Charlie H. Bridges, MD, FACS, PC
Our Lady of the Lake Medical Plaza
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Phone: (225) 767-0394 Fax: (225) 767-3904

August 22, 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:

I am a solo provider of urological health care in Baton Rouge, LA. Through joint ventures our local urologists have been able to provide the most up-to-date health care by purchasing needed new technology. These new technologies have offered health care delivery on an outpatient basis and have significantly shortened hospital stays ultimately improving health care. To terminate these joint ventures will only hurt our patients.

Sincerely,

Charlie H. Bridges, MD

202

CardioVascular
center
at Wesley

August 15, 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 Center at Wesley and our 17 individual 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.

The CardioVascular Center at Wesley is a new IDTF Cath Lab located in Wichita, Kansas. We operate two catheterization suites and employ a staff of 11 Registered Nurses and Registered Radiologic Technologists. Although this is a new facility, serving only 240 patients to date, these 11 professionals have over 170 years of experience caring for cardiovascular patients in hospital settings. It is because of that vast experience in this specialized type of health care that I feel I can speak to the benefits of these types of non-hospital outpatient catheterization labs. Hospital cath lab schedules are crowded with both inpatients and outpatients that often have to wait several days or even a week to get their procedure performed. It is not uncommon for patients to get delayed so late in the day that inpatients have to stay an additional night or outpatients are sent home and rescheduled to come back another day. Having the ability to schedule these outpatient procedures in a facility that is exempt from the emergency patients and the acute patients that clog the schedule with multi-vessel angioplasties and emergency procedures allows better access for these patients to a more efficient diagnosis of their condition. This not only saves precious hospital beds for those who really need it, but allows for those patients who are waiting to be diagnosed to get that diagnoses sooner and at a lower cost. Additionally, I would be remiss if I did not also mention that patient satisfaction is improved ten fold over a hospital setting. Patients and their families who have had one of these procedures in a hospital state over and over how much they prefer coming to our facility. The staff are more focused on care, the setting is less stressful and the patient goes home much sooner with fewer complications.

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CardioVascular
center
at Wesley

The CardioVascular Center 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 be that it 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,

Dick Lewis
Director
The CardioVascular Center at Wesley

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AFFILIATED THERAPY GROUP PRACTICE, INC.

August 23, 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 Revision to Payment Policies under the Physicians Fee Schedule and Other Part B Payment Policies for CY 2008; Proposed Rule

Dear Mr. Weems,

I have been a practicing physical therapist in the State of Texas for almost 30 years. In those 30 years of practice, 24 have been in private practice. Over the years I have become increasingly alarmed at the number of patients I have seen whose previous experience with therapy was provided in a physician-owned clinic. In many cases the patient has never had appropriate measurements taken before and after treatment. They rarely had specific treatment goals, and in most cases only changed clinics because they were not getting better and decided to seek alternate physician support. That is when they are often referred to our clinic.

By now, most if not all, have exhausted their Medicare therapy benefit and if not for the current exemption process, they would have to be referred on to a hospital based therapy department. Because of this loop-hole in the Stark Law in the form of "in-office ancillary services" many patients will never have the opportunity to receive therapy services from an experienced professional whose major focus is on their care and not the possible bonus their care may bring. Just yesterday, I received the resignation from my new graduate PTA with only two months experience who was offered $5.00 per hour more at a physician owned clinic. The only way a physician can afford this type of salary inducement is to be billing as many visits as possible from each of their self referred patients. The only way to stop this type of abuse is to stop the profit which allows it to occur in the first place.

Lastly, we recently saw a patient that had been receiving therapy at a physician owned clinic which was contra-indicated for her diagnosis. This elderly patient with a diagnosis of stenosis was going three times a week for three weeks of extension exercises and could not understand why she continued to hurt. Again, she is an example of someone who has used their entire therapy benefit receiving inappropriate care. After only three visits in our clinic with the appropriate plan of care she is well on her way to recovery. The government was billed for six unnecessary treatments that were actually making her worse.

In closing, I would like to thank you for your consideration in this most pressing issue. The time is now to stop the positive reinforcement by paying these physicians for their negative behavior. Referring to their own clinic clouds their professional judgment and unduly burdens our government by paying for inappropriate care and preventing professional therapy treatment that can help given in the right environment.

Sincerely,

Karen L Ross, PT, DPT
Affiliated Therapy Group Practice, Inc
4738 S. Padre Island Drive
Corpus Christi, Texas 78411
klrpt@msn.com

2041

Rural/Metro Ambulance
50 Years of Serving Others

August 23, 2007

Leslie Norwalk, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-1541-P
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:

Rural/Metro 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).

Rural/Metro is the nations second largest ambulance service provider and an active member of the American Ambulance Association. We commend 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 often our patients is not in a condition to sign a claims authorization during the time we are treating and transporting them. Many patients 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, Rural/Metro agrees with the AAA and 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

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CMS to abandon this approach, and to instead eliminate the beneficiary signature requirement for ambulance services altogether.

Under the current requirement, when the patient is physically or mentally incapable of signing, ambulance service staff have 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 service staff to document that the patient was unable to sign, the reason and that no one could sign for the patient.

The Proposed Rule would create a new exception to the beneficiary signature requirements for emergency ambulance transport services. Under this exception, an ambulance service would be permitted to submit a claim to Medicare for payment without the patient's signature provided each of the following conditions was met:

1. The patient 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 patient'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 service employee caring for the patient during the transport, stating that the patient 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. 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, Rural/Metro 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 new requirement (in bold above) 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. Rural/Metro **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 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 service would in every situation now have the additional burden in trying to communicate to the patient 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, Emergency Department Admitting Record, etc.

Rural/Metro also strongly objects to the requirement that ambulance service staff 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 service 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 services and on the receiving hospitals. Consider what this rule requires—the ambulance has just taken an emergency patient to the ED, often overcrowded with patients, and would have to ask the receiving hospital staff 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.

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.

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 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 patient should be the overriding focus of all parties, not another form signed by already overburdened ED personnel.

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.

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.

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 patients signature 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.

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. ambulance services with less than 10 claims per month), ambulance services must submit claims electronically. Thus, the patient 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.

Therefore, Rural/Metro requests 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.

In light of the above, Rural/Metro urges 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.

Sincerely,

Tina Hull
Division General Manager

Office of the Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8018
Baltimore, MD 21244-8018

August 23, 2007

Dear Administrator:

As a member or the American Association of Nurse Anesthetists (AANA), I am writing to support the CMS proposal to boost the value of anesthesia work. Under CMS proposed rule Medicare would increase the conversion factor compared with current levels. (72 FR 38122. 7/12/2007) If adopted, the CMS' proposal would help to ensure that Certified Registered Nurse Anesthetists as Medicare Part B providers can continue to provide Medicare beneficiaries with access to anesthesia services.

As a sole provider of anesthesia services in a small farming community of 6,000 people (Hillsboro Il) we have seen an increase in our Medicare roles. I have many roles as I am on call 24/7 and am responsible for all the anesthesia needs in the Operating Room and the Emergency Dept. as well as administrate the Department through Billing, Quality Assurance, Performance Improvement, accreditation through JCAHO and policy and procedure writing and review. We have additionally seen reimbursements decrease.

The increase in Medicare payment is important for many reasons. Medicare currently under-reimburses for anesthesia services, putting at risk the availability of anesthesia and other healthcare services for Medicare beneficiaries. Our small hospital has gone to Critical Access as have others in the farming belt. We are still providing 24/7 anesthesia coverage but many of our neighbors have cut their availability. Financially this has helped them but at the expense of our beneficiaries health access availability. Studies by the Medicare Payment Advisory Commission 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 the 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 1/2007. However, the value of anesthesia work was not adjusted by this process until this proposed rule.

Lastly, 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.

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).

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 the anesthesia work in a manner that boosts Medicare anesthesia payment.

Sincerely,

Bart A. Wetzel CRNA
Vigilant Anesthesia Inc.
121 Lakewood Drive
Hillsboro Illinois 62049

CARSON CITY FIRE DEPARTMENT

"Service with Pride. Commitment. Compassion"

August 23, 2007

Leslie Norwalk, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-1385-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.

Dear Ms. Norwalk:

The Carson City Fire Department provides emergency ambulance services to our community in Carson City, Nevada. The proposed rule regarding the acquisition of patients' signatures on emergency transports would have a severely negative direct impact on our operation and the high quality health care we provide to Medicare beneficiaries. In addition, we believe this proposed rule will inappropriately provide incentives to seek signatures from patients who are in need of medical care and under mental duress. Additionally, this proposed rule would have a negative impact on wait times in the emergency room, impacting our operations and the operations of emergency rooms throughout the country. We therefore urgently submit comments on the ills of the proposed rule.

In summary, here are the points we would like you to consider:

- Beneficiaries under duress should not be required to sign anything;
- Exceptions where a beneficiary is unable to sign already exist and should not be made more stringent for EMS;
- Authorization process is no longer relevant (no more paper claims, assignment now mandatory, HIPAA authorizes disclosures);
- Signature authorization requirement should be waived for emergency encounters.

We understand that the proposed rule was inspired by the intention to relieve the administrative burden for EMS providers. However, the "relief" being proposed by CMS

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would have the unintended effect of increasing the administrative and compliance burden on ambulance services and hospitals, and would result in shifting the payment burden to the patients if they fail to comply with the signature requirements at the time of the incident. Accordingly, we urge CMS to abandon this approach and, instead, eliminate entirely the beneficiary signature requirement for emergency 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 allow for a representative of the ambulance provider or hospital to sign on behalf of the beneficiary when the patient is unable to sign, documenting that the beneficiary was unable to sign, the reason, and that no one could sign for the beneficiary.

The proposed rule directly conflicts with the existing rule. It requires that the provider representative sign **contemporaneously** with the transport and **seek an additional signature** from the hospital in the event a patient is unable to sign.

BENEFICIARY UNDER DURESS SHOULD NOT BE REQUIRED TO SIGN ANYTHING

Emergency ambulance providers have no admission departments and no registration desks. The same individuals responsible for providing medical care and transportation to the hospital are also responsible for fulfilling the administrative functions. All EMS encounters are emergent in nature, and medically necessary ambulance transports in particular are stressful events on patients.

CMS has recognized this and modified its rules for obtaining Advance Beneficiary Notice and Acknowledgement of HIPAA Privacy Notices, creating exceptions that do not require ambulance crews to interrupt their care to seek a signature from a patient under their care.

In fact, CMS has deemed that all emergency encounters put the patient under great duress. Under such duress, patients would sign anything in order to get the care they require. Therefore, any signature obtained in an emergency situation cannot be relied upon.

Yet the proposed rule is so burdensome on ambulance crews that they will have every incentive to obtain a patient's signature even though the patient is under mental duress. The very reason a person needs ambulance transportation often contraindicates the appropriateness of attempting to obtain a signature from the beneficiary.

EXCEPTIONS WHERE BENEFICIARY IS UNABLE TO SIGN ALREADY EXIST AND SHOULD NOT BE MADE MORE STRINGENT FOR EMS

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. The proposed exception essentially mirrors the existing requirements that the beneficiary is unable to sign and that no authorized person was available or willing to sign on his or her 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 subdivision (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 requirement that an ambulance provider obtain documentation of the date, time, and destination of the transport. Nor do we object to the requirement that this item be maintained for four 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., the 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 <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 of trying to communicate to the beneficiary or his or her 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, in addition to the trip transport that will already include the date, time, and name of receiving facility.

AUTHORIZATION PROCESS IS NO LONGER RELEVANT (NO MORE PAPER CLAIMS, ASSIGNMENT NOW MANDATORY, HIPAA AUTHORIZES DISCLOSURES)

Purpose of Beneficiary Signature

a. Assignment of Benefits – 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.

Signatures Not Required for ABNs for Emergency Transports

The Third Clarification of Medicare Policy regarding the Implementation of the Ambulance Fee Schedule states that Advanced Beneficiary Notifications only be issued for non-emergency transports. The ABNs which require beneficiary signature "may not be used when a beneficiary is under great duress," which would include emergency transports. Would not the requesting of a Medicare Beneficiary's signature for any other reason during an emergency transport be less duress?

Signature Already on File

Almost every covered ambulance transport is either to or from a facility; i.e., a hospital or 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 skilled nursing facilities, can mean more than only entities owned by or which are part of the facility. The term already includes physicians providing services at 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 ten 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, along with the date. Thus, the issue of the beneficiary signature should not be a program integrity issue.

SIGNATURE AUTHORIZATIONS REQUIREMENT SHOULD BE WAIVED FOR EMERGENCY ENCOUNTERS

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 dually 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.

Thank you for your consideration of these comments.

Sincerely,

R. Stacey Giomi, Fire Chief
Carson City Fire Department

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August 23, 2007

CENTERS FOR MEDICARE AND MEDICAID SERVICES
DEPARTMENT OF HEALTH AND HUMAN SERVICES
ATTN: CMS-1385-P
P.O. BOX 8018
BALTIMORE,MD 21244-8018

I am certain you are receiving hundreds of letters pertaining to the 2008 Physician Fee Schedule, and I can only guess that you will be getting a superabundance form letters pretty soon having to do with urologists who have part ownership in surgical service companies who stand to lose their shirts if what is proposed to happen does happen. So I will not give you another form letter but one that says quite simply that what CMS plans to do is to without a doubt completely wreck what's barely left alive of the private health care system in the U.S. If there is any hope for CMS to reconsider its purpose to not lay the burden of future cuts on the backs of the physicians in private practice, I sincerely hope that this letter is of some help in stemming the tide of the collectivization of medicine.

Let me be very clear that if the proposed changes for the Physician Fee Schedule for 2008 go forward unamended as they stand, this act of turpitude will spell doom for many of the services that patients now receive from any doctor in this soon-to-be globalized country. By now you must have read the litany of complaints discovering to you the constant drone of the chainsaw as it hacks and hews at the paltry amounts doctors are reimbursed for their efforts at maintaining a modicum of good health of the average American patient. But as a urologist I must bring to your attention the additional facts germane to my own specialty, viz., that these proposed cuts can only undermine the urologist's capability to provide the most current state-of-the-art in high-tech surgical treatment in the disease categories of kidney stone and benign prostate disorders.

To cut to the chase, CMS wholly intends to make it impossible for urologists to have any vested ownership in limited liability companies which currently provide necessary and useful surgical services for the treatment of these disease entities. For stone disease in the kidney, a machine called a **SHOCK WAVE LITHOTRIPTER** is brought by a privately owned company to either a hospital or ambulatory surgery center so that a patient with a kidney stone can be treated under anesthesia as an outpatient. This is usually reimbursed according to a subleasing agreement between the hospital and the lithotripter company. Medicare pays the hospital and the hospital gives an agreed upon portion, (usually a small fraction of what the hospital gets), back to the company which could be owned by a group of doctors who expect to make some modest profit for their investment. It's all quite simple and, according to the **STARK LAW II**, all very legal--if we can somehow forestall the ominous things looming for next year.

Urologists have also been using a **LASER** device to help men with large prostates. This procedure, too, is done in the outpatient setting under anesthesia. Just like the lithotripter, the laser company brings the device to the hospital or ambulatory surgery center for the particular cases it was ordered for. And once again, according to the agreed upon sublease terms, the hospital renders a portion of its Part A receipts to the company which may indeed have several doctors as vested partners. For this arrangement, the patient gets the proper state-of the-art treatment, the hospital gets its reimbursement and the company gets paid. This three way partnership is done in so many other business transactions it is hard to imagine why CMS thinks this is somehow being abused. Everybody is a winner here, so why is this now viewed with suspicion all of a sudden?

Look at it this way. We doctors, (and I will confess right now that I am not invested in any company nor do I have any controlling interest in any surgery center), can't keep our office doors open if our fees keep getting cut. I know all about the SGR, (Sustainable Growth Rate), which is simply an unworkable mathematical formula based on unrealizable expectations of the GDP. So why do we doctors have to bear the brunt of all the payment cuts that CMS makes? The cost of living keeps going up which means we have to keep giving our employees wage increases. Our operating expenses which include office rental, malpractice insurance, health insurance benefits for office staff not to mention the costs that are borne in our personal lives are not being matched by our ever dwindling revenue, much of which in the specialty of urology comes from Medicare because so many of our patients are over 65 years old.

If you do not care about my argument that doctors are not getting any richer off of medical or surgical services, then look at what is going to happen to the average Medicare recipient. If doctor-invested companies providing lithotripter and laser services are forced to divest their rosters of all partners who are physicians, then the companies will become insolvent. Then there will be no more lithotripters and no more laser prostate surgeries. Well, you say, that's not true, because the hospitals own these devices. And there's the rub! Because the hospitals do not own these things in the main because they have been intimidated by the riskiness of the investment which is, of course, predicated on a constantly evolving scenario of technological updating in which expensive inventions are obsoleted even before the patent is dry. So the private companies are the only act in town in a huge portion of the country.

What we are asking for is fairness—fairness for ourselves and a reasonable chance to make an honest wage and , yes, fairness for our patients who really deserve to get the best care we can possibly give them—without going into hock!

So, we implore you to show us some mercy. Do not crush our chances to keep our little companies going. Quite frankly we are doing a lot of good for people; and we, too, need to show a small margin of profit for the risks that are taken to make a going concern of the business venture.

Doctors have been patient so far, but the premise that we are abusing the good will of CMS does not wash. Further cuts in reimbursement can only result in the catastrophic discontinuation of high quality medical care that has noteworthily characterized the doctor-patient relationship in our country. Ideologically speaking, what CMS seems to want to do is to make it impossible for

private health care to continue so that a nationalistic socialized collective system as in Canada and Europe will be explanted to our shores. It might make some of the CMS punditocracy heady with anticipation at the hated system of private practice we have now, but if those same idealogues became ill themselves, would they want their bodies treated by the medical denizens of Canadian or European countries? I kind of doubt it. As a proof, I don't see many Americans rushing off to other countries for anything a doctor does as a matter of everyday practice in this country—and done well to be sure. Even Fidel Castro had to go shopping in Spain for his care. And Cuba is supposed to be an exemplar to the world of nationalized health care. **NOT!**

So please take care of what you do because I fear that the common good of our countrymen will be shortchanged on the altar "good intentions", while the hoped-for fruit of enhancing the promise of a rosier tomorrow will fall victim to incestuously inbred bad thinking.

Sincerely yours,

W. Patrick Flanagan Jr MD

W. PATRICK FLANAGAN, JR., M.D.
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NEBRASKA ASSOCIATION OF PATHOLOGISTS, INC.

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August 23, 2007

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

RE: Physician Self-Referral Provisions

Dear Sir;

I am writing this letter 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. My pathology practice is located in Omaha, Nebraska, where I am a member of a 20 pathologist practice group that is based in one of Nebraska's largest hospitals. I also serve as the President of the Nebraska Association of Pathologists, which represents the great majority of the practicing pathologists in the state.

Recent CMS initiatives to end self-referral abuses in the billing and payment for pathology services are important steps to end abusive billing practices. 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.

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. These abusive practices add a significant financial incentive towards the performance of additional testing by clinicians as more testing adds to the profit line. In the end, the patient is at risk for additional testing, which may not be clinically indicated, as well as the burden of additional medical costs.

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.

Some 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; restrictions on physician self-referrals are an important program safeguard to ensure that clinical decisions are determined on the basis of patient care and not financial incentive. 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.

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

Respectfully submitted,

W. West

William W. West, M.D.
President, Nebraska Association of Pathologists

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ADULT PEDIATRIC UROLOGY

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JOHN D. HORGAN, M.D., F.A.C.S.
BRUCE E. LUNDAK, M.D.
ANDREW F. TRAINER, M.D.
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LARIS E. GALEJS, M.D.
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MELISSA A. FELDHAUS, A.P.R.N.

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

Dear Mr. Kuhn:

I am a urologist who practices at Adult and Pediatric Urology in the Nebraska and Iowa area. We do have a very large Medicare population in our area. I'm concerned about the recent proposed changes to the physician fee schedule rules that were published on July 12, 2007. These rules concern the Stark self-referral rule and the reassignment and purchased diagnostic test rules.

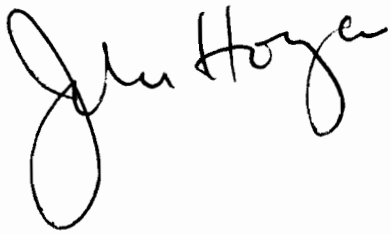
The charges proposed in these rules will have serious impact on the way medical care is delivered to our patients concerning the in-office ancillary services exception; the definition should not be limited in any way. It is important for urologists to have the ability to provide pathology services for our patients. This allows quality care to be provided in an efficient and cost effective manner.

The proposed changes to the reassignment and purchased diagnostic test rules will make it difficult, if not impossible for me to provide prompt imaging, diagnostic testing, therapies, and surgeries. As a result care will be delayed and costs will rise. By offering these services, we give our patients quality and timely service with the highest quality standards. We also provide these services at significantly reduced costs as compared with our local hospitals.

The prohibition of per click payments for space and equipment rentals will prohibit our ability to offer superior imagining and minimally invasive lithotripsy care to our patients. Through a joint venture with one of our progressive local hospitals we were able to obtain the most innovative technology for our patients. Instead static images, we now provide real time imaging. This eliminates the need for catheterizations and cystoscopies in the bulk of our patients. Had we been prevented from proceeding with this venture, the more established hospitals in our area would only offer antiquated equipment that they had already owned. While obviously more profitable for them, it was clearly less beneficial for our patients. This is a clear example where these ventures benefit patient care.

The Stark regulations and the reassignment and purchased diagnostic test rules go far beyond what is necessary to protect the Medicare program from fraud and abuse. The rules should be revised to only prohibit those specific arrangements that are not beneficial to patient care.

Thank you for your consideration,



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Fire Department

"Serving the community since 1926"

John M. Scherrei
Fire Chief
County Fire Warden

4410 Cathedral Oaks Road
Santa Barbara, CA 93110-1042
(805) 681-5500 FAX (805) 681-5563

August 21, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1385-P
P.O. Box 8010, Baltimore, MD 21244-8018

RE: "BENEFICIARY SIGNATURE, Proposed change Section 424.36

The Santa Barbara County Fire Department operates an emergency ambulance service within it's jurisdiction. The Department compliments CMS for attempting to improve the authorization process by which providers are allowed to bill for emergency services. We believe the present proposal adds additional complications to an already burdensome process. Therefore the Department recommends against adoption of the proposed change for the following reasons.

1) The proposed change is presented as a sympathetic effort to provide ambulance providers with an additional option for obtaining authorization in the absence of a beneficiarity signature. However, the proposed change does not remove previous requirements but only adds the additional requirement of obtaining a signature from a receiving facility. This adds an additional requirement to an already burdensome process performed during delivery of emergency medical care to an injured or ill patient.

2) The proposed change implies that the emergency treatment process stops when the patient is delivered to the treatment facility. The real circumstances of emergency medical care is that when a patient is delivered to a treatment facility, the personnel of that facility take over the patient's emergency care. The projected 5 minute time period for obtaining a signature is not realistic since the treatment facility personnel are usually committed to providing continuing care to the patient. Assisting with ambulance provider authorization becomes a low priority.

3) Upon delivery of the patient to the treatment facility, the priority of the ambulance provider is to return the ambulance to its service area, which is often quite distant. A requirement to stay at a treatment facility, waiting for a signature, will slow down a return to it's service area.

4) The proposed change requires the ambulance provider to obtain a signature from the treatment facility contemporaneous to delivery of the patient. The proposed change does not require the treatment facility to provide such a signature. As indicated above, provision of such a signature will not be a priority of the treatment facility and will likely have the unintended consequence of degrading the timely recovery of the ambulance response capability.

In closing, the Santa Barbara County Fire Department recommends not adopting the recommended change to Section 424.36. If you have questions concerning the Department's position and understanding of this issue, please contact Bill Turpin of the Department's ambulance billing section at the above address or by telephone at 805-681-5520 or by email at bill.turpin@sbcfire.com.

Sincerely, Bill Turpin Bill Turpin, Departmental Assistant

Rinaldi
PHYSICAL THERAPY

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
Baltimore, MD 21244-8018

RE: **Physicians Self-Referral Issue**

Dear Ms. Weems,

I would like to comment on the July 12 proposed 2008 physicians fee schedule rule, specifically the issue surrounding physician self-referral and the "in-office ancillary services" exception.

Working in a private physical therapy practice I have seen many negative changes in the way patients receive physical therapy. Our referrals from physicians have decreased greatly due to physician owned physical therapy. I have seen many situations where patients have come to our practice because they were previous patients and had successful results, tell us that they were told they had to see the therapist in the doctor's office. Most patients aren't brave enough to speak up to their trusted family physicians. I have also heard patients say they were sending their spouse to our facility, but when they went to their doctor, they had to see their physical therapist, and no other option was available to them.

I feel patients are being pressured to see the physician's physical therapists. I feel that patients are lead to believe that they are not able or do not have a choice when it comes to physical therapy. I do not feel as if physician owned physical therapy practices are ethical. I like to think that we are a highly ethical practice and genuinely have the patients well being at heart. I can not say the same thing about the rapidly growing physician owned physical therapy practices in this area.

Thank you for your time and consideration of my comments. Thank you also for your attention on this matter. I hope Medicare will see what a negative impact this is making and take action to correct it.

Sincerely,

Jen Zura
Rinaldi Physical Therapy

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Universal Physical Therapy, P.C.
WHERE YOUR HEALTH IS OUR UNIVERSE

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August 22/07

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

Dear Mr. Weems:

As a physical therapist in private practice and a citizen concerned about how our health care dollars are spent I wanted to alert you to what I would consider a major problem.

Physician Self-Referral Issues.

In your open discussion on the federal physician self-referral laws (also known as the Stark laws). This is seems to be taking steps in a positive direction to clear out and overlooked to the fraud and abused has been provided by some health practitioner. One such area that the legislators may want to look at is physician owned physical therapy/rehabilitation services. Without thinking much deeper, anyone would realize that if a system of self referral for profit is in place, it is going to be abused. Physical therapy facilities that are owned by doctors have been quantitatively shown to severely over utilize physical therapy. There is a report published by the OIG clearly documenting the over utilization of rehab services when they are provided in a doctor's office or a facility that is owned by them. The amount of money that can be saved by prohibiting the provision of physical therapy and other related rehab services in a doctor's office would be incredible.
Using the justification by physician which is "We want be sure the physical therapy services is appropriate and necessary " is no longer appropriate and necessary in this field. With high physical therapist education and current direct access for PT on more than 44 State makes the physical therapist is only qualified but also recognize as a most profession involve with neuromuscular and movement impairment . Having a physical therapy practice in a physician office or patient walk to medical/rehab facilities where there is a medical doctor/director, chiropractor and a physical therapist. The combination of the three creates a perfect environment for abuse. These patients are seeking help for their medical

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problem and they put their trust in this medical provider however the abusive of referral arrangement and unnecessary services that build up huge bills for diagnostic tests and treatment, especially physical therapy, which is severely over utilized.

My practice has location in the Bronx, NY. As a physical therapist who provide the highest quality rehabilitation care in our community. Providing therapy is not just a job to me: it is my profession, my career, and my passion. I have my name on the door and my reputation on the line when I provide my patients with therapy services. I deliver the best rehab care that can be offered. As a physical therapist in private practice I receive most of my referrals by word of mouth, but mostly from physicians that have come to know the work that I do and trust that I will take good care of their patients. We take pride in our profession and the care that we provide. We would never compromise the provision of our services and frankly we are excited when our patients achieve their goals and we are able to discharge them from our care with full function restored.
Slowly but surely, more and more physicians are realizing the earning potential to bill for physical therapy. Many of them are taking an unused area of their office, putting in some equipment and in some cases hiring unlicensed personnel to provide "physical therapy". Little change in overhead but big changes in positive cash flow.

Yes, we want to make a living. Nothing fancy, just enough to comfortably live in the metropolitan area and take care of our families. This is becoming increasingly difficult and I am looking to you to please help. By eliminating physical therapy as a designated health service (DHS) furnished under the in-office ancillary services exception, CMS would reduce a lot of abuse and unnecessary expenses.

I would appreciate the opportunity to let me share my concern about this law and it's affects on quality of patient care.

Sincerely,

Mamdouh Eldeeb, PT

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John W. McClean, M.D.	Thomas H. Patterson, M.D.	Matthew G. Baker, PA-C	Alfred W. Mazur, M.D.	Gina Riner, A.P.N.
Hematology/Oncology	*Urology*	*Urology*	*Urology*	*Internal Medicine*

August 22, 2007

Re: Physician Self Referral Provisions

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

Ladies and Gentlemen:

Let me introduce myself. I am a practicing Urologist and have been Board Certified for 28 years and have seen many changes occur in the scope of our practice. In fact probably 80% of the minimally invasive and invasive procedures that we accomplish are very different from those that were taught in our Residency Programs. Each of these have provided better outcomes for our patients, better comfort, shorter hospital stays and for the most part have been time saving. I'm worried that the attack on these services including Lithotripsy, Laser services and Cryotherapy services unduly have focused on urology. In the many years that we have been participating in joint ventures they have brought services to our communities where they otherwise would not be available. Hospitals those particularly in my area which is rural which are either not for profit or more recently for profit hospitals are very reluctant to buy new equipment for us. Understandably if I'm going to be doing three to five procedures per month the powers that be that buy equipment, amortize justifiably are worried about buying new technology that may become obsolete. However with the joint ventures we are able to control the quality of equipment that we utilize and as a Medical Director it is incumbent upon us to be certain that people utilize these services safely and that the outcomes are in keeping with high standards. In my experience we have never had to discipline a physician for over utilization and we monitor this very carefully. The arrangements that one that you are reviewing are beneficial to the Medicare patient population and certainly serve us in rural areas importantly. Previously CMS has never attacked the imaging that we utilize for therapeutic measures. These are hospital outpatient, for the most part, procedures and are not done in Imaging Centers. Therapeutic procedures as utilized in urology the referring physician performs the professional portion of the procedure and the professional fee is greater than a profit distribution or payment for the technical fee with the referring physician would earn from his investment interest in any joint venture. The ability to drive 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. Lithotripsy is a prime example of physicians and patients desiring a better way to treat kidney stones and the treatment of same and the cost as well as hospital data is self evident. Self policing with physicians involved in the management and ownership of these joint ventures has been of high quality and

is superior to any vendors that do not have physicians involved. Our teaching of Technologists both for laser services, Lithotripsy and Cryotherapy is very extensive and the ability to maintain these Technologists in our employment provides superior services than vendors or having hospital employees try and provide this service. The numbers on an annual basis that a Technologist would be involved with are larger than any single physician would have and they are truly very much involved in the end product of a timely efficient treatment with diminished chances of re-treatments and additional expense. Safety is also monitored very carefully. Spreading the use of costly equipment in the long run reduces overall capital costs. It's shameful when we see two or three hospitals within a several mile radius each duplicating capital expenses for imaging services to be certain that the competitive edge is not lost. If you would remind everyone that in the **ALSV Thompson** case the court held at the Extracoporial Shock Wave 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 would exempt these procedures that are not otherwise DHS from the proposed prohibitions to under arrangements.

The Per Click Fee Ban does not address the difficulty that we Urologists have in convincing hospitals to free up capital for buying new equipment. They are wary of new equipment being obsolete and candidly physicians in the past have convinced hospitals to buy equipment that sits in the corner and gathers dust. However we are all endeavoring to provide the best therapy minimally invasive in character and as much as possible as an outpatient for the patient's welfare. Joint ventures in urology permit us to do this. The entrepreneurial risk is avoided by the hospitals and is shared by physicians. We need to be able to provide our patients services that will help them in this manner. They also benefit as well when additional ancillary services can be combined i.e. removal of a stent, ureteroscopy and Cystoscopy.

Percentage Fee Prohibition: The hospitals avoid risks by creating arrangements where compensation is set as a percentage of reimbursement for the procedure. Of course certain third party payers provide low reimbursement as compared to others which reimburse more generously. The competitive environment of vendors will ultimately bring reimbursement into a reasonable trough. However if compensation is based on the lowest payer the service company will not be fairly compensated for his investments efforts and risk and we find that this happens as well that the Technologist that accompany the equipment tend to be poorly trained and in fact may not even be within the pool for being hired by highly regulated physician entities. I speak truthfully because I am a Medical Director for a Lithotripsy Company.

The Stand in the Shoes Proposal has a far sweeping impact. The CMS proposal to have a hospital Stand in the Shoes of an ambulatory surgery center that it owns or controls would have the effect of turning hundreds and perhaps thousands of procedures that are not of themselves DHS into DHS procedures. Burden of Proof is such that the Stark Laws were never intended to be extended in this manner. It means that CMS is the accuser and that the entity that has helped to foster relationships within the Stark guidelines would assume the role of an accuser. An effort to shift the burden from itself to the providers who are taking care of Medicare patients is grossly unfair and is not within the scope of sensible justice.

In short please keep in mind that a urology joint venture enables sharing of an expensive capital technology like Lithotripsy, laser units and Cryotherapy units that permit many hospitals to afford these services whereby they could not purchase them individually. Not only the purchase would be difficult but contracting at times with individual entities provides a Technician who is totally unfamiliar with the procedure and may have been poorly trained. We as physicians cannot entrust the care of our patients with entities such as this. CMS only needs to look at the data at the present time as to how physician joint ventures have brought Cryotherapy for example to multiple smaller hospitals and we have data currently that 3, 5 and 8 year follow-ups are competitive with radical prostatectomy with or without robotic assistance, external beam radiation and Brachytherapy. Certainly if we had not been able to explore these areas and assume entrepreneurial risk the savings available to prostate cancer patients for CMS would not be available to them. We ask that CMS accept the Burden of Proof that the law has historically placed upon the one creating the rules and not try to shirk their responsibilities. Please note that the proposed "under arrangements" provision to make certain that therapeutic services provided by urology to joint ventures are not DHS services if they would be so only because of the site where they are delivered. Do not implement Per Click Percentage Fee structures and please preserve the access and cost savings that the shared service model has created.

This is a complex issue and as a practicing Urologist for more than 30 years I find that the efforts that joint ventures have made have clearly advanced our abilities to provide timely care, minimally invasive care, cost effective care, and to preserve the expertise within the smaller communities.

Thank you for your consideration.

Sincerely,

Thomas H. Patterson, M.D., F.A.C.S.
KNOX CO., ILLINOIS

THP/bln

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July 10, 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

To Whom It May Concern:

As the Chief Medical Officer of a company that helps private practitioners place CT scanners and MRI units into their offices, I would like to make comments to various issues that you raised in your recently released 2008 Professional Fee Schedule proposal. As a physician, I am acutely aware of both the clinical and cost issues that are important to the Medicare beneficiary and CMS. After a general statement, I will address the issues as they were enumerated in your proposal.

For clinical quality and patient radiation safety reasons, we place only new, not used or refurbished, scanners in doctors' offices. We think that new platforms with new detectors give the doctor the image quality that he needs to further care for his patient in an immediate fashion. The patient is benefited by having less radiation exposure by using new technology. Equally as important for the Medicare beneficiary's safety, we encourage the doctor to use only the number of slices needed to make the diagnosis, rather than using multi-slice overkill that over exposes the patient to radiation scatter. For example, if the patient has blood in their urine, they need a CT of the abdomen and pelvis. The hospital or imaging center would use a 16, 32, 64, or now a 128 slice scanner to perform this task. Yet to make practically any diagnosis of the urinary tract, a new dual slice scanner is just as accurate with significantly less radiation exposure for that patient. Of course, if the patient has a cardiac disease, the higher slice unit is a necessity to make an accurate diagnosis. While it is much cheaper for the doctor, at least initially, to buy a used or refurbished piece of equipment, we think that you will agree with us that it is better clinically and better for the Medicare patient to be scanned on new equipment.

More specifically, below I address your enumerated topics:

1. Changes to Reassignment and Physician Self-Referral Rules Relating to Diagnostic Tests (Anti-Markup Provision)

   While we agree with the concept and general construction of the Anti-Markup Provision, several unintended consequences occur that may prove harmful. For example, in this digital and teleradiology generation, our doctors often say that they get better service on the scans that they do in their office more quickly from the teleradiology doctor than they do from their local radiologist. Some of these teleradiology companies, however, prefer for the medical group to do a global bill, rather than having their own billing department. In those cases, the medical group may keep seven (7) to ten (10) percent of the professional fee for their billing service. Even though your proposal states that it intends to eliminate "...gaming, whereby the performing physician's or other supplier's net charge to the billing entity is inflated to cover the cost of equipment or space that is leased to the performing physician ...." , it would seem to eliminate the very rational and appropriate billing services provided to the teleradiologist. Certainly that was not your intent.

