognized by CMS	% of Total
>$50,000	85	14%
$25,000 - $50,000	67	11%
<$25,000	449	75%
Total	601	

A more equitable approach may be for CMS to use the SBA maximum rates using the distinct rules for each equipment category. There is a 2% difference in the interest rate assumptions for equipment costing greater than $50,000 versus equipment costing less than $25,000. The current approach ignores the higher interest costs of small loans as compared to large loans, something comparable to assuming the same interest rate for a credit card and a mortgage.

3. CMS currently assumes that the useful life of equipment is greater than 7 years. This is contrary to the approved equipment list published by CMS, which states that 65% of all equipment has a useful life of 7 years or less. **We recommend that the useful life assumptions be consistent with your approved equipment list assumptions.** This leads to a 0.5% reduction in the SBA interest rate maximum estimate.

4. CMS has not addressed the comments submitted by a majority of the commenters to the *Final Rule* for the 2007 Medicare Physician Payment Schedule. CMS received comments that the interest rates should be prime plus two percent, others recommended rates significantly lower than prime plus two percent. CMS instead uses the SBA maximum rates. **CMS should be clear in the *Final Rule* regarding the actual assumptions that it is utilizing and the rationale for this decision.**

Pricing of High Cost Disposable Medical Supplies

As stated in our opening to this comment letter, the refinements to the identified practice expense inputs have been thorough and timely. However, the pricing of these inputs needs further attention. The *Proposed Rule* did not address the RUC's repeated comment that high cost disposable medical supplies should be priced on an annual basis. There are currently 50 such supply items on the CMS approved supply list. We request that you address the following RUC recommendation in the *Final Rule:*

> **High cost disposable medical supplies (priced at or above $200) should either be reported separately with HCPCS II codes or individually identified within the payment bundle and then re-priced on an annual basis.**

Physician Practice Information Survey Data

CMS currently utilizes practice expense data and physician hours from the 1995-1999 AMA Socioeconomic Monitoring System (SMS) survey to calculate a "practice expense per hour" estimation for each specialty. At several meetings, the RUC has recognized that these data are outdated and that there is a significant need for new survey data. On March 24, 2006, a multi-specialty sign-on letter (signed by more than 70 organizations) was sent to CMS with the following recommendation:

> *We are all in agreement, however, that moving forward, it is imperative that a multi-specialty practice expense survey be conducted to collect recent, reliable, consistent practice expense data for all specialties and health care professionals.*

We urge CMS to work with the AMA and other physician and health professions organizations to achieve this goal.

The RUC appreciates that CMS has expressed support of this survey process. The AMA, in coordination with over 70 specialty societies and the Gallup organization, has initiated a survey effort and plans to provide the data from the Physician Practice Information (PPI) Survey to CMS in the Spring of 2008 for implementation for the 2009 Medicare Physician Payment Schedule.

The RUC recommends that CMS utilize recent, reliable, and consistent practice expense data for all specialties and health care professionals.

Diagnostic Arthroscopy – Non-facility Practice Expense Inputs

At the October 2006 RUC Meeting, the Practice Expense Review Committee reviewed a request from CMS to establish non-facility inputs for the following arthroscopy codes:

29805 Arthroscopy, shoulder, diagnostic, with or without synovial biopsy,
29830 Arthroscopy, elbow, diagnostic, with or without synovial biopsy,
29840 Arthroscopy, wrist, diagnostic, with or without synovial biopsy
29870 Arthroscopy, knee, diagnostic, with or without synovial and
29900 Arthroscopy, metacarpophalangeal joint, diagnostic, includes synovial biopsy

The American Academy of Orthopaedic Surgeons and the American Society for Surgery of the Hand indicated at that time that these services are not performed in the non-facility setting and should not be priced in that setting. The CMS claims data supports this assertion. The utilization of these services is very low in general, only a few thousand are performed per year for the Medicare population and only about 100 have been reported as performed in a physician's office.

It is our understanding that an individual physician has approached CMS and requested non-facility practice expense inputs for the preceding codes. The RUC agrees with the specialty societies that it not appropriate to price these services in the non-facility setting. Office-based diagnostic arthroscopy would not permit contemporaneous treatment of pathology noted at the time of the diagnostic procedure. Such treatment can require extended anesthesia time and an extensive array of operative equipment and surgical implants, which would not be available in an office setting. Therefore, the development of practice expense inputs for the non-facility setting is not indicated. **The RUC recommends that the practice expense relative value associated with 29805, 29830, 29840, 29870 and 29900 for the non-facility setting should remain designated N/A.**

Professional Liability Insurance (PLI) RVUs (TC/PC) Issue

Two alternative suggestions appear in the July 12, 2007 *Proposed Rule,* page 38142, regarding corrections to the technical component (TC)/ professional component (PC) professional liability insurance (PLI) RVU allocation issue. The American College of Radiology (ACR) had initially identified the TC methodology calculation issue in December 1999. Subsequently, ACR recommended that CMS should "flip" the PLI RVUs associated with each of the component parts. The RUC did not recommend a "flip" of the technical and professional components, but had recommended the equalization as a stopgap measure.

The RUC had indicated the following in its October 9, 2006 Comment letter on the Proposed Rule to CMS:

> In the Final Rule for the 2005 Physician Payment Schedule, CMS responded to these comments as follows:
>
> *Physician work RVUs are used to adjust for risk of service. Because technical component services do not have physician work RVUs, they are still valued using charge-based RVUs instead of the resource-based malpractice RVU methodology. We look forward working with the ACR and the other interested specialty organizations to examine alternative methodologies that would allow technical component services to also reflect resource-based malpractice RVUs.*
>
> The RUC intends to discuss this issue further and recommend alternate methodologies for allocation of the PLI RVUs. However, the immediate effects of the DRA provision will remove significant resources from the Part B pool, an estimated $200 million. CMS should instead appropriately reallocate PLI RVUs within the physician fee schedule by accepting the RUC interim recommendation to establish the technical component PLI RVU to be equivalent to the professional component PLI RVU for each CPT code. A long-term strategy should then be explored to allow technical component PLI RVUs to reflect resource-based professional liability costs.

In the July 12, 2007 *Proposed Rule*, CMS indicates that "we would like to better understand how, and if, technicians employed by facilities purchase PLI or how their professional liability is insured. In addition, we are soliciting comments on what types of PLI are carried by facilities that perform technical services."

The RUC Professional Liability Insurance (PLI) Workgroup convened via conference call on July 31, 2007, to further discuss a response to the above questions. The Workgroup determined that liability cost for clinical staff, compared to professional liability cost for the physician service, is inseparable from general practice setting liability insurance cost. Therefore, since there are not separately identifiable PLI premiums paid for the professional technical staff, TC PLI costs should already be included in both the professional component PLI RVU for office-based services and in the facility payment for services performed in hospitals and other facilities. This is consistent with how PLI is handled in the rest of the Physician Payment Schedule, where clinical staff are not included in the PLI resource-based calculation, and where there is no distinction between facility and non-facility PLI.

CMS asks what types of insurance policies are carried by facilities that perform only technical services. General business insurance to insure customers (patients), employees, office, equipment, etc, is considered a component of practice expense and should not be confused with professional liability insurance, or as CMS terms it "malpractice insurance."

A compelling example of inequity created with TC PLI is that CMS currently states that the liability for a MRI technologist to perform an MRI of an upper extremity joint is higher than an Obstetrician performing an amniocentesis. The total PLI RVUs for the MRI in the example below should be about one-forth of the amniocentesis code (0.31/4 =0.08) to represent the relative difference in PLI premiums between the dominant specialties. Therefore, the example below solidifies that using only the professional component is the appropriate approach.

Code	Descriptor	Physician Work RVU	Physician Intra-Service	PLI RVU	Clinical Staff Time	National Avg PLI Premium per CMS
59000	*Amniocentesis; diagnostic*	1.30	20 minutes	0.31	70 minutes – RN	Obstetrician $69,514
73221	*MRI, joint upper extremity*	1.35	20 minutes	0.45 PC=0.06 TC=0.39	71 minutes – MRI Tech	Radiologist $16,913

The PLI Workgroup understands there are no identifiable separate costs for professional liability for technical professionals. The PLI Workgroup recommends that CMS reduce the PLI technical component to zero. The PLI RVUs should then be recalculated to ensure that these PLI RVUs are redistributed across all physician services. This would be accomplished by modifying the budget neutrality adjustment applied as the last step in the methodology of assigning PLI RVUs. The total pool of available PLI RVUs would not change as a result of our proposal.

The RUC is sharing the PLI Workgroup discussion with CMS now as the comment period concludes on August 31. However, the RUC has received a request to further discuss this issue at its September 27-29, 2007 RUC meeting. The RUC will provide final comments and/or recommendations following this discussion.

Liability Premium Data

In 2006, the Physician Insurers Association of America (PIAA) informed the RUC that they had submitted PLI premium data for six pilot states to CMS. The RUC anticipated that following the release of the November 2006 Final Rule and collection efforts for the GPCIs, CMS was to review this data and determine if it met the appropriate requirements. **The RUC requests a response on the status of the use of the PIAA data.**

The RUC understands that CMS is currently reviewing data collected for GPCIs and preliminary data may be available to compare to the PIAA premium data submitted to CMS. **The RUC requests that CMS share the preliminary report on the data comparison between PIAA data and data collected by CMS contractor on national liability premium per Medicare specialty.**

Coding - Additional Codes from the Five-Year Review

In May 2007, the RUC submitted recommendations for nine issues identified for review as part of the 2005 Five-Year Review. The RUC recommended increases for 33 codes, decreases for 10 codes, and to maintain the same value for 15 codes. We thank CMS for accepting the RUC's recommendations for the following issues:

- Partial Mastectomy (19301)
- Insertion of Heart Pacemaker (33207)
- Anoscopy and Proctosigmoidoscopy (45300, 45303, 45305, 45307, 45308, 45309, 45315, 45317, 45320, 45321, 45327, 46600, 46604, 46606, 46608, 46610, 46611, 46612, 46614, 46615)
- Eye Exams (92002, 92004, 92012, 92014)
- Audiology Services (92557, 92567, 92568, 92569, 92579, 92601, 92602, 92603, 92604)
- Nursing Facility Care (99304-99318)
- Domiciliary Care (99326-99328, 99334-99337)
- Home Care (99343-99345, 99347-99350).

This Five-Year Review submission was the result of significant effort and experience of the volunteer physicians who participate in the RUC Process. We truly appreciate the

participation and diligent review conducted by CMS staff during the course of the past two years.

However, the RUC is disappointed to learn that CMS rejected the RUC's recommendation to refer CPT code 93325 *Doppler echocardiography color flow velocity mapping (List separately in addition to codes for echocardiography)* to the CPT Editorial Panel and proposes instead that this service be bundled.

At the February 2007 RUC Meeting, the RUC discussed the inherent nature of providing the services described in 93325, 93307 *Echocardiography, transthoracic, real-time with image documentation (2D) with or without M-mode recording; complete,* and 93320 *Doppler echocardiography, pulsed wave and/or continuous wave with spectral display (List separately in addition to codes for echocardiographic imaging); complete* on the same day by the same physician, as illustrated in the following table:

Same Day Occurrences for 93325 with Codes Billed Together at Least 90% of the Time Produced from the 2005 5% Sample File

CPT Code 1	CPT Code 2	Code 1 Services	Same Day Billed Occurrences	% of Time Code 1 Billed with Code 2
93325	93320	138,398	136,433	98.58%
93325-TC	93320-TC	23,039	22,645	98.29%
93325-26	93320-26	211,640	206,755	97.69%
93325	93307	13,8398	130,949	94.62%
93325-TC	93307-TC	23,039	22,298	96.78%
93325-26	93307-26	211,640	197,093	93.13%

The RUC discussed its policy for other services that are inherent in the provision of physician services. The RUC supports the CPT Editorial Panel and its decision to move toward an approach of including radiological guidance, conscious sedation, or other services within a new CPT code if these services are inherent to the procedure. The data for 93320, 93325, and 93307 are clear and the RUC recommended that this issue be referred to the CPT Editorial Panel for review. Specifically, the RUC recommended that a single code be created to report the services currently reported in 93320, 93325, and 93307.

The RUC commends cardiology for developing a coding proposal to address this issue. This proposal was presented at the June 2007 CPT Editorial Panel Meeting and a new code was created for *CPT 2009*. The RUC has scheduled a review of this new bundled

service at the September 2007 RUC Meeting. Cardiology is currently surveying this code and will develop recommendations to the RUC to ensure that the resources included in this new code reflect the typical patient and remove any redundancies in the physician work, time, or direct practice expense inputs.

The RUC strongly urges CMS to allow this issue to be addressed within current processes and not finalize your proposal to bundle 93325 in 2008. We understand that CMS initially brought this issue to the Five-Year Review of the RBRVS and would like to see it addressed promptly. We believe that the specialty has moved forward and CMS should recognize that the process is working to resolve the agency's concerns, while ensuring that the resources required to provide this service are accurately reflected in CPT and the RBRVS.

The RUC understands that the impact tables included in the *Proposed Rule* do not include this proposal, which has significant budgetary consequences. If CMS finalizes this proposal, the **RUC urges a redistribution of the relative values within the RBRVS.**

Anesthesia Services

CMS requested a RUC review of the physician work of anesthesia services in the *Final Rule* published in the December 1, 2006, *Federal Register.* To address this request the RUC formed the Anesthesia Workgroup which reviewed this issue at length during two conference calls and three face-to-face meetings. Based on the extensive review of all the building block components and validation of the Post-Induction Period Procedure Anesthesia (PIPPA) work by surgeons on the Workgroup familiar with anesthesia services associated with their specialty, the RUC reached unanimous agreement that the revised model predicts anesthesia undervaluation. The RUC recommended to CMS that Anesthesia work is undervalued by 32%. **The RUC urges CMS to finalize and implement the RUC recommendation regarding the work component of Anesthesia services.**

Although not specifically mentioned in the *Proposed Rule*, the RUC during its review of the anesthesia services identified the following three services that may be misvalued based on the current RUC analysis on the anesthesia services:

- 00142 *Anesthesia for procedures on eye; lens surgery*
- 00210 *Anesthesia for intracranial procedures; not otherwise specified*
- 00562 *Anesthesia for procedures on heart, pericardinal sac, and great vessels of chest; with pump oxygenator*

The RUC recommended that CMS allow review of the base units associated with these procedures at an upcoming RUC meeting. CMS staff have provided direct

communication that the agency prefers review of these services immediately. In accordance with this communication, specialty society recommendations for CPT code 00142 will be presented at the September 2007 RUC meeting and the remaining two codes 00210 and 00562 will, at the request of the specialty, be referred to the CPT Editorial Panel to create more clarity in the coding descriptors. The RUC is in agreement with this approach.

Budget Neutrality/Five-Year Review Work Adjuster

In this *Proposed Rule*, CMS announces that the Five-Year Review Work Adjuster will increase from -10.1% to -11.8%. **The RUC strongly urges CMS to eliminate this work adjuster.**

The Omnibus Budget Reconciliation Act of 1989 requires that increases or decreases in relative value units (RVUs) for a year may not cause the amount of expenditures for the year to differ by more than $20 million from what expenditures would have been in the absence of these changes. To limit the increases in Medicare expenditures as mandated by the statute, CMS has applied various adjustments to the Medicare Physician Payment Schedule, including re-scaling the RVUs, creating a separate "work adjuster," or applying a budget neutrality adjustment to the Medicare conversion factor. In 2007, CMS created a new "work adjuster" to ensure budget neutrality following the implementation of the improved work RVUs from the 2005 Five-Year Review of the RBRVS.

In 1993 - 1995, CMS achieved budget neutrality by uniformly reducing all work relative values across all services. The RUC strongly objected to using work relative values as a mechanism to preserve budget neutrality. These adjustments to the work relative values caused confusion among the many non-Medicare payers, as well as physician practices, that adopt the RBRVS payment system. The constant re-scaling also impeded the process of establishing work RVUs for new and revised services. The RUC argued that any budget neutrality adjustments deemed necessary should be made to the conversion factor, rather than the work relative values.

In 1997, following the first Five-Year Review of the RBRVS, CMS modified the approach to apply budget neutrality and implemented a separate work adjuster. This approach was short-lived as CMS converted this adjustment to the conversion factor in 1999. CMS later articulated that the creation of the work adjuster was not effective.

> "We did not find the work adjustor to be desirable. It added an extra element to the physician fee schedule payment calculation and created confusion and questions among the public who had difficulty using the RVUs to determine a payment amount that matched the amount actually paid by Medicare." (*Federal Register*, Vol. 68, No. 216, Pg. 63246).

From 1998 to 2006, CMS has implemented all work neutrality adjustments by adjusting the Medicare conversion factor. The RUC requests that CMS consider the history and these additional arguments to reconsider the agency's position on this issue:

1.) Adjusting the conversion factor does not affect the relativity of services reflected in the recommended RVUs. Adjusting the RVUs has the potential to inappropriately affect relativity. For example, if Service A has 0.50 work RVUs and 1.00 total RVUs, while Service B has 1.00 work RVUs and 1.50 total RVUs, then the relative value of Service B to Service A is 1.50 (i.e., 1.50/1.00). Effectively reducing the work RVUs of both services by 12%, as proposed, would mean Service A would have 0.44 work RVUs and 0.94 total RVUs, while Service B would have 0.88 work RVUs and 1.38 total RVUs. After this adjustment, the relative value of Service B to Service A would be 1.47 (i.e., 1.38/0.94). Thus, the adjustment to the work RVUs can inappropriately affect the relativity among services, whereas an adjustment to the conversion factor would not. This impact on relativity seems most acute on those services for which the RUC and CMS agreed that work has not changed. Adjusting the work RVUs for these services effectively reduces their relative value, contrary to RUC and CMS intent in maintaining the current value. This gets to the very heart of the Medicare physician fee schedule as a resource-based relative value scale.

2.) If the work RVUs are adjusted as proposed, it will dampen the improvements to the E/M services valuation. CMS has publicly lauded the RUC for recommending these increases to E/M and we would surmise that the agency would want to achieve the full benefit of these improvements. If the RVUs continue to be adjusted as proposed, it will obfuscate the hard work done by the RUC and the consensus reached within medicine. The RUC went through a very detailed and difficult process to arrive at its recommended changes in work RVUs for E/M. Adjusting the conversion factor leaves the recommended changes in E/M work RVUs at the level determined to be appropriate by the RUC and CMS.

3.) An adjustment in the Medicare conversion factor is preferable because it has less impact on other payers who use the Medicare RVUs. That is, an adjustment in the Medicare conversion factor will not necessarily affect the payment rates of other payers who use the Medicare RVUs and their own conversion factors. However, any adjustment in the RVUs will impact the payment rates of such payers. The payment rates of payers who peg their rates to a percentage of Medicare will be affected regardless. The RUC believes that CMS must consider such "ripple effects" as it decides how to adjust for work neutrality.

4.) The RUC believes an adjustment to the conversion factor is preferable because it recognizes that budget neutrality is mandated for monetary reasons. Thus, the conversion factor, as the monetary multiplier in the Medicare payment formula, is the most appropriate place to adjust for budget neutrality.

5.) Applying the work neutrality adjustment to the conversion factor would coincide with CMS' current mission of making the Medicare payment transparent.

The RUC argues that applying budget neutrality to the work RVUs to offset the improvements in E/M and other services is a step backward and strongly urges CMS to instead apply any necessary adjustments to the conversion factor.

The RUC also strongly urges CMS to use unadjusted work relative values as the allocator of indirect expenses. CMS had responded to commenters in the November 2006 *Final Rule*, stating that "as recommended by the commenters, we will not use the budget-neutralized work RVUs to calculate indirect PE." We urge you to address this issue in this 2007 *Final Rule.*

CMS Definition of Pre-Service Time

In both March and May of 2007, the RUC requested that CMS consider a modification to the definition of physician pre-service time to be consistent with the pre-service definition utilized for the practice expense methodology. The current CMS definition of pre-service time for physicians is as follows:

Pre-service period:

The pre-service period includes physician services provided from the day before the operative procedure until the time of the operative procedure and may include the following:

- *Hospital admission work-up*
- *The pre-operative evaluation may include the procedural work-up, review of records, communicating with other professionals, patient and family, and obtaining consent*
- *Other pre-operative work may include dressing, scrubbing and waiting before the operative procedure, preparing patient and needed equipment for the operative procedure, positioning the patient and other "non-skin-to-skin" work in OR*

The following services are not included:

- *Consultation or evaluation at which the decision to provide the procedure was made (reported with modifier -57)*

- *Distinct evaluation and management services provided in addition to procedure (reported with modifier -25)*
- *Mandated services (reported with modifier -32)*

The RUC recommended that for purposes of defining physician work, the physician pre-service period instead begin when the decision for surgery is made, similar to the CMS definition for clinical staff time. Physicians may engage in many of these pre-service activities (eg, review of records, communicating with other professionals) prior to the day before the operative procedure.

The RUC is engaged in an effort to standardize physician pre-service time. However, the RUC operates under the policies and guidelines established for the RBRVS by CMS. In order for the RUC to proceed with this project, CMS must first determine if the agency will revise the pre-service physician time definition. **We understand that this must be accomplished via rulemaking and urge you to consider including this proposal in the *Final Rule.***

Other Issues – Anticoagulation Management

The RUC strongly disagrees with the CMS decision to continue to consider anticoagulation management codes (99363 and 99364) to be bundled into the work of E/M codes. We are especially concerned by CMS's position since the initial impetus for the creation of these codes was the statement by CMS that these services were not managed as well as they should be and that the existing coding structure failed to provide incentives to optimize care. During the creation of the code, the CPT Editorial Panel and the RUC were very careful to create protections in the code that would prevent work from anticoagulation management being included in selecting the level of E/M codes. CMS did not offer any explanation for its decision to bundle these codes into E/M services when it published the final rule for the physician fee schedule for 2007. There is still no explanation offered in the 2008 proposed rule.

These CPT codes are recognition of the important work of managing serious disease and the CMS decision to not pay separately for this service could have a devastating impact. The RUC strongly encourages CMS to reverse its position that these services are bundled and instead change their status to a separately payable, covered service. Anticoagulation management services are an important responsibility, and CMS should recognize the extensive work involved by paying separately for this service.

The RUC appreciates the opportunity to offer these comments to CMS. We look forward to the work ahead to further improve the RBRVS.

Sincerely,

William L. Rich, III, MD, FACS

cc: RUC Participants

AMGA
American Medical Group Association®

August 24, 2007

Herb Kuhn, Acting Deputy Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018, Baltimore, MD 21244-8108
By electronic submission

Re: *Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile*

Dear Mr. Kuhn:

Thank you for the opportunity to comment on the proposed rule regarding revisions to the payment policies under the Physician Fee Schedule, and other Part B Payment Policies for CY 2008, document, CMS-1385-P. The American Medical Group Association (AMGA) is an association that represents medical groups, including some of the nation's largest, most prestigious multi-specialty medical practices, independent practice associations and integrated health care delivery systems. AMGA members' 65,000 physicians deliver health care to more than 50 million patients in 40 states, including 15 million capitated lives.

CODING--ADDITIONAL CODES FROM 5-YEAR REVIEW

AMGA Recommendation: AMGA strongly urges CMS to wait for and fully consider the RUC's decisions about the work and practice expense for CPT 93325 before taking any action on the proposal to bundle this code into others.

CMS proposes bundling CPT 93325, Doppler echocardiography color flow velocity mapping (List separately in addition to codes for echocardiography), into CPT codes 76825-8, 993303-4, 993308, 993312, 993314-15, 993317, 93321, and 93350. This is of tremendous concern to our members who are cardiologists and represents a substantial and unwarranted cut for cardiology services payments.

We have learned that our colleagues at the American College of Cardiology (ACC) have been working with CMS to resolve concerns about 93325 for nearly two years. CMS identified 93325 as a procedure to be included in the most recent five year review of the RBRVS. The ACC conducted a survey and presented a recommendation on the physician work RVUs to the AMA/Specialty Society RVS Update Committee (RUC). The RUC did not address the work RVUs, but instead recommended that the issue be

referred to the CPT Editorial Panel to consider whether 93325 should be bundled with CPT 93307 (transthoracic echocardiography). The ACC and the American Society of Echocardiography (ASE) disagreed with this recommendation because 93325 is used with many codes other than 93307 and therefore, they did not propose a new code combining 93307 and 93325 at the time.

In March, 2007 ACC and ASE submitted a proposal to the CPT Editorial Panel for a new code combining 93307, 93325 and 93320 (spectral Doppler). The CPT Panel approved the new code in June for implementation in January 2009. The ACC proposal and the CPT Panel decision left 93325 available for use as an add-on code for all echocardiography base codes other than 93307. The ACC and ASE are now conducting a survey to determine the physician work and practice expense associated with the new code, and will present a recommendation to the RUC in September. This new code is fully expected to address any outstanding issues relative to Medicare utilization of 93307 and will have been analyzed in depth by appropriate national medical societies, the CPT editorial panel, and the RUC.

In the current Notice of Proposed Rulemaking for the 2008 Medicare Physician Fee Schedule (CMS 1385-P), CMS proposes to bundle 93325 into all other echocardiography procedures. Payment rates for the other echo procedures would not be adjusted to reflect the physician work and practice expense associated with 93325. CMS asserts that 93325 is now an integral part of all echocardiography procedures. We want to make certain that CMS staff is aware of the new code approved by the CPT Editorial Panel and to note that the vast majority of Medicare billing for 93325 occurs in conjunction with 93307, so separate reporting of 93307 will fall dramatically when the new code is introduced.

Color flow Doppler is not intrinsic to all echocardiography procedures. Use of the color flow add-on varies significantly across the different echo services. There is considerable diagnostic value in use of this technology and there is distinct physician work and practice expense associated with 93325 that is not accounted for in the relative value units for the other echo codes. Bundling, as proposed, flies in the face of these realities and is, without additional payment, inappropriate and unfair.

The public-private partnership of RUC and CMS has been successful for a long time and produces thoughtful decisions and outcomes. We urge CMS to continue in its cooperative efforts in that regard. Finally, we concur with the ACC and strongly urge CMS to wait for and fully consider the RUC's decisions about the work and practice expense for the new code before taking any action on CPT code 93325.

PROPOSED ELIMINATION OF EXEMPTION FOR COMPUTER-GENERATED FACSIMILES

AMGA Recommendation: AMGA strongly recommends that CMS provide an additional two years to properly educate all parties involved in e-prescribing to allow time for software upgrades, and in some cases, software purchase and testing, to take place.

AMGA supports the evolutionary adoption of SCRIPT-enabled software and the use of e-prescribing. There are obvious benefits to moving in this direction. Among them are increased patient safety; cost savings, once systems have been paid for and established; and efficiency. However, based on information we have received from our members, we strongly suggest allowing an additional two years before dropping the exemption.

In response to CMS' request for information concerning industry readiness, one of our members, the Everett Clinic, Everett, Washington, a 225 physician group practice, conducted an informal survey of pharmacies in its region (independent pharmacies, chain retailers and mail order pharmacies). Everett Clinic found that less than half of the pharmacies were aware of the CMS proposal to end the computer generated fax exemption (see attached letter from the Everett Clinic). Of the 47% of pharmacies currently accepting electronic prescriptions, 98% receives 1% or less of its total prescriptions electronically. When asked about barriers currently preventing implementation of e-prescribing, costs associated with implementation and computer system limitations, were cited by the pharmacies.

Presently, 95% of the pharmacies surveyed are printing electronic prescriptions and manually reentering the information prior to dispensing. The benefits of e-prescribing are obviously not being realized when prescription information is being manually reentered. Moreover, it has also come to our attention that not all software vendors, even those offering e-prescribing programs, have products that are compliant with the SCRIPT standards. Hence, the barriers to acquiring compliant software for some already invested in electronic infrastructure, are elevated.

Although these results are informal, they clearly indicate that many pharmacies are not prepared to deal with the elimination of the facsimile exemption. Until all trading partners are ready to implement SCRIPT-enabled software, the elimination of the computer generated fax exemption makes little sense, given CMS' stated objectives.

Regardless of CMS' decision, several important considerations need to be incorporated into a final rule. Under no circumstances should inability to communicate via required means become a burden to patients. Those seeking to have a prescription filled should not be denied services nor in any other way be penalized because a pharmacy and/or prescriber is not compliant, hence pharmacies must be able to accept faxed prescriptions even if the pharmacy cannot be sure that the prescriber transmitted the prescription in compliance with the regulation (i.e. the prescriber transmitted the fax by a fax machine). Provisions must exist to cover circumstances when either side of a prescription filling communication cannot accept electronic transactions. Faxed prescriptions must be allowed as a back-up option when e-prescribing systems are temporarily not functional.

<u>If implemented as proposed, elimination of the exemption will likely produce more use hand written prescriptions rather than greater participation in SCRIPT compliant e-prescribing. AMGA believes that CMS should provide another two years to educate properly all parties involved in these transactions and allow time for software upgrades,</u>

and in some cases, software purchase and testing, to take place. We therefore strongly urge CMS to postpone finalizing this proposal until January of 2010.

TRHCA--SECTION 101(b): PQRI

AMGA Recommendation: ***AMGA requests that CMS allow medical groups to collect and periodically submit statistically valid, medical group level quality data focusing on the quality measures for high cost/high volume chronic conditions such as those included in the Physician Group Practice demonstration; and allow payment and measurement at the group level.***

In December 2006, Congress passed the Tax Relief and Health Care Act of 2006 (TRHCA) which created the Physician Quality Reporting Initiative (PQRI). Under the PQRI, physicians may receive a 1.5% bonus payment from CMS if they submit data on various quality indicators.

The PQRI is designed to accept data from solo physicians and small group practices. Because of administrative and technology issues, most large multi-specialty medical groups are unlikely to report data under PQRI. Costs to submit data using the G-code system are prohibitively expensive since retooling existing, sophisticated, often proprietary software, and training personnel, are expensive and onerous. Estimates at creating interfaces necessary for medical group Electronic Medical Records (EMR) systems to abstract and submit data through G-codes range in the hundreds of thousands of dollars.

In response, multi-specialty medical groups developed a reporting proposal (Proposal) that would encourage medical group participation in the PQRI. The Proposal allows groups with the capability to collect and distribute quality data to submit data through the existing Medicare Physician Group Practice (PGP) Demonstration process or through existing data registries. Quality measures would focus on high cost/high volume conditions included in the PGP demonstration. In fact the quality measures in the PGP demonstration cover the majority of costs paid by Medicare. Patients with a diagnosis of Congestive Heart Failure alone make up approximately 43% of total Medicare payments.

Because the PGP quality indicator set includes process and outcomes measures, providers would be rewarded for results, not just reporting, representing a significant step in transforming Medicare into a better purchaser of health care. Moreover, the Proposal would support the use of electronic medical record systems to report quality data that will provide more reliable and actionable data for improving beneficiary care.

Many medical groups are large enough for sampling to provide sufficiently robust data to measure quality. They also have a proven track record as efficient providers of care. By and large, such medical groups perform as a single entity, should be measured as a single entity, and have any bonuses or rewards paid as a single entity, allowing use of their existing mechanisms to efficiently distribute feedback reports and funds.

We ask CMS to allow medical groups to collect and periodically submit statistically valid, medical group level quality data; focus quality measures on high cost/high volume chronic conditions such as those included in the Physician Group Practice demonstration; and allow payment and measurement at the group level. These steps would produce large amounts of reliable data focused on high cost diseases and would advance the quality of care.

To that end, we follow with an outline of key elements, with some observations and commentary, that would support this proposal and would allow all those with capability and interest to report quality and related data using periodic, aggregated reporting based on data sampling from existing electronic sources (supplemented as necessary by manual abstraction and similar means):

Medical Group-Level Reporting Proposal for PQRI

1. **Medical group-level reporting option for PQRI**
   - 1.1. For physicians who are members of a medical group that elects the medical group option, the medical group would become its own reporting entity
   - 1.2. Patients would be assigned to medical groups as in the PGP demonstration project, based on the plurality of primary care services (retrospective, based on claims data)
   - 1.3. Measures to be reported:
     - a. Initially, the 32 measures defined in the PGP demonstration project, phased in over three years (year 1: diabetes; year 2: congestive heart failure, coronary artery disease; year 3: hypertension, screening for breast cancer and colorectal cancer)
     - b. Future goals: Broaden disease coverage (COPD and others), receive payment for outcomes, and expand measures to include patient-reported outcomes

2. **PQRI mechanisms for quality reporting—three options:**
   - 2.1. Current PQRI method: Claims-based reporting via G codes and CPT II codes
   - 2.2. Practical immediate approach: Extend the quality component of the PGP demonstration
     - a. Advantages
       - Establishes the concept of medical group-level reporting, and extends the option to all medical groups capable of reporting
       - Accepted mechanism and measure set for reporting at the medical group level
       - Machinery is already in place, via RTI and the Iowa QIO (IFMC)
       - Does not require an EMR or registry (internal or external), but these tools can make medical record abstracting more efficient
       - Practical way for medical groups to take a pro-active position on accountability for quality and care coordination
       - Could substantially increase participation in PQRI, in the short term
     - b. Disadvantages
       - Fundamentally claims-based, so this could delay CMS's registry-based reporting

- Requires substantial effort for medical record abstraction (~ 1.0 FTE per medical group for the current five modules in year 3, with the current sampling method)
- Data collection is retrospective (may require locating charts from 2 years ago)
- Long delays in obtaining feedback; comparative data is limited to other PGP demo participants—no opportunity to stimulate rapid-cycle improvements in care

2.3. Future approach: Registry-based reporting, from EMR and claims data

a. Advantages

- Greater accuracy—determine denominators from EMR problem list or disease registry within medical group, eliminating the false positives (6–15%) and false negatives (25%) that occur in claims data[1]
- Reflects entire population of patients treated—does not require sampling
- Physicians have more time to focus on the patient—no additional documentation required, enhancing their productivity
- Registry would provide timely feedback and comparative performance data, at multiple levels—medical group, practice site, specialty
- Provides incentives to invest in EMRs and systems and services that enhance care coordination, rather than billing systems
- Automatically tied to structured documentation in EMR—does not require audit of individual medical records, only of the overall process

b. Challenges

- Requires disease registry or structured problem lists in EMR, coded so they can be mapped to accepted measure definitions, most of which are based on claims data (e.g., map SNOMED-coded problems in EMR to ICD-9-CM Dx codes)
- Requires specific prompts in EMR to create structured data (vs. dictated notes)
- Medical group must document in the EMR those services that were obtained from other providers (often diabetic eye exams, mammograms, flu vaccine; may include HbA1c testing for diabetes patients followed by an outside endocrinologist)
- Patient attribution—in the PGP demo, "assigned beneficiaries are those for whom the PGP has provided more primary care services than any other provider" (retrospectively attributed, based on Medicare claims from all providers)

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[1] Using claims data to define patient populations can introduce significant errors. In AMGA's work with Health Hero Network on a CMS demonstration project involving home monitoring and care management for high-cost Medicare beneficiaries, claims data are used to identify patients who have CHF, COPD, or diabetes. According to an independent review of medical records by Milliman, 10–16% of patients identified by claims data as having CHF or COPD, even using stringent criteria, did not actually have the disease. The corresponding figure was 5–6% for diabetes.

Participants in the Medicare Physician Group Practice Demonstration have reported similar error rates when using claims data to populate disease registries. Depending on definitions and timeframes, some or all of these "false positive" patients would be included as denominator cases when quality measures are based on claims data.

Relying on claims data can also lead to many "false negatives." A recent study performed for CMS by the Palo Alto Medical Foundation and the California QIO found that only 75% of patients who had diabetes were identified as such, using standard definitions based on administrative data. As a result, many diabetes patients are omitted from quality measures based on claims data.

3. Other issues

3.1. Payment mechanism—three options:

a. Replicate both efficiency and quality components of PGP demo

b. Extend quality component of the PGP demo—omit weighting system?

- In the PGP demo, claims-based measures are weighted 4, abstracted measures 1

c. Mirror pay-for-reporting concept in the current PQRI program

3.2. Current CMS exploration of registry-based reporting (addressed in the NPRM for updating the Medicare fee schedule)

a. This may create another option for medical groups with EMRs and a registry like Anceta or WCHQ that could support the PGP measures or their functional equivalent

b. CMS essentially proposes registry reporting at the physician level, with 74+ measures, rather than the medical group level, with a more focused set of measures. The current thinking on use of registries and the five options mentioned in the proposed rule, all share the fundamental focus that is merely variation on the theme of G code and individual physician reporting, a fatal flaw from the perspective of AMGA

3.3. Additional costs

a. For the PGP demo, CMS contracts with RTI and IFMC (Iowa QIO), and medical groups incur costs for medical record abstraction and data management

b. With registry reporting, providers would presumably pay costs of registry, and CMS would benefit from "consolidation" (dealing with a small number of systems that meet their specs, as for HospitalCompare; same as for Joint Commission Core Measures)

3.4. Sampling—three uses for a more efficient (adaptive) method:

a. For medical record abstraction in the proposed medical group reporting option for PQRI (incorporate adaptive sampling method into data collection tool provided by IFMC and pre-populated with claims data by RTI, or into registry like Anceta or WCHQ)

b. For auditing medical record abstraction in the proposed expansion of the PGP demo

c. For medical record abstraction that may be required in CMS's proposal for registry-based reporting (may include a full set of 74+ measures)

4. Basic Quality Reporting Mechanism in Current PGP Demonstration Project

4.1. RTI extracts data from Medicare National Claims History (NCH) File (approx. 6 months lag)

4.2. Assigns beneficiaries to medical group providing the plurality of primary care services during the year (retrospective)

4.3. Selects patient population for each disease "module," based on claims data

a. Diagnosis codes, services provided

b. Limited to the assigned beneficiaries with full-year Medicare eligibility and at least two office or other outpatient E&M visits at the PGP

4.4. Computes performance on claims-based measures (including claims from other providers)

a. Topping-up option (100% of patient population): medical groups may request list of numerator cases lacking evidence of compliance in claims data, and may report compliance from medical record or on-line system that is available at the point of care

b. Hybrid option (sample of 411 patients, plus 50% oversample): medical group may choose to abstract data for claims-based measures, in which case RTI will pre-populate the abstraction tool with data from claims

4.5. Creates random sample of patients for medical record abstraction (for non claims-based measures and hybrid option for claims-based measures) and pre-populates data collection tool developed by IFMC with patient demographics and other information from claims

a. 411 patients per module, plus 50% oversample (total 615 patients)
b. Same sample for all measures within a module (except primary prevention), although different patients may be eligible for individual measures
c. If fewer than 411 patients qualify for a measure (e.g., atrial fibrillation), the entire patient population is used

4.6. Medical group abstracts data for sample patients, using the data collection tool, and uploads data via QNet

4.7. RTI provides feedback reports to the medical group—currently in performance year 3 of PGP demo, but groups have not yet received all reports from performance year 1

4.8. Calculate quality component of performance payment
a. Claims-based measures are weighted 4 times abstracted measures
b. Reward both quality improvement and high quality—earn quality-based payments if, for each separate measure, the medical group:
- Achieves the higher of 75% compliance or the Medicare HEDIS mean ***OR***
- Demonstrates 10% reduction in the gap between their administrative baseline and 100% compliance **or** achieves the 70th percentile of the Medicare HEDIS level

AMGA supports development of structural measures to be used as part of the PQRI program. Broadening reporting beyond a focus on single medical specialty/disease specific guidelines and measures will aid evolution to strategies that encourage the provision of coordinated care that emphasizes the necessary interdependency of primary care and specialty care.

The use of several kinds of measures that are most likely to be indicators of patient-centered care is warranted. These indicators include: Electronic Medical Record systems; electronic patient registries; professional care coordinator(s), the use of structured or planned visits; multi-disciplinary case management; care coordination mechanisms, such as timely notification to all practitioners regarding a change in treatment or prescriptions; written feedback between primary care and specialists regarding urgent referral visits; and, creation and maintenance of treatment plans based on individual patient needs rather than disease-specific treatment guidelines.

AMGA supports development of structural measures for use in the PQRI but recommends specifically creation and payment of incentives for those who meet these performance measures:

Structural Measures: EMR systems, electronic patient registries, home or telephonic monitoring devices, professional care coordinator(s), integrated teams of primary and specialty care.
Process Measures: Patient monitoring, case management, medication management, written (electronic or paper) feedback between primary and specialty physicians regarding treatment changes and referrals, multi-specialty treatment plans, patient self-management training.
Outcomes Measures: Reduced hospitalizations, re-admissions, and bed days of care (BDOC); reduced nursing home admissions, re-admissions and BDOC; reduction in ER visits; patient satisfaction surveys; and savings compared to Medicare fee for service baseline.

IDTF ISSUES

AMGA Recommendation: AMGA suggests targeted oversight of non-compliant IDTFs, including audits, monitoring, and enforcement to address existing compliance problems and does not oppose the intent of the performance standards.

In our comments for the CY 2007 final rule regarding Independent Diagnostic Testing Facilities (IDTF) regulations, we supported CMS' stance vis a vis IDTFs, even calling for a fundamental reexamination of the need for such entities. While CMS construed our comments as a call for abolition of IDTFs, we meant only to suggest a reexamination of the IDTFs that engaged in impermissible acts. No IDTF should be closed that is compliant with law and regulation and meets the service needs of otherwise un-served communities and patients.

CMS' approach to solving long standing concerns and demonstrated compliance problems continues to emphasize application of additional layers of performance standards. We remain unconvinced that more ineffective actions along the lines of those taken in the past, will yield compliance remediation results. We believe that the answer to problems in this quarter lies in audits, monitoring and enforcement actions where warranted. However skeptical we may be about "more of same," we do not oppose the intent of performance requirements CMS posits.

PHYSICIAN SELF-REFERRAL PROVISIONS

AMGA Recommendation: We urge CMS to reconsider and rescind the proposed changes to per-click arrangements and to study their scope and effects carefully to determine if concerns for fraud and abuse exist, and what the impact on patient care would be if such arrangements were significantly modified.

The proposed solution to addressing problems that seem to have begun with anatomic pathology "pod" labs, and perhaps other professional diagnostic work, will compound already complicated and burdensome regulations, and may produce significant unintended consequences. At the risk of stating the known, we point out that our medical care financing system is unique. At the Federal level, it is a heavily regulated system that imposes price fixing, among many other rules, on a significant sector of the realm, by some estimates 40 percent of total health care spending. This so-called pluralistic delivery system also provides a large role for the private sector, regulated, by and large, by the States, which imposes its own volume control, payment, and other limitations and rules. However, market forces play a part, albeit in limited form, in this.

Most physicians are, even if they tend not to think of themselves in this vein, are self-employed, small business people. The ability to generate a profit is fundamental to the existence of this approach to health care financing. The proposed rules regarding

physician self-referral provisions call into question some of the basic assumptions built into the system. The professional component of Medicare billing is priced via a long standing, scientific approach that takes numerous inputs into account and arrives at a Medicare reimbursement rate. Other Federal programs use some or all of these formulations for their payment bases and, on a selective basis, many private payors follow suit.

This price fixing confronts the buying, selling and other market forces that remain in the mix and produces tension: A scientific, input based, regionally, and otherwise adjusted fee, is supposed to be the correct payment for a service. The creative, entrepreneurial, efficiency-seeking steps taken by buying and selling entities, applying their market leverage, sometimes produce arrangements that call into question the correctness of the Federally arrived at price. This dynamic is an integral feature of the system. The changes being proposed in the notice of proposed rulemaking challenge this fundamental reality, an underpinning of the pluralistic system: Either Medicare fees are correct or they are not. If not, the whole longstanding RBRVS system is challenged. That is neither desirable nor necessary.

On the matter of "services under arrangement" we point out that a comprehensive look at such arrangements is needed to gain deep understanding and draw proper conclusions about this matter and about MedPAC's suggestions. Reliance on concerns and anecdotal evidence is not sufficient to that end. We know from some of our members that there are services done under arrangements that do not result in higher utilization and referral abuse. Many of the arrangements are leases or other under arrangements contracts, do result in significant community and patient benefit and avoid duplication of services, thus producing costs savings to the program overall. Such favorable circumstances should be identified and must factor into any regulatory changes contemplated.

We believe that the appropriate amount of regulation to assume program integrity is warranted, but no more than that should be applied. CMS has seeming viewed its role from an almost prosecutorial perspective, casting a broad net with presumed wrongdoing as the focal point for putative preventive action. Rather than auditing and investigating real or potential abusive and impermissible practices, and taking appropriate administrative or legal action, the agency is using the proverbial "cannon to swat the 'pod' lab fly". We strongly suggest a full reexamination of the problem and application of narrowly drawn remedies.

We ask CMS to consider these kinds of actions rather than risk adding unnecessary complexity, hence confusion and heightened risk of unforeseen, negative repercussions on the broader and non-fraud and abuse problematic practice of medicine:

- Seek from the HHS Office of Inspector General issuance of a special fraud alert directed to the practice of anatomic pathology and "pod" lab practices
- Strengthen interpretation to maximize the enforcement utility of Civil Money Penalties and Exclusion for Circumvention Schemes, 42 USC 1395 nn (g) (4)[2]
- Employ tools already available to investigate abuses and take remedial action where warranted

We are frankly confused at the stance CMS proposed *vis a vis* the unit of service payments in space and equipment leases (per click arrangements). CMS ruminates on the long history of actions and contemplations on the subject of per click arrangement and related issues. The rationale for allowing such arrangements was detailed. The abnegation of this history was succinct and almost nonchalant, effectively prohibiting legal and allowable arrangements in spite of the fact, as stated in the proposed rule, that "...the statute does not expressly forbid per-click payments to a lessor for patient referred to the lessee."

We question CMS' premise that wholesale change is necessary based only on the speculation of wrongdoing. There seems to be neither evidence of wrongdoing cited nor a suggestion that there is wrongdoing, only that the stage may be set for it. There are countless per-click arrangements in place (they have been allowed for years), likely representing millions of dollars of joint venture enterprises, equipment acquisition costs, service agreements, etc., that would need to be disassembled, and in a hurry. Many of such deals involve deployment of high cost equipment such as MRIs or stereotactic radiosurgery (such as the GammaKnife® or CyberKnife®) technology that serves patients, sometimes in very large service areas. If these arrangements must be dismantled, there is a heightened risk that access to the machinery may be lost. The implications for disruption of patient care and normal business arrangements are huge. We urge CMS to reconsider and rescind this proposed change and to study per-click arrangements, their scope and effects to determine if susceptibility concerns for fraud and abuse do, in fact, exist, and if so, what the impact on patient care would be if such undertakings were significantly modified or disappeared altogether.

The in-office ancillary services rule exception was created to facilitate and allow continuation of patient care as widely practiced in the United States. Patients had available a number of diagnostic testing capabilities that the doctor could use in the

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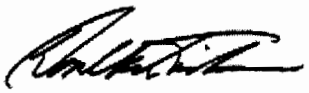
[2] (4) Civil money penalty and exclusion for circumvention schemes

Any physician or other entity that enters into an arrangement or scheme (such as a cross-referral arrangement) which the physician or entity knows or should know has a principal purpose of assuring referrals by the physician to a particular entity which, if the physician directly made referrals to such entity, would be in violation of this section, shall be subject to a civil money penalty of not more than $100,000 for each such arrangement or scheme. The provisions of section 1320a-7a of this title (other than the first sentence of subsection (a) and other than subsection (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a(a) of this title.

practice setting to provide and enhance patient care in terms of convenience for the patient and proximity to the physician for diagnostic and treatment application. While the medical practice world has changed a great deal since this exception was implemented, the underlying realties of patient care and convenience have not. We believe that no changes to the exception should be considered without great study and analysis. If problems are unearthed, solutions should be focused and targeted to the practices in question. The principles and specifics of the in-office ancillary services exception, as currently manifested, should stand.

Thank you for the opportunity to comment. Should you have questions or desire additional information, please contact George Roman, Senior Director, Health Policy, of my staff at (703) 838-0033 ext. 342 or by email at groman@amga.org.

Sincerely,



Donald S. Fisher, Ph.D., CAE
President and CEO

Attachment: Letter from The Everett Clinic

The Everett Clinic

For the whole you.

George Roman
Senior Director, Health Policy
American Medical Group Association
1422 Duke Street
Alexandria, VA 22314

July 26, 2007

Subject: CMS Proposed Rule Change: E-Prescribing and Computer Generated Fax Exception

Dear Mr. Roman:

The Centers for Medicare & Medicaid Services (CMS) issued a proposed rule on June 29, 2007 that included a provision that would eliminate the exemption for computer generated faxes from the e-prescribing standards effective January 1, 2008.

At the Everett Clinic we began implementing electronic prescribing in 2003. All of our providers have sent some prescriptions electronically. Currently, we electronically send over 20,000 prescriptions weekly. We will have the SCRIPT standard implemented as of 10/1/2007 via the Epic Ambulatory system. However, we will be using a computer generated fax to transmit prescriptions. Greater than 95% of Epic practices are planning on doing this as of 1/1/2008.

We will not be able to accomplish a timeline of implementation by 1/1/08. This is true for many medical groups and we believe a timeline of 1/1/2010 is more reasonable and attainable. Being able to utilize fax machines as the transmission device after 1/1/08 ensures the continued implementation of Electronic Health Records and a continued advancement in patient safety.

We have completed a survey of 160 pharmacies which includes major regional and national chains, mail order and independent pharmacies. They do prefer receiving electronically generated faxed prescriptions vs. hand written prescriptions. Their awareness of the rule changes and readiness are as follows:

- 47% are aware of the CMS Rule change
- 78% can accept an electronic prescription into their pharmacy computer system
- 47% are currently accepting electronic prescriptions with 98% receiving 1% or less of their total prescriptions electronically
- Cost/transaction and the computer system limitations are the two reasons noted why pharmacies are not implementing the electronic receipt

Advanced Imaging
Allergy
Anesthesiology
Behavioral Health
Cancer/Oncology
Cardiology
Cosmetic Surgery
Critical Care
Dermatology
Diabetes/ Endocrinology
Ear, Nose & Throat
Facial Rejuvenation
Family Practice
Gastroenterology
Geriatric Care
Gynecology
Hand Center
Head & Neck Surgery
Hearing Aid Center
Hematology
Infectious Disease
Internal Medicine
Laboratory Services
Neurology
Obstetrics
Occupational Medicine
Ophthalmology
Orthopedics
Outpatient Surgery Centers
Pediatric/ Adolescent Care
Pharmacy Services
Physical Medicine & Rehab
Pulmonary
Rheumatology & Arthritis
Skin Surgery & Laser
Sleep Center
Spine Center
Sports Medicine
Surgery
Urology
Vision Centers
Walk-In Clinics

3901 Hoyt Avenue
Everett, WA 98201
425-259-0966
www.everettclinic.com

- 95% are printing their prescriptions out and reentering their prescriptions after receiving them electronically due to computer systems limitations

Moving back to paper prescriptions decreases the quality of patient care in the following ways

- No integration of prescribing data into Electronic Health Records
- Reintroduction of medication errors that are part of written prescriptions and are eliminated via electronic prescribing and fax transmission (eg: bad handwriting, missing information)

We believe in moving to electronic prescribing utilizing the SCRIPT standard. However, we would like to ensure the timeline is able to be implemented. We believe a more reasonable date for full electronic implementation is 1/1/2010.

Sincerely,

Al Fisk, MD, MMM
Medical Director
The Everett Clinic

Jennifer Wilson Norton, RPh, MBA
Director of Pharmacy Services
The Everett Clinic

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August 21, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Sir or Madam:

On behalf of the American Clinical Laboratory Association, please find enclosed comments regarding the 2008 physician fee schedule proposed rule. If you have any questions, please do not hesitate to call.

Sincerely yours,

Peter Kazon

Enclosure

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ACLA

American Clinical Laboratory Association

COMMENTS OF THE
AMERICAN CLINICAL LABORATORY ASSOCIATION
ON THE 2008 PHYSICIAN FEE SCHEDULE PROPOSED RULE

CMS-1385-P

The American Clinical Laboratory Association ("ACLA") is pleased to have this opportunity to comment on the Physician Fee Schedule Proposed Rule for 2008 ("Proposed Rule"). 72 *Fed. Reg.* 38122 (July 12, 2007). ACLA represents local, regional and national clinical laboratories across the country. Because the Proposed Rule includes several provisions of significance to clinical laboratories, it will have a direct impact on ACLA members. ACLA's comments will focus, in particular, on (1) the proposed changes to the reassignment and physician self-referral provisions; (2) the provisions related to the clinical laboratory fee schedule; and (3) other provisions related to clinical laboratories.

I. Physician Self-Referral Provisions

In the Proposed Rule, CMS proposes to complete the multi-year process that began in 2004 when CMS expressed concern about possible exploitation by some providers of loopholes in Medicare billing and self-referral provisions. In the 2005 Final Rule, CMS promised to monitor compliance with reassignment rules, to analyze the impact of the physician self-referral prohibition with regard to "pod" labs and to make such changes in the physician self-referral prohibition as it determined to be necessary in a separate rulemaking. 69 *Fed. Reg.* 66236 (Nov. 15, 2004). In the Proposed Rule for 2007, CMS discussed several possible remedies, including revisions to reassignment regulations that would incorporate provisions of the purchased diagnostic test rules, anti-markup requirements, changes to the minimum requirements needed for a "centralized building" set forth by the regulations implemented under the physician self-referral law (also called the "Stark law"), and other changes. 71 *Fed. Reg.* 49892, 49054-57 (Aug. 22, 2006). CMS declined to address these issues in the 2007 Final Rule, stating that it would continue to study the issues further and issue final regulations in the near future. 71 *Fed. Reg.* 69624, 69688 (Dec. 1, 2006). Instead, CMS reiterated its commitment to "addressing revenue-driven arrangements that may be facilitating over utilization of diagnostic services." *Id.* In fact, CMS noted that Medicare has always had provisions that were designed to limit the ability of physicians to profit from their referrals for diagnostic tests; however, recent changes in the law may have created confusion as to the continued applicability of these provisions leading to an overutilization of these services. Based on the additional information gathered in last year's rule, CMS has now decided on the best approach to take to curb these abuses.

CMS is proposing to make changes in two applicable regulations. First, it will change the provisions in Part 424, Medicare Conditions for Payment, by amending § 424.80, which cover the prohibition on reassignment of claims, as follows:

- If a physician or medical group bills for the Technical Component ("TC") or Professional Component ("PC") of a service, following a reassignment from another physician or

other supplier, it could only be paid the lowest of the following--

- The physician's or other supplier's net charge to the billing physician or medical group;
- The billing physician's or medical group's actual charge; or
- The applicable fee schedule amount for the service.

In essence, this would prevent the billing physician or group from marking up the amount charged by the performing physician or supplier.

- The one exception to this anti-markup requirement would be if the service was performed by a full time employee of the billing physician or group.

- "Net charge" could not include any charge that was intended to cover the cost of equipment or space leased to the performing physician or supplier.

- The billing physician or medical group would have to identify the physician or other supplier that performed the test and indicate the net charge on the claim. Medicare would not pay if this information were not provided.

- To bill the TC, the physician or medical group would directly perform the PC.[1]

In addition, CMS also proposes to change Part 414, which covers payment for Part B medical and other services, by amending the rules for purchased diagnostic tests in § 414.50, by making the following changes:

- Implementing the same billing limitations proposed for § 424.80, which ensure that the billing physician or supplier cannot mark up the service.

- Clarifying that the restrictions apply regardless of whether the service was "purchased" or "reassigned."

- Imposing the same limitations on "net charge" and the same exception for services furnished by full-time employees that are included in the proposed changes to § 424.80.

- Not including the requirement that the medical group directly perform the PC, if it bills for the TC.

ACLA strongly supports the proposals offered by the Proposed Rule for the reasons set out below, and urges CMS to implement them without delay or grace period. We believe that this action is not only warranted, but reflects a reasoned approach that is targeted at the most

[1] At one point in the Proposed Rule, CMS states that it does not intend to impose this requirement, although it is included in the draft regulatory text. ACLA supports the inclusion of this requirement in both § 424.80 and § 414.50 and believes that it will act as a further check on inappropriate billing.

abusive arrangements, and that should not unduly burden legitimate arrangements. In addition, as set out below, ACLA also has offered some suggestions on specific issues related to these proposals on which CMS requested further comment.

A. Anti-Markup Provision

1. Background

In last year's Proposed Physician Fee Schedule Rule for 2007, CMS expressed concern about new types of joint ventures that had begun to spring up by which a physician group practice contracted with an outside supplier for the provision of diagnostic services that physicians in the group then ordered. 71 *Fed. Reg.* 48982, 49054 (Aug. 22, 2006). According to CMS, many of these joint ventures were organized by an entity that obtained the necessary equipment and space, and then identified a pathologist and histotechnologist to furnish the necessary pathology services. In order to comply with the requirements of the Stark law and the prohibition on reassignment, certain unique and cumbersome procedures were required. For example, according to CMS, often the entity that organized the joint venture would subdivide the space into separate areas or cubicles, so that the referring group practice could meet the Stark law requirement that the service be furnished in a "centralized" building or space under the exclusive control of the group practice. The pathologist and the histotechnologist would then move from cubicle to cubicle, as they examined each referring group's slides. As CMS noted in the 2007 Proposed Rule, while the physician group paid a discounted fee to the organizing entity and the pathologist for the review of each slide, the physician group billed Medicare for the entire pathology service, typically at a significant markup over its acquisition price, thereby earning a significant profit on the "spread" between the acquisition price and the amount paid by Medicare. In billing for these services, the group practice would take advantage of recent changes in the Medicare reassignment rules that permitted physicians to bill for services if they had a contractual arrangement with the physician furnishing the services.

Although CMS proposed a number of different approaches to resolve these issues in the 2007 Proposed Rule, when the time came to issue a Final Rule, CMS determined that it needed more time to study the issue. In particular, it expressed concern that it did not wish to take any action that would adversely affect legitimate multi-specialty physician practices. ACLA was concerned about the delay that resulted from CMS' decision to take more time to review these issues but we are pleased that CMS has now developed a reasonable and carefully targeted strategy designed to curb these arrangements. Nonetheless, it appears that many took last year's delay as a sign that CMS did not intend to act decisively, and as a result, in the interim, these arrangements have rapidly proliferated. Therefore, CMS must move quickly to implement the proposed changes that it has developed over the past year to address these concerns.

2. There are Several Reasons for Taking Action Against These Types of Arrangements.

a. These arrangements have long been a subject of concern.

There are a number of reasons for proceeding to take action against these joint ventures at this time. As CMS noted last year, concerns were expressed about the growth of these ventures in 2004, when CMS first moved to implement Section 952 of the Medicare Modernization Act ("MMA"), which created the "contractual arrangement" exception to the reassignment rule.

Moreover, even before that, the OIG has long expressed concerns about joint ventures involving a referrer and an entity that supplies the requested services. In the very first set of anti-kickback "safe harbor" regulations, the OIG expressed concern about joint ventures between referring physicians and a supplier of the goods and services requested by the physicians. It noted that such arrangements "are not arms length transactions where the joint venture shops around for the best price on a good or service. Rather, it has entered into a collusive arrangement with a particular provider or supplier or items or services that seeks to share its profits with referring physician partners." 56 *Fed. Reg.* 35952, 35978 (July 29, 1991).

In 2003, the OIG issued a Special Advisory Bulletin about similar entities that it called "contractual joint ventures," which bear a remarkable similarity to the arrangements that CMS described in last year's Proposed Rule.[2] It noted that in many of these arrangements, the venture's "Owner" was the health care provider that purported to go into a new line of business with another "Manager" or "Supplier" that managed the business. However, according to the OIG:

> [T]he Owner neither operates the new business itself nor commits substantial financial, capital, or human resources to the venture. Instead, it contracts out substantially all of the operations of the new business. The Manager/Supplier typically agrees to provide not only management services, but also a range of other services, such as the inventory necessary to run the business, office and health care personnel, billing support, and space. While the Manager/Supplier essentially operates the business, the billing of insurers and patients is done in the name of the Owner. ...While the contract terms of these arrangements may appear to place the Owner at

[2] The OIG recently did a study of three joint venture pathology arrangements and released its results. The description of the entities, and the arrangements between the organizers of the joint venture arrangements and the owner/physicians, who were also the prime referrers, further underlines the similarity between these joint venture laboratories and the contractual joint ventures about which the OIG has expressed concerns. *See* Review of Pathology Services Claimed by Urology Tyler, P.A. Tyler, Texas From May Through December 2004, OIG, A-05-05-00037 (June 2007); *see also* Audit of Pathology Laboratory Services Claimed by Atlantic Urological Associates, P.A. for Calendar Year 2004, OIG, A-04-05-03002 (June 2007); *see also* Audit of Pathology Laboratory Services Claimed by Florida Urology Physicians, P.A. for the Period September Through December 2004, OIG, A-04-05-03005 (June 2007).

> financial risk, the Owner's actual business risk is minimal because of the Owner's ability to influence substantial referrals to the new business.

Special Advisory Bulletin, *Contractual Joint Ventures*, OIG (April 2003).

In this year's Proposed Rule, CMS recognizes that these new arrangements create the exact same type of concerns as the OIG noted. According to CMS:

> [A]llowing physician group practices or other suppliers to purchase or otherwise contract for the provision of diagnostic testing services and to then realize a profit when billing Medicare may lead to patient and program abuse in the form of overutilization of services and result in higher costs to the Medicare program.

72 *Fed. Reg.* 38122, 38179.

In sum, there can be little question that the types of arrangements described by CMS last year and again this year create significant issues for the Medicare Program and have long been the subject of concern. Moreover, as discussed below, there is ample empirical evidence that such arrangements lead to an increase in utilization and higher Medicare payments. In fact, as will be discussed in greater detail, recent OIG audits of three joint venture laboratories show astonishing rates of increase in utilization once the group practice maintained a financial interest in its referrals. In one case, where the rate of increase was 699%, the average number of services performed on a prostate cancer patients increased from one per patient to nearly nine. Another group practice increased its average number of specimens per patient from four to nearly twelve, a 230% increase. The *lowest* increase in utilization found by the OIG was 26%. In all cases, the average number of services paid to the group practices significantly exceeded the average paid by the Medicare carrier to other providers. We think these utilization increases, which are linked to financial interests, adequately demonstrate the true purpose of these arrangements and the cost to the Medicare program. Further, as also discussed below, acting to curb such abuses will have no adverse effect on the quality of services received by patients, or their access to necessary services.

b. The evidence demonstrates that these arrangements lead to increased utilization and higher Medicare costs.

Both the OIG and CMS have long had concerns about the types of arrangements at issue here. As CMS itself notes in this year's Proposed Rule, giving physicians an opportunity to earn a profit on their referrals leads to overutilization and higher costs to the program. Because the referring physician can earn a profit on each test ordered, there is an incentive to order more services. It is this conclusion, drawn from common sense, industry practices and empirical studies that led to the enactment of the Stark physician self-referral law. Several of the studies that support this conclusion are summarized below.

- In 1988, Congress mandated that the OIG conduct a study on the physician ownership of and compensation from health care entities to which physicians make referrals. *See Financial Arrangements Between Physicians and Health Care Businesses: Report to Congress*, OIG (May 1989) at 18-21. One aspect of this study focused on the impact of physician ownership arrangements on utilization. In its analysis, the OIG found that patients of referring physicians who own or invest in independent clinical laboratories received 45% more clinical laboratory services than all Medicare patients in general, regardless of the place of service. These patients also received 34% more services from independent clinical laboratories than all Medicare patients in general. According to the OIG, in 1987, this increased utilization of clinical laboratory services by patients of physician-owners cost the Medicare program $28 million.

- In 1989, the GAO conducted a study analyzing the patterns of physician referrals to clinical diagnostic laboratories and diagnostic imaging centers in Maryland and Pennsylvania. *See Medicare: Referring Physicians' Ownership of Laboratories and Imaging Centers*, GAO (June 8, 1989). In this study, the GAO found that in, for example, Maryland physician owners tended to order more, and more costly, laboratory services. The comparable figures for physicians who had an ownership interest in laboratories were .53 services per physician visit and $9.93 per service, while those for non-owners were .27 services per visit and $8.68 per service. *Id.* at 8.

- The Florida Coast Containment Board analyzed the effect of joint venture arrangements on access, costs, charges, utilization, and quality, with respect to health care. *See* 63 Fed. Reg. 1659, 1661 (Jan. 9, 1998). As reported by CMS in the 1998 proposed rule on the Stark self-referral law, the Board found that doctor-owned clinical laboratories, diagnostic imaging centers, and physical therapy and rehabilitation centers performed more procedures on a per-patient basis and charged higher prices than facilities that were not physician owned.

- In January of 2007, McKinsey Global Institute ("MGI") prepared a report comparing the health care costs in the United States to other countries. *See Accounting for the Cost of Health Care in the United States*, McKinsey Global Institute (Jan. 2007). In its report, MGI concluded that for several reasons, the United States spends more of its wealth on health care than any other developed country. One of the reasons for this difference in spending was attributed to physician compensation that is based on a fee-for-service reimbursement system, coupled with the increased profit shares attributable to physician ownership in medical facilities. *Id.* at 15-18. MGI observed that facilities that are largely owned by physicians incentivize physicians to treat their patients in facilities where they are co-owners due to profits that are shared among physician-owners. *Id.* at 51.

Just recently, the OIG released audits of three physician practices that were engaged in the type of joint venture arrangements that are the subject of CMS' concern.[3] The OIG found exceptional increases in utilization once the practices entered into these joint venture arrangements and showed that utilization by each of the practices significantly exceeded the average in the carrier area. Utilization by one joint venture laboratory in Leesburg, Florida was 65% more than at other Medicare providers in the same carrier jurisdiction. This practice showed the lowest increase in the number of specimens per case billed by the group, an increase of 26% after the financial relationship was formed. A second joint venture laboratory in Sarasota, Florida claimed payment for 58% more services than the average Florida Medicare provider, and its utilization of prostate biopsies was *seven times (699%) greater* after it entered into the arrangement. Substantial increases also occurred with a group practice affiliated with a San Antonio, Texas joint venture laboratory. This practice increased utilization from four to nearly twelve specimens per patient, an increase of *230%* after it entered into a financial relationship with a joint venture laboratory. The services performed by this group were, according to the OIG report, *124% higher* than the average claimed by other Medicare providers in the same carrier jurisdiction. Even assuming there were new standards in practice evolving, as the groups alleged, it is noteworthy that the groups did not implement these new standards until after they became participants in one of these arrangements, and thereby obtained the ability to profit from these referrals.[4]

Further, in most instances, these types of joint venture arrangements clearly link profits to the number of biopsies that the self-referring physician orders. We are aware of efforts by these joint venture promoters to demonstrate the profit opportunity available to a practice that increases the number of specimens in a self-referral arrangement through investment pro-forma financial statements provided to prospective members of the arrangement, which assume that members would order 12 prostate biopsies for all patients.

In sum, there is a wealth of empirical data that supports the correlation between physician affiliation with an entity to which it refers diagnostic testing and increased utilization of the services offered by that entity. Given the studies above, it is clear that the arrangements about which CMS has expressed concern incentivize physicians to request additional services for patients, which ultimately increases Medicare expenditures.

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[3] *See* Review of Pathology Services Claimed by Urology Tyler, P.A. Tyler, Texas From May Through December 2004, OIG, A-05-05-00037 (June 2007); *see also* Audit of Pathology Laboratory Services Claimed by Atlantic Urological Associates, P.A. for Calendar Year 2004, OIG, A-04-05-03002 (June 2007); *see also* Audit of Pathology Laboratory Services Claimed by Florida Urology Physicians, P.A. for the Period September Through December 2004, OIG, A-04-05-03005 (June 2007).

[4] The conclusion in each of the reports that medical necessity and documentation requirements were generally complied with is qualified by the absence of national or local standards for the number of tissue samples that should be examined for urology patients with prostate-related diagnoses. In these cases, OIG concluded that medical necessity for biopsies could not be determined in the absence of national or local coverage determinations by Medicare.

c. The current proposals will have no adverse effect on quality or access.

Proponents of these arrangements often argue that they are necessary to ensure that patients have access to services that they would not otherwise obtain, or in order to ensure the quality of the services provided. For example, because many of the arrangements are targeted at particular specialties, such as urologists, gastroenterologists, or dermatologists, it is sometimes argued that these joint venture arrangements are able to specialize in analysis of these types of specimens and thereby provide a higher level of service. Nothing could be further from the truth and to the extent that comment is made, we strongly urge CMS to reject it.

First, many national and regional laboratories and pathology groups have pathologists who are subspecialty certified and perform pathology services within those subspecialties. These specialists have training and experience that is at least comparable (if not superior) to the training of pathologists working at the joint venture laboratories. Indeed, many of the individuals who now work at these joint venture entities received their training and experience working for other independent laboratories.

Second, pathology groups and independent laboratories, *because* they have no financial ties to the referring group, must compete on the basis of diagnostic capability, quality, turnaround time, and service-- the very factors that a referring physician should consider in furtherance of patient care. In contrast, where a practice maintains a financial interest in each referral that is sent to his own group practice laboratory, there is an additional financial element to the decision of where to send the biopsy that is not solely driven by patient interest.

Further, if referring physicians are concerned that these specialized services are not available elsewhere, there is nothing in CMS' current proposals that prevents delivering pathology services to patients in the same way. A physician can still refer specimens to one of these laboratories. The only thing that the physician cannot do is mark up the cost, when billing Medicare. Thus, the only thing that is affected is the referring physician's ability to earn a profit—not the referral itself. Alternatively, the pathologist performing the service can simply bill Medicare directly for the service, and be paid the full reimbursement level.

This argument, which attempts to confuse access to the services with the ability to earn a profit on them, has often been made when Medicare threatens to take action against such arrangements. When Medicare proposed changes to the Stark law, the exact same argument was made. One commenter argued that certain restrictions would force patients to travel long distances to obtain services and discourage them from obtaining needed services. CMS correctly rejected this argument. It noted:

> The law only imposes restrictions on a physician who makes a referral for a designated health service if he or she has a financial relationship with the ancillary services provider... However, nothing in the law prevents physicians from making available convenient ancillary services when the physician has no financial interest in the provision of the services. For

> example, a physician may arrange for a diagnostic services provider to perform diagnostic tests in the physician's office for which the diagnostic services provider bills... *Section 1877 of the Act reflects the Congress' unmistakable intent to recognize and accommodate the traditional role played by physicians in the delivery of ancillary services to their patients, while constraining the abuse of the public fisc that results when physician referrals are driven by financial incentives.*

66 *Fed. Reg.* 856, 861-862 (Jan. 4, 2001) (emphasis added).

The CEO of one company that organizes these joint venture arrangements has recently been quoted as stating that these new proposals will not affect the company's ability to furnish services. Indeed, this individual stated that the company supported CMS' desire to prevent program abuse and that these new provisions would not affect its plans to expand its operations. Jondavid Klipp, Laboratory Economics, Vol. 2; (7) at 2 (July 2007). Thus, there is no basis to believe that access to quality services will be impaired.

The existence of such financial relationships creates a substantial risk that the treating physician's selection of a pathologist or pathology lab for patient care will be determined solely or primarily by revenue potential, rather than an objective assessment of the quality, service and qualifications of the pathologist to perform the type of pathology service needed. Rather than improving quality and access, these arrangements expose patients to more frequent, more numerous, and potentially unnecessary biopsies, significantly increasing expenditures for pathology services while compromising the quality of care. By removing the financial incentives to increase utilization of pathology services through the provisions of the Proposed Rule, CMS will eliminate this dangerous conflict of interest. Thus, CMS should reject any concerns that suggest that access or quality of care will be adversely affected by these new provisions.

d. For the most part, these proposals simply clarify Medicare's long-standing prohibitions on markup.

Finally, as CMS has noted, these provisions are simply a clarification of certain requirements that already exist. Since 1994, Medicare has limited the ability of physicians to mark up the cost of the TC of a pathology service. 58 *Fed. Reg.* 63626 (Dec. 2, 1993). Thus, the new proposals simply make clear that the "contractual arrangement" exception to the reassignment rules added by the MMA does not abrogate this existing limitation. It is true that CMS is adding a similar limitation to the purchase or reassignment of the PC, but there were already other limitations that existed on those arrangements. CMS has adopted the current proposal, apparently because it believed it would be less burdensome than the other limitations that already are in place. Thus, its action here is a modest extension of current requirements.

Some providers of services have apparently argued that they are not subject to the purchased diagnostic testing rules because they are not *purchasing* the services, but are simply reassigning them. As CMS has noted, if the services are being furnished by an outside supplier who is not a full-time employee, there is no practical distinction between the "purchase" of a

service and the "reassignment" of a service. In either case, the service is being furnished by an outside supplier, who is not an employee. The group is paying the supplier for that service, at a deeply discounted rate, and then billing for it at the full charge. It makes little difference whether that payment is characterized as a "purchase" or a "reassignment"—the net result is the same.

In sum, there is little question that these proposals are necessary and will help prevent unnecessary utilization and protect the Medicare Trust Fund. We turn now to our comments on the specifics of the proposals themselves.

3. Suggestions on the Specific Proposals

ACLA strongly supports these new provisions and believes, in particular, that the requirements preventing the markup of these services will limit overutilization of these services without adversely affecting access or quality.[5] We believe, however, that there are several additional points that should be emphasized and several areas where some clarification is appropriate.

First, CMS intends to change both the reassignment rules in § 424.80, and the purchased diagnostic test requirements in § 414.50. The purchased diagnostic testing rules make clear that if the TC or the PC of a test is performed by outside suppliers (i.e., anyone other than a full time employee), then the billing limitations, including the anti-markup provision, would apply. Section 424.80, which deals with the provisions on reassignment, is quite clear that nothing in the provision supersedes the rules covering purchased diagnostic testing. Thus, it should be clear that the requirements of § 414.50 apply, even if the physician or group billing is acting under the contractual arrangement exception to the reassignment rules. In order to avoid any confusion in this area, however, we believe it would be useful for CMS to re-state this conclusion. In addition, further clarification could be provided by including, in both the reassignment rules in § 424.80 and the purchased diagnostic test rules in § 414.50, the requirement that to bill for the TC of the service, the physician or medical group must directly perform the PC of the service.

Second, we have questions about the fact that the amendment to § 424.80 is being added to subsection § 424.80(d), which is the section specifically relating to reassignments involving contractual arrangements. The anti-markup requirements incorporated into the amendment should, and we believe are intended to, apply to reassignments under both the contractual reassignment rules, as well as the employee reassignment exception under subsection (b)(1). By placing the amendment in subsection (d), one might mistakenly conclude that the anti-markup

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[5] CMS has not proposed any penalty for failing to follow the new billing provisions, including the anti-markup requirements, other than the fact that it will not pay for the services if the appropriate information is not submitted on the claim. CMS should also make clear, however, that there are other fraud and abuse provisions that would be implicated if these requirements were not followed. For example, the civil money penalty provisions permit the OIG to obtain penalties against providers who knowingly "seek payment in violation of the terms of an agreement or a limitation on charges or payments under the Medicare program...." 42 CFR § 1003.100(b)(1)(ii). This provision appears to be applicable if a group or physician attempted to mark up the cost of a service above the amount permitted by the new requirements. Such action also might constitute a violation of the Federal False Claims Act.

requirement is limited to contractual reassignments. This ambiguity could be addressed by placing the amendment in a new subsection (e) and by making specific reference to reassignment "under subsections (b)(1) and (b)(2) above" in the text of the amendment after the words "following a reassignment" in the first sentence.

Further, we are also concerned that the anti-markup provisions in the reassignment amendment could be construed as applying to independent laboratories, notwithstanding the fact that the CMS commentary clearly states that the anti-markup provisions do not apply to independent laboratories. While the express language of the amendment pertains specifically to physicians and medical groups, the reassignment rules in § 424.80, nevertheless, pertain generally to "claims by suppliers," which include independent laboratories and suppliers other than physicians and group practices. For the sake of clarity, the amendment should expressly state that its application is limited to claims by physicians and medical groups and does not apply to claims by independent laboratories.

In the case of the purchased diagnostic test provision, CMS expressly stated in the preamble of the Proposed Rule that it was proposing in § 414.50 that: "(4) the anti-markup provision not apply to independent labs that have not ordered the TC." 72 Fed. Reg. 38122, 38180. However, this limitation does not appear in the draft regulatory language. Among other things, we are concerned about potential errors that could occur when these regulations are translated to Manual provisions unless these important distinctions have been made up front. The current provisions of the Medicare Claims Processing Manual pertaining to purchased diagnostic tests and interpretations (Chapter 16, §§ 30.2.9 and 30.2.9.1) apply to both physicians and "other suppliers," such as independent laboratories. They are not limited to physicians and medical groups as are the amendments to § 414.50. The Manual provision at § 40.2, Payment Limit for Purchased Services, does remove the existing anti-markup limitation for purchased technical components when purchased by an independent laboratory. We would urge that the amendment to § 414.50 be clear that the anti-markup provisions for both the PC and the TC do not apply to independent laboratories and that the Manual provision at § 40.2 be revised to include the PC as well as the TC.

In addition, there also appears to be a drafting error regarding the application of deductibles and coinsurance to the anti-markup limits in proposed § 424.80 and § 414.50. In both sections, the maximum payment is set as an amount that is net of deductibles and coinsurance, i.e., "less the applicable deductibles and coinsurance." The price limitation should represent the Medicare allowable amount, which should *include* any coinsurance or deductibles to be paid by the Medicare beneficiary. In other words, the combined payments by Medicare and the beneficiary should not exceed, for example, the supplier's net charge to the billing physician or medical group. As written, it would appear that the combined Medicare and beneficiary payment to the physician could exceed the amount that a physician paid a supplier by 20%, the applicable coinsurance for physician fee schedule services. We are reasonably certain that this is not what CMS intends. It would be clearer to revise this language as follows: "the payment to the billing physician or medical group, *including applicable deductibles and coinsurance*, may not exceed the lowest of the following amounts."

Another area in which CMS has left some ambiguity is in what is meant by a "full-time employee." This is an important point because the payment limitations established by the new rules do not apply if the service is performed by a full-time employee. There is no definition in Medicare of a "full-time employee" nor does there appear to be any commonly accepted definition in the law generally. The Department of Labor's Bureau of Labor Statistics uses 35 hours per week as the definition of "full-time" and, therefore, ACLA believes this is a reasonable standard to use in this instance. U.S. Census Bureau, *Stat. Abstract of the United States, 2007* at 371. We note this was the standard that CMS proposed using last year, when it proposed changes in this area. *See* 71 Fed. Reg. 48982, 49057. Employee is usually defined in other Medicare provisions by reference to "common law" requirements. *See* 42 CFR §§ 411.351, 1001.952(i). As a result, in order for the physician or other supplier to be considered "full-time," the individual must be an employee, as that term is usually defined in Medicare, of the billing group or physician, and must routinely work 35 hours per week.

The other ambiguity that we believe should be addressed is how to determine the "net charge" for the service. Often, the "net charge" per slide will be easy to determine; for example, where the supplier of the pathology service is paid a unit price based on the number of slides prepared or read. However, the arrangements could vary, and therefore, it may be useful for CMS to provide additional guidance on how to establish the "net charge." For example, in some situations, a physician or group might agree to pay a supplier a set amount per month or per year to prepare and read all the slides that were referred. In this case, there is no set price per slide, although it might be relatively easy to establish. CMS should make clear that the billing physician or group must still be able to calculate its unit price, which would reflect its payments divided by the number of slides referred.

The Proposed Rule reviews how to deal with the situation where there are payments going between the referring physician and the physician performing the work. It uses an example where the performing physician charges the group $100 per slide, but is also paying rent to the purchasing physician of $50 per slide. In that case, CMS states, and we agree, that the net charge should be $50 per slide. However, we are also concerned that some participants in joint venture laboratories may inappropriately try to inflate the acquisition cost of the service, and argue that other related costs, such as separately purchased or leased equipment, supplies, insurance, etc., should also be included. This would have the effect of raising the net charge, and permit the billing groups to charge Medicare a higher price. We do not believe this should be the case. If the service is being purchased or reassigned, then there must be clear documentation of what the billing physician is paying the supplier to furnish the service, regardless of whether that payment is on a per slide, per month or annual basis. It is that cost that should be the basis for the calculation of "net charge," reduced where necessary, as CMS has proposed, by other fees being paid to the billing person or entity from the supplier furnishing the service. The billing physician should not be permitted to include other charges that he or she is paying separately for the purchased or reassigned service. As a result, the billing individual or entity should be able to demonstrate the basis on which the per-slide net charge is calculated, and that basis should include only payments that the billing physician or group is making to the supplier of the services. The basis of the calculation should be reasonable, fixed in advance of the performance of the services being measured, uniformly applied over time, verifiable and documented. In

addition, the data used to calculate the measurement should be available to the Secretary upon request. This is comparable to the standards used in calculating certain tests for group practices under the Stark law. *See* 42 CFR § 411.352(d)(1)-(2).

Finally, we also urge CMS to review carefully the specific provisions of § 414.50 and of § 424.80 to ensure they are consistent. In several cases, we note there are slight variations between the language in comparable provisions that may create questions. (For example, proposed § 414.50(a)(3)(i) states net charge does not include "any charge that is intended to *reflect* the cost of equipment or space leased to the outside supplier...," while § 424.80 states it does not include "any charge that is intended to "*cover or address*" the cost of this equipment. This difference may not be significant, but there seems no reason that the language is not the same.) Similarly, only § 414.50 includes a provision that the requirements apply regardless of whether the service is "purchased" or "reassigned." Only § 425.80 includes the requirement that to bill for the TC, the entity must perform the PC, which is a current requirement. Finally, inasmuch as the point of the provisions is to make the rules consistent, regardless of whether the service is purchased or reassigned, CMS may also wish to review the Claims Processing Manual to ensure that all provisions there are consistent with these requirements. For example, the limitations of purchased interpretations, which are found only there, in § 30.2.9.1, may simply create confusion, given the other changes that are being made in this Proposal.

Most importantly, as noted above, these provisions should be implemented without any further delay. When CMS decided to take additional time to develop its proposals last year, it gave time for many of these arrangements to expand into new areas. ACLA does not believe there is any need for any additional time once these provisions are finalized. They should be made effective January 1, 2008, along with other provisions of the Final Rule. Those currently involved in these arrangements cannot argue they have not had adequate notice or need additional time to comply, as CMS first proposed these limitations well over a year ago. If the provisions become effective in January 2008, these entities will have had almost 18 months notice of CMS' concern and of its intention to take action. Moreover, there is no need to provide time for these arrangements to "unwind" or "restructure." The provisions simply impose requirements on how the services are billed. The joint ventures themselves do not need to take any other complex or difficult action, other than simply to comply with the billing requirements that CMS is announcing.

With these suggestions, ACLA strongly supports the provisions included in the Proposed Rule.

4. Provisions Related to Services Furnished by Histotechnologists

CMS also states that it is concerned that its anti-markup provisions will not address one situation that nonetheless creates an opportunity for abuse. That is, there are situations where the TC is performed by a non-physician, such as a histotechnologist, whose job is to process the specimen and create the slide. In some instances, the histotechnologist may be a full- or part-time employee of the organizer of the joint venture, or of the group. Alternatively, the individual may simply be an independent contractor who works for numerous separate practices. This

histotechnology service is usually done under the general supervision of a pathologist; however, the histotechnologist cannot bill for the service in his or her own right. As a result, the group or referring physician may simply bill for these services without a formal reassignment or purchase.

As a result, this type of arrangement creates many of the same issues that exist in the other situation discussed above. The group obtains the service at a deeply discounted rate, but then bills Medicare for the full amount. As a result, there is an incentive for overutilization, just as with any other service. Indeed, the risk is even greater, because in many instances today, the reimbursement for the TC performed by the histotechnologist is several times the reimbursement for the PC. Because there is no technical reassignment or purchase, however, it appears that CMS takes the position that the new proposals would not apply to this situation. CMS has asked for comment on how to best to address this situation, and it has particularly focused on the situation where the service is furnished in a "centralized building" according to the Stark law.

CMS is correct in its approach to this issue. Where an individual performs this service in a "centralized building" it is likely that he or she is performing this service for many different groups. The individual may even be moving from one cubicle to another, as CMS pointed out in last year's Proposed Rule. As a result, there is little investment or risk incurred by the referring physicians. If, as often happens, the histotechnologist is an employee of the organizer of the joint venture arrangement, then the group may only pay a percentage of the individual's cost. Clearly, some of these same risks also exist where a group brings a histotechnologist on site, and, as discussed below, it may also be appropriate for Medicare to examine these arrangements as well. Nonetheless, as a first step, it is reasonable to try to limit the situation where the histotechnologist performs services in a space that would otherwise qualify as a "centralized building" under the Stark self-referral laws.

We believe that could be accomplished by adding language to the definition of "centralized building" definition in §411.351 that states as follows:

> *Centralized building* means all or part of a building, including, for purposes of this subpart only, a mobile vehicle, van, or trailer that is owned or leased on a full-time basis (that is, 24 hours per day, 7 days per week, for a term of not less than 6 months) by a group practice and that is used exclusively by the group practice. In the case of a space used for the performance of the Technical Component of a diagnostic test, which is billed by a group practice, such space can qualify as a centralized building only if the group complies with the requirements of § 414.50 or § 424.80(d)(3) when billing for the Technical Component.[6]

This is consistent with the approach being taken in connection with the reassignment and purchased diagnostic testing rules.

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[6] The reference to § 424.80(d)(3) could be changed to "§ 424.80 (e)," if CMS elects to move the proposed purchased diagnostic testing provisions from § 424.80(d)(3) to a new § 424.80(e) as suggested above.

If CMS implemented this requirement, a group or physician would not be able to mark up what it paid for the TC of a test, performed in a centralized building, unless it was performed by a full-time employee. This is consistent with other requirements that CMS has proposed to include under the reassignment and purchased diagnostic testing rules. Basically, it imposes the same markup requirement on services performed by contractor or part-time histotechnologists. As with those other provisions, it would not prevent the *referral*, it would simply prohibit the markup. Furthermore, in this case, the restrictions would apparently not apply if the group brought the services on site. Moreover, such a limitation would also combat another concern that CMS expresses later in the rule: that services furnished today under the in-office ancillary services ("IOAS") exception often have little connection to the physician practice, and often are "nothing more than enterprises established for the self-referral of [Designated Health Services ("DHS")]." 72 Fed. Reg. 38122, 38181.

If CMS does take this action, it should clarify several other points. First, in some instances, these joint ventures try to use the "physician services" exception to the Stark self-referral law. Thus, a group or physician might try to argue that in making its referral, it was not utilizing the IOAS exception, but was instead using the other exception for physician services. There has always been some confusion as to whether the physician services exception can apply to the TC of a physician service. CMS may wish to take this opportunity to address that issue. However, even if this exception is available, the service would still likely have to be done under the supervision of a "physician in the group," as that term is defined in the regulations. That definition requires that the physician be acting "in the group practice's facilities." Therefore, if the physician services exception is applicable, it should be made clear that in the case of diagnostic services, to qualify as the "group practice's facilities," the same limitations would apply that apply to centralized buildings.[7]

We strongly support the changes to the centralized building definition discussed above, and urge CMS to implement it as outlined above, and in the Proposed Rule.