   We also agree with your decision not to implement the "purchased test interpretation rule". However, we see occasions when a medical group will purchase a scanner and start out by hiring a part time technologist to work in their office. The Anti-Markup proposal would seem to preclude hiring a part time technologist, even within your office space, and billing Medicare. Perhaps a requirement that the technologist who works directly with the medical group on site would have to work at least half time

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would achieve your goals, while allowing practices needed flexibility.

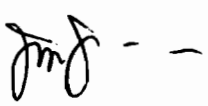
3. In-Office Ancillary Services Exception:

While CMS chose to leave this exception intact, you solicit comments as to appropriate services to be delivered as part of the in office patient care. As you note, much has changed in the practice of medicine since Congress passed the original Stark bill. But with those changes has come new standards of care for the Medicare beneficiary. For example, in 1991 the standard work up for urinary tract stones and hematuria was the intravenous pyelogram. Today, it is the CT scan. Our doctors with CT scanners in-office can save their patients time, money, and anxiety. Over and over we hear how grateful patients are that they can have their complete diagnostic work up done in one trip to one site. Even more impressive are the testaments to the immediate feedback that the patient gets about his illness from the urologist, who studies the scans immediately, often shows the patient appropriate views, and tells them what he thinks on the spot. And lastly, the physicians acknowledge that the clinical quality of their product has improved as they have gotten more involved with performance of the scans. Not rarely, the office physician has made a correct diagnosis missed by the radiologist formally reading the study. As opposed to being abusive, these in-office scanners (be they CT or MRI) have saved Medicare money by eliminating inefficiencies. Our experience, particularly with our client base of urologist, internist, neurologist, gastroenterologist, and orthopedist, is that they do the same number of scans whether they have the scanner in the office or send them out. Radiologists, who complain loudest about anyone owning a CT or MRI scanner other than them, are trained to read X-Rays, not own pieces of equipment. In today's digital age, taking the imaging study to the point of contact with the Medicare patient makes both clinical and economic sense for CMS. The radiologists get to read and charge for all of the X-rays either way, because CMS's predecessors have mandated such.

Lastly, let me address The Prohibition of reassignment of claims by suppliers (d) (3) Reassignment of the technical or professional component of diagnostic test services, on page 571 of your proposal. The conditions stated in (iii) on page 573 states, "To bill for the technical component of the service, the physician or medical group must directly perform the professional component of the service." This statement would directly seem to contradict your rejection of the "Purchased test interpretation Rule" where you eliminated the exact language contained herein. The Anti-Markup Provision would seem to address any concern here, as you previously stated.

Thank you for your attention to this matter. Physicians all over America, who have complied with both the spirit and letter of your regulatory law and guidance, anxiously await your response.

Sincerely,



Joseph Jenkins MD

LAWRENCEVILLE UROLOGY, P.A.
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August 22, 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**

Dear Sir or Madam:

I am writing to express to you my concerns about proposals in the recently released 2008 physician fee schedule. As a physician practicing in Lawrenceville, New Jersey, I am concerned that many of the proposed changes will needlessly and unjustifiably harm Medicare patients and physicians. Although I believe that it is worthwhile to prevent abuse in practices, many proposals will extend beyond that goal and hamper legitimate joint venture arrangements.

As a urologist, I have been involved with providing lithotripsy to my patients. Many of our patients have benefited from this medical care, when hospitals would not purchase lithotripsy machines. By accepting the risk of providing these expensive services, especially while the hospitals refuse to do so, urologists have expanded patient access to worthwhile and effective treatments for kidney stones. This has made the treatment of kidney stones much less invasive and certainly less expensive to Medicare.

Lithotripsy ventures are therapeutic joint ventures, which are separate and distinct from "diagnostic" ventures such as those that physicians and hospitals may have propagated.

It appears that lithotripsy ventures have 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 such as physician owned lithotripsy.

I appreciate your time.

Sincerely,

Jarad S. Fingerman, D.O.

JF/mtp

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August 16, 2007

Mr. Kerry N. Weems
Administrator – Designate
Centers for Medicae 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 Licensed Physical Therapist, practicing in South Texas. After graduating from Physical Therapy school I was a therapist in the U.S. Army, then in several general hospitals and private clinics. After the army, hospital and private clinics I started my current practice. My practice is a rehab center that has expanded to various locations. In over 25 years of practice I have had the privilege of working with many fine doctors and colleagues, but also I have seen a growing threat to the patients, to government funding sources and to our profession, which is the purpose of this letter.

Physician Self-Referral Issues: I wish to comment on the July 12 proposed 2008 physician fee schedule rule, specifically the issue surrounding physician self-referral and in the "in-office ancillary services" exception.

(1) In the cities where our offices are located, very frequently we find a new Physical Therapy office has opened up in conjunction with a physician or a physician group practice. We recently received a patient who had been a patient at one of the prominent physician owned PT clinics in our area. He had refused to continue therapy at that clinic because he felt he was not receiving enough attention in his therapy – often being sent off to do exercises in the gym by himself. This patient expressed great surprise when he found that the person guiding him in his exercises in our gym was an LPT. He would have been happy to just have a tech supervise him! This is unfortunately not an isolated incident, once every month or two we will get a patient like this.
(2) The "in-office ancillary services" exception has provide a loophole that has really impacted the economy of rehab because it has produced a way for physicians to take advantage of a captive referral base to refer to their own offices. With this self-referral is the tendency to over utilization thus putting an unnecessary pressure on the limited Medicare and Medicaid funds.

(3) The two most common statements in justification that I have personally heard local physicians use to justify their own PT is that they want to supervise better the therapy and they want the therapy to be more convenient for their patients. Before these same physicians ever considered setting up their own therapy they have told me they appreciated referring to a therapist because they don't know how to evaluate for therapy or what modalities to prescribe because they are not familiar with PT interventions. How did they all of a sudden become educated and capable of "closely supervising" the therapy when they found the opportunity to increase their income with it? As far as convenience for their patients: Many times their office is not the closest therapy clinic to the patient's home, it is just the closest to the original point of referral.

I believe the evidence is that by eliminating physical therapy as a designated health service (DHS) furnished under the in-office ancillary services exception, CMS would decrease abuse, over-utilization and expenses and improve the quality of patient care.

Thank you very much for your consideration of my comments.

Sincerely,

PT from 78550 zip code

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Diplomate, American Board of Urology Fellow, American College of Surgeons

Kevin P. Rozas, M.D.
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August 23, 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

Dear Ladies and Gentlemen:

I am a urologist practicing in Atlanta, Georgia. In this area we have been providing quality and 'state of the art' care for Medicare patients with renal and ureteral stones over the last 20-25 years. This has been achieved through a urologic joint venture which has enabled us to provide this 'state of the art' care primarily with lithotripsy and other minimally invasive treatments of stones. Through these arrangements we have been able to keep up with modern technology and provide pretty much pain-free, efficient and minimally invasive treatment for our patients' stones. These ventures were primarily set up to bring this equipment to our area as the hospitals were reluctant to invest the capital in treatment technology which they feared would soon be obsolete. Joint ventures such as this provide a valuable service to the community and should not be prohibited just because they are done at the hospital. There has been no evidence shown that the urology joint ventures have been abusive. The primary purpose of these ventures has been to improve patient care and improve access to better treatment for patients. Without physician joint ventures, this would not have been available in the past or present in many areas. These ventures enable sharing of expensive capital technology between multiple hospitals who cannot afford to purchase equipment themselves and this has brought clinical benefits to thousands of Medicare beneficiaries while saving CMS millions of dollars through the efficiency of shared services. There has been no evidence that physician ownership has corrupted medical decision making on the contraire of provided benefits to many hospitals and patients and should continue to do so in the future.

Thank you for your consideration in this matter.

Sincerely,

E. Wylly Killorin, Jr., M.D.

EWK:ccf

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August 21, 2007

Center for Medicare and Medicaid Services
Department of Health and Human Services
Baltimore, Maryland

Dear Ladies and Gentleman:

My name is Dr. Charles F. White, Jr. I'm a urologist in private practice in Mobile, Alabama. I'm writing this letter on behalf of the other urologists within our group practice, as indicated by our letterhead. We are owners in a joint venture partnership that provides lithotripsy services for Mobile and Baldwin Counties. We currently service four hospitals. Prior to the formation of Mobile Bay Lithotripsy (our joint venture) lithotripsy services were controlled by the only for-profit hospital within this region. Over the past few years with our partnership we have been able to expand the availability of services to a larger number of hospitals that serve both rural, urban and suburban regions. Our technology is a vast improvement over the preexisting technology, which had fallen out of date because of the before mentioned controlling factors.

Urinary lithiasis is a common problem, which frequently demands immediate therapy and spans all echelons of society. This is especially true in the deep south (commonly known as the stone belt). We have been able to provide these services, whereas in the past they were limited because of patients inability to pay, availability due to location, and limited technological capabilities.

The proposed new regulations regarding physician fee schedules cause great concern amongst virtually every practicing urologist. We are particularly concerned with the new provisions; under-arrangement contracting; procedure fee prohibition; percentage fee prohibition; stand-in-the-shoes provision and in-office ancillary services exceptions.

Concerning under-arrangement contracting, we believe that our private adventure has lowered hospital costs by sharing this expensive technology amongst four different hospitals in our region. Again, I want to emphasize that we serve both urban, suburban and rural regions. Our lithotripsy services are strictly therapeutic, and those of you who have experienced the pain of renal colic (obstruction) can sympathize with the relief that therapy affords. The risk of over-utilization is minimal in that we are treating an acute process, which demands treatment to alleviate pain, suffering and further medical complications.

Concerning your new provision of per procedure fee prohibition, as I mentioned earlier our equipment is state of the art and has allowed us to treat patients who otherwise would not have been candidates for lithotripsy because of this new technology. This is only available because we have invested in this technology, rather than waiting on hospital budgetary constraints. Individual payments per procedure are not made directly to a physician. They are

instead are made to a corporation which is a joint venture amongst a broad group of physicians and the lithotripsy service provider (Mobile Bay Lithotripsy).

Regarding the stand-in-the-shoes provision, ambulatory service centers (ASC's) have greatly reduced overall cost of outpatient surgery and outpatient therapeutic and diagnostic procedures. Many of these ventures are joint-owned between hospitals and the participating physicians and limitation of their contractual abilities would greatly restrict lithotripsy services, which are most commonly performed as outpatient procedures.

Regarding in-office ancillary services, over the last several years we have greatly expanded services, which are offered through our office, rather than in the traditional hospital setting. We believe that this has greatly improved cost effectiveness and has expanded patient access. Again, we want to emphasize that we consider lithotripsy and other ancillary services such as radiation therapy, pathological services and other invasive urological services to be therapeutic rather than diagnostic.

In conclusion, we ask CMS to carefully consider these therapeutic joint ventures, which have greatly expanded patient access, comfort, and availability and have simultaneously reduced the costs associated with traditional in-hospital services. It would be an expensive mistake to once again limit all the therapeutic services previously outlined to a hospital controlled setting.

Thank you for your time and attention to this very important matter.

Sincerely,

A. Greer Megginson, M.D.
G. Coleman Oswalt, Jr., M.D.
Charles F. White, Jr., M.D.
Dino N. Frangos, M.D.
S. Harbour Stephens III, M.D.
Paul A. Scott, Sr., M.D.

CFW/rr

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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 Policies for CY 2008; Proposed Rule

Physician Self-Referral Issues:

I am a physical therapist in private practice in New York City. I have two outpatient clinics in the boroughs of Brooklyn and Staten Island. I have been practicing for thirteen years. I am also the co-chairman of the Alliance of Independent Physical Therapists, a special interest group of the New York Physical Therapy Association. I am imploring you to have CMS remove physical therapy from the list of designated health services (DHS) furnished under the in-office ancillary services exception to the Stark law. This would significantly reduce the amount of programmatic abuse, overutilization of physical therapy services under the Medicare program, and enhance the quality of patient care.

My patient's and I have been harmed by physician owned physical therapy practices. Many times patients live within one block of my office but must go far out of their way to the physician's office or to "his" physical therapy office because their physician will not give them the prescription. Due to the repetitive nature of physical therapy this is abusive to the patient. Many times due to the broad definition of in-office ancillary services and something called "centralized building" the PT office is not even in the same building as the doctor. Centralized building means the building or leased space must be owned or leased full time on an exclusive basis by the physician. Therefore, the physician is not even there to supervise the treatment. Due to medicare referral requirements the physician has a captive referral base of physical therapy patients to their offices. Because physician direct supervision is not needed to administer physical therapy services many times non-licensed personnel are performing the therapy and it is billed under the MD. An increasing number of physician owned physical therapy clinics are using the reassignment of benefits laws to collect payment in order to circumvent "incident- to" requirements.

Unfortunately, the in-office ancillary service exception encourages physicians to create physical and occupational therapy practices as a way to supplement their income. Therefore, physical therapy should not qualify for the exception. Any therapy service that is not provided on an incident-to basis , and is not needed at the time of the MD office visit in order to assist the physician in his/her diagnosis or plan of treatment should not be include in the exception. The centralized building definition should also be removed as this provides absolutely no benefit to the patient and only contributes to abuse. Restrictions should be placed on ownership and investment in physical therapy services, this was the original intent of the Stark laws. I strongly urge CMS to remove physical therapy as a designated health service (DHS) under the in-office ancillary exception of the federal physician self-referral laws.

I would like to thank you for your consideration of my comments on the July 12th proposed 2008 physician fee schedule rule, specifically the issue surrounding physician self-referral and the "in-office ancillary services" exception. My comments are intended to highlight the abusive nature of physician-owned physical therapy services and support the removal of PT services from permitted services under the in-office ancillary exception.

Sincerely,

Richard Orsini PT

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August 23, 2007

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

Dear Sir or Madam:

I am writing you as a practicing physician with an office in Marlton, New Jersey. 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 effect on the healthcare system. I believe that CMS could address its concerns in a much less intrusive manner.

In the past years, physicians have tried to use free market enterprise in order to recuperate lost revenues secondary to cuts in reimbursement from Medicare and insurance companies. Our present basis of government is free market and, therefore, at every turn when regulations are made against physicians, physicians react in some way and in some manner. Whether this manner is helpful or detrimental to the healthcare system in the United States is a debatable issue. Physicians in this area have tried to supplement their incomes, not by bilking the system and over ordering tests but by practicing safe and quality medicine. We have increasing difficulties acquiring help from graduating residents to come and practice in South Jersey because the salaries offered as a new specialist cannot support living in this area. It is a shame that in today's society an individual can spend four years in medical school, six years in residency and earn a better living if he or she were to play a doctor in a television soap opera than he or she can in practicing medicine. Constraints caused by litigation and restraints caused by how physicians are directed to practice, has taken medicine out of the hands of physicians and caused over ordering of medications and testing. This is a very unfortunate situation and is only going to continue to get worse if the government continues to place restraints on our free market.

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It is imperative that the CMS **reconsider** a decision to change the present Stark laws. The Stark laws are already unfair and to tighten them any more than they already are will undoubtedly change the system in a negative manner. Physicians most likely will once again make a maneuver in order to alter how they treat and how they care for patients simply because non-physicians have tried to dictate how this should be done. I am not going to go into specific reasons why physician ownership in surgical centers, radiation oncology, laboratories, and radiology services should be banned or tightened. The reasons are many and I would be glad to extrapolate upon them if requested to do so. However, if physicians decided not to accept Medicare for treatment of patients, which has happened in some areas of the United States, this might increase and would not be good for the care of our aging population.

Respectfully,

S. Goldenberg, MD, FACS

Samuel F. Goldenberg, M.D., F.A.C.S. mm

SFG/mm

DICTATED, NOT READ
SIGNED IN ABSENCE TO EXPEDITE

A.S. Deshmukh M.D., / Urology

Fort Miami Medical Center

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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 Gentleman:

As a physician practicing in Toledo, Ohio, I am acutely aware of the both the clinical and cost issues that are reported to the Medicare beneficiary and CMS. As a urologist, I have been involved with providing my patients with lithotripsy and any other cutting therapies for urologic disease services that would not have been widely available to the Medicare beneficiary unless joint ventures had provided the services. These joint ventures took the risk of providing costly services when hospitals were unwilling to do so, yet in the recent fee schedule proposal the CMS attacks the substance of the very joint ventures that by all account have saved Medicare millions of dollars.

The joint ventures came into play because, indeed, hospitals balk at buying state of the are technology such as new Lasers, even if it is clinically superior, because of the expense and the fact that the rapidly changing technology makes today's best, tomorrow's obsolete. Through the urology joint ventures, we have been able to improve clinical care and take that risk of obsolescence. Sometimes, hospitals do not invest in 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.

In Toledo where I have practiced for the last thirty or more years, initially hospitals did join us in the venture, but did pull the plug and ran away. Without the physician's taking the lead, the whole of Northwest Ohio could not have been supplied with the Lithotripsy care to the patients. These patients would have had to travel hundreds of miles, lose wages, and be put in a position that they would have felt uncomfortable without their own physician's input and support.

A.S. Deshmukh M.D., / Urology

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August 23, 2007

A single hospital often does not have enough volume to justify the expense of a large capital investment. However, the physicians who want up to date treatment are willing to invest with other physicians who practice at other hospitals. Thus, the joint ventures involve physicians so that the usage can be spread among several hospitals.

The fact is that the stone is an ~~adherent~~ inherent problem that is not going to go away by wishing it away and requires treatment. Physicians only refer those patients to those centers who need treatment as indicated clinically.

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 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 big mistake to jeopardize these ventures as they have been time tested and proven model.

Sincerely yours,

A. S. Deshmukh, M.D.

ASD/fjs

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Thad Beagle, CPA (inactive)
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*Board Certified

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 urologist in a rural retirement area, I have been and continue to be active in the care of many Medicare and Medicaid patients. I am writing to you today to express my extreme concern regard legislation being considered, which if passed, would be catastrophic to the patients I treat.

My entire county has only one hospital and I have a significant number of patients that drive more than 50 miles to receive urological care. Our hospital delivers good quality care to the patients it serves but by itself it cannot be all things to all people.

Due to the financial restraints under which our hospital functions, it has been necessary for many physicians in this community to go above and beyond to assure that the patients we serve receive the best care possible.

My urological partner and I were put in a position years ago in which it was necessary for each of us to put ourselves at financial risk to guarantee that our patients would have access to the equipment and staff necessary for lithotripsy treatment. We knew what our patients needed and we did what it took to take care of our patients. Working together with other rural urologists we pooled capital to share a mobile lithotripter which is now helping patients all over North Central Arkansas.

This lithotripsy procedure is one which must be done at our hospital for numerous reasons. Our local hospital provides significant support in the care, anesthesia, and post operative monitoring of these patients. The legislation which is currently being considered by CMS would prohibit the hospital from billing for this procedure merely because the hospital wasn't able to afford the machine. This is ridiculous. **They are the only hospital in this county.** They are providing vital support.

This legislation will basically outlaw this treatment to rural Arkansans and all rural Americans. This legislation is attacking the care of our patients under such phrases as "Under Arrangements, Per Click Fee, Percentage Fee Arrangements, Stand in the Shoes, and Burden of Proof".

I understand the desire of CMS to stop fraud and abuse. Stopping medical care will do that but certainly you realize there has got to be a better way. You will NEVER help people by denying them care!!!!!

Where there is abuse; SMASH IT!!! But don't let political paranoia withhold medical care from people in need. The same holds true for cryotherapy and laser prostate ablation. Just because these procedures are being performed at a hospital does not prove abuse. Putting the burden of proof on innocent physicians obviously needs to be reevaluated. It's hard to believe I needed to even write that last sentence!

Think about what you are doing! My patients are just elderly and frequently poor Arkansans who did not think ahead far enough to retire in Washington, D.C.

- In the ALS v. Thompson case the court held that 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.

I am asking that CMS:

- Accept the burden of proof that the law has historically placed upon the one creating the rules, and not try to shirk their responsibility,

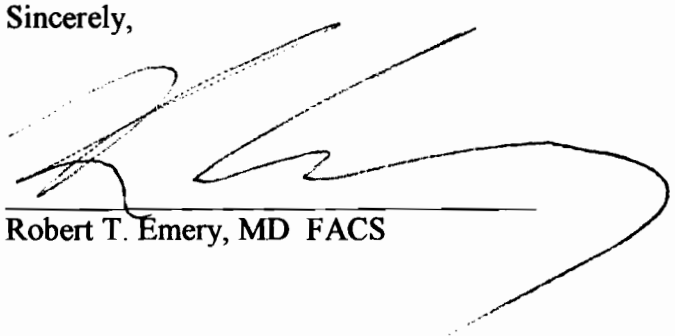
- Clarify that as a result of the ruling in ALS v. Thompson lithotripsy would not be subject to the proposed under arrangements restrictions,

- 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 in an ASC to clarify that legitimate joint ventures are not forced to abandon all ASCs with any hospital participation.

Sincerely,



Robert T. Emery, MD FACS

24 August 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

RE:CMS-1385-P (BACKGROUND, IMPACT)
ANESTHESIA SERVICES

Dear Ms. Norwalk:

I am a Certified Registered Nurse Anesthetist (CRNA) and have been a member of the American Association of Nurse Anesthetists (AANA) since my initial certification some thirty (30) years ago. The majority of that time, I have provided anesthesia services to Medicare recipients on a fee for service basis.

While the cost of living and the cost of doing business have steadily increased, the reimbursement for anesthesia services has remained static in some years and decreased in others. Anesthesia practitioners find it more and more difficult to provide services to Medicare beneficiaries in this atmosphere of dwindling reimbursement.

I am writing you to support the Centers for Medicare and Medicaid Services (CMS) proposal (72 FR 38122, 7/12/2007) to increase the value of anesthesia work by 32%. Under the CMS' proposed rules Medicare would increase the anesthesia conversion factor (CF) by 15% in 2008 which is an improvement over current levels. Adoption of CMS' proposal would go a long way in helping CRNAs, as Medicare Part B providers continue to perform these services to Medicare beneficiaries.

Medicare currently under reimburses anesthesia services (at 40%) as compared to other services (at 80%). This proposed rule would adjust anesthesia services for 2008. Additionally, the CMS proposed change in the relative value of anesthesia work would help correct the value of anesthesia services which are behind inflationary adjustments.

I am sure your have already been made aware that the 36,000 CRNAs in the U.S. provide 27,000,000 anesthetics annually, and that CRNAs are the primary anesthesia providers in rural and medically underserved America.

I support CMS' acknowledgement that anesthesia payments have been undervalued, and the proposal to increase the valuation of anesthesia work in a manner that boosts Medicare anesthesia payments.

Sincerely,

Rodney K Cannaday, CRNA

Rodney K. Cannaday, CRNA
4011 Oak Creek Dr.
Nacogdoches, TX. 75965-6528

John W. Lovett, MD

Urology Associates of Southeastern NC
1905 Glen Meade Road
Wilmington, NC 28403

August 24, 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

To Whom It May Concern:

I am writing as an actively practicing urologist in North Carolina with 20 years of clinical experience. I am very aware of the clinical and the cost issues that are important to the Medicare beneficiary and CMS. Given the length of my clinical experience I feel very qualified to comment on these issues as they relate to the proposed changes in CMS physician self-referral provisions. Specifically I would like to comment on your proposals, as they would impact imaging in office.

I joined a urology group in 1987 that was active in providing in-office radiology services. The standard of care for urologic imaging at that time was the Intravenous Pyelogram (IVP). My group elected to not invest in plain film tomography with non-ionic contrast when that became the standard of care in the 1990's for hematuria evaluation, but continued to perform KUB's for stone monitoring and retrograde pyelography in selected cases. Our patients continue to benefit from these in-office services, when clinically indicated, in terms of time-savings, convenience and direct interpretation / evaluation by their urologist that they have appreciated for over 20 years.

In recent years CT scanning of the abdomen & pelvis has become the standard of care for evaluating and managing urologic conditions such as urolithiasis, hematuria and genitourinary masses. Advances in technology have made it cost effective for my practice to invest in CT scanning and we are once again providing point of service, state-off-the-art urologic imaging services in our office. And our patients love it! No longer are they waiting for scheduling, traveling for studies and using their time to obtain off-site urologic imaging evaluation. The direct review of the digital studies with the patient has returned our practice to the level of immediate and direct care and interpretation that patients and we so appreciated earlier in my practice.

Ten years ago, I would have gotten different diagnostic studies to evaluate blood in the urine, abdominal pain, possible kidney stones, a kidney mass, or possible metastasis from a primary cancer, but today I get a CT scan. It is faster, less invasive and more comfortable for the patient and provides better information. The number of scans I

order is determined by the clinical needs of my patients. In my clinical work it is only a question of where, not whether, my patient is going to get a CT scan if their condition demands it. In-office scanning is simply more convenient for my patient and, in addition, enhances care, as the patient and I are able to review the digital images in a more complete and timely fashion.

My practice invested in a new scanner, not a used or refurbished unit. This required a larger investment and involves greater annual service/maintenance costs, but our 5 urologist/2 PA practice felt that a new scanner with the latest detectors and platform would give us better images while avoiding potential greater exposure of our patients to x-rays from an older, used scanner. We also invested in a dual slice scanner, for similar reasons: very good image quality with reduced patient radiation exposure compared to larger slice # machines.

I acknowledge the impression in today's radiology world is the more slices the better, but believe that these multi-slice units are not needed to provide the image quality uologists need to diagnose 99% of what we deal with on a daily basis, and, because of the radiation scatter of the wider multi slice field, patients are exposed to added radiation by using more slices than needed. This is not to discount the severity or significance of the diseases our patients deal with at all. Rather, a dual row scanner is ideal for imaging and managing the conditions seen in our specialty. And I acknowledge that new is better than used.

Addressing the Anti Mark-Up Provision Proposal, the digital images that our CT scanner produces can be read either off the scanner monitor or on a remote (on-site or off-site) monitor with equal clarity. We happen to have an excellent relationship with our local radiology group, who provide prompt, thorough interpretation and documentation. Our effective relationship involves our submitting for technical reimbursement and their submitting for professional interpretation reimbursement on non-contrast renal and contrast studies. With this our patients benefit from direct image review in our office with their urologic provider while receiving interpretation of preoperative and contrast studies by a radiologist.

Though this does not involve any mark-up on our part, we certainly feel that if we did not have a viable local alternative that we would not want to be denied the option of using a teleradiolgy company with our billing globally and paying the radiologist at a rate minus our cost of managing the professional component. And even more critical to all who incur the financial risk to provide the benefit of in-office CT imaging to their patients, I do not feel a discount of any type should be applied simply because of the location of the scanner.

The Anti Markup Proposal would seem to eliminate the possibility of hiring a part-time technologist in the early stages of setting up an in-office CT scanning service. I ask for clarification as the current proposal harms fully compliant in-office scanners which may need only half time operation in the early phases.

In your commentary you ask for discussion of which type of doctors should be allowed to put scanners in their offices. I see patient convenience, improved clinical care and cost savings to the patient. My patients receive convenient, state-of-the-art evaluation of their conditions with in-office CT imaging is. I believe I have added to the quality of the care I provide to my patients, while instituting no additional cost (technical +

professional) to CMS on the scans I obtain. And I provide added value by reviewing the digital images with my patient in a timelier manner.

In closure I must frankly ask, when was the last time a radiologist went over the average CT study with a patient? Thank you for your time in considering my views.

Sincerely yours,

John W. Lovett, MD

John C. Braun, DDS, MD
1782 Hunters Run Road
Meridian, Mississippi 39305

August 24, 2007

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

RE: Medicare Pay Increases for Anesthesia Services

Dear Sir:

I would very much like to thank you, in advance, for the planned increase in 2008 reimbursement for anesthesia services! The 32% work undervaluation and underpayment for anesthesia services, due to the flawed "conversion factor" formula, along with the across-the-board yearly reductions in Medicare/Medicaid payments, has been exceedingly painful for all anesthesia providers. It seems particularly unfair and ironic that Medicare recipients get annual COLAs (cost of living adjustments), while their Doctors get annual pay cuts.

If I may, I would like to make one last comment. I understand that it is planned to give the CRNAs (Certified Registered Nurse Anesthetists) a 12% pay increase, while giving the Anesthesiologists only a 4% increase. **This is a 300% larger pay increase to the nurse that the doctor.** Since the anesthesiologist has gone to medical school for 4 years and completed a 4 year Anesthesiology/Critical Care/Pain Management residency, and the CRNA has never attended medical school and has only two years of anesthesia training, there seems to be no basis for this discrimination. Doctors are always held to a higher standard of care than nurses, have higher malpractice premiums, and of course have higher malpractice judgments against them than nurses. It seems only fair that the anesthesiologist should get the 12% increase, not the nurse anesthetists, to help defray these additional expenses.

I know that you will give careful consideration to these genuine concerns. Let me thank you once again for any and all help in rectifying the inequities in anesthesia reimbursement.

Respectfully,

John C. Braun, DDS, MD

John C. Braun DDS. MD

PHYSICIANS CARDIOVASCULAR DIAGNOSTIC CENTER, L.L.P.
2955 HARRISON STREET, SUITE 300

BEAUMONT, TEXAS 77702-1157

August 23, 2007

Herb B. Kuhn, Deputy Administrator (Acting)
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: 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 Physicians Cardiovascular Diagnostic Center, L.L.P. I 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.

Physicians Cardiovascular Diagnostic Center, L.L.P. is a Joint Commission accredited IDTF located in Beaumont, Texas. Seven cardiologists utilize our facility to perform diagnostic cardiac and vascular catheterizations on 800 patients per year.

Physicians Cardiovascular Diagnostic Center, L.L.P. 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 huge 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.

The proposed 2008 APC payment code 0080 listed in the August 2, 2007 Federal Register is an 11.2% increase from the 2007 rate. The equivalent PFS codes 93510TC, 93555TC, 93556TC are inversely being cut. Tying non hospital outpatient cath lab reimbursement to a reasonable percentage of the hospital APC rates would correct this inequitable situation.

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 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,

Lisa Peterson

Lisa Peterson, RN, BSN
Administrator
Physicians Cardiovascular Diagnostic Center, L.L.P.

UROLOGY ASSOCIATES, LTD.

GENERAL UROLOGY • PEDIATRIC UROLOGY • URODYNAMICS • ULTRASONOGRAPHY

George M. Patterson, M.D.
R. Andrew Whisnant, M.D., F.A.C.S.
David A. Kagey, M.D.

August 22, 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 Sirs,

I am writing to you as a practicing Urologist in Roanoke, Virginia. I am concerned about the recent proposals made by CMS regarding Medicare which I believe will create unnecessary harm to patients and physicians and have a detrimental effect on the healthcare system in my community. As a Urologist, I have been involved with providing my patients Lithotripsy and other therapies for Urologic disease. These services would not be available in my community and to my patients including the Medicare beneficiaries unless the Urologists in my community and in Southwest Virginia did not provide a joint venture to provide these services. These joint ventures took the risk of providing the services when my local hospitals have not been willing to do so. I am concerned that the 2008 Physicians Professional Fee Schedule proposal will limit our ability to provide these services to our community even though they have saved Medicare millions of dollars.

The purpose of the proposed changes to the Stark regulation regarding services furnished under contract appears to ban physician joint ventures from contracting with hospitals to provide therapeutic services that are designated health services. These proposals are so broad they would ban any legitimate arrangements for services only because they are performed in a hospital setting. This includes laser treatments for benign prostate cancer and stone disease as well as lithotripsy. CMS seems to take the view the physicians who invest in these ventures do so at the expense of good patient care. My experience has been quite the opposite. Our local hospitals have refused to purchase lithotripsy and laser services in the past and these services would not be available unless the Urologists in our area had not come together to provide this service. Several years ago the American Lithotripsy Society won a lawsuit against CMS (ALS v. Thompson) that held that extracorporeal shockwave lithotripsy is not a designated health service even though it is provided under arrangements with the hospital. This service is highly beneficial to patients and providers and will continue to be so if CMS exempted these procedures that are not otherwise designated health services from the proposed prohibitions to under arrangements.

As you noted in your proposed regulation, Congress did not explicitly prohibit "per click" arrangements. The legislative history states that per-procedure and other similar compensation arrangements are permitted and CMS should not prohibit compensation arrangements that Congress intended to permit. The per-click fee arrangement is essential to bringing new and improved treatments to

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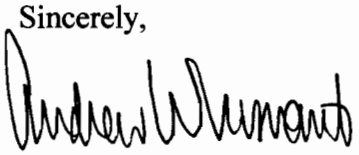
my community by allowing my local hospitals to pay the doctor-joint ventures to bring these new treatments to them, without the hospital having to take any financial risk for the services. We are not able to determine for a patient in advance what procedure may be required for treatment of his disease and the per-click fees are the most accurate and fair way to determine a compensation.

Percentage compensation arrangements are also reasonable and fair as some insurers pay low amounts and others higher. Generally commercial payments are higher than medicare payments. It is difficult to understand why CMS cares and if you change the reimbursement schedule, this will harm the medicare patient by denial of access to these procedures.

My final concern is the CMS proposal that would allow CMS or the office of the Inspector General to decide whether a referral was made contrary to Stark requirements and would leave the burden of proof on the health provider to prove that this referral was not made in violation of the Stark requirements. This is concerning to me in that it would make CMS the judge and the jury and penalties would be extended to any one who causes a claim to be submitted in violation of the regulations. At present, I take care of the healthcare problems of the Medicare beneficiary at a price set arbitrarily by CMS and with this burden of proof proposal, I now face the potential burden of a hidden tax in which I must prove my actions were legal rather than the Government agency which writes the law proving that my action was illegal.

In summary, I would ask CMS to separate the beneficial therapeutic joint ventures that are not of themselves designated health services from the abusive and potentially questionable diagnostic ventures that physicians and hospitals may have propagated. Without a doubt, it should be clear to CMS that the Urology joint ventures in my community have brought access to new technology for Medicare patients and have brought needed efficiency to our area and simultaneously saved CMS money. It would be a great mistake to jeopardize a time-tested and proven model that currently works.

Sincerely,



R. Andrew Whisnant, M.D., F.A.C.S.
Urology Associates, Ltd
102 Highland Avenue Suite 105
Roanoke, Virginia 24013

RAW/bke

August 22, 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 Centers for Medicare and Medicaid Services:

My name is John M. Allen, M.D. I am a Urologist from Jonesboro, AR, and am writing this letter on behalf of the patients of Northeast Arkansas and Southeast Missouri. I am concerned that proposed revisions to the Stark law will hurt my Medicare patients.

I provide lithotripsy and cryotherapy services to Medicare patients through Urology joint ventures. Without these joint ventures, my patients would not have access to these services locally. I share this expensive equipment with other urologists in Arkansas and Southeast Missouri so that it is in use 5 days per week rather than sitting idle in a Hospital. It is the most cost effective way to deliver these health care services, especially in rural markets like ours.

Hospitals have no interest in purchasing high tech equipment which may be rendered obsolete within a few years. I have more than enough difficulty just trying to convince our local hospitals to procure basic urologic equipment, let alone any of the newer technologies that come to market. Physicians are willing to take that risk.

I am also a member of a Hospital-Physician joint venture which operates a new Ambulatory Surgery Center (ASC) that serves many of my Medicare patients. They love its small size and easy access. Without local Physician capital, which financed 50% of the construction costs, the ASC would never have been built. Again, it was a Physician, not Hospital, driven enterprise. I firmly believe that Physicians, not Hospitals, are the most important link in ensuring that our patients get the best medical care possible.

Finally, CMS's attempt to shift the burden of proof to the provider when accused of a Stark violation is onerous and an insult to my integrity and honesty. Believe it or not, we physicians did not take the Hippocratic Oath to pad our bottom line. My patients deserve better from their government institutions and their elected officials.

Sincerely,

John M. Allen, M.D.

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PROVIDENCE PATHOLOGY ASSOCIATES, P.A.

Joseph R. Modzelewski, Jr. MD, MBA, FCAP
Medical Director of Laboratories

Elizabeth D. Wofford, MD, FCAP
Pathologist

Samuel H. deMent, MD, FCAP
Pathologist

August 23, 2007

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

Dear Sirs:

I'm a board certified pathologist practicing in Columbia, South Carolina at Providence Hospital and a member of a three man pathology group. I want to thank the CMS for efforts to end self–referral issues related to the billing and payment for pathology services. My specific area of concern lies with the arrangements to give physician groups a share of the revenues for pathology services not performed by the clinician but with employment arrangement with pathologists (i.e., POD labs). I believe these arrangement are in violation of Stark Law (anti-kickback, self referral) and applaud your division for identifying these arrangents and attempting to curtail them. I believe clinicians should not be able to profit for pathology services unless the clinician is capable of personally performing or supervising that service.