B. In-Office Ancillary Services Exception

CMS also notes that it is concerned that the IOAS exception may be abused in some cases, and that it is being used in ways that were not contemplated by Congress. As demonstrated by the joint venture arrangements discussed above, arrangements utilizing the IOAS exception have little connection to the group practice that is billing for the services. As CMS notes, the services are furnished "in a building that is not physically close to any of the group practice's other offices," and the services are furnished by physicians who "have virtually no relationship with the group practice." In sum, as previously noted, CMS states that these arrangements are little more than "enterprises established for the self-referral of DHS." 72 Fed. Reg. 38122, 38181.

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[7] CMS may also wish to emphasize that the personal services exception in Stark would not be available because that exception only applies where the remuneration is paid by an entity to a referring physician, which would not be the case here. 42 CFR § 411.357(d).

ACLA supports CMS' concern and believes that additional action is necessary. However, because of the complexity of the self-referral law, and this important exception, it is difficult to formulate any specific recommendations, beyond those that we have made above. We would be happy to work with CMS, and other organizations, to review and respond to specific proposals that may be put forward.

II. Clinical Laboratory Issues

A. Reconsideration Process

In the Proposed Rule, CMS discusses several issues related to payment for new clinical laboratory tests, which are usually paid under either a "cross-walking" or "gapfilling" process. CMS noted that in response to last year's rule, it had received comments that the method used by contractors to determine their price for gapfilled tests should be more specific. CMS states in the Proposed Rule that interested parties should submit comments on this issue at this time. 72 *Fed. Reg.* 38122, 38161.

In addition, CMS also proposes a reconsideration process that would apply to the basis for payment and the amount of payment for any new test for which a new or substantially revised Healthcare Common Procedure Coding System ("HCPCS") code is assigned on or after January 1, 2008. As part of the reconsideration process for the basis for payment, CMS would accept written public comments for a 60-day period from the date that CMS posts its basis for payment determination on the agency website. If a commenter recommends that the basis for payment should be changed from gapfilling to crosswalking, the commenter may also recommend the code or codes to which to crosswalk the new test. Those commenters who submitted written comments during the comment period would have the opportunity to present their comments at the next clinical laboratory public meeting. According to CMS, based on comments received, CMS may reconsider its determination and may change the basis for payment from crosswalking to gapfilling (or vice versa). Once the basis for payment is reconsidered, the new basis for payment would be final and not subject to another reconsideration. Similar to the reconsideration process for the basis for payment, CMS proposes to permit reconsideration of the amount of payment for both crosswalking and gapfilling. Based on comments received, CMS may reconsider its determination of the amount of payment and may revise the national limitation amount for the new test.

Finally, if CMS changes its determination as a result of reconsideration, the new determination regarding the basis for, or amount of, payment is effective January 1 of the year following reconsideration. In addition, CMS proposes that the jurisdiction for reconsideration decisions would rest exclusively with the Secretary. The Secretary's decision not to reconsider a determination would not be subject to administrative or judicial review.

With regard to the first issue relating to gapfilling, ACLA notes that in the past there has been concern about widely varying rates set by carriers when gapfilling is used. As a result, there has been a hesitancy to utilize gapfilling, even for tests that are new and where few tests can serve as a point of comparison. These carrier differences have in part been fueled by several

different issues. First, it has never been clear what carriers are supposed to be looking at when setting "gapfilling" rates. Further, there has not been a clear process for submitting information to the carriers by which the confidential information submitted can be protected. Further, carriers are not required to issue any kind of analysis that sets out how they arrived at their gapfilled rates, which also makes the process less transparent. Finally, CMS has directed carriers to focus, among other things, on the "resources required to perform the test." This directive inappropriately leads carriers to focus on the *direct* "cost" of performing the test, which can often vary significantly among providers depending on methodology and other factors. However, as with every health care service, a focus strictly on "cost" will fail to include any recognition for the *indirect or non-tangible* costs, such as the extensive research and development time and costs that go into the creation of any new test, and will also fail to consider the value that the test brings to the healthcare system. Properly utilized diagnostic tests improve patient care and can significantly reduce downstream medical costs by informing early, effective intervention. Therefore, the "cost" of a test, even if addressed comprehensively to address all costs of development and performance, is only one component of its true value. ACLA is pleased that CMS is proposing a reconsideration process, as it should create a path by which the price for new tests set by gapfilling can be reviewed. We would be happy to work with CMS to develop more specific procedures related to the gapfilling process.

Second, ACLA is generally pleased with the new reconsideration process being proposed by CMS. It is always useful if interested parties have a method to appeal decisions of the agency and point out areas where there may be disagreement. We believe the process that CMS has set out is generally appropriate. We do have one suggestion that we believe will improve the process. Under CMS' proposal, an entity can request reconsideration on a payment determination within 60 days of the date on which it is posted by CMS. That individual can then speak publicly at the public meeting held in July on new tests. However, it does not appear that there will be any opportunity for other interested parties to comment on the request. Thus, if someone requests reconsideration on a payment determination, it is not clear that others would have advance notice and an opportunity to submit their views on this request at the July public meeting. It would be useful for CMS to announce, as part of its announcement for the July meeting, that it will be considering the reconsideration request and invite comment, either written or orally, on that request. In this way, CMS will receive other views on the matter that is the subject of the reconsideration.

Third, we are concerned about CMS' decision to only permit reconsideration requests within 60 days of the time the final determinations are posted. As a result, in such cases, CMS should permit requests for reconsideration to be made later than 60 days after the posting of the CMS determination. Thus, we suggest that comments for the reconsideration process be submitted until the end of the first quarter of the next calendar year (i.e., April 1st).

B. Date of Service for the TC of Physician Pathology Issues

Last year, CMS made changes in the date of service ("DOS") requirements for "stored" specimens. In the new rule, CMS proposes to make the same rules applicable to the TC of a pathology test. This means that for the TC of a pathology service, the date of service will usually

be the date the specimen was collected. As CMS is aware, there continue to be issues related to the stored specimen requirements, which have created problems for some laboratories. As a result, ACLA again urges CMS to reconsider the provisions and to shorten the time period for stored specimens, at least for outpatients.

III. TRHCA – Section 104: Physician Pathology Services

Finally, CMS also states that it intends to implement the "grandfather" provision applicable to the TC of pathology services furnished to hospital patients. 72 *Fed. Reg.* 38122, 38205. Under the current provision, laboratories can bill Medicare for the TC of a service furnished to hospital patients if the hospital had a prior relationship with an independent laboratory for this service. CMS states that this will expire at the end of the year.

As CMS is aware, Congress has repeatedly extended this provision each year in the past. As a result, we again urge CMS simply to implement the grandfather on a permanent basis, for all the reasons that we have advised in the past. Even if CMS does not choose to do so, however, we believe that it would be useful for CMS not to implement this provision for at least six months after the end of the year. In the past, laboratories prepared to implement this provision, and then Congress acted, often just before the year's end, or even thereafter, to extend the provision. This creates difficult billing issues, because laboratories must be poised to implement the new requirements and inform customers of the change. Then if Congress acts, they must go back to customers and explain that the change is not going to occur, after all. CMS has similar issues, as it must inform carriers to implement, only to revoke that instruction shortly thereafter.

As a result, because Congress is again considering extending this provision, we believe it would be useful if CMS stated that, if Congress does not act and extend the provision, it intends to delay enforcement until at least July 1, 2008. That would permit laboratories and hospitals (and CMS) time to determine if Congress was going to act again with regard to the provision and take the necessary action to inform hospitals.

Thank you for the opportunity to comment. If you have any questions or need any further information, please do not hesitate to contact us.

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August 22, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1385-P -- Proposed Revisions to the Payment Policies Under the Physician Fee Schedule and Other Part B Payment Policies for CY 2008

To Whom It May Concern:

On behalf of the American Association for Respiratory Care (AARC), I am pleased to submit comments to the Centers for Medicare and Medicaid Services (CMS) on the subject proposed rule. The AARC is a 43,000 member national professional association of respiratory therapists. Respiratory therapists treat high-risk patients with chronic conditions such as asthma and chronic obstructive pulmonary disease (COPD) including emphysema and chronic bronchitis.

CMS is proposing to clarify the definition of respiratory therapy services to remove services in the current definition that CMS believes should only be provided by a physician and are inappropriate to include in a respiratory therapy plan of care. We believe that CMS may be unaware that the proposed revisions have the unintended consequence of eliminating certain provisions of respiratory services that are the core of the respiratory therapy profession.

The AARC is opposed to any changes that would virtually undermine the respiratory therapy profession and eliminate the ability of the respiratory therapist to perform services for which they are educated, trained and competency tested and that are included in their scope of work.

We believe the following comments will provide CMS with valuable information to fully understand the respiratory therapy scope of practice and aid in re-evaluating the changes CMS is proposing in the subject rulemaking.

"CORF ISSUES"

Revisions to the Definition of Respiratory Therapy Services Furnished in a CORF

- **The AARC strongly opposes revisions to the definition of respiratory therapy services provided in a CORF that would eliminate the ability of the respiratory therapist to perform diagnostic tests including pulmonary function and spirometry tests, obtain blood gas analyses, and assess the patient's progress toward the rehabilitation goals established by the physician-certified plan of treatment. Respiratory therapists by virtue of their training and competency testing provide such services as part of their scope of work. To eliminate these vital services as respiratory services furnished in a CORF under a physician's rehabilitation treatment plan would undermine the very nature of the respiratory therapy profession.**

CMS is clarifying the CORF rules to distinguish between physicians' services that are diagnostic and therapeutic services separately billable under Medicare Part B and CORF physicians' services, which are administrative in nature, such as consultation with and medical supervision of non-physician staff, team conferences, case reviews and review of the therapy plan of treatment, as appropriate. These policies are not new. What is new are changes to the definition of respiratory therapy services in which CMS proposes to eliminate services that are the very core of the respiratory therapy profession because the current wording of the definition implies that these services are ones that should be furnished exclusively by physicians.

At issue are two items currently listed as respiratory therapy services under §410.100(e) that CMS proposes to eliminate. They are:

v. Diagnostic tests to be evaluated by a physician, such as pulmonary function tests, spirometry and blood gas analysis; and
vi. Periodic assessment of chronically ill patients and their need for respiratory therapy.

CMS states that it is removing from the definition "the services of establishing the medical and therapy-related diagnosis and the provision of E/M services because these services are provided by the physician, as necessary, to establish the respiratory therapy plan of treatment...as well as other services that under current clinical standards should not be provided by respiratory therapists, but rather should be entrusted to the physician."

Diagnostic services are a vital part of the definition of a CORF

Section 1861(cc)(2) of the Social Security Act defines the term "comprehensive outpatient rehabilitation facility" as one which

> "Is primarily engaged in providing (by or **under the supervision of physicians) diagnostic,** therapeutic, and restorative services to outpatients for the rehabilitation of injured, disabled, or sick persons." [Emphasis added]

With respect to diagnostic tests, it appears that CMS is interpreting the term "to be evaluated by a physician" as the physician's interpretation of the test in which the physician is paid a professional component. In that regard, the AARC agrees that this is a physician service that should be separately billable under Part B and Medicare payment should be made directly to the physician. However, to remove the ability of the CORF to furnish diagnostic services, or the technical component of the services, as part of an established rehabilitation plan included in the CORF facility payment is clearly in opposition to the statutory provision.

Assessment and evaluation are integral services in the respiratory therapy scope of work

The current wording in the definition with respect to "periodic assessment" is very broad. It implies that physicians should evaluate their chronically ill patients from time to time to determine if they are in need of respiratory therapy. In other words, the assessment as currently stated is not in the context of a patient for whom a respiratory plan has already been established. In such case, the AARC understands why CMS would deem this assessment to be a physician service.

However, the removal of this service from the definition of respiratory therapy services should not preclude periodic assessment, evaluation and monitoring by a respiratory therapist under a physician-established treatment plan in order to determine how well the patient is meeting the rehabilitation goals and recommending modifications in the respiratory treatment plan based on the patient's response. These are vital respiratory therapy services appropriately provided to CORF patients by respiratory therapists under the supervision of a physician and in accordance with current medical and clinical standards.

The very essence of CORF services is one in which a physician's plan of treatment is carried out under the medical direction of the CORF physician in consultation with and medical supervision of non-physician staff. This is consistent with CMS' definition of CORF physician services as being administrative in nature. Further, in order to receive Medicare payment, current CMS instructions state, "respiratory therapy must be a covered service and must be reasonable and necessary for the diagnosis or treatment of an illness or injury **and performed by** respiratory therapists...as recognized by applicable State law." [Emphasis added]. The intention of the CORF benefit is that non-physician practitioners will provide the rehabilitation services as appropriate to carry out the patient's plan of treatment established by the physician.

Conducting pulmonary function tests, spirometry, blood gas analyses and periodic evaluation of the patient by the respiratory therapist under an established plan of treatment are and should continue to be included in the definition of respiratory therapy services. By incorporating our recommendations below into the final rule, CMS will ensure that the definition of respiratory therapy services is "limited to those services that are appropriately provided to CORF patients by respiratory therapists under a physician-established plan of treatment in accordance with current medical and clinical standards.

Recommendation: The AARC strongly recommends that CMS incorporate the following revisions into the definition of respiratory therapy services in order to continue to permit respiratory therapists to perform services under a physician's supervision and for which they are educated, trained and competency tested to perform as part of an established respiratory therapy plan.

1. **Revise §410.100(e)(1) to read:**

   "Respiratory therapy services ***are for the assessment, treatment, and monitoring of patients with deficiencies or abnormalities of cardiopulmonary function."***

Adding the word "assessment" back into the definition is consistent with the definitions of other therapies provided by the CORF, such as physical therapy, occupational therapy, speech-language pathology and social and psychological services, all of which include the term "assessment" as part of the definition of their respective services. In this context, the assessment is carried out as part of a physician-established plan of treatment.

2. **Revise §410.100(e)(2) to include the following services:**

   (v) Pulmonary function tests, spirometry and blood gas analyses; and,
   (vi) Assessment, evaluation and monitoring of the patient's responses to the respiratory care plan of treatment

These services are inherent in any rehabilitation plan that is carried out by the respiratory therapist. Therefore, these services should remain an integral part of the overall definition of respiratory therapy services. To further substantiate our recommendation, the education and competency testing that a respiratory therapist must complete in order to be licensed are highlighted in detail below.

As noted earlier, the respiratory therapist is the only allied health care professional specifically educated and competency tested in all aspects of respiratory and pulmonary care. As part of their education and competency testing, respiratory therapists are required to perform the following tasks:

1) **Evaluate** patient data in the patient record;
2) **Collect and evaluate** additional pertinent clinical information about a patient's needs for respiratory/pulmonary care that require the respiratory therapist to:
    a. **Assess** patient's overall cardiopulmonary status by *inspection* to determine
        i. General appearance (e.g., muscle wasting, venous distention, peripheral edema, diaphoresis, clubbing, cyanosis, capillary refill, chest configuration, evidence of diaphragmatic movement, breathing pattern, accessory muscle activity, asymmetrical chest movement, intercostals and/or sternal retractions, nasal flaring]
        ii. Cough, amount and character of sputum
        iii. Transilumination of chest, Apgar score, gestational age
    b. **Assess** patient's overall cardiopulmonary status by *palpation* to determine
        i. Heart rate, rhythm, and force
        ii. Asymmetrical chest movements, tactile fremitus, crepitus, tenderness, secretions in the airway
    c. **Assess** patient's overall cardiopulmonary status by *auscultation* to determine presence of
        i. Breath sounds [e.g., normal, abnormal]
        ii. Heart sounds and rhythms [e.g., normal, abnormal]
        iii. Blood pressure
    d. **Perform** procedures including
        i. Pulse oximetry
        ii. **Blood gas**/hemoximetry analysis
        iii. **Pulmonary functio**n laboratory studies [e.g., flows, volumes, diffusion studies, pre- and post-bronchodilator]
3) **Recommend** procedures to obtain additional data
4) Select, assemble, use and troubleshoot equipment as well as performing quality control procedures and ensure infection control;
5) **Initiate and modify** a variety of therapeutic procedures including
    a. **Evaluate and monitor** the patient's objective and subjective responses to respiratory care
        i. Obtain a blood gas sample and perform pulse oximetry, blood gas and co-oximetry analyses, and capnography
        ii. Interpret blood gas and co-oximetry results
        iii. Perform spirometry, determine vital capacity, measure pulmonary compliance and airways resistance, interpret airway graphics, measure peak flow
        iv. **Monitor** airway pressure
        v. **Measure** F1O2 and/or liter flow
        vi. **Monitor** endotracheal or tracheostomy tube cuff pressure; and
        vii. Auscultate chest and interpret changes in breath sounds

6) **Independently modify treatment techniques** based on the patient's response
7) **Recommend modifications in the respiratory care plan** based on the patient's response.

[Emphasis Added]

While there are numerous other tasks that the respiratory therapists perform, we highlight the above in order to emphasize to CMS the role the respiratory therapist plays in performing certain diagnostic tests, assessing, evaluating and monitoring the patient's condition and determining the need for modifications to the individual's therapy and treatment plan.

The examination matrix for the Certified Respiratory Therapist is provided as **Attachment A.** The examination matrix for the Advanced Respiratory Therapist is provided as **Attachment B.** These services are integral components of respiratory therapy, for which the respiratory therapist professional is educated, competency tested and is legally sanctioned to perform in nearly every state. A more detailed discussion of the respiratory therapy profession is contained in the remainder of our comments.

The Respiratory Therapist Technician as CORF Personal

- **The medical and health care community no longer uses the term "respiratory therapist technician". In fact, for over a decade, the accepted reference terminology for the profession is "respiratory therapist." The AARC concurs that CMS should revise the qualifications of an individual furnishing respiratory therapy services in a CORF to ensure that the individual meets the educational and training level of the respiratory therapist.**

The current conditions of participation recognize respiratory therapy technicians as CORF personnel. CMS is proposing to revise the conditions of coverage to ensure that only an individual who meets the educational and training level of the respiratory therapist, rather than the respiratory therapy technician, can provide respiratory therapy services in a CORF. According to CMS this change is necessary to be consistent with G codes that were established several years ago to recognize certain CORF respiratory therapy services and the respiratory therapist as the appropriate level of personnel to provide them.

Respiratory therapy education mandates the teaching of diagnostics, patient assessment and evaluation

All respiratory therapists are now required to be graduates of accredited respiratory therapy education programs with a minimum of an associate degree. Upon graduation, the individual ***is*** considered a respiratory therapist, eligible to sit for the professional competency examination administered by the National Board for Respiratory Care (NBRC). Only graduates of accredited respiratory therapy education program are eligible to take the NBRC credentialing examination.

Successful passing of the NBRC competency exam earns the respiratory therapist the professional credential as a Certified Respiratory Therapist (CRT). Meeting certain experiential and/or education requirements qualifies the CRT to sit for the advanced placement credentialing exam and earn the credential as a Registered Respiratory Therapist (RRT). However, it must be clearly stated that all respiratory therapists must now have a minimum of an associate degree and must all obtain the CRT credential. The nationwide respiratory therapy education system no longer is structured to teach to a technician level.

All respiratory therapists must be graduates of education programs accredited by the Commission on Accreditation of Allied Health Education Programs (CAAHEP). CAAHEP is the largest programmatic accreditation program in the health sciences field. In collaboration with its Committees on Accreditation, CAAHEP reviews and accredits nearly 2000 educational programs in nineteen (19) health science professions and occupations. CAAHEP is recognized by the Council for Higher Education Accreditation (CHEA).

The Committee on Accreditation for Respiratory Therapy (CoARC), an Accreditation Committee under CAAHEP sets the education standards and essentials that all 413 respiratory therapy education programs must meet to achieve and maintain accreditation. The CoARC standards are the *minimum* standards of quality used in accrediting programs that prepare individuals to enter the respiratory therapy/care profession.

CMS states that is inappropriate for respiratory therapists to render diagnostic tests, patient evaluation and assessment. The CoARC Standards require all respiratory therapy education programs to teach the following in order to be accredited:

- Acquiring and evaluating clinical data
- Assessing the cardiopulmonary status of patients
- Performing and assisting in the performance of prescribed diagnostic studies such as obtaining blood samples, blood gas analyses, pulmonary function testing, and polysomnography
- Evaluating data to assess the appropriateness of prescribed respiratory care
- Establishing therapeutic goals for patients with cardiopulmonary disease
- Participating in the development and modification of respiratory care plans
- Case management of patients with cardiopulmonary and related diseases

In addition to performing respiratory care procedures, respiratory therapists are involved in clinical decision-making and patient education. The scope of practice for respiratory therapy includes, but is not limited to:

- Initiating prescribed respiratory care treatments, evaluating and monitoring patient responses to such therapy and modifying the prescribed therapy to achieve the desired therapeutic objectives
- Initiating and conducting prescribed pulmonary rehabilitation

- Providing patient, family, and community education
- Promoting cardiopulmonary wellness, disease prevention, and disease management
- Participating in life support activities as required
- Promoting evidence-based medicine, research, and clinical practice guidelines

The respiratory therapist must undergo competency testing

Respiratory therapists upon graduating from an accredited respiratory therapy education program must take the competency examination administered by the NBRC, in order to practice as a respiratory therapist. The NBRC is a member of the National Organization for Competency Assurance (NOCA), and its examination programs are accredited by the National Commission for Certifying Agencies (NCCA). Accreditation by the NCCA signifies unconditional compliance with stringent testing and measurement standards among national health testing organizations.

The NBRC issues professional credentials upon successful passing of the competency examination. The entry-level examination awards the Certified Respiratory Therapist (CRT) credential. Graduates of advanced level respiratory therapy education programs after taking the CRT examination and obtaining the CRT credential, may sit for the Registered Respiratory Therapist (RRT) examination and be awarded the RRT credential.

All NBRC examinations are based on a national job analysis research and all examinations have been validated. This research demonstrates that the examinations are predictive of job performance.

Certified Respiratory Therapist

For the CRT examination (**Attachment A**), the content area includes testing the competency of the candidate to:

- Evaluate and monitor patient's objective and subjective responses to respiratory care
- Independently modify therapeutic procedures based on the patient's response
- Recommend modifications in the respiratory care plan based on the patient's response
- Initiate and conduct pulmonary rehabilitation and home care within the prescription

Diagnostic testing for which the respiratory therapist must be competent includes the following:

- Pulse oximetry, capnography
- Tidal volume, minute volume, peak flow, vital capacity
- Arterial sampling – percutaneous or line
- Blood gas/hemoximetry analysis

- Lung mechanics [e.g., MIP, MEP, pulmonary compliance, plateau pressure, airways resistance]
- Tracheal intubation
- Pulmonary function laboratory studies [e.g., flows, volumes, diffusion studies, pre- and post-bronchodilator]

Registered Respiratory Therapist

A respiratory therapist applying for the Registry Examination must have passed the CRT exam, which establishes the therapist's competency in diagnostic testing, assessment and patient evaluation. The Registry examination consists of a written portion and a clinical simulation portion; and tests advanced skills of the respiratory therapist.

The Content Matrix for the Registry exam (**Attachment B**) includes but is not limited to such content areas as:

- Patient data evaluation and recommendations
- Review existing data in the patient record
    - Evaluate and monitor patient's objective and subjective responses to respiratory care
    - Recommend modifications in the respiratory care plan based on the patient's response
- Determine the appropriateness of the prescribed respiratory care plan
    - Recommend modifications when indicated
- Initiate and conduct pulmonary rehabilitation and home care within the prescription.

Each of the content areas has extensive sub-sections that determine the respiratory therapist's competency in assessing, evaluating and making recommendations to the physician regarding modifications to the course of treatment.

Almost all states have respiratory therapy state licensure laws

Respiratory therapists are licensed in 48 states, the District of Columbia and Puerto Rico. Only Alaska and Hawaii do not regulate the practice of respiratory therapy, although the legislative process to do so is currently underway in both states.

All states currently use the NBRC CRT examination as the official state licensing examination. Therefore, all licensed respiratory therapists must have passed the CRT exam. We would again state that an applicant for the CRT exam must be a graduate of a CoARC accredited respiratory therapy education program. Thus, licensed therapists will have been uniformly educated and competency tested on the content areas CMS is proposing to eliminate.

Respiratory Therapy Scope of Practice

All respiratory therapy licensure laws include a scope of practice. The scope of practice for respiratory therapy licensure provides state legal authority for respiratory therapists to render diagnostic services, and a "determination" of the patient's respiratory condition (i.e., evaluation and assessment of the patient).

When legislative efforts to license respiratory therapists began over 25 years ago, the AARC developed a template for a respiratory scope of practice to ensure consistency among states. This scope of practice has been used uniformly throughout the country as licensure laws have been enacted. The model scope of practice is as follows:

"Practice of Respiratory Care" includes, but is not limited to: the administration of pharmacological, **diagnostic and therapeutic agents** related to respiratory care procedures necessary to implement a treatment, disease prevention, pulmonary rehabilitative, or **diagnostic regimen prescribed by a physician**; transcription and implementation of the written or verbal orders of a physician pertaining to the practice of respiratory care; observing and monitoring signs and symptoms, general behavior, general physical response to respiratory care treatment and **diagnostic testing, including determination of** whether such signs, symptoms, reactions, behavior or general response exhibit abnormal characteristics; and implementation based on observed abnormalities, or appropriate reporting, referral, respiratory care protocols or changes in treatment pursuant to the written or verbal orders by a person licensed to practice medicine under the laws of the State of _____; or the initiation of emergency procedures under the regulations of the Board or as otherwise permitted in this Act. The practice of respiratory care may be performed in any clinic, hospital, skilled nursing facility, and private dwelling; or other place deemed appropriate or necessary by the Board; in accordance with the written or verbal order of a physician, and shall be performed under a qualified Medical Director." [Emphasis added]

Respiratory therapists work under the supervision and/or medical direction of a physician

State laws require that respiratory therapists must work under the medical direction or supervision of a licensed physician. Respiratory therapists execute the physician's orders, whether the orders are written, verbal, or telecommunicated. Respiratory therapists are not independent practitioners and may not bill Medicare directly for their services.

Respiratory therapists have always worked in collaboration with physicians. It was the pulmonary medicine physicians who, in the 1940s, took the initiative for organizing the respiratory therapy profession. Pulmonary physicians needed assistants with expertise in respiratory procedures. Over that last 60 years, the profession has advanced knowledge and scope.

In the last decade, in recognition of the respiratory therapist's expertise, hospitals and other health care providers including CORFs have sanctioned, and physicians have approved respiratory therapists' execution of respiratory therapy patient-driven protocols. These protocols are a set of medical, staff-approved care plans driven by the patient's condition and response to therapy that allow the respiratory therapist to initiate, change, discontinue, or restart treatments and services.

Use of protocols is widely accepted and is also included in the scope of practice in most state respiratory therapy licensure laws. The use of protocols underscores the confidence that the medical community has in the education, competency and expertise of the respiratory therapist.

Recommendation: The current personnel qualifications for respiratory therapists in §485.70(j) and (k) are outdated. We recommend CMS revise the personnel qualifications at §485.70(j) to read as follows and eliminate (k) altogether:

(j) A *respiratory therapist must* –

1) **Be licensed by the State in which practicing, if applicable, or in the case of an individual in a State that does not provide for licensure, is legally authorized to perform respiratory therapy services (in the State in which practicing) under State law (or the State regulatory mechanism provided by State law.)**
2) **Have successfully completed an education program accredited by the Commission on Accreditation of Allied Health Education Programs (CAAHEP) in collaboration with the Committee on Accreditation for Respiratory Care (CoARC); and,**
3) **Have obtained a professional respiratory therapist credential from the National Board for Respiratory Care (NBRC) upon successful passing of a competency examination for respiratory therapists administered by the NBRC.**
   - ***i.*** **Delete.**
   - ***ii.*** **Delete.**
   - ***iii.*** **Delete. [obsolete]**

New paragraph *3)* updates and replaces subparagraphs *i* and *ii*. We also recommend deleting subparagraph *iii* as obsolete. The NBRC will only accept examination applicants who are graduates of CAAHEP-approved respiratory therapy education programs. Subparagraph *iii* was promulgated when the educational system for respiratory therapy was still developing and the education system had limitations. This is no longer the case and this requirement is no longer relevant or applicable.

- **The CORF benefit category is the only one under the Medicare statute that specifically recognizes respiratory therapy services. As such, respiratory therapists should be afforded the same opportunity as other non-physician practitioners in working with the referring physician or CORF physician in developing the plan of treatment that relates to their particular specialty. This is especially important since the respiratory therapist is the professional best qualified to assist the physician in determining the type, amount, frequency and duration of the respiratory therapy services to be furnished.**

CMS has instructed the physician to work collaboratively with physical therapists, occupational therapists or speech-language pathologists in developing their specialties' plans of treatment in the CORF setting. With respect to respiratory therapy, however, CMS has dictated that the respiratory therapy plan must be established entirely by the physician, with no input from the respiratory therapist. This is totally unreasonable and not only undermines the very scope of practice of the respiratory therapist but infringes on the practice of medicine.

The AARC acknowledges that a longstanding problem with coverage of respiratory therapy services under Medicare is the fact that there is no specific benefit category under Part B. To that end, a Congressional legislative initiative is underway that would recognize respiratory therapy services as a Part B benefit and permit certain qualified respiratory therapists to furnish services under the general supervision of a physician. In the interim, the only statutory provision that recognizes respiratory therapy services is in the CORF setting.

In actual practice, physicians regularly utilize the professional expertise and judgment of respiratory therapists as they develop the patient's plan of treatment. Should a physician wish to receive professional input from an RT in developing the plan of care, he or she should be permitted to do so. A physician would not seek input in developing a plan of care from a respiratory therapist unless he or she believes it would be in the best interest of the patient. We do not believe it is prudent for CMS to interfere with this working relationship by requiring the physician to establish a respiratory plan of treatment without consultation with those the respiratory therapists who typically perform the services and who are competency tested and educated in all aspects of respiratory and pulmonary care.

Respiratory therapy services provided in a CORF setting are primarily pulmonary rehabilitation services. The dynamic nature of pulmonary disease and the requirement that the health care practitioner be able to assess the patient and recognize a change in the patient's physical condition which will warrant a change in the overall treatment plan for the patient is continuously on going. Many patients suffer from co-morbidities that can impact the course of therapy and require a change in a treatment plan. Evaluation and assessment of the patient by health care professionals, such as the respiratory therapist who oversee the actual rehabilitation, is essential.

While rehabilitation plans can certainly be generated with an anticipated set of services, it is within the respiratory therapist's scope of practice to assess and evaluate the patient to obtain pertinent clinical information that can benefit the physician in reviewing the plan and its anticipated goals. A respiratory therapist's insight can assist the physician in deciding whether revisions in the type, frequency, amount and duration of the services are required for the individual patient.

Recommendation: The AARC recommends that CMS remove the restriction that the respiratory plan of treatment be established entirely by the physician. CMS should permit physicians to work with respiratory therapists who will provide the actual therapy when establishing patient care plans for respiratory therapy services furnished in CORFs. CMS should revise its instructions and provider educational materials (e.g., MedLearn Article MM3315) to reflect this change and instruct carriers to include the provider education article in its next regularly scheduled bulletin consistent with current instructions.

Summary

By virtue of their education and training, respiratory therapists are educated in diagnostic testing and patient assessment, evaluation and monitoring. There is nothing in the statute that precludes either a respiratory therapist from providing diagnostic and therapeutic services under the supervision of a physician or a CORF from furnishing the technical component of the services. In fact, as stated previously, the statute defines a CORF as one that is primarily engaged in diagnostic services, among other things, and such services should continue to be provided as part of a plan of treatment as CORF services when furnished by non-physician personnel.

The AARC is opposed to any revisions to the definition of respiratory therapy services in a CORF setting that would preclude the respiratory therapist from performing pulmonary rehabilitation services for which they are educated, trained and competency tested to provide. Diagnostic tests such as pulmonary function tests, blood gas analyses and spirometry are core elements of a respiratory therapy plan that are routinely conducted by respiratory therapists and should not be eliminated from the definition. Periodic assessment and evaluation of the patient with respect to achieving certain goals of a treatment plan is the mainstay of the respiratory therapy profession and should also not be eliminated from any definition of respiratory therapy services.

The AARC has provided sufficient information and irrefutable documentation about the respiratory therapy profession that will enable CMS to make further revisions to the proposed rule to address our concerns, including updating the definition of "respiratory therapist" to reflect current standards.

The AARC appreciates the opportunity to comment and encourages CMS to consider our recommendations in finalizing the changes to CORF services. If CMS staff has further questions about our comments, or desires additional information or clarification, we would be most happy to either meet with staff directly, or have staff contact Cheryl West, Director of Government Affairs, at 972-243-2272, or E-mail at west@aarc.org.

Sincerely,

Toni Rodriquez, EdD, RRT
President

Attachments

CRT Examination Matrix

Content Area	Cognitive Level: Recall	Application	Analysis	Number of Items
I. Patient Data Evaluation	**7**	**18**	**0**	**25**
A. Review existing data in the patient record	2	4	0	6
B. Collect and evaluate additional pertinent clinical information	5	14	0	19
II. Equipment Application and Cleanliness	**13**	**17**	**0**	**30**
A. Select, assemble, use, and troubleshoot equipment	10	15	0	25
B. Ensure infection control	2	0	0	2
C. Perform quality control procedures for blood gas analyzers, co-oximeters, and sampling devices; oxygen analyzers; mechanical ventilators; gas metering devices [e.g., flowmeter]	1	2	0	3
III. Therapeutic Procedure Initiation and Modification	**15**	**38**	**32**	**85**
A. Maintain records and communicate information	1	4	2	7
B. Maintain a patent airway including the care of artificial airways	1	2	2	5
C. Remove bronchopulmonary secretions	1	2	0	3
D. Achieve adequate respiratory support	1	4	2	7
E. Evaluate and monitor patient's objective and subjective responses to respiratory care	4	5	0	9
F. Independently modify therapeutic procedures based on the patient's response	2	4	19	25
G. Recommend modifications in the respiratory care plan based on the patient's response	1	9	2	12
H. Determine the appropriateness of the prescribed respiratory care plan and recommend modifications when indicated	1	3	5	9
I. Initiate, conduct, or modify respiratory care techniques in an emergency setting	1	3	0	4
J. Act as an assistant to the physician performing special procedures including bronchoscopy, cardioversion and intubation	1	1	0	2
K. Initiate and conduct pulmonary rehabilitation and home care within the prescription	1	1	0	2
Totals	**35**	**73**	**32**	**140**

Open cells show an examination could include items from indicated cognitive levels.
Shaded cells prevent appearance of items on examinations.

	Recall	Application	Analysis
I. Patient Data Evaluation	**7**	**18**	**0**
A. Review Existing Data in the Patient Record Including	**2***	**4**	**0**
1. Patient history [e.g., present illness, admission notes, respiratory care orders, progress notes, diagnoses, DNR status]			
2. Physical examination relative to the cardiopulmonary system [e.g., vital signs, physical findings]			
3. Pulmonary function results			
4. Blood gas results			
5. Imaging studies [e.g., radiographic, CT, MRI, PET, V̇/Q̇ scan, angiogram]			
6. Monitoring data			
a. pulmonary mechanics [e.g., maximum inspiratory pressure, vital capacity]			
b. respiratory monitoring [e.g., rate, tidal volume, minute volume, I:E, inspiratory and expiratory pressures; airway graphics]			
c. pulmonary compliance, airways resistance, work of breathing			
d. noninvasive monitoring [e.g., V_D/V_T, capnography, pulse oximetry, transcutaneous O_2/CO_2]			
B. Collect and Evaluate Additional Pertinent Clinical Information	**5**	**14**	**0**
1. Assess patient's overall cardiopulmonary status by **inspection** to determine			
a. general appearance [e.g., muscle wasting, venous distention, peripheral edema, diaphoresis, clubbing, cyanosis, capillary refill, chest configuration, evidence of diaphragmatic movement, breathing pattern, accessory muscle activity, asymmetrical chest movement, intercostal and/or sternal retractions, nasal flaring]			
b. cough, amount and character of sputum			
2. Assess patient's overall cardiopulmonary status by **palpation** to determine			
a. heart rate, rhythm, and force			
b. asymmetrical chest movements, tactile fremitus, crepitus, tenderness, secretions in the airway, tracheal deviation			
3. Assess patient's overall cardiopulmonary status by **auscultation** to determine presence of			
a. breath sounds [e.g., normal, abnormal]			
b. heart sounds and rhythms [e.g., normal, abnormal]			
c. blood pressure			
4. Interview patient to determine			
a. level of consciousness/sedation, orientation to time, place and person, emotional state, ability to cooperate, level of pain			
b. presence of dyspnea and/or orthopnea, work of breathing, sputum production, exercise tolerance and activities of daily living			
c. social history [e.g., smoking, substance abuse]			
d. advance directives [e.g., DNR status]			
5. Assess patient's learning needs			
6. Review chest radiograph to determine			
a. position of endotracheal or tracheostomy tube			
b. presence of or change in pneumothorax or subcutaneous emphysema, other extrapulmonary air, consolidation and/or atelectasis, pulmonary infiltrates			
c. presence and position of foreign bodies			
d. position of or change in hemidiaphragms, hyperinflation, pleural fluid, pulmonary edema, mediastinal shift, patency and size of major airways			
7. Perform procedures including			
a. 12-lead ECG			
b. pulse oximetry, capnography			
c. tidal volume, minute volume, peak flow, vital capacity			
d. bedside spirometry [e.g., FVC, FEV_1]			
e. arterial sampling – percutaneous or line			
f. blood gas/hemoximetry analysis			
g. lung mechanics [e.g., MIP, MEP, pulmonary compliance, plateau pressure, airways resistance]			
h. ventilator pressure-volume and flow-volume loops			
i. apnea monitoring			
j. overnight pulse oximetry			

* The number in each column is the number of items in that content area and cognitive level contained in each examination. For example, in category I.A., two items will be asked at the recall level, four items at the application level and no items at the analysis level. The items could be asked relative to any tasks listed (1-6) under category I.A.

	Recall	Application	Analysis
k. tracheal tube cuff pressure and/or volume			
l. tracheal intubation			
m. pulmonary function laboratory studies [e.g., flows, volumes, diffusion studies, pre- and post-bronchodilator]			
8. Interpret procedure results including			
a. pulse oximetry, capnography			
b. tidal volume, minute volume, peak flow, vital capacity			
c. bedside spirometry [e.g., FVC, FEV_1]			
d. blood gas/hemoximetry analysis			
e. lung mechanics [e.g., MIP, MEP, pulmonary compliance, plateau pressure, airways resistance]			
f. apnea monitoring			
g. overnight pulse oximetry			
h. tracheal tube cuff pressure and/or volume			
i. pulmonary function laboratory studies [e.g., flows, volumes, diffusion studies, pre- and post-bronchodilator]			
j. ventilator pressure-volume and flow-volume loops			
k. auto-PEEP			
9. Recommend blood gas analysis, pulse oximetry, transcutaneous O_2/CO_2 monitoring to obtain additional data			
II. Equipment Application and Cleanliness	**13**	**17**	**0**
A. Select, Assemble, Use, and Troubleshoot Equipment Including	**10**	**15**	**0**
1. Oxygen administration devices			
a. low-flow devices [e.g., nasal cannula]			
b. high-flow devices [e.g., air entrainment mask]			
2. CPAP devices – mask, nasal, or bi-level			
3. Humidifiers [e.g., bubble, passover, cascade, wick, heat moisture exchanger]			
4. Pneumatic aerosol generator (nebulizer)			
5. Resuscitation devices [e.g., manual resuscitator (bag-valve), mouth-to-valve mask resuscitator]			
6. Ventilators			
a. pneumatic, electric, fluidic, microprocessor			
b. noninvasive positive pressure			
7. Artificial airways			
a. oro- and nasopharyngeal airways			
b. endotracheal tubes			
c. tracheostomy tubes and buttons			
d. intubation equipment [e.g., laryngoscope and blades, fiberoptic devices, exhaled CO_2 detection devices]			
8. Suctioning devices [e.g., suction catheters, specimen collectors, oropharyngeal suction devices]			
9. Gas cylinders, regulators, reducing valves, connectors and flowmeters, air/oxygen blenders			
10. Point-of-care blood gas analyzers			
11. Patient breathing circuits			
a. continuous mechanical ventilation			
b. IPPB			
c. CPAP, PEEP valve assembly			
d. non-invasive ventilation			
12. Aerosol (mist) tents			
13. Incentive breathing devices			
14. Percussors and vibrators			
15. Positive expiratory pressure (PEP) devices			
16. Vibratory PEP [e.g., Flutter®] mucous clearance devices			
17. Manometers [e.g., water, mercury, and aneroid]			
18. Respirometers [e.g., flow-sensing devices (pneumotachometer)]			
19. ECG machines (12-lead)			
20. Vacuum systems [e.g., pumps, regulators, collection bottles, pleural drainage devices]			
21. Oximetry monitoring devices [e.g., pulse oximeter, transcutaneous]			
22. Metered dose inhalers (MDI), MDI spacers			
23. Dry powder inhalers			
24. Spirometry screening equipment for bedside			
25. Troubleshoot speaking tubes and valves			

	Recall	Application	Analysis
B. Ensure Infection Control	2	0	0
1. Assure selected equipment cleanliness [e.g., select or determine appropriate agent and technique for disinfection and/or sterilization, perform procedures for disinfection and/or sterilization, monitor effectiveness of sterilization procedures]			
2. Assure proper handling of biohazardous materials			
C. Perform Quality Control Procedures For	1	2	0
1. Blood gas analyzers, co-oximeters, and sampling devices			
2. Oxygen analyzers			
3. Mechanical ventilators			
4. Gas metering devices [e.g., flowmeter]			
III. Therapeutic Procedure Initiation and Modification	15	38	32
A. Maintain Records and Communicate Information	1	4	2
1. Record therapy and results using conventional terminology as required in the health care setting and/or by regulatory agencies			
a. specify therapy administered, date, time, frequency of therapy, medication, and ventilatory data			
b. note and interpret patient's response to therapy including			
1) effects of therapy, adverse reactions, patient's subjective and attitudinal response to therapy			
2) auscultatory findings, cough and sputum production and characteristics			
3) vital signs [e.g., heart rate, respiratory rate, blood pressure, body temperature, pain level]			
4) pulse oximetry, heart rhythm, capnography			
c. verify computations and note erroneous data			
2. Communicate information			
a. regarding patient's clinical status to appropriate members of the health care team			
b. relevant to coordinating patient care and discharge planning [e.g., scheduling, avoiding conflicts, sequencing of therapies]			
3. Apply computer technology to			
a. document patient management			
b. monitor workload assignments			
4. Communicate results of therapy and alter therapy per protocol(s)			
5. Explain planned therapy and goals to patient in understandable terms to achieve optimal therapeutic outcome			
6. Counsel patient and family concerning smoking cessation and disease management education			
B. Maintain a Patent Airway Including the Care of Artificial Airways	1	2	2
1. Properly position patient			
2. Insert oro- and nasopharyngeal airways			
3. Identify tube placement by available means			
4. Change tracheostomy tubes			
5. Maintain			
a. proper cuff inflation			
b. adequate humidification			
6. Perform extubation procedure			
C. Remove Bronchopulmonary Secretions	1	2	0
1. Perform			
a. postural drainage and percussion and/or vibration			
b. nasotracheal suctioning			
c. oropharyngeal suctioning			
2. Suction artificial airways			
3. Administer aerosol therapy, administer prescribed agents [e.g., bronchodilators, corticosteroids, saline, mucolytics]			
4. Instruct and encourage bronchopulmonary hygiene techniques			
D. Achieve Adequate Respiratory Support	1	4	2
1. Instruct in			
a. proper breathing technique, encourage deep breathing, instruct and monitor techniques of incentive spirometry			
b. inspiratory muscle training techniques			
2. Initiate and adjust			
a. IPPB therapy			

	Recall	Application	Analysis
b. continuous mechanical ventilation settings			
c. noninvasive ventilation			
d. elevated baseline pressure [e.g., CPAP, PEEP]			
e. combinations of ventilatory techniques [e.g., SIMV, PEEP, PS, PCV, IRV, inspiratory hold]			
3. Select ventilator graphics [e.g., waveforms, scales]			
4. Administer			
a. aerosolized drugs [e.g., bronchodilators, corticosteroids, mucolytics]			
b. oxygen – on or off a ventilator			
5. Initiate and modify weaning procedures			
6. Position patient to minimize hypoxemia			
7. Prevent procedure-associated hypoxemia [e.g., oxygenate before and after suctioning and equipment changes]			
8. Adhere to infection control policies and procedures [e.g., Standard Precautions]			
E. Evaluate and Monitor Patient's Objective and Subjective Responses to Respiratory Care	**4**	**5**	**0**
1. Recommend and review chest radiograph			
2. Obtain a blood gas sample			
a. by puncture			
b. from an arterial or pulmonary artery catheter			
3. Perform			
a. pulse oximetry			
b. blood gas and co-oximetry analyses			
c. capnography			
4. Interpret blood gas and co-oximetry results			
5. Observe changes in sputum characteristics			
6. Observe for signs of patient-ventilator dysynchrony			
7. Perform spirometry, determine vital capacity, measure pulmonary compliance and airways resistance, interpret airway graphics, measure peak flow			
8. Monitor mean airway pressure, adjust and check alarm systems, measure tidal volume, respiratory rate, airway pressures, I:E, and maximum inspiratory pressure			
9. Measure F_IO_2 and/or liter flow			
10. Monitor endotracheal or tracheostomy tube cuff pressure			
11. Auscultate chest and interpret changes in breath sounds			
F. Independently Modify Therapeutic Procedures Based on the Patient's Response	**2**	**4**	**19**
1. Terminate treatment based on patient's response to therapy			
2. Modify treatment techniques including			
a. IPPB [e.g., volume, flow, pressure, F_IO_2, mouthpiece/mask]			
b. Incentive breathing devices			
c. aerosol therapy			
1) modify patient breathing patterns			
2) change type of equipment, change aerosol output			
3) change dilution of medication, adjust temperature of the aerosol			
d. oxygen therapy			
1) change mode of administration, adjust flow, and F_IO_2			
2) set up or change an O_2 blender			
e. bronchial hygiene therapy [e.g., alter patient position and duration of treatment and techniques; coordinate sequence of therapies such as chest percussion, postural drainage, and PEP therapy]			
f. management of artificial airways			
1) reposition or change endotracheal or tracheostomy tube			
2) change type of humidification equipment			
3) initiate suctioning			
4) inflate and/or deflate the cuff			
5) perform tracheostomy care			
g. suctioning			
1) alter frequency and duration of suctioning			
2) change size and type of catheter			
3) alter negative pressure			
4) instill irrigating solutions			
h. mechanical ventilation			
1) improve patient synchrony [e.g., sensitivity, mode]			
2) enhance oxygenation [e.g., F_IO_2, PEEP/CPAP level, inspiratory time]			
3) improve alveolar ventilation [e.g., tidal volume, rate]			

	Recall	Application	Analysis
4) adjust I:E settings			
5) modify ventilator techniques [e.g., pressure support, pressure control]			
6) adjust noninvasive positive pressure ventilation			
7) monitor and adjust alarm settings			
8) adjust ventilator settings based on ventilator graphics			
9) change type of ventilator, change patient breathing circuitry			
i. procedures for weaning from mechanical ventilation			
G. Recommend Modifications in the Respiratory Care Plan Based on the Patient's Response	**1**	**9**	**2**
1. Recommend			
a. institution of bronchopulmonary hygiene procedures			
b. sedation and/or use of muscle relaxant(s)			
c. insertion or change of artificial airway [e.g., endotracheal tube, LMA, tracheostomy]			
d. procedures for weaning from mechanical ventilation			
e. extubation			
f. discontinuing treatment based on patient response			
2. Recommend changes in			
a. patient position			
b. aerosol drug dosage or concentration			
c. F_IO_2 and oxygen flow			
3. Recommend changes in mechanical ventilation to			
a. improve patient synchrony [e.g., sensitivity, mode]			
b. enhance oxygenation [e.g., F_IO_2, PEEP/CPAP level, inspiratory time]			
c. improve alveolar ventilation [e.g., tidal volume, rate]			
d. adjust I:E settings			
e. modify ventilator techniques [e.g., pressure support, pressure control]			
f. adjust noninvasive positive pressure ventilation			
g. monitor and adjust alarm settings			
h. adjust ventilator settings based on ventilator graphics			
i. change type of ventilator, change patient breathing circuitry			
j. alter mechanical dead space			
k. modify ventilator settings to			
1) eliminate auto-PEEP			
2) reduce plateau pressure			
4. Recommend use of pharmacologic interventions including			
a. bronchodilators [e.g., adrenergics, anticholinergics, theophyllines]			
b. antiinflammatory drugs [e.g., leukotriene modifiers, corticosteroids, NSAID, cromolyn sodium]			
c. mucolytics/proteolytics [e.g., acetylcysteine, RhDNAse]			
d. sedatives			
e. diuretics			
H. Determine the Appropriateness of the Prescribed Respiratory Care Plan and Recommend Modifications When Indicated	**1**	**3**	**5**
1. Analyze available data to determine pathophysiological state			
2. Review			
a. planned therapy to establish therapeutic plan			
b. interdisciplinary patient and family plan			
3. Determine appropriateness of prescribed therapy and goals for identified pathophysiological state			
4. Recommend changes in therapeutic plan when indicated based on data			
5. Perform respiratory care quality assurance			
6. Develop outcomes of			
a. quality improvement programs			
b. respiratory care protocols			
7. Monitor outcomes of			
a. quality improvement programs			
b. respiratory care protocols			
8. Apply respiratory care protocols			
I. Initiate, Conduct, or Modify Respiratory Care Techniques in an Emergency Setting	**1**	**3**	**0**
1. Treat cardiopulmonary collapse according to			
a. BCLS			
b. ACLS			
c. Pediatric Advanced Life Support (PALS)			
d. Neonatal Resuscitation Program (NRP)			

	Recall	Application	Analysis
2. Participate in			
a. intra-hospital patient transport			
b. disaster management			
J. Act as an Assistant to the Physician Performing Special Procedures Including	**1**	**1**	**0**
1. Bronchoscopy			
2. Cardioversion			
3. Intubation			
K. Initiate and Conduct Pulmonary Rehabilitation and Home Care Within the Prescription	**1**	**1**	**0**
1. Explain planned therapy and goals to patient in understandable terms to achieve optimal therapeutic outcome			
2. Educate patient and family in disease management			
3. Counsel patient and family concerning smoking cessation			
4. Instruct patient and family to assure safety and infection control			
TOTALS	**35**	**73**	**32**

Registry Examination for Advanced Respiratory Therapists (RRT)

RRT Examination Matrix

Content Area	Cognitive Level: Recall	Application	Analysis	Number of Items
I. Patient data evaluation and recommendations	**6**	**2**	**12**	**20**
A. Review existing data in the patient record	0	1	3	4
B. Collect and evaluate additional pertinent clinical information	2	4	8	14
C. Recommend procedures to obtain additional data	0	1	1	2
II. Equipment application and cleanliness	**2**	**5**	**11**	**18**
A. Select, assemble, use, and troubleshoot equipment	2	4	9	15
B. Ensure infection control	0	0	1	1
C. Perform quality control procedures for blood gas analyzers, co-oximeters, and sampling devices; oxygen analyzers; pulmonary function equipment; mechanical ventilators; noninvasive monitors [e.g., transcutaneous]; record and monitor qc data using accepted statistical methods	0	1	1	2
III. Therapeutic procedure initiation and modification	**3**	**7**	**52**	**62**
A. Maintain records and communicate information	0	1	4	5
B. Maintain a patent airway including the care of artificial airways	0	0	3	3
C. Remove bronchopulmonary secretions	0	0	3	3
D. Achieve adequate respiratory support	0	1	5	6
E. Evaluate and monitor patient's objective and subjective responses to respiratory care	1	1	7	9
F. Independently modify treatment techniques based on the patient's response	1	1	9	11
G. Recommend modifications in the respiratory care plan based on the patient's response	1	1	10	12
H. Determine the appropriateness of the prescribed respiratory care plan and recommend modifications when indicated	0	1	4	5
I. Initiate, conduct, or modify respiratory care techniques in an emergency setting	0	1	3	4
J. Act as an assistant to the physician performing special procedures	0	0	2	2
K. Initiate and conduct pulmonary rehabilitation and home care within the prescription	0	0	2	2
Totals	**7**	**18**	**75**	**100**

Open cells show an examination could include items from indicated cognitive levels. Shaded cells prevent appearance of items on examinations.

	Recall	Application	Analysis
I. Patient Data Evaluation and Recommendations	**2**	**6**	**12**
A. Review Existing Data in the Patient Record Including	**0***	**1***	**3***
1. Patient history [e.g., present illness, admission notes, respiratory care orders, progress notes, diagnoses, DNR status]			
2. Physical examination relative to the cardiopulmonary system [e.g., vital signs, physical findings]			
3. Lab data [e.g., CBC, chemistries/electrolytes, coagulation studies, Gram-stain, culture and sensitivities, urinalysis, pleural fluid]			
4. Pulmonary function results			
5. Blood gas results			
6. Imaging studies [e.g., radiographic, CT, MRI, PET, $\dot{V}/\dot{Q}$ scanangiogram]			
7. Monitoring data			
a. pulmonary mechanics [e.g., maximum inspiratory pressure, vital capacity]			
b. respiratory monitoring [e.g., rate, tidal volume, minute volume, I:E, inspiratory and expiratory pressures; airway graphics]			
c. pulmonary compliance, airways resistance, work of breathing			
d. noninvasive monitoring [e.g., V_D/V_T, capnography, pulse oximetry, transcutaneous O_2/CO_2]			
8. Maternal and perinatal/neonatal history and data [e.g., Apgar scores, gestational age, L/S ratio, pre/post-ductal oxygenation studies]			
B. Collect and Evaluate Additional Pertinent Clinical Information	**2**	**4**	**8**
1. Assess patient's overall cardiopulmonary status by **inspection** to determine			
a. general appearance [e.g., muscle wasting, venous distention, peripheral edema, diaphoresis, clubbing, cyanosis, capillary refill, chest configuration, evidence of diaphragmatic movement, breathing pattern, accessory muscle activity, asymmetrical chest movement, intercostal and/or sternal retractions, nasal flaring]			
b. cough, amount and character of sputum			
c. transillumination of chest, Apgar score, gestational age			
2. Assess patient's overall cardiopulmonary status by **palpation** to determine			
a. heart rate, rhythm, and force			
b. asymmetrical chest movements, tactile fremitus, crepitus, tenderness, secretions in the airway, tracheal deviation			
3. Assess patient's overall cardiopulmonary status by **auscultation** to determine presence of			
a. breath sounds [e.g., normal, abnormal]			
b. heart sounds and rhythms [e.g., normal, abnormal]			
c. blood pressure			
4. Interview patient to determine			
a. level of consciousness/sedation, orientation to time, place and person, emotional state, ability to cooperate, level of pain			
b. presence of dyspnea and/or orthopnea, work of breathing, sputum production, exercise tolerance and activities of daily living			
c. social history [e.g., smoking, substance abuse]			
d. advance directives [e.g., DNR status]			
5. Assess patient's learning needs			
6. Review chest radiograph to determine			
a. quality of imaging [e.g., patient identification, positioning, exposure]			
b. position of endotracheal or tracheostomy tube			
c. presence of or change in pneumothorax or subcutaneous emphysema, other extrapulmonary air, consolidation and/or atelectasis, pulmonary infiltrates			
d. position of chest tube(s), nasogastric and/or feeding tube, pulmonary artery catheter, pacemaker, and other catheters			
e. presence and position of foreign bodies			
f. position of or change in hemidiaphragms, hyperinflation, pleural fluid, pulmonary edema, mediastinal shift, patency and size of major airways			
7. Perform procedures including			
a. 12-lead ECG			
b. pulse oximetry, capnography			
c. tidal volume, minute volume, peak flow, vital capacity			
d. bedside spirometry [e.g., FVC, FEV_1]			
e. arterial sampling - percutaneous or line			
f. blood gas/hemoximetry analysis			
g. lung mechanics [e.g., MIP, MEP, pulmonary compliance, plateau pressure, airways resistance]			

* The number in each column is the number of items in that content area and cognitive level contained in each examination. For example, in category I.A., no items will be asked at the recall level, one item at the application level and three items at the analysis level. The items could be asked relative to any tasks listed (1-8) under category I.A.

	Recall	Application	Analysis
h. ventilator pressure-volume and flow-volume loops			
i. apnea monitoring			
j. overnight pulse oximetry			
k. tracheal tube cuff pressure and/or volume			
l. tracheal intubation			
m. pulmonary function laboratory studies [e.g., flows, volumes, diffusion studies, pre- and post-bronchodilator]			
n. auto-PEEP detection			
8. Interpret procedure results including			
a. transcutaneous O_2/CO_2 monitoring			
b. pulse oximetry, capnography			
c. tidal volume, minute volume, peak flow, vital capacity			
d. bedside spirometry [e.g., FVC, FEV_1]			
e. blood gas/hemoximetry analysis			
f. lung mechanics [e.g., MIP, MEP, pulmonary compliance, plateau pressure, airways resistance]			
g. overnight pulse oximetry			
h. tracheal tube cuff pressure and/or volume			
i. pulmonary function laboratory studies [e.g., flows, volumes, diffusion studies, pre- and post-bronchodilator]			
j. ventilator pressure-volume and flow-volume loops			
k. auto-PEEP			
C. Recommend Procedures to Obtain Additional Data Including	**0**	**1**	**1**
1. Radiographic and other imaging studies			
2. Lung mechanics [e.g., pulmonary compliance, airways resistance, work of breathing]			
3. Blood gas analysis, pulse oximetry, transcutaneous O_2/CO_2 monitoring			
II. Equipment Application and Cleanliness	**2**	**5**	**11**
A. Select, Assemble, Use, and Troubleshoot Equipment Including	**2**	**4**	**9**
1. Oxygen administration devices			
a. low-flow devices [e.g., nasal cannula]			
b. high-flow devices [e.g., air entrainment mask]			
2. CPAP devices – mask, nasal, or bi-level			
3. Humidifiers [e.g., bubble, passover, cascade, wick, heat moisture exchanger]			
4. Pneumatic aerosol generator (nebulizer)			
5. Resuscitation devices [e.g., manual resuscitator (bag-valve), mouth-to-valve mask resuscitator]			
6. Ventilators			
a. pneumatic, electric, fluidic, microprocessor			
b. noninvasive positive pressure			
c. high frequency			
7. Artificial airways			
a. oro- and nasopharyngeal airways			
b. endotracheal tubes			
c. tracheostomy tubes and buttons			
d. intubation equipment [e.g., laryngoscope and blades, fiberoptic devices, exhaled CO_2 detection devices]			
8. Suctioning devices [e.g., suction catheters, specimen collectors, oropharyngeal suction devices]			
9. Gas delivery, metering, and clinical analyzing devices			
a. gas cylinders, regulators, reducing valves, connectors and flowmeters, air/oxygen blenders			
b. oxygen concentrators, air compressors, portable liquid oxygen systems			
10. Patient breathing circuits			
a. continuous mechanical ventilation			
b. IPPB			
c. CPAP, PEEP valve assembly			
d. non-invasive ventilation			
11. Aerosol (mist) tents			
12. Incentive breathing devices			
13. Percussors and vibrators			
14. High Frequency Chest Wall Oscillation (HFCWO) [e.g., ThAIRapy Vest®]			
15. He/O_2 therapeutic gas			
16. ECG machines (12-lead)			
17. Arterial catheters			
18. Oximetry monitoring devices [e.g., pulse oximeter, transcutaneous]			
19. Metered dose inhalers (MDI), MDI spacers			
20. Dry powder inhalers			
21. CO, He, O_2 and specialty gas analyzers			
22. Bronchoscopes			

	Recall	Application	Analysis
23. Select, assemble, and use speaking tubes and valves			
24. Troubleshoot speaking tubes and valves			
B. Ensure Infection Control	0	0	1
1 Assure selected equipment cleanliness [e.g., select or determine appropriate agent and technique for disinfection and/or sterilization, perform procedures for disinfection and/or sterilization, monitor effectiveness of sterilization procedures]			
2. Assure proper handling of biohazardous materials			
C. Perform Quality Control Procedures For	0	1	1
1. Blood gas analyzers, co-oximeters, and sampling devices			
2. Oxygen analyzers			
3. Pulmonary function equipment			
4. Mechanical ventilators			
5. Noninvasive monitors [e.g., transcutaneous]			
6. Record and monitor QC data using accepted statistical methods			
III. Therapeutic Procedure Initiation and Modification	3	7	52
A. Maintain Records and Communicate Information	0	1	4
1. Record therapy and results using conventional terminology as required in the health care setting and/or by regulatory agencies by noting and interpreting patient's response to therapy including			
a. auscultatory findings, cough and sputum production and characteristics			
b. vital signs [e.g., heart rate, respiratory rate, blood pressure, body temperature, pain level]			
c. pulse oximetry, heart rhythm, capnography			
2. Verify computations and note erroneous data			
3. Communicate information relevant to coordinating patient care and discharge planning [e.g., scheduling, avoiding conflicts, sequencing of therapies]			
4. Apply computer technology to			
a. document patient management			
b. monitor workload assignments			
5. Communicate results of therapy and alter therapy per protocol(s)			
6. Explain planned therapy and goals to patient in understandable terms to achieve optimal therapeutic outcome			
B. Maintain a Patent Airway Including the Care of Artificial Airways	0	0	3
1. Insert oro- and nasopharyngeal airways			
2. Perform endotracheal intubation			
3. Maintain			
a. proper cuff inflation			
b. adequate humidification			
4. Perform extubation procedure			
C. Remove Bronchopulmonary Secretions	0	0	3
1. Perform			
a. postural drainage and percussion and/or vibration			
b. nasotracheal suctioning			
2. Suction artificial airways			
3. Administer aerosol therapy, administer prescribed agents [e.g., bronchodilators, corticosteroids, saline, mucolytics]			
4. Instruct and encourage bronchopulmonary hygiene techniques			
D. Achieve Adequate Respiratory Support	0	1	5
1. Instruct in			
a. proper breathing technique, encourage deep breathing, instruct and monitor techniques of incentive spirometry			
b. inspiratory muscle training techniques			
2. Initiate and adjust			
a. IPPB therapy			
b. continuous mechanical ventilation settings			
c. noninvasive ventilation			
d. elevated baseline pressure [e.g., CPAP, PEEP]			
e. combinations of ventilatory techniques [e.g., SIMV, PEEP, PS, PCV, IRV, inspiratory hold]			
3. Select ventilator graphics [e.g., waveforms, scales]			
4. Administer			
a. aerosolized drugs [e.g., bronchodilators, corticosteroids, mucolytics]			
b. oxygen – on or off a ventilator			
5. Position patient to minimize hypoxemia			
6. Prevent procedure-associated hypoxemia [e.g., oxygenate before and after suctioning and equipment changes]			
7. Adhere to infection control policies and procedures [e.g., Standard Precautions]			

	Recall	Application	Analysis
E. Evaluate and Monitor Patient's Objective and Subjective Responses to Respiratory Care	1	1	7
1. Recommend and review chest radiograph			
2. Obtain a blood gas sample			
a. by puncture			
b. from an arterial or pulmonary artery catheter			
c. from arterialized capillary blood			
3. Perform			
a. pulse oximetry			
b. blood gas and co-oximetry analyses			
c. capnography			
4. Interpret blood gas and co-oximetry results			
5. Observe changes in sputum characteristics			
6. Observe for signs of patient-ventilator dysynchrony			
7. Measure and record vital signs, monitor cardiac rhythm, evaluate fluid balance – intake and output			
8. Perform spirometry, determine vital capacity, measure pulmonary compliance and airways resistance, interpret airway graphics, measure peak flow			
9. Monitor mean airway pressure, adjust and check alarm systems, measure tidal volume, respiratory rate, airway pressures, I:E, and maximum inspiratory pressure			
10. Measure F_IO_2 and/or liter flow			
11. Monitor endotracheal or tracheostomy tube cuff pressure			
12. Auscultate chest and interpret changes in breath sounds			
F. Independently Modify Treatment Techniques Based on the Patient's Response	1	1	9
1. IPPB [e.g., volume, flow, pressure, F_IO_2, mouthpiece/mask]			
2. Incentive breathing devices			
3. Aerosol therapy			
a. modify patient breathing patterns			
b. change type of equipment, change aerosol output			
c. change dilution of medication, adjust temperature of the aerosol			
4. Oxygen therapy			
a. change mode of administration, adjust flow, and F_IO_2			
b. set up or change an O_2 blender			
c. set up an O_2 concentrator or liquid O_2 system			
5. Specialty gas [e.g., He/O_2, NO] therapy [e.g., change mode of administration, adjust flow, adjust gas concentration]			
6. Bronchial hygiene therapy [e.g., alter patient position and duration of treatment and techniques; coordinate sequence of therapies such as chest percussion, postural drainage, and PEP therapy]			
7. Management of artificial airways			
a. change type of humidification equipment			
b. initiate suctioning			
c. inflate and/or deflate the cuff			
d. perform tracheostomy care			
8. Suctioning			
a. alter frequency and duration of suctioning			
b. change size and type of catheter			
c. alter negative pressure			
d. instill irrigating solutions			
9. Mechanical ventilation			
a. monitor and adjust alarm settings			
b. change mechanical dead space			
G. Recommend Modifications in the Respiratory Care Plan Based on the Patient's Response	1	1	10
1. Recommend			
a. institution of bronchopulmonary hygiene procedures			
b. sedation and/or use of muscle relaxant(s)			
c. insertion or change of artificial airway [e.g., endotracheal tube, LMA, tracheostomy]			
d. procedures for weaning from mechanical ventilation			
e. discontinuing treatment based on patient response			
2. Recommend changes in			
a. patient position			
b. aerosol drug dosage or concentration			
c. F_IO_2 and oxygen flow			
3. Recommend changes in mechanical ventilation to			
a. improve patient synchrony [e.g., sensitivity, mode]			
b. enhance oxygenation [e.g., F_IO_2, PEEP/CPAP level, inspiratory time]			

	Recall	Application	Analysis
c. improve alveolar ventilation [e.g., tidal volume, rate]			
d. adjust I:E settings			
e. modify ventilator techniques [e.g., pressure support, pressure control]			
f. adjust noninvasive positive pressure ventilation			
g. monitor and adjust alarm settings			
h. adjust ventilator settings based on ventilator graphics			
i. change type of ventilator, change patient breathing circuitry			
j. alter mechanical dead space			
k. modify ventilator settings to			
1) eliminate auto-PEEP			
2) reduce plateau pressure			
4. Recommend use of pharmacologic interventions including			
a. bronchodilators [e.g., adrenergics, anticholinergics, theophyllines]			
b. antiinflammatory drugs [e.g., leukotriene modifiers, corticosteroids, NSAID, cromolyn sodium]			
c. mucolytics/proteolytics [e.g., acetylcysteine, RhDNAse]			
d. sedatives			
e. analgesics			
f. diuretics			
g. surfactants			
H. Determine the Appropriateness of the Prescribed Respiratory Care Plan and Recommend Modifications When Indicated	**0**	**1**	**4**
1. Review			
a. planned therapy to establish therapeutic plan			
b. interdisciplinary patient and family plan			
2. Recommend changes in therapeutic plan when indicated based on data			
3. Perform respiratory care quality assurance			
4. Develop outcomes of			
a. quality improvement programs			
b. respiratory care protocols			
5. Monitor outcomes of respiratory care protocols			
6. Apply respiratory care protocols			
7. Conduct disease management education			
I. Initiate, Conduct, or Modify Respiratory Care Techniques in an Emergency Setting	**0**	**1**	**3**
1. Treat cardiopulmonary collapse according to			
a. BCLS			
b. ACLS			
c. Pediatric Advanced Life Support (PALS)			
d. Neonatal Resuscitation Program (NRP)			
2. Treat tension pneumothorax			
3. Participate in			
a. land/air patient transport outside the hospital			
b. intra-hospital patient transport			
J. Act as an Assistant to the Physician Performing Special Procedures Including	**0**	**0**	**2**
1. Bronchoscopy			
2. Tracheostomy			
3. Intubation			
K. Initiate and Conduct Pulmonary Rehabilitation and Home Care Within the Prescription	**0**	**0**	**2**
1. Explain planned therapy and goals to patient in understandable terms to achieve optimal therapeutic outcome			
2. Educate patient and family in disease management			
3. Counsel patient and family concerning smoking cessation			
TOTALS	**7**	**18**	**75**

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August 21, 2007

Center for Medicare and Medicaid Services
Department of Health and Human Services
ATTN: CMS-1385-P
PO Box 8018
Baltimore, MD 21244-8018

RE: July 2, 2007 Medicare Physician Fee Schedule Proposed Regulations

Ladies and Gentlemen:

I am a practicing urologist in Waterbury, Connecticut. As such, I care for many patients with kidney and ureteral stones. Our region seems to have a disproportionate share of this disorder. I am also the owner of a joint-venture LLC that provides lithotripsy services. We have state-of-the-art equipment with specialty-trained technicians. The quality of care provided by this organization is superb. It is far better than what we had prior to the advent of this company.

Prior to having an LLC administering lithotripsy services, we had to rely on a van that transported a single machine between New Haven and Farmington, Connecticut. Thus, our patients were forced to travel great distances to receive treatment that should be administered locally. Many of the patients are elderly or incapable of driving and, thus, many family members were inconvenienced for this simple, straightforward, outpatient procedure.

Connecticut was one of the last states to have a lithotripsy unit. Prior to having one in our state, our patients were forced to travel to Massachusetts and New York, under a great strain. Many of the patients had to spend the night in a motel in order to be at the machine on time in the morning; this was at a cost out of their own pocket. The current arrangement that we have is outstanding. Patients are treated at a convenient time without causing a disarray of their lives. They are able to return back to their homes or employment at full capacity shortly after the treatment.

Since the treatment is done locally, the patient and physician stay in close contact. We are able to monitor our patients very carefully. We understand the treatment they receive, and can also be helpful in preventing further stone episodes. The equipment that we use is state-of the art and, since this equipment is used in many different hospitals, it is replaced more frequently than those machines owned by a single hospital. Thus, state-of-the-art medicine can be brought to the local community. The current arrangement works very well for the patient and the patient's family.

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UROLOGY SPECIALISTS P.C.

Joseph P. Antoci, M.D., D.A.B.U.
Robert A. Feldman, M.D., D.A.B.U.
Michael J. Flanagan, M.D., D.A.B.U.
Anthony Kim, M.D., D.A.B.U.
York P. Moy, M.D., D.A.B.U.
Sagar M. Phatak, M.D.
Stephen B. Siegel, M.D., D.A.B.U.
Lisa Oliveira, APRN, MSN

As we all know, medical care is a local phenomenon. I have been in practice for over thirty years. I have lived through the terrible time that we had when patients had to travel the great distances described above. This may seem like a minor event to healthy folks. However, taking an elderly woman or man who cannot drive, who has various medical disabilities, and driving hundreds of miles to receive a 20-minute treatment is totally absurd. It cost our patients a great deal more money, it costs the healthcare system a great deal more money, and it costs the country a great deal more money due to the lost days of work by the caregivers that accompany the family members. Lithotripsy is a therapeutic modality. A kidney stone is a finite entity that can be easily documented. Over-utilization is quite unlikely, since one has to see a kidney stone in order to treat it.

It is very clear to me that the current system works and works well. I can compare this to previous systems where we did not have local therapy with state-of-the-art equipment as we do now. The past was miserable for these patients.

The equipment that we are currently using is outstanding. The companies perform a great deal of procedures and, thus, have the buying power to have state-of-the art equipment for our patients. Our hospitals are very slow in purchasing new equipment and it is a constant battle to upgrade what we have at the hospitals. Since the equipment is portable, it makes very little sense to have an expensive piece of equipment sitting in a hospital seven days a week when it is only used two or three days a week. It is also equally absurd to have patients with a painful illness travel great distances to receive a 15- to 20-minute therapeutic session that has well in excess of a 75% success rate.

In conclusion, I would like to state that the current arrangement that is in existence in Connecticut works very well for the patients. It is a far cry from what we had years ago. Any changes that reduce the availability of this equipment to our patients or force patients to travel great distances or inconvenience them for this simple outpatient therapy, are absurd. The LLC that is currently administering shockwave therapy has negotiated costs with the hospital and, thus, the hospital is doing fine. It is my impression that the current arrangement with shockwave therapy should serve as a model for other types of technology being considered. In this day and age, with the miniaturization of medical equipment, it seems ridiculous for a hospital to invest millions of dollars in equipment that is not used on a seven-day basis, when it can readily transport it on an as-needed basis. I would be happy to comment with personal anecdotes. I would be happy to provide you with the names of patients who have benefited by the current system and a larger number of patients who felt that they were abused by the old system where they had to travel great distances for this treatment.

Respectfully,

Robert A Feldman MD

Robert A. Feldman, M.D.
RAF/lw

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August 21, 2007

Mr. Kerry N. Weems
Administrator – Designate
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
ATTENTION: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

RE: Medicare Program: Proposed Revisions to Payment Policies under the Physician Fee Schedule and Other Part B Payment Policies for CY 2008; Proposed Rule

Dear Mr. Weems,

As a practicing therapist in the Midwest for 19 years, I have witnessed a lot of changes in physical therapy. Unfortunately, many of the recent changes are not for the betterment of the patient or the profession. As an owner and practicing therapist, I spend as much time addressing business issues, such as regulations and decreasing reimbursements, as I do treating patients.

Probably the most disturbing trend of late is the Physician Owned Physical Therapy (POPT). Despite Peter Stark's efforts, lobbyists have been able to convince CMS that it is OK for physicians to own, operate, and make a profit from physical therapy. I emphatically disagree.

I would like to provide the following arguments against POPTs:

- Locally, we have two large orthopaedic groups. One has had their own Physical therapy practice for years, and it is strictly for patient convenience. The other group, however, is beginning their own therapy and has stated directly to me that this isn't about quality of our patient care, it is about **MONEY**. As they are seeing less reimbursement for their medical services, they are looking for alternative income sources.

  If you go to the AAOS (American Academy of Orthopaedic Surgeons) website, you will find a position statement on POPTs. The paragraph under 'Legislative Activity' insinuates that therapists' efforts to stop POPTs is financially motivated rather than patient care motivated. I went to school for six years and did a one year residency to be able to care for patients. This is my profession! If I had wanted to get rich, I would have left years ago.

- OIG Report to Leslie Norwalk, dated May 1, 2006: This report outlines the problems found in POPTs in 2002.

  'Based on a simple random sample of 70 physical therapy line items billed by physicians and rendered in the first 6 months of 2002, we found that 91 percent of physical therapy billed by physicians and

allowed by Medicare during the first 6 months of 2002 did not meet program requirements, resulting in $136 million in improper payments.'

- The point to be noted here is that this is a six month representation that showed $136 million in improper payments. What happened during the last half of 2006, and in the years since? We know that POPTs have increased over that time, so there has probably been an incremental increase in improper charges. Later in the report (paragraph 5) it is stated:

  'The total allowed for physical therapy claims has increased from $353 million in 2002 to $509 million in 2004, and the number of physicians who billed for more than $1 million in physical therapy has more than doubled, from 15 to 38 in the same 2-year period.'

- I also take exception to the statement on page 3, paragraph 3:

  'The "incident to" rule allows physicians to bill for physical therapy performed by any nonphysician staff (including, but not limited to, licensed therapists).'

  This allows anyone, from a lay person to a physician's assistant to a nursing aide to provide physical therapy to patients as long as they are employed by the physician. What a contradiction compared to every other aspect of physical therapy care (hospitals, nursing homes, private practices) where licensure in not only State mandated, but required by CMS. Admittedly, there are some therapists already practicing who provide substandard care. It is scary to imagine what an untrained person might do to a patient that results in harm rather than benefit.

I previously mentioned that one of the local groups just added physical therapy to their practice. Doctors who previously never saw any value in physical therapy, are now referring on a regular basis to their own therapy – a perfect illustration of referral for profit. In addition, we are hearing complaints from patients that they are being directed by physicians in this group to their physician-owned therapy instead of being given a choice. Most have refused because they have been satisfied customers of ours and wonder why anyone would want to travel 30 miles round-trip, three times a week.

Before I close, I would like to take an opportunity to address several other statements in the AAOS Position Statement: http://www.aaos.org/about/papers/position/1166.asp

- **Under the Introduction: 'Physical therapy as a profession developed due to the initiative of doctors specializing in the field of musculoskeletal medicine who sought to enhance the recovery and rehabilitation of their patients through focused training in exercise.'**

  Right, and Al Gore invented the Internet! In fact, PT was originally a function of nurses:

  In the United States, Physical Therapy began in 1914 in Portland, Oregon, with Reed College and Walter Reed Hospital graduating the first physical therapists, then called "reconstruction aides." These were nurses with a background in physical education needed to help manage the devastating effects of the First World War. Source: http://www.eugenept.com/history.html

- **Under Quality of Care: 'In office therapy allows therapists and physicians to work together as a team, exchanging information and sharing ideas.'**

  In this day and age of computers, faxes and efaxes only the human component remains as a major factor hindering communication. Our practice does typed notes for each patient return to the physician for follow-up appointments. A big hindrance to effective communication is the allied healthcare worker employed by the physician who is improperly educated to process or comprehend information passed on by the therapist or patient.

- **'A study comparing on-site physical therapy delivered in physician offices versus other sites concluded that patients who receive on-site physical therapy lose less time from work and resume normal duties more quickly.'**

  This vague reference to a 'study' holds no validity. While I haven't had the opportunity to look at the reference listed, it does state in the title of the article that it was done in three general practices – not exactly representative of the hundreds of therapist-owned practices in the U.S.

  Like any profession, physical therapy has those who excel, those who get by, and those who need to find another profession. In our area, we find that therapist-owned practices far excel in results obtained, when compared to hospital-based or physician-based practices. The main reasons for that is that some of the best therapists are in therapist-owned settings, and physical therapy is the sole focus of our business.

- **'Frequent and timely feedback between therapists and physicians also reduces over utilization of services.'**

  The OIG report would argue against this statement. Moreover, CMS has already set up requirements for Plans of Care, prescription renewals, and patient re-checks which safeguard against this. Interestingly, we have run into resistance from surgeons in this area who don't want to bother with the Plan of Care or seeing the patient for a re-check because 'they make their money by cutting'.

  Most physicians, including orthopaedic surgeons, have very little idea what therapy does to identify and correct problems. We have a Family Practice Residency Program in our area. The Director of the Program told me that even the osteopathic doctors get only about one hour of lecture in physical therapy during their seven years of school and three years of residency. Our practice gives a presentation each year to help inform them better about physical therapy.

- **'According to a study, 70 to 80 percent of medical errors are related to interpersonal interaction issues.'**

  This is another 'unknown study'. Proximity of people during conversation does NOT guarantee understanding. Listening is critical as is valuing what the messenger has to say. It works both ways.

- **Access to Care. 'This eliminates the need for patients to travel to two different appointments.' 'Prohibiting POPTS would substantially reduce patient options regarding where to receive proximate care.'**

  As mentioned earlier, most physicians aren't interested in the follow-up visits. Meanwhile, if on the rare occurrence a therapy clinic is not in or next door to a physician's office, it may be CLOSER to the patient's home. Therapy practices tend to locate near a concentration of physician offices and spaced out across a metropolitan area for patient convenience. The subsequent argument that rural clients may suffer by traveling long distances or have delays in treatment also fails to hold water. First of all, if a therapist is employed in a physician's office, he / she could just as well own their own practice independently next door or in the same building. As far as treatment delays, show me a POPT that will operate from 7 am to 7 pm like I do! We do this for patient convenience.

During the writing of this letter, it has finally dawned on me why physical therapists want to work for POPTs: Guaranteed patients – no marketing is necessary – I just come in and work my hours and go home. If I don't have any patients, it is my physician's / boss's fault. The problem with this is that it also eliminates healthy competition among physical therapists, and this will eventually result in a decline in the standard of care. Therapist-owned therapy is highly competitive and this forces us to be increasingly better at what we do – provide quality care to the patient.

With these thoughts in mind, I sincerely hope strong consideration will be given to removing Physical Therapy Services from the 'permitted services' under the 'in-office ancillary exception' currently in effect.

Please feel free to contact me at (260) 483-2422.

Respectfully Yours,

John J. Straessle, PT

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ACTING FIRE CHIEF
RICK BARBER

CITY OF BRUNSWICK
DIVISION OF FIRE

August 21, 2007

Centers for Medicare and Medicaid Services
Dept. Of Health and Human Services
Attn: CMS-1385-P
PO Box 8018
Baltimore, MD 21244-8018

Dear Sir/Madam:

We disagree with your proposed revisions to the "Beneficiary signature" section 424.36 for CY 2008, **(CMS-1385-P)**. The above rules on ambulance services, including the requirement to obtain a "signed contemporaneous statement" from a representative of the receiving facility documenting the date and time the patient was received at the facility would indeed prove burdensome for this Division of Fire.

We have staff and resource limitations and need our ALS emergency ambulance and fire/medics promptly return from area hospitals to cover the next emergency in our city. We ask that you consider our concerns and not require this signed statement as it would cause time delays to staff at area emergency rooms.

Thank you,

Rick Barber
Acting Chief

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Florida Society of Dermatologic Surgeons

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August 24, 2007

The Honorable Herbert Kuhn
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Washington, DC 20201
Phone: 202-690-6726
E-mail: herb.kuhn@cms.hhs.gov

Re: CMS 1385-P: 2008 Medicare Fee Schedule

Coding – Multiple Procedure Payment Reduction for Mohs Surgery

Dear Administrator Kuhn:

As President of the Florida Society of Dermatologic Surgeons (FSDS), and as representative of the entire board and membership of the FSDS, a 277 member organization created solely for the education of Dermatologic physicians treating skin cancer, I wish to represent our extreme concern about the proposed rule change presented in the 2008 Medicare Fee Schedule concerning Mohs Surgery, and wish to comment on this proposed rule change, if I may. I am referring to Section II.E.2(P-122) of the 2008 Medicare Fee Schedule in which it states:

"Based on the revisions to the code descriptors and a clearer understanding regarding the technical elements of the procedure, the CPT Editorial Panel removed the Mohs procedure from the -51 modifier list. The code descriptors for Mohs surgery codes were developed to take into account the different level of physician work intensity based on anatomic site. The RVUs associated with the codes for each anatomic location were assigned, as they are for other procedures, after a thorough discussion by the RUC of all aspects of the service. RVUs were developed for each Mohs surgery base code based on an assumption that each code is performed separately. Because the RVUs for these services do not take into account the efficiencies that occur when multiple procedures are performed in one session, we do not believe that these codes should continue to be exempt from the multiple procedure payment reduction. Therefore, we are proposing to eliminate the modifier -51 exemption and apply the multiple procedure payment reduction rules to these codes."

Mohs Surgery is a cost-saving procedure in most cases. Over the years Medicare has saved millions, maybe billions, by having difficult skin cancers treated economically in the Mohs surgeon's office. Prior to Mohs surgery, most skin cancers were removed by plastic or general surgeons in the hospital, with all of the expenses involved: the operating room, the frozen tissue sections, the pathologist, the anesthesiologist, etc. Mohs Surgery eliminates the separate charge of a pathologist for frozen sections, since this is built into the Mohs Surgery codes, and the Mohs Surgeon is the pathologist checking the tissue, as well as processing the tissue. Most Mohs Surgeons do not need the expense of a hospital or ambulatory surgery suite to perform their procedures, unless there are concerns for the patient, as in tumors that track down neurological pathways through the skull, or in large defects that require an extensive repair. As it is now, Medicare allows the Mohs Surgeon to repair the patient's skin cancer defect the day of surgery, or remove more than one cancer that requires removal on a different body site on the same date, without being penalized by the multiple reduction rules. With the proposed rule change, the patient will need to be rescheduled for a different date for more surgery if they need repair of their wound, or perhaps referred to an outside Plastic Surgeon who will want to use expensive hospital services, etc. With the proposed rule change, the Mohs surgeon will need to reschedule the patient for more surgery on a different date if there is more than one cancer that requires Mohs surgery. The expense of operating a Mohs surgery suite, which includes the salary of the histotechnologist preparing the tissue, the experienced nurses involved in patient care, as well as the front office staff, building and equipment expenses, etc., does not allow the Mohs surgeon to give discounts and stay in business. The procedure itself has already given a huge discount to Medicare in the treatment of skin cancer.

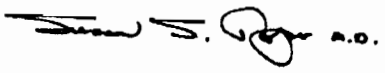
Since Florida treats more skin cancer than any other state in the nation due to our large senior citizen population, the burden of this Proposed Rule Change will fall principally on the shoulders of our Floridian skin cancer patients and the Mohs surgeons who treat them. This Proposed Rule CMS change will cause a regional inequity in the Medicare payment system, and the states in the sunbelt and Florida in particular will suffer.

The Proposed Rule Reduction also penalizes our skin cancer patients, many of them veterans from World War 2, Korea, and Vietnam, many of whom reside in Florida. These veterans do not take kindly to rationing of care. They prefer to visit the Mohs Surgeons in private practice or in the academic centers rather than overburden the overtaxed VA system, where one has to wait 6 months or longer to have a skin cancer removed in some cases. Removal of skin cancer at the VA Hospital often requires much more extensive surgery on the Plastic Surgery service than would be required in a Mohs Surgeon's office surgery suite. I personally attend the VA Dermatology clinic at the James Haley VA Hospital in Tampa, Florida, as a volunteer physician, having done so for 20 years. We do not have a Mohs Surgeon at the VA. If it weren't for the Mohs Surgeons in private practice and in the academic centers, the veterans having skin cancer problems would have a lot more morbidity and mortality from their skin cancers. I expect this to change, if the Proposed Rule Reduction for Mohs Surgery is implemented.

In summary, the Florida Society of Dermatologic Surgeons, respectfully requests that the Proposed Rule, Section II.E.2(P-122) of the 2008 Medicare Fee Schedule **NOT** be implemented,

due to the negative impact this will have on patient care nationwide, and Florida in particular. We respectfully request that the Medicare system continue to exempt the Mohs procedure base codes, 17311 and 17313, from the multiple procedure reduction rule, and that this exemption be permanent. As I have previously mentioned, it is in our patients' best interest to maintain this cost-effective and tissue sparing procedure, and not to penalize the Mohs Surgeons for cost effectively doing the job in one visit that would normally take 2-3 specialists to do much more expensively. I would appreciate the opportunity to discuss this issue with CMS anytime you are available. Please feel free to contact me at my office or by e-mail.