The changes the CMS propose do not limit the availability or delivery of pathology services. POD lab arrangments are motivated by financial gain and thus create conflict of interest, where the patient can suffer by compromise of patient care and integrity.

Sincerely,

Sam deMent

Samuel H. Dement, MD

2435 Forest Drive • Columbia, SC 29204 • Phone 803.256.5334 • Fax 803.256.5454

PHYSICAL THERAPY PLUS

August 24, 2007

Mr. Kerry N. Weems, Administrator – Designate
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
ATT: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

RE: Physician Self-Referral Issues

Dear Mr. Weems:

I am a Physical Therapist and owner of three (3) private clinics. In this role I feel there are issues that should be addressed, from my perspective, regarding the revisions under the proposed July 12 Physician Fee schedule rule for CY 2008.

With the allowance of physician-owned physical therapy clinics, I have seen referrals decline and heard from my patients stories of their experiences with these doctors.

Not only have the referrals greatly diminished, I've also seen a change in the way the orders from those physicians are now being written, when they do send a patient to my clinics.

In the past an order might be written for 2-3 times a week for 2-4 weeks, giving my therapists an opportunity to help a patient avoid surgery. Now, the orders are for 1-2 visits. The physician/surgeon knows little can be accomplished in that time frame. Thus, when the patient returns to the doctor and complains that the pain remains, they are told surgery is in order since "Physical Therapy did not work." And, most often the patient is encouraged to have their after-surgery therapy at the surgeon's own physical therapy clinic. The message, although not always in spoken words, is that they will have better care in the physician owned physical therapy clinic.

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Brunswick, GA 31520
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I believe that by allowing physicians to refer to their own therapy clinics you provide an atmosphere where over usage and over utilization of these facilities is a great temptation. To continue to allow this practice is an encouragement to continue the abusive financial arrangements that have been created by physician-owned physical therapy services.

Another area of concern to me is the Medicare Cap. My clinics are located where there is a high population of retired people. If a patient has a knee replacement and uses most of the Medicare allowance of $1780 and then comes back later with a diagnosis that is not an allowed exception, that patient must go to the hospital for therapy. Tell me how Medicare saves money by paying the hospital rather than a private clinic? This makes no sense to me. And, should the exception to the cap rule be deleted for 2008, as proposed, more patients will be forced to the hospital for additional care. Medicare also requires that their patients be treated by a licensed Physical Therapist, with one-on-one time dedicated to that patient alone. Physician owned clinics use aides/techs to deliver the care to Medicare patients.

I make every effort to comply with the guidelines set-forth by Medicare. When I hire a new therapist they tell me no one has ever explained and demanded their paperwork be so concise and compliant for Medicare standards. In addition, they say they have never been allowed to spend so much quality time in patient care. It is discouraging to be so diligent in the operation of my clinics and see physicians use loop-holes that allow them financial advantage.

I hope that you will seriously consider the removal of physician owned physical therapy clinics from the list of "in-office ancillary services" exceptions.

Thank you for allowing me to share with you my feelings in this matter. I look forward to seeing how these issues will be resolved.

Sincerely yours,

Elizabeth Daniel P.T.

Elizabeth Daniel, PT

Lyman R. Brothers III, M.D., Board Certified
Stacy J. Childs, M.D., Board Certified
James B. Haden, M.D., Board Certified

ADULT AND PEDIATRIC UROLOGY

UROLOGY CLINIC, PC

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August 21, 2007

Center For Medicare and Medicaid Services
Dept. Of Health and Human Services
Attn: CMS-1385-P
P.O. Box 8018
Baltimore, Maryland 21244-8018

Re: July 2, 2007 Medicare Physician Fee Schedule Proposed Regulations

Dear Ladies and Gentlemen:

I am a urologist practicing in a three person group in the rural communities of Steamboat Springs and Craig, Colorado. I am an owner in a joint venture partnership that provides lithotripsy service and laser resection of benign prostatic hyperplasia for prostate problems.

The rural communities of Steamboat Springs and Craig, Colorado would not be afforded these contemporary medical services, if it were not for our partnership. The two communities, including the service area of the two hospitals, do not have enough patients with these diagnoses to justify the expenditures necessary to purchase the equipment. Prior to this partnership, supplying ESWL services and laser BPH services to the hospitals, the patients in our community had to travel three hours, one way, to Denver for these services.

I have several concerns regarding the proposal under discussion. First, your concern that physicians over-utilize and cause higher costs to Medicare is preposterous. The procedures that we do are therapeutic and not diagnostic and if you are concerned that procedures are being done necessarily, why don't you audit the x-rays or audit the charts. If there is unnecessary use of this equipment or fraudulent activity, why not just prosecute those physicians that are doing this? Next, your concern about per procedure fees, at least in a rural setting, equally is absurd. There is no way that our hospitals could lease or purchase this equipment and thus, a per procedure fee is the most practical.

For the above and several other reasons, I urge you to listen to those of us who are in the trenches trying to pay our overhead and continue to practice medicine in the environment of fee reduction and onerous paperwork that make us all want to retire early or get into another career.

Thank You,

Stacy J. Childs, M.D.

Stacy J. Childs, M.D.

SJC/hb

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Steven R. Goldsmith, M.D.
Marco A. Guerrero, M.D.
Charles A. Herzog, M.D.
James N. Mohn, M.D.
Richard D. Taylor, M.D.
Valerie K. Ulstad, M.D.
Kyuhyun Wang, M.D.

Leslie V. Norwalk, Esq.
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
P.O. Box 8011
Baltimore, MD 21244-1850

August 23, 2007

To Whom It May Concern:

I am the Cardiology Non-Invasive Lab Manager at Hennepin County Medical Center in Minneapolis, Minnesota. We do a large volume of echocardiograms and stress echocardiograms, 80% of which we do using the contrast-imaging agent Definity (Perflutren – Bristol Myers Squibb).

I understand that Medicare is proposing to eliminate separate payment for echo contrast agents. Under this proposal, reimbursement would be identical whether or not a contrast agent was used. We are a safety-net hospital and serve an under-served population. If this proposal passes, our patients would no longer have access to contrast agents, and thus obtain less accurate results from echocardiography. We believe that this is a disservice to patients, in particular low-income patients, as the non-contrast echocardiogram would often be sub-standard and additional testing would become necessary. With contrast costing nearly $300,000 a year, our hospital could not continue to provide contrast to patients without reimbursement.

I truly hope that you will take patient care and safety into account as you proceed with this decision. If I can answer any questions for you, please feel free to contact me.

Thank you,

Lorrie Fane

Lorrie Fane
RDMS, RDCS
Manager, Non-Invasive Lab
Cardiology, O5
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612-873-6307
lorraine.fane@co.hennepin.mn.us

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Address

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Phoenix, AZ 85032

August 21, 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

Dear Ladies and Gentlemen:

I am writing this letter as a practicing physician with an office in Scottsdale, Arizona. I am deeply concerned about certain reports made by CMS regarding Medicare. As I believe, they will unduly and unnecessarily harm patients and physicians and have a detrimental effect on the health care system.

As a urologist, I have been involved with providing my patient lithotripsy and other cutting edge therapies for urological disease. These are services that would not be provided to my patients including Medicare beneficiaries because of the expense to the hospital. This has been provided to these patients through urology joint ventures giving the hospital access to these technologies. These joint ventures took the risk for providing quality services when the hospital is unwilling to do so. Yet in July 2, 2007, the released 2008 physician professional fee schedule proposal, CMS tax is up and so the very joint ventures that accounts have saved Medicare millions of dollars.

It should be clear to CMS that the urology community therapeutic joint ventures have brought an access to new technology for Medicare patient.

This has brought the needed efficiency to the market and simultaneously saved CMS hundreds of millions of dollars. If CMS tries to stop abusive arrangements, it would be a great mistake to jeopardize such a time-tested proven model.

Sincerely

John A. Bamberl, D.O.

JAB/gls/ccm

Dictated, but not read

Ms. Leslie Norwalk
Centers for Medicare and Medicaid Services

Aug. 23, 2007

Re: CMS-1385-P
Anesthesia Coding

Dear Ms. Norwalk;

I wish to express my support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule.

There is currently a large disparity in payments for anesthesia care when compared to payments for other physician services, and I appreciate the fact that you are addressing this issue. The $4.00 increase proposed by the RUC will help to correct the current undervaluation of anesthesia services.

Please follow the recommendation of the RUC and implement the increase in the conversion factor for anesthesia services.

Thank you.

Sincerely,

Kevin Whitaker, M.D.
8300 W. 38th Ave.
Wheatridge, CO 80033

August 24, 2007

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: **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

Mr. Weems,

I am a Physical Therapist and clinic supervisor working in Apple Valley, Minnesota. I hold a Masters degree in Physical Therapy and have been practicing full time Physical Therapy in an outpatient orthopedic setting since February of 1998. I am also an active member of the American Physical Therapy Association since 1995.

I'm writing to briefly comment on the July 12 proposed 2008 physician fee schedule rule, I hope to highlight the potential for fraud and unethical care of Medicare beneficiaries if physician-owned Physical Therapy services are allowed to continue.

- Physician-owned arrangements can take advantage of a captive patient base, undermining a patient's ultimate right to choose health care services and the providers of those services.

- Physician-owned arrangements and in-office ancillary service arrangements promote potential for over-utilization of services for financial reasons. It creates an incentive to provide service for profit without regard to the best interest of patients.

I support and request the removal of Physical Therapy services as a designated health service (DHS) from the list of permitted services under the in-office ancillary exception of the federal physician self-referral laws.

Thank you for your time in carefully considering this issue.
Regards,

Paul Breyen MA, PT, Cert. MDT
The Institute for Athletic Medicine
15650 Cedar Avenue – Suite 160
Apple Valley, MN 55124-7283

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 cautiously optimistic about the proposal to increase anesthesia payments in the 2008 Physician Fee Schedule. Anesthesia services for Medicare patients have been grossly undervalued for far too long.

Anesthesiologists complete twelve years of rigorous education and training in order to practice one of the most demanding, stressful, and important occupations in the country. This training requires huge sacrifices as it encompasses nearly all waking hours. In my case, I also had to join the military to pay for medical school. This added three additional years before I could begin my practice.

As you are aware, we act as the patient's advocate pre-operatively – assuring that their health issues have been optimized to minimize their risk of surgical complications (death, heart attack, stroke, etc.).

During surgery, we function as the patient's cardiologist, internist, pulmonologist, nurse, ER physician, psychiatrist, and all else necessary to keep them alive and well while surgeons dissect their hearts, livers, brains, etc.

Postoperatively, we serve as their pain specialist while continuing to address their individual medical needs.

With all these functions and responsibilities comes extraordinary stress (and lawsuits).

It is unfair that our hourly wage for these efforts is less than mechanics, plumbers, or even nurses working in the same OR. It's about one fifth of our lawyer's hourly fee.

Our senior patients require the best and brightest anesthesiologists to achieve optimal outcomes. However, Medicare's absurdly low reimbursement to anesthesiologists has resulted in many good anesthesiologists choosing to work in Medicare-free locations.

As the Chairman of our Anesthesiology Department, I observe with dismay as excellent anesthesiologists leave our hospital (where their skills are critically needed) and practice in less demanding settings where they are reimbursed fairly. Some have left the field of anesthesiology entirely for occupations that contribute significantly less to our society.

It is obvious that the present formula used to establish anesthesia conversion rates is grossly flawed. I encourage you to implement the anesthesia conversion factor increase as recommended by the RUC as soon as possible!

Sincerely,

David Gwyn Woodward M.D.

Subject: 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 in private practice. I have been in practice for about 15 years and have 3 associates. I am board certified in clinical electrophysiology and have a clinical doctorate in physical therapy from MGH institute of Health Professions in Boston, Massachusetts. My practice is an outpatient clinic specializing in orthopedic physical therapy and electrodiagnostic testing. Referral for profit, without a doubt, has compromised my practice and damaged the integrity of healthcare in our community. Though there is ample physical therapy choice through the local hospital and my clinic, physician-owned physical therapy services are proliferating in our town and surrounding communities. This proliferation is not from need of services but obviously from financial incentive/benefit of the physician owners.

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 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-utilization of physical therapy services under the Medicare program, and enhance the quality of patient care.

On a personal note, a real life true story may paint the clearest picture of physician-owned physical therapy. I had a patient we will call Robert. Our local orthopedic physician referred this patient to my clinic for physical therapy due to shoulder pain. This physician had been a prominent orthopedist in our community for 15 years but due to family concerns had decided to move his practice to Atlanta during Roberts's ongoing physical therapy. Though Robert improved he had some signs and symptoms consistent with probable rotator cuff pathology that needed further evaluation. As our local orthopedist had already moved to Atlanta, I was instrumental in referring Robert to a different orthopedist in the nearby community. After the fact, I found this was a big mistake not only for my practice but for the patients' care.

The patient was seen by the orthopod in the nearby community and agreed that he likely had a rotator cuff or labral tear and an MRI would be scheduled. He was to continue his physical therapy as many patients do not require surgery with rotator cuff or labral tears. Following his appointment with the new out of town orthopedic specialist, Robert came by my clinic wanting to talk with me. Even though Robert lives within walking distance of our clinic, the new orthopedic physician wanted him to be treated in a clinic in the new orthopedic physician's town. Investigation showed this clinic to be smaller with less state-of-the-art equipment. The staff in the physicians' preferred physical therapy clinic was less credentialed and had less experience than myself and associates. **Further investigation showed that the new orthopedic physician had part ownership in the facility.** He self-referred the patient to be treated by less qualified personnel, with less equipment and 30 minutes away from Roberts' home. Through a series of "lucky" circumstances Robert did return to our facility for continued care. This is a real-life

everyday occurrence here in my community. We now have a 5 orthopedic physician group in a nearby community and a Family physician in our community that offer physician-owned physical therapy services specifically for self-referral. These facilities were opened even though there was no need for additional services in our small town. It has negatively impacted both the small local hospital and my practice. I can't compete as I will never have an opportunity to see these patients because of the predetermined referral pattern (self-referral) based on financial incentive for the physician group that owns their own physical therapy services.

This problem does not stop in my community. In a 50 mile radius there are two large neurosurgical groups and virtually all the orthopedic practices have physician owned physical therapy services. These practices have proliferated in my region over the past 10 years and I see no end in sight. For the benefit of patient choice and the integrity of our health care system I strongly suggest **removing physical therapy from the "in-office ancillary services" exception to the federal physician self-referral laws.**

Dr. Matt Hornsby DPT, ECS
Doctor of Physical Therapy
Board Certified Specialist, Clinical Electrophysiology

DAGOSTINO
PHYSICAL
THERAPY

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

RE; Medicare Program- Physician Self- referral Issues

Dear Mr. Weems:

It is about time that on behalf of Medicare recipients you are willing to look at eliminating physicians who own physical therapy departments from billing for these services. Since the early 1970's it has been known that when a physician owns a PT setting they bill somewhere in the neighborhood of 60% more service and charge more money for that service. They perform this physical therapy with lesser trained individuals and the physician does not participate in the delivery of this service. In short is just a moneymaker for them. The early studies were done by Blue Cross of Michigan. Since that time such studies as the Florida study, the Swedlow Workers' Compensation Study in California, and even the OIG reports confirm my statements.

My patients are complaining about the inferior care at my local Orthopedic Office. The physical therapist spends less then 15 min with the patient and the remainder of the treatments is performed by techs. If they are late, their care gets cut in time because the clinic is so impacted. They never see the same physical therapist. As stated by one of my astute seniors ". Quality and continuity of care sucks"

Physician owned clinics do not contribute to the health and well-being of our seniors. They are just another scam like selling ashtrays to the military for $500.00.

I hope you have the courage to eliminate this waste in healthcare.

Sincerely,

James J Dagostino DPT, PT
Doctor of Physical Therapy

3809 Plaza Drive, Suite 112 • Oceanside, CA 92056 • (760) 941-2630 • Fax (760) 941-4617
www.dagostinopt.com

Jerome F. Johnson, M.D.
15651 N. Boulder Dr.
Fountain Hills, Arizona 85268
August 22, 2007

Centers for Medicare and Medicare Services
Dept. of Health and Human Services
Attention: CMS - 1385 - P
PO Box 8018
Baltimore, Md. 21244 - 8018

Dear Sirs,

In the mid-1970's I was in a solo urological practice in Findlay, Ohio and striving to make available the finest urological care possible to my many patients. A then revolutionary German-inspired procedure to actually fracture kidney stones with amplified sound waves was a resound success in Europe but not available to us in the United States mostly because of the extravagant expense of the technology and the unwillingness of medical institutions to finance such expertise owing, in large measure, to the transient use of medical developments which are all too soon replaced by even newer designs in treatment. In the case of AKSM, many Ohio urologists, sensing the beneficial impact this would have on our communities, banded together to acquire this technology; this was a considerable risk to most of us that had young families at that time. AKSM surrounded themselves with a highly distinguished legal staff to make sure to the nth degree that there would be no violation of state or federal laws and that a self monitoring process would be in constant operation so as never to challenge the Stark regulations that eventually came to pass. Mechanisms to protect quality control are still in active effect today and our patients have benefited from this ethical approach all these subsequent years. Now I myself, after 30 years in practice, have had to retire from the career that I still love because of medical concerns and I am now myself a Medicare recipient. I have been both provider and patient in my lifetime; I know both sides of the desk now. I know the doctors are not using this technology "just as an opportunity to make money on referrals"; the

oath of Hippocrates is just as valid today as it was in my time. For we Medicare patients, there is no disguising the pain one experiences when suffering under the presence of a stone; it is quite an easy matter for any managed care or government agency to see if this tool of treatment is overused or not. Even in this era of falling reimbursements, please continue to let this physician-owned entity operate according to the provisions of the current Stark law.

Respectfully,

Jerome F. Johnson M.D.

Jerome F. Johnson, M.D.

2/10

Rockland Urology Associates, P.C.

6 Medical Park Drive • Pomona NY 10970 • Phone: 845.354.5000 • Fax: 845.354.9469

Leonard J. Rudin, M.D., F.A.C.S.
Richard Kroll, M.D., F.A.C.S.
John G. Giella, M.D., F.A.C.S.
Richard M. Evans, M.D., F.A.C.S.
Kathleen L. Latino, M.D., F.A.C.S.
Mitchell C. Fraiman, M.D., F.A.C.S.

Diplomates – American Board of Urology

August 23, 2007

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

Dear Sir or Madam:

I am concerned that proposals in the 2008 Proposed Physician Fee Schedule may adversely impact Medicare recipients and health care providers. CMS's laudable efforts to eliminate abusive practices may preclude availability of needed legitimate joint venture arrangements resulting in denial of necessary medical care to many patients.

Urology joint ventures have provided effective, minimally invasive treatment options for my patients, including Medicare beneficiaries. Physician assumption of risk has enabled our hospitals to offer our patients access to technologies which the hospitals have been unable or unwilling to acquire. Unintended consequences of some proposals in the 2008 Physician Fee Schedule threaten patient access to therapies that have in millions of dollars of Medicare savings.

CMS proposal that providers potentially bear the burden of proving that referrals were not made in violation of Stark appears to contradict our constitutional presumption of innocence. American jurisprudence tradition holds this burden as unreasonable. In addition issues of fair market valuation of services are often subjects and debatable. Creating a system wherein CMS or its contractors are the sole judges of appropriate compliance with referral regulations is prejudicial to health care providers due process entitlement.

Physician investors indemnify hospitals from risk of low volume services provided at minimal profit margins. The proposed ban on per click lease arrangements would deprive patient access to state of the art care in many areas. Unavailability of lithotripsy services, for example, would either obligate patients to travel great distances, with long waiting lists, or alternatively subject themselves to more invasive and often more expensive therapeutic options.

Percentage-based fee arrangements facilitate access to costly treatment modalities with predicted low volume. Prohibition of proportional compensation for services would certainly deprive many patients of their best treatment choices.

Rockland Urology Associates, P.C.

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Mitchell C. Fraiman, M.D., F.A.C.S.

Diplomates –American Board of Urology

Prejudicial Medicare reimbursement to ambulatory surgical centers would also appear to discourage physician-hospital partnership in ASC's, likely resulting in an increase in physician owned ambulatory surgical centers and possibly higher volume.

The 2008 proposals would appear to prohibit non-abusive, legitimate arrangements for therapeutic as well as diagnostic designated health services. Calculus lithotripsy, prostate laser procedures and prostate cancer cryosurgery treatment volumes are often insufficient to justify hospital capital expenditures. Physician joint ventures enable these technologies to be shared among a number of hospitals whose collective patient base permits access to these treatment options that would otherwise be unavailable.

It is understandable that CMS react to possible questionable diagnostic imaging arrangements. However, overuse or improper referral arrangements have not been associated with urological services including laser therapy. Why would CMS wish to place at risk such valuable and legitimate services which are only considered DHS by virtue of a hospital venue? ALS v. Thompson established that extracorporeal shock wave lithotripsy is not a DHS despite its provision under arrangement with a hospital. Medicare patients and physicians would be well served if CMS also exempted procedures that are not otherwise DHS from proposed prohibitions to under arrangements.

The referring physician's professional fee for these services exceeds his/her joint venture investor's distribution which mitigates the incentive for abuse.

In conclusion, I ask CMS to distinguish those beneficial therapeutic joint ventures which are not of themselves DHS from abusive and questionable diagnostic ventures that physicians and hospitals may have engaged in. There is no doubt that the urological community's therapeutic joint ventures have greatly increased patient access to new technology for Medicare beneficiaries and brought needed efficiencies to the market, while simultaneously saving CMS hundred of millions of dollars. Medicare patients would suffer grave injustice if time tested, proven, legitimate joint venture health care models were prohibited as a consequence of CMS's efforts to address abusive arrangements.

Sincerely,

Richard Kroll, M.D., F.A.C.S.

intermountain
physical therapy &
hand rehabilitation

August 23, 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 Office PT/OT Services*

Complimentary PreOp Prep

Complimentary Patient Aftercare

Complimentary Post Discharge Consultation

Hand Rehabilitation

Upper Extremity Rehabilitation

Lymphedema Treatment

Industrial Rehabilitation

Employee Analysis

Custom Splinting & Orthotics

Dear Mr. Weems;

This is simply a list of reasons the "in-office ancillary services" that created a loophole for physicians to own their own Physical and Occupational Therapy Offices is a bad idea.

- **Reason #1: Monetary.**
  Physicians have financial incentive to prescribe unnecessary treatment to Medicare beneficiaries and possibly to inflate their charges. As you know there is a no incentive like financial incentive.
- **Reason #2: Inconvenient for the Patients.**
  The doctors do not give patients a choice of where to receive treatment, even if a different clinic would be closer the patients home or just more convenient for them.
- **Reason #3: Unavailable treatment.**
  In the event a doctor prescribes unnecessary treatment for Medicare beneficiaries the Medicare cap will be reached and there will be no benefits available when the patient really needs them.
- **Reason #4: Increased Taxes.**
  Someone will have to pay for the consequences of this irrational service arrangement.

Thank you for considering these comments.

Sincerely,

L. Kelly, BOM

1015 12th Ave. So., Suite 105, Nampa, Idaho 83651 Telephone 208/467/4357 Facsimile 208/467/4395

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Cascades
UROLOGY CENTER

Andre Gilbert, MD, FACS
Diplomate, American Board of Urology
Fellow, American College of Surgeons

Findlay, August 24th, 2007

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

Dear Mr. Kuhn:

I am an urologist who is a solo practitioner in a small town. I am writing to comment on the proposed changes to the physician fee schedule rules that were published on July 12, 2007 that concern the Stark self-referral rule and the reassignment and purchased diagnostic test rules.

The changes proposed in these rules will have a serious impact in the way I practice medicine and will not lead to the best medical practices. With respect to the in-office ancillary services exception, the definition should not be limited in any way. It is important for patient care for urologists to have the ability to provide pathology services in their own offices. It is equally important to allow urologists to work with radiation oncologists in a variety of ways to provide radiation therapy to patients. Also a cooperative effort between urologists and radiologists has long been established, with huge benefits to our patients.

The proposed changes to the reassignment and purchased diagnostic test rules will make it difficult, if not impossible for me to provide the convenient services that so many of my patients appreciate in having it available at our office (specially the elderly ones) – it includes imaging studies, laboratory tests, in-office prostate therapies, among others.

The proposed "under arrangement" rule, will prohibit the provision of these services. It will delay therapy and financial burden will be inflicted to our patients. There is a tremendous positive feedback when the patients realize they not only can they see me, but get a great portion of their workup done at the same facility.

The prohibition of per click payments for space and equipment rentals will limit the efficacy in which we can care for our patients.

The sweeping changes to the Stark regulations and the reassignment and purchased diagnostic test rules go far beyond what is necessary to protect the Medicare program from fraud and abuse.
The rules should be revised to only prohibit those specific arrangements that are not beneficial to patient care.
Thank you for your consideration.

Andre Gilbert, MD, FACS

1651 North Lake Court • Findlay, Ohio 45840 • Phone: 419-423-8090 • Fax: 419-423-8902
www.cascadesurologycenter.com

August 22, 2007

Office of the Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8018 **RE: CMS–1385–P (BACKGROUND, IMPACT)**
Baltimore, MD 21244–8018 **ANESTHESIA SERVICES**

Dear Administrator:

I am a CRNA, one of three CRNA's who provides the only anesthesia services available at the only hospital in our Wisconsin county of Richland. I have been an anesthesia provider in the rural setting for the majority of my career, although I was also a Clinical Anesthesia Instructor in a CRNA teaching program, and also served on the Board of Nursing for the State of Wisconsin for nine years, and also served as Chair of the BON.

The form letter below makes the salient points.

I am one of those providers in rural America. **I also know that I could not get a carpenter, plumber or electrician agree to do any work even here, for a third less than 1992 prices! Why would my government expect this of our rural facilities?**

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, this process did not adjust the value of anesthesia work until *this* proposed rule.

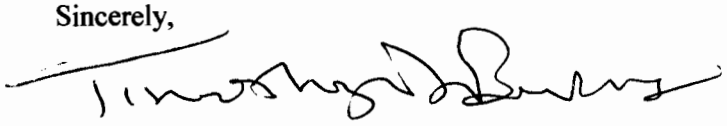
--Third, CMS' proposed change in the relative value of anesthesia work would help to correct the value of anesthesia services which have long slipped behind inflationary adjustments.

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,



Timothy D. Burns CRNA
700 Sunny Lane
PO BOX 555
Richland Center, WI 53581

244

WAKE FOREST
SCHOOL of MEDICINE
THE BOWMAN GRAY CAMPUS

Department of Anesthesiology

August 21, 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 a pediatric anesthesiologist at Wake Forest University in Winston-Salem, NC and I enjoyed your speech and candor at the anesthesia legislative meeting in D.C. this past May. I am glad that the CMS has looked into the relative undervaluation of Anesthesia work and appears prepared to act on this.

I think it is clear to all who are aware of this issue that this is not sustainable because the cost of caring for these patients exceeds their reimbursement by Medicare, creating access issues for some of our most needy and deserving citizens

At Wake Forest we take care of a large number of Medicare patients. Our department as a whole has been very financially challenged as a result of the relative undervaluation of anesthesia work.

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,

Thomas Wesley Templeton M.D.
Assistant Professor of Anesthesia

Corporate Office

#78 Kenrick Plaza
St. Louis, MO 63119
Phone: 314.962.8020
Fax: 314.962.6570

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North County Sports Fitness & Rehabilitation Center
Phone: 314.895.4664 Fax: 314.731.2340

Physical Therapy of Ferguson-Florissant
Phone: 314.521.3000 Fax: 314.521.7800

South St. Louis Rehabilitation
Phone: 314.962.8020 Fax: 314.962.6570

The Physical Therapy Center
Phone: 314.849.4455 Fax: 314.849.2844

West County Sports Fitness & Rehabilitation Center
Phone: 314.996.3500 Fax: 314.996.3501

Woodlake Physical Therapy & Sports Clinic
Phone: 314.469.0760 Fax: 314.469.0034

Farmington Facility

Farmington Hand & Physical Therapy
Phone: 573.756.2320 Fax: 573.760.8677

St. Charles Physical Therapy Facilities

St. Charles Sports & Physical Therapy O'Fallon
Phone: 636.240.7000 Fax: 636.240.7513

St. Charles Sports & Physical Therapy St. Charles
Phone: 636.947.7678 Fax: 636.947.4350

St. Charles Sports & Physical Therapy St. Peters
Phone: 636.441.7500 Fax: 636.441.3004

St. Charles Sports & Physical Therapy Wentzville
Phone: 636.332.1313 Fax: 636.332.2929

Hand Therapy Facilities

Hand Therapy of Chesterfield
Phone: 314.469.8569 Fax: 314.469.0395

Hand & Physical Therapy of Des Peres
Phone: 314.822.4400 Fax: 314.822.4111

Hand Therapy of Ferguson-Florissant
Phone: 314.521.3000 Fax: 314.521.7800

Hand Therapy of North County
Phone: 314.895.4664 Fax: 314.731.2340

Hand Therapy of St. Charles County
Phone: 636.300.4300 Fax: 636.300.4301

Hand & Physical Therapy of South County
Phone: 314.842.4222 Fax: 314.842.9393

Hand Therapy of South St. Louis
Phone: 314.961.9992 Fax: 314.961.0306

Home Health Services

St. Louis Home Health
Phone: 314.352.7889 Fax: 314.352.7411

August 22, 2007

Mr. Kerry Weems
Administrator-Designate
Centers for Medicare and Medicaid Services
US Department of Health & Human Services
Attention: CMS – 1385 – P
P.O. Box 8108
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 writing to you as a physical therapist in private practice for nearly 30 years regarding physician self-referral issues and the July 12 proposed 2008 physician fee schedule rule. Under the current model of allowing "incident to" therapy services in physician offices, it has become quite apparent from the huge increase expenditures in Part B that abuse is rampant. In short, when the person writing the referral and controlling the number and intensity of the visits also stands to gain financially, the system is ripe for abuse. Time and again studies, including MedPac, have shown that the "gatekeeper model" has the best chance of limiting unnecessary visits and controlling costs. The breakdown in the "gate keeper" system occurs, however, when the gatekeeper stands to gain economically from simply signing his name to a prescription pad.

One of the most common arguments we hear in defense of the "in office" therapy, particularly in Missouri where state law prohibits such arrangements, is convenience to the patient and communication with the physician. When and where this is truly an issue, we have simply had therapists lease space at fair market value from the referring physician, while the treating therapist does all their own billing and collection. This provides for the convenience of the patient while removing any incentive for overutilization of services.

Finally, thank you in advance for your concern in this matter.

Sincerely,

Bill Hopfinger, P.T.

BATESVILLE SURGERY
& CT Imaging

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*Jay R. Jeffrey, MD FACS
*David L. Posey, MD FACS
*Z.T. Beyga, MD

Otolaryngology

*Todd M. Rumans, MD
Robert Hale, AuD, CCC-A
Audiologist

Urology

*Hunter L. Brown, MD FACS
*Robert T. Emery, MD FACS

Thad Beagle, CPA (inactive)
Clinic Administrator

*Board Certified

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 urologist in a rural retirement area, I have been and continue to be active in the care of many Medicare and Medicaid patients. I am writing to you today to express my extreme concern regard legislation being considered, which if passed, would be catastrophic to the patients I treat.

My entire county has only one hospital and I have a significant number of patients that drive more than 50 miles to receive urological care. Our hospital delivers good quality care to the patients it serves but by itself it cannot be all things to all people.

Due to the financial restraints under which our hospital functions, it has been necessary for many physicians in this community to go above and beyond to assure that the patients we serve receive the best care possible.

My urological partner and I were put in a position years ago in which it was necessary for each of us to put ourselves at financial risk to guarantee that our patients would have access to the equipment and staff necessary for lithotripsy treatment. We knew what our patients needed and we did what it took to take care of our patients. Working together with other rural urologists we pooled capital to share a mobile lithotripter which is now helping patients all over North Central Arkansas.

This lithotripsy procedure is one which must be done at our hospital for numerous reasons. Our local hospital provides significant support in the care, anesthesia, and post operative monitoring of these patients. The legislation which is currently being considered by CMS would prohibit the hospital from billing for this procedure merely because the hospital wasn't able to afford the machine. This is ridiculous. **They are the only hospital in this county.** They are providing vital support.

This legislation will basically outlaw this treatment to rural Arkansans and all rural Americans. This legislation is attacking the care of our patients under such phrases as "Under Arrangements, Per Click Fee, Percentage Fee Arrangements, Stand in the Shoes, and Burden of Proof".

I understand the desire of CMS to stop fraud and abuse. Stopping medical care will do that but certainly you realize there has got to be a better way. You will NEVER help people by denying them care!!!!!

Where there is abuse; SMASH IT!!! But don't let political paranoia withhold medical care from people in need. The same holds true for cryotherapy and laser prostate ablation. Just because these procedures are being performed at a hospital does not prove abuse. Putting the burden of proof on innocent physicians obviously needs to be reevaluated. It's hard to believe I needed to even write that last sentence!

Think about what you are doing! My patients are just elderly and frequently poor Arkansans who did not think ahead far enough to retire in Washington, D.C.

- In the ALS v. Thompson case the court held that 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.

I am asking that CMS:

- Accept the burden of proof that the law has historically placed upon the one creating the rules, and not try to shirk their responsibility,

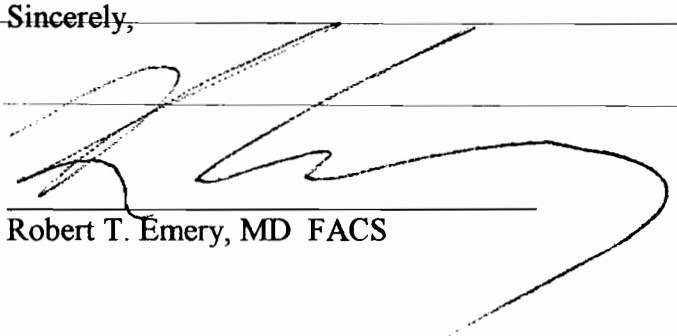
- Clarify that as a result of the ruling in ALS v. Thompson lithotripsy would not be subject to the proposed under arrangements restrictions,

- 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 in an ASC to clarify that legitimate joint ventures are not forced to abandon all ASCs with any hospital participation.

Sincerely,



Robert T. Emery, MD FACS

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Alliance for Pediatric Quality

August 31, 2007

Mr. Drew Morgan
Centers for Medicare and Medicaid Services
Department of Health and Human Services
ATTN: CMS-1385-P
PO Box 8018
Baltimore, MD 21244-8018

Dear Mr. Morgan:

The following is a response from the Alliance for Pediatric Quality to the Center for Medicare and Medicaid Services' recent Proposed Rule addressing the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions.

To establish a unified voice for issues related to improving the quality of pediatric health care, four national organizations recognized as leaders in pediatrics formed the Alliance for Pediatric Quality (Alliance). These organizations are the American Academy of Pediatrics (AAP), The American Board of Pediatrics (ABP), Child Health Corporation of America (CHCA) and the National Association of Children's Hospitals and Related Institutions (NACHRI). Our intent is to measurably improve the quality of health care for America's children by exercising greater influence on the national pediatric quality agenda. Priority areas for action are quality measurement and improvement, health information technology and strategic national relationships.

We appreciate the opportunity to submit comments to this Proposed Rule. If you have any questions, please contact me at bmarshall@aap.org or 800/433-9016, ext 4089. In keeping with our mission we support this important endeavor and believe the AAP should continue to participate in the future.

Sincerely,

Rebecca Marshall

Rebecca Marshall
Manager, Health Information Technology Initiatives
American Academy of Pediatrics

BM/

On behalf of the Executive Team for the Alliance for Pediatric Quality:

Robert Perleman, M.D.
American Academy of Pediatrics

Ed Zimmerman, MS
American Academy of Pediatrics

Paul Miles, M.D.
The American Board of Pediatrics

Donna Payne
Child Health Corporation of America

Mary Gorman
National Association of Children's Hospitals and Related Institutions

Alliance for Pediatric Quality Comments on the Centers for Medicare and Medicaid Services Proposed Rule: Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions August 31, 2007

The Alliance for Pediatric Quality (Alliance) is pleased to offer comments on the Proposed Rule to eliminate the exemption of computer-generated fax prescriptions from adhering to the National Council of Prescription Drug Programs (NCPDP) SCRIPT standard. The Alliance supports the concept of e-prescribing. In June 2007, the American Academy of Pediatrics, an Alliance member organization, published in its journal, *Pediatrics*, a policy statement titled, "E-Prescribing in Pediatrics: A Rationale and Functionality Requirements." The policy statement was accompanied by a technical report of the same title.