Respectfully,



Susan S. Roper, M.D.
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cc: Terrence Kay, Director, Hospital and Ambulatory Policy Group
Amy Bassano, Director, Practitioner Services Division
Diane Baker, MD, President, American Academy of Dermatology
David Brodland, MD, President, American College of Mohs Surgery
Alastair Caruthers, MD, President, American Society of Dermatologic Surgery
Sharon Tiefenbrunn, MD, President, American Society for Mohs Surgery

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GOLD CROSS SERVICES, INC.

August 22, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1385-P
PO Box 8018
Baltimore, MD 21244-8018

RE: Comments to the Rule Making Process on CMS-1385-P

Dear Sirs:

On July 12, 2007, CMS published the Proposed Rule in the Federal Register. I would like to submit the following comments relating to the current requirement on providers of obtaining a signature of the beneficiary.

As you can imagine, it is very difficult if not impossible for providers in an emergency situation to obtain the required signature. Further, and for similar reasons, it is just as difficult for providers in a *non-emergency* situation to obtain the signature. Many times the patient is confused, weak, and suspicious of what the crew is asking them to sign, and there are no family members yet in attendance at the patient's location. It is also very costly and time consuming for providers to attempt to get a signature after the trip has been concluded.

We question the need for the signature since assignment of Medicare benefits is mandatory for covered services. The signature is not needed in order to submit claims as HIPAA regulation, 45 C.F.R. 164.506(c)(3) states:

> (3) A covered entity may disclose protected health information to another covered entity or a health care provider for the payment activities of the entity that receives the information.

Thus, our argument is the signature should not be required. Additionally, the signature is already on file at the SNF or hospital from/to which the patient was transported. Duplicating the requirement for a signature is very costly and imposes a burden on ambulance service providers.

It is our sincere recommendation that CMS take this opportunity to eliminate the burden of the beneficiary signature on ambulance services. Please feel free to contact me at 801-975-4304 if you have any questions or need additional information from me.

Sincerely,

Jared D. Miles,
President

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José O. Ortega, M.D.
Tracy R. Ray, M.D.

Administrator
H. Michael Immel, FACMPE

August 1, 2007

Via Email and Hand Delivery

Leslie Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
P.O. Box 8018
7500 Security Boulevard
Baltimore, MD 21244-8018

Attn: CMS-1385-P

Support for Establishing Practice Expense RVUs for Non-Facility Arthroscopy Procedures

Dear Administrator Norwalk:

I am pleased to submit these comments in support of CMS' proposal to establish non-facility practice expenses ("PE") relative value units ("RVUs") for arthroscopy procedures. This proposal was discussed in the recently published Medicare Physician Fee Schedule Rule (*Federal Register*, Volume 72, Page 38, 135).

As you can see I am a member of the Andrews Sports Medicine & Orthopaedic Center in Birmingham, Alabama. I am also the founder and medical director of the Andrews Institute in Pensacola, Florida. I am a member of the American Board of Orthopaedic Surgery and the American Academy of Orthopaedic Surgeons. I have served on the Board of Directors of the American Orthopaedic Society for Sports Medicine (serving as Secretary of that Board from May 2004 to May 2005 and currently serve as its Second Vice President). I have also served on the Board of the Arthroscopy Association of North America, and the International Knee Society. I am a Clinical Professor of Orthopaedic Surgery at several medical schools including the University of Alabama Birmingham, the University of Virginia, the University of South Carolina, and the University of Kentucky.

In the realm of sports medicine, I am, among other things, the Co-Medical Director of Auburn University Athletics and the Senior Orthopaedic Consultant for the University of Alabama. I am also the Medical Director for the Ladies Professional Golf Association and I am a member of the Medical and Safety Advisory Committee of USA

Baseball. Finally, I am the Senior Orthopaedic Consultant for the Washington Redskins Professional Football Team and the Medical Director for the Tampa Bay Devil Rays Professional Baseball Team.

Relative to diagnostic office based arthroscopy procedures these procedures are currently being performed around the country and are considered to be safe, effective, and very worthwhile. Such procedures are obviously tolerated well, cause little – if any – discomfort, and produce excellence diagnostic results. In fact, articles dating back to the early 1990s establish that office based arthroscopies are appropriate for the "non-facility" setting. I direct your attention, for example, to Small NC, et. al., Office Operative Arthroscopy of the Knee: Technical Considerations and a Preliminary Analysis of the First 100 Patients. *Arthroscopy.* 1994 Oct; 10(5):534-9.

Unfortunately, Medicare's current policy does not compensate doctors for these procedures. Instead, Medicare unnecessarily funnels most arthroscopies to the hospital outpatient and ambulatory surgical settings. For patients who do not need the many resources available in these facilities, this is neither cost-effective nor in keeping with the patient's preference.

For these reasons, I urge CMS to establish non-facility RVUs, consistent with the price information submitted by the manufacturer for the equipment and supplies. Such a decision will advance patient care and may well allow Medicare to redirect resources (savings) to other physician payment issues.

Thank you for considering this request.

Sincerely,

James R. Andrews, M.D.

cc: Pamela West, CMS (via email)
Ken Simon, M.D., CMS (via email)
William Rogers, M.D., CMS (via email)
Brad Henley, M.D., AAOS (via email)
Bob Fine, AAOS (via email)
Matt Twetten, AAOS (via email)

DEBBIE WASSERMAN SCHULTZ
20TH DISTRICT, FLORIDA

CHIEF DEPUTY WHIP

COMMITTEES:
STEERING AND POLICY
COMMITTEE ON APPROPRIATIONS
SUBCOMMITTEES:
CHAIR, LEGISLATIVE BRANCH
FINANCIAL SERVICES

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August 30, 2007

Leslie Norwalk, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

RE: CMS-1385-P -- Proposed Revisions to Medicare Payment Policies (CPT Codes 93325 & 17311-17315)

Dear Administrator Norwalk:

I write to express my concerns over several Medicare payment policy revisions currently under consideration by your agency. It is critical that Medicare payment schemes are not only fair and appropriate, but based on the realistic needs of patients seeking treatment. In particular, I am concerned about two proposals, one that I understand will negatively affect the prompt treatment of skin cancer, especially for the elderly population, and the other that negatively affects cardiology treatment for small children and infants.

I hope the agency will consider these concerns and take appropriate corrective action before issuing its final rule.

CPT Code 93325 - Echocardiography services and pediatric cardiology concerns

This payment coding change deals with bundling Medicare payment for a particular service: Doppler Color Flow velocity mapping (CPT Code 93325), into all echocardiography services, thereby eliminating separate payment for these services effective January 1, 2008. I am concerned about the potentially negative impact such action would have upon a distinctly non-Medicare population – pediatric cardiology – and the potential impact on patient access to care in Florida and across the country.

I understand that this code is used, along with other imaging procedures, by pediatric cardiologists to look at structural abnormalities within the heart, in order to accurately diagnose a patient's medical condition. The Doppler Color Flow procedure is used by a physician to develop clinical decisions on treatment options. It is essential to help appropriately diagnose small children and infants.

I also am told that the CPT Editorial Panel has already approved a new code that will address the overwhelming majority of Medicare coding issues in this area for adults. Specifically, the CPT panel did not recommend bundling 93325 into any other services, such as pediatric cardiology, yet CMS is now proposing to do so. I urge the Agency to reconsider this change and heed the advice of medical practitioners on this subject.

CPT Code 17311-17315 - Mohs Micrographic Surgery and skin cancer treatment

Section II.2 of the proposed rule recommends reducing reimbursements for "surgical procedures performed during the same operative session ... by 50 percent." Currently, the Mohs surgery codes are exempt from the multiple procedure payment reduction rules; however, the proposed change will remove that exemption. This proposal will have the consequence of placing skin cancer patients, especially the more elderly and less mobile patients, at greater risk due to delayed medical procedures.

As you know, over a million people are diagnosed with skin cancer each year and many of these individuals are diagnosed with multiple skin cancers at the same time. Therefore, my constituents, and many Florida residents, often face the need for multiple procedures to rid themselves of skin cancer. Currently, these multiple procedures can be accomplished in one visit to the doctor's office. Reducing the need for multiple office visits is not only efficient, but reduces the burden on patients. However, by reducing reimbursements for multiple procedures during the same doctor's visit by fifty percent by removing the Mohs micrographic surgery from its exempt status, many patients will have to wait, and return for a subsequent office visit to ensure the procedure in fully covered by Medicare.

Most obviously, it is of deep concern to me that this reimbursement change would delay needed medical care for a highly curable form of cancer. What may not be obvious to the agency is that this places an extra burden on the elderly population that is often less mobile and need more assistance in scheduling and getting to the doctor's office in the first place. Subsequent office visits may be greatly delayed, putting these patients at greater risk of having their cancers spread. We should be taking steps to make treatment for this segment of the population easier, not harder. I believe this reimbursement change would be a step backwards for treatment, not only of cancer, but for our elderly population that is at the most risk.

I urge the Agency to reconsider the proposed changes to the Medicare payment policies and weigh the practical effects these changes will have on important segments of our population - the young and elderly. I would appreciate you keeping my office informed of your actions. Thank you.

Sincerely,

Debbie Wasserman Schultz
Member of Congress

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Mr. Kerry N. Weems
Administrator – Designate
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1385-P
P. O. Box 8018
Baltimore, MD 21244-8018

August 16, 2007

Subject: Medicare Program; Proposed Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Rule

Dear Mr. Weems,

I am a licensed physical therapist practicing in Virginia for 12 years. I have been a PT for 22 years. I have practiced in Pennsylvania, Florida and Virginia. I currently own my own physical therapy practice. I want to comment on the proposed changes to CMS rules regarding in-office ancillary services exception to the federal physician self referral laws.

I have looked into the matter of physician self-referral in the past. In looking at the American Medical Association Code of Ethics I found that the AMA actually feels it is unethical to refer for profit, EXCEPT, when those services are provided "on premises". At the same time the AMA Council on Ethics and the Judicial Affairs (CEJA) states that "under no circumstances may physicians place their own financial interests above the welfare of their patients". I think it is a rationalization to feel that because the physician is on-premises that a potential conflict of interest and possible overutilization of services does not exist.

When I opened my practice in Virginia, there were two orthopedic surgeons in my building. They liked the work I did and felt I helped their patients reach their best potential. When one of those doctors left the practice to open his own practice he approached me about renting space from him at his new building. His comments to me were very telling. He felt that if I was paying him rent, he had an "interest" in making sure I did well. He felt that if he had a "stake" in the therapy that he would refer more patients to therapy. That made me think, and I hope you will follow my reasoning. First, he was not a large referral source to begin with, but if he would refer more patients if he had a "stake" in therapy then maybe he was not referring patients who needed the therapy. Second, that the patients he had did not need the therapy but if he had a "stake" in the therapy, then they did need it. See, he was either not sending them because he did not profit, or he would send them because then he would profit. I just found his logic and rationale a bit unethical. When one of his new partners arrived from Pennsylvania I spoke with him at length about how I viewed our relationship. I would own the therapy and simply rent space from them. He, however, felt that they should own the therapy practice as it would generate "$100,000.00 profit" per year according to the first doctor whom I knew more personally. I have owned my practice for 6 years and have never seen that kind of profit. The number of patients that would have to been seen would be huge for the 3 doctors in that practice to refer to PT.

Additionally, in this country we honor ones right to choose. Patients get to choose their family doctor, they choose their specialist. If they need a cardiologist they ask friends and family about their experiences and they choose. When a doctor owns an interest in therapy, or lab, or radiology office, they tend to "direct" patients. Many of the patients I have treated in the past have told me they would have returned to my therapy office when they had another physical issue, (i.e. knee replacement, hip surgery, back pain), but the doctor they saw referred them to the therapy "at their office". I had lost one patient when the therapy office at one physician's office did not accept the patients insurance. I used to get many of their patients with that insurance. When they started to accept that insurance, they actually called patients that were under my care at that time and told them that "they now accepted their insurance" and that they should now come to their office for PT. As I said, I actually lost one patient due to that incident. This exemplifies the lengths some physician offices will go to self-refer.

Many of my patients that have been treated at the local physician-owned offices have commented that they were treated rudely. They felt that they had "no choice" but to go there because that is where "my doctor sent me; I thought I had to go there". They felt, and I agree, that they were treated that way because the doctor had a captive patient base. This exemplifies the tendency to see patients, some Medicare beneficiaries, as money to be made, not patients to be treated.

The AMA code of ethics makes an exception for the services being offered "on premises", however, as a licensed physical therapist, there is not a state in the country that requires direct physician supervision. It, however, gives the physicians a way to rationalize the need to add PT as a revenue generating business.

Finally, and most important I think, is the potential for fraud and abuse. This exists as long as physicians are able to refer Medicare beneficiaries to entities in which they have a financial interest, especially in the case of physician-owned physical therapy services. It was proven so when a study in Florida in 1991, the Florida Health Care Cost Containment Study – a survey of 3,000 health care facilities –was published. The study concluded that physical therapy referral for profit resulted in major overutilization of services.

- Physician-owned physical therapy facilities provide 62% **more** patient visits per full time physical therapist, when compared to non-physician owned clinics.
- The patients referred have 43% **more** treatments when compared to non-physician owned clinics.

Physicians who own practices that provide physical therapy services have an inherent financial incentive to refer their patients to the practices they have an interest in and to overutilize those services for financial gain. By eliminating physical therapy as a designated health service (DHS) furnished under the in-office ancillary services exception, CMS would reduce a significant amount of programmatic abuse, overutilization of physical therapy services under the Medicare program, and enhance the quality of patient care.

In summary, I believe it is in the Medicare beneficiaries' best interests as well as the interests of CMS to eliminate physical therapy as an in-office ancillary service for physicians. It removes the incentive for possible fraud and abuse and therefore fiscally responsible. I thank you for reading my comments and ask that you consider them in your decisions.

Sincerely,

Carl Bruno PT

Carl Bruno, PT

Coalition For The Advancement Of Brachytherapy

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August 23, 2007

Herb Kuhn
Deputy Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Rule; CMS-1385-P

Dear Mr. Kuhn:

The Coalition for the Advancement of Brachytherapy (CAB) is pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS) in response to the July 12, 2007 *Federal Register* notice regarding the 2008 Physician Fee Schedule proposed rule.

The Coalition for the Advancement of Brachytherapy was organized in 2001 and is composed of the leading developers, manufacturers, and suppliers of brachytherapy devices, sources, and supplies. CAB's mission is to work for improved patient care by assisting federal and state agencies in developing reimbursement and regulatory policies to accurately reflect the important clinical benefits of brachytherapy. Such reimbursement policies will support high quality and cost-effective care. Over 90% of brachytherapy procedures performed in the United States are done with products developed by CAB members and it is our mission to work for improved care for patients with cancer (see attachment 1).

Resource-Based PE RVUs—PE Proposals for CY 2008

CAB has continued concerns regarding the potential impact of significant reductions in practice expense values on access to cancer care, particularly in the case of some brachytherapy procedures.

Under the new practice expense methodology, two Breast brachytherapy and two High Dose Rate (HDR) brachytherapy codes are slated to be significantly reduced over the four-year transition period. CPT codes 77781 and 77782 are the primary procedures reported for ovarian, breast and cervical cancer treatments. The proposed reductions may force providers and patients to resort to other cancer treatments that may not be the best treatment option for the patient, due to decreased reimbursement.

For example, CPT 77781 has a 24.6% reduction from 2007 to proposed 2008 practice expense RVUs and a 79.1% reduction in 2010 practice expense RVUs at the end of the transition period (see Table 1).

Table 1 Practice Expense Reductions for selected Brachytherapy Codes

CPT	Descriptor	2006 PERVU	2007 PERVU	2008 Proposed PERVU	2010 Proposed PERVU	2007-2008 Proposed Percentage Change	2006-2010 Proposed Percentage Change
19296	Placement of breast catheter for radiation	125.75	114.90	104.91	84.88	-8.7%	-32.5%
19298	Placement of breast catheter for radiation (tube/button)	42.28	37.39	32.20	21.81	-13.9%	-48.4%
77781	High intensity (HDR) brachytherapy; 1-4 source positions or catheters	20.89	16.73	12.61	4.37	-24.6%	-79.1%
77781-26		0.53	0.50	0.47	0.40	-6.0%	-24.5%
77781-TC		20.36	16.23	12.14	3.97	-25.2%	-80.5%
77782	High intensity (HDR) brachytherapy; 5-8 source positions or catheters	21.16	18.94	16.73	12.31	-11.7%	-41.8%
77782-26		0.80	0.77	0.74	0.68	-3.9	-15.0%
77782-TC		20.36	18.17	15.99	11.64	-12.0	-42.8%

CPT codes 19296 and 19298 are codes used for catheter placement in the treatment of partial breast brachytherapy, a type of breast conservation therapy. These codes are used in conjunction with HDR brachytherapy codes 77781 & 77782. By decreasing the length of a course of radiation therapy and improving the quality of life for these women, healthcare providers can dramatically increase the number of women opting for breast conserving surgery and radiation therapy. In order for this to occur, reimbursement for breast brachytherapy procedures must be adequate and appropriate. Continued reductions in reimbursement due to the significant decreases in practice expense RVUs may limit access to breast conservation therapy for women with breast cancer.

Further, the one-year impact of all the CMS Physician Fee Schedule proposals on these brachytherapy codes ranges from –17.5% to –29.4% in 2008 (see Table 2).

Table 2 Total Reduction in 2008 Proposed Payment for selected Brachytherapy Codes

CPT	2007 Payment	2008 Proposed Payment	2007-2008 Proposed Percentage Change
19296 Placement of breast catheter for radiation	$4,506.39	$3,718.46	-17.5%
19298 Placement of breast catheter for radiation (tube/button)	$1,660.67	$1,319.04	-20.6%
77781 High intensity (HDR) brachytherapy; 1-4 source positions or catheters	$723.08	$510.82	-29.4%
77782 High intensity (HDR) brachytherapy; 5-8 source positions or catheters	$840.19	681.55	-18.9%

CAB would ask that CMS consider patient access to quality cancer care in making any final determinations regarding practice expense reductions, which may impact the ability of physicians to offer certain treatment options to their patients in freestanding cancer centers.

Resource-Based PE RVUs—Discussion of Equipment Usage Percentage

In the 2008 proposed rule, CMS states that they continue to receive comments regarding their use of the equipment usage assumption of 50%. In addition, CMS states that MedPAC continues to support an unspecified higher utilization rate and that the AMA RUC has requested an equipment usage percentage in the range of 70% to 80%.

CAB agrees with CMS that there is insufficient empirical evidence at this time to justify an alternative proposal and suggests that the equipment usage assumptions be studied in greater detail.

CAB supports the CMS decision not to revise the 50% equipment usage assumption.

Resource-Based PE RVUs —Equipment Interest Rate (Discussion)

In the proposed rule, CMS states that there has been much discussion regarding the appropriate interest rate utilized in the calculation of equipment costs. The Coalition commends CMS on their analysis of the 2007 Small Business Administration (SBA) data on loans and applicable interest rates and agrees that the current 11% interest rate assumption is appropriate.

CAB supports the CMS decision to retain the 11% interest rate used in the calculation of equipment costs.

Impact—Sustainable Growth Rate

The proposed rule indicates that payment rates for physicians' services will be reduced by 9.9% for 2008, a reduction required by the statutory formula that takes into account substantial growth in overall Medicare spending. CMS anticipates further negative updates in future years.

While we understand that CMS is required by law to update the conversion factor on an annual basis according to the sustainable growth rate (SGR) formula, we do not support reductions under the SGR system forecasted for 2008 and subsequent years. The SGR formula is unreasonable and impractical as it is tied to the overall U.S. economy (gross domestic product) and does not accurately reflect the health care costs of treating Medicare beneficiaries. The SGR formula should not include the costs of Medicare-covered outpatient drugs. Additionally, the current formula does not account for the costs and savings associated with new technologies. The current SGR formula must be replaced with a method that allows payment updates to keep pace with practice cost increases.

CAB recommends that CMS replace the Sustainable Growth Rate in 2008 with an annual update system like those of other provider groups so that payment rates will better reflect actual increases in physician practice costs.

Conclusion

CAB recommends that CMS more closely examine the impact of all 2008 Medicare Part B payment policies that impact radiation oncology procedures. Reductions in the proposed practice expense relative value units (RVUs) for some brachytherapy procedures combined with the forecasted reductions in the annual update factor could have an impact on the provision of brachytherapy procedures to Medicare beneficiaries in a freestanding radiation oncology center.

Brachytherapy offers important cancer therapies to Medicare patients. Appropriate payment for procedures and sources required to provide brachytherapy is necessary to ensure that Medicare beneficiaries will continue to have full access to high quality cancer treatment in a freestanding cancer center.

We hope that CMS will take these issues under careful consideration during the development of the 2008 Physician Fee Schedule final rule, as they will have a great impact on provider's ability to offer important cancer treatments to Medicare beneficiaries. Should CMS staff have additional questions, please contact Wendy Smith Fuss, MPH at (703) 534-7979.

Sincerely,

Janet Zeman
Chair

George Clark
Vice-Chair

Attachment 1

Coalition for the Advancement of Brachytherapy (CAB)

The Coalition for the Advancement of Brachytherapy (CAB) is a national non-profit association composed of manufacturers and developers of sources, needles and other brachytherapy devices and ancillary products used in the fields of medicine and life sciences. CAB members have dedicated significant resources to the research, development and clinical use of brachytherapy, including the treatment of prostate cancer and other types of cancers as well as vascular disease. Over 90% of brachytherapy procedures performed in the United States are done with products developed by CAB members.

Member Companies

BrachySciences
C.R. Bard, Inc.
Cytyc Corporation
IsoRay
MDS Nordion
Nucletron Corporation
Oncura
SIRTeX Medical, Inc.
Theragenics Corporation
Varian Medical Systems
Xoft, Inc.

CAB Advisory Board

American Brachytherapy Society
American College of Radiation Oncology
Association for Freestanding Radiation Oncology Centers
Society for Radiation Oncology Administrators

Comments for CMS for the Physician Fee Schedule Regulation (1385P)

Noting the CMS request for comments on inpatient telemedicine services, we felt the need to make the agency aware of the special needs we have here at Avera St. Luke's Hospital in Aberdeen, South Dakota in this area of concern. Our project was originally built with federal grant dollars that were targeted at establishing telemedicine connections in rural America. Our project is about 10 years old and like many other similar projects around the country, ours didn't get going in the area of telemedicine for several years for a variety of reasons. Instead, our project grabbed onto distance education and after some in roads were made in the areas of reimbursement for telemedicine services, our project took off 3 years ago.

Our facility is 200 miles from the next largest medical center in the region, Sioux Falls, South Dakota, Bismarck, North Dakota and Fargo, North Dakota. Telemedicine seemed like an ideal fit for our facility and with a growing emphasis on infection control measures, we began a more organized effort into telemedicine. A group of Infectious Disease specialists in Sioux Falls came to us in 2004 and offered their services to us by videoconference. There are only 8 ID specialists in our state, 6 in Sioux Falls and 2 in the Black Hills, 5 hours away. The first physician to take advantage of this service was our Oncologist. He began referring patients, primarily inpatients to start, to our project in 2005. With obviously positive feedback from his patients, his referrals began to increase to outpatients as well. Soon, other physicians and providers in our region learned of the success of our telemedicine connections for Infectious Disease and began referring their patients to us. It took less than a year for our project to explode, to the point where we needed additional equipment, space and staff, to keep up with the work load. The reaction from the referring physicians, other than oncology, primarily family practice and internal medicine physicians, was incredible. And the reaction and acceptance of our patients was similarly gratifying. To date, we have had nearly 80 different providers from our region refer patients to us for telemedicine, which has now expanded into other specialties that we can't provide here in Aberdeen.
Currently, we offer Pulmonology, Endocrinology, Pediatric Gastroenterology, Pediatric Cardiology and Infectious Disease specialties by videoconference on a regular basis. Recruiting these specialists to our part of the country has become increasingly more challenging and we continue to work hard to bring these specialties here, but in the meantime, telemedicine has filled the void wonderfully. And we continue to get requests from our staff to get access to other specialties like neurology and even adult cardiology by telemedicine.

Since January of 2006 through July of this year, we have seen 810 patients in the 5 specialty areas mentioned earlier. 551 of those patients saw ID specialists, 111 saw an adult or child pulmonologist, 48 saw an adult endocrinologist, 73 saw a pediatric cardiologist and 27 have seen by a relatively new telemedicine service provider, pediatric gastroenterology. Currently we provide adult and child psychiatry telemedicine services from here, but our primary role in the area of telemedicine is that of a so-called spoke site. We have accessed other specialties as well on special occasions, but the 5 referred to earlier have been our main providers in the past 2 years.

Of those 800 plus telemedicine consults in the past 19 months, we would estimate that around 33 to 35 percent of those patients were seen as inpatients. Probably 80 percent that were originally seen in the hospital as inpatients, were eventually seen as outpatients following discharge. Despite reimbursement issues for follow ups by telemedicine, our telemedicine providers have continued to provide follow up telemedicine service to give the best possible care to their patients and to give the best possible response to their referring collegues patients. It should also be noted that in addition to eICU service at our facility from our sister hospital in Sioux Falls, we also provide telemedicine service in our ICU. Frequently we are called upon to make a telemedicine connection to an infection disease specialist or a pulmonologist for patients in our ICU. These are critically ill patients who need this service to first of all, stay alive and also to stay home. While we have no firm data in place, there is no question that we have saved many costly and for us, dangerous transports by using telemedicine technology. It would not be uncommon for us to get an order for an ID consult at 3 in the afternoon and connect the ICU patient to a specialist in Sioux Falls by 4. Then as that patient recovers and moves out of the ICU, the telemedicine specialist will continue to follow that patient until discharge. It has been an incredible service we have been providing, but barring changes in the CMS reimbursement codes for telemedicine, we are not optimistic that a year from now such services will be available.

Just 4 years ago, only 15 to 20 percent of our videoconference connections were made for telemedicine purposes. Today, over 50 percent of our connections are for telemedicine consultations. While follow up service is certainly necessary following discharge, it has become more apparent to our referring and telemedicine physicians that follow up care while patients are still hospitalized is even more important. We would urge CMS to take our comments into consideration when considering additional codes for telemedicine inpatient follow up care. We are relatively certain that there are many more communities in this country who find themselves in a similar situation. Too small and too rural to easily attract qualified specialists and too distant to allow for easy travel to a larger, more equipped medical center. Therefore telemedicine technology has been implemented and embraced by both patients and providers in our region. We prove that statement every day here because of the continued growth in our telemedicine program.

I am including an abstract put together to support inpatient follow up telemedicine.

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attachm

A Brief Retrospective Review of Medical Records Comparing Outcomes for Inpatients Treated via Telehealth versus Face-to-Face Protocols: Is telehealth equally effective as face-to-face visits for treating neutropenic fever, bacterial pneumonia, and infected bacterial wounds?

Aristides Assimacopoulos, MD, Infectious Disease Specialists, PC; Rabiul Alam, MD, Infectious Disease Specialists, PC; Manuel Arbo, MD, Infectious Disease Specialists, PC; Jawad Nazir, MD, Infectious Disease Specialists, PC; Din Chen, PhD, South Dakota State University; Susan Weaver, MSN, CNP, Avera Research Institute.

Abstract

Context: The incidence of infectious diseases in the US has been increasing since 1980. Re-emergent conditions, multidrug-resistant bacteria, newly identified infections, and bioterrorism, have prompted public health surveillance and control initiatives, including the use of telehealth technology. Infectious diseases, such as West Nile Virus, pose a particular threat to rural areas, where access to infectious disease specialists (IDS) is limited. However, reimbursement for in-patient consultation, follow-up consultation, or subsequent care visits is not provided when these services are delivered via telehealth measures. **Objective:** The purpose of this study is to investigate the efficacy of telehealth technology in providing timely, efficient and prudent infectious disease care for rural patients. **Design:** We conducted a retrospective, comparative review of medical records (n=107) from inpatients at a rural hospital who received face-to-face IDS treatment, with records from inpatients at outlying hospitals who received telehealth IDS treatment. Outcome measures, including number of days hospitalized, number of days receiving IV antibiotic, survival, and transfer to another hospital, were compared for 3 commonly occurring infectious diseases: neutropenic fever, bacterial pneumonia, or bacterial wound infection. **Results:** Patients treated via telehealth had fewer days on antibiotics and fewer days hospitalized than patients treated via face-to-face intervention. Survival rates did not differ significantly between groups, but was lower for telehealth patients. Fewer telehealth patients required transfer to another hospital. Results were statistically significant only for selected outcomes and conditions. **Conclusions:** IDS treatment for the conditions studied is equally effective when delivered via telehealth measures, as when delivered via face-to-face methods.

Introduction

Mortality from infectious diseases has declined in the US since 1900; yet, the incidence of these diseases has been increasing since 1980.[1] Newly-identified infections, such as avian flu, and re-emergent diseases, such as rubella,[2] are continuing to create a substantial health and economic burden. Emerging infectious diseases (EIDs) are now defined as those whose incidence has increased in the last 20 years or is expected to increase in the near future[3] (eg., Acquired Immune Deficiency Syndrome [AIDS], Legionnaire's disease, Lyme disease, and multidrug-resistant tuberculosis, among others).[1] In addition to the acute health care threat of these diseases, there now is increasing evidence that certain infectious microbes may cause or contribute to the development of various chronic diseases, including heart disease, stomach ulcers, and some forms of cancer.[4] With the current threat of bioterrorism (such as anthrax), and the outbreak of unexpected diseases, public health officials now stress the importance of being prepared to address infectious diseases. [2]

Infectious Diseases in Rural Areas: The threat of EIDs also is relevant in rural America, an area occupied by nearly 25% of the US population, but only by 10% of physicians.[5] Minnesota, for example, which accepts more refugees per capita than any other state,[6] has an increasing incidence of infectious diseases, such as malaria and tuberculosis, commonly carried by refugees.[7] South Dakota, another rural state, reported the most US cases of West Nile virus in humans, as of July 2007.[8] Currently, South Dakota is served by 8 Infectious Disease Specialists (IDS) who practice either in Sioux Falls or in Rapid City, the two largest towns in the state, located on the extreme eastern and western borders, respectively (a distance of 400 miles). According to the National

Rural Health Association, rural residents requiring health care are disadvantaged over urban residents due to greater transportation difficulties, disparate Medicare payments to hospitals and physicians, and a current health professional shortage of 2,157, compared with 910 in urban areas.[5]

The role of telehealth in combating EIDs: Within its published strategy to combat EIDs (*Preventing Emerging Infectious Diseases: A Strategy for the 21st Century*), the Centers for Disease Control and Prevention (CDC) established 4 goals: surveillance and response; applied research; infrastructure and training; and prevention and control.[2] In promoting this strategy, the CDC found that surveillance and systematic compilation of data, and sharing of data among providers and public health agencies, is fundamental to prevention and control.[1] It also is apparent that current modes of care, such as shortened hospital stays and the increasing number of patients receiving home health care, require new ways to assess and to monitor patients.[2]

Telehealth technology is a valuable tool in meeting the challenges of EIDs within rural populations. Both primary care and IDS providers employ telehealth to assess patients quickly, thus avoiding the risks and costs of travel. Telehealth enables timely follow-up as test results become available and/or as the patient's condition changes. Pertinent laboratory results, reports, and other materials are faxed between facilities, as necessary. Electronic medical records may be accessed, and information shared among providers and public health agencies. Telehealth technology enables accumulation of patient and demographic data simultaneous to providing patient care. The Institute of Medicine notes several benefits to using telehealth technology in rural areas, including: i) enabling rural hospitals to keep more inpatients in the community and to increase their quality of care;

ii) providing a learning experience for primary care providers through interactive consultation with remote specialists; iii) compensating for the supply shortage of specialists; and iv) enhancing the delivery of care and the stability of rural health care systems by promoting networks among physicians.[9] Of 455 telemedicine projects assessed worldwide in 1999, the Agency for Healthcare Research and Quality (AHRQ) found that 80% utilized this technology mainly for consultations or second opinions.[10]

In 2006, the American Medical Association (AMA) deleted the Current Procedural Terminology (CPT) codes by which physicians/providers bill for telehealth inpatient confirmatory consultations (99271-99275) and for follow-up inpatient consultations (99261-99263), and the Centers for Medicare and Medicaid Services (CMS) ceased to reimburse for these services. Subsequent care codes currently are not approved by CMS for telehealth billing. CMS, however, continues to reimburse for subsequent care when the service is delivered via face-to-face visits from IDS providers. The IDSs involved in this study currently provide telehealth subsequent care with no means of reimbursement for their services.

Purpose

The purpose of this study is to investigate the efficacy of telehealth in providing timely, efficient and prudent infectious disease care for rural patients.

Hypothesis

Delivery of infectious disease treatment for neutropenic fever, bacterial pneumonia, and infected bacterial wounds via telehealth technology is equally effective as equivalent

treatment delivered via conventional, face-to-face patient consultation. Efficacy is defined as clinical treatment outcomes for each condition studied (Table 1).

Table 1 Definition of study diagnoses and treatment outcomes measured as indicators of efficacy.

Condition	Definition	Treatment Outcomes Measured Following IDS Consultation
Neutropenic fever	Fever (>100.5°F) resulting from opportunistic infection due to abnormally low neutrophil granulocyte count (<1000 cells/mm^3).	• Number of days receiving IV antibiotic therapy • Number of days hospitalized • Patient survival • Patient transfer to another hospital
Bacterial pneumonia	Acute inflammation of lungs due to bacterial infection, leading to plugged alveoli and bronchioles, and fibrous exudates.	
Bacterial wound infection	Bacterial invasion of a break in the skin, causing local cellular injury, secretion of toxin, or antigen-antibody reaction in the host, with acute infection leading to sepsis.	

Methods

We conducted a retrospective, comparative review of medical records (January 1, 2006-December 31, 2006) from an inpatient population at Avera McKennan Hospital (a 490-bed facility located in Sioux Falls, South Dakota) and records from sister telehealth hospitals (Figure 1). The Avera Health System patient records database was queried to retrieve records for patients diagnosed with one of 3 commonly occurring infectious diseases: neutropenic fever, bacterial pneumonia, or bacterial wound infection. Records were excluded if patients were not seen by an infectious disease specialist. A total of 107 records were selected and divided into two groups: Group A (n = 59), inpatients at Avera

McKennan Hospital who received treatment via face-to-face consultation with an infectious disease specialist; and Group B (n = 48), patients from sister hospitals who received treatment via telehealth with an infectious disease specialist. Providers were contacted to confirm endpoints that were not available on the patient records. Records were reviewed and data recorded in accordance with HIPAA guidelines. The study was conducted in accordance with FDA Good Clinical Practice Regulations (CFR 21, parts 50, 56, and 312), ICH GCP Guidelines (E6), clinical safety data management guidelines (E2A), and was approved by the Avera Institutional Review Board.

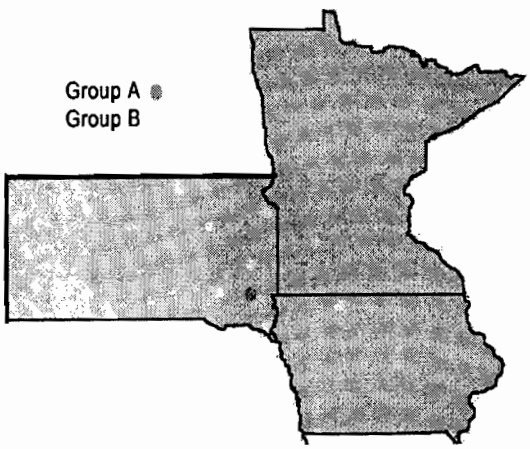

Figure 1 Locations of hospitals represented in this study.

Study population: Data from records included patients ranging in age from 23-75 years, with a mean age of 62 years. Of 107 records analyzed, 46% of patients were female, 54% male, with 55% from a metropolitan area of the rural Midwest (Sioux Falls) and 45% from outlying rural areas (Table 3). Ethnicity was not addressed as a variable in this study.

Table 3 Study population, Groups A and B

					Diagnosis		
Group	n	Total Female	Total Male	Mean age	Neutropenic fever	Bacterial pneumonia	Bacterial wound infection
A	59	22	37	59	13	19	27
B	48	27	21	66	13	9	26

Results

Results show favorable outcomes for telehealth on most measures, compared with face-to-face interventions (Table 4). Patients treated via telehealth had fewer days on antibiotics than patients treated via face-to-face intervention (Figure 1). These results were statistically significant for all 3 study conditions. Likewise, patients receiving telehealth spent fewer days hospitalized than patients receiving face-to-face, for all 3 study conditions (Figure 2); however, this result was statistically significant only for patients with bacterial pneumonia. Survival rates did not differ significantly between Group A and Group B, although this was lower for telehealth patients. Fewer total patients from Group B required transfer to another hospital, but this result was not statistically significant for any of the study conditions. Patients in Group B received fewer subsequent care visits from infectious disease specialists while hospitalized, than did patients in Group A.

Table 4 Combined outcomes for Group A compared with Group B

Outcome	Group A (Face-to-Face)	Group B (Telehealth)	*P*
Days on IV antibiotic (mean)	13.345	6.913	0
Days hospitalized (mean)	10.690	6.479	0.016
% Survival	0.948	0.894	0.112
% Transfer	0.107	0.085	0.352

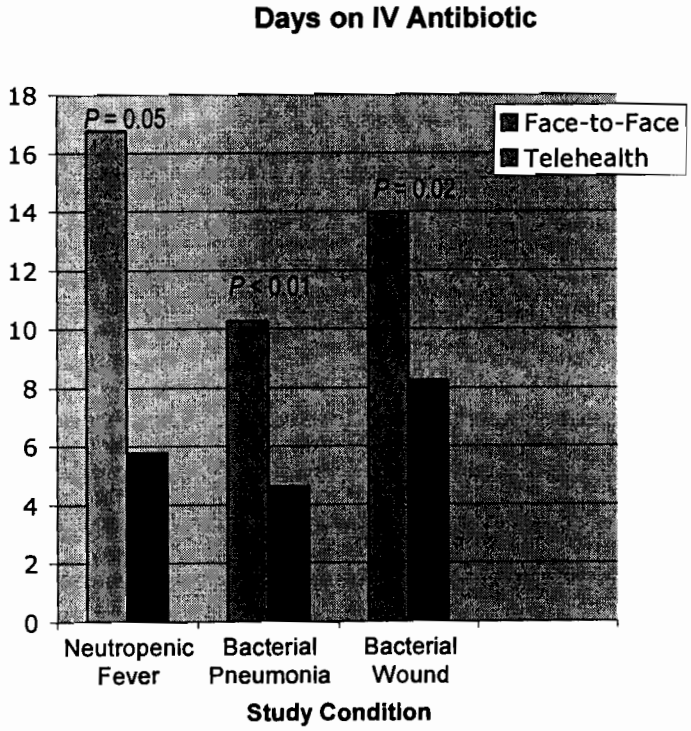

Figure 1 Days receiving IV antibiotic for face-to-face vs. telehealth consultation for all study conditions.

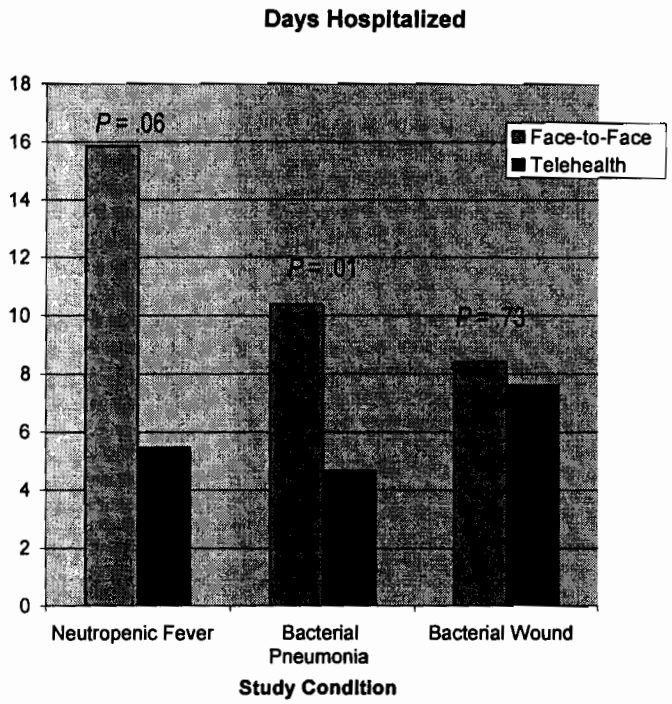

Figure 2 Days hospitalized for face-to-face vs. telehealth consultation for all study conditions.

Discussion

This initial retrospective comparison of medical records indicates IDS telehealth services are clinically more effective than face-to-face visits for some outcome measures for the conditions studied. The study, however, is only an initial analysis of efficacy and does not account for comorbid conditions, demographic characteristics, patient satisfaction and other confounding variables. Given these results and the purpose of undertaking this study we conclude that, for the conditions studied, IDS telehealth services are an effective form of care delivery in rural areas. If CMS codes for this subsequent care have never been reimbursed for the AMA's stated reason that telehealth delivery of subsequent care presents a potential decreased usage of rural primary care physicians, then we must

consider two additional questions: 1) is specialist consultation clinically effective; and 2) what are the clinical and economic implications for rural patients if telehealth specialist consultations are not available?

Is specialist consultation effective? This study was not designed to assess this variable for the conditions studied; however, we can contribute evidence from studies previously conducted. Hospital by-laws generally stipulate any patient admitted to a local hospital must have an attending onsite physician or primary care provider (PCP). The PCP monitors the patient and manages comorbidities, based on experience with the patient over time. For infectious diseases, an IDS may provide specialist consultation services at the request of the PCP, but the PCP remains in charge of the patient's case. This system illustrates two hallmark developments of current medical care for health professionals: working with an expanding knowledge base and coordinating patient care.

Current medical care now entails a significantly increased volume of research and new knowledge. In at least two studies examining this issue, researchers concluded that it no longer is possible for clinicians to remain fully abreast of this expanding information and to apply it to patients. [11, 12] The effectiveness of specialist participation in disease treatment has been documented in areas such as cardiology[13] and infectious diseases.[14] Specialists have been shown to utilize more resources, but also to be more knowledgeable about their area of expertise than generalists, and to achieve superior patient outcomes.[15] In its 2007 report examining quality improvement strategies, the AHRQ found that coordination of patient care, including shared primary-specialty care, is a fundamental element in achieving improved patient outcomes.[16] This collective evidence indicates that specialist involvement is generally beneficial for patients.

What are the clinical and economic implications for rural patients if telehealth specialist consultations are not available? If specialty care is, therefore, considered beneficial to patients, and is indeed reimbursed by CMS for face-to-face subsequent care, can rural primary care physicians effectively address infectious diseases without IDS telehealth assistance? In its 2007 report, the National Rural Assembly found that rural health care continues to be handicapped by limited availability, accessibility, and funding of basic services, as well as by a continual shortage of health care providers.[17] A resource of advice via telehealth may seem a logical route not only to enhanced care for the rural patient, but also to care in parity with that delivered to urban residents. To date, at least one study has examined potential healthcare costs and patient outcomes, if telehealth services are not available.[18] Results from this study indicated that a typical Medicare patient would have traveled approximately 202 miles to an urban center if telehealth facilities were not available. At the time of this study (2000), this equated to approximately $66 per trip, not including meals, lodging, or lost wages. Of patients assessed in this study, 77% reported they would have traveled for care had telehealth not been available and that HCFA would have paid for that care in the traditional manner. The report authors concluded that costs to Medicare would potentially increase, not only from travel expenses, but also from ensuing costs if patients seek local care that results in lack of prevention, early diagnosis, and suboptimal clinical outcomes. [18]

Current initiatives show widespread support for rural telehealth projects within many government and private organizations, such as the Federal Communication Commission's Rural Health Care Pilot Program, [19] the Telehealth and Medically Underserved Advancement Act of 2007 (HR 1601), and the Health Care Access and Rural Equity Act

(H-CARE, HR 2860).[20] Additional government strategies incorporate telehealth specifically as a key tool in addressing infectious diseases. Examples include the CDC's Public Health Information Network (PHIN) and its Emerging Infections Programs.[21,22] The PHIN includes a specific strategy (Rural Information Center Health Service [RICHS]) to promote the development of integrated rural surveillance systems at all levels,[23] thus utilizing telehealth technology already in place within many rural areas, such as South Dakota.

Data from this initial study show that telehealth consultation and subsequent care for 3 commonly occurring infectious diseases is equally effective as face-to-face consultation in a rural population. Future studies can examine the potential costs to patients for increased travel (including ambulance services), lost wages, and exacerbated disease due to delayed treatment. In its report, the Institute of Medicine observes that current telehealth initiatives are impeded by inconsistent and unclear guidelines from major payers, such as Medicare, and that a more comprehensive approach is needed.[9] Given the results of this study and evidence from studies examining various aspects of this issue, refusal of CMS funding for rural telehealth specialist patient subsequent care is in direct opposition to the numerous government and privately funded initiatives outlined in this report, as well as to evidence documenting telehealth efficacy. The availability of needed IDS telehealth services in rural areas may indeed be jeopardized by continued lack of funding.

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Mr. Kerry N. Weems
Administrator-Designate
Centers for Medicare and Medicaid Services
U.S. Department of health and Human Services

August 15, 2007

Re: Physician Self-Referral Issues

I am writing you to express my concern over the continued exception of physical therapy in the "in-office ancillary services" portion of the federal physician self-referral laws. As a physical therapist in the State of California for 27 years and a private practice owner, I am frequently in contact with patients that continue to be "directed" to a physician owned PT office. Patients should have the ability to seek treatment with whatever provider they choose and not be forced to seek treatment with a provider that benefits financially from the referral The explanation given to the patient is that the physician can oversee and guide the patients care if they go to the physician own physical therapist. As an autonomous profession, each and every physical therapist develops their own plan of care when treating a patient and we all know that the physician does not have the time or commitment to guide the patient's care.

Physician direct supervision is not needed to administer physical therapy services. In fact, an increasing number of physician owned physical therapy clinics are using the reassignment benefit laws to collect payment in order to circumvent the "incident-to" requirements.

The "in-house ancillary services" exception is so broad in definition that it facilitates the creation of abusive referral arrangements. The physical therapist should decide when the patient has met their goals and be discharged to a home program, not the referring physician that has a financial stake in the amounts of visits/revenues generated. This exception has created a loophole that has resulted in the expansion of physician owned arrangements that provide physical therapy services. Because of Medicare referral requirements, physicians have a captive referral base of physical therapy patients in their offices. Physical therapy treatment is repetitive in nature and there is no real convenience for the patient to receive services in the physician's office than an independent physical therapy clinic that has only one goal in mind, the patient's progression toward functional goals.

In my opinion their in NO benefit for a patient to be referred to a physician owned therapy clinic, only a chance for abuse. It starts to create a monopoly type situation in which freedom of choice is all but eliminated

Thank you very much for taking the time to consider my comments.

Sincerely,

Douglas Hoeck PT

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Puget Sound Anesthesia Service

Jim Kroll, CRNA, MS, ARNP

2029 161st Avenue N.E. • Snohomish, Washington 98290 • (206) 654-9025
Fax (425) 397-8257

August 20, 2007

Ms. Leslie Norwalk, JD
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8018
Baltimore, MD 21244–8018

RE: CMS–1385–P (BACKGROUND, IMPACT)
ANESTHESIA SERVICES

Dear Ms. Norwalk:

As a member of the American Association of Nurse Anesthetists (AANA), I applaud the support the Centers for Medicare & Medicaid Services (CMS) is providing to boost the value of anesthesia work by 32%. If adopted, CMS' proposal would help to ensure that Certified Registered Nurse Anesthetists (CRNAs) as Medicare Part B providers can continue to provide Medicare beneficiaries with access to anesthesia services. Without it, there is little incentive for CRNAs to remain medicare providers.

- Studies by the Medicare Payment Advisory Commission (MedPAC) and others have demonstrated that Medicare Part B reimburses for most services at approximately 80% of private market rates, but reimburses for anesthesia services at approximately 40% of private market rates.
- CMS' proposed change in the relative value of anesthesia work would help to correct the value of anesthesia services which have long slipped behind inflationary adjustments.

Additionally, if CMS' proposed change is not enacted and if Congress fails to reverse the 10% sustainable growth rate (SGR) cut to Medicare payment, an average 12-unit anesthesia service in 2008 will be reimbursed at a rate about 17% below 2006 payment levels, and more than a third below 1992 payment levels (adjusted for inflation). This is patently unfair given that America's 36,000 CRNAs provide some 27 million anesthetics in the U.S. annually, in every setting requiring anesthesia services, and are the predominant anesthesia providers to rural and medically underserved America. Medicare patients and healthcare delivery in the U.S. depend on our services. The availability of anesthesia services depends in part on fair Medicare payment for them. I support the agency's acknowledgement that anesthesia payments have been undervalued, and its proposal to increase the valuation of anesthesia work in a manner that boosts Medicare anesthesia payment.

Sincerely,

James Kroll

James Kroll, CRNA
2029 161st Avenue NE
Snohomish, Washington 98290

Levas Physical & Occupational Therapy
Certified McKenzie Spine Therapist
American Physical Therapy Association
Orthopaedic Certified Specialist

MICHAEL G. LEVAS, P.T., O.C.S., CERT. M.D.T.
Certified Mechanical, Diagnosis, and Therapy

LPT
(858) 455-1222
FAX 455-7101

August 20, 2007

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Mr. Kerry N. Weems
Administrative-Designate
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1385-P
P O Box 8018
Baltimore, MD 21244-8018

Dear Mr. Weems,

Please find enclosed a letter that I responded to in February of this year that I received from the Private Practice Section (PPS) of the APTA regarding my personal experience with Physician Owned Physical Therapy Services (POPTS) and the dramatically negative effect it has played on my business.

To give you an update since I submitted my letter to PPS February, I have closed a third office do to loss of patient volume. I have now closed three (3) offices in a eleven (11) month period and I' am on the verge of loosing my hand therapy clinic in one of my existing offices do to physicians ownership of a nearby facility. I have also had to reduce my staff by another four (4) staff members do to loss of patient volume. The situation that has been created by allowing physician ownership of physical therapy practices has not only impacted my business and my family finances but also those of my staff.

Please feel free to contact me if I can be of any further assistance.

Sincerely,

MGL PT

Michael G. Levas P.T. O.C.S.
Cert. M.D.T.

Levas Physical & Occupational Therapy
Certified McKenzie Spine Therapist
American Physical Therapy Association
Orthopaedic Certified Specialist

MICHAEL G. LEVAS, P.T., O.C.S., CERT. M.D.T.
Certified Mechanical, Diagnosis, and Therapy

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February 25, 2007

Stephen E. Anderson, P.T.
C/O APTA, Private Practice Section
1055 N. Fairfax St. Suite 100
Alexandria, VA 22314

Dear Mr. Anderson:

I am responding to your letter dated February 2, 2007. Upon reading your letter I felt it necessary to share with you an others my journey, challenges and path my business has taken and the effects of Physician Owned Physical Therapy Services (POPTS) or Referral For Profit has had on me the past twenty years. I will attempt to be as concise as possible.

After graduating from physical therapy school in 1975 I immediately went to work for a well known orthopedic group in Southern California. In my early years of my professional development, I was mentored by my relationship with them for five years. From there I was "recruited" by another well known hospital, to start their first out patient Sport Physical Therapy program. I felt this was an ideal situation for me not only to continue to develop my professional skills but how to "learn" the business of physical therapy and the health care industry. It was also an ideal opportunity for me to develop and establish relationships with potential referring physicians. After five years of developing this extremely successful out patient program, the hospital administration, and I had very different views on the continued direction of that facility. I felt confident that after ten years of clinical experience and five years of management from a business standpoint, I was ready to venture out on my own. All the referring physicians that were supporting me told me that I had their continued support, or so I thought!

In January of 1985 I opened my first office and to my delight, I started the first week with nearly a full patient schedule. My practice continued to grow. After just three months, I was approached by one of my referring physicians. He informed me that he and another physician had formed a partnership which included a total of fourteen (14) orthopedic physicians. At that time, all of the fourteen physicians had been referring their patients to me. This physician was very up front with me and told me that they were" losing too much money" by continuing to refer P.T. out and the "wave of the future" was physician owned P.T. practices. At that point he stated that my name had come up among their group to run their clinic for them. The arrangement would be for the group to take over my lease and pay me "pennies" on the dollar for my equipment. Of course they were unable to make me an equal partner because the partnership they formed was a "medical partnership" and therefore I was excluded. They offered me a base salary and a small percentage of the business to work for them. They also made it clear that they would build their own P.T. clinic with or without me. They gave me thirty days to respond to their offer. As you can image, I agonized over this decision for the next several weeks.

The lack of confidence in myself at that time truly showed through and I reluctantly sold out to them. I ran their clinic for nine months and was miserable every day!! I finally resigned and worked around town for the next year. After getting over my "bitterness", I opened my current business in 1987. I was fortunate to develop a single referral source at that time which was enough to keep me going until I could develop additional referrals. Meanwhile, much to my dismay, I sat back and watched the POPTS clinic grow and grow. Finally, in 1994, everyone in private practice was ecstatic to see the *Stark Bill* put enough pressure on POPTS clinics which forced many of them to sell to the private practice therapists or close down. After 1995, I had the opportunity to recapture some of my previous referral resources and I began to once again grow my business. In the next six years I grew from one location to six offices all geographically located throughout town. I went from five employees to forty. I continued to work on a clinical basis half time and the remainder of my time was spent managing and marketing. Unfortunately, in the early 2000's, there was new legislature introduced that once again allowed for POPTS.

In 2003, a therapist (who I sub leased space from in Poway) was essentially "forced' out of her practice by the orthopedic group across the court yard from her. After the physicians took over, the managing partner of the orthopedic group allowed me to stay there for a short while. Shortly after that, they informed me that I would need to find my own space because they were getting very busy and needed my space. I moved across the street and started my practice there. Unfortunately, in July of 2006, I had to close that office due to a lack of referrals.

This new legislature also affected my Mission Valley office. In 2004 my main referring orthopedic group (who made up 40% of my referrals at my La Jolla office and 25% of my referral to Mission Valley) informed me that they were in the process of opening their own P.T. Initially, they offered to "buy me out" of my La Jolla office because they wanted the space (turn key) and the staff. This time I said NO! A few months later, the other large orthopedic group in La Jolla (that accounted for approximately 15% of my referrals) moved their office conveniently right next door to another POPTS clinic and began sending their patients there. Their reason was "for the patient's convenience"

One of my most lucrative offices is in Mission Valley and is associated with a large orthopedic group. In 2001, they built a new facility with modern design, equipment, MRI, surgery center and physical therapy. At that time, the doctors did not want to own their own P.T. During the construction phase of the building the physician group invited five different therapy companies to make a presentation to them on what each therapy group could provide in regards to services and the benefits of having that particular therapy group located next door to them. The physicians wanted the "convenience" of having physical therapy right next door. I was fortunate to be chosen. I opened that office in July 2002 and have PT/OT (Hand Therapy) pool therapy etc. They supported me for the most part. In June 2006 the groups managing partner came to me and stated that they had purchased another physician's practice and it also included a PT department. He stated that his group now had an "obligation" to support its new P.T. practice. He continued to inform me that his group would continue to send me hand

patients for now, but P.T. referrals would stop! Since then, I have learned that they are planning to have Hand Therapy built out by early summer 2007. This group accounts for 75% of my P.T referrals and 90% of my hand referrals.

Needless to say, I have downsized and restructured in a major way. I have gone from six offices to four and I will be closing another office in July when the lease ends due to a lack of patient volume. Additionally, I have cut my staff from forty to twenty and I will need to make even more staff cuts soon. My Administrator's position has essentially been eliminated. She has been with me for eighteen years!! Obviously, this has impacted my income for the past several years.

I hope this information has been helpful. As long as we are at the mercy of a "referral system" we will never truly be autonomous as a profession. It goes without saying that Referral For Profit/POPTS is a terribly uneven playing field for those of us who truly want to elevate the profession and be independent. Since I've taken the time to write this letter I have two suggestions:

1) Legislation needs to be pasted that ONLY licensed Physical Therapist can own physical therapy practices. I don't believe that physicians, business men, business owned home health agencies, personal injury attorneys , corporations, or even hospitals should own their own physical therapy. Other professionals such as lawyers, CPA's and physicians have exclusivity of ownership and only those in that particular profession can own their practices.

2) Physical therapists that work for anyone or anywhere, other than a P.T. owned facility, should be considered for license forfeiture.

I know this appears harsh but the ownership of Physical Therapy clinics by non licensed individuals has gotten out of control and has allowed them to steal the physical therapist's livelihood.

If I can be of any further assistance in any way, please feel free to contact me.

Sincerely,

Michael G. Levas P.T. O.C.S.
Cert. M.D.T.

cc:
R. Scott Ward P.T., PhD
President, APTA

ADDRESS AND FORMAT FOR COMMENTS

There has never been a better time for us to make our voice heard about the abusive financial arrangements that are created by physician-owned physical therapy services.

It is apparent that CMS is exploring ways in which to tighten the physician self-referral laws and eliminate abusive practices. In addition, CMS is in the process of finalizing Stark Phase III regulations in which this issue will be addressed in the coming year.

A high number of separate and distinct comments on the problem of physician-owned physical therapy services could have an impact on the agency's approach to regulating these arrangements. It is important for physical therapy to express its viewpoint and arguments, offering specific examples of how these arrangements have negatively impacted their practices and their patients.

Individualize your comments. Your personal experiences and insights will provide the most compelling information. In addition, CMS is more likely to discount comments that appear to be "form letters."

Address to:

Mr. Kerry N. Weems
Administrator - Designate
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018.

Subject:

Medicare Program; Proposed Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Rule

Identify yourself:

Explain that you are a physical therapist. Provide brief background on yourself and describe where you practice, how many years you have been in practice, etc.

OR;

If your comments are on behalf of an APTA state chapter or component section, provide brief background on yourself, your role in the component, the membership of the component, and any characteristics of their practices.

State the purpose of the letter: Your heading should read: **Physician Self-Referral Issues**.

Explain that you wish to comment on the July 12 proposed 2008 physician fee schedule rule, specifically the issue surrounding physician self-referral and the "in-office ancillary services" exception. Your comments are intended to highlight the abusive nature of physician-owned physical therapy services and support PT services removal from permitted services under the in-office ancillary exception.

PRIVATE PRACTICE SECTION

APTA
American Physical Therapy Association

1055 N. Fairfax Street, Suite 100, Alexandria, VA 22314 TEL (703) 299-2410 FAX (703) 299-2411 (800) 517-1167 WEBSITE www.ppsapta.org

February 2, 2007

Dear Private Practice Section member:

As a physical therapist engaged in providing patient care in an increasingly competitive market, you are well aware that one of the most serious challenges facing our profession is physician ownership of physical therapist services. We have all seen the evidence that the ability of physicians to control the referral of patients to physical therapy practices in which they have an ownership interest is driving up health care costs and leading to inappropriate patient care. In addition, it is creating anti-competitive situations that have caused unnecessary hardships for many private practitioners. We are calling on your help to document your stories and evidence of these problems.

The American Physical Therapy Association and the Private Practice Section have made combating referral for profit arrangements one of our highest priorities, and our efforts are having an impact. Policy makers in Washington are growing increasingly concerned about the impact of physician ownership and referral practices related to limited-service specialty hospitals, imaging services, and diagnostic laboratory testing. Efforts by the Centers for Medicare and Medicaid Services (CMS) to tighten federal regulations allowing physicians to invest in so-called "pod laboratories" made front-page news in the *Wall Street Journal*. Although opposition from physicians convinced the agency not to implement the restrictions for 2007, CMS indicated that it is still considering the policies and could propose new regulations later this year.

It is time that policy makers clearly recognize the serious problems caused by physician ownership of physical therapist services to which they refer their patients. In order to provide federal and state policy makers with a clear and accurate picture of the crisis currently facing physical therapists, we need your help. We are asking you to provide us with a written summary describing the problems you and your practice have personally encountered as a result of physician ownership of physical therapist services. To the extent possible, this summary should include:

- Data on the loss of patient referrals
- Solicitations or warnings received from physicians opening their own PT practices
- Any patients you may know who have been harmed, inconvenienced, or coerced – even indirectly – as a result of physician control of referrals and would be willing to describe their experience. This last point is critical – we must be able to demonstrate the harm these arrangements cause to patients and society through higher costs, poor care, or patient dissatisfaction.

Many of you have generously offered to help in the fight against referral for profit – this is your opportunity! It is our intention to compile and forward the detailed information you provide to CMS and other policy makers, including your name and contact information (and that of patients harmed by referral for profit arrangements, if they are willing to be contacted) – if you do not want your identification included in this information, please state explicitly that you wish to keep

your experience anonymous. Either way, we will keep you informed of the results of our information-gathering and the use of the information with federal and state policy makers.

Please send your comments in writing by March 15 to the Private Practice Section, APTA at:

1055 N Fairfax St, Ste 100
Alexandria, VA 22314

You may also fax your comments to (703) 299-2411 or send them electronically to privatepracticesection@apta.org.

Thank you in advance for your time and attention to this critically important issue.

Sincerely,

Stephen E Anderson, PT
President
Private Practice Section of APTA

R Scott Ward, PT, PhD
President
American Physical Therapy Association

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Children's Mercy
HOSPITALS & CLINICS
www.childrensmercy.org

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August 16, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

RE: CMS-1385-P, CODING - ADDITIONAL CODES FROM 5-YEAR REVIEW

To CMS:

As a physician who provides echocardiography services to Medicare patients and others at Children's Mercy Hospitals and Clinics, I am writing to object to CMS's proposal to "bundle" Medicare payment for color flow Doppler (CPT Code 93325) into all echocardiography "base" services. This proposal would discontinue separate Medicare payment for color flow Doppler effective on January 1, 2008, on the grounds that color flow Doppler has become "intrinsic to the performance" of all echocardiography procedures.

In conjunction with two-dimensional echocardiography, color Doppler typically is used for identifying cardiac malfunction (such as valvular regurgitation and intracardiac shunting), and for quantitating the severity of these lesions. In particular, color Doppler information is critical to the decision making process in patients with suspicions of heart valve disease and appropriate selection of patients for valve surgery or medical management. In addition, color flow Doppler is important in the accurate diagnosis of many other cardiac conditions.

CMS's proposal to "bundle" (and thereby eliminate payment for) color flow Doppler completely ignores the practice expenses and physician work involved in performance and interpretation of these studies. While color flow Doppler can be performed concurrently or in concert with the imaging component of echocardiographic studies, the performance of color flow Doppler increases the sonographer time and equipment time that are required for a study; in fact, the physician and sonographer time and resources involved have, if anything, increased, as color flow Doppler's role in the evaluation of valve disease and other conditions has become more complex. The sonographer and equipment time and the associated overhead required for the performance of color flow Doppler are not included in the relative value units for any other echocardiography "base" procedure. Thus, with the stroke of a pen, the CMS proposal simply eliminates Medicare payment for a service that (as CMS itself acknowledges) is important for accurate diagnosis and that is not reimbursed under any other CPT code.

Moreover, CMS is incorrect in assuming that color flow Doppler is "intrinsic" to the provision of all echocardiography procedures. I understand that data gathered by an independent consultant and submitted by the American College of Cardiology and the American Society of Echocardiography confirm that color flow Doppler is routinely performed in conjunction with

CPT code 93307. However, these data, which were previously submitted to CMS, also indicate that an estimated 400,000 color flow Doppler claims each year are provided in conjunction with 10 echocardiography imaging codes other than CPT Code 93307, including fetal echo, transesophageal echo, congenital echo and stress echo. For many of these echocardiography "base" codes, the proportion of claims that include Doppler color flow approximates or is less than 50%. More recent data submitted by the ASE in response to the Proposed Rule confirms that this practice pattern has not changed over the past several years.

For these reasons, I urge you to refrain from finalizing the proposed "bundling" of color flow Doppler into other echocardiography procedures, and to work closely with the American Society of Echocardiography to address this issue in a manner that takes into account the very real resources involved in the provision of this important service.

Sincerely yours,

Geetha Raghuveer, MD
Section of Cardiology

ForTec Medical Inc.®

Your Medical Laser Rental Company

August 23, 2007

Dr. Donald Romano
Centers for Medicare & Medicaid Services
Center for Medicare Management
C4-25-02
7500 Security Blvd.
Baltimore, Maryland 21244

Dear Mr. Romano,

I am writing on behalf of ForTec Medical, Inc. to express our strong support for the proposed Medicare regulations that were published on July 2, 2007. We are encouraged by your proposals knowing that they have the potential to return the fair market nature and integrity that this sector of healthcare is now lacking.

Founded in 1988, ForTec Medical, Inc. leases surgical lasers to hospitals throughout the US on a per case basis. Historically a "non-physician owned' business model, ForTec has built its' business by providing cutting edge quality surgical lasers and skilled technician support to its customers.

While ForTec welcomes healthy competition, we have seen a dramatic proliferation of physician owned laser LLC's over the past three years. We now find ourselves competing against our former customers in what has become an unfair and anticompetitive market. The fact that physicians; exercise control over the patient, have access to our pricing structure, and improperly influence the hospital's purchasing decisions are a few of the factors that have led to ForTec's inability to compete fairly. On a larger scale, these facts have led to today's anticompetitive market.

Our experience has confirmed the following:

1. Financial motivation is driving treatment choices. While options exist for treatment of diseases, physician ownership of equipment plays a key role in influencing what the patient will ultimately be prescribed. The greater the utilization of his/her equipment, the larger will be the financial return on investment.

2. Steerage is driven by physician's potential financial gain. We know of instances where hospitals that chose to honor equipment contracts have "lost" patients to competing facilities. In other words, physicians have steered patients to alternative facilities who were willing to engage with their LLC medical equipment company.
3. Over utilization exists as created by practices that, due to ownership, use treatments that yield lower efficacy outcomes. This trend often creates the need to retreat patients adding additional cost burdens to our healthcare system.
4. Physicians pressure hospitals to use their LLC despite not being the low cost provider. These bully tactics further contribute to escalating healthcare costs.

Without adoption of CMS's proposed regulatory changes, ForTec may be forced to allow physician ownership of our company simply as a means of survival. Furthermore, if left unchecked these scenarios will grow exponentially with LLC's forming around multitudes of surgical equipment across all surgical specialties.

We understand that this is an ongoing battle and in fact we have already learned of strategies being developed to circumvent the new proposed regulations if adopted. One such strategy includes a "cross ownership" business model in which LLC "A" would deliver laser cases to the investors of a separate LLC "B", and visa versa. Another includes where physician groups might simply try to re-characterize their "per service" rentals as block leases. CMS should be clear that any such scheme or "testing of the waters" will not be tolerated.

Finally, CMS needs to assert that any arrangement that involves rentals or leases of equipment and technical support will be considered as "performing" the DHS for the purposes of the definition of "entity".

We fully expect that many of the physician owned ventures and lobbies will seek to delay the implementation by claiming disruption to clinical services. In our experience, there are numerous independent businesses ready to service and purchase these assets and take over contracts without creating interruption of services.

We commend and applaud CMS's efforts to close these loopholes which are not in the best interest of the patient. Clinical efficacy, not financial gain, should be the motivating factor in patient care. The newly proposed regulations will reinstate balanced competition, fair market pricing, and help to reduce healthcare costs.

Respectfully Submitted,

Drew C. Forhan
President & CEO

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ReedSmith

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Thomas W. Greeson
Direct Phone: 703.641.4242
Email: tgreeson@reedsmith.com

August 20, 2007

VIA OVERNIGHT COURIER

Centers for Medicare & Medicaid Services
Dept. of Health & Human Services
Attn: CMS 1385-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1385-P/
PHYSICIAN SELF-REFERRAL ISSUES

To Whom It May Concern:

As a partner at Reed Smith LLP who regularly advises radiology groups located throughout the United States on reimbursement and regulatory matters including the Stark Law, I am submitting these comments to request that CMS clarify that the proposed expansion of the anti-markup provisions to cover the professional component of diagnostic tests (whether such services are purchased or reassigned) would mean that the Stark Law exception for purchased diagnostic tests would also cover payments for the purchased or reassigned professional component of a diagnostic test in addition to the technical component of a diagnostic test.

Current Scope of Stark Exception for Purchased Diagnostic Tests

Under the current Stark regulations, a medical practice is not acting as an "entity" that submits claims for designated health services when it bills Medicare for diagnostic tests it obtains pursuant to the "purchased diagnostic test" rule ("PDT Rule") set forth at 42 C.F.R. § 414.50 and Section 3060.4 of the Medicare Carriers Manual. 42 C.F.R. § 411.351 – *Entity*. Currently, the PDT Rule and its anti-markup provision apply solely to the technical component of a diagnostic test. Thus, the Stark exception for purchased diagnostic tests only permits a medical practice to bill Medicare for the technical component of a diagnostic test obtained pursuant to the PDT Rule. If the medical practice bills Medicare for the professional component of a diagnostic test ordered by one of its physician-owners, those professional services must qualify for protection under either the "personally performed" services exception or the "physician services" exception to Stark.

Clarification that the Stark Exception for Purchased Diagnostic Tests Now Applies to Both the Technical and Professional Components

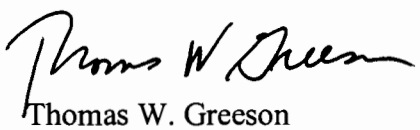
Although CMS is proposing to expand the PDT Rule set forth at § 414.50 to also apply to the professional component of a diagnostic test, it was not totally clear whether CMS also proposed to similarly expand the scope of the PDT exception to the Stark regulations so that a medical practice will not be acting as an "entity" subject to Stark when it bills for the professional component of a diagnostic test that it either purchases or obtains through reassignment in accordance with § 414.50. Our confusion arises from several sources. First, § 411.351-*Entity* provides that a physician's practice is not acting as an "entity" when it bills Medicare for "a diagnostic test in accordance with § 414.50." The phrase "diagnostic test" is currently interpreted to mean only the technical component, in part, because § 414.50 applies solely to the technical component. However, once § 414.50 would be expanded to apply to both the technical and professional components, it would seem that the reference to billing for "diagnostic tests" is expanded to include both the technical and professional components since: 1) a medical practice will be able to bill for both the technical and the professional component in accordance with § 414.50 and 2) the phrase "diagnostic test" is not otherwise defined by regulation. Thus, one could logically assume that because § 414.50 is being expanded to apply to both the technical and professional components that the Stark exception for purchased diagnostic tests is similarly being expanded to apply to both components of the test. We are unclear, however, as to whether this interpretation is correct in light of the fact that the reference to the Medicare Carriers Manual is being replaced with a reference solely to Chapter 1, § 30.2.9 (Payment for Purchased Diagnostic Tests) of the Medicare Claims Processing Manual rather than to both § 30.2.9 and § 30.2.9.1 (Payment for Purchased Interpretations).

Therefore, we recommend that CMS consider further revising § 411.351-*Entity* to clarify that the exception for purchased diagnostic tests applies to both the technical and professional components of diagnostic tests if billed in accordance with the requirements of § 414.50 and Chapter 1, §§ 30.2.9 and 30.2.9.1 of the Medicare Claims Processing Manual. We recommend that the Stark exception for purchased diagnostic tests be expanded to also apply to the professional component for the same reason that the purchased technical component is exempt from Stark – namely that the incentive for a physician to profit from self-referral will be eliminated (or diminished) once the professional component is subject to the anti-markup provision of the PDT Rule. If the incentive to self-refer is curtailed, the risk of abuse to the programs is similarly minimized. It was undoubtedly for this same reason that CMS excepted purchased technical component tests from the definition of "entity" in the Stark II, Phase II final rule. Thus, we recommend that the Stark exception for purchased diagnostic tests be revised to clearly also apply to purchased and reassigned professional component interpretation services.

I appreciate this opportunity to comment on these significant changes to the anti-markup provision and the Stark regulations and can be reached by phone or email if a CMS staff member has any questions or wishes to discuss the above comments further.

Sincerely,

Reed Smith LLP



Thomas W. Greeson

TWG:HMZ:jap

August 17th, 2007

Center for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244

Re: Proposed Full-Time Physician Employee Requirement

To Whom It May Concern:

As the sole owners of Pathology Solutions, L.L.C. ("Pathology Solutions"), we are writing to respectfully request that the Centers for Medicare and Medicaid Services ("CMS") reconsider its proposed full-time physician employee requirement in order for a urology or gastroenterology physician practice (the "Practice") to bill and collect from the Medicare program for the professional pathology services rendered by a pathologist (the "Pathologist") to its patients. Pathology Solutions owns and operates a laboratory that provides technical laboratory services to Practices which have part-time Pathologists. As described in more detail below, we believe that it should not matter to CMS if the Pathologist is an employee or independent contractor nor should it make a difference whether the Pathologist works full-time hours or not because we believe: (a) the overall quality of the professional services provided to Medicare patients would improve; (b) the provision of professional pathology services by physician practices will be revenue neutral to the Medicare program; (c) Medicare patients would not be subjected to any unnecessary testing simply because physician practices have hired or engaged pathologists; (d) Medicare already has sufficient safeguards in place to protect the program from financial abuse; and (e) to do otherwise would interfere with the practice of medicine.

1. Background. Pathology Solutions, operates an anatomic pathology laboratory located in Eatontown, New Jersey. We specialize in providing Practices who have Pathologists with technical laboratory services. As you may know, many Practices either hire a Pathologist as an employee or engaging one as an independent contractor to be an integral part of the physician practice on a part-time basis in order to provide professional pathology services to their patients. In some instances, Practices are also engaging pathology physician practices as independent contactors in order to arrange for the provision of professional services by part-time pathologists to their patients.

Pathology Solutions has relationships with Practices that provide professional pathology services to patients using the TC-PC model (the "Model"). In the Model, the physicians in the Practice will send anatomic pathology specimens taken from their patients during ambulatory surgery procedures to our laboratory (the "Laboratory"). The Laboratory prepares slides from each anatomic pathology specimen and sends them to the offices of the Physician Practice. Physically present in the Physician Practice's offices, the part-time Pathologist interprets the slides and prepares reports for each patient's ordering physician. The Practice provides the part-time Pathologist with an office, microscope and dictation equipment. In the TC-PC model, our Laboratory prepares the slide and Pathology Solutions bills the Medicare program for the technical services it

renders for the patients of the Physician Practice while the Practice bills the Medicare program for the professional services rendered by its Pathologist to Medicare patients on a part-time employee or independent contractor basis. Under no circumstances would Pathology Solutions sell its technical services to a Practice.

CMS's proposed requirement that a pathologist must be a full-time employee in order for a Practice to bill and collect from the Medicare program for professional pathology services would eliminate the TC-PC model and drive Pathology Solutions out of business. Practices that use the TC-PC model only have a sufficient volume of anatomic pathology specimens to engage or hire a part-time Pathologist. Even if a Practice could support a full-time and employed Pathologist, the Practice would need to use part-time pathologists in order to be able to arrange for vacation, personal holiday and sick time relief as well as coverage while the Pathologist is taking continuing medical education courses. For the following reasons, we believe that CMS should reconsider its proposal to require a Pathologist to be a full-time employee in order for the Practice to bill and collect from the Medicare program for the professional services rendered.

2. Improved Quality of Professional Pathology Services. In the TC-PC model, we believe that the quality of the professional services provided to Medicare patients improves significantly. Among other reasons, it is our understanding that many of the Practices who use the Model do so because of general dissatisfaction with the professional pathology services provided by the national commercial laboratory companies who have exclusive agreements with many of the major third party insurers (e.g. Aetna, Blue Cross Blue Shield). Whether it is slow turnaround time on pathology reports or difficulty in asking follow-up questions of generally unavailable pathologists who are located at remote national commercial laboratories, Practices that we do business with tell us that having their own Pathologist translates into better quality professional pathology services to their patients in a timelier manner. With a Pathologist physically present in its offices, Practices inform us that they are able to enhance the quality of patient care rendered to Medicare patients through improved pathology consultations. From our perspective, the Practice's Pathologist typically specializes in the Practice's area of medicine (e.g. urology or gastroenterology) which further improves the reliability and quality of the professional interpretations and the associated face-to-face pathology consultations. In contrast, physician practices that send anatomic pathology specimens to large national commercial laboratories do not: (a) choose the pathologists who interpret the slides and send them reports; and (b) know the qualifications of the pathologist to whom important patient care decisions are ultimately entrusted.

3. Revenue Neutral to the Medicare Program. In the Model, Practice's have advised us that the Medicare program does not spend an additional penny on professional pathology services than it otherwise would spend in the traditional model by which anatomic pathology specimens are referred to a national commercial laboratory and the ordering physician simply receives the pathologist's report. By using the TC-PC model, a Practice bills and collects from the Medicare program based on the then current Medicare physician fee schedule. Because the Practice incurs the costs associated with providing its Pathologist with an office, microscope and dictation equipment, the payment by Medicare of the practice expense component of the physician fee to the Practice is fully justified. We also believe the Model is revenue neutral to the Medicare program because it will not lead to unnecessary tests ordered for Medicare patients.

4. No Unnecessary Testing. In the TC-PC model, Practices benefit from providing higher quality professional pathology services to their Medicare patients. We do not believe, however, that a Practice which provides professional pathology services to its patients would lead to unnecessary testing of Medicare patients for the simple reason that the Model is based on using anatomic pathology specimens taken from patients during ambulatory surgery procedures.

It is longstanding CMS policy that physicians who perform ambulatory surgery cases can own ambulatory surgery facilities. While there are very rare exceptions, physicians who perform ambulatory surgery do not perform invasive procedures for financial reasons. Similarly, the Pathologist in a Practice interprets slides prepared from specimens taken from patients who have had ambulatory surgery. Like virtually all physicians who are not likely to perform unnecessary ambulatory surgery due to the invasive nature of the procedure, we do not believe the same

physicians would take extra specimens or order tests that are not needed from a Medicare patient for financial benefit.

To the contrary, we believe that testing of anatomic pathology specimens taken from Medicare patients will likely be reduced by the TC-PC model. In the Model, a Practice is likely to have a Pathologist who specializes in the Practice's area of medicine. For example, a Practice that specializes in gastroenterology would employ or engage a part-time pathologist who specializes in gastroenterology. Unlike the large national commercial laboratories where a gastroenterology patient's specimen could be read by a pathologist who specializes in dermatology, a Practice that has a Pathologist who specializes in the same area of medicine as the Practice will, as a result of his or her expertise, not need to practice defensive medicine by ordering additional tests as we understand is oftentimes the case in the large commercial laboratory companies because slides are randomly assigned to pathologists, regardless of his or her specialty.

Finally, it is our understanding that the General Accounting Office ("GAO") studies undertaken in the early 1990s that lead to the Stark Law prohibition on referring physician ownership of laboratories did not analyze utilization of anatomic pathology services. In fact, we know of no study that would demonstrate that a referring physician who benefits financially from the provision of anatomic pathology services takes more specimens from a Medicare patient and/or orders unnecessary tests. Why is there no such study results showing over utilization of anatomic pathology services? The simply answer is that a colon or prostate biopsy is much more invasive to a patient than clinical laboratory tests like the dip stick urine, finger stick for hematocrit or even a venipuncture for blood analysis. In the absence of studies to the contrary, we do not believe CMS should be concerned about the potential for over utilization of anatomic pathology tests ordered on Medicare patients by a Practice that has engaged or employed a Pathologist on a part-time basis to provide professional pathology services to its patients.

5. Medicare Already Has Sufficient Safeguards In Place. Any potential concerns that CMS has relating to a Practice hiring or engaging a part-time Pathologist to provide professional pathology services to its patients is already sufficiently addressed by the current: (a) Medicare reassignment rules; (b) Stark Law; and (c) Anti-Kickback Law. The Medicare reassignment rules permit independent contractors, whether an individual or entity, to assign the right to bill and collect for professional services with no prohibition on part-time status. Similarly, each of the Stark Law and the Anti-Kickback Law as well as their respective implementing regulations does not prohibit part-time employment or independent contractor relationships. Each such law and its applicable regulations, however, have independent contractor restrictions that would need to be satisfied by a Physician Practice that: (a) engaged a Pathologist or a pathology physician practice as a part-time independent contractor; or (b) hired a Pathologist as a part-time employee. In addition, a Practice would be required to satisfy the Stark Law's in-office ancillary exception requirements in order to provide professional pathology services to its Medicare patients. From our vantage point, the foregoing regulatory restrictions are more than adequate to protect the Medicare program from financial abuse and Medicare patients from unnecessary testing.

6. Interference with the Practice of Medicine. The adoption of the full-time employee requirement by CMS would, in our view, unfairly interfere with the practice of medicine. While we do not believe that it is CMS's intention to do so, the effect of a CMS decision to adopt the full-time employee requirement would severely limit a Practice's right to organize itself as it sees fit to deliver quality care to its patients and such a CMS decision would have serious implications nationwide with respect to the practice of medicine. While some might argue that the full-time employee requirement does not interfere with the practice of medicine because it only prohibits Medicare reimbursement in certain circumstances, the reality is that CMS would prohibit a Practice from hiring or engaging a part-time pathologist which is the common mode of operation for Practices using the TC-PC model. For any Practice with a significant number of Medicare patients, the elimination by CMS of reimbursement for professional pathology services provided by a part-time pathologist employee or an independent contractor would interfere with the multi-disciplinary approach that it has decided best serves its patients.

7. Summary. In the absence of compelling reasons to the contrary, CMS's proposal to require a Practice to have a full-time Pathologist as an employee in order to bill and collect for professional pathology services rendered to Medicare patients should not be adopted because this requirement would effectively eliminate the TC-PC model. The TC-PC model relies on the use of part-time employees and independent contractors. A Practice that can provide professional pathology services to its patients by hiring or engaging a Pathologist on a part-time basis improves the timeliness and quality of professional services provided to Medicare patients. In addition, the provision of professional pathology services to its patients by a Practice would be revenue neutral to the Medicare program. Moreover, Medicare patients would not be subjected to unnecessary testing due to the invasive nature of ambulatory surgery procedures that generate anatomic pathology specimens. Toward this end, neither the GAO's studies of physician owned laboratories or any other study that we are aware of has shown that a physician's financial interest relating to the provision of anatomic pathology services leads to over utilization of laboratory tests ordered.

It is also important to note that CMS already has adequate safeguards in place to protect against financial abuse of the program through the existing Medicare reassignment rules as well as the Stark Law and Anti-Kickback Law. None of the foregoing prohibits part-time employees or independent contractor relationships. In addition, a CMS decision not to permit Medicare reimbursement for part-time pathologist employees or independent contractors, in effect, interferes with the practice of medicine by effectively eliminating this specific multi-specialty approach to providing patient care to Medicare patients because virtually all Practices that use the TC-PC model do not have a sufficient number of patients to support a full-time and employed Pathologist.

Finally, physician practice-based anatomic pathology services are the wave of the future. Pathology Solutions, through its laboratory, is facilitating this wave of better quality professional services to Medicare patients. Do not throw the baby out with the bath water by making it virtually impossible for a physician practice to provide professional pathology services to it patients by adopting the full-time employee requirement as a pre-requisite for billing and collecting from the Medicare program.

SINCERELY YOURS,

PATHOLOGY SOLUTIONS, L.L.C.

Frederic R. Gross, M.D., Member

Michael Aquino, M.D., Member

WEST SHORE UROLOGY, P.L.C.

JOSEPH A. SALISZ, M.D.
KEVIN T. STONE, M.D.
BRIAN R. STORK, M.D.
CALEB J. FLEMING, M.D.

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MUSKEGON, MICHIGAN 49444-1837
PHONE (231) 739-9492 • FAX (231) 733-5376

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08/27/2007

Centers for Medicare and Medicaid Service
Department of Health and Human Services
Attn: CMS-1385-P Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

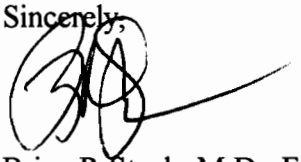
Dear Sirs:

I am 38-year-old urologist currently practicing in Muskegon, Michigan. I have been in private practice now for five years. I am writing because I am concerned about possible changes in the Stark Law that could interfere with our ability to provide quality care for our patient's locally. When I first arrived in Muskegon five years ago, our patient's with kidney stones had to travel approximately 40 miles to Grand Rapids, Michigan, to undergo lithotripsy. After partnering with Butterworth Hospital and American Kidney Stone Management Corporation, we were able to obtain access to a mobile lithotripter which we utilize at Hackley Hospital in Muskegon, Michigan. Having lithotripsy service in our community has allowed us to reduce patient wait times from 4-8 weeks to 1-3 weeks. In addition, many patients that previously had to undergo cystoscopy and stent placement while waiting for treatment in Grand Rapids are able to forgo those procedures now that lithotripsy is available locally.

My concern is that changes in the Stark Legislation may no longer make it possible for our patients to receive routine kidney stone treatments in Muskegon. With Medicare's focus on quality and pay for performance, it is not clear to me why you would consider jeopardizing these services. The physician-hospital partnership that we have been able to create has allowed our community to continue to have access to state of the art lithotripsy technology.

I appreciate your attention and consideration of my thoughts on this issue. If necessary, I would be glad to speak with you in person regarding this matter. I can be reached in the office at (231) 739-9492 or at home at (616) 850-0430.

Sincerely,



Brian R Stork, M.D., F.A.C.S., Diplomat American Board of Urology
BS:NM:tmc

a u r o r a
medical associates, p.c.

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SUSAN A. SHERMAN, M.D.
ENDOCRINOLOGY, DIABETES, AND OSTEOPOROSIS
DIPLOMATE AMERICAN BOARD OF INTERNAL MEDICINE
DIPLOMATE SUBSPECIALTY BOARD OF ENDOCRINOLOGY AND METABOLISM

SOWMYA SURYA, M.D.
ENDOCRINOLOGY AND DIABETES
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M. EUGENE SHERMAN, M.D., F.A.C.C.
CARDIOLOGY AND INTERVENTIONAL CARDIOLOGY
DIPLOMATE AMERICAN BOARD OF INTERNAL MEDICINE
DIPLOMATE SUBSPECIALTY BOARD OF CARDIOVASCULAR DISEASE

August 27, 2007

VIA OVERNIGHT MAIL

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Physician Fee Schedule Proposed Rule
File Code [CMS–1385–P]
Issue Area: Physician Self-Referral Provisions -- Under Arrangement Services

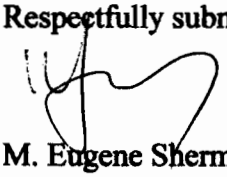
To Whom It May Concern:

I am a practicing cardiologist in Aurora, Colorado, and I am writing to express my objection to CMS's proposed changes to the Stark regulation related to under arrangement services. I have read and support the positions taken in the submission written by Tom Crane of the law firm, Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C. In my experience, under arrangement services by cardiologists are cost effective and improve quality of care. CMS should treat these services like other similar extension of practice services. There are numerous bona fide reasons for physicians to own and operate service providers furnishing arranged-for services, among them including:

- The physicians can provide the service at a lower cost than the hospital.
- The physicians can provide the service more efficiently.
- The physicians can provide the service with higher quality. Colorado Heart Institute, LLC has been a leader in demonstrating the use of quality data in improving cardiovascular care.
- Physicians in our facility have been the leaders in promoting participation in national data registries such as the ACC's NCDR.
- The arranged-for service avoids duplication of services.
- The hospital has problems raising the necessary capital and maintaining state-of-the art technology.
- The physicians desire a greater level of clinical excellence by becoming more involved in the management of the service.
- A physician-run service has more streamlined management and decision-making.
- The service is not a priority for the hospital, but is a priority for the physicians.