In order for a prescription to be successfully transmitted electronically from the provider to the pharmacy, both the provider and the pharmacy must have the appropriate technology available and in place. If the pharmacy can accept electronic prescriptions, but the provider cannot send them, the provider will likely either revert to hand-written prescriptions or print out the computer-generated prescription for the patient to carry to the pharmacy. If the provider can send SCRIPT-compliant electronic prescriptions but the pharmacy cannot receive them, there may be confusion and delays in filling the prescription, which may result in the patient missing scheduled doses and/or multiple phone calls between the pharmacy and the provider to locate the prescription. In this case, it is also likely that the provider would revert to hand-written or printed prescriptions until he or she is certain that the local pharmacies can accept electronic prescriptions. Before this rule is implemented, at least 90% (or more) of pharmacies should be able to accept SCRIPT-compliant e-prescriptions.

In addition, many electronic health record (EHR) vendors are only just beginning to offer SCRIPT-compliant e-prescribing to providers. While the Certification Commission for Health Information Technology (CCHIT) now requires certified EHR vendors to be able to generate SCRIPT-compliant e-prescriptions (for 2007 certifications), some vendors may charge providers an annual fee to switch from computer-generated faxing to SCRIPT-compliant e-prescribing, or providers may need to upgrade their systems to the more recent, 2007 CCHIT-certified version. Providers, particularly those in solo or small group practices, may not have sufficient financial incentive to invest in the upgraded technology and will revert to hand-written or printed prescriptions.

The Alliance for Pediatric Quality supports the elimination of the exemption for computer-generated faxes, but believes that more time is needed to educate providers about this change, to allow providers to communicate with local pharmacies to ensure that SCRIPT-compliant electronic prescriptions will be accepted, to allow providers to prepare for any financial burden required to make the change, and to allow sufficient time for providers to upgrade their systems and conduct tests of the system with local pharmacies. We therefore recommend that the exemption be eliminated no sooner than January 1, 2010.

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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

August 27, 2007

Ladies and Gentlemen:

I am a urologist practicing in Ocala, Florida, located in North Central Florida. We have been providing lithotripsy and prostate laser services to area hospitals through a urology joint venture. It has come to my attention that CMS has targeted such partnership arrangements as being inappropriate. I feel that without such a partnership, the Medicare and Medicaid recipients in the area, as well as the commercially insured and of course the uninsured, would not have these services available. This is because hospitals in this area are reluctant to invest hundreds of thousands of dollars into such technology, because they understand that the utilization of these services falls below that necessary to sustain the expensive equipment.

By forming these partnerships, we as urologists, who understand the technology and its value to our patients, including many Medicare and Medicaid recipients. In our particular situation, the equipment is mobile and covers three counties in North Central Florida. If it were not for this partnership arrangement, these services would not be available to us in North Central Florida. Some claim that these services are available through providers not affiliated with the physicians. While this is partially true, no other provider will meet our needs. Let me illustrate one true-life experience I had.

I admitted a patient through the Emergency Department of a hospital, which does not contract with the partnership for lithotripsy or laser services. The patient had a stone with intractable pain and could not be discharged without treatment. The treatment of choice was lithotripsy. When I tried to arrange the lithotripsy, the vendor providing the services to this hospital said they could send a unit from Tampa, some 100 miles away, in 2-3 weeks. Option number two was ureteroscopy and laser. Again, the laser vendor was based in Tampa and could be in the Ocala area in 2-3 days. I discussed this with the patient, and we transferred the patient to the hospital, which contracted with the partnership, and I was able to arrange treatment that same day. This is because the partnership's equipment and staff is responsible to us, and several day's or week's delay in treatment is unacceptable to us, but obviously it is acceptable to an unaffiliated vendor.

The CMS proposals which would jeopardize the practice of urology and the successful providing of medical services to Medicare and Medicaid recipients are those affecting 'under arrangements', 'per click fee', 'percentage fee arrangements', and burden of proof'.

Services in our area are only available to our patients because we physicians have brought the technology to the area. If it were not for the 'under arrangement'

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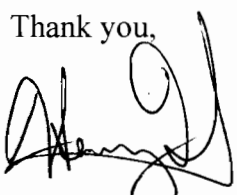
scenario, these patients would be subjected to more invasive treatment, necessitating longer hospital stays and more complications. Urology joint ventures such as these are for treatment and not for diagnostic testing, and are therefore not amenable to abuse, unless there is fraud being perpetrated. If CMS feels that some partnerships are fraudulent, then investigation of those partnerships is in order, not a blanket ban on such arrangements. If the 'under arrangements' prohibition is carried through, the Medicare and Medicaid recipients in our area will definitely be adversely affected.

The arrangements for providing these services often have 'per click fee', or 'percentage fee' arrangements. This type of business arrangement is for the benefit of the hospitals, as it allows the hospital to provide the new technology and beneficial services, while limiting its exposure. Most hospitals are under tighter and tighter fiscal restrictions, due to the uninsured, increasing expense of qualified nurses and staff, and a variety of other economic pressures. These payment arrangements are common practice in other businesses for good reason; they make good sense and benefit all involved. Prohibiting such arrangements would make new technology and equipment beyond the reach of only the largest, and government sponsored hospitals.

The 'burden of proof' proposal, as I understand it, would require me, the provider, or the hospital, or both, to prove that the arrangement is not in violation of the law. Though I am not a Constitutional attorney, I believe that a person should be innocent until proven guilty. In any court cases in which I have been an expert, the burden of proof is always on the prosecution NOT the defense. I believe that placing the burden of proof on the providers in unfair and probably unconstitutional.

I would like to summarize by stating that therapeutic services provided by 'under arrangement' joint ventures and partnerships have brought new technology and better care to millions of Medicare and Medicaid recipients so far, and would probably be expected to continue as such. If allowed to continue, new and often expensive technology would be available to many hospitals, which would otherwise not be able to afford the technology and equipment if not for these arrangements. If there are specific arrangements or ventures, which are abusive or fraudulent, CMS should investigate those, instead of a blanket policy prohibiting the good with the bad. The 'per click' and 'percentage fee' arrangements which many hospitals favor, help bring financially marginal, but clinically beneficial treatment to millions of Medicare and Medicaid recipients, and should be allowed to continue. Finally, the burden of proof for compliance with the prevailing laws should rest with the regulatory agencies charged with doing so, not with the accused.

Thank you,



Harvey Taub, M.D.

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August 27, 2007

VIA FEDEX

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: IDTF Issues

To Whom It May Concern:

Thank you for the opportunity to submit these comments on CMS-1385-P, "Proposed Revisions to Payment Policies under the Physician Fee Schedule and other Part B Payment Policies for CY 2008," with respect to IDTF Issues. Our specific comment concerns the proposed new standard applicable to the operation of an Independent Diagnostic Testing Facility ("IDTF"), 42 C.F.R. §410.33(g)(15), which would provide as follows: "Does not share space, equipment, or staff or sublease its operations to another individual or organization." CMS proposes that this new standard would apply only to fixed-base (physical site) IDTFs but is also seeking comment on establishing a similar requirement for mobile IDTFs.

Please clarify whether the proposed prohibition on sharing of space, equipment and staff is intended to apply to an arrangement where an entity that operates a Medicare-certified IDTF leases or subleases space and/or qualified technical staff for the operation of the IDTF from a hospital on a full-time, exclusive basis. If the arrangement between the parties includes leased space and staff on a full-time basis, arguably the staff and space are not "shared" by the IDTF and the hospital. Therefore, such leasing or subleasing arrangements should be permissible under proposed §410.33(g)(15). However, the terms of the proposed standard §410.33(g)(15) are not sufficiently clear to determine whether the leasing/subleasing model described above

would be permissible. Therefore, please clarify whether CMS interprets §410.33(g)(15) to prohibit an IDTF from entering into a full-time lease or sublease of space, staff or equipment with a hospital.

We also seek clarification of CMS' statement that fixed base (physical site) IDTFs may not commingle waiting rooms or receptionists. In some cases, an IDTF may lease or sublease space on an exclusive basis from a hospital in a hospital-owned building where the physical configuration of the building may require the use of a central waiting area for all patients, with a reception desk that is manned by both hospital personnel (for patients seeking hospital services) and IDTF staff. IDTF reception staff then direct IDTF patients down a common hallway to the space occupied by the IDTF on an exclusive basis. The use of the common waiting area and common hallway are addressed in the lease or sublease that is drafted to comply with applicable regulatory safe harbors and/or exceptions. Please clarify whether CMS will permit an IDTF to utilize a common waiting area in a building where the IDTF enters into a lease or sublease with a hospital for the full-time, exclusive use of space for the operation of the IDTF.

We further ask that CMS clarify whether CMS intends to prohibit only new space, equipment, or staff sharing arrangements from the effective date of the rule when published as final and will grandfather such arrangements already in place as of the date of publication of the final rules, or whether CMS will require such existing arrangements to unwind. If CMS does not intend to grandfather existing arrangements, we request that the effective date for the implementation of §410.33(g)(15) be delayed until January 1, 2009 to permit existing arrangements to be restructured to come into compliance with the standard and suggest that CMS issue further sub regulatory guidance to ensure the provider and supplier community is aware of what types of arrangements are permitted.

Finally, we request that CMS clarify whether proposed §410.33(g)(15) will permit an IDTF that leases or subleases space and/or staff from a hospital to purchase back-office services from the hospital. These types of services may include, for example, transcription, billing, collection, recordkeeping, and computer access services, payable either based upon a flat fee set in advance, or at cost plus to the hospital. Purchasing these types of services do not appear to qualify as leasing or subleasing "space, equipment or staff" or subleasing the operations of the IDTF to another individual or organization and should be permitted to encourage efficiency in the delivery of services by the IDTF.

As requested, we have enclosed two copies of the original of this letter. Thank you for your consideration of these comments.

Respectfully Submitted,

STEVENS & LEE

Catherine R. Urban

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BAY AREA RENAL STONE CENTER
FOR THE TREATMENT OF KIDNEY STONES

6002 49th Street North, St. Petersburg, FL 33709-2139
Telephone: 800-225-ESWL or 727-521-3929
web site: barsc.com

August 27, 2007

Centers for Medicare and Medicaid Services
Dept of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-1850

Re: Physician Self-Referral Provisions

Dear Sir or Madam:

Bay Area Renal Stone Center was established in 1986 by urologists and has been providing urologic services to urologists and their patients on the West Coast of Florida since that time.

HealthTronics is now the General Partner and over 100 urologists have varying degrees of ownership. Shock-wave lithotripsy, stone, and prostate laser services are provided at a fixed site in St. Petersburg. Medicare beneficiaries utilize the outpatient services through an under-arrangement contract that BARSC has with a local hospital facility.

We also provide mobile shock-wave lithotripsy and laser services on a per click basis with over 65 facilities located on the West Coast of Florida. Our services are accredited by JCAHO and we have been very proud of our reputation as a quality provider of shock-wave lithotripsy/laser services for over 20 years!

We are very concerned with the proposed regulations and the negative effect that it would have on our urologists and their Medicare patients should several of the proposed regulations be approved. We offer the following comments.

Since February, 1987, we have been contracting with a local hospital (under arrangement) to provide all local Medicare patients quality shock-wave lithotripsy and laser services. A Certificate of Need was given by the State of Florida to build our free-standing site. We are not an ASC. Urologists bring their patients from several counties to avail them of our nationally-recognized services. We contract and are paid directly by third party payors for our services. Since we are not an ASC or hospital, there is no direct payment available from Medicare to cover our services to your beneficiaries.

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. The current proposal will stop all care to local Medicare recipients if we can not provide services under arrangement.

There has been controversy for many years regarding physician ownership. The designated health services should not include physician-owned entities merely because they provide outpatient hospital services. Most urology joint venture services are therapeutic services. There have never been reported abuses in this area because of ownership. In 1992, Florida studied therapeutic versus diagnostic services and came to the conclusion that there was no over-utilization when physicians have ownership in and render therapeutic services. Also, our facility since 1986 has an established Medical Advisory Board that works to ensure that safe, quality and appropriate services are provided by highly trained technologists under the direction of the patient's urologist to care for their patients.

We have nine expensive shockwave lithotripsy units that travel throughout the West Coast of Florida. The facilities we provide service to schedule our services when patients and their urologists are in need of our services. The facility saves money by not having to buy expensive equipment which may be used only one day a week or less.

Per Click Fee Ban: We provide services to those facilities on a per click basis. That way the hospital facility only pays us for actual service rendered. We provide only therapeutic services through our joint venture. The urologist documents on the hospital chart pre-procedure exactly what the patient disease process is and the need for treatment prior to providing the per click service. We bill the hospital monthly for services rendered on a per click basis just as the hospital bills third party payor and Medicare for services rendered and is reimbursed on a per click basis.

The facilities do not want to buy the expensive equipment nor do they want to pay us a set fee that may be higher than what they would pay on a per click basis. We provide service to many facilities that have a low volume of patients. They would not be able to provide these services without service agreements through a joint venture such as ours.

In ***ALS vs. Thompson***, lithotripsy was clarified as to not be subject to proposed under-arrangement restrictions. We request that under arrangement provisions be allowed for therapeutic services by urology joint ventures. We request that the prohibition of per click fees related to these same joint ventures providing out-patient hospital services be dropped to allow this continued cost-effective sharing of technology.

Sincerely,

Margie Irvin

Margie Irvin, CEO
E-mail: mirvin@barsc.com

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN™

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August 23, 2007

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Leslie V. Norwalk, Esq.
Acting Director
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 443-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Program; 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 Ms Norwalk:

The American Academy of Pediatrics (AAP) appreciates the opportunity to provide comments on the July 12th 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 Rule." Although very few pediatric services are included in the Medicare program, payment policies introduced in Medicare are frequently adopted by the Medicaid program and eventually by private payers.

The Academy offers comments on the following issues to ensure that CMS policies appropriately accommodate the unique aspects of health care services delivered by primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists:

- Medicare Conversion Factor and Five-Year Review Work Adjuster
- Echocardiography Services
- Moderate (Conscious) Sedation
- Preventive Medicine Services and the Medicare Primary Care Exception
- Pulse Oximetry

[Please see Appendix A for detailed comments on these issues.]

The Academy appreciates the opportunity to provide comments on the July 12th proposed rule and looks forward to working with CMS to ensure that the physician fee schedule accurately reflects the work value of physician practice and pediatric care.

Sincerely,

Jay E. Berkelhamer, MD, FAAP
President

JEB/ljw

Appendix A
AAP Comments
July 12th Notice of Proposed Rulemaking
"Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Rule

Medicare Conversion Factor and Five-Year Review Work Adjuster

While we are disappointed that a legislative fix has not yet been introduced to eliminate the need to propose annual cuts in the Medicare conversion factor, we understand that CMS must do so in an effort to maintain budget neutrality. Adjustments to the Medicare conversion factor are certainly preferable to the approach CMS adopted last year, when a separate Five-Year Review Work Adjuster was implemented on top of the initial reduction to the conversion factor.

In its proposed rule, CMS announces that the Five-Year Review Work Adjuster will increase from -10.1% to -11.8%. The Academy strongly urges CMS to eliminate this work adjuster since the rescaling of work relative value units (RVUs) to offset the Five-Year Review improvements causes confusion among non-Medicare payers and impedes the process of establishing work RVUs for new and revised services. CMS should instead apply any necessary adjustments to the conversion factor.

Echocardiography Services

CMS proposes to bundle CPT code 93325 (*Doppler echocardiography color flow velocity mapping*) into codes 76825, 76826, 76827, 76828, 93303, 93304, 93307, 93308, 93312, 93314, 93315, 93317, 93320, 93321, and 93350. This runs counter to the CPT Editorial Panel's recommendation that 93325 be bundled *only* with code 93307. CMS' unilateral decision concerns us due to its lack of administrative due process, the extremely negative impact this regulatory action will have on pediatric cardiology 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 has approved the development of a new code for 2009 that will combine 93325 with 93307 and 93320. The American Medical Association/Specialty Society Relative Value Scale Update Committee (RUC) will be considering recommendations for work and practice expense for this new code during its September 2007 meeting.

This new code is fully expected to address any outstanding issues relative to current Medicare utilization of 93307, which is predominantly reported in older patient populations. Furthermore, this new code was developed after extensive research and involvement by stakeholder national medical societies, the CPT Editorial Panel, and the RUC.

As a result of CMS' proposal to bundle 93325 into CPT codes other than those recommended by the RUC/CPT Editorial Panel, the 93325 bundling issue now directly impacts a distinctly non-Medicare population -- pediatric cardiology. Furthermore, 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 pediatric cardiology and develop appropriate new work and practice expense recommendations for consideration by the RUC.

Our second concern focuses on the extremely adverse impact this proposal will have on pediatric cardiology. The surveys performed to set the work relative value units (RVUs) for almost all of the echocardiography 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 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, 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 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 echocardiography laboratory 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 payers 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, we are concerned with proposals that place adult and pediatric patients in the same grouping, as it pertains 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 practice 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. [please 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. In 1997, *CPT Assistant* referenced the uniqueness of the 93325 for the pediatric population, stating that Doppler color flow velocity is "... even more critical in the neonatal period when rapid changes in pressure in the pulmonary circuit can cause significant blood flow changes, reversals of fetal shunts and delayed adaptation to neonatal life." It should also be recognized that Doppler flow velocity mapping is an essential medical service being provided to patients with congenital and non-congenital heart disease in the pediatric population.

The following vignettes will illustrate the importance of the Doppler color flow velocity mapping (93325) remaining as a separate and distinct medical service and as an add-on code (+) for pediatric echocardiography services. These are just a few examples of the many complex anatomic and physiologic issues that pediatric cardiologists typically face on when performing echocardiograms on infants and children with complex congenital or non-congenital heart disease.

Vignette I: Congenital Heart Disease (*CPT Assistant* 1997)
A three-day-old neonate with transposition of the great vessels was initially treated with an atrial septostomy with a planned arterial switch procedure at seven days. On the third day post Raskind balloon septostomy increasing cyanosis is seen with saturation dropping to the low 70s. A repeat transthoracic echocardiography (93304) with color flow Doppler study is performed (color flow Doppler is coded in addition as a 93325). The physician reviews the echocardiographic images and prepares a report. The echocardiogram shows a closed patent ductus arteriosus and a small atrial septal defect. The child is returned to the cath-lab for a repeat septostomy and prostaglandin is restarted.

Vignette II: Non-Congenital Heart Disease
A two-month-old infant is referred by the pediatrician to a pediatric cardiologist for a persistent murmur in an otherwise healthy infant. The pediatric cardiologist is concerned about a patent ductus arteriosus as a possible diagnosis. A ductus arteriosus, connecting the pulmonary artery and the aorta, is an essential structure during fetal life. Normally, the ductus arteriosus closes in the first few days after birth in healthy term infants. A persistent ductus arteriosus can give rise to long-term complications and needs to be followed carefully to evaluate if further intervention is needed (medical vs. surgical). Echocardiography permits an accurate diagnosis of a patent ductus arteriosus with assessment of both the hemodynamic impact if there is a shunt. Estimated pulmonary artery pressure is obtained by Doppler imaging and can exclude other associated defects also. Color flow Doppler will be able to outline the flow of a patent ductus arteriosus from the aorta to the pulmonary artery. Color flow Doppler in this baby revealed no cardiac defects or patent ductus arteriosus and the murmur was determined to be innocent.

Vignette III: Congenital Heart Disease
An eight year-old child, with complex cyanotic congenital heart disease (functional single ventricle) is post-op completion of a fenestrated Fontan procedure several years ago. He has had a progressive decrease in saturations over the last year. There are several possible explanations and the pediatric cardiologist performs an echocardiogram to help determine the etiology. Color flow Doppler (93325) is essential to help elucidate the postoperative anatomy and blood flow patterns, but the process is complex and time-consuming involving assessment of the surgically constructed lateral tunnel or extracardiac conduit searching for a residual fenestration shunt or obstruction to flow, assessment of flow patterns through the previously surgically constructed Glenn anastomsis between the superior vena cava and pulmonary artery, assessment for obstruction to flow through the bulboventricular foramen, assessment for significant AV valve or semilunar valve insufficiency, and assessment for collateral vessels directing venous (desaturated blood) into the heart that may have developed over time. Any or all of these findings will then help dictate the next step in the care of this patient.

Finally, we are concerned that this change will adversely impact access to care for pediatric cardiology patients. Since this proposal will ultimately be reflected in Medicaid and commercial payment rates, it effectively reduces payment for pediatric cardiology services. The effect of this change on pediatric cardiology programs throughout the country will likely be an increase in the need for subsidies from already resource-challenged children's hospitals and academic programs, or a significant increase in Medicaid payment for the proposed bundled services in order for pediatric cardiology patients to have the same access to care and resources that they do today.

Moderate (Conscious) Sedation

The moderate sedation codes (99143-99150) are included on the fee schedule as Status Indicator "C" (Carrier Priced), with no published RVUs. Given CMS' direct involvement in the development of these codes, it disappoints us that the Status Indicator for the codes is "C". Furthermore, we are dismayed that CMS continues not to accept the April 2005 RUC recommendations for the codes and publish them in the 2008 RBRVS proposed rule.

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

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

Providing moderate sedation to patients undergoing certain outpatient procedures requires a certain level of provider skill and training and incurs medical legal liability, but is also associated with greater patient satisfaction, improved outcomes, and cost savings over similar procedures provided with anesthesia in an operating room. Furthermore, the far-reaching shortage of pediatric anesthesiologists at children's hospitals has created the need for moderate sedation services provided by other hospital-based physicians. In most metropolitan areas of the United States, these children's hospitals form the safety net for subspecialty care provided to children in the Medicaid program. This critical service is directly supported by the publication of relative values of these codes.

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

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

Preventive Medicine Services and the Medicare Primary Care Exception

Over the past four years, the Academy has made several requests for CMS to consider including preventive medicine services as part of the Medicare primary care exception. We take this opportunity to reiterate our request.
When CMS revised teaching physician rules (Medicare Carriers Manual Transmittal 1780, November 22, 2002), a "primary care exception" was established (§15016(C)(3)). This exception permitted the teaching physician to submit claims to Medicare for certain low and medium intensity Evaluation and Management services (99201-99203, 99211-99213) furnished by residents, subject to certain oversight rules, in a primary care clinic.

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

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

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

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

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

Preventive Medicine Service	New	Established
Infant (<1 year)	99381	99391
Early childhood (1-4 years)	99382	99392
Late childhood (5-11 years)	99383	99393
Adolescence (12-17 years)	99384	99394
Early adulthood (18+ years)	99385	99395

S0302 Early Periodic Screening Diagnosis and Treatment (EPSDT)

Pulse Oximetry

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

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

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

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ForTec Medical Inc.®

Your Medical Laser Rental Company

August 27, 2007

Re: Stark III Proposal

Mr. Donald H. Romano:

I am writing this letter in support of The Stark III proposal now in the comment period.

As a sales manager in healthcare, I have seen gross abuses of the current Stark Law, which include, but are not limited to:

1. Investments in treatments beyond ESWL, such as lasers, brachytherapy, and cryotherapy.
2. Doctors who threaten hospitals into using the doctor's company
3. Hospitals that violate contracts because they feel that the ramifications of a broken contract will be less severe than not letting the doctor have his/her way.
4. Doctors who steer patients to equipment they own, rather than use a third party that the hospital is contracted with, even if it means having the patient travel to a non-convenient hospital. Hospital administrators are aware of steerage, but fear that turning their docs in will just mean more lost business.

Once again, I am in full support of your proposed regulations and the hope that they carry with it...the hope that the urology sector of healthcare will return to the ethical standards it upheld prior to the proliferation of doctor owned LLCs a few years ago.

Further, our industry needs to have the aforementioned issue addressed. If left unchecked, this trend will transcend urology and will affect other specialties.

Sincerely,

James Soltis

James A. Soltis
Regional Sales Manager

www.fortecmedical.com/www.laserrental.com

▶Corporate Headquarters ▶10125 Wellman Road ▶Streetsboro, OH 44241 ▶Tel: (800) 963-7101 ▶Fax: (330) 655-8894

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8277 Wind Song Drive
Olive Branch, MS 38654

August 27, 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: File Code CMS-1385-P
Physician Self-Referral Provisions
Section II.M.3; In-Office Ancillary Services Exception

Dear Sir or Madam:

I am a physical therapist working within a physician owned physical therapy practice. I would like to strongly encourage keeping the current Stark Laws as they are and continue to allow physical therapists and physicians to work hand in hand in this model. I have worked in all types of settings from hospitals, to private practice, to corporations, to physician owned practices, and my current setting in a physician owned setting is far and away the best model for the patients.

Working in the same office with the physicians dismantles the barriers of communication that used to hinder my treatment when I was in private practice. Also working on the same technological platform as the physicians allows me to easily access physician notes, operative reports, return to work forms, etc. that might be pertinent to the patient's treatment plan. Probably one of the most satisfying things about working in a physician owned setting is that none of the therapists are motivated, in most circumstances, to improve their personal profits by over-billing and increasing the length of stay such is the case in most private practices and corporate settings.

In a physician owned model we are able to get patients better in 30-40% fewer visits, secondary to quicker entry into rehab, which in turn results in 30-40% lower case cost for payors. The patients satisfaction surveys we conduct are over 98% positive and patients overwhelming tell us that they fell their care was a 5/5. Patients also felt very positive about having their physician so close in case of questions or problems. And speaking of problems this model makes it very easy to get immediate physician attention when contraindications are encountered in therapy.

Please leave the Stark Laws as they are and allow physical therapy to remain in-house in physicians' office for better communication, better patient care, and lower case cost.

Sincerely,

Greg Perry

Greg L. Perry, PT

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August 27, 2007

Mr. Herb B. Kuhn
Acting 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: Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008

Dear Mr. Kuhn:

We are pleased to submit these comments on the proposed rule for Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 on behalf of the American Association for Geriatric Psychiatry (AAGP). The AAGP is a professional membership organization dedicated to promoting the mental health and well-being of older people and improving the care of those with late-life mental disorders. Our membership consists of more than 2,000 geriatric psychiatrists as well as other health care professionals who focus on the mental health problems faced by senior citizens. Our comments will address the proposed increase in work RVUs for certain nursing facility codes and the proposed conversion factor update for 2008.

Proposed Work RVUs for Nursing Facility Services

CMS proposes to accept the recommendations of the AMA's Specialty Society Relative
Value Update Committee (RUC) for the seven codes that describe initial nursing facility care, subsequent nursing facility care and an annual nursing facility assessment (CPT codes 99304-99310). We strongly support the proposed changes, which are consistent with our position that the physician work of nursing home care has increased as the acuity and complexity of the nursing home patients and the regulatory burden associated with their care has increased.

AAGP participated in the survey that resulted in RUC recommendations for increased work RVUs for all the codes in this family. Our analysis indicates that if the conversion factor does not change in 2008, the payments for these services will increase by more than $164 million over what they would have

been absent these changes. We wish to express our appreciation to the RUC and to the CMS staff who worked closely with us and with the other physician groups whose members provide care to this vulnerable population. The timing of the changes in the nursing facility codes and the 5-year review cycle required special consideration without which the necessary changes in work RVUs would not have occurred.

Proposed Conversion Factor Update for 2008

Ironically, the appropriate changes in payment for nursing facility care described above will be largely wiped out by the proposed -9.9 percent update of the conversion factor for 2008. We continue to be deeply concerned about the impact of the sustainable growth rate (SGR) formula on payments for nursing facility care and all the psychiatric services under the fee schedule. We believe if a reduction of this magnitude is put into place, the quality of care and beneficiary access to physicians' services will be adversely affected. We again urge you to use your discretion to revise the calculation of physician expenditures and to support efforts in Congress to replace the SGR policy.

Specifically, we do not think physician expenditures should include the cost of prescription drugs furnished incident to a physician's service. As you know, drugs administered in a physician's office are not paid for under the physician fee schedule; including them in the estimates of spending under the fee schedule holds physicians accountable for an expense that is largely outside their control, and one that is rising very rapidly.

In addition, we believe that the estimate of physician expenditures should be adjusted to account for increased outlays related to new national coverage decisions. Coverage decisions that expand beneficiary access to advancements in medical diagnosis and treatment should be treated in a manner similar to changes in law and regulation that are expected to affect outlays for physicians' services. In our view, there is no difference between a change in law that extends Medicare coverage and a change in national coverage policy initiated by CMS.

For psychiatry, a negative update to the fee schedule and other changes in work and practice expense relative value units (RVUs) would result in a 10 percent reduction in total Medicare payments for the specialty in 2008. This cut comes in the face of forecasted increases in practice costs. For our members who predominantly care for patients over age 65, these payment policies are likely to threaten the financial viability of many of their practices. Current payment rates already fail to recognize adequately the added costs of caring for a frail population with multiple chronic conditions and the additional time that must be given to family members and care givers.

While we do not have evidence of a significant increase in the number of psychiatric practices that have placed limits on new Medicare patients, our members are especially vulnerable to these limitations. We do know that a number of geriatric psychiatry practices are near bankruptcy or have been forced to close. Many other geriatric psychiatrists are actively re-evaluating the financial feasibility of maintaining their geriatric practice. At a time when there is growing evidence of undiagnosed and untreated mental illness in the senior population, these policies are likely to erode access to mental health care for growing numbers of elderly and disabled beneficiaries.

Conclusion

We strongly support the proposed increases in work RVUs for nursing facility care. Regrettably, these increases will do little to overcome a proposed 9.9 percent across the board cut in payment for these and all other services we provide. In sum, the payment policies for the Medicare Physician Fee Schedule combined with the limited and discriminatory Medicare benefit for mental illness care can further burden Medicare beneficiaries and jeopardize their access to effective treatment. We are deeply troubled by the prospect of reduced payment for the services of geriatric psychiatrists at a time when there is evidence that these practices are struggling to remain financially viable. We believe that CMS should take every opportunity to exercise its discretion to expand access to psychiatric services for Medicare beneficiaries. We hope you will reconsider your options for updating the fee schedule and will join with us in asking Congress to replace the current SGR policy.

Thank you for this opportunity to comment on the proposed rule.

Sincerely,

Gary Moak, MD
President

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PUEBLO CARDIOLOGY ASSOCIATES, P.C.

CARDIOVASCULAR DISEASES

Christian Stjernholm, M.D., F.A.C.C.
Jack A. Boerner, M.D., F.A.C.C.
James A. Sbarbaro, M.D., F.A.C.C.
John M. Stachler, M.D., F.A.C.C.
Stephen D. MacKerrow, M.D., F.A.C.C.
George Y. Paik, M.D., F.A.C.C.
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Matthew T. Sumpter, M.D.

1925 East Orman Ave., #A640
Pueblo, CO 81004
(719) 564-1544

Aug. 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 physician in Pueblo, Colorado and 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.
- The arranged-for service avoids duplication of services.
- The hospital has problems raising the necessary capital.
- 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,

Jack Boerner, MD

cc: Tom Crane

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Vascular Center of Pueblo, LLC

1008 Minnequa Avenue, Suite 100, Pueblo, CO 81004

August 27, 2007

VIA FEDERAL EXPRESS

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 writing on behalf of the Vascular Center of Pueblo ("VCP") as a supplemental submission to the letter written by Tom Crane of the law firm, Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C. We write this letter to express our objection to CMS's proposed changes to the Stark regulation related to under arrangement services that would have the effect of creating an impermissible physician ownership in a DHS entity. We offer the following comments to give our unique perspective of the history, operation, and compliance measures of VCP.

VCP is a Colorado Limited Liability Company owned one-half by four physicians who specialize in cardiology, and one-half by the local hospital. VCP has seven (7) non-physician employees including nurses, registered cardiovascular invasive specialists, clerical and administrative workers. VCP has a six (6) person Board of Managers, three of whom are cardiologists, appointed by the cardiologist owners, and three of whom are appointed by the hospital. One of the hospital Board appointees is the Chief Medical Officer of the hospital system. The Board meetings are generally focused on clinical activities and improvements. I am the VCP Medical Director and am supported by an Administrative Manager, and a Clinical Manager. Together we manage the company on a day-to-day basis.

VCP commenced operations in October, 2006 and has operated continuously since that time providing a full range of cardiac catheterization laboratory services to patients of our local hospital under arrangements with the hospital. Services we provide currently include diagnostic cardiac catheterization, percutaneous coronary interventions such as balloon angioplasty and stent, and implantation of permanent pacemakers and implantable cardioverter defibrillators.

VCP is located within the hospital, in space exclusively used by VCP. Patients are transferred between VCP and the hospital by gurney. VCP's clinic space is owned by the hospital, and rented to VCP for its use by a long term lease at market rates.

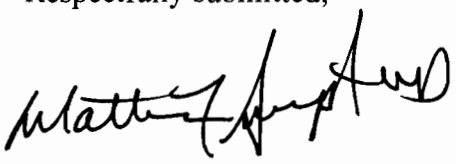
The vast bulk of the services are provided to the hospital based on flat fees for specific categories of service that include the full costs for these services (personnel, medical supplies and devices, equipment, space, etc.). Thus, VCP assumes the risk of all costs of providing the service, including the costs of medical supplies and implantable devices, the capital costs of x-ray, hemodynamic monitoring, and related accessory equipment, the capital and operating costs of the real property used by VCP, and the labor costs for all clinical and administrative employees.

The agreed-upon fees with the hospital are exhaustively reviewed. VCP has developed proprietary software to benchmark all costs of providing services, and to identify best practices for the delivery of care. In addition, all fees are reviewed periodically by a third-party valuation company to assure that such fees are fair market value. Each party fully understands this legal obligation.

Physician ownership and participation in the management of VCP has resulted in a business focused on clinical excellence and cost effectiveness. VCP participates in routine clinical performance activities of the hospital, such as: In its routine JCAHO inspections that are part of its review of the hospital: 1) VCP has never received a Request for Improvement (RFI). 2) VCP and the hospital participate in the American College of Cardiology's Cath, PCI, and ICD Registries where quality data is routinely reported and benchmarked to national results. In addition, the Physician owners have actively participated in the evaluation and implementation of cost saving measures, while maintaining a focus on clinical quality. VCP has demonstrated an on-going commitment to clinical care by establishing and reporting key quality indicators to the Board of Managers, while advancing new Quality Initiatives, such as joining the Colorado ACC Door-2-Balloon initiative program.

This history demonstrates why our arrangement with our local hospital provides clinical-driven cost-effective services. CMS would advance no legal or policy interests if it implements the changes it proposes.

Respectfully submitted,



Matthew T. Sumpter, M.D.
Medical Director

257

Jan Thomas Turley, M.D.
200 South 20th Street, Suite C
Rogers, Arkansas 72758
(479) 636-9669

Centers for Medicare and Medicaid Services
Dept. of Health and Human Services
Attn: CMS-1385-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

Dear Ladies and Gentlemen:

I am concerned that the new proposals from July 2, 2007 included in the proposed physician fee schedule for 2008 could adversely affect the patient care in my area. I have practiced in Northwest Arkansas for 34 years and in earlier years it was necessary to send the patients 4-5 hours to Little Rock, 3-4 hours to Tulsa, Oklahoma or to Kansas City for lithotripsy for renal stone or for other procedures including laser, cryoablation and microwave therapy/treatments for the prostate. I am concerned that these new proposals could set us back some twenty years in patient care. With these proposals, only the larger institutions will be able to afford the financial risk and volume required to support and sustain the offering and profitability of advanced urological treatment modalities. This, of course, is not in the best interest of physicians and patients living in rural areas.

The model in present use for lithotripsy has worked out quite nicely over the years. It has allowed physicians and patients the freedom of choice of different hospitals, operating room schedules and emergent local access to lithotripsy services. In this model, patients have benefited from access to trained, experienced personnel and equipment that is state of the art delivered to them locally in a very efficient manner. If we were to take a giant step back we would have none of this. Certainly, the quality of care for our patients would potentially deteriorate rapidly at increased cost or would vanish altogether.

Extracorporeal shockwave lithotripsy is not a designated health service (DHS) as previously upheld by ALS v. Thompson and may not fall under any of these rules but may be indirectly affected by fear of lack of reimbursement by hospitals or the unjust burden of proof associated with claim submission. The "per click" fee works well for both low and high volume facilities and allows for smaller, rural hospitals to offer these services locally to patients with little or no risk with adequate compensation. The percentage fee reimbursement is reasonable and fair. A weekly, monthly or yearly rental fee would not work given the great disparity of case loads and effectiveness of treatment. There is a definite financial gamble in technology and instrumentation. It places large financial risks on the hospital to invest in instrumentation (driven by local providers)

which may not remain as effective or become a gold-standard in the ever-changing area of surgical technology. Facilities would be forced to take financial risks with regard to instrumentation which may or may not live up to treatment expectations when they already have closets full of abandoned technology and instrumentation.