CMS would advance no legal or policy interests if it implements the changes it proposes, and so I urge CMS to retain its existing policies

Respectfully submitted,



M. Eugene Sherman, MD FACC

CC: Tom Crane

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Where Oncology Nurses Connect

Oncology Nursing Society

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August 22, 2007

Herb B. Kuhn
Acting Deputy Administrator
Centers for Medicare and Medicaid Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for Calendar Year 2008 [CMS-1385-P]

Dear Acting Deputy Administrator Kuhn:

On behalf of the Oncology Nursing Society (ONS) – the largest professional oncology group in the United States, composed of more than 35,000 nurses and other health professionals dedicated to ensuring and advancing access to quality care for all individuals affected by cancer – we appreciate this opportunity to submit comments regarding the 2008 proposed Physician Fee Schedule. As part of its mission, the Society stands ready to work with policymakers at the local, state, and federal levels to advance policies and programs that will reduce and prevent suffering from cancer, particularly among the Medicare population, which is disproportionately affected by cancer. We thank you in advance for your attention to our comments and concerns, as well as those submitted by our colleagues in the cancer community.

BACKGROUND

ONS has repeatedly commented to the Centers for Medicare and Medicaid Services (CMS) and Congress that Medicare payments for oncology nurses' services fall far short of what is necessary to cover the costs of the full range of care provided by oncology nurses to Medicare beneficiaries with cancer. This problem proves twofold: (1) current payments are insufficient for the costs they are designed to cover, and (2) a variety of services being performed by oncology nurses on behalf of Medicare beneficiaries are not paid for in any fashion. While ONS appreciates that Congress provided in the Medicare Modernization Act (MMA) a temporary increase in practice expense payments for 2004 and 2005, and CMS previously provided some additional payments to community-based cancer care providers vis-à-vis its demonstration authority, we are

very concerned that systematically Medicare's payment methodology and reimbursement rates fail to ensure access to quality cancer care for all Medicare beneficiaries. Moreover, we have heard from our nurses on the ONS Outpatient Chemotherapy Advisory Panel that the under-payment for drug administration, coupled with the reduction in reimbursement for chemotherapy drugs, poses a threat to access to care for Medicare beneficiaries with cancer, particularly those served in rural communities and satellite clinics.

The provision of quality cancer care – in all settings – requires a multidisciplinary team of professionals, including physicians, registered nurses, nurse practitioners, clinical nurse specialists, social workers, pharmacists, nutrition counselors, and laboratory technicians. Working along side with their physician colleagues, oncology nurses are on the front-lines of the provision of quality cancer care and, each day, utilize very specialized skills to coordinate and deliver the comprehensive, high-quality cancer treatment and supportive care Medicare beneficiaries need and deserve. Specifically, oncology nurses play an essential role in: administering chemotherapy, managing patient therapies and side-effects, stabilizing patients during an emergency, documenting important information in patient charts, working with Medicare and other payers to ensure that patients receive the appropriate treatment, providing counseling to patients and family members, triaging patient questions and problems, in addition to many other daily acts on behalf of people with cancer

We have previously commented to the agency that we believe a number of items and services (please see list below for your reference) are not currently covered by Medicare payments. In response, CMS has stated that the current chemotherapy administration payments are designed to cover the costs of these items and services; we respectfully take issue with this assertion. Current payments do not cover the costs of the time and clinical staffing that is necessary for the activities directly related to safe chemotherapy administration, let alone also to support these other critical patient services and supplies. As such, we feel strongly that CMS must take action to provide additional payments for the full range of nursing and related services provided to Medicare beneficiaries with cancer, including:

- **Patient treatment education (a.k.a. cancer treatment or chemotherapy "teaching")** – typically a one-hour educational patient visit to the oncology office spent one-on-one with the oncology nurse reviewing their cancer treatment plan, explaining possible side effects, discussing how to manage side effects and recognize and report serious problems, answering patient and family questions, etc. This educational session is separate from the discussions these patients have with the physician and takes place at an alternate time, when the shock of the diagnosis of cancer has worn

off and the patient and his/her caregiver are ready to learn about treatment. The nursing time for initial patient education and ongoing "teaching" for patients receiving any form of cancer care is not billable, nor do we believe is captured in any way under payment for current services. ONS feels strongly that to help manage patient side effects, reduce adverse events, and improve patient outcomes, Medicare should reimburse separately for both initial and ongoing patient treatment education.

- **Chemotherapy admixture** – This includes the time and supplies (*e.g. syringes, needleless systems, pumps for use in the office, diluents, chemotherapy biological hood, toxic waste containers, chemo gown, and gloves, etc.*) needed to prepare chemotherapy and supportive care drugs for administration to the patient. The costs associated with supplies have increased significantly, due to additional federal regulatory safety requirements – which, while extremely important, are unfunded mandates on physician-office practices.

- **Disposal of chemotherapy waste** – cost of a licensed "toxic waste hauler" to pick up and dispose of chemotherapy waste, cost of supplies to decontaminate work surfaces, and annual cost of county fees related to the generation of hazardous waste.

- **Supplies to establish an intravenous line to administer medications** – many patients have an implanted central venous access device. The cost of the supplies to use this device – each time – ranges from a minimum of $7.00 up to $15.00, depending on the manufacturer.

- **Advice/Triage Nurse** – oncology nurses respond to numerous phone calls each day from patients, family members, home care nurses, hospice nurses, pharmacies, etc. In this role, oncology nurses answer questions, troubleshoot problems, and keep patients out of costly hospitals by early intervention of problems and side effects.

- **Nurses' time** to assess the patient prior to starting treatment, start the intravenous line, answer questions and troubleshoot problems during treatment, monitor the patient during and after the infusion of chemotherapy, and conduct ongoing patient treatment education (see above). Moreover, with more clinical trials (including those involving Medicare beneficiaries) being moved into the community setting, nurses are spending a significant amount of time completing necessary forms, recruiting patients for participation, documenting progress and outcomes, and meeting other requirements for regulatory documentation; none of this work is reimbursed by Medicare.

- **Other essential supportive care services** – including nutrition counseling, social work services and case management, psychosocial counseling, and handling precertifications/authorizations for hospital admissions, chemotherapy procedures, supportive drugs, CAT/PET scans, and MRIs (this alone can take a single nurse between four and five hours a day).

As always, ONS stands ready to work with CMS to develop appropriate payment for these and other oncology supplies and services.

RESOURCE-BASED PE RVUS

While ONS generally supports the adoption of a bottom-up methodology for allocation of direct practice expense (PE) across all services, the Society is concerned that Congressional intent related to the chemotherapy administration payment provisions in the MMA has not been realized. During the development and consideration of the MMA, the Society engaged in lengthy discussions with Members of Congress and their staff about the need to permanently correct historic underpayment for oncology nursing and drug administration services. It was our understanding from those conversations that it was the intent of Congress to have CMS correct long-standing problems with the payment methodology for drug administration services, and that the envisioned result was increased and additional payments for services provided by oncology nurses.

Chemotherapy administration payments have not increased to the degree envisioned; additional payments for other oncology nurses services have not been made, and due to cuts to the second hour of drug administration, practices potentially are facing chronic financial losses with respect to the provision of chemotherapy to Medicare beneficiaries. We have serious concerns that without comprehensive attention to – and correction of – payments for drug administration and oncology nursing services, practices will not have the resources necessary to delivery comprehensive, quality cancer care to all Medicare beneficiaries in need. Moreover, we are very concerned about the adverse impact the automatic cuts imposed by the Sustainable Growth Rate formula (should they be implemented in 2008) will have on chemotherapy administration payments and access to care for Medicare beneficiaries with cancer.

CODING – PAYMENT FOR IVIG ADD-ON CODE

We commend CMS for recognizing that intravenous immunoglobulin (IVIG) therapy plays a critical role in treating myriad autoimmune disorders and for taking action to ensure its availability for patients. Two members of our Outpatient Chemotherapy

Advisory Panel recently informed us that they continue to face challenges in procuring IVIG, and indicated that reimbursement for the drug is below their acquisition costs, contrary to the findings of the Office of Inspector General of the Department of Health and Human Services. As such, we continue to have concerns about ensuring patient access to this important therapy. We support CMS's decision to continue to provide payment in 2008 for G0332 (pre-administration-related services) to help cover the additional practice costs associated with procuring IVIG, scheduling patients for IVIG infusions, and other services related to the administration of the drug.

ASP ISSUES

Members of our Outpatient Chemotherapy Advisory Panel have informed us that their practices continue to face many challenges associated with reimbursement for chemotherapy and supportive care drugs for people with cancer. Their comments, concerns, and experiences regarding the impact of reimbursement changes (e.g. Average Sales Price calculations) for chemotherapy drugs fall into five basic thematic categories:

(1) reimbursement of many chemotherapy medications is below cost, and, as such, some practices are unable to administer some drugs to patients, because of insufficient reimbursement;

(2) fluctuating ASP+6% figures and the lag between manufacturer price increases and ASP adjustments cause some chemotherapy agents to be "underwater" (see above for patient impact);

(3) unlike, as promised by Congress - and envisioned by the MMA - the payment decreases on the drug side have not been off-set by increased reimbursement for the services to administer chemotherapy;

(4) the overall drop in payment for the provision of chemotherapy in physician offices is significant, and some practices are facing difficult decisions with respect to how best to "keep their doors open;" and

(5) many Medicare patients do not have supplemental insurance and are unable to pay their 20% coinsurance - some of these patients are sent to hospital outpatient settings for their treatment, some patients opt not to proceed with treatment, and, in many cases, the practices are left assuming the loss because Medicare does not provide payment to cover bad debt in physician office settings. The referral of these patients to hospital outpatient settings is not a solution, as it shifts the costs/loss to

hospitals, can diminish the availability of free care pools, often increases the overall costs for the patient, and may require the patient to travel a great distance to receive care.

ONS has serious concerns about what our members are reporting and the potential adverse impact on patient access to care. ONS urges CMS to give full and fair consideration to the comments from our colleagues in the cancer community with respect to specific recommendations regarding how to modify ASP, so patient access to care can be ensured.

CAP ISSUES

The Society has previously gone on record with CMS, articulating our overall concerns about the Competitive Acquisition Program (CAP) for chemotherapy and supportive care drugs. ONS urges CMS to ensure that CAP vendors are required to meet all aspects of laws and/or regulations that wholesalers and manufacturers are required to meet when they ship drugs to physician practices. After accepting the drug from the CAP vendor – presuming it was prepared, stored, and transported appropriately – it is our understanding that, generally, the responsibility for appropriate storage, administration, etc. then falls to the facility that accepted the drug. Our comments here will focus on the questions related to "transporting CAP drugs" and "prefilled syringes."

ONS believes that the CAP should permit direct delivery to multiple sites, as well as allow transport of CAP drugs to another site by an employee of the practice who is working under the supervision of the physician. While we share others' concerns about the "risk of damaging a drug that has not been kept under appropriate conditions while being transported," we believe that by allowing physicians, registered nurses, and other qualified staff – as permitted under state law – to take responsibility for such a transfer, the likelihood of such damage occurring is minimal, since these individuals are knowledgeable about drug stability and understand how to handle, package, transport, and store such drugs. Allowing this group of professionals to assume and maintain responsibility for CAP drug transportation allows greater flexibility in scheduling patient drug administration, and permits practices to store CAP drugs at a satellite location without having to arrange for a special visit around a CAP shipment to a clinic location that may not be open every day. As part of this intra-practice transfer, we recommend that signed transport sheets be used to verify safe passage, and that CAP vendors and practices have an agreement in writing with respect to drug transportation policies.

We appreciate that CMS acknowledges that "admixture services for injectable drugs require specialized staff, training, and equipment." To that end, ONS members have expressed specific concern about drugs being delivered to physician office practices already reconstituted in their vials and/or in prefilled syringes. It is difficult to envision an outside pharmacy providing drugs to practices already "admixed" and in an IV bag unless they were "next door" to the office. ONS previously has gone on record in opposition to any CAP that would permit the preparation and delivery of drugs already reconstituted in their vials and wishes to extend that concern to include prefilled syringes.

For any drug that comes in powder form, once reconstituted, it only has a certain amount of time that it is stable, and - in most cases - such drugs would need refrigeration, as a result. Some drugs already come in liquid form and may or may not need refrigeration to store them in their "packaged" state; if these drugs are provided through the CAP, the patient's caregiver may not be able to confirm that the drug has been prepared and stored according to instructions and safely. Drugs that have been admixed have stability issues, depending on the drug. Premixed therapies would be wasted, if orders are changed or drug needs to be held due to low counts. If physicians or nurses cannot be assured that the drugs have been stored at the proper temperature, mixed with the proper solution, or otherwise handled appropriately - they would be destroyed, thus leading to terrible waste and economic inefficiencies. Some drugs simply cannot be prepared in advance, because they are not stable long enough, once prepared. As such, we caution CMS in moving to permit the inclusion of prefilled syringes in the CAP.

DRUG COMPENDIA

ONS thanks CMS for including a discussion of - and soliciting public comment on - the process by which the agency may revise the list of compendia for determining medically-accepted off-label indications for drugs. The Society maintains a long-standing interest in ensuring that Medicare beneficiaries with cancer have timely and unencumbered access to - and coverage of - off-label use of all U.S. Food and Drug Administration (FDA) approved therapies, biologics, and prescription drugs, if they have been recognized for treatment of patients' specific cancer - or side effects - in established medical or drug reference compendia. To that end, previously, ONS has sent correspondence to CMS (July 25, 2005) and the Medicare Coverage Advisory Committee (February 27, 2006), urging the agency to recognize and utilize the *National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium*. We remain hopeful that CMS - utilizing existing authority - will add this cancer-specific

compendium to its current mandated reference list; we urge the agency to take this action as quickly as possible.

We join with others in the cancer community in expressing our concern that the compendia currently recognized by CMS are not keeping up-to-date with regulatory approvals and published scientific and clinical evidence. Moreover, given that one of the three current compendia, as noted in the proposed rule, is no longer in existence and a second is changing ownership, name, and format - modifications which may lead the agency to cease its use - ONS is concerned that the agency does not have an adequate number of currently available compendia upon which to base its coverage decisions.

We further are concerned that the timeline outlined by CMS in the proposed rule appears to be quite lengthy. While we appreciate the agency's interest in being deliberative, such a process must be balanced with the need of people with cancer to have prompt access to the prescription therapies that their health care providers determine are most appropriate for them. Given that CMS, the Agency for Healthcare Research and Quality, and the Medicare Evidence Development and Coverage Advisory Committee (previously the Medicare Coverage Advisory Committee) have all studied this issue, and the agency now is receiving public comment, we urge CMS to take action to promptly implement a process to ensure additional compendia are available for the agency to utilize for its off-label coverage decisions. Such timely action will help ensure that Medicare beneficiaries with cancer have unencumbered access to the therapies their health care providers determine are most appropriate for them, based upon the most recent, valid, and reliable data.

THEARPY STANDARDS AND REQUIREMENTS

ONS has 106 members in its Lymphedema Management Special Interest Group (SIG), a sub-specialty cohort of oncology nurses, who are involved in the provision of lymphedema care to people with cancer. It is our understanding that due to a change made by the agency in 2004, oncology nurses are no longer considered to be "qualified" providers of lymphedema care, who can bill under CMS "therapy" codes. Our members have informed us that this policy is prohibiting them from being able to provide lymphedema care and services to Medicare beneficiaries in need. This restriction concerns ONS greatly, as the Society considers lymphedema care to be an integral part of quality, comprehensive care and an essential service that oncology nurses provide to their patients undergoing or recovering from treatment. We submitted comments to you on this matter in November 2006, and have not received any response or acknowledgement from the agency with respect to this

correspondence. For your reference, we have attached those original comments, and we thank you in advance for your attention and response to our concerns.

TRHCA-SECTION 110: ANEMA QUALITY INDICATORS

With respect to anemia treatment for people with cancer, ONS wishes to take this opportunity to respectfully request that the agency reopen portions of the recent "National Coverage Decision (NCD) for Erythropoiesis Stimulating Agents (ESAs) for Non-Renal Disease Indications (CAG-00383N)." The Society submitted comments earlier this summer with respect to ESA use in cancer and related neoplastic conditions which stated our position that we believe that Medicare ESA payment policy should be reflective of the full-range of national practice guidelines, Food and Drug Administration (FDA) scientific determinations, and other valid and reliable evidence. It is our understanding that the NCD is not consistent with national evidence-based guidelines and FDA drug labeling, and, as such, we are concerned about its potential adverse impact on Medicare beneficiaries with cancer. Therefore, we join with our other colleagues in the cancer community in respectfully requesting that the agency delay implementation of the NCD, while modifications can be made to the policy to ensure that it is evidence-based, aligned with expert opinion, and ensures patient safety and well-being.

Summary

ONS feels strongly that the nation will be able to sustain and bolster the safety-net of community-based cancer care and continue to deliver quality, comprehensive cancer care to all in need, ***only*** if Medicare ensures adequate access to - and reimbursement for the full range of cancer treatment and related care - in all cancer care settings. The Society maintains that people with cancer should be assured access to comprehensive quality care that proves the most effective and appropriate for them. As such, ONS has serious concerns that taken together – Medicare payment policies, the current and expected nursing shortage, and the projected increase in the overall number of cancer cases over the next twenty years – pose a serious threat to the ability of our nation to provide quality cancer care to all who may be in need. ONS advocates that clinical decisions with regard to the best course and type of treatment – and appropriate care delivery setting – should be evidence-based and made by health care providers, together with their patients, and should not be dictated or otherwise influenced by payment practices or policies.

Please know that we stand ready to work with you, your colleagues, and other cancer community stakeholders to craft and implement Medicare payment policy changes that

ensure access to quality cancer care for seniors with cancer and prove fiscally responsible for the nation. As always, we thank you for this opportunity to submit comments, and are grateful to you and your colleagues for your full and fair consideration of our concerns, recommendations, and requests. If we can be of any assistance to you or your staff, or if you have any questions, please feel free to contact us or our Washington, DC Health Policy Associate, Ilisa Halpern Paul (202/230-5145, ilisa.paul@dbr.com).

Respectfully submitted,

Georgia M. Decker, MS, RN, CS-ANP, AOCN®
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ONS
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November 7, 2006

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
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200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Acting Administrator Norwalk:

On behalf of the Oncology Nursing Society (ONS) – the largest professional oncology group in the United States, composed of more than 35,000 nurses and other health professionals who are dedicated to ensuring and advancing access to quality care for all individuals affected by cancer, we are writing to bring to your attention an issue impacting access to quality, comprehensive cancer care for Medicare beneficiaries with cancer, particularly those seniors with breast cancer who suffer from lymphedema. As part of its mission, the Society stands ready to work with policymakers at the local, state, and federal levels to advance policies and programs that will reduce and prevent suffering from cancer, particularly among the Medicare population, which is disproportionately affected by cancer. We thank you in advance for your attention to this important cancer care issue.

Lymphedema Care: Essential Component in Comprehensive, Quality Cancer Symptom Management Provided by Oncology Nurses

As you may know, lymphedema is swelling (edema) caused by blocked lymph nodes; the accumulation of lymph fluid subsequently leads to painful swelling of the arms and/or legs. Lyphedema usually is caused by trauma or damage to the lymph nodes, which often occurs during treatment for breast cancer (e.g. mastectomy and/or removal of lymph nodes). Lymphedema has a serious adverse impact on quality of life, as it causes pain and pressure, distorted posture, and altered self-image due to the significant swelling of limbs/body parts. Moreover, lymphedema can involve severe edema, which causes pain, restricted movement, disability, and can cause skin breakdown, infections, and, rarely, lymphangiosarcoma. A significant proportion of the two million breast cancer survivors in the United States who have had lymph nodes removed or irradiated during treatment are likely to develop lymphedema in the affected arm.

Although no cure exists for lymphedema, symptoms can be managed effectively through care and therapy which reduce swelling and increases mobility. Lyphedema treatments include meticulous skin care, compression garments or bandages, exercises, massage, and manual

lymphatic drainage. In addition to providing cancer treatment (e.g. chemotherapy, radiation therapy), oncology nurses maintain principal responsibility for managing patient treatment side-effects and symptoms. Maximizing quality of life and minimizing treatment of side-effects such as pain, fatigue, nausea/vomiting, sleep/wake disturbances, infection and bleeding, constipation, depression, mucositis, dyspnea, and lymphedema are central goals and responsibilities of oncology nurses. As such, taking steps to prevent and reduce the adverse effects of lymphedema is a key component of oncology nursing care.

Current CMS Lyphedema Payment Policy Restricts Access to Care Provided by Oncology Nurses

ONS has 106 members in its Lyphedema Management Special Interest Group (SIG), a sub-specialty cohort of oncology nurses who are involved in the provision of lymphedema care to people with cancer. For the past two years, the Society has received complaints, concerns, and comments from members of the Lymphedema Management SIG regarding the Centers for Medicare and Medicaid Services' (CMS) current lymphedema care payment policy. It is our understanding that due to a change made by the agency in 2004, oncology nurses are no longer considered to be "qualified" providers of lymphedema care who can bill under CMS "therapy" codes. Our members have informed us that this policy is prohibiting them from being able to provide lymphedema care and services to Medicare beneficiaries in need. This restriction concerns ONS greatly, as the Society considers lymphedema care to be an integral part of quality, comprehensive care and an essential service that oncology nurses provide to their patients undergoing or recovering from treatment.

It is our understanding that generally lymphedema care being billed as "incident-to" therapy services cannot be billed to Medicare if provided by a nurse, unless that nurse meets the requirements in place to be a qualified "therapist." However, we believe the current definition is unfairly restrictive and precludes most registered nurses from being considered "qualified therapists." Moreover, we understand that while nurses still may bill lymphedema care "incident-to," they cannot use "therapy" codes for billing such services, and that no other appropriate codes exist to capture and garner payment for these services. Registered nurses are licensed health professionals and many oncology nurses additionally are certified by the Oncology Nursing Certification Corporation. As such, ONS maintains that oncology nurses should be considered qualified providers for the purposes of billing for - and payment of - lymphedema care provided in outpatient settings.

Our members inform us that the current policy precludes them from being able to deliver comprehensive symptom management to their patients in the office setting, as it requires them often to refer their patients off-site for lymphedema care - to a provider who may be inconveniently located, and/or not familiar with, trained in, or knowledgeable of all the other factors and variables impacting someone being treated for cancer. As such, we have concerns that this payment policy unintentionally is hampering patient care coordination, posing access challenges to patients, and potentially placing patients in the hands of providers who are not best suited to provide them with this care which should be given in the context of their broader cancer treatment program.

Recommendation

Oncology nurses are essential to the provision of lymphedema care, as they most often are the health professional on the cancer care team who recognizes/diagnoses that the patient is suffering from lymphedema and manages the patient's other symptoms associated with cancer treatment. ONS urges CMS to revise its current policy and permit oncology registered nurses to bill for the provision of lymphedema care under all outpatient billing scenarios and codes currently permitted for other providers.

Summary

Thank you very much for your consideration of our concerns and your attention to our request. Please know that we stand ready to work with you and your colleagues to ensure that oncology nurses can provide lymphedema care to all Medicare beneficiaries in need. Should you or your staff have any questions, please contact us, or our ONS Health Policy Associate in Washington, DC, Ilisa Halpern Paul (202/230-5145, ipaul@gcd.com). Thank you again for your consideration of our views.

Respectfully submitted,

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August 15, 2007

Via Email and Hand-Delivery

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Acting Administrator
Centers for Medicare & Medicaid Services
P.O. Box 8018
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Baltimore, MD 21244-8018

Attn: CMS-1385-P

Establish Non-Facility Practice Expense Relative Value Units for Arthroscopy Procedures

Dear Administrator Norwalk:

In reviewing the proposed 2008 Medicare Physician Fee Schedule Rule, I was pleased to note that CMS is considering extending reimbursement for arthroscopy procedures to physicians who perform these important diagnostic procedures in their offices. I strongly support this proposal and urge CMS to quickly adopt it through the final 2008 Medicare Physician Fee Schedule Rule.

With respect to my qualifications, I am an Associate Professor of Surgery and Director of the Sports Medicine Fellowship Program at the University of Chicago Medical Center. In addition, I am a member of the American Academy of Orthopaedic Surgeons and currently serve on the Academy's Board of Councilors. I am also a member of the American Orthopedic Society for Sports Medicine.

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My sports medicine practice specializes in minimally invasive arthroscopic procedures of the shoulder, elbow, hip, knee, and ankle. I am a team physician for both the Chicago Blackhawks and the United States volleyball team. I also serve as team physician for all varsity sports at Concordia University. As such, I am keenly aware of the need to establish appropriate and fair reimbursement for physicians performing arthroscopy procedures in their office.

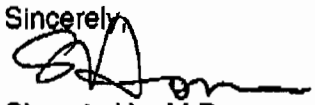
Over the past several years, arthroscopies have proven to be safe and effective when performed in a physician office. Moreover, performing these diagnostic procedures in the office setting is more convenient for the patient and often allows doctors to achieve a diagnosis more quickly and accurately.

Unfortunately, Medicare does not currently provide reimbursement for diagnostic arthroscopy procedures when they occur in the physician office. I personally have stopped performing certain procedures which could otherwise be easily handled in my office because of inadequate reimbursement. My only alternatives at times are to send patients to the hospital for arthroscopy testing or to order other procedures, such as MRIs.

Accordingly, I was pleased to note that CMS is considering establishing non-facility practice expense relative value units for arthroscopy procedures. I strongly urge CMS to adopt this proposal in the final 2008 Medicare Physician Fee Schedule Rule. Doing so would be in the best interest of not only my patients but also the entire Medicare program.

Thank you for your attention to this important matter.

Sincerely,



Sherwin Ho, M.D.

cc: Pamela West, CMS (via email)
Ken Simon, MD, CMS (via email)
William Rogers, MD, CMS (via email)
Brad Henley, MD, AAOS (via email)
Bob Fine, AAOS (via email)
Matt Twetten, AAOS (via email)

August 21, 2007

Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-1850

Re: CMS-1385-P
THERAPY STANDARDS AND REQUIREMENTS

Dear Sir or Madam:

The Georgia State Board of Physical Therapy Examiners submits the following comments on the proposed rules changing the definition of "physical therapist" in Section 484, Title 42 of the Code of Federal Regulations. The proposed rules are part of the 2008 Proposed Revisions to Payment Policies Under the Physician Fee Schedule and Other Part B Payment Policies for Calendar Year 2008, found in Volume 72 of the Federal Register, published on July 12, 2007.

Under subsection (i)(B) and (ii)(B) of the proposed definition of "physical therapist" an applicant would need to have "passed the National Examination approved by the American Physical Therapy Association." We strongly suggest that CMS rely on state licensure and that the additional examination requirements contained in subsections (i)(B) and (ii)(B) of the definition of "physical therapist" be deleted from the final rule. At the very least, the Centers for Medicare and Medicaid Services ("CMS") should delay promulgation of the proposed rule until CMS has had an opportunity to understand the examination, credentialing, and licensing processes currently in place.

We, along with all of the other state boards of physical therapy examiners, have already adopted a national qualifying exam for physical therapists, the National Physical Therapy Examination ("NPTE"). The Federation of State Boards of Physical Therapy ("FSBPT") develops and administers the NPTE in close collaboration with the state boards. Working together, we have developed a national passing score. The FSBPT has done an outstanding job of meeting our needs. Likewise, the NPTE has been a valuable tool in screening physical therapist applicants. Through the NPTE, we have been able to successfully filter applicants. In turn, we, as a policing body, have been able to protect the public by ensuring that only qualified therapists are licensed care for our citizens.

CMS should not usurp the states' function of licensing physical therapists and other professionals. Health care professional credentialing and licensing is a classically state function. Licensing and credentialing are the domain of the states. CMS' proposal would inappropriately transform a state function into a federal function. There is no justification for this action, and CMS should prevent it by removing the proposed rule.

CMS respects states' rights and state licensure for other health care professions, and it should continue to do so with respect to physical therapists. For example, CMS' regulations define a physician as a "doctor of medicine ... legally authorized to practice medicine and surgery by the State in which such function or action is performed." 42 C.F.R. § 484.4 (2006). Likewise, a registered nurse is defined as "[a] graduate of an approved school of professional nursing, who is licensed as a registered nurse by the State in which practicing." 42 C.F.R. § 484.4. Establishing requirements that are different than what the states require for licensing PTs would be inconsistent with not only the rights of the states, but also CMS' own standards.

Moreover, the federal government should not impose an additional burden on the states, particularly since its stated desire for a national examination already satisfied and its other stated goals would not be better met by the burden it proposes to impose. The proposed unfunded mandate could result in the development of a second exam, which would create confusion and more work for the states, without benefit. Our resources are already limited and stretched.

In the preamble to the proposed regulations, CMS says that it is seeking uniformity. The fact of the matter is that uniformity and consistency across the nation and across provider settings already exists. State licensing requirements apply to physical therapists without regard to where they practice. All states accept CAPTE accreditation. All states accept the NPTE and have adopted the same passing score. No federal regulation is required.

In fact, the proposed regulations would likely defeat CMS' own goal of uniformity. If, for example, the APTA were to approve a different exam than the NPTE, which the regulations would permit it to do, physical therapists, patients, including Medicare and Medicaid beneficiaries and recipients, and others could face substantial confusion and interruption of service. As a state board of physical therapy examiners, we would continue to have authority to select an exam of our choice for licensing purposes. However, under the proposed rule, a physical therapist would have to pass a second exam approved by the APTA to qualify for Medicare reimbursement. Thus, patients might be forced to change physical therapists as they become Medicare or Medicaid eligible, and the current uniformity and continuity of standards across the country would be lost. Thus, the proposed rules undermine CMS' ambition for uniformity of standards.

CMS and the federal government should not empower an advocacy group, like the APTA, to establish an examination or any qualifications for professionals to provide healthcare services to patients. The APTA's mission is to advocate and promote the profession. As a licensing body, our mission is to ensure that physical therapists are qualified to provide physical therapy services and are authorized to do the work for which they are trained. The FSBPT, the organization to which we look for the national licensing exam, was created to eliminate, protect against and prevent the inherent conflict of interest that the APTA would have if it were to have authority over the examination and credentialing processes. Even the APTA recognized this conflict of interest problem two decades ago when it created the Federation of State Boards of Physical Therapy. CMS must not allow this conflict of interest to become a rule.

The Georgia State Board of Physical Therapy Examiners strongly urges CMS to require only state licensure. Most importantly, CMS should remove the additional examination requirements contained in subsections (i)(B) and (ii)(B) of the definition of "physical therapist." At a minimum, CMS should delay promulgation of the proposed rule until CMS has had an opportunity to understand the examination, credentialing, and licensing processes currently in place.

We appreciate the opportunity to comment on the proposed rules regarding physical therapist and physical therapy assistant qualification requirements.

Respectfully yours,

The Georgia State Board of Physical Therapy

By:
Name: George B. Hamil, Jr. P.T
Title: PT Board Member

Anesthesia Resources

PO Box 10402
Fargo, North Dakota 58106-0402

Ms Leslie Norwalk, JD
Centers of Medicare and Medicaid Services
Department of Health and Human Services
PO Box 8018
Baltimore, MD 21244-8018

Paula Schmalz
Anesthesia Resources
PO Box 10402
Fargo, North Dakota 58106-0402

August 20, 2007

Dear Ms Norwalk:

As a member of the North Dakota Association of Nurse Anesthetists, I write in support of the CMS proposal to increase the value of anesthesia work by 32%. This would increase the anesthesia conversion factor by 15% in 2008 compared with current levels as defined in 72 FR 38122 of 7-12-2007.

If adopted, the CMS proposal would help ensure that Certified Registered Nurse Anesthetists (CRNAs) continue to provide Medicare beneficiaries with access to anesthesia services under Part B.

With over 36 million CRNAs practicing in the United States giving the majority of anesthetics in the United States it is imperative that cost of these services not be undervalued.

Third party insurance companies follow closely the Medicare reimbursement rates, thus I will be impacted on the CMS decision to revise existing Medicare Part B reimbursement which is currently approximately 40% of private market rates. I request that you consider the impact on accessibility of anesthesia services in the future.

I thank you for your attention.

Sincerely,

Paula Schmalz, CRNA

Paula Schmalz, CRNA
Anesthesia Resources

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THE REHABILITATION HEALTH CENTER
AT PARK WEST

August 20, 2007

REHABILITATION &
HEALTH CENTER, INC.
James A. Porterfield
PT, MA, ATC
Elizabeth Roth
PT, MA
Sussan Decker
PT
Debi Benjamin
PTA
Linda Martell
PTA

Mr. Kerry N. Weems
Administrator – Designate
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1385-P
PO Box 8018
Baltimore MD 21244-8018

Re: Physician Self-Referral Issues

Dear Mr. Weems,

Please reference the Medicare Program; Proposed Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Rule.

This letter is in comment to the July 12 proposed 2008 physician fee schedule rule, specifically the issue surrounding physician self-referral and the "in-office ancillary services" exception.

I know first hand of the disruption of services and the alterations in individual lives as a result of the greed and power of referral for profit. Referral for profit is simply not right and creates over-utilization of services and unnecessary expense. By eliminating physical therapy as a designated health service furnished under the in-office ancillary services exception, CMS would reduce the abuse and tell the public that they, as well, do not agree with the concept referral for profit. In our unofficial survey of Medicare patients, we found that the majority also question the legality and ethics of this financial incentive for physicians to be able to bill for and profit from physician therapy services.

I have been a Physical Therapist since 1974 and in private practice since 1989. I am an advocate of technology, clear definition of effective treatment, and caring for people.

Referral for profit certainly changed my life and created a great deal of angst for my staff and my family. See the attached story.

I encourage CMS to stop referral for profit for PT services, and to work more closely with the APTA to develop intervention programs that are best for most.

Sincerely,

James A. Porterfield PT, MA, ATC

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PHONE 330-564-4100 · TOLL-FREE 866-883-5071 · FAX 330-564-4106

The Demise of the
Rehabilitation and Health Center, Inc at Crystal Clinic 2006
James A. Porterfield PT, MA, ATC

In 1987, I was privileged to be a member of a committee that developed and built a complete musculoskeletal center. The center housed thirty physician specialists, including Orthopedist, Rheumatologists, Plastic Surgeons, Hand Surgeons, Physiatrists, Physical and Occupational Therapists, and Orthotist/Prosthetists, all working together to treat the patient. The building also had six outpatient surgery suites, a pain management center, a state of the art diagnostics and a laboratory. This unique clinic was a patient centered, collaborative model of health care for people with neuromusculoskeletal disorders – a one-stop shop.

Because I wasn't a physician, I eventually lost the battle to own my own space in the building. A physician group owned the building. We all owned our own businesses and no one profited from one another. We wrote, traveled and researched together. We presented 5 to 6 clinical education programs per year and were seriously involved in resident and community education. It was a state of the art neuromusculoskeletal center and for years the business thrived.

In 2001, the environment began to change, conflict arose and the physicians decided to change their manner of payment. Every physician became their own business. Eat what you kill was the concept. By this time, the founders had retired and the culture progressively changed.

Three years ago the physicians approached me saying don't take this personally but we are planning to incorporate all the ancillary services, placing them under one physician-owned umbrella. The plan was to keep the staff together and retain me as their manager. There was no offer for payment for my existing practice. For a year we attempted to negotiate a mutually beneficial arrangement. It became very clear that the more they wanted, the more they wanted. I declined their offer and made plans to move my office and remain an independent practice.

It was surprising to me that they had five separate proposals from companies that would help them develop a referral for profit business in PT. One national company was hired to provide Physical Therapy services, and I moved our facility to a new location, being forced to start over at age 57. On the up side, it has been a very positive experience, re-entering the medical community, and the down side is nondisclosure to those patients who are being directed into their clinics.

As a PT for 34 years and business owner for 17 years, I have learned a great deal from this experience and I now recognize the ramifications of greed and power, and the value and worth of truly caring for people and being true to your convictions.

Urology Associates
OF PORT HURON, P.C.

Marshall Kamer, M.D., F.A.C.S.
Thomas A. Coury, M.D.
Glenn G. Betrus, M.D.
Frank Ferres, P.A.-C.

1037 Water Street, Suite 1 • Port Huron, Michigan 48060 • Telephone: (810) 984-4194 • Fax: (810) 984-4674

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August 23, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

RE: PHYSICIAN SELF-REFERRAL PROVISIONS

Ladies and Gentlemen;

As a practicing urologist in the State of Michigan, it has been brought to my attention that once again there is consideration of revision of the Stark Law. As a Urologist, I have been involved with providing my patients extracorporeal shock wave lithotripsy for kidney stone disease for several years. I have been involved in a joint venture, and without these joint ventures access in a smaller community would be extremely difficult. I had to travel as did my patients for many years to the Detroit area over an hour away to provide these services. Due to a joint urologic venture, we have been able to provide mobile lithotripsy services. As I understand the CMS proposal is to ban physician joint ventures for therapeutic services. The concern is that this goes contrary to good patient care. I find this quite the contrary, I am insulted that this is felt to be the case. I am not aware of any notable situation in this country where this indeed has happened. I find it difficult and almost hypocritical that hospitals are allowed to initiate these ventures and are constantly trying to encourage us to refer our patients to them when they have these services available. They are, however, frequently reluctant to invest in these services that are beneficial to our patients. When we as physicians invest in these services to try and improve patient care for the patients in our community it is looked at as only a means to benefit the physicians and not our patients.

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Urology Associates
OF PORT HURON, P.C.

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August 23, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

RE: PHYSICIAN SELF-REFERRAL PROVISIONS

Ladies and Gentlemen;

I am a urologist in Port Huron Michigan, and have been treating individuals with kidney stones via lithotripsy through a urology joint venture. I am concerned in regard to proposed changes to the Stark Law, which may jeopardize this or future joint ventures. One of the proposed revisions would involve "under arrangements" which would prohibit a hospital from billing Medicare for any referrals if the service was provided to the hospital under arrangements by the physician in which the physician is an investor. Joint ventures, especially lithotripsy, provides a valuable service to the community and allows utilization of equipment which would not otherwise be available to the hospital due to its cost and limited utilization. The current generation of lithotripsy equipment has a wider clinical application than those lithotripsy units available in the past. The advantage of a joint venture is that the hospital does not need to make a large capital investment and yet still can receive equipment that is "state of the art". This would clearly not be possible with these machines if each hospital had to individually purchase this technology. In our local community this would mean that most patients would have to drive at least one hour to a center that offered a fixed lithotripsy unit.

I am specifically asking that;

1) CMS clarify that the results of the ruling in ALS vs Thompson Lithotripsy would not be subject to the proposed "under arrangements" restrictions;

2) clarify the proposed "under arrangements" provision to make certain that therapeutic services by urology joint ventures are not prohibited services if they would be so only because of the site they are delivered;

3) drop any prohibition of Per Click or Percentage Fees as related to these therapeutic joint ventures in order to preserve access and cost savings that the shared service model has created; and

4) clarify the "Stand in the Shoes" provision to exempt hospital ownership or control in an ambulatory surgery center to clarify that legitimate joint ventures are not forced to abandon all ambulatory surgery centers with any hospital participation.

Thank you, in advance, for your consideration in regard to the matter.

Sincerely,

Marshall Kamer

Marshall Kamer, M.D.

MK/dja

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August 22, 2007

Mr. Kerry Weems
Administrator-Designate
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

RE: Physician Office PT/OT Services

Mr. Weems,

I appreciate your taking the time to listen to my concern of in-office ancillary service arrangements.

Medicare recipients are in need of care that they will need without the risk of over-utilization. Physicians are in a position to refer recipients to in-office Physical Therapy and Occupational Therapy services where they have financial interests.

Eliminating in-office ancillary services would allow patients to receive quality care at outpatient Physical Therapy and Occupational Therapy clinics, thereby eliminating the pressure patients would feel to go to their physicians' office, thus reducing the inherent financial incentive for over-utilization.

Thank you for considering these comments and concerns, and the elimination of "in-office ancillary services."

Sincerely,

Daniel Paulson

Daniel Paulson, Physical Therapist

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y Craig, MS, PT, AT, C • and
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Mr. Kerry N. Weems
Administrator - Designate
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Subject: Medicare Program; Proposed Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Rule

Mr. Weems,

My name is John Teepe, MPT. I am a physical therapist who has practiced in outpatient orthopedics for ten years. I direct a facility for ProRehab in Chesterfield, Missouri.

My letter concerns physician self-referral issues. I wish to comment on the July 12th proposed 2008 physician fee schedule rule, specifically the issue surrounding physician self-referral and the "in-office ancillary services" exception.

The potential for fraud and abuse exists whenever physicians are able to refer Medicare beneficiaries to entities in which they have a financial interest, especially in the case of physician-owned physical therapy services. Physicians who own practices that provide physical therapy services have an inherent financial incentive to refer their patients to the practices they have invested in and to overutilize those services for financial reasons. By eliminating physical therapy as a designated health service (DHS) furnished under the in-office ancillary services exception, CMS would reduce a significant amount of programmatic abuse, overutlization of physical therapy services under the Medicare program, and enhance the quality of patient care.

The "in-office ancillary services" exception has created a loophole that has resulted in the expansion of physician-owned arrangements that provide physical therapy services. Because of Medicare referral requirements, physicians have a captive referral base of physical therapy patients in their offices.

Due to the repetitive nature of physical therapy services, it is no more convenient for the patient to receive services in the physician's office than an independent physical therapy clinic.

Physician direct supervision is not needed to administer physical therapy services. In fact, an increasing number of physician-owned physical therapy clinics are using the reassignment of benefit laws to collect payment in order to circumvent "incident to" requirements.

Thank you for your consideration of my comments.

Sincerely,

John Teepe, MPT

Administration • 13537 Barrett Parkway Dr., Suite 105 • Ballwin, MO 63021 • Phone 314-821-9126 • Fax 314-821-9142

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August 21, 2007

Centers for Medicare and Medicaid Services
Dept. Of Health and Human Services
Attn: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Dear Ladies and Gentlemen:

I am sending this letter to you in response to the proposed changes to Stark regulations that one finds in the new proposed Medicare Physicians Fee Schedule. The first area of concern is what is called under arrangement "agreements" where physician joint ventures provide therapeutic services to hospitals that are also designated health services (DHS). As ventures, these are banned only when performed in a hospital setting. Hospitals gain a lot by not having to expend sparse funds on buying entire new laser systems which may change rapidly over time. It is frequently to their advantage to let physician joint ventures take the risk making these services possible as well as coming up with the capital necessary to provide them. This concern is particularly true in a single hospital whose volume of patients that would benefit from a certain piece of technology is not large enough. Such things as laser lithotriptors can be taken to many different hospitals making their joint volumes sufficient enough to warrant the capital expenditure.

Another significant concern is to ban "per-click fee" forms of payment arrangements from a hospital to a physician joint venture providing therapeutic services. Once again these are arrangements that allow hospitals to protect themselves and transfer risk associated with capital investment to the physician joint venture. This is an especially valuable way for hospitals that have somewhat low volumes to still provide state of the art treatments to their patients with traveling equipment. By going to several hospitals, a joint venture is able to have enough volume that it makes the arrangement feasible to begin with. On the other hand the small volume hospitals don't want to have to contract a set payment and find that the amount of services provided in a year's period of time do not cover that cost. For them to pay based simply on their usage eliminates risk for the hospital involved. Currently this is a very familiar form of payment from hospitals to physician owned joint ventures that provide stone lithotripsy services often on a traveling basis to a number of hospitals. Such a ban on per-click services certainly should not apply to a service that is not a DHS to begin with. Eliminating such per-click agreements as a permitted form of compensation may well dry up the availability of new therapeutic therapies particularly on a traveling bases to small volume hospitals in the future. This could certainly harm access of Medicare patients to convenient care particularly in small towns or rural areas. This same reasoning applies if there is a ban to "percentage fee reimbursement."

Finally, another area of concern is changes in proving what may or may not be a violation of Stark rules. These proposed regulations would shift the burden of proof not from the government but to the provider and other parties to an agreement that ultimately may be found to be in violation of Stark rules. As noted in the proposed rules, penalties extend to anyone who "causes a claim to be submitted in violation of the regulations." This could mean that any party to a contract that CMS believes is in violation could be subject to large and crippling fines. Currently, Stark exceptions require payments to be made at fair market value and unrelated to the volume of referrals or other business generated between parties. This "you are guilty until you prove yourself innocent" can again have a chilling effect on physician owned ventures trying to provide needed medical services to hospitals on a traveling basis. Again hospitals whose volumes as a stand alone situation would not be able to warrant bringing technologies to Medicare recipients outside of big cities or in rural areas.

I hope these observations are of value to recognize the flaws in proposed regulations. I recognize that Medicare would vastly prefer that a non-professional entrepreneur provide such services to hospitals but many times physician owned arrangements are the only entities who will pick up the ball and operate such ventures to the betterment of all Medicare patients. I hope these new regulations will not be adopted as written because it will cause real problems with patient access in areas such as mine in small city Texarkana, Texas.

Sincerely,

Patrick J. Somerville, M.D.
PJS/klp

Job #: 767464

Three Rivers UROLOGY, P.C.

RONALD G. CERCONE, M.D., F.A.C.S.
DANIEL J. COLE, M.D.
LAWRENCE A. COLLINS, M.D.
JAMES J. McCAGUE, M.D., F.A.C.S.
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August 22, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1385-T
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Physician Self-Referral Provisions

Ladies and Gentleman:

My name is Dr. Lawrence A. Collins. I am a practicing urologist in the Pittsburgh area. I have been providing lithotripsy services and other specialized urologic services to my patients for many years now using cutting edge technology, which has been provided through physician joint ventures. I feel that I have been able to give excellent care to my patients because of the availability of these cutting edge therapies, which would not otherwise be available were it not for the joint venture services that we have provided.

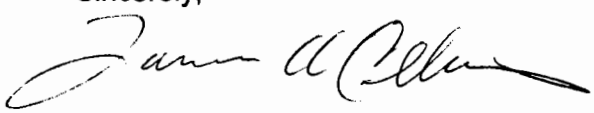
I understand that currently CMS is entertaining some proposals regarding the delivery of health care through these physician joint services. I am concerned that should the services that we are currently providing be disallowed because of changes in Medicare and Medicaid regulations, this would actually eventually adversely affect the care that we are capable of giving to our patients. I fully understand the concerns that you might have regarding conflicts of interest or when it comes to physician's own equipment that is used to deliver health care. I think you should realize, however, that we are talking now about therapeutic delivery rather than diagnostic procedures.

I do not believe there has been any abuse of the system when it comes to health care delivery using joint venture equipment. Furthermore, I believe you should realize that when this equipment is used to deliver health care, specifically laser treatments of the prostate and lithotripsy, it should be recognized that the fee that is obtained by the urologist who is giving the treatment is the major portion of any reimbursement that would occur from the treatment. An increase in distribution to the physician from utilization of the equipment is minimal in comparison to the reimbursement for the delivery of the patient care using the equipment.

Also I think CMS should realize that a lot of these procedures would probably not even be available to our patients were it not for the joint venture approach being utilized by urologists. Hospitals in general are reluctant to spend the cash necessary to obtain some of these more expensive pieces of equipment. If the CMS disallows the current arrangements, it is almost certain that Medicare, Medicaid, and other patients would receive less than optimal therapy.

I hope that you will take this into account in your deliberations. Thank you for your attention to the issues that I have addressed.

Sincerely,



Lawrence A. Collins, MD

LAC/cmc:maf:78448

Santa Cruz
Medical Clinic
An Affiliate of Santa Cruz Medical Foundation

August 24, 2007

Department of Health and Human Services
Attention CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018
Re: Proposed reconfiguration of CA physician payment localities

The Santa Cruz Medical Clinic is a multi-specialty physician group which cares for over 100,000 patients in Santa Cruz County. Approximately 12% of our patients are Medicare beneficiaries. We have previously commented on several occasions to CMS and have advocated since 2002 that Santa Cruz County be removed from California's Rest of State (Locality 99) designation. The failure of CMS to have made this adjustment despite clear evidence that significant economic and demographic changes have occurred since the last reconfiguration of physician payment localities in 1996 has significantly harmed our medical group and has also harmed the health care delivery system in this county. Therefore, we appreciate the opportunity to comment on the three options outlined in the proposed physician payment rule for 2008 with respect to reconfiguration of physician payment localities in California.

Santa Cruz County has been uniquely disadvantaged since the last reconfiguration in 1996 with respect to CMS physician payment localities. Not only has Santa Cruz County had the largest underpayment within Locality 99 in California each year since 1996, we have also had the largest boundary payment difference between our county and San Mateo/Santa Clara Counties, the largest of any adjoining counties in the nation. We note that the hospitals in this county (which is a one-county Metropolitan Statistical Area) now have the highest wage index/Geographic Adjustment Factor of any MSA in the nation. The status quo has Santa Cruz County's physicians paid at the lowest level in California and the hospitals of this county paid at the highest level in the nation. As a result we continue to lose local physicians who are drawn to practice in neighboring localities, and our Medicare beneficiaries are facing critical access issues.

The GAO has recently called for a national reform of the payment localities. They interviewed many providers in this county, including several in this organization, during the development of their report. We are concerned that only one of the three proposed options in the rule reflects the recommendations of the GAO. Neither Option 1 nor 2

includes an iterative reconfiguration of California's localities, which was the approach used by CMS in 1996 and by the GAO.

We therefore support Option 3 which constructs six payment localities for California. CMS describes the application of a 5% floor for a given locality based upon the highest GAF of a county within that locality. CMS presented this option in past Federal Register proposals. However, we believe CMS miscalculated the designation of the new payment localities in California. We recommend that the text described in the proposed rule be accepted but that CMS should recalculate the county groupings accurately. We have attached a table showing this recalculation which would also move adjoining San Benito County into Locality 02.
Further, we are confused as to the actual GAF for Santa Cruz County. The proposed rule's Option 1 and Option 2 lists Santa Cruz's GAF at 1.100 but lists its GAF in Option 3 at 1.098. This is not due to rounding errors as similar inconsistencies are noted for other counties. This is important in that the proposed Option 3 reconfigures counties based on these values. CMS should share not only the source GPCIs used to calculate the GAFs but also should share the cost input data used in the calculation of the county GPCIs, such as rent and wage index data.

We are concerned about the proposed decrease in GAF values for several other SF Bay Area counties notably Santa Clara County. We find it difficult to understand how Santa Clara County, in a non-census year for GPCI recalculation, could have a 9.2% decrease in its GAF. CMS should publish in the final rule the detail source data that led to this abrupt, disruptive, and unanticipated decrease.

If CMS were to select Option 1 we strongly recommend that each county that is removed from Locality 99 (and Locality 03) be assigned into its own fee schedule areas. This is especially true given that the most likely eligible counties (Santa Cruz, Monterey, Santa Barbara, and San Diego) all currently exist as one county Metropolitan Statistical Areas in the Hospital GAF. Further, we recommend that an iterative 5% threshold be applied if you choose this option.

CMS must correct this problem this year. CMS must not defer the implementation of this long-awaited reform to a state medical society. Thank you for your attention to our comments and recommendations. We understand that the California Medical Association will provide CMS a copy of its current policy with respect to locality reform. We are aware that this policy recommends that CMS institute those changes necessary to improve payment accuracy and to mitigate decreases in payments to rural counties. We believe that all three options are consistent with that policy. We believe that the past delegation by CMS to state medical societies to initiate and to approve proposed localities revisions is inappropriate. Our organization includes optometrists, physical therapists, audiologists, speech pathologists, occupational therapists, physician assistants, podiatrists, and nurse practitioners. All of these providers bill CMS for services provided

to Medicare beneficiaries. However, none of these providers are represented by the state medical society. Therefore, CMS, as it acknowledged in the 2005 final rule, bears the responsibility to update the physician payment localities.

Sincerely,

Christine Griger MD

Christine Griger, M.D.
Chair, Santa Cruz Medical Clinic, Inc.

Cc. Sam Farr, Anna Eshoo Members of Congress
Diane Feinstein, Barbara Boxer US Senate

Proposed CMS Option 3	Corrected CMS Option 3 (Corrected Counties in Yellow)	Actual County GAF	CMS Threshold
Locality 01	Locality 01	GAF	
San Mateo	San Mateo	1.204	Floor for this Locality is
San Francisco	San Francisco	1.201	95% of San Mateo
Marin	Marin		*95% of 1.204 =*
	Santa Clara	1.148	*1.1438*
Locality 02	Locality 02		
Santa Clara	Contra Costa	1.134	
Contra Costa	Alameda	1.129	
Alameda	Orange	1.128	
Orange	Ventura	1.128	Floor for this Locality is
Ventura	Los Angeles	1.121	95% of Contra Costa
Los Angeles	Santa Cruz		*95% of 1.134 =*
	Monterey		
Locality 03	Locality 03		
Santa Cruz	Sonoma		
Monterey	Napa		
San Diego	San Diego	1.053	
Sonoma	Santa Barbara	1.053	Floor for this Locality is
Napa	Solano	1.051	95% of Sonoma
Sonoma	Sacramento	1.047	*95% of 1.076 =*
Solano	El Dorado	1.033	*1.0222*
	San Bernardino	1.023	
Locality 04	Locality 04		
Sacramento	Placer	1.021	
El Dorado	Riverside	1.017	
San Bernardino	San Luis Obispo	1.015	
Placer	San Joaquin	1.006	
Riverside	Yolo	0.995	
San Luis Obispo	Stanislaus	0.979	Floor for this Locality is
San Joaquin	Merced	0.977	95% of Placer
	Nevada	0.975	95% of 1.021
	Kern	0.973	0.96995
	Locality 05		
	Sierra	0.967	All remaining CA
	Amador	0.967	Counties move
	Rest of CA	< 0.967	to Locality 05

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Mr. Kerry N Weems
Administrator – Designate
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS- 1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

August 16, 2007

Dear Mr. Weems:

RE: Physician Self-referral Issues; CMS- 1385-P Medicare Program; Proposed Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Rule

I am a Physical Therapist who has worked in the field for nearly 12 years. I am writing to express my concern for the "in-office ancillary services" exception. The potential for fraud and abuse is present when physicians are able to refer Medicare beneficiaries to entities in which they have a financial interest, especially in the case of physician-owned physical therapy services. Physicians who own practices that provide physical therapy services have an inherent financial incentive to refer their patients to the practices they have invested in and to over utilize those services for financial reasons. By eliminating physical therapy as a designated health service furnished under the in-office ancillary services exception, the Centers for Medicare and Medicaid Services (CMS) would reduce a significant amount of programmatic abuse, over utilization of physical therapy services under the Medicare program, and enhance the quality of patient care.

In my experience, I have seen Physician owned practices that provide physical therapy services excessively refer patients to their practice. I have worked in States that have direct access to physical therapy services as well as those that do not and see over utilization of physical therapy services by Physician owned practices in both environments. I believe strongly that the loop-hole that exists should be closed.

Thank you for considering my comments.

Sincerely,

Peter S. Ames, PT

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Urology & Ultrasound Associates, Inc.

Frank D. Greco, M.D.
Board Certified Urologist
100 Delafield Road, Suite 312
Pittsburgh, PA 15215
Telephone: 412-781-7222 Fax: 412-781-7050

August 23, 2007

Centers for Medicare and Medicaid Services
Dept. of Health and Human Services
Attn: CMS-1385-P
PO Box 8018
Baltimore, MD 21244-8018

RE: Physician self-referral provisions

Dear Sir or Madam,

I am an urologist in active practice in the Pittsburgh, Pennsylvania area. I have been in practice for approximately 23 years and have tried to provide the best possible care for my patients. I think that the proposed changes in the Stark Law will affect my ability to provide good patient care. I have never allowed any financial arrangement to interfere with my treatment of patients. I am very upset by the implication that monetary involvement and ownership change our treatment decisions. The oath we take when we become doctors forbids that we do this and most doctors that I know, do not let monetary issues interfere with their ability to take care of patients.

New innovations to prior technologies are constantly being introduced into the healthcare system. Maintaining the most current state of the art technologies, such as the new laser for the treatment of benign prostate disease, is expensive. With joint ventures, doctors are able to partner with the hospitals and allow more doctors to use the same equipment, so there is actually a reduction in the expense incurred. If services furnished under arrangements are prohibited, this type of funding would be impaired. Of course this also applies to accredited ambulatory surgical centers which are owned by the hospitals. The same thing would occur in these settings if joint ventures were not allowed. To ban "per click" fees would be an impairment to joint ventures. To accommodate hospital fear of failure, urology joint ventures have accepted "per click" fee contracts. By doing so, urology joint ventures take the entrepreneurial risk and hospitals then avoid the risks of patient volume being lower than projected. Also banning percentage fees would be another impairment to joint ventures because hospitals avoid risk by compensating on percentages. Certain third party payers provide lower reimbursements while others reimburse more generously so a percentage fee is probably the most fair for the hospitals involved in these joint ventures. Remember that urology joint ventures enable the sharing of expensive capital technology such as lithotripsy between many hospitals that cannot afford to purchase the equipment by themselves or cannot justify such a purchase due to their low case volume. Urology joint venture have brought clinical benefits to thousands of Medicare patients while saving CMS millions of dollars through the efficiency of the shared service models.

Thank you very much for consideration of these matters. Please let me know if there is anything we can be of help to in making this decision.

Sincerely,

Frank D. Greco, MD

FDG/vrs

Jaworski Physical Therapy, Inc.

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August 21, 2007

Mr. Kerry N. Weems
Administrator- Designate
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1385-P
PO Box 8018
Baltimore, MD 21244-8018

Re: Medicare Program Proposed Revisions to Payment Policies: Physician Fee Schedule and Other Part B Payment policies for Proposed Rule. **Physician Self-Referral Issues.**

I am a physical therapist in independent practice in Northeast Ohio. My practice is a Medicare Certified Outpatient Rehabilitation Agency and has been in existence for 22 years. We provide a comprehensive outpatient therapy program consisting of physical, occupational and speech therapy services.

In the 12-18 months we have had several physician groups establish outpatient physical therapy clinics. There was no basis to opening these clinics other than for the economic advantage of the physician owners. In our geographic area, there are several excellent independent providers as well as several hospital systems that provide rehabilitation services. The community has excellent access to rehabilitation services. No specialized services were provided to meet an unmet need in the community.

These physician owned clinics have placed us at a significant competitive disadvantage in our attempts to secure new patients and in many situations to retain past patients. Because these physicians no longer actively refer patients to us, our practice has lost 30% of its business and as a result has had to close one its practice locations.

It is not good public policy to allow these physicians to own physical therapy clinics. There is a definite potential for a "conflict of interest" which occurs when the physician has an economic incentive to refer for a service. These situations also result in these clinics enjoying an unfair competitive advantage over similar providers in a market area. This lack of competition can affect quality of care and cost of services.

I would respectfully request that CMS remove physical therapy from the "in-office ancillary services" exception to the federal physician self-referral laws.

Sincerely,

Michael Jaworski PT, MHS, MBA
President

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6150 Emerald Street • North Ridgeville, Ohio 44039
Phone: (440) 327-1602 • Fax: (440) 327-1656

August 22, 2007

Mr. Kerry N. Weems
Administrator – Designate
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Subject: **Physician Self-Referral Issues;** Medicare Program; Proposed Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Rule

Dear Mr. Weems:

I am a physical therapist in practice in central Ohio and have been practicing physical therapy for 13 years. I have enjoyed a collegial professional relationship with a number of orthopedic surgeons in the area based on positive patient outcomes which has contributed to my successful practice of physical therapy.

I am compelled to write this letter to inform you of my concern for the fraud and abuse from physician-owned physical therapy services that I know is occurring in central Ohio and hear is happening across the country after talking to my colleagues. The potential for fraud and abuse exists whenever physicians are able to refer their patients to entities in which they have financial interest and there is an inherent financial incentive for them to do just that. There is also a national trend for physicians to open their own clinics to supplement their incomes. Orthopedic groups are doing this and the trend is beginning to spread to large primary care physician groups as physicians and their administrators begin to discuss the opportunity at their conferences. By eliminating physical therapy as a designated health service (DHS) furnished under the in-office ancillary services exception and central location exception, CMS would reduce a significant amount of programmatic abuse, overutilization of physical therapy services under the Medicare program, and improve the safety and quality of patient care. I will outline specific examples of potential fraud and abuse below and recommend that the Office of the Inspector General look deeper into the issue of physician self-referral to physical therapy practices that they own.

One example of potential fraud and abuse that is occurring in central Ohio is a large orthopedic group that owns their own building and leased a large space over a long period of time to a large physical therapy corporation. They opened their own physical therapy practice under the central location exception right across the street and refer their patients to their own clinic. The physician group actively recruited all of the physical therapists from the physical therapy company that leased space in their building. Some physical therapists chose not to join

the physician group but some felt compelled to join them or they would be out of a job once the referrals that they currently received were now being sent across the street to the physician owned physical therapy clinic. It is not realistic to believe that the patients will exert their own will and choose to go elsewhere. Physicians do have influence over their patients and trust that their physicians will send them to the appropriate caregiver. This particular physician group hired a business consulting group to set up their physical therapy practice and were paying them based on a percentage of profit which goes directly against the Office of the Inspector General's Special Advisory Bulletin on the Practices of Business Consultants dated June 2001. This business consulting group is working with a number of physician groups around the country. The business consulting group also set up the system so that all care provided by their 10 + physical therapists are all billed under one particular physical therapist.

Another common arrangement that is occurring in central Ohio is that physicians are opening their own physical therapy clinic and entering into a contractual joint venture agreement with a physical therapist to entice physical therapists to work with them since there is a shortage of physical therapists. One particular physician who referred patients to us for several years suddenly stopped referring when he opened his own physical therapy practice. The physical therapist that entered into a joint venture agreement with the physician was recruited away from a nursing home working with a geriatric population to work in outpatient orthopedic and pain management setting. There is certainly a quality of care issue, in my opinion, since the physical therapist just decided to switch fields after 15 years in geriatrics. I also am concerned that these common arrangements go against the Office of the Inspector General's Special Advisory Bulletin on Contractual Joint Ventures dated April, 2003.

A physical therapist told me of a patient that had called to cancel an appointment with them because the physician wanted that patient to see a different physical therapist in the clinic that the physician owned. The patient told the physician that they already had a physical therapist and the physician told the patient that he would drop her if she chose not to follow his recommendations. Overutilization of physical therapy services at physician owned physical therapy centers and the national trend of physician owned physical therapy services is well documented. The findings in the OIG report (OEI-09-02-00200) released May 1, 2006 found that 91 percent of physical therapy billed by physicians in the first 6 months of 2002 failed to meet program requirements, resulting in improper Medicare payments of $136 million. The Inspector General found that the total payments for physical therapy claims from physicians skyrocketed from $353 million in 2002 to $509 million in 2004, and that the number of physicians billing the program for more than $1 million in physical therapy more than doubled in that 2-year period. To get around this data collection, some physician groups are using the reassignment of benefits to collect copayments which also allows them to circumvent "incident-to" requirements and the need to have a physician onsite while physical therapy services are being rendered until 7:00 or 8:00 pm. Due to

the repetitive nature of physical therapy services, it is no more convenient to receive these services in the physician's office than an independent physical therapy clinic.

Since these comments have been solicited from CMS, I suspect that a number of physical therapists and some patients will come forward with this type of information. I know I can speak for myself and several colleagues that we have been hesitant to inform CMS about some of these arrangements without protected anonymity in fear of repercussions and cut off referrals from the medical community. I respectfully ask that you respect my anonymity but use this information as it is intended to protect the quality of care that patient's receive and to level the playing field by eliminating fraudulent and abusive physician self-referral situations in physical therapy.

Thank you very much for considering my comments and bringing this important issue to the attention of CMS.

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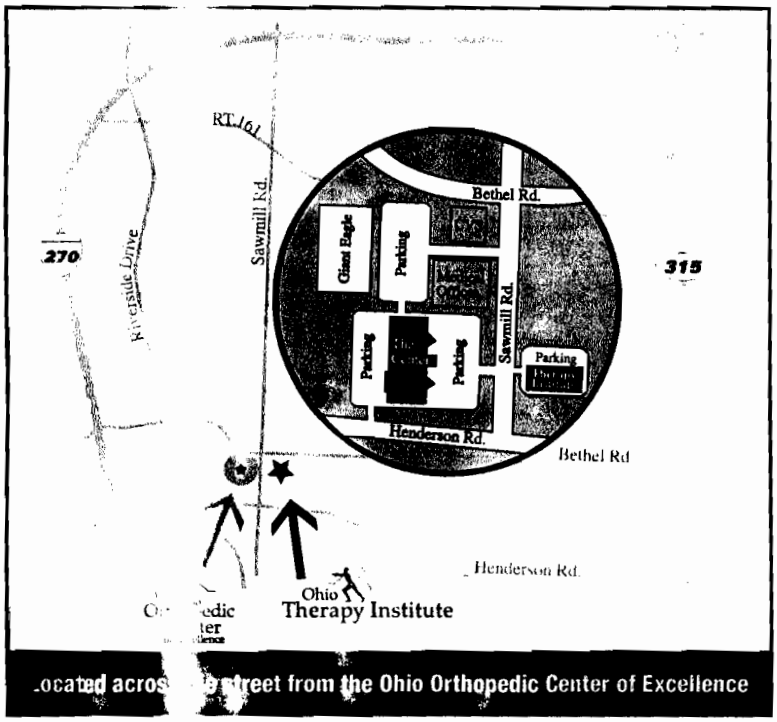
Ohio
Therapy Institute



Patient Appointment Date: _____

Time: _____

Therapist: _____

Please arrive 10 minutes prior to your scheduled appointment in order to fill out paperwork.

The Ohio Therapy Institute is owned and operated by the Ohio Orthopedic Center of Excellence in order to provide their patients the highest level of rehabilitative care.

Ohio Therapy Institute
4604 Sawmill Road
614-459-1050 (phone) • 614-459-1717 (fax)

July 29, 2007
Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, Maryland 21244-8018
Re: CMS-1385-P (Anesthesia Coding)
Dear Ms. Norwalk:

On behalf of the American Academy of Anesthesiologist Assistants (AAAA), I am writing to express the strongest support by Anesthesiologist Assistants across the country for the proposed increase in anesthesia payments under the 2008 Physician Fee Schedule. I find it imperative that CMS take immediate action to correct the gross undervaluation of anesthesia services that are currently being experienced by anesthesiologists nationwide.

Anesthesiologist Assistants (AA) provide high-quality patient care while practicing exclusively under the medical direction of anesthesiologists in the Anesthesia Care Team (ACT). In many ways, the financial viability of our profession is linked inexorably to that of the anesthesiologists with whom we work.

Currently, the anesthesia community is saddled with a disparate undervaluation for services rendered. Since the RBRVS came on line more than ten years ago, the Medicare reimbursement for anesthesia services has fallen to $16.19 per unit. If left uncorrected, this payment structure will not be able to sustain the high-quality anesthesia care being provided to the citizens of our country. With the burgeoning elderly population that we face, now is more critical than ever to ensure the continued strength of our healthcare infrastructure.

In an attempt to alleviate the burden of this situation, the RUC has recommended that CMS increase the anesthesia conversion factor by 32% (~$4.00/unit) to offset this long-standing undervaluation of anesthesia services. I am pleased that the Agency has made this initial step to rectify this discrepancy, and I fully support implementation of the updated payment structure.

Thank you for your consideration of this important matter.

Sincerely,

Melodie Dunbar AA-C

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www.AdvancedPTC.com

August 19, 2007

Kerry N. Weems, Administrator – Designate
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
ATTN: CMS-1385-P
PO Box 8018
Baltimore, MD 21244-8018

RE: Medicare Program: Proposed Revision to Payment Policies under the Physician Fee Schedule and other Part B policies for CY 2008

Dear Mr. Weems:

Many states have taken the lead in banning Physician Self-Referral issues. Isn't it time our federal government do the same? Numerous studies by the Office of the Inspector General identified major discrepancies concerning reimbursement for federally funded Medicare patients in Physician Owned Physical Therapy center (POPTS):

- Costs per visits were higher
- Total number of visits were higher
- Quality of care was lower due to non-license ancillary workers providing treatment

It is my understanding that this type of self-referral issue was banned in the initial Stark I legislation but for some reason, in-office physical therapy centers we not included. As a result, there has been tremendous growth in in-office physical therapy centers. And there is no valid justification for it.

- *Not enough providers?* Within 15 miles we have 3 hospitals, 2 out-patient rehabilitation centers, 6+ skilled nursing facilities and 12+ private PT-owned physical therapy centers. Yet in the past few years, EVERY orthopedic physicians group opened their own PT center.
- *POPTS provide better supervision?* "I'll be able to keep an eye on you" is a common statement but patients only see their physician during scheduled MD appointments because the MD is either seeing patients in private rooms, making rounds or performing surgery in the hospital or is off once a week.
- *POPTS provide better quality?* If a patient complains to his physician about a PT-owned clinic, the MD may refer elsewhere. Therefore, as in any business, patient satisfaction is paramount so scheduling appropriately to staff size and facility space is our lifeline. But with POPTS, there is a monopoly of referrals so over scheduling/overcrowding/overuse of non-licensed personnel may upset patients but the MD financial gains win out.

Here is my story:
When Stark I was passed, the clinic I had worked in for 3 years was being disbanded. To this day, I do not know how many or who were the physician's who owned the facility because it ran independently. In any event, I took another job for a PT-owned clinic. But within a few weeks (to qualify for the grandfather clause of Stark I), the physician's next door intimidated him to sell to them or they would stop referring. He was near retirement and took the deal. Under the new ownership we were told to increase our billing with unnecessary modalities. I resigned within 6 weeks of my hire. While I investigated the possibility of opening my own clinic and to cover my bills, I took a job in a local POPTS. Here I was told I would need to see 4 patients an hour. I refused citing every rule and regulation I knew. The physicians backed off and let me treat 2 patients per hour. Six months later I left to open my own facility. Interestingly I received many referrals from this group of MDs due to the quality of care and outcomes I achieved.

Since opening my practice in 1990 I have enjoyed steady growth every year. The facility occupies 12,000 square feet which includes private treatment rooms and three gyms with state-of-the-art equipment for orthopedic, neurological, pediatric, women's health, performing arts, industrial medicine, lymphedema, and aquatics therapy. In 2003 we employed 16 PT's with advanced degrees and specialized techniques.

However, the following year we experienced a **40% LOSS OF PATIENT VISITS DUE TO 2 NEW POPTS** opening in our neighborhood. The reason given: ***"Nothing against you. We're loosing too much money to managed care and can make money with in house PT."*** I was crushed! I (we) did nothing wrong. No lawsuit. No upset referral source. No irate patient. No disgruntled employee. After 14 successful years of building a positive reputation in the community, I lost almost half my practice because the MDs needed to increase their bank accounts. To make matters even worse, they even hired some of my therapists for their offices!

So I am urging you to reconsider CMS's position of referral-for-profit and ban POPTS to uphold the original intention of the Stark Law even eliminating those previously grandfathered!!!

Thank you for your consideration.

Sincerely,

Jill Tomasello

Jill M. Tomasello, PT, OCS, FABDA, Cert. MDT
Director

Brian R. Hoke, P.T., S.C.S.

Physical Therapist • Board Certified Sports Clinical Specialist

August 21, 2007

Mr. Kerry N. Weems
Administrator - Designate
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: Medicare Program
Proposed Revisions to Payment Policies under the Physician
Fee Schedule and Other Part B Payment Policies for CY 2008

Dear Mr. Weems:

I ma a physical therapist in independent private practice in Virginia Beach, Virginia and I have been a participating provider in the Medicare program since 1998. I have been a licensed physical therapist for twenty-six years and hold both an entry level baccalaureate and a post-professional doctoral degree. In addition, I hold board certification in a specialty area of physical therapy.

It has come to my attention that CMS is considering revisions to payment policies for the 2008 Physician Fee Schedule to address the expanding problem of physician self-referral and the current in-office ancillary services exception. I strongly support the removal of physical therapy from the permitted services under the in-office ancillary exception.

The existing inclusion of physical therapy services under the in-office ancillary services exception has resulted in a tremendous expansion of physician owned physical therapy services in the geographic region that I provide services for Medicare beneficiaries. This is particularly true of the orthopaedic surgery group practices, where all groups of four or more orthopaedists in my area now own and operate a physical therapy service within their office. These physicians regularly practice self-referral for their Medicare patients.

As you might imagine, the proliferation of physician self-referral has had a very negative effect on patient choice of their physical therapy provider. The physician often cites the proximity of the physical therapy service as the reason for the self-referral under the guise that the physician will have better access to the physical therapist during the patient's rehabilitation. This has occurred even when I have personally referred patients to these physicians for consultation and when the patient has clearly expressed to the surgeon that they would like to receive their physical therapy services under my care. Patients have also apologetically expressed to me later that they felt pressured to use the physician's in-office physical therapy service because they were concerned that doing otherwise would negatively affect their ongoing working relationship with the physician/owner.

Physician ownership of physical therapy services represents an avoidable conflict of interest. It my belief that elimination physical therapy from allowed in-office ancillary services for the 2008 Physician Fees Schedule will result in greater patient choice, more appropriate utilization of physical therapy services, and a significant cost savings to the Medicare program.

Respectfully submitted,

PT, SCS

Brian R. Hoke, P.T., S.C.S.

1016 First Colonial Road Virginia Beach, VA 23454
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August 8, 2007

Dear Sir or Madam,

Thank you for considering the AMA/Specialty Society RVC recommendation to increase the anesthesia conversion factor to more fair levels of reimbursement. As Anesthesiologists we are committed to providing exceptional care and safety to the medicare patients in our country yet for years this "undervalvation" has unfairly plagued our specialty relative to other physicians and it is nice to hear of positive reform. Thank you for all your efforts!

Sincerely,

Timothy M Madren MD
Anesthesiologist
ST Elizabeth Regional Health

198

excel physical therapy

jeff ostrowski pt
owner partner
pa lic no PT006927L

joseph uhl pt atc
owner partner
pa lic no PT006116L

August 20, 2007

Mr. Kerry N. Weems
Administrator - Designate
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018.

Subject: Medicare Program; Proposed Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Rule

Dear Mr. Weems:

I am a physical therapist in the Philadelphia, Pennsylvania area. I have owned and operated an outpatient physical therapy practice in this area since 1990. We currently employ 40 physical therapists. In 2006, our practice performed over 80,000 treatments to patients. I am writing to comment on the July 12 proposed 2008 physician fee schedule rule, specifically the issue surrounding physician self-referral and the "in-office ancillary services" exception. I urge CMS to remove physical therapy from the "in-office ancillary services" exception to the federal physician self-referral laws. I cannot overstate how devastating the current in-office ancillary services exception for physical therapy is to my practice, our profession, to Medicare beneficiaries and to our tax paying citizens. I have numerous examples below:

- Most orthopedic surgery groups in this area have their own physical therapy centers. I know for a fact that some of these centers offer bonus plans to physicians and support staff for referrals of patients to physical therapy. Obviously, this is abusive in that financial incentives and not medical necessity are dictating referrals.

- My therapists have reported numerous occasions where a patient wanted to come to our practice for therapy but the physician would not give them the required referral, stating that they had to attend therapy at the physician's office. This is unconscionable especially since the credentials and experience of our therapists were superior to those employed by these physicians, not to mention the idea of convenience for the patient.

- There have been other occurrences when we have had patients in therapy that then went to a follow-up visit with their orthopedic

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northwest racquet club & fitness center
grant avenue & kowalstown road
philadelphia pa 19115
215.676.6700
fax 215.676.3716

7901 bustleton ave
suite 204
philadelphia pa 19152
215.335.7400
fax 215.335.7404

the shoppes at smithbridge
331 wilmington west chester pike
suite one
glen mills pa 19342
610.558.5866
fax 610.558.6103

261 old york road
suite 305
jenkintown pa 19046
215.886.5520
fax 215.886.5523

1616 walnut street
suite 210
philadelphia pa 19103
215.545.8617
fax 215.545.9355

3370 progress drive
suite k
bensalem pa 19020
215.639.1600
fax 215.639.8216

534 e lancaster avenue
wayne pa 19087
610.964.1700
fax 610.688.2000

surgeon. The patient was progressing appropriately with their treatment program and there was no reason not to continue the current plan. However, the surgeon pulled the patient out of therapy at our clinic and required them to attend therapy at the physician-owned clinic. Obviously, this increases costs unnecessarily.

- We have had numerous occurrences that indicate the poor service and quality provided in some of these physician-owned clinics. One recent patient received hot packs and ultrasound for one year at a physician-owned clinic. The patient finally received a second opinion and was referred to one of our therapists. The patient experienced a 50% reduction in symptoms in 4 visits with our therapist.

- A few of the larger orthopedic groups in the area that own therapy services will not let my therapists even in the door to market our services to the physicians for fear that they will lose therapy revenues. This decision is made with no care to the consequences on the patient when one considers that there are many reputable therapy centers that would be more convenient for the patient to attend because they are closer to home. This is clearly abusive to say the least.

The potential for fraud and abuse exists whenever physicians are able to refer Medicare beneficiaries to entities in which they have a financial interest. Physicians who own physical therapy services have an inherent financial incentive to refer their patients to the practices they have invested in and to over-utilize those services for financial reasons. By eliminating physical therapy as a designated health service (DHS) furnished under the in-office ancillary services exception, CMS would reduce a significant amount of programmatic abuse: over-utlization of physical therapy services under the Medicare program. The "in-office ancillary services" exception has created a loophole that has resulted in the expansion of physician-owned arrangements that provide physical therapy services. Because of Medicare referral requirements, physicians have a captive referral base of physical therapy patients in their offices.

In addition, the "in-office ancillary services" exception is defined so broadly in the regulations that it facilitates the creation of abusive referral arrangements. My understanding is that the in-office exception was created to promote accessibility for patients seen by a physician in a group practice by allowing these patients to receive a needed test or procedure on the same day in the same building. This I can appreciate and support. However, in almost no case can physical therapy be categorized as needed on the same day of the physician visit. Furthermore, the physical therapy patient is not seen by the physician each time they attend therapy, so there is no inherent benefit to being in the same building. The only material benefit is to the referring physician's income. Finally, due to the repetitive nature

of physical therapy services, it is no more convenient for the patient to receive services in the physician's office than an independent physical therapy clinic. It is often more convenient for the patient to travel to a therapist's clinic closer to where they live.

In closing, I have a vested interest in protecting Medicare from the abusive practices noted above. I believe that the over-utilization from these physician-owned practices has inflated outpatient rehabilitation expenditures which will result in unfairly targeting outpatient therapy for further reimbursement limitations. Not only will this harm my practice, but more importantly it will harm Medicare beneficiaries. They will have further arbitrary limitations placed of the care they need because of the abusive practice of physician self-referral. Please close this harmful loophole.

Sincerely,

Jeff Ostrowski, PT, CEO
PA License # PT006097L

Cardiovascular Institute
of Fort Worth

August 22, 2007

Herb B. Kuhn, Deputy Administrator (Acting)
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Mail Stop: C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Proposed Revisions to Payment Policies Under the Physicians Fee Schedule, and Other Part B Payment Policies for CY 2008

Dear Mr. Kuhn:

On behalf of the Cardiovascular Institute of Fort Worth and our seventeen individual practicing physicians, we appreciate the opportunity to submit comments to the Centers for Medicare & Medicaid Services ("CMS") regarding the ***"Resource-Based PE RVU's"*** section of the above referenced July 2, 2007 Proposed Rule. We are specifically concerned with the 2008-2010 PE RVU's established for non-facility outpatient cardiac catheterization procedure codes and the significant negative impact that could result for our practice and our patients if these values are finalized for the 2008 Physicians Fee Schedule.

The Cardiovascular Institute of Fort Worth is an Independent Diagnostic Testing Facility that has been in existence since 1991. We currently have seventeen physicians on staff and perform over 1000 cardiovascular diagnostic procedures per year.

The Cardiovascular Institute of Fort Worth is a member of the Cardiovascular Outpatient Center Alliance (COCA) and as such we have actively been involved in the work that COCA has accomplished this year to collect and submit direct and indirect cost data to the AMA's Practice Expense Review Committee (PERC) of the Relative Value Scale Update Committee (RUC). Unfortunately, this process did not allow all of COCA's data to be considered and resulted in PE RVU recommendations to CMS that severely undervalued the direct and indirect costs associated with providing these procedures to our patients.

It is apparent from the July 2, 2007 Proposed Rule that CMS has accepted the RUC recommendations without considering the detailed direct cost information that COCA provided to CMS in May 2007. The PE RVU values set out in the July 2 Proposed Rule would result in a draconian cut in reimbursement for cardiac catheterizations performed in

Cardiovascular Institute
of Fort Worth

practice or IDTF locations. For example, if the 2007 conversion factor is applied to the technical component of the primary three CPT codes for a Left Heart Cath (93510TC, 93555TC, and 93556TC) the reimbursement in 2008 would be cut by **32%** and when fully implemented the total reimbursement would be reduced by **49%**. These reductions would undoubtedly result in the closing of the majority of non-facility outpatient cardiac catheterization labs in the country forcing all patients who now benefit from improved access and lower costs into more acute hospital settings.

We request that CMS review the additional cost data provided by COCA and establish PE RVU's for outpatient cardiac catheterization procedures that more reasonably reflect the direct and indirect costs of providing these procedures. If the proposed RVU's are allowed to stand, the outcome will inevitably that will cost the Medicare program more in direct APC payments **and** Medicare patients more in higher deductibles and co-insurance.

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

Sincerely,

Sydney A. Madden, RN, CVRN
Director
Cardiovascular Institute of Fort Worth

Mark Whitley, Vice President
HCA – North Texas Division

Nasim Akhtar, M.D.

George Khammar, M.D.

Marilyn King-Rankine, M.D.

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Cardiovascular Institute
of Fort Worth

Phil Lobstein, M.D.

Amir Malik, M.D.

Joseph Marcella, M.D.

Lorren Mott, M.D.

Giri Mundluru, M.D.

C.P.K. Nair, M.D.

G.R. Reddy, M.D.

Syed Shah, M.D.

Sergio Sanchez Zambrano, M.D.

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200

UROLOGY ASSOCIATES, P.C.
John D. Andenoro, M.D.
Amy McKerrow, M.D.

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August 25, 2007

The Center for Medicare and Medicaid Services
Department of Health and Human Services
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Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

SUBJECT: July 2, 2007 Medicare fee schedule proposed regulations.

Dear CMMS:

As a urologist practicing in a rural area of northwest Montana, I am writing to express my concerns that the proposed Medicare physician fee schedule (MPFS) rules could significantly adversely affect our community, by increasing the cost of care and likely limiting the availability of certain significant services.

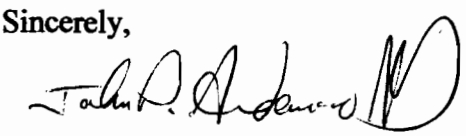
Nearly 15 years ago, the urologists of the state of Montana recognized the need to provide up-to-date, technologically advanced surgical services that represented capital costs too great to be borne by our several and various institutions throughout the state. Thus, a group was formed to provide lithotripsy and laser surgical services (for both urolithiasis and benign prostatic hyperplasia) treatments. That equipment is leased back to the institutions on a case-by-case basis, as it travels around the state. Thus, it makes these services available throughout our state while freeing our institutions' capital budgets and only having them spend money for resources to perform these operations as they are needed. The group maintains maintenance and refurbishment contracts to keep this equipment in excellent working order on a continuous basis. The group also employees highly trained technologists, who transport, operate, and service the equipment. The high case volumes in which these technologists are able to participate offers an opportunity to keep our service at a consistent level of excellence, rather than diluting the training and familiarity with the equipment that would be required amongst our dozen or so member institutions.

As such, the MPFS should specify that lithotripsy is **not a designated health service (DHS)** under Medicare. This would be in keeping with the *American Lithotripsy Society versus Thompson* case. This is also in keeping with congressional legislation that has, heretofore, intended that "under arrangement contracting" would only require a compensation exception and not an ownership exception.

The idea that **per procedure fee prohibition** would be instituted is also not in the best interest of our institutions. This would either require the institutions to acquire these sorts of devices (lithotriptors and high-powered, costly lasers) or would require our patients to travel great distances. Our own local hospital (Kalispell Regional Medical Center) informed our medical staff last year that it expected a $5,000,000 budget deficit. The hospital's CEO went on to inform us there would be **no capital budget** for the coming year. As the nearest institution that would be able to offer such services is 120 miles away, in Missoula, I anticipate this would require 50-75 patients per year, to travel to Missoula both for preoperative appointments, surgeries involving the technologies in question, and follow-up visits with the surgeons who treated them, as well as potential additional treatments. That would mean more than 50,000 patient miles traveled to obtain such services in Missoula, if CMS rule changes mean these technologies will no longer be available to our area, because of their prohibitive cost. Perhaps hospitals could negotiate for such services by instituting a "bulk" annual contract; however, this will shift the financial risk for providing these services to the hospitals and away from any groups or partnerships that have heretofore leased such equipment to these institutions, unless hospitals can continue only to pay for this equipment as it is needed, on a per-procedure basis.

By extension, as a surgeon and specialist in a field which has seen rapid technological innovation over the last several decades, I can only expect this to continue. If our institutions are able to raise the capital to acquire these high-cost technologies, which they have thus far been able to lease, they will be loathe to replace them when newer, updated, better equipment becomes available and will most likely try to "get by" until equipment on hand is broken or no longer serviceable. The ability for hospitals to lease this type of equipment allows them to demand, from the leasing agent, that they have the most up-to-date, reliable, safe, and effective systems available and that these systems be operated by well-trained, knowledgeable technologists. Rule changes that foist a higher financial burden on our hospitals will only further strain their finances and likely will lead to higher costs to patients. That might have little meaning to the federal government who, as a payer, unilaterally determines at what rate they will pay for services. It is very likely the increased capital costs will be passed on, in some way, to our patients either directly or through our local insurers and payers. Because of this and for the concerns mentioned above, I hope such groups and partnerships will continue to be able to work with our hospitals, to provide the most up-to-date, safe, and effective treatment for our patients, as we have been doing for more than 15 years.

Sincerely,



John Andenoro, M.D.

JDA/cdf

cc: Senator Jon Tester
Senator Max Baucus
Representative Dennis Rehberg