In some areas we have no free-standing ambulatory surgery centers (ASC). We do not have one in this area at this time. Our ASCs our partially hospital owned and, as such, would fall under these new proposed rules/regulations and would cause a disruption in patient care.

In my mind, I see a definite difference between *therapeutic* joint ventures where the patient is unarguably afflicted with a kidney stone or prostatic disease with the opportunity of treatment with new and diverse therapy options. Much of the aforementioned financial risk may be borne by the providers themselves in order to treat with the most up to date technology as deemed by our own peer group, not CMS. *Diagnostic* ventures are a separate issue and in my opinion should be looked at with different eyeglasses.

In summary, I would hate to see the "baby thrown out with the bath water" in broad, sweeping, new proposed self referral provisions. My personal experience has been with the lithotripsy services and they have been in one word – fantastic. The remainder of physician owned services will be proven or not in time. If treatment modalities are approved by the FDA and the insurance carriers, then we as physicians should be able to offer, and our patients should be afforded the opportunity to receive such treatment options and follow-up locally, provided by their local physicians. If you have read this far I thank you for hearing me out and I sincerely hope you do the right thing.

Respectfully,

Jan T. Turley, MD
Rogers, Arkansas

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DePuy Spine
a Johnson & Johnson company

DePuy Spine, Inc.
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August 28, 2007

Mr. Herb Kuhn
Director, Center for Medicare Management
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

Dear Mr. Kuhn:

RE: Comments on Interim Relative Value Units for CPT Codes 22857, 22862 and 22865 CY 2008 File Code 1385-P

DePuy Spine, Inc. (a Johnson & Johnson company) submitted a comment letter on the interim RVUs during the comment period for the Final Rule With Comment Period published in the December 1, 2006 Federal Register (71 FR 69624). This comment letter noted the practice expense (PE) Relative Value Unit (RVU) for CPT code 22857 was 32 percent less than the corresponding value for lumbar spinal fusion, CPT code 22558. On May 21, 2007, another comment letter was submitted to Ms. Amy Bassanno, Director of Practitioner Services, Centers for Medicare & Medicaid Services, from Johnson & Johnson Government Affairs & Health Policy requesting a revision to the PE RVUs for CPT codes 22857, 22862 and 22865.

In the Proposed Rule With Comment Period published in the July 12, 2007, Federal Register (72 FR 38122), there has been an increase of 2.47 in the PE RVU for 22857. It is our understanding that this increase in PE RVUs is due to reassigning the physician specialty mix from "All Physician" to Orthopaedic Surgery. We appreciated CMS changing this calculation.

As mentioned in our previous letter, as well as the letter submitted by the North American Spine Society, 22862 (Revision including replacement of total disc arthroplasty (artificial disc) anterior approach, lumbar, single interspace) and 22865 (Removal of total disc arthroplasty (artificial disc), anterior approach, lumbar, single interspace) are performed by the same specialty mix that performs code 22857.

We respectfully request that CMS use a similar calculation for the PE RVUs for related CPT codes 22862 and 22865 as was used for code 22857.

Thank you for your time and attention to this matter. I can be reached at either (610) 594-2282 or skelly8@dpyus.jnj.com. We would be happy to discuss this issue further.

Sincerely,

Susan Kelly

Susan Kelly

cc: Amy Bassano, CMS
Steve Phillips, J&J

National Cardiovascular Partners

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August 28, 2007

Mr. Herb B. Kuhn, Deputy Administrator (Acting)
Centers for Medicare and Medicaid Services (CMS)
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 Acting Deputy Administrator Kuhn:

National Cardiovascular Partners (NCP) (www.ncplp.com) is an innovative service delivery model founded on the belief that both patients **and** physicians can benefit from care provided by the physician in an environment designed with the needs of individual patients at the forefront. Our operational mission is to facilitate the formation of outpatient cardiac catheterization labs and hospital-based cardiovascular programs through physician partnerships, while constantly focusing on the management process in order to ensure strong and effective outcomes. NCP's unique approach in the healthcare arena is to maintain constant focus on the patient within a context of a quality based and economically efficient services. To date, NCP has affiliations with over forty board certified cardiologists in six distinct markets in Texas, within the cities of El Paso, Houston, San Antonio and Sugar Land. In 2008, NPC through its affiliated six partnerships is projected to provide services to over 7,500 patients, of which over 60% are Medicare beneficiaries. In fact, our corporate Medical Director, Patrick J. Cook, MD, FACC, FACP, who is associated with the Texas Heart Institute, has been meeting with Dr. Debra L. Patterson, Medical Director for TrailBlazer Health Enterprises, LLC for the purpose of expanding the scope of services provided in an outpatient cat lab facility. A copy of recent correspondence between Dr. Patterson and Dr. Cook, as well as a list of our physician partners is attached for your reference.

In order to accomplish this mission and take care of our patients, as they deserve, NCP is dependent on the sound and fair decisions of our policy and regulatory partners such as the Centers for Medicare and Medicaid Services. Toward that end, we are extremely concerned about the Resource-Based Practice Expense Relative Scale Value Update (PE RVU's) section of the above-referenced July 2, 2007 Proposed Rule. If the 2008-2010 PE RVU's established for non-facility outpatient cardiac catheterization procedure codes are implemented, a **significant** negative impact will result for our patients, our physicians, and our capacity to deliver services in an economically efficient model for CMS.

10000 Memorial Drive ■ Suite 540 ■ Houston, TX 77024
T: 713.812.7586 ■ F: 713.812.7594
www.ncplp.com

From a policy, parity and patient-benefit and protection perspective, the proposed payment methodologies are extremely problematic in that CMS has proposed **cutting** the 2008 Physician Fee Schedule (PFS) rate for cardiac catheterization care by 32.2% **at the same time** as proposing an 11.2% rate **increase** in the 2008 Ambulatory Payment Classifications (APC) for hospital outpatient catheterization services. Such a disparity makes no sense, and only harms patients in the long run.

NCP strongly urges CMS to listen closely and take action on the requests of our professional association, the Cardiovascular Outpatient Center Alliance (COCA), including conducting a thorough review of the additional cost data provided to you by the organization. We also respectively request that you establish PE RVU's for outpatient cardiac catheterization procedures that more reasonably reflect the direct and indirect costs of providing these procedures. If the current CMS proposals stand as they presently are, Medicare costs will rise and patients will suffer. Thank you for your attention to this matter of critical important to those whom we serve at National Cardiovascular Partners. Please contact us directly with any questions.

Sincerely,

David W. Budke
President

cc: Debra Patterson, MD
Medical Director, TrailBlazer Health Enterprises

Patrick J. Cook, MD, FACC, FACP
Corporate Medical Director, NCP

Steve Blades
COCA

Patrick Cook, MD
Arthur Springer, MD
Jaime Benrey, MD
Mark J. Schnee, MD
Michael J. Mihalick, MD
Jorge A. Garcia-Gregory, MD
Arup Achari, MD
Robert P. Walmsley, MD
Antoine Younis, MD
George Younis, MD
Surendra Jain, MD
Ifran Iftikhar, MD
Randeep Suneja, MD
George Mammen, MD
Anil Odhav, MD
Rajen Metha, MD
James Feldman, MD
Carmelo Otero, MD
Roman Pachulski, MD
Martin Radvany, MD
Stefan R. Kiesz, MD
Ron Mahoney, MD
Earl Magin, MD
Byron Ellis, MD
John Passmore, MD
Bruce Ennis, MD
Subroto Gangopadhyay, MD
Steven Yong, MD
Sangeeta Saikia, MD
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October 18, 2006

Via U.S. Mail
Debra L. Patterson, M.D.
Medical Director
TrailBlazer Health Enterprises, LLC
Executive Center III
8330 LBJ Freeway
Dallas, Texas 75243-0992

RE: Medicare Coverage of Interventional Cardiology Procedures

Dear Dr. Patterson:

As a cardiologist associated with the Texas Heart Institute and the medical director of Travis Center Angiography, a freestanding cardiac catheterization laboratory, I noted with interest TrailBlazer's recent revisions to its local coverage determinations ("LCDs") entitled "Interventional Cardiology: C-42AB-R1," and "Cardiac Catheterization – C-37AB-R7." Of particular interest was TrailBlazer's clarification that Medicare coverage of interventional cardiology procedures is limited to the inpatient or outpatient hospital context. Through this letter, I hope to initiate a dialogue with TrailBlazer regarding the future of Medicare coverage of interventional cardiology procedures, which I believe will ultimately extend to the non-hospital setting.

As you know, in 2001 the American College of Cardiology ("ACC") and the Society for Cardiac Angiography and Interventions ("SCA&I") issued a joint "Expert Consensus Document on Cardiac Catheterization Laboratory Standards." At that time, the ACC and SCA&I concluded that "the performance of elective coronary interventions in hospitals without on-site cardiac surgery capability [and by implication, freestanding cardiac catheterization laboratories] cannot be endorsed at this time."[1] In September 2005, the performance of interventional cardiology procedures in the freestanding setting was again addressed in research undertaken by the Agency for Healthcare Research and Quality ("AHRQ") at the bequest of the Centers for Medicare and Medicaid Services. Specifically, AHRQ was asked to investigate the following "key question": "Do Freestanding Cardiac Catheterization Clinics and Hospitals Have Comparable Complication Rates for Interventional Catheterization Procedures?"[2] AHRQ responded:

> Our searches identified no articles or meeting abstracts that potentially met our *a priori* inclusion criteria. Thus, no evidence-based conclusion is possible for this question. An ACC/SCAI consensus document recommended that such procedures not be performed in freestanding settings, and *we found no*

[1] Bashore et al, 37 J. AMER. COLL. CARDIOLOGY 2170, 2180 (2001).
[2] AGENCY FOR HEALTHCARE RESEARCH AND QUALITY, CARDIAC CATHETERIZATION IN FREESTANDING CLINICS: A REVIEW 27 (Sept. 7, 2005).

information to suggest that [percutaneous coronary intervention] procedures are currently being performed in this setting.[3]

I mention the above studies for two reasons: (1) because in reaching their conclusion that they could not recommend elective coronary interventions in settings without on-site surgery capability, the ACC and SCA&I acknowledged that their recommendation *might change, in time*; and (2) because the AHRQ's conclusion that percutaneous coronary interventions are not currently being performed in the freestanding setting, *is incorrect*. In fact, the freestanding cardiac catheterization laboratory for which I serve as medical director has been performing percutaneous coronary interventions for non-government program patients with very good results. Since our program began in July 2004 we have performed over 2,700 procedures, of those procedures 5% have been peripheral interventions and 2% have been coronary interventions. Accordingly, I have attached for your review graphs indicating the outstanding results we have achieved in the performance of such procedures and the overall improved patient satisfaction. I should additionally note that our facility is accredited by the Joint Commission on Accreditation of Healthcare Organizations ("JCAHO"), and has recently been contracted by several commercial payors to provide percutaneous coronary interventions. My partners at Laurus Healthcare have several other cardiac programs under development and we feel that a face to face meeting with you would be timely and mutually advantageous.

In light of the above, I am requesting an opportunity to meet with you to discuss in more detail our experience and results in performing interventional cardiology procures in the freestanding setting. Again, I request this opportunity simply for purposes of initiating a dialogue with TrailBlazer on what I believe to be the next logical step in the progression of Medicare coverage of interventional cardiology, that is, coverage in the freestanding setting. Our shared goal, as I know you will agree, is to provide a superior clinical outcome in the most cost effective environment.

Thank you for your time and attention to this matter. Please do not hesitate to contact me should you have any questions, or if I can be of further assistance. I look forward to speaking with you.

Very truly yours,

Patrick J. Cook, MD, FACC, FACP

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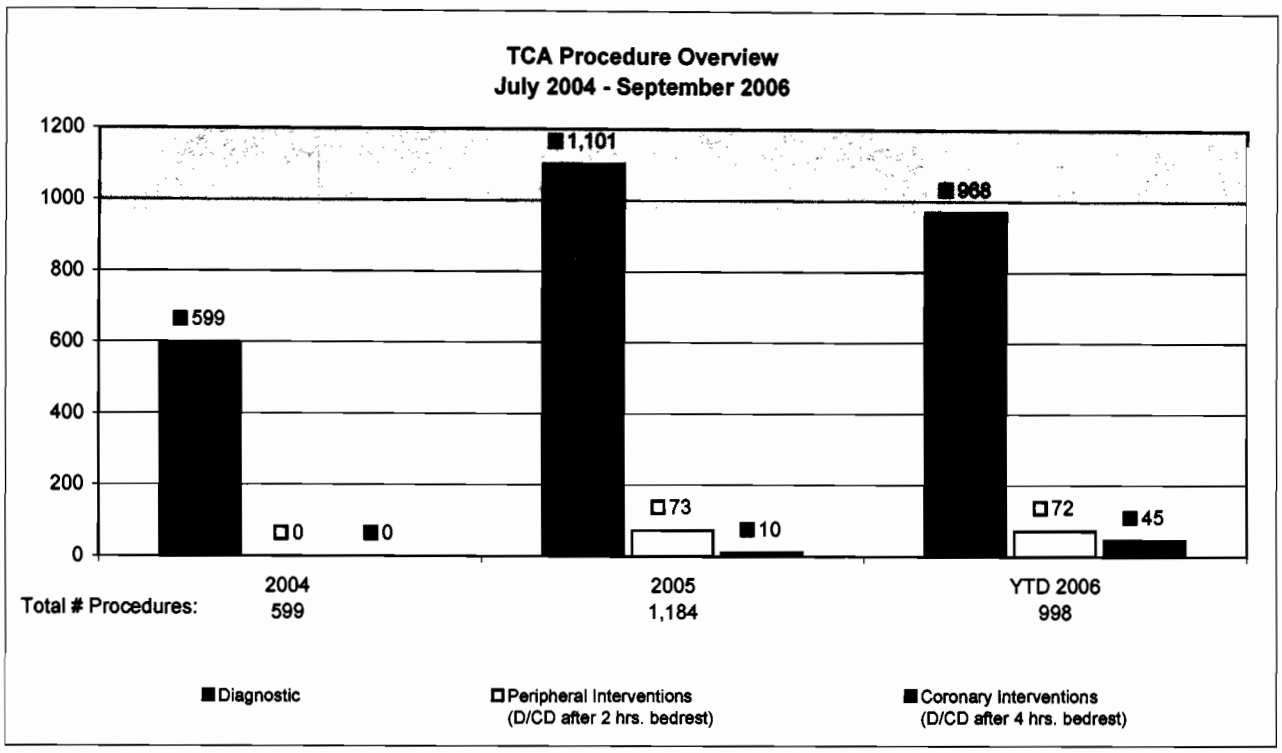
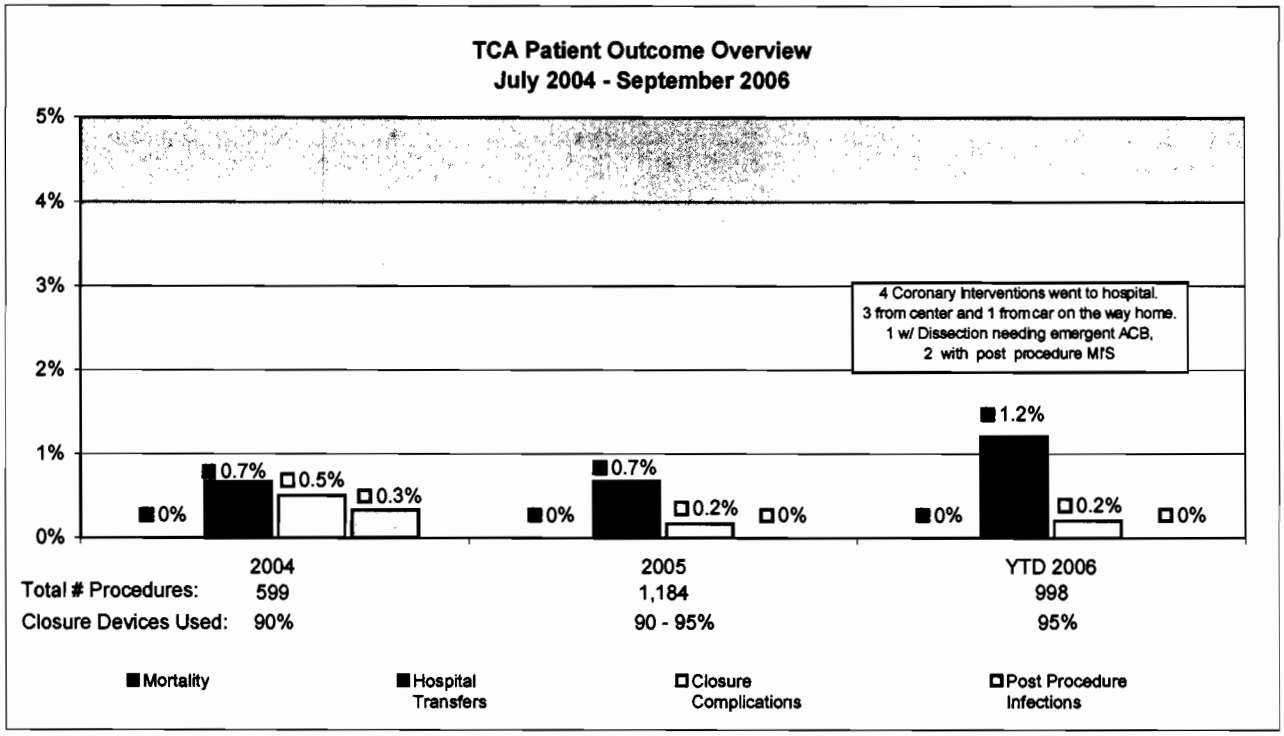
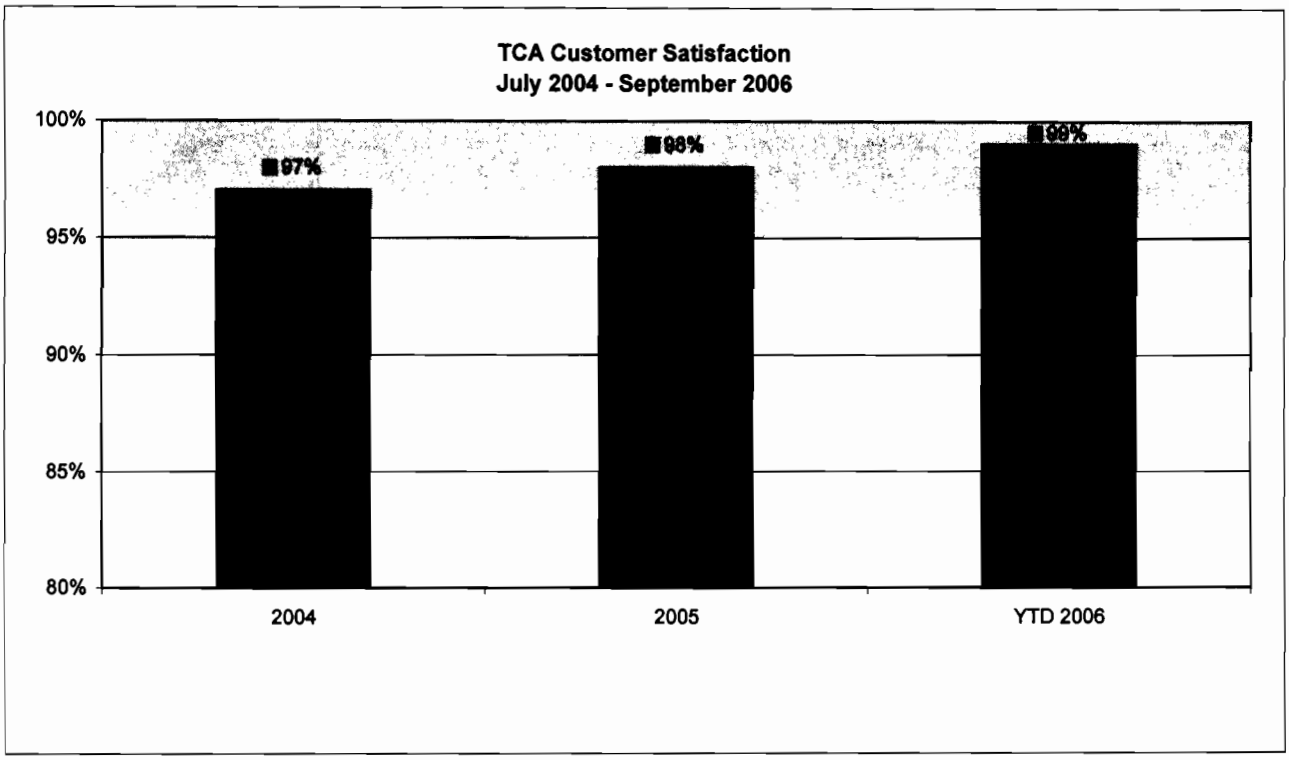
[3] *Id.* (emphasis added).


TCA Procedure Overview
July 2004 - September 2006
1200
1000
800
600
400
200
0
599
0
0
1,101
73
10
968
72
45
Total # Procedures:
2004
599
2005
1,184
YTD 2006
998
Diagnostic
Peripheral Interventions
(D/CD after 2 hrs. bedrest)
Coronary Interventions
(D/CD after 4 hrs. bedrest)


TCA Patient Outcome Overview
July 2004 - September 2006
5%
4%
3%
2%
1%
0%
4 Coronary Interventions went to hospital.
3 from center and 1 from car on the way home.
1 w/ Dissection needing emergent ACB,
2 with post procedure MI'S
0%
0.7%
0.5%
0.3%
0%
0.7%
0.2%
0%
0%
1.2%
0.2%
0%
Total # Procedures:
Closure Devices Used:
2004
599
90%
2005
1,184
90 - 95%
YTD 2006
998
95%
Mortality
Hospital
Transfers
Closure
Complications
Post Procedure
Infections


TCA Customer Satisfaction
July 2004 - September 2006
100%
95%
90%
85%
80%
97%
98%
98%
2004
2005
YTD 2006

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OCT 3 0 2006

Telephone Number: 469-372-6074
Fax Number: 469-372-2649

October 25, 2006

Patrick J. Cook, MD, FACC, FACP
Laurus Healthcare
Travis Center Angiography
6655 Travis, Ste. 250
Houston, TX 77030

RE: Medicare Coverage of Interventional Cardiology Procedures

Dear Dr. Cook:

This letter acknowledges receipt of your correspondence dated October 18, 2006, in the Medicare Medical Director's office October 24, 2006, concerning the above referenced subject.

As soon as your concerns are researched, a Medicare representative will fully respond to your correspondence. Your patience is appreciated.

Sincerely,

Gloria J. Garcia

Gloria J. Garcia
Project Coordinator for
Debra L. Patterson, M.D.
Medical Director
TrailBlazer Health Enterprises, L.L.C.

/gg

January 11, 2007

Via U.S. Mail
Debra L. Patterson, M.D.
Medical Director
TrailBlazer Health Enterprises, LLC
Executive Center III
8330 LBJ Freeway
Dallas, Texas 75243-0992

RE: Request for Meeting to Discuss Medicare Coverage of Interventional Cardiology Procedures

Dear Dr. Patterson:

This letter is in follow-up to my October 18, 2006 correspondence to you, regarding "Interventional Cardiology: C-42AB-R1," in which TrailBlazer clarifies that Medicare coverage of interventional cardiology procedures is limited to procedures performed in the inpatient or outpatient hospital setting.

As I mentioned in my prior letter, I am a cardiologist associated with the Texas Health Institute, and I also serve as the medical director of Travis Center Angiography, a freestanding cardiac catheterization laboratory. We have been performing on appropriate non-government program patients at Travis Center Angiography for the past fifteen months, with very good clinical results. Our shared goal, as I know you will agree, is to provide superior clinical outcomes to Medicare beneficiaries in the most cost effective environment. To that end, I would very much appreciate the opportunity to meet with you to discuss in more detail our experiences and results in performing such percutaneous coronary interventions in the non-hospital setting. I am, of course, willing to come to Dallas to meet with you at your convenience.

I very much look forward to speaking with you regarding this issue, and accordingly, will be following up with your office to ascertain when I might have an hour of your time. Please do not hesitate to contact me should you have any questions, or if I can be of assistance.

Very truly yours,

Patrick J. Cook, MD, FACC, FACP

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Telephone: 469-372-6074
Fax: 469-372-2649

January 19, 2007

Patrick J. Cook, MD, FACC, FACP
Laurus Healthcare
10000 Memorial Drive, Suite 540
Houston, TX 77024

Re: Meeting to Discuss Medicare Coverage of Interventional Cardiology Procedures

Dear Dr. Cook:

I received your letter dated January 11, 2007, in which you request an hour to meet with me and to discuss cardiac interventional procedures in the outpatient setting. You may schedule such a meeting by calling my administrative assistant, Gloria Garcia, at 469-372-6074.

Yours very truly,

Debra L. Patterson, MD
Medicare Medical Director

DLP:gg

April 19, 2007

Via U.S. Mail

Debra L. Patterson, MD
Medical Director
TrailBlazer Health Enterprises, LLC
Executive Center III
8330 LBJ Freeway
Dallas, TX 75243-0992

Re: Medicare Coverage of Interventional Cardiology Procedures

Dear Dr. Patterson,

Thank you for taking time to meet with myself, Vicki Cawley and Ned Schwing on March 9, 2007. It was certainly a pleasure to meet you.

I am writing to inquire how things went at the recent committee meeting in regards to Medicare coverage of interventional cardiology procedures and certain devices in an outpatient setting.

Again, thank you for all of your assistance.

Very truly yours,

Patrick J. Cook, MD, FACC, FACP

May 3, 2007

Via U.S. Mail

Debra L. Patterson, MD
Medical Director
TrailBlazer Health Enterprises, LLC
Executive Center III
8330 LBJ Freeway
Dallas, TX 75243-0992

Re: Medicare Coverage of Interventional Cardiology Procedures

Dear Dr. Patterson,

I though you might find this article of interest. I am looking forward to catching up with you. Please contact me to schedule a time to tour Travis Center Angiography.

Again, thank you for all of your assistance.

Very truly yours,

Patrick J. Cook, MD, FACC, FACP
713-526-5511 ext 4206

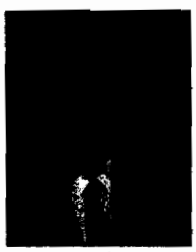
SCAI

SCAI News & Highlights

The Society for Cardiovascular Angiography and Interventions

SCAI Weighs in on PCI Without On-Site Surgery; Focus Is on Quality Standards

In early February, SCAI released to widespread international support an expert consensus document examining the current and future role of percutaneous coronary intervention (PCI) without on-site cardiac surgical backup, a report first commissioned in 2004. Then, as now, two words have consistently characterized the project—quality and controversy.



Gregory J. Dehmer, M.D., FSCAI

"As *the* society representing the majority of interventional cardiologists in the United States, we felt it was our responsibility to conduct an objective evaluation of an increasingly common practice and offer recommendations to ensure compliance with stringent quality standards," said Gregory J. Dehmer, M.D., FSCAI, chair of the expert panel and SCAI's president.

Though a focus on quality has fueled the project, controversy was its spark. Controversy surrounds the practice of PCI without cardiac surgical backup, despite its being successfully performed in leading medical institutions throughout the world. Some may interpret the just-released report as a veiled approval of PCI without on-site surgery and a contradiction of established ACC/AHA/SCAI practice guidelines. However, this is not the intent of the document, Dr. Dehmer noted.

"The consensus document is not an open endorsement of PCI without on-site surgical backup. Instead, we are acknowledging that it *is* being performed well at many facilities and offer our expert opinion on how such programs should be organized, supervised, and performed," Dr. Dehmer said. "The goal is to improve the quality of coronary interventional care worldwide."

Indeed, the consensus document included authors from several countries and has been endorsed by 12 international societies representing interventional cardiologists around the world (see sidebar on p. 2).

The expert consensus document was unveiled

(continued on page 2)

CT UPDATE

SCAI Offers Hands-on Training to Help Interventionalists With Cardiac Multidetector CT Angiography Certification Requirements

In response to feedback from members as well as forthcoming increases in the training and competency standards recommended by SCAI and other specialty societies, SCAI has greatly expanded its offering of the popular **Cardiac CT: Learning by the Cases** course. Between now and January 2008, the Society will hold the

(continued on page 12)

Tradition Continues

Judkins Cardiac Imaging Symposium to Kick Off Annual Scientific Sessions

SCAI co-founder Melvin P. Judkins, M.D., FSCAI, probably wouldn't be surprised, but he would be delighted to see how the symposium that bears his name has changed over the years, according to Warren K. Laskey, M.D., FSCAI.

"The **Judkins Cardiac Imaging Symposium** anchors us to our past," explained Dr. Laskey, a former President of SCAI who has chaired the event for 10 of its close to 20 years of existence. "But it really has evolved since the time when we did nothing but x-ray angiography. Now there's just so much other imaging

(continued on page 3)

SCAI

PCI-Surgical Backup (continued from page 1)
and publicized at a major telebriefing hosted by Dr. Dehmer on Feb. 5.

Growing Trend

There is no question that the practice of PCI without on-site surgery is becoming increasingly common. As of February 2007, primary PCI programs without on-site surgical backup were operating in 40 states. Both primary and elective PCI were being performed without on-site surgery in 27 states. Between 2001 and 2004, 39 facilities without on-site cardiac surgery submitted PCI data to the ACC-National Cardiovascular Data Registry (ACC-NCDR™), a number that climbed to 75 in 2005. International data from 39 countries responding to SCAI's request for information indicate that PCI is performed without on-site surgical backup in 90 percent of these countries.

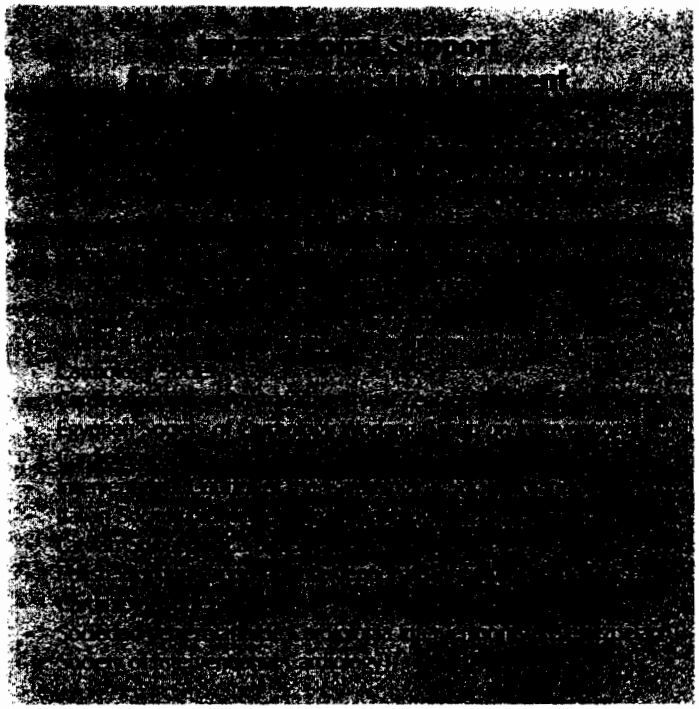
Critics say that, at least in the United States, the trend is fueled by financial motives and worry that quality is being placed on a back burner. Supporters counter that patients who live in remote or economically deprived areas benefit when PCI is available in their local communities.

One thing is certain, emergency coronary artery bypass graft (CABG) surgery is necessary far less often today than in the past. In the early days of balloon angioplasty, 1.0 percent to 2.5 percent of patients died and 1.9 percent to 5.8 percent required urgent CABG surgery. Today, high-volume centers report an in-lab mortality rate of about 1–2 per 1000, and a 0.3 percent to 0.6 percent incidence of urgent CABG surgery.

Perhaps the strongest argument in favor of PCI in hospitals without cardiac surgery programs is the need to rapidly treat patients experiencing an acute myocardial infarction (MI). Restoration of coronary blood flow within the target 90 minutes becomes more challenging if the patient requires transfer to a PCI center with cardiac surgery. As a result, primary PCI at nonsurgical hospitals is common—and was designated a Class IIb indication in the 2005 revision of ACC/AHA/SCAI PCI guidelines.

The 2005 PCI guidelines recommend against elective PCI in nonsurgical centers, however, rating it a Class III indication, as did the 2001 set of guidelines. Nonetheless, many hospitals performing primary PCI without surgical backup have launched elective PCI programs. One key reason: the difficulty of maintaining high-quality facilities and highly skilled nurses, technicians, and physicians in a program that treats only a small number of patients with MI each month.

"The problem is that there are many fewer MI patients than there are patients needing elective procedures," Dr. Dehmer said. "It becomes very hard to sustain a program with primary PCI alone."



Recommendations

The SCAI consensus document recommends that PCI programs operating without on-site cardiac surgery—

- Maintain case volumes of at least 200 PCIs per year for the facility;
- Employ highly skilled interventional cardiologists who have performed more than 500 PCIs through-

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out their career (or are mentored by an experienced interventionalist), who have a personal annual case volume of at least 100 PCIs including ≥ 18 primary PCIs per year, and meet national benchmarks for procedural success and complication rates;
- Train all support personnel in the management of PCI patients;
- Establish an on-call schedule that supports operation of the laboratory 24 hours a day, 365 days a year;
- Select patients and lesions carefully to control the risk of complications;
- Establish a close alliance with cardiovascular surgeons, including formalized and tested protocols for emergency transfer of patients;
- Activate emergency transport at the first clear signs of a PCI complication, thereby ensuring that the time to the initiation of cardiopulmonary bypass does not exceed 120 minutes; and
- Collect appropriate outcomes data and submit them for comparison with state or national performance standards.

The message behind the consensus document is PCI quality, whether the procedure is performed in hospitals with cardiac surgical backup or without. "Ensuring that *all* PCI programs meet appropriate performance metrics is likely to save more lives than requiring all PCI programs to have on-site surgery," Dr. Dehmer said.

The first data from a large randomized controlled trial on PCI without cardiac surgical back-up is expected sometime in 2008, when the Atlantic Cardiovascular Patient Outcomes Research Team (CPORT) will report its findings.

The executive summary of the expert consensus document, as well as a President's Page editorial by Dr. Dehmer, is published in the March 2007 issue of *Catheterization and Cardiovascular Interventions*. These documents, plus the full text of the document, can be found at *www.scai.org*. ■

Judkins Symposium ***(continued from page 1)***

technology that's being brought to the discipline."

The full-day event, which will take place Wednesday, May 9, kicks off SCAI's 30th Annual Scientific Sessions in Orlando, FL.

What's unique about the Judkins Symposium is its comprehensive mix of both fundamentals and innovations, stressed Dr. Laskey. "My goal has always been to provide a mix of old and new," he continued. "It's a mix of the basic stuff people need to know about the myriad of imaging modalities as well as the practical stuff."

Warren K. Laskey, M.D., FSCAI

The morning will be devoted to what Dr. Laskey calls the "core curriculum," an overview of various imaging technologies. Chandra Sehgal, Ph.D., of the Hospital of the University of Pennsylvania, for example, will discuss the physics of ultrasound. Jenss Schmidt-May, Ph.D., of Philips Medical Systems in Hamburg, Germany, whom Dr. Laskey calls "probably the smartest person in the world about x-ray tubes," will give a talk called, "Advances in X-ray Tube Technology: Angiography and MDCT."

Other presentations will include "Digital Fluoroscopy and Fluorography: A to Z," "Flat Panel Technology: What Does the Clinician Need to Know?", "Physics of MRI: Teslas, Hz and Resolution," and "Physics of X-radiation."

"The morning speakers are more of the academic people who are highly regarded in the scientific realm," explained Dr. Laskey. "These sessions are for people who want to get the didactic aspects."

In the afternoon, the attention will shift to creative clinical applications of the scientific information presented in the morning sessions. "The afternoon is more free-wheeling," said Dr. Laskey. "The speakers are people who are well-known in the clinical community explaining how to use this information in real life."

Neil J. Weissman, M.D., of Georgetown University, for example, will discuss the use of ultrasound in the cath lab. Robert L. Wilensky, M.D., of the University of Pennsylvania, will tackle the topic of MRI. And John C. Messenger, M.D., of the University of Colorado, will handle CT. "Dr. Messenger's lab is pushing the envelope when it comes to what you can do with this technology in the cath lab," noted Dr. Laskey.

Other afternoon presentations will include "Radiation Safety: Practical Applications in the Cath Lab," "Radiographic Contrast Media: Always Something New," and "Electro-Mechanical Imaging Modalities: Dead or Alive?"

And, Dr. Laskey emphasized, the symposium doesn't just cover imaging itself; it will also feature an important talk about policy developments affecting imaging. Former American College of Cardiology President Pamela S. Douglas, M.D., of Duke University, will give a talk called "The Practicing Cardiologist and Imaging Technology."

"The move toward credentialing and competence

(continued on page 7)

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

MEDICARE
Part A Intermediary
Part B Carrier

Telephone: 469-372-6074
Fax: 469-372-2649

cc. P. Cook.
RD
RD

May 10, 2007

Patrick J. Cook, MD
Travis Center Angiography
6655 Travis, Suite 250
Houston, TX 77030

Dear Dr. Cook:

Thank you for your most recent letter and article. The policy team has not yet addressed this issue of payment of coronary angiography outside the hospital. Be assured that we shall take this topic up for discussion, and I will certainly let you know the outcome of such discussions.

Thank you for your assistance.

Yours very truly,

Debra L. Patterson, MD
Medicare Medical Director

DLP:gg

July 18, 2007

Via U.S. Mail

Debra L. Patterson, MD
Medical Director
TrailBlazer Health Enterprises, LLC
Executive Center III
8330 LBJ Freeway
Dallas, TX 75243-0992

Re: Medicare Coverage of Interventional Cardiology Procedures

Dear Dr. Patterson,

Thank you for your recent update regarding expanding the scope of Medicare coverage for outpatient catheterization procedures.

I fully appreciate and understand that the discussion of providing outpatient coronary interventions is going to generate a great deal of debate. As a possible starting point to expand the scope of services in an outpatient setting, I suggest we move forward with guidelines and criteria for elective ICD/pacemaker procedures. Currently a majority of these services are performed in outpatient labs (freestanding and hospital based).

I would like to recommend TCA for a pilot demonstration site to be able to show quality outcomes, improved patient satisfaction and significant cost savings for the system.

As I mentioned to you in May, we would very much appreciate your touring TCA to review the operation and scope of services and to continue our discussion in person.

Again, thank you for all of your assistance.

Very truly yours,

Patrick J. Cook, MD, FACC, FACP
713-526-5511 ext 4206

240

RADIOLOGY
IMAGING ASSOCIATES P.C.

August 28, 2007

VIA OVERNIGHT MAIL
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attn: CMS-1385-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1385-P / Comments on Sections II. I. & II. M.

To Whom It May Concern:

As a radiology practice that has been providing imaging services to the Denver community for more than 40 years, Radiology Imaging Associates ("RIA") feels compelled to comment on the documented trend in overutilization of imaging services by referring physicians and CMS's attempts in the 2008 Medicare Physician Fee Schedule proposed rule to curb such abuses through revisions to the purchased diagnostic test rule and the Stark regulations.

We begin our comments by applauding CMS its concerted and relatively comprehensive effort to address what, from our perspective, appears to be an alarming proliferation of referring physicians entering into "lease" or similar purchased test arrangements with imaging centers for the primary purpose of enabling physicians to profit from their own referrals. As CMS may be aware, a number of government and private sector studies have clearly documented the rapid growth in utilization of imaging services and its link to physicians' financial conflicts of interest when self-referring imaging studies to facilities in which they have a financial interest – particularly the more technologically sophisticated and higher cost services such as CT, MRI and nuclear medicine.

For example, the Blue Cross and Blue Shield Association estimated that for the period of 1999 through 2001, its health plan expenditures per member, per month for outpatient radiology services increased by 18% for x-ray, 45% for CT and 47% for MRI.[1] Similarly, the Executive Director of MedPAC testified before Congress in March

1 Blue Cross Blue Shield Association, "Blue Cross and Blue Shield Plans Respond to Challenge of Keeping Medical Technology Affordable," October 14, 2003. Available at: http://bcbshealthissues.com/proactive/newsroom/release.vtml?id=54477.

of 2005 that for the period of 1999 through 2003 utilization of MRI for body parts other than the brain grew 99 percent, CT for body parts other than the head increased 82 percent and nuclear medicine services grew an astounding 85 percent.[2] One of the factors cited as potentially contributing to the rapid growth was the ability of physicians to supplement their professional fees with revenues from ancillary services. Thus, MedPAC recommended that Congress strengthen the Stark Law in order to prevent referring physicians from indirectly profiting from their own imaging service referrals. A sentinel study published in the American Journal of Roentgenology in 2000 confirmed MedPAC's observation that physician self-referral may be contributing to the uncontrolled growth in imaging services by reporting that when a managed care organization prohibited certain non-radiologist specialties from billing for imaging services, total billings for imaging services declined 20 to 25 percent from the amount of billings that were expected given the previous trend in imaging growth. This decline appeared to be due, in large part, to the fact that approximately half of the imaging previously performed by self-referring physicians ceased when the physicians lost the ability to retain a financial interest in the technical component services.[3]

These studies simply confirm what RIA has suspected for years which is that the loopholes in the Stark Law have lead to both overutilization of imaging services and a decline in the quality of services provided to patients. Thus, we applaud CMS's efforts to address these issues by proposing changes to the IDTF standards, purchased diagnostic test rule, reassignment rules and Stark regulations. Although we generally agree with the concept behind the proposed changes, we would like to comment on how the proposed changes should be modified so as not to negatively affect or impact physicians who are not engaged in self-referral of imaging, clinical lab or other ancillary services.

Independent Diagnostic Testing Facility Issues (Section II. I.)

CMS is proposing to add a new performance standard at 410.33(g)(15) which would prohibit an independent diagnostic testing facility ("IDTF") from sharing space, equipment or staff or subleasing its operations to another individual or organization. This standard would clearly put an end to the questionable "lease" arrangements that have been proliferating between IDTFs and referring physicians and, thus, we agree with adding such a provision to the IDTF performance standards. The one aspect of the provision which may require further clarification, however, is the prohibition on sharing "staff." The preamble discussion on page 38171 of the Federal Register, states that the

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2 See "MedPAC Recommendations on Imaging Services" (March 17, 2005) at http://www.medpac.gov/publications/congressional_testimony/031705_TestimonyImaging-Hou.pdf

3 Moskowitz H, Sunshine J, Grossman D, Adams L, Gelinas L. The Effect of Imaging Guidelines on the Number and Quality of Outpatient Radiographic Examinations. *AJR* 2000; 175: 9-15.

prohibition on sharing staff would include "supervising physicians." We note that such a prohibition on sharing of supervising physicians with "another individual or organization" would appear, at least on the plain face of the language, to preclude an IDTF from contracting with a radiology group to provide supervision services since the IDTF would technically be "sharing" the services of the radiologists with the radiology group and any other facility or IDTF where those radiologists may also provide supervision or interpretation services. It is our experience that most IDTFs obtain professional services under contract with a radiology group rather than through employed physicians. Thus, a prohibition on sharing the services of a radiologist would greatly hinder IDTFs from obtaining the necessary physician supervision services. We recommend that the prohibition on sharing "staff" be limited to sharing of non-physician personnel.

Physician Self-Referral Issues (Section II. M.)

II.M.1. - Anti-Markup Provision

CMS is proposing to expand the anti-markup provision to apply to the professional component of diagnostic tests billed by a physician or medical group if those interpretations are either purchased from another physician or medical group or obtained pursuant to a reassignment from a physician who is not a full-time employee. If this provision was adopted we presume that it would discourage referring physicians from contracting radiologists, pathologists or other specialists to perform the necessary interpretation services for diagnostic tests that the referring physician would then bill for since it would essentially eliminate the financial incentive for doing so. In fact, if a referring physician billed for professional services performed by a contracted specialist, the physician would theoretically lose money on each service billed since he could not mark-up the charges to account for the physician's billing, collection and bad debt costs.

We agree with the concept and reasoning behind expanding the anti-markup provision to apply to the professional component of diagnostic testing. We believe, however, that such an expansion could have the unintended consequence of negatively impacting a significant number of radiology groups throughout the country (including our practice) who regularly utilize independent contractor and part-time employees to provide services and fill coverage gaps. For example, two of the radiologists in our group recently retired from full-time practice and are now working as part-time employees. Their services, even if provided on a part-time basis, are extremely valuable to RIA and our ability to provide timely, high quality services to our patients. If RIA was prohibited from billing Medicare any more than it pays those radiologists for their services, it could be become difficult financially to retain their services since each service billed to Medicare would actually result in a financial loss to the group (since we would not be reimbursed for our overhead costs).

In addition, it is our understanding from our colleagues in the radiology community that there are many areas of the country (particularly rural) that are experiencing a shortage of professional radiology services since the demand for services is outpacing the supply of radiologists. As a result, it is not uncommon for radiology groups to engage independent contractors to fill the void for what can be an extended period of time while the group attempts to recruit a permanent radiologist. Again, applying the anti-markup provision to services provided by independent contractors and part-time employees of radiology groups can make it financially untenable for groups to utilize these services – particularly in areas with a substantial Medicare population.

We agree with expanding the anti-markup provision to purchased or reassigned interpretation services in order to eliminate a referring physician's financial incentive to bill for those services. However, in order to avoid negatively impacting radiology practices or other non-referring physician practices that regularly and legitimately utilize the services of independent contractor and part-time employees, we recommend that the anti-markup provision only apply to those physicians or medical groups that bill for purchased or reassigned professional interpretations that were performed pursuant to an order written by the treating physician or a practitioner who are members of that medical group. The anti-markup provision for professional services should not be applied to physicians or groups (such as radiology practices) that bill for professional services performed by an independent contractor or part-time employee if those services were performed pursuant to the order of another practitioner who is independent of the group and, thus, would not profit from his or her referral. We think such an exception to the anti-markup provision is necessary in order to preserve the ability of radiology groups to utilize part-time and contractor physicians but also reasonable since it would not increase the risk of overutilization or other Medicare program abuse.

II.M.3. - In-Office Ancillary Services Exception

CMS is soliciting comments as to: (1) whether certain services should not qualify for protection under the in-office ancillary services exception to the Stark Law and (2) 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.

Services That Should Not Qualify. It is our understanding that one of the original and primary purposes of the in-office ancillary services exception was to enable physicians to provide to their own patients certain ancillary services that would directly assist the physician with diagnosing and treating the patient and that are relatively simple to administer or fall within the physician's expertise. For example, performing a urinalysis or taking an x-ray that could be done while the patient is in the office, interpreted by the treating physician and used by the physician during that same patient visit to determine the course of treatment. In other words, the ancillary service was

performed in some part by the physician and integral to the services being provided to the patient during his or her visit to the office.

It seems to us, however, that the exception has infinitely expanded by referring physicians to include a variety of ancillary services that: (1) are complex enough that they need to be supervised and/or performed by other physician specialists since the services fall outside the scope of the referring physicians training and qualifications and (2) are not performed and/or the results used during the same patient visit. For example, we are aware of physician practices that own or lease CT, MRI or other complex imaging equipment but, because those practices do not specialize in radiology, they typically contract with a radiologist or radiology group to train and supervise the technologists, ensure the equipment is properly calibrated, and additionally interpret these imaging studies for them. Because the interpretation of these studies is significantly more sophisticated and complex than, for instance, interpreting a plain film x-ray or ultrasound, the interpretations are rarely performed by non-radiologists. In addition, the interpretations are typically performed after the patient has left the office and, thus, the results cannot be utilized by the physician on the same day as the patient's visit. So, although the physician will ultimately utilize the results of the study, the physician does not actually interpret the study nor is the study immediately helpful in treating the patient.

We suggest that, at least with respect to imaging services, CMS consider restricting the scope of the in-office ancillary services exception to apply only to imaging services such as plain film x-ray studies and ultrasound that can be performed, interpreted and the results used concurrently to inform the physician's diagnosis and/or treatment of the patient on the same day as the patient's visit. Any imaging services that are complex enough that the results cannot be obtained or interpreted on the same day as the patient's visit should not qualify for protection under the in-office ancillary services exception as these services will, in most cases, need to be supervised and performed by a radiologist. The referring physician will have little, if any, involvement in the actual performance, supervision or interpretation of the imaging service and, thus, should not be permitted to bill for those services under the in-office ancillary services exception simply because the physician or the group practice happens to own a piece of imaging equipment.

We recommend that the imaging modalities of MR, CT and PET be specifically excluded from those radiology and other imaging services that can qualify for the in-office exception. Clearly limiting the scope of imaging services that qualify for the in-office ancillary services exception would be one of the most straight-forward methods of attacking head-on the escalating problem of physician self-referral and the inevitable overutilization that results from referring physicians being enable to generate revenue from ordering and billing for imaging services that fall outside the scope of their training and in which they typically have little involvement.

II.M.5 - Per Click Payments

We support CMS's proposal to revise the space and equipment rental exceptions to the Stark Law to prohibit "per click" payments in those situations where a physician leases space or equipment to a DHS entity, such as a hospital or IDTF, and the DHS entity utilizes the leased space or equipment to furnish services to patients referred by the physician lessor. This revision is consistent with the goal of eliminating or at least reducing the ability of a referring physician to directly profit from his or her own referrals for DHS and, consequently, reduce the risk of overutilization.

We note, however, that in our experience the flip-side relationship where a DHS entity leases space and/or equipment to a referring physician to perform and bill for technical component services the physician orders for his patients (under the in-office ancillary services exception) is also prevalent and can also lead to overutilization if it is based on a "per click" payment since the physician pockets the difference between the lease fee and the reimbursement from Medicare and other third-party payors. Thus, we would also urge CMS to revise the space and equipment rental exceptions to prohibit "per click" lease payments by physician lessees.

Of course, as CMS may be aware, it has been our experience that these leasing arrangements are usually between a DHS entity and a physician group practice or investment entity owned by a group of physicians rather than individual physicians. So, in order for the revisions to the space and equipment rental exceptions to really have any effect on overutilization and physician self-referrals, CMS would also need to eliminate or modify the indirect compensation exception or carry through on its proposal to develop some type of "stand in the shoes" provision for physicians investors.

We appreciate this opportunity to comment on the numerous and significant changes CMS is considering with respect to the IDTF standards, 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,

P. Ricci

Peter E. Ricci, MD
President

WEST SHORE UROLOGY, P.L.C.

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August 28, 2007

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 Sirs:

I am a 44-year-old urologist currently practicing in Muskegon, Michigan and have been in a private group practice now for 12 years. I am writing to express concern about recent proposals made by CMS regarding Medicare and physician self-referral provisions. I am both angered and offended by the inference that hospital physician partnerships are only for the purpose of physician investment and do very little to improve patient care. The vast majority of physicians strive very hard to maintain a high degree of integrity and provide the very best care for our patients.

Physician hospital partnerships are relatively new to Michigan in my experience but have clearly improved quality of care. When I first arrived in Muskegon 12 years ago, patients with kidney stones had to travel approximately 40 miles to Grand Rapids, Michigan to undergo lithotripsy. After partnering with Spectrum 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. Another lithotriptor (partnering with other urologists) comes to Mercy Hospital in Muskegon, Michigan. These partnerships have improved our ability to serve the community as it has allowed us to reduce patient wait times from 4-8 weeks to 1-3 weeks. Patients are also not required to travel a significant distance for their treatment. (I might add patients are also given the option of using the hospital lithotriptor of their preference).

During the 12 years of my practice, I have also found it difficult to convince hospitals to purchase up to date technology in order to improve patient care. There is a risk that new equipment/technology will become obsolete quickly and it is often difficult for hospitals to justify or risk purchasing this up-to-date equipment/technology. By forming physician hospital partnerships physicians have been able to assume some of the risk and reassure the hospitals that this equipment/technology is worthwhile. It is my belief that if the proposed changes were to take effect patient care would suffer and I would make a strong recommendation that you reconsider the current proposal.

I appreciate your attention and consideration of my thoughts on this issue. If necessary, I would be glad to speak with you regarding this matter. I can be reached at my office at (231) 739-9492 or at my home (231) 780-5252.

Sincerely,

Kevin T Stone, MD, Diplomat American Board of Urology
KS:NM:tmc

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ForTec Medical Inc.®

Your Medical Laser Rental Company

August 27, 2007

Mr. Romano
Centers For Medicare & Medicaid Services
CMS-1385-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, Maryland 212244-1850

Dear Mr. Romano,

I am pleased that CMS has issued the proposed regulations published July 2, 2007 relating to the Physician Feel Schedule for 2008 which included further clarifications of the Stark regulations. It is clear that CMS/HHS has a good understanding of the questionable business ventures that plague the healthcare industry and if left unchecked by your authority, these self-referring entities stand to contribute greatly to the rising costs of medical care in the United States.

ForTec Medical pioneered the surgical laser outsource industry. For almost 20 years, we have been providing independent high quality surgical laser services to thousands of hospitals in cities and communities throughout the Eastern US. While mobile ESWL Lithotripsy has historically found "protection" from the Stark Laws, many of these same LLCs have most recently introduced other types of medical equipment into their business model including diagnostic devices, prostate cryotherapy, and surgical lasers for kidney stones and BPH.

Perhaps the motive of adding surgical lasers along side mobile ESWL Lithotripsy equipment can be best understood by reviewing attachment #1, which is the American Lithotripsy Society's *Membership Announcement* dated May 18, 2005. Along with a name change notice, you can read several mission-type statements like "protect the practicing urologist", "promoting the broader interests of the practicing urologist", "protecting your economic interest in new technologies".

ForTec has experienced a tremendous growth in unfair competition from physician owned laser companies who self-refer kidney stone and prostate lasers for patient treatment. Many of my sales team members can account instances where surgeons have applied "influence" with hospital administrators to use the company in which they have an investment. There are numerous occasions where my company's' contracts have been blatantly breached by facilities who felt they had no choice but to "do business" with Dr. "S"s' company. There are

the brave others, who have stood their ground and chosen to honor their existing contract only to find that Dr. "S" eventually steered his patients to a competiting hospital across town who was willing to welcome the new business from Dr. "S".

Since Dr. "S" has access to OR pricing, this valuable insight can be used to establish lucrative pricing points at which his company can charge. I know of scenarios where LLC pricing was established at well above market and would characterize this practice as being "abusive". Abusive in the sense that case costs were nearing double of what the market would normally bear.

The medical industry has historically benefited from competition that was free of physician ownership influence. Independent (non-physician owned) equipment companies have created a market that delivers new technology in abundance, efficiently, and at affordable costs to healthcare facilities everywhere. The phenomenon of physician LLC business ventures eliminates competition due to doctor influence. In many cases, LLC ventures charge higher than fair market costs to healthcare facilities. Finally, surgeon investment has and will place focus on what is owned by the physician (or his company) and not necessarily the treatment that is best for the patient.

Further insights can be revealed upon reading the front cover article (attachment #2) of a company newsletter published by a physician owned LLC who delivers mobile ESWL Lithotripsy, prostate (BPH) laser, and kidney stone laser services to its members. In the second paragraph, its CEO states that "its ventures have made over $250 million in distributions to its members". In a large part, those "distributions" were enabled via the profits from Medicare and private insurance reimbursements for services rendered. The vast majority of those revenues were born out of physician investment in equipment that was self referred for patient treatments.

As a prospective patient I want my surgeon to provide the treatment that is best for me and not just use the equipment in which he is invested. All treatments for kidney stones and prostate (BPH) vaporization are not created equal. Each treatment brand has its' unique degree of efficacy, costs, and reimbursement levels and some are clearly better than others.

Fair market pricing should prevail over LLC owner influence. Clinical efficacy (not financial gain) should be the determining factor in patient treatment choices. ForTec offers a multitude of different BPH and kidney stone treatments from which a surgeon can choose depending on what is most appropriate for the

patient...independent of physician ownership. If all BPH treatments were reimbursed at the same value, the most effective treatment of choice would stand alone.

Again, *thank you* for taking your position as represented in the proposed regulations. There is no doubt that if passed, the regulations will return focus on the patient and efficacy, rather than the financial advantages of owning (and the profits from) one technology over another.

Sincerely,

Bradford P. Hall
Director Sales and Marketing
ForTec Medical, Inc.

ATTACHMENT #1

Membership Announcement
May 18, 2005

Since 1987 the American Lithotripsy Society (ALS) has served a vital function for the urologic community: To promote the study and management of stone disease and to protect the economic interest of physician ***ownership in lithotripsy technology.***

As new technologies have emerged, urologists are now in the position to explore opportunities in ownership and utilization of new surgical and therapeutic technologies. In order to more fully encompass both **Lithotripsy** and other emerging procedures, the American Lithotripsy Society has expanded efforts to address and protect the practicing urologist(s).

The American Lithotripsy Society has evolved into the Urology Society of America (USA) in order to continue its support of lithotripsy, promote and serve the urologist's scientific and economic interest in future technologies, and address related urology practice issues. The Urology Society of America is not de-emphasizing ***lithotripsy,*** but rather continuing to serve the lithotripsy community while expanding its role of promoting the broader interests of the practicing urologist.

Doctor, what does this mean to you??
By becoming a member of the Urology Society of America you will be joining an organization which is unique in its function to serve you, the practicing urologist, by reporting on emerging technologies and practice management issues, protecting your economic interest in new technologies while continuing to support lithotripsy technology and ownership as previously accomplished by the America Lithotripsy Society.

Allied, Clinical and Urology Practice personnel, what does this mean to you??
The Urology Society of America will continue to serve the needs of the allied members whose main focus and interest is lithotripsy. The Renal Certification Exam and re-certification for allied members will continue to be offered by USA. Certification of lithotripsy sites will continue through our partnership with the Accreditation Association of Ambulatory Health Care (AAAHC). We will continue to address lithotripsy-related subjects at meetings and allied forums. The Urology Society of America will continue to be your best resource and opportunity to network with other lithotripsy professionals. For practice managers, urology practice staff and health care administrators, the Urology Society of America will continue to provide information on subjects important to you: continuous quality improvement, practice management, billing, coding and medical records management, to name a few.

If you were a previous member of ALS, you will want to become a member of the successor organization: USA. If you have submitted your 2005 membership dues to the Urology Society of America, we thank you for your support and pledge to continue to serve your interests now and in the future. If you have not yet sent in your membership dues, we urge you to become a member today by returning in the enclosed dues invoice with your payment. We look forward to continuing to expand the mission of the practicing urologist and lithotripsy providers in the future. We are excited about the 2006 annual meeting in San Francisco, March16-19, 2006. If you have any questions please contact the USA office at 781-895-9078 or www.urologysocietyamerica.org

ATTACHMENT #2

[redacted] is continuing to implement its much-anticipated ownership restructuring with a June 30 completion date. A comprehensive redemption program is the cornerstone of the restructuring effort and affords [redacted] members the "exit strategy" many have inquired about over the years.

Since its inception, [redacted] and its joint ventures have made over $250 million in distributions to its members – proving itself a reliable, high quality provider of medical services as well as a superior investment for [redacted] owners. However, the same investment model that has made [redacted] so successful over the years needs to be changed to assure [redacted] continued success and long-term viability.

"... the same investment model that has made [redacted] so successful over the years needs to be changed to assure [redacted] continued success and long-term viability."

After a year of deliberation, the [redacted] Board authorized the comprehensive redemption program for [redacted] members who no longer practice urology. The comprehensive redemption program offered a one-time, voluntary buyout for qualified [redacted] members. Approximately 15% of [redacted] units were redeemed, effective March 31, 2007, with a total of $7 million payout to those who opted for the buyout.

The comprehensive redemption program offers the long-term plan [redacted] has been seeking. "We're very pleased to have offered this program to the [redacted] physicians who have been so supportive over the years, while at the same time leaving the company in a much more competitive position for the future" said [redacted] Chairman of the Board and Chief Executive Officer [redacted]

The next step of the ownership restructuring is the sale of additional [redacted] units to actively practicing [redacted] members. Eligible members will have the opportunity to purchase additional units up to a pre-determined level. The goal of fairness was crucial in developing this offering. All actively practicing members will now have the opportunity to own the same number of units as all other members. This new offering will be completed by June 30 and all members purchasing additional units will be eligible for the second quarter 2007 distribution on the additional units.

August 27, 2007

VIA FEDERAL EXPRESS

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: File Code CMS-1385-P
Physician Self- Referral Provisions
Section II.M.3; In-Office Ancillary Services Exception

To whom it may concern,

I am a Physical Therapist, presently working in a Physical Therapy Clinic located with in a Physician owned building. I have, in the past, worked in several different therapy settings, whether hospital based, private practice or physician owned. I up hold the therapy profession and am appalled when hearing of infractions related to poor therapy care or inappropriate billing. However, that is not to say that all clinics or therapist follow this trend. Nor should they be punished for the errors of others.

I understand the concern of Insurances companies with respect to profit gains related to 'referring with in a clinic'. However there is much benefit related to being a Physical Therapy clinic located with in a Physician clinic. At any moment I can promptly, not just call, but walk to the physician to discuss concerns I may have. I have immediate access to test results completely. I can request the physician see the patient for a recheck, which happens immediate, as the physical therapy clinic is located in the same building. These are just a few of the benefits of working within a Physician building. Thus to say there will be exceptions of certain patients being seen in certain areas is almost a disservice to health care. Instead there has to be a better way to control possible infractions without having the patients suffer from such a forward thinking service. But making such limits to where patients can be seen, our medical system continues to be stagnant to change, if not stepping backward. Health care, instead, should be moving forward.

Yours in concern for the PATIENT

A Concerned Physical Therapist

August 28, 2007

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

Re: File Code CMS-1385-P
Physician Self Referral Provisions
Section II.M.3: In-Office Ancillary Services Exception

Dear Sir or Madam,

I am a Physical Therapist who works within a physician's building providing services of rehab. I have worked in a variety of settings in the past, including home health, and outpatient hospital based therapy. I feel this environment for treating patients is very convenient for the following reasons.

First, it allows patients to be treated for therapy in the same building which allows less travel time for patient. Second, physicians and therapists have enhanced communications which in return gives better quality and outcomes for patients.

Working within a physicians building also allows immediate attention of contraindications that could potential harm the patient. Revisions of the PT plan of care can also be done immediately. There is easier access to patient's medical records, diagnostic tests, which allows the therapist to treat the patient accordingly.

Overall, I feel this type of environment is cost effective, because the treatment of patients results in less visits by 30-40 % with the same clinical outcomes.

As a rehab provider, please continue to support the model for partnership between physicians and therapists. This type of environment allows quality care in a cost affective manner which benefits the patients and the health care industry.

As a health care industry, we need to consider the best for the consumer, who is the patient.

Sincerely,

Apolle Ostert, PT

August 28, 2007

VIA FEDERAL EXPRESS

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: File Code CMS- 1385-P
Physician Self-Referral Provisions
Section II.M.3; In-Office Ancillary Services Exception

Dear Sir or Madam;

I am a Physical Therapist, working for a company who contracts Physical Therapy services, within a physician practice. I had worked in a similar setting many years ago. I chose to work in this type of setting for a couple of reasons.

Located within the same building as the physicians and utilizing EMR (electronic medical records), enables me to have quicker contact and responses from the physicians. The patient benefits due to decreased delay in MD response and immediate changes to the plan of care. Other types of facilities would have a delay due to fax turn around time and/ or returned phone messages.

In this setting, the physicians are more open to therapist-physician communication for patient related issues as well as information sharing. The physicians are also more active in providing input for treatment guidelines for certain diagnoses. Again the patient benefits with this type of open communication.

Now, I do believe that rehab within a physician setting needs to be examined closely to prevent over utilization and certain parties from seeking financial gains. However, I believe this is equally true in hospital based and private practice settings. Changes need to be made across the rehab settings.

Professionally,

Paige Blue, PT

Paige Blue, PT

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BURR • • • FORMAN

results matter

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August 28, 2007

VIA FEDERAL EXPRESS

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: File Code CMS-1385-P
Physician Self-Referral Provisions
Section II.M.3; In-Office Ancillary Services Exception

Dear Sir or Madam:

In the Thursday, July 12, 2007, Federal Register, the Centers for Medicare & Medicaid Services ("CMS") requested comments on whether changes are needed to the in-office ancillary services exception (the "IOAS Exception") to the federal physician self-referral law (commonly referred to as the "Stark Law"). On behalf of several physician groups and physical therapy providers, I am writing to specifically address the following question posed by CMS: "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)". I will limit my comments to the offering of physical therapy in a physician's office.

As a threshold matter, it is suggested that CMS does not have the legal authority to exclude certain categories of designated health services ("DHS") from the IOAS Exception based on the method of billing (*i.e.,* physical therapy billed incident to versus under a Part B supplier number assigned to the physician group). In enacting the IOAS Exception, Congress specifically allowed DHS, including physical therapy, to be billed by the "physician performing or supervising the services, by a group practice of which such physician is a member under a billing number assigned to the group practice, or by an entity that is wholly owned by such physician or such group practice". 42 USC 13955nn(b)(2) (emphasis added). In fact, CMS recognized the appropriateness of billing under the physician practice's supplier number in the March 26, 2004 Federal Register: "...if the physical therapist reassigns his or her right to payment to the group, and the group bills using its own billing number (with the physical therapist's number indicated on the bill), then the [IOAS Exception] billing requirement would be met." (69 Fed. Reg. 16054, 16076). While the Secretary of the Department of Health and Human Services does have the statutory authority to impose other requirements to the IOAS Exception to address program or patient abuse, such requirements must fall within the statutory framework of the exception. For CMS to

only permit incident to billing for physical therapy provided in a physician's office would be in direct contravention of the statutory IOAS Exception, which specifically allows a group practice to bill for DHS under a billing number assigned to the group.

CMS has suggested that the IOAS Exception requires a close connection between the DHS and the physician group. Therefore, physician groups should bill for physical therapy only on an incident to basis in order to increase physician supervision of such services. However, under the IOAS Exception DHS must be provided in a manner that meets the physician supervision requirements under applicable Medicare payment or coverage rules for the specific service at issue. The current Medicare payment and coverage rules allow physician groups to bill for physical therapy on an incident to basis, which requires direct supervision by a physician, or as a Part B supplier, which does not impose a physician supervision requirement. In the March 26, 2004, Federal Register, CMS correctly states that the IOAS Exception "is not the appropriate vehicle for addressing concerns with the supervision requirements in current coverage and payment rules and policies." (69 Fed. Reg. 16054, 16071). Accordingly, unless and until the Medicare payment and coverage rules for physical therapy are changed to limit physical therapy provided by a physician group to incident to billing only, it is not appropriate to use the IOAS Exception to impose such limitation.

Consistent with the requirements of Section 60.1 of the Medicare Benefit Policy Manual, incident to services and supplies must be furnished under the direct supervision of a physician. Direct supervision means that a physician must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. As is clear under Medicare policy, this does not mean that the supervising physician has to be present in the room when the service is performed and, in fact, the supervising physician need not be aware of the actual offering of the physical therapy service. Importantly, the physician providing the direct supervision need not be the same physician upon whose professional service the incident to service is based. Consequently, the physician who ordered physical therapy and is familiar with the patient's diagnosis and treatment may not be involved in providing the therapy supervision. It is hard to see how the current incident to billing rules would serve to more closely connect physical therapy to the physician practice as compared to the physician group billing as a physical therapy supplier. Under either scenario, the physician group practice is responsible for the conduct and actions of its physical therapists and the care of its patients. The only difference is that under incident to billing a physician must be in the office suite, which, as described above, does not result in any increased integration of the services to the group.

Additionally, limiting the IOAS Exception to only those physical therapy services provided incident to a physician's services unreasonably and arbitrarily distinguishes between those therapy services provided by an outside, independent physical therapist and those provided by an in-office, employed physical therapist. This distinction creates an uneven playing field within the physical therapy profession by allowing independent physical therapists to practice without any physician supervision, while requiring physician group practice physical therapists, with the same credentials, to work only with physician supervision. Such an arbitrary distinction in no way enhances patient care or addresses the program abuse concerns of CMS.

CMS has also questioned whether DHS "not needed at the time of the office visit to assist the physician in his or her diagnosis or plan of treatment" are appropriate for inclusion under the IOAS Exception.

However, Congress could have, but did not, limit the IOAS Exception in such a manner. In the context of physical therapy (as well as many other DHS such as occupational and speech therapy, radiation therapy, prosthetics, and orthotics), the service is not intended to assist in the diagnosis of a patient, but rather treatment of the patient once a diagnosis is rendered. Further, physical therapy, as well as radiation therapy, are treatment services provided over an extended period of time that will not always coincide with a physician office visit. Even under incident to billing, Section 60.1 of the Medicare Benefit Policy Manual recognizes that each occasion of service by the auxiliary personnel do not need to be the occasion of the actual rendering of a service by the physician. Accordingly, even if CMS requires physician practices to bill for physical therapy on an incident to basis, the therapy could still be provided apart from a physician office visit.

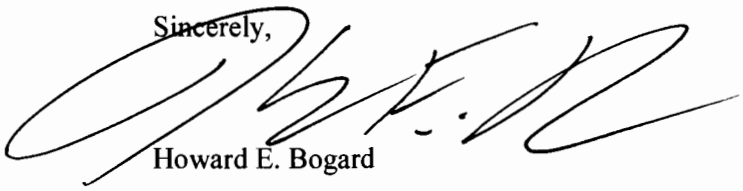
Furthermore, from a public policy standpoint, the IOAS Exception in its current form greatly benefits patients and enhances patient care. Limiting the IOAS Exception in the manner proposed by CMS would eliminate those benefits while doing nothing to alleviate the program abuse concerns of CMS. Among the benefits of the IOAS Exception for physical therapy services are a higher standard of patient care, increased patient convenience, and cost savings. According to the American Academy of Orthopaedic Surgeons ("AAOS") Position Statement on Physician-Owned Physical Therapy Services "[i]n-office therapy allows therapists and physicians to work together as a team, exchanging information and sharing ideas. The frequency and immediacy of feedback allow for the fine-tuning of therapeutic protocols that serves to improve patient outcomes. 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."[1] The current IOAS Exception fosters coordinated, tailored, and efficient treatment by the physician and the physical therapist by allowing the providers to work closely together and communicate directly. For example, when therapy is not as effective as anticipated, the physician can easily coordinate with the physical therapist to revise the treatment plan. Revising the treatment early will result in fewer office visits, and reduce the potential for treatment errors.

Finally, the IOAS Exception as it currently stands adequately addresses the concerns of CMS regarding program abuse by limiting the use of the exception to certain circumstances which satisfy specified supervision, location and billing requirements. Limiting the Exception further for only certain types of DHS would unduly interfere with the practice of medicine. As noted previously by CMS, "a number of physical and occupational therapy organizations complained that physicians would use the [IOAS] exception to expand the scope of the services they provide within their practices and thus capture additional revenues from their own referrals. These commenters suggested tightening various elements of § 411.355(b). As we [CMS] explained more fully in the Phase I preamble (66 FR 880), we believe the final rule reflects the balance that the Congress sought between regulating physician financial relationships and not unduly interfering with the practice of medicine." (69 Fed. Reg. 16054, 16070).

[1] American Academy of Orthopaedic Surgeons, *Position Statement: Physician Owned Physical Therapy Services,* Dec. 2004, *available at* http://www.aaos.org/about/papers/position/1166.asp.

From both a legal and public policy standpoint, the contemplated revisions to the IOAS Exception are inconsistent with Congress' intent and would not be in the best interest of Medicare patients. I appreciate your thoughtful consideration of these matters.

Sincerely,



Howard E. Bogard

HEB/slm

Rinaldi
PHYSICAL THERAPY

August 21, 2007

Mr. Kerry N. Weems
Administrator-Designate
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Subject: Medicare Program Part B Policies

Re: Physician Self-Referral Issues

Dear Mr. Weems,

This is a letter for serious consideration regarding the July 12 proposed 2008 physician fee schedule rule, specific to the issue of physician self-referral and "in-office ancillary service" exception that include physical therapy services.

I am a physical therapist in private practice who has experienced hardship in business due to the rule that permits physicians to self-refer for physical therapy services. The loophole that exists within Stark Phase III regulations has allowed physicians to capitalize on their referral-making ability for their own profit.

This loophole has not only allowed the creation of a monopolistic scheme of self-referring physicians that "control where a patient goes in order to control where the money flows", but also has actualized fraud and abuse of the system as a result.

Naturally as you let that statement sink in, you will agree that such schemes are contrary to ideal CMS policy and to the free-enterprise system that is the backbone of American capitalism. As you probably already know, Medicare is having problems with the sustainable growth rate of utilization and that physician visits are a massive part of this, as it equates to VOLUME. Thus abolishing the in-office ancillary services exception for physical therapy will obviously benefit the Medicare program as it abolishes the referral for profit scheme, and eases the burden on the Medicare system. It also restores parity to the marketplace.

Much like former NY Attorney General Eliot Spitzer's investigation yielded evidence that referral for profit arrangements between insurance companies and brokers led to fraud, increased consumer pricing, and a drag on the economy, physician referral for profit also imbues elements of fraud, abuse and over-utilization and thus creates a drag on the Medicare program and quashes the efficiency of a free market system to compete at higher quality of value for service.

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In the past few years, the number of self-referring physicians has skyrocketed, putting small practices such as mine in jeopardy. Last Fall (2006) my top referring physician group decided to merge practices with another group and also include physical therapy in their "arrangement" (their "arrangement" also included a new building with underground parking, a racquetball court for the doctors to play on during lunch, and softball batting cages for another doctor's kids–he's the coach, after all), as well as diagnostics and pharmacy.

The result: no new referrals from this group as their referral coordinator told me that she was "not allowed to refer out to any other physical therapy other than their own." I was good enough to see their tough patients and their VIPs previously, but no longer.

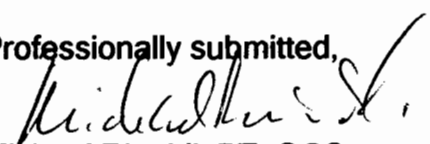
Consider also that if you were to spend millions on a new facility and put in money-making services in that facility, would you potentially overuse or misuse those services in order to make the money necessary to pay down your loan? It doesn't take a Harvard MBA to figure out that answer. The broadly defined exception rule allows for such situations to occur as such physicians have a captive audience of potential patients to refer to their own facility. And for patients who truly need physical therapy, services can be attained conveniently at any independent physical therapy clinic. There simply is no benefit to attaining service at a physician's office.

In summary, the loophole in Stark III has created:

- Situations of self-referral abuses
- A burden on the Medicare Part B program
- Monopolistic practices in the marketplace

This information I believe you will find helpful. The more you review information such as this the more you will be moved to act to eliminate physical therapy services from the allowed physician ancillary exceptions.

Professionally submitted,



Michael Rinaldi, PT, OCS
Rinaldi Physical Therapy

MANKATO CLINIC

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August 27, 2007

CENTERS FOR MEDICARE AND MEDICAID SERVICES
DEPARTMENT OF HEALTH AND HUMAN SERVICES
ATTENTION CMS 1385 P
MAIL STOP C42605
7500 SECURITY BLVD
BALTIMORE MD 212441850

RE: PHYSICIAN SELF REFERRAL PROVISIONS

Ladies and Gentlemen:

As a physician practicing in Mankato, Minnesota, I am most aware of the issues of clinical and cost issues that are important to Medicare beneficiary on the CMS. As an urologist I have been involved with providing patient lithotripsy and other cutting edge therapies for urologic diseases and services that would not have been widely available to Medicare beneficiary without the involvement of urology joint ventures that dramatically expanded patient access by taking the risk of providing costly services. The 2008 Professional Fee Service Proposal attacks the very substance of these joint ventures. Let me address the different Anti-Physician Ownership Proposal separately as they were enumerated in the proposal.

1) Under Arrangements. The substance of the CMS proposal is to band legitimate physician joint ventures from contracting with hospitals to provide therapeutic services.

Indeed, hospitals baulk at buying state of the art technology. As such, only through joint ventures such as the ones being discussed are these services available.

2. CMS Perclick Fee.

CMS's proposal to band perclick fees flies directly in the face of congressional intent as you noted in your commentary. CMS should not band a compensation method that congress stated is permitted.

3. Percentage Fee Reimbursement.

The same entrapenural spirit that created value for the perclick fee arrangement did the same for the percentage fee arrangement. As new therapies are developed Medicare patients will be harmed by denial of access to these procedures.

4. Burden of Proof.

CMS proposes any action involving Stark Regulations; that is the provider that would have to ~~approve~~ prove the referrals were not made in violation of Stark. Most Stark exceptions require payments be made at fair market value and in a manner that does not reflect volume of value of referrals. Experts often disagree on what is fair market value. Now we as physicians must face the undeclared burden of a hidden tax which I must prove that my actions were legal rather than the government agency which writes the law proving that my action was illegal.

In this conclusion I would ask the CMS to differentiate 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 urology community can see that our therapy joint ventures have broadened access to new technology and brought efficiencies which were needed.

Most sincerely yours,

Michael C. James, MD
Department of Urology

MCJ/jae
D: 08/27/2007 13:26:08
T: 08/27/2007 13:30:40
Voice ID: 175255 184436
cc:

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Mankato, MN 56002

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caring.

August 27, 2007

MEDICARE AND MEDICAID SERVICES
DEPARTMENT OF HEALTH AND HUMAN SERVICES
ATTN: CMS-1385-P MAIL STOP C4-2605
7500 SECURITY BLVD
BALTIMORE MARYLAND 21244-1850

To Whom It May Concern:

I am a physician practicing in Mankato, MN. I am acutely aware of both the clinical and cost issues that are important to the Medicare beneficiary and CMS. As an urologist, I have been involved with providing my patients lithotripsy and other cutting edge therapies for urologic 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 2007 release/2008 physician professional fees schedule proposal, CMS attacks the substance of the very joint ventures that by all accounts have saved Medicare millions of dollars.

I would ask CMS to differentiate between 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 in the urology community can say that our joint therapy ventures have broaden access to new technology for Medicare patients, brought needed efficacy to the market, and simultaneously saves CMS 100s of millions of dollars. To jeopardize such a time, tested and proven model would have seemed full heartily, even in the CMS's rational attempt to eliminate bad behavior.

Sincerely Yours,

Gary S. Goldberg, MD
Department of Urology

GSG/glt
D: 08/27/2007 15:04:01 T:08/27/2007 15:23:12
Voice Job ID: 175405 Document ID: 184725
cc:

This document has been electronically authenticated by Gary S. Goldberg, MD.
08/28/2007 11:50:48

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Pathology Consultants P.C.

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Phone 541 341 8033
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August 23, 2007

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

Re: Physician Self-Referral Provisions

To Whom It May Concern:

Pathology Consultants, PC is seizing 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." Our group of eleven board-certified pathologists serves three hospitals and numerous clinics in Eugene, Springfield, and Coos Bay, Oregon. We are all members of the College of American Pathologists and have enjoyed a long history of providing the local pathology needs of the Eugene, Springfield, and Coos Bay areas. Recent developments in our community in the form of proposed kick-back schemes and "pod" laboratories threaten the quality of local pathology services.

Thank you CMS for undertaking this important initiative to end self-referral abuses in the billing and payment for pathology services. We are aware of arrangements in our practice area that give physician groups a share of the revenues from the pathology services ordered and performed for the group's patients. Our belief is that these arrangements are an abuse of the Stark law prohibition against physician self-referrals and we support revisions to close the loopholes that allow physicians to profit from pathology services.

Specifically our pathology group supports 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. We 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. We 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,

Debra A. Groom, MD
Michael J. Hahn, MD
Michael G. Herz, MD
Lauren A. Hammock, MD
Jeffrey A. Houck, MD
Brent D. Kehn, MD
Daniel P. Kerrigan, MD
Denis M. McCarthy, MD
J. Robert McFarlane, MD
Lamont A. Wettstein, MD
L. Samuel Vickers, MD
David S. Meyers, MD

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Citizen Advocacy Center

A Training, Research, and Support Network for Public Members of Health Care Regulatory and Governing Boards

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

August 28, 2007

RE: CMS-1385-P
Therapy Standards and Requirements

Gentlemen:

The Citizen Advocacy Center (CAC) submits this comment on the above-referenced proposed rules published in the Federal register on July 12, 2007. Under the proposed rules, the definition of "physical therapist" in Section 484, Title 42 of the CFR would be changed. Under the proposed rules, physical therapists would, among other things, be required to pass a national examination approved by the American Physical Therapy Association (APTA), a private professional association.

CAC is a not-for-profit 501-C-3 organization serving the public interest by enhancing the effectiveness and accountability of health professional oversight bodies. We offer training, research and networking opportunities for public members and the health care regulatory, credentialing, and governing boards on which they serve.

CAC opposes the proposed rule change, and urges CMS not to make this rule final. There is absolutely no justification to support this rule. We say this as an organization that strongly supports national uniformity in testing of all types of health professionals. For the physical therapy profession, national uniformity in testing is already the case. In order to be licensed in any of the 50 states, a physical therapist must take and pass the National Physical Therapy Examination (NPTE) developed and administered by the Federation of State Boards of Physical Therapy (FSBPT). Not only is there in place a national test, there is a single national passing score.

Unlike APTA, the FSBPT is not a private professional association whose mission is to promote the interests of the physical therapy profession. Rather, FSBPT is an organization composed of the state physical therapy licensing boards. These boards, created by their state legislatures, have a different mission than APTA. The boards are statutorily mandated to protect and promote the public health and safety, and are

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mandated to ensure that only qualified individuals who pass the NPTE and who meet all other statutory and regulatory requirements are licensed to practice.

One need only look at the medical profession to understand the difference between relying on the licensing board community to develop qualifications tests, and relying on private professional associations whose mission, as stated above, is different. A few years ago, in medicine, the American Medical Association (AMA) opposed the creation of an additional exam (USMLE III) by the Federation of State Medical Boards (FSMB) and their partner, the National Board of Medical Examiners (NBME). The USMLE III requires medical students demonstrate satisfactory communications skills before they are allowed to enter a residency, making passing the test a condition of licensing in the several states. Had the AMA been in charge of test development, there would be no such requirement.

For CMS to consider handing over to a private professional association (in this case APTA) the power to decide what will and will not be included in a qualifications exam runs the risk that the exam will not be as rigorous as it should be, and runs the risk of compromising public health and safety. It is an unnecessary risk for CMS to take in the case of physical therapists, because, as stated above, there already exists a national exam subscribed to by all state physical therapy licensing boards.

CMS currently relies exclusively on state licensing in defining "doctors of medicine" and "registered nurses." It should do the same for physical therapists.

Sincerely,

David A. Swankin, Esq.
President and CEO, CAC

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736 Oak Avenue
River Edge, NJ 07661

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.

Re: **Physician Self-Referral Issues**

Dear Sir:

I am a practicing/licensed physical therapist with over ten years of experience. I am licensed in the State of New York and New Jersey. Currently, I am a supervisor of an orthopedic outpatient clinic in Bergen County, New Jersey. The past 3-4 years I have seen many physician owned physical therapy services (POPTS) "popping" up all over Bergen County and as a result many physician referrals have diminished in private physical therapist owned facilities.

The growing number of POPTS facilities is a great concern of mine. In an ideal world, the physicians would only recommend physical therapy(PT) for those who truly need it. These POPTS facilities ideally would only see the patients for as many visits that required skilled PT. Everyone knows we do not live an ideal society. The potential to overuse PT services and over bill will ultimately result from these type of facilities which in turn will hurt Medicare as well as other insurance companies.

I have had multiple experiences with patients that have been redirected by physicians because the facility had a strong "relationship" with that particular doctor. One example, I was treating a patient after a shoulder surgery. The patient had 12 visits at our facility and was progressing normally. I sent a progress note to the referring M.D. The operating doctor returned my Progress note with a huge X scratched on the front and a check mark that indicated discharging the patient from our facility. Immediately, I called the patient to find out what had happened. The patient stated the doctor wanted him to go to another facility. When I asked if that facility was in the basement of that doctor's office he responded, yes. When I asked if he mentioned any other facilities he said the doctor insisted upon the facility in his building only. In another example, I was treating a woman who was very happy with our services. She told me her husband had a tear in his elbow and would need surgery as well as PT. She told her husband to come to our facility. When I spoke to her again she said her husband had the surgery and he was instructed to go to the basement of his doctor's office to talk with one of his girls. Upon speaking to the girl he realized that the orthopedic office was affiliated with the PT office in the basement. They went ahead and tried to schedule PT appointments when the patient realized that it conflicted with his follow up appointment with the doctor. The girl at the desk said that she could switch the doctors appointment right from her computer. These are two of many examples of abuse that is happening in our area with POPTS facilities. If this continues; patient care will decline, the

field of physical therapy will erode and insurance utilization will become greatly abused.

Thank you for your time and consideration in regards to POPTS.

Sincerely,

Kenneth S. Weinkauf, PT

273

Three Rivers UROLOGY, P.C.

LAWRENCE A. COLLINS, M.D.
JAMES J. McCAGUE, M.D., F.A.C.S.
DANIEL J. COLE, M.D.
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FAX (724) 934-5533

Dear Sirs

I am writing to you today in response to the proposed changes to Under Arrangements, Per Click Fee, Percentage Fee arrangement, "Stand in the Shoes" and Burden of Proof. I am a practicing Urologist in Pittsburgh, Pennsylvania, and have been for over twenty-one years. The thought of yet another change in Stark regulation as in pertains to physician owned ventures, and lithotripsy in particular, is disturbing. The notion that physician ownership is "corrupting medical decision making" is an affront to my integrity, particularly as it pertains to therapeutic services such as lithotripsy.

I have, and will continue to treat my patients according to there best interest. AKSM, of which I am a "shareholder", has provided the highest standard of medical care to its patients, along with quality control, treatment monitoring and efficacy parameters, patient education, while still providing "state of the art" technology to its physician users and patients. I see this as a personal attack on my character and integrity, which I have established over the last two decades. I certainly agree that there are physicians, hospital systems, insurance providers and Government Agencies that have abused the Medicare system over its lifetime. But to single out these well-established services for potential abuse, when there is no data to support this, is inappropriate, and is it self, abusive.
Thank you for you time and attention to this matter.

R.G.Cercone M.D.,F.A.C.S.

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Department of HealthEast
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August 15, 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 Chris Laird and I am an Associate Administrator at St. Joseph's Hospital-HealthEast Care System which is a provider of image guided robotic stereotactic radiosurgery. We thank you for the opportunity to comment to the Centers for Medicare and Medicaid Services (CMS) 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 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.

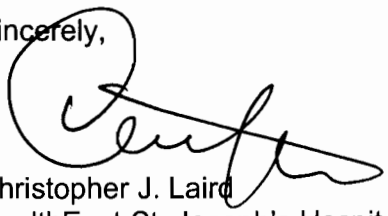
Addendum B: 2008 Relative Value Units and Related Information Used in Determining Medicare Payments for 2008

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. We 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.

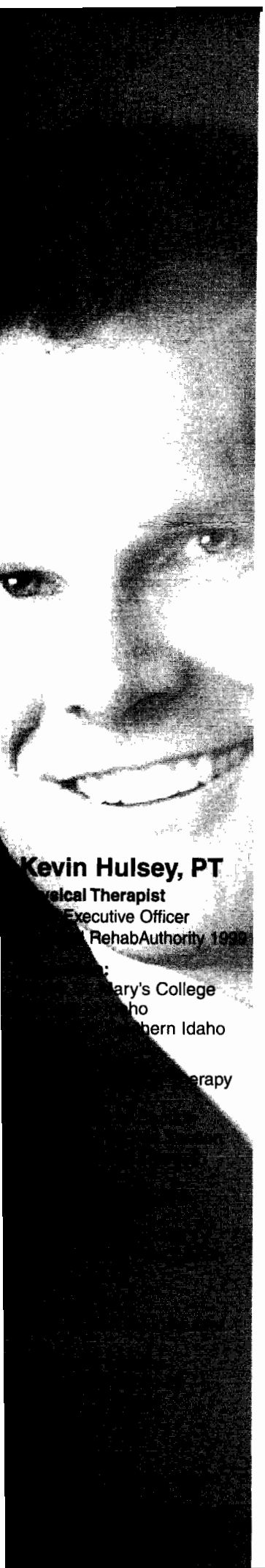
Conclusion

In summary, we 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,



Christopher J. Laird
HealthEast-St. Joseph's Hospital
and Member of The CyberKnife Coalition



REHABAUTHORITY
Physical Therapy • Back & Neck Specialists

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20 AUGUST 2007

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.

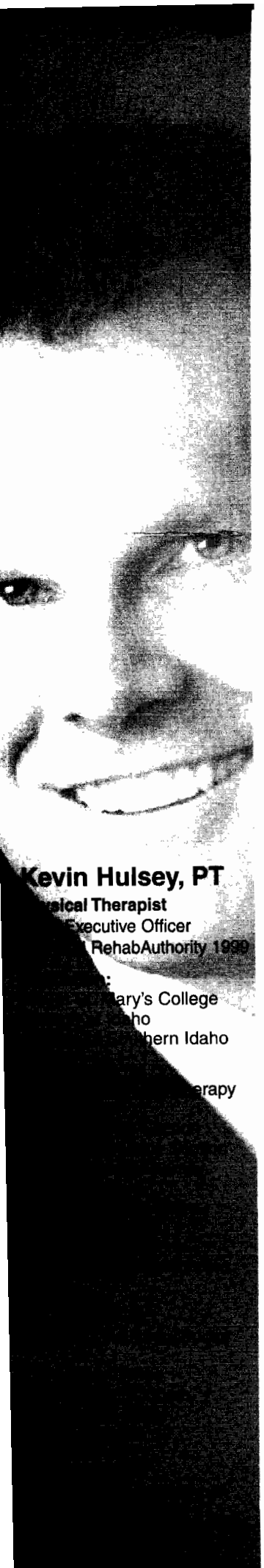
Subject: **Physician Self-Referral Issues.** Medicare Program; Proposed Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Rule

To Whom It May Concern:

My name is Kevin Hulsey and I am a Doctor of Physical Therapy. I am in private practice in Idaho. I currently own 10 small clinics throughout the State of Idaho. I have been in private practice for 8 years.

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 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-utilization of physical therapy services under the Medicare program, and enhance the quality of patient care.

In Idaho there are several physicians opening their own physical therapy companies. Physicians have offered many reasons for opening their own clinics, "we can't find good therapists," "we want to be able to control the therapy," "we want to make it convenient for our patients," etc. However, those same physicians are recruiting the same local physical therapists, which are not competent away from the physician office, but suddenly become competent when they are in the physician office. Their desire to control the therapy is unrealistic, surgeons do not have the time, the desire, nor has the knowledge to provide oversight to a physical



REHABAUTHORITY
Physical Therapy • Back & Neck Specialists

therapist that been educated for seven years in a unique body of knowledge to provide a unique service that surgeons are not educated to provide. 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 benefits laws to collect payment in order to circumvent "incident-to" requirements. Lastly, 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.

The CMS "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 of physical therapy patients in their offices.

Thank the Acting Administrator for her consideration of your comments.

Sincerely,

Kevin Hulsey, PT, DPT, CEO

Kevin Hulsey, PT, DPT, CEO

Experience the Difference!

276

LEONARD BIEL, Jr., M.D., P.C.
114 East 90th Street
New York, NY 10128

Telephone: (212) 369-7070
Fax: (212) 369-8158

Urology

Aug. 22, 2007

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

Re: Proposals in recently released
2008 Physician Fee Schedule

Gentlemen,

I am writing to express my opinion and concern regarding certain provisions of the proposals in the recently released 2008 proposed physician fee schedule. I have practices urology in New York City since 1954. During that period I have witnessed tremendous technological advances with incredible benefit to the patient. Despite the costs of the technology there has been less hospital time to be paid for and generally medical care and health have improved. As a urologist I have been able to view first hand the benefits and effects of these new advances. But I have also noted an increase in regulations many of which have been provided by non-medical personnel and without apparent consultation with them. I have seen technology improve, cost more, but in the end they have saved time and money and I leave it to you to decide which is more important.

I'm a urologist and not an attorney or politician and I confess that I view some of the remarks and explanations of the new regulations seen through a haze. But one thing is very clear: more regulations and demands made upon professional personnel makes for less patient care since there is no way to increase the 24 hour day. Regrettably, dictating and copy machines increase the burdens on both the writer and the reader.

I understand there is some question as to who has the new technology available. In my own institution, Mt. Sinai - a major New York City hospital - the technology available to my department is not owned by the institution. Lithotripsy was originally exclusively confined to the Bronx Veterans' Administration Hospital. The advances in minimal prostatic surgery and vaporization procedures is not available in the hospital with which I am familiar. Yet these technologies save hospital costs andneedless to say, patient's time.

It seems to me that unless changes in regulations are made with conjoined consultation between the professionals who have to perform the procedures and the payors and manufacturers, no satisfactory solution will be obtained. In an aside, many Americans are leaving the country for care, specifically to India and Thialand. There are, of course, financial considerations here. These are also important and the new technology definitely impacts on this.

For someone who really loves his profession, I would ask you to consider the following: "Please don't fence me in."

Sincerely,

Leonard Biel, Jr., M.D.

LBjr:w

277

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.

Regarding: 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 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. My 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.

I have been a physical therapist for over 20 years and have worked in hospitals, extended care facilities and private practice settings. In almost all of these settings I have been witness to, and affected by, physician owned physical therapy situations. It is my firmest conviction that these situations serve only to further the income of the physician who owns them. I have seen over utilization, system abuse, and anti-competitive activity as a result of physician owned physical therapy practice.

As I look to the future I see an aging population, a static or shrinking Medicare revenue base, and a static or shrinking number of providers to serve this growing elderly population. I ask you to take whatever steps you can to restrict Medicare funds from feeding self-referral situations. With the limited resources available we cannot afford needless waste from system abuse and anti-competitive practice.

I thank you for your time and action in serving the best interest of America's senior citizens.

Physical Therapist
21234

August 15, 2007

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

Mr. Weems:

I am a physical therapist writing to you regarding the problems of physician self referral to ancillary services in which the physician has a financial interest whether it be in the physician's office directly or at another location. Physical Therapists refer to these types of situations as "referral for profit" arrangements. As the name implies, the primary reason for the referral is for profit, not patient care. In my specific situation, we have a hospital based outpatient therapy clinic located in the same building as a group of physicians. Access to services is simply a matter of which floor the elevator stops at. We have multiple therapists in our clinic who are specialists in orthopedic and neurological disorders – many of which are specialized by the specific joint involved. In spite of our expertise and literally being on site in the same building, these physicians apparently felt the need to hire their own employed physical therapist who does not have near the experience or credentials as the hospital based staff and cannot possibly provide the same level of expertise as the hospital based staff in the same building. This therapist was hired solely for the purpose of creating revenue for the physicians. This letter is not commenting on the quality of the therapy being provided but simply that there was no reason other than profit for the addition of this therapy to the physician practice.

I would strongly urge CMS to remove physical therapy as a designated health service (DHS) permissible under the in-office ancillary exception of the federal physician self-referral laws.

Sincerely,

Concerned Physical Therapist
Sioux Falls, SD 57105

TEXAS SOCIETY OF PATHOLOGISTS
Focusing on Excellence in Medicine
SINCE 1921

August 22, 2007

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

On behalf of the Texas Society of Pathologists (TSP) I 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." We have had a number of discussions about this most recently at our Board of Directors meeting on August 11, 2007 and would like to submit the following comments.

TSP applauds CMS for undertaking this important initiative to end self-referral abuses in the billing and payment for pathology services. We are aware of arrangements in Texas that give physician groups a share of the revenues from the pathology services ordered and performed for the group's patients. We believe these arrangements are an abuse of the Stark law prohibition against physician self-referrals and support revisions to close the loopholes that allow physicians to profit from pathology services they did not supervise or perform.

Specifically we 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. We believe that a physician should not profit from laboratory services unless that physician personally performs or supervises the services.

Opponents to these proposed changes assert that their captive pathology arrangements enhance patient care. The Medicare program should ensure that providers furnish care in the best interests of their patients. Restrictions on physician self-referrals are an imperative program safeguard to ensure that clinical decisions including choice of laboratory are made 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,

V.O. Speights, Jr., DO
President

EXECUTIVE OFFICE
Shari Rhodes, CMP, Executive Director • 401 West 15th Street • Austin, TX 78701-1680
512/370-1510 • FAX 512/370-1635 • www.texpath.org

UROLOGIC SPECIALTIES, P.A.

280

Philip S. Affuso, M.D. • Raymond B. Andronaco, M.D. • John F. Kerns, M.D. • Richard Lee, M.D.

106 Grand Avenue, Englewood, New Jersey 07631
6045 Kennedy Boulevard, North Bergen, New Jersey 07047
201-569-7777 • Fax 201-569-6861

August 22, 2007

Center for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-13850P
PO Box 8018
Baltimore, MD 21244-8018

Dear Sir or Madam,

I am writing concerning the misguided interpretation of the proposed 2008 Physician Fee Schedule as well as the proposed Stark 3 bill.. As a physician practicing in New Jersey, I can appreciate the concerns the public has regarding abusive physician self referral but the fact of the matter is that more Medicare recipients will be harmed than helped for the sake of the few physicians out for personal gain.

We entered into a joint venture to allow us to deliver services not previously offered by our hospitals. I refer specifically to lithotripsy, and extremely expensive proposition for hospitals to undertake during these very difficult times of cutbacks. These services are able to be offered in the community in familiar surroundings without adding the burden of excessive travel. We have also been able to offer service on demand for urgent and emergent cases. Previously, patients would have a wait of 4 to 6 weeks often in pain or require ancillary treatments which could be avoided by more available services. By blocking these joint ventures, you would effectively be denying readily available services and would also be increasing, not decreasing, Medicare expenditures.

We have assumed financial risk for the sake of patient care by entering into these ventures. Our hospitals in New Jersey provide excessive uncompensated care for indigent patients and can ill afford the capital necessary to provide these expensive services.

CMS has shifted the supposed burden of proof regarding referrals unfairly onto the physicians. It is difficult, if not impossible, to prove or disprove that and illegal referral occurred. How can we be expected to prove that our actions are legal when CMS will be sitting in judgment with an interpretation of a law contrary to the intention of Congress? This would, on the surface, be an abuse of power.

As far as fee arrangements, per click fees are not abusive and should not be applied to lithotripsy as the original intent of Congress was to apply this to designated health services which lithotripsy is not. To extend this to lithotripsy would be directly contrary to Congressional recommendations. Hospitals often cannot afford anything but a per click arrangement because of the expense of the technology and the drain on the limited capital most hospital have. We physicians have assumed great risk so that patients and hospitals can benefit. It would be immoral to change this. To ban this would prevent patient access to advanced modern and proven therapies.

BABIN PHYSICAL THERAPY

371 W. ESPLANADE AVE
KENNER, LA 70065
504-467-5520 FAX: 504-471-0740

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

Re: **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

I am a physical therapist and private outpatient physical therapy practice owner in business for 13 years. My business has been adversely affected by the proliferation of physician owned physical therapy businesses and physician self-referral arrangements. I have had countless patients complain to me about the poor quality of care they received at these offices and the physician's unwillingness to refer them to facilities other than their own.

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, overutilization of physical therapy services under the Medicare program, and enhance the quality of care.

The broadly defined regulation of the "in-office ancillary services" facilitates the creation of abusive referral arrangements. This has created a loophole that has resulted in the dramatic 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.

Physician direct supervision is not needed to administer physical therapy services. 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 on this matter.

Sincerely,

Michael D Babin, PT

Michael D. Babin, PT

STATE OF ALABAMA
BOARD OF PHYSICAL THERAPY
100 NORTH UNION STREET, SUITE 724
MONTGOMERY, AL 36130-2040

Email: nk.horner@pt.alabama.gov
or sheila.wright@pt.alabama.gov

Phone: *(334) 242-4064*
(334) 242-3603
(888) 726-9743
Fax: *(334) 242-3288*

Nettie Katharin Horner
Executive Director

August 20, 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 State of Alabama Board of Physical Therapy 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 "[p]assed 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, 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.

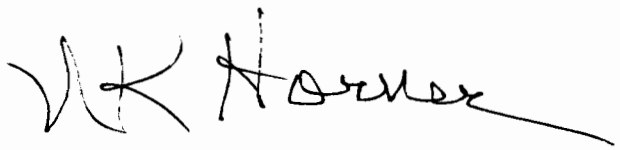
CMS and the federal government should not empower an advocacy group, like the APTA, to establish an examination or any qualifications for professionals to provide healthcare services to patients. The APTA's mission is to advocate and promote the profession. As a licensing body, our mission is to ensure 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 State of Alabama Board of Physical Therapy 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 therapist assistant qualification requirements.

Respectfully yours,

The State of Alabama Board of Physical Therapy



By: Nettie Katharin Horner
Executive Director

SUMMIT PHYSICAL THERAPY
MAXIMIZE YOUR POTENTIAL

Jennifer Lutz, MPT

1667 Rombach Ave.
Wilmington, OH 45177
Tel 937-383-3293
Fax 937-383-3296

August 21, 2007

Re: **Physician Self-Referral Issues**

Dear Kerry N. Weems-

This letter is in regards to the July 12th proposed 2008 physician fee schedule rule, specifically the issue surrounding physician self-referral and the "in-office ancillary services" exception. Below are my comments intending to highlight the abusive nature of physician-owned physical therapy (P.T.) services and support P.T. services removal from permitted services under the in-office ancillary exception.

Let me start by telling you about myself. I have been a physical therapist for 7 years and currently work in a small private outpatient clinic. I have seen many changes in this short amount of time including wonderful therapists and mentors losing their jobs and closing their doors because the loss of patients to physician owned P.T. clinics have created a financial burden. I've seen therapist friends who swore they would never work for a physician-owned practice taking jobs working for doctors as independent P.T. practices were no longer around to work for. I've seen patients upset because the therapist they've always seen and have created a relationship with is no longer around as they had to close their doors. We are a profession that revolves around physician referral and I believe the physicians have taken advantage of this by profiting from their own P.T. clinics.

Recently I was treating a patient in our small town who ended up going to the "big city" to see a doctor as she was going to need ankle surgery. She asked me if she could see me for her P.T. after her surgery and I told her we would be happy to treat her. I called her just prior to her surgery to see how she was doing and answer any pre-surgical questions she might have. The patient then preceded to tell me that the doctor had told her she needed crutch training prior to her surgery and he wanted her to make an appointment with his therapist to receive training. My patient told her doctor that her drive to his office was 45 minutes and she'd like to come to our facility, closer to her home to be seen by a therapist she already knew. The doctor told her that he wanted her to drive the 45 minutes and come to his office because his therapists knew the exact kind of training needed and his preferences. How infuriating! Not only was this incorrect information as all therapists can give crutch training but it also undermined my skills and made me look incompetent as many patients believe all their physician tells them. This is only an example of the abuse that occurs with physicians who own practices. Due to the repetitive nature of physical therapy services, it is no more convienent for the patient to receive services in the physician's office than an independent physical therapy clinic

closer to their home. Direct physician supervision is not needed to administer physical therapy services.

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. These physicians have an inherent financial incentive to refer their patients to the practices they have invested in and 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, overutilization of P.T. services under the Medicare program, and enhace the quality of patient care.

Thank you for your time and consideration of my comments. I hope this letter has been informative.

Sincerely-

Jennifer Lutz, M.P.T.

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RIATA THERAPY SPECIALISTS P.L.L.C.

Physical Therapy and Wellness

August 17, 2007

To Whom It May Concern:

I am writing to share some brief comments regarding the proposed revisions to the Medicare Payment Policies, specifically the physician self-referral issue. I am a physical therapist who has been practicing just over seven years. I have practiced in several different environments: physician-owned practice, corporate-run practice, and private practice. So, I have observed the detrimental effects that physician self-referral has had on the practice life of physical therapists from many different angles.

It has been my observation that, when physicians are allowed to refer business to a practice in which they have a financial interest, several problems typically occur. Those problems are: 1) patients are not provided with accurate information regarding their freedom to chose their own provider which often results in patients driving long distances from their homes and often receiving less than adequate care from a therapist who may not be a specialist in the area of the patient's injury due wholly or in-part to the physician's recommendation that the patient use "his/her" therapist, 2) utilization of therapy services tends to be higher with more frequent visits and longer lengths of stay than in private practice or even corporate settings due to financial incentives to provide that care, 3) inappropriate early discharge of patients (prior to the patient meeting treatment goals) is more common, because the frequency of visits tends to be higher in a physician-owned setting (3/wk. versus 1 or 2/wk. for example) and monetary Medicare caps are met more quickly than in other settings.

I do not believe that it is necessary or beneficial for patients to be seen in a "physician-supervised" setting, because those patients are typically supervised no more closely than patients in other settings. Most diagnoses on prescriptions for therapy are vague ("hip pain" or "shoulder injury") and the prescription is often for "evaluation and treatment", so the physical therapy diagnosis and plan of care are determined by the therapist with minimal physician input or oversight. Medicare already has requirements in place so that the physician receives information about evaluation and plan of care prior to initiation of treatment and upon re-assessment of patients every 30 days (after the initial 60 days of treatment). Most physicians who have their own practice are no more aware of the patient's plan of care and treatment regimen than those physicians who take the time to read the reports sent by therapists upon regular evaluation of their Medicare patients.

Office: 817.288.0121
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www.riatatherapy.com

RIATA THERAPY SPECIALISTS P.L.L.C.
Physical Therapy and Wellness

Therapists who work in physician-owned practices are no less qualified than other therapists, typically, but I believe that they are enticed to work in these practices due to higher salaries. Because the physician is not just their referral source, but also their employer, they are also less likely to propose changes in plans of care that might conserve Medicare dollars or benefit the patient because of those loyalties.

In general, when looking at quality of care, I do not think that I am alone in stating that it is more likely for any provider to be concerned with quality of care when their own financial well-being is not directly tied to the referral of patients for that care. I would ask that anyone considering this important issue consider these points when making decisions that affect the well-being of patients, the conservation of Medicare dollars, as well as the well-being of therapists outside the physician-owned market. Thank you for taking the time to review these comments. I will look forward to seeing how the input of therapists across the country affects the decisions being made on this important issue.

Sincerely,

Tina Neuwirth PT, MPT, OCS

Tina Neuwirth, PT, MPT, OCS

Office: 817.288.0121
Fax: 817.288.0124

2008 L. DON DODSON DRIVE ◆ SUITE 105 ◆ BEDFORD, TEXAS 76021

www.riatatherapy.com

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W. Daniel Doty, M.D., F.A.C.C., F.A.H.A.
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G. Ramon Aycock, M.D., F.A.C.C.
F. James Fleischhauer, M.D., F.A.C.C.
S. Marcus Borganelli, M.D., F.A.C.C.
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Brent D. Videau, M.D., F.A.C.C.
Andrew Scott Kees, D.O., F.A.C.C.
James L. Lonquist, M.D., F.A.C.S.
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August 27, 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 Langhorne Cardiology Consultants, M.D.'s, P.A. and our 23 individual 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.

Our practice, d/b/a Cardiology Consultants, P.A., has been serving the Greater Pensacola area for 30 years. We have 2 non-hospital outpatient cath labs within our practice that each average approximately 800 cases per year. These outpatient facilities allow the more critical diagnostic caths, as well as interventional and electrophysiological cases to be performed in the hospital in a timelier manner.

Langhorne Cardiology Consultants, M.D.'s, P.A. 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,

Andrew Radoszewksi, M.B.A., M.P.H., CMPE
Administrator

BROOKS℠
Health System

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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.

RE: Physician Self-Referral Issues

Dear Mr. Weems,

I am a physical therapist and I currently practice with Brooks Rehabilitation in Jacksonville, FL. I have been in practice in several settings and two states since my graduation from physical therapy school 22 years ago. 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.

My current position within Brooks Rehabilitation is to provide advanced residency and fellowship training for physical therapist practitioners. In one of our physical therapy out-patient centers, our staffing is provided by physical therapists, each of whom has significant advanced training in orthopaedic physical therapy. A physician group who had been a primary referral source for this practice recently employed a physical therapist within their office whose skill level did not match that of the physical therapists within the Brooks facility. However, very soon after the physician's opened their physical therapy clinic within their own office, the referrals dropped significantly. It is clear that the physicians are referring to their employed physical therapists regardless of the patient's complexity or service needs.

Multiple studies have demonstrated that when physicians have the ability to profit financially, as a result of making a referral, this situation will lead to over utilization of services. Specifically in the case of physical therapy, the California Workers Compensation Agency has identified significant over utilization of physical therapy services when the physician employed physical therapists within the physician's office. In Florida where I currently practice, a legislatively mandated study, demonstrated over utilization of physical therapy services when physicians profited financially from the referral to physical therapy services.

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I find it interesting to hear the accounts of physicians who report that the patient receives better care secondary to improved communication from the physician employing the physical therapist. Communication is critical to improved care when healthcare providers are each providing services to a given patient, however, this employment relationship is no guarantee of improved communication. It does not take a "rocket scientist" to figure out the true motivation for these relationships. You can select any large physician journal and/or attend a physician conference and the decision to employ a physical therapist within the physician's office becomes extremely clear. The advertisements from the consultants to assist the physicians in opening a physical therapy practice within their office do not EVER speak to the improved care of the physician's patients. Rather they talk about the increased revenue that this venture will produce. Personally, this is the clearest demonstration of the physician's motivation for entering into the practice of providing physical therapy services within their office.

In addition I wanted to make the points that the "in-office ancillary services" exception is defined so broadly in the regulations that it facilitates the creation of abusive referral arrangements. In addition, 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. 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 benefits laws to collect payment in order to circumvent "incident-to" requirements.

In conclusion I want to highlight the abusive nature of physician-owned physical therapy services and support physical therapy services removal from permitted services under the in-office ancillary exception. 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. I strongly support any effort to eliminate abusive financing arrangements under the Stark law that are created solely for profit without regard to the best interest of the Medicare beneficiary. **I strongly urge the CMS to remove physical therapy as a designated health service (DHS) permissible under the in-office ancillary exception of the federal physician self-referral laws.**

Sincerely,

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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

RE: **Physician Self-Referral Issues**

Dear Sir:

I am a licensed and practicing physical therapist in the state of New Jersey. I have been practicing for the past 13 years, with the last 5 years specifically in a physical therapist-owned outpatient orthopedic clinic. I am currently the Director of Clinical Services and oversee our 5 centers in the Bergen County area of Northern New Jersey. In this position, I have had the opportunity to witness, first hand, the impact physician-owned physical therapy services have had on our practice and on the Medicare beneficiaries in our communities.

I would like 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, in this case, physician-owned physical therapy services. It has been demonstrated, repeatedly, with every new physician-owned physical therapy site that opens in this area, that the physicians who own the practice have an inherent financial incentive to refer their patients to these practices and over utilize those services for apparent financial reasons. Many of the physician-owned physical therapy practices are in the same suite and/or building as an orthopedic group here in Bergen County. (Not only are orthopedic physicians opening their own physical therapy services on site, the newest trend we have discovered in Bergen County is podiatrists and family practice/internal medicine doctors and groups jumping on the physical therapy "bandwagon"). One orthopedic group, in particular, prior to opening "their own" physical therapy, had sent us a total of 130 patient referrals in a year. Since they have opened their own physical therapy center in the same suite as their office, we have received an average of approximately 60 patients per year; a reduction of over 50%. Of these 60 patients, they tend to have the most limited physical therapy benefits (some have no benefits at all) or have exhausted their Medicare physical therapy cap. Upon evaluation we found these Medicare beneficiaries have made little progress towards their functional goals and are in need of continued skilled care.

In speaking with patients we treat who are under the care of physicians who own physical therapy services, I have had numerous reports that the patient was "strongly urged" by their doctor to attend physical therapy in their specific office, even though it was quite a far distance from their home and the hours of operation were not convenient. I have even had patients report being told, "we cannot be responsible for your outcome of your procedure if you do not attend physical therapy at our practice". When marketing for our practice, I also had a physician's assistant say specifically, "Our PT is very slow and he (the senior MD partner) will not let anyone go, all PT patients will be kept here." In my opinion, this is fraudulent and abusive. Physical therapists licensed in the state of New Jersey can evaluate and treat any non-Medicare beneficiary without a referral or direction from a physician. Even when treating Medicare beneficiaries, we, the physical therapists evaluate and develop the treatment plan and goals, then forward it to the physician for them to incorporate into the patient's plan of care.

An additional concern I would like to discuss, is the increasing amount of physician-owned physical therapy practices in this area that are being reviewed and audited by Medicare, secondary to their billing "problems". We have been approached by 2 specific practices to consult and advise on denied Medicare payment for their physical therapy services. Upon further conversation, the reasons for denial of payments appeared to be secondary to over utilization and the disregard of skilled physical therapy vs. non-skilled physical therapy. This alone is a sufficient reason for eliminating physical therapy as a designated health service (DHS) furnished

under the in-office ancillary services exception. By doing this, 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.

I would like to thank you, Mr. Weems, for your consideration of my comments regarding the matter of physician-owned physical therapy services.

Sincerely,

Keri L. Bratcher, PT, MPT

Keri L. Bratcher, PT, MPT

Teresa Wolterman
Physical Therapist
Cincinnati, OH 45247
(513)703-3657

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

August 19th 2007

Mr. Kerry Weems:

I am writing you regarding physician self-referral issues. 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. Currently physical therapy services are part of this exception.

I obtained my Masters of Physical Therapy in 2002. My first job, that same year, was at Spectrum Rehabilitation, a hospital outpatient physical therapy facility in Cincinnati, Ohio. We received many referrals from the Wellington doctors, a practice of orthopedic surgeons. After 1.5 years the Wellington doctors opened a physician owned physical therapy practice. Many physical therapists at Spectrum lost their jobs because of the decrease in patient volume. It is not ethical for a physician to refer to a physical therapy center in which they have inherent financial incentive. Also physical therapy services can easily be over utilized for financial gain.

I currently work as a physical therapist for the McCullough-Hyde Memorial Hospital outpatient physical therapy department in Oxford, Ohio. A local orthopedic surgeon currently sends us many patients because of the quality of our physical therapy department. We guide our treatment based upon current evidence and research. In the future, this orthopedic consortium may open their own physician owned physical therapy practice. As a result, this will decrease our patient load.

Why would a physician want to own a physical therapy practice, unless there was a financial incentive? 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 over utilization of physical therapy services and enhance the quality of patient care.

Thank you for your consideration of this topic.

Sincerely,

Teresa Wolterman MPT

Teresa Wolterman MPT

August 10, 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

To Whom It May Concern:

As a Urologist physician practicing in Wilmington, NC, I am acutely aware of both the clinical and cost issues that are important to the Medicare beneficiary and CMS. Since I have placed a CT imaging device in my office, I would like to comment on your proposals as they would impact imaging in office.

First, let me state that the standard of care for work up of many of the patients that I see is the CT scan. Ten years ago, I would have gotten different diagnostic studies to evaluate blood in the urine, abdominal pain, possible kidney stones, a kidney mass, or possible metastasis from a primary cancer, but today I get a CT scan. So the number of CT scans that I order is the same today as it was before I put the scanner in my office, it is just more convenient for my patients. In my clinical work, it is only a question of where, not whether, my patient is going to get a CT scan if their condition demands such.

Second, I bought a new scanner, not a used or refurbished unit. Even though it may have initially cost me more money, I felt that a new scanner with the latest detectors and platform gave me better images and my patient less radiation exposure than if I bought a used piece of equipment. I also bought a dual slice scanner, for much the same reasons: reduced patient radiation exposure while getting all the needed diagnostic information. The impression in today's radiology world is the more slices the better, but the fact is that these multi slice units are not needed to diagnose 99% of what I deal with on a daily basis, and because of the radiation scatter of the wider multi slice field, patients are needlessly exposed to added radiation by using more slices than needed. So the dual row scanner is ideal for my patient.

Third, addressing your Anti Mark-Up Provision Proposal, the digital images that my CT produces can be read either off the scanner monitor or on some remote monitor with equal clarity. While I have chosen to use my local radiologists to read my scans, some teleradiology companies give excellent service and very quick turn around. In the future, I may need to globally bill because many teleradiology companies prefer not to do so. I would essentially pay the radiologist his professional fee minus a 7-10% billing administration fee. Your anti markup proposal, however, would seem to forbid such an arrangement, although your language only speaks to eliminating much larger space or equipment lease fees. I assume that you did not intend to harm a reasonable and fair market value approach as I have described above, but clarification would be appreciated.

Fourth, the Anti Markup Proposal would seem to eliminate the possibility of hiring anyone less than a full time technologist, if the practice intends to bill Medicare. While I understand your purpose in eliminating sham operations, your proposal harms fully compliant in office scanners which may need only half time operation when initially installed. Please clarify this provision.

Fifth, in your commentary, you ask for discussion of which type of doctors should

be allowed to put scanners in their offices. My own experience should be instructive in answering that question, because what I see is patient convenience, improved clinical care, and cost savings to the patient and Medicare. As previously mentioned, I did just as many CT scans before I put a scanner in my office as I do now: in other words, I am not over utilizing CT because I have one in place. While the radiologist complains about other doctors putting scanners in office, the fact is that our patients are benefited and the radiologist gets to read all the scans, regardless. It is cost neutral to CMS and clinical quality rises because the sight of scanning is the same as the site of care. For the Medicare beneficiary that has transportation problems or trouble getting friends or family to accompany them to the doctor, my ability to give them "one stop" care is very rewarding. The same is true for countless numbers of my peers

Let me outline a couple of scenarios that clarify my comments. Hardly a day goes by that a patient does not come into our office with an acute kidney stone attack. The standard evaluation nowadays is a non-contrasted CT of the abdomen and pelvis. We can see the patient (on an office visit charge), do the CT scan on the spot, make an interpretation even before the radiologist sees the scan for official reading and make a disposition on the patient. If we did not have the scanner, the patient would probably be seen in the ER (at a much higher cost and longer waiting time) and have to be referred to our office for follow-up (an additional appointment for the patient). We would have to seek out the scan and grapple with hospitals' reluctance to speedily get us the images and interpretation due to HIPPA concerns before being able to make a disposition. As a second example, patients with a history of bladder or kidney cancer are commonly scanned with CT to assess for recurrent disease. With a scanner in our office, we see the patient, get the follow-up CT on the spot, review and interpret the scan on the spot again before the radiologist makes the official interpretation and inform the patient of the results all in one office visit. Before we had the scanner in our office, we saw the patient, scheduled the CT at an imaging center (a tedious and time consuming task for our clinical or clerical staff), sent the patient home, made them go to the imaging center (an extra trip for them) where they got the scan and went home to wait for a couple days while the radiologist interpreted the scans and sent me a report after which I would need again to make a special request to have the images sent to me so that I could review them (more delay for the anxious patient) and call the patient with the results. Moreover, if there were important findings on the CT, I would need to schedule another office appointment to go over the scan with the patient (again, an additional office visit with its time and expense to the patient and the Medicare system).

I hope these two examples clarify the convenience to the patient and the savings to the "system" of my having in office CT scan. No excess studies are ordered--the patient is going to get the scan somewhere regardless--and there are fewer office or ER visits, less anxiety waiting for results and less administration and phone calls on my end scheduling, retrieving and communicating with patients about their studies.

In conclusion, I would ask you to clarify the Anti Markup provision sections mentioned above and to recognize the value of having physicians provide new in office scanning capability to the fragile Medicare patient base.

Sincerely,

Edward W. [illegible] MD

Edward W. Whitesides, MD
Urology Associates
Wilmington, NC
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Carolina Lithotripsy, LTD.

August 17, 2007

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

Re: July 2, 2007 Medicare Physician Fee Schedule Proposed Regulations

Ladies and Gentlemen:

I am a urologist who lives in Kinston, NC. I have an ownership in a partnership venture which provides lithotripsy services to multiple hospitals in eastern North Carolina. I feel compelled to provide you with my comments regarding the above referenced proposed regulations.

When extracorporeal shock wave lithotripsy (ESWL) was first approved in the US in 1985, availability of this technology was very limited. Because I live in a region with a high incidence of stones, I and many of my colleagues became very interested in this technology. We took the time to investigate, speak with our German colleagues who had developed this technology, and reached the conclusion that this new approach to stone treatment should offer our patients great advantage over the treatment methods which were available at that time (endoscopic or open surgery).

Initially, I sent my patients to Charlottesville, Virginia since it was the nearest ESWL device. Attempts to get local hospitals to consider purchasing a device were unsuccessful because the technology was very expensive and "unproven". Therefore, led by a urologist colleague from Fayetteville, NC a group of NC urologists had no alternative but to purchase the technology ourselves. We assumed significant financial risk in order to provide our patients with this technology.

To make a long story short, we have been providing mobile ESWL services to approximately 22 hospitals, many in small rural areas, for many years, always offering the highest quality of care and upgrading to the newest and latest equipment.

Although the aforementioned proposed rules were probably well intentioned and may have merit, some sections are clearly misguided and will have a profound negative effect on lithotripsy services. I am particularly concerned about the three following proposed provisions:

1) Under Arrangements
2) Per Procedure Fee
3) Percentage Fee

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Under Arrangement:

Our present business structure allows for many small hospitals to offer the latest ESWL equipment and service that would otherwise be impossible because of the capital expenditures necessary. The sharing of risk and equipment allows this to be done at a much reduced cost and in a much more convenient fashion.

Please clarify why lithotripsy is a DHS when it was specifically ruled not to be a DHS in a previous court case (*American Lithotripsy Society vs. Thompson*).

Why is lithotripsy proposed to be a DHS when performed in a hospital but not a DHS when not performed in a hospital if performed by our partnership venture?

Please remember that lithotripsy is a *therapeutic* service and not a *diagnostic* service which precludes the possibility of over utilization. In all lithotripsy cases, a patient must have an imaging study (x ray or ultrasound) which documents whether or not the patient has a stone.

Changing the under arrangement provisions does not make sense with regard to lithotripsy. Since I believe that more that three fourths of all lithotripsy in the US is provided "under arrangement" changes required by this rule would cause a marked negative change in the care of patients who have stones. I would anticipate reduced lithotripsy access for government patients.

Per Procedure Prohibition:

Congress clearly intended that per procedure fees be preserved as noted in the Stark legislative history. It would seem that CMS should not be able to contradict the legislative intent through a prohibition of such fee arrangements. Our lithotripsy LLC relies on the Stark indirect compensation arrangement. Please confirm that the per procedure payment prohibition would not apply to this.

Percentage Fee Prohibition:

Please clarify that the percentage fee prohibition does not apply to the indirect compensation arrangements as provided by Stark. Lithotripsy reimbursement rates vary by payer and vary significantly with time. Percentage fee arrangements allow for vendors and hospitals to share fairly in market risks.

Concern of Unintended Consequences:

North Carolina is a Certificate of Need (CON) state. Thirty eight (38) states have CON laws and twenty seven (27) strictly regulate operating rooms/ASCs. These proposed changes clearly are intended to shift HOPPS to the ASC rates. Therefore, if the proposed rules are implemented as written it would create conflicts with the health care planning policies and methodologies in these states.

A large number of services in North Carolina are provided under arrangement on per procedure or percentage payment arrangement with hospitals by companies owned at least in part by physicians. Many of these are hospital physician joint ventures. If these were precluded (which would be the

practical result of such enforcements), then it appears to me that the access to many of these services would be interrupted, especially in small and rural hospitals, and especially with regard to government patients. It will be very difficult or impossible to obtain CON's for many additional provider owned ASCs where the services could be legally provided. Whatever the faults and negative points of CON laws, they have done a reasonable job in North Carolina of ensuring access to all groups of patients (especially the poorly and uninsured) particularly in rural areas and small hospitals. These laws have encouraged the sharing of technology and services which have resulted in more cost savings and care quality than is generally recognized.

I have briefly addressed only the major parts of my concerns. The newly proposed rules, if implemented, would have very negative effects on kidney stone patients at many sites in North Carolina (and I am sure many other states). It does not make sense.

This is a complicated and serious proposal. Most physicians, including myself, have a difficult time understanding the nuisances of these proposed rules (the tax code is even easier to understand than this stuff). My physician colleagues only want to take care of patients.

We understand first hand that our health care system has many challenges. Meaningful change is necessary, but it should be thoughtful change. I hope this will not be another example which will illustrate that no matter how bad things are, the government or its agency can make them worse.

Thank you for taking my comments into consideration. I hope you will modify and clarify these proposed rules.

Sincerely,

Dan A. Myers, M.D.

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SOUTHERN COLORADO UROLOGY ASSOCIATES P.C.

James L. Bruffy M.D.
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August 27, 2007

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 21244-8018

Re: Physician Self-referral Provisions.

Ladies and Gentlemen:

I am a urologist who has practiced in rural Colorado since 1972. I have seen many changes and improvements in the treatment of kidney stone and prostate problems. I have seen how difficult it is for patients and families to travel to urban areas for health care and I have seen how difficult it is for individual hospitals to purchase new technology. In order to have the availability of lithotripsy for treatment of kidney stones and laser for treatment of enlarged prostates I have entered into joint ventures. I am concerned about your apparent attack on legitimate physician joint ventures.

CMS's proposals that are most worrisome were called: Under Arrangements, Per Click Fee, Percentage Fee Arrangements, Stand in the Shoes, and Burden of Proof. I would like to address these separately.

Under Arrangements:

- 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.

- CMS should limit the reach of Stark to only those arrangements that are known to be abusive and that Congress intended to reach.

    - CMS' stated concern is about physician joint ventures that provide radiology equipment. Those joint ventures are circumventions of the Stark prohibitions on physician referrals to imaging centers. The physician investors get the same benefit as if they owned the imaging center. Instead they lease the equipment on a "per click" basis to the imaging center.

    - 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

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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.

- In 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 will 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.

- 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.

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- 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.

- 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.

1. Per Click Fee Ban:

   - Explain to CMS that hospitals are 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.

   - Sometimes the patient will need a procedure that is less often performed and it is difficult to calculate this in to the compensation arrangement. Give examples from your practice, e.g. a lithotripsy that requires insertion or removal of a stent; ureteroscopy; cystoscopy.

2. 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.

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- 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.

- 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.

3. 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.

4. 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.

   - Tell CMS that such an effort to shift the burden from itself to the providers who are taking care of Medicare patients is unfair and outrageous and offends your sense of justice.

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- 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.

5. 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 because due to their case volume. Many rural areas are also served by this same shared service concept that urology joint ventures have fostered. In my service area in rural Colorado one lithotripter and one laser service many small hospitals. These patients would otherwise have to travel 100-200 miles for treatment.

6. 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.

7. I am requesting CMS to:
    - Accept the burden of proof that the law has historically placed upon the one creating the rules, and not try to shirk their responsibility,

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- 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 your consideration.

Sincerely,

James L. Bruffy, M.D.

James L. Bruffy, M.D.

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August 27, 2007

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

Dear Sir or Madam:

I am Robert Kolosseus and I practice urology in Las Cruces, NM. As a urologist, I have been involved with providing my patients, including Medicare beneficiaries, lithotripsy and other cutting edge therapies for urological disease. These services have been made available through physician owned joint ventures. The 2008 Physician Professional Fee Schedule proposal attacks the substance of the joint ventures that have helped provide more services and overall saved CMS money. The problems with the CMS proposal are as follows.

Under Arrangements

The CMS proposal will ban physician joint ventures from contracting with hospitals to provide 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.

The "cutting edge" equipment needed to provide high quality care services is often not purchased by hospitals for various reasons. Physician joint ventures have been and should be an avenue through which the technologies can be obtained. If there is a question regarding over utilization of these physician owned services, this has not been identified for urologic procedures such as laser or cryotherapy services. Also, for urologic procedures, the professional fee is larger than the technical fee a physician investor may receive. Thus, the portion of the technical fee is not an incentive for referral of patients. Prohibiting services under arrangements should not apply to services where an investor physician performs the professional portion of the service.

Per Click Fee

Again, many hospitals do not want to spend capital on the new equipment but physicians are willing to take the risk together to bring the best services to their patients. The urology joint ventures take the risk of providing the new technology and a per click compensation arrangement minimizes hospital risk. Other intermittently performed ancillary procedures would be very difficult to factor into the per click compensation arrangement.

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. 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 themselves DHS into DHS. Subsequently, an ASC with hospital ownership would not be able to contract on a per click basis or on a percentage basis. If the proposal is finalized, physicians would likely withdraw from ownership in ASC's where hospitals are investors.

Burden of Proof

The portion of the CMS proposal in which the provider is required to prove that any referrals were not in violation of Stark laws is unacceptable. The burden of proof should lie with any entity making claims of violation of Stark laws. We are being pushed too far with this proposal on top of already decreasing or stagnant reimbursement in general when our cost of running a business continues to steadily increase.

Summary

Please clarify provisions regarding therapeutic services provided by urology joint ventures in regards to their true designated health service statues and not locations where they are performed. Continue to allow per click or percentage fees with the non DHS therapeutic joint ventures as they are a fair method of sharing risk. Also I believe CMS should accept the burden of proof when a Stark law violation is claimed.

Thank you for your attention.

Sincerely,

ROBERT C KOLOSSEUS MD PC

City of Omaha
Mike Fahey, Mayor

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1516 Jackson Street
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Robert C. Dahlquist
Fire Chief

"Beneficiary Signature for Ambulance Transport Services"

August 28, 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

To whom it may concern,

This is a letter to address *Beneficiary Signature for Ambulance Transport Services* Section 424.36 file code CMS-1385-P.

As I am sure you can appreciate, we too are limited in staffing and resources. Much like you cannot accept faxes due to these issues, we are at our limit with new regulations from various entities as we try to assign people to train our staff for yet a new regulation. We are limited with our valuable staff resources and the time that needs to be allotted to train 680 EMT's and monitor compliance will severely hamper our Emergency Services Bureau.

Where we understand that your suggested changes came about because of issues you face we encourage you to re-think the solution. It is very difficult to obtain a signature from any patient that is transported due to an altered level of consciousness and emergent patient treatment needs and often they have no family that accompanies them or is willing to sign for them. Who is "authorized" also becomes an issue as we may or may not be able to determine who is authorized. Patients are often hesitant to sign even with elaborate education because they feel they are making an obligation to self-pay if they are denied and they simply do not have the money.

We have time constraints and often pending emergencies that require quick turn around. Tracking down a staff person from the hospital who is authorized to fulfill the requirements is difficult at best and a person assigned to do so because of this requirement only adds cost and staff issues from the hospital end.

A trainer to train employees to now come up with a signed statement that encumbers all the details in this task and then assigning someone to ensure this has been done is extremely difficult, and in some cases impossible with our current staffing. Assigning someone to track down this documentation when it has not been done appropriately and getting an accurate statement from the EMT or retrieving a signature at a later date is nearly impossible.

We truly appreciate the difficulties that come to the attention of your office but we ask that you please not extend that same or increased level of difficulty toward ambulance services and fire departments across the country. It poses a huge burden with financial impact to our already strained resources.

Thank you for your time. We hope that you will take our situation into consideration.

Sincerely,

Robert C. Dahlquist
Fire Chief

RCD/mb

2794

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Diplomate, American Board of Urology

August 18, 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

RE: PHYSICIAN SELF REFERAL PROVISIONS

Ladies and Gentlemen:

I am writing this letter in a hopeful attempt to enlighten you on the current situation involving the physician self referral provisions. I do not purport to understand all of the proposed rules and regulations and I can say with certainty that I do not understand all of the current rules and regulations. I also know first hand that the hospitals and institutions that I work at do not understand them either.

I do know a lot about the art of medicine and the care of my patients. This is partly because of my four years of medical school following four years of college and six years of residency training in the surgical discipline of Urology. It is also from my experience as a patient with a chronic disease that has allowed me to experience the field of medicine from the other side. After completing fourteen years of training (and that is by doing everything in the shortest amount of time without breaks) and with an enormous debt, I choose to move back home. I started my practice at the earliest possible age of 31 in July 2001. I have been in practice for just over six years.

I practice in central Louisiana in the city of Alexandria. The population is around 100,000. As with most of America, we have a critical shortage of urologist here too. We have two private hospitals, one VA hospital, one state charity hospital, two rehabilitation hospitals and three surgical centers in our community. We are viewed as a referral center that covers areas from East Texas to West Mississippi and everything in between. We have six practicing Urologist in an underserved area and we all work very hard long days

and weeks. Three of the urologist are over the age of sixty and on the edge of retirement. Over the past five years we have seen the loss of residents from Tulane rotating through the VA and the local charity state hospital as well as the full time urologist that supported them. In the surrounding communities we have lost other urologist to retirement. To say the least, we are overwhelmed with patient care.

My average day starts with surgery at 6:30 AM and rounds at the hospital prior to that. My office closes at 5:00 PM but I rarely finish seeing patients and completing notes until well after 6:00 PM. I then round and see my inpatients and any consults. If I have no emergencies I will be lucky to be home prior to 7:30 PM. The reality is that I rarely arrive prior to 9:00 PM and I am hopeful to see my children prior to them going to bed. This is not only during the week but on the weekend also. I am on call every fourth weekend and in order to afford the other urologist some free time we cover an entire weekend at a time. The on call urologist starts Thursday night and ends Monday morning. The weekend can be brutal to say the least. I can go two weeks without eating a meal with my family. On the weekends that I am not on call I will spend an average of six hours a day catching up on charts, dictations, reviewing labs and returning calls to patients. Yes, I return calls on the weekend because I have no other time to return them.

I know that I am not alone. Most all of the urologists outside of large metropolitan areas work just as I do. We all trained together and see each other at CME events. In Louisiana alone there are just over 100 urologists. They see no relief in site and have been forced to change their practice patterns just as my group has. We recently resigned from the other private hospital in our community in order to limit our work hours and improve the care for our patients. We have also stopped seeing consults at three rehab facilities. We do not participate in any surgical center and rarely provide services to them. Only one of my partners is gracious enough to have clinic once a month at the local state charity hospital. He also sees a clinic at the local VA hospital but this is in jeopardy too. Both of these facilities lack any other urologic care. In fact, the local VA hospital has said it is a conflict of interest for any of the four members of my group to see any VA patient in our office because my partner has a clinic there. This forces not just a few but hundreds of veterans to either go without or travel great distances to receive care. It is truly a travesty for our veterans to deny them necessary treatment.

My group has not only started limiting the facilities that we practice, we have also stopped taking various insurances also. It is important for CMS to understand that there is not a lack of patients; there is a lack of well trained specialists. We stopped seeing all Medicaid patients last year forcing them to travel well over 100 miles for all but emergent care. We did not renew our Tricare contracts and we are now considering becoming non participating physicians for Medicare. Despite all of these changes, we are still seeing the same amount of patients if not more. While our frustration level of trying to practice at multiple facilities has improved, our work hours have not. We struggle to find ways to become more efficient and better use our precious time. Yet we feel that most legislation designed to prevent possible fraud or cut cost makes this impossible. How are we to see more patients efficiently during this time of too many patients and too few specialists if further proposals prevent this? It is not possible to

effectively treat a patient when they have to leave your office for labs, x-rays or tests at another facility.

I AM HOPEFUL THAT YOU WILL BE ABLE TO RECOGNIZE THE CHANGES YOU ARE MAKING IS LIMITING HEALTH CARE FOR NOT ONLY MEDICARE PATIENTS BUT VETERANS AND OTHER OTHERS ALIKE. I wrote the preceding because my personal situation is similar to others and important to understand. I will try to give true life experiences that will show how your proposed changes will continue to cause access problems to health care.

I want CMS to know that I desire my patients do well. I desire them to become cancer free and I desire they have no complications from there surgeries. I cry with them. I pray with them. I rejoice with them. I develop personal relationships with them. And I live in a small community so I see them all of the time. I attend funerals for them too. I know what I am doing is good. I am providing superior care and I have binders of cards and gifts from patients to prove it. My complications are very low and my patient outcomes are very good. I have never and will never recommend treatments for patients based on incentives. I know that I care for my patients more than hospitals and more than insurance plans. I fight for them to receive the best care. The care that is frequently hindered by hospitals trying to limit expenses and follow every new and crazy regulation and health plans trying limit payment for any and everything.

THE ISSUES I WOULD LIKE TO DISCUSS INCLUDE:

1) BURDEN OF PROOF
2) PER CLICK FEE BAN
3) "SET IN ADVANCE" AND PERCENTAGE-BASED FEE PROHIBITION
4) SERVICES FURNISHED UNDER ARRANGEMENTS
5) STAND IN THE SHOES PROPOSAL

I have tried to understand what "DHS" means. I have tried to educate myself on this and other regulatory matters. As best I can understand, CMS is trying to eliminate any physician ownership in any type of service provided to any Medicare patient. They are willing to go to extremes to prevent possible corruption but have failed to recognize the negative impact it will have. I am to the point of throwing up my hands and crying wolf. Here are some real life examples:

- With only six urologist in the community we are forced to share high cost items. These include items such as ultrasound. There are two groups in town. We shared one ultrasound machine until three years ago when possible legal issues arose. We were forced to purchase another ultrasound specifically for our group. The cost was over $70,000. It is an item that we use daily in our practice. We will use it to do prostate biopsies to diagnose prostate cancer as well as many other problems. We use it to make sure a patient does not have a blocked kidney from say a stone. We look at testes for possible tumors or trauma or even

torsion. Ultrasound is and has been for many years an integral part of urology practice. Because well over 90% of all trans rectal ultrasound imaging is done by a urologist in his office, hospitals will rarely purchase this type of equipment. In our community, none of the hospitals or rehab facilities has this capability. When I am forced to do a prostate ultrasound at the hospital, I have to bring the equipment from my office. Despite the difficulty with time and effort, it is frequently the only way to provide necessary care. We have never been able to have reimbursement from the hospital for the use of our equipment. While this was and is frustrating the numbers of cases were previously few but this has changed.

Recently gold seeds have been found to improve radiation therapy for prostate cancer by enhancing the localization of the prostate for the radiation oncologist. The urologists who are the experts in prostate imaging were approached about placing gold seeds into the prostate prior to radiation treatment. We originally were given the gold seed and we placed the seed in an office setting. Our office never billed for the seed only the procedure. We were then informed it was illegal for the hospital to give us the gold seed and we would have to purchase the gold seed. Well, this is not a covered item and no reimbursement was available. We would have to pay out of pocket for the gold seed which cost more than the reimbursement for the procedure. Despite not billing for it, the hospital said it would be viewed as illegal for them to provide the seed. Even though we were only trying to help the hospital treat the patient.

We tried to go another route. We were going to do the procedure in the hospital. Please recognize that this is much more expensive for CMS. The hospital refused to purchase a trans rectal ultrasound though. They did not have the numbers to justify it. They asked for the use of our office machine. We agreed initially until we were informed they did not intend on paying for its use. Please recognize that this is a very low cost procedure and the burden of performing the procedure is far greater than the reimbursement to the physician. Our office did not think this was possible. The hospital then agreed to paying a percentage of the fee they were reimbursed. They also discussed a per use or per click fee. It has now been in "legal" for six months. It does not appear that this will happen because the physicians have some type of ownership in the ultrasound.

I try to understand this but I cannot. If I am lucky I will break even on the deal. With the number of cases performed the amount of monies received from the hospital would be extremely small. It may account for $1,000 to $2,000 per year split between 4 to 6 urologist. This is a perfect example of how this type of legislation would further harm patient care.

- My second example which is also true has to do with stone disease. My hospital does not have an adequate volume of patients to justify having a full time lithotripsy machine. The machine we use is partially owned by urologist and is rotated between hospitals in my community and hospitals over 100 miles away.

This is the only way we are able to have this service. It is in our community only once a week and it rotates between hospitals. We have access to it at my facility once every other week. We have a state of the art machine and it works well. This is because the physicians involved demand quality. We measure outcomes and follow patients to make sure that the machine is working well. We have a dedicated radiology tech that specializes in lithotripsy imaging and this too improves care.

It was not long ago that the hospital tried to use a machine of less quality. It was an attempt to save money. They chose to cut cost. The machine was not as effective and no specialized personal would be available to provide support. This type of action by the hospital further shows that it is traditionally the physician that demands superior care and not the institutions we practice at. Due to the high cost of the equipment and our limited access to lithotripsy, we find ourselves doing a large number of ureteroscopy and laser treatments for stone disease. This leads to my next true life example which involves our lasers.

- With regards to stone disease we have recently had another problem. Our hospital had the laser used for treating stones go out. It was old and stopped functioning. They have tried for months to replace the laser but state that the funds are not available. While other urologist are involved in owning superior lasers for stone treatments we are not. It has turned into a major problem costing CMS more money and myself more time. How does it cost more money and time? It is simple. Let me explain.

  When a patient with a stone presents to the hospital we previously had the capability to remove the stone with laser and place a stent that could be removed in the office setting at a later date. We no longer have this capability. We have to place a stent in the o.r. and have the patient return for a second costly surgery at a later time. We are forced to do two surgical procedures in the more costly hospital setting instead of one procedure.

  We discussed trying to purchase a laser for stones independent of the hospital, a laser that could be used at both facilities and possibly a surgical center. The laser could be rented on a per click or under arrangement basis but this too appears to not be possible. The urologists in my community need the necessary equipment to provide timely treatment. We also need it so we can practice urology in an efficient way in order to allow us to see our family at night. A laser that would allow us to not only treat patients with one surgical procedure but improve the time we as surgeons have to spend in the o.r. It was concluded that we would likely not be in compliance with present or future CMS rules. THIS IS A TRUE LIFE EXAMPLE OF HOW YOUR DECISIONS ARE AFFECTING THE ACCESS FOR PATIENTS TO TIMELY AND COST EFFECTIVE HEALTH CARE.

- The next example is very close to my heart. It involves the treatment of prostate and kidney cancer. Two diseases that I am at risk for having. My father has suffered with both of these cancers. When I arrived in my home community six years ago I was the only urologist trained in cryosurgery. I am still the only urologist who performs this procedure in my community. All of the other urologist refer appropriate candidates to me. When I first attempted to do cryosurgery in my facility there was no provider for the service. In fact, there is only one provider for cryosurgery services in Louisiana still today. It just so happens to be the cryosurgery mobile service provider that I helped to form.

I would like to point out that the volume of cryosurgery procedures I and others have performed have nothing to do with ownership. I perform about 12 to 15 procedures PER YEAR. This is not a large number. It is also important to know that the return of my investment in this service company has been minimal while the risk initially was great. This is a risk that physicians are willing to take in order to provide quality care. This is also a good example of how most hospitals are risk averse even when new technology is in need. While CMS has been able to show some abuse patterns with certain imaging and DHS services, they have never found any abuse with service companies such as these. I can say with certainty that they will not find it either because I truly do not believe it exists. When you start discussing surgical procedures on patients that could have life altering consequences you are talking serious. This goes back to the beginning of medical school where we are not only trained but "programmed" to do no harm. I dare to say that the number of surgeons and urologist doing unnecessary surgical procedures is exceedingly low or non existent. We do not play politics with our patient care, we do what is right.

Cryosurgery is sometimes the only salvage procedure for patients with recurrent prostate cancer following radiation. I know personal friends whom I have performed cryosurgery of the prostate for radiation failure prostate cancer that are disease free today. These are patients who had no other option and would have died from their disease without this procedure. This procedure that the hospital refused to purchase because of cost. THIS IS ANOTHER PERFECT EXAMPLE OF HOW YOUR PROPOSED LEGISLATION WILL COST LIVES.

One last point on cryosurgery and percentage based fee arrangements. My hospital has told me I could no longer perform certain types of cryosurgery on patients with certain insurances because the cost of the service was greater than the reimbursement from the insurance company. Specifically, I have been asked to not do cryosurgery of renal masses on patients with various forms of private insurance. A PERCENTAGE BASED FEE ARRANGEMENT WHICH YOU PROPOSE TO RESTRICT is one reason why problems like this exist. It could allow the service to be provided even in situations where one insurance provider is much lower than the rest.

- I have just witnessed the failure of a joint venture in a surgical center between physicians and the local hospital in my community. It was a direct result of one very important issue. If the hospital owned any part of the surgical center there was great fear that it may be viewed by CMS as a stark violation for physicians to refer to that particular surgical center. Yes, this occurred right here in my community. I saw CMS destroy this partnership between two respected groups, the physicians and the hospital, because of the possible "STAND IN THE SHOES" legislation that is being proposed. If this occurs, ASC's throughout America will change and not for the better but for the worse.

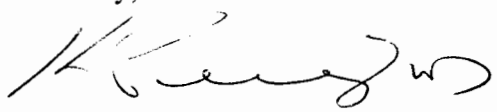
I apologize for the length of my letter but it was important to show true life examples. If you look back over it I am sure you will find why all of the above listed anti-physician ownership proposals would have a negative impact on healthcare. I addressed all of them except one. I did not address the Burden of Proof proposal. I am not sure how to address it. How is it possible for me to prove that I did not violate one of the Stark laws if accused by CMS. Please review this carefully. This is like trying to make a law abiding citizen prove he did not break the speed limit. "We accuse Mr. Smith of breaking the speed limit. Mr. Smith, please prove you did not break the speed limit." Even if there is no proof he broke the speed limit, it would be impossible for him to prove he did not.

This is not only unfair it is outrageous and offends everyone's sense of justice. If you remember above the problems with the hospital paying for the use of our ultrasound machine, the hospital states that they are unable to obtain a "fair market value" for the service. They are in fear of having the "burden of proof" placed upon them. Because of this they have refused to provide any reimbursement and thus have limited treatment to patients. In this real life situation, more health care dollars have been spent on obtaining a fair market value then would have been spent on the cost of the machine.

In closing, I hope I have been helpful in showing how most of the joint ventures by physicians outside of the DHS list are of value. There is so much more I would like to express but I fear you will not view it as helpful. We are in a time of crisis with regards to health care in our society. We are beginning to see the limiting of health care to Veterans and Medicare patients alike. Please make decisions based on fact and not fear. Please consider the possible consequences of your choices. Allow physicians to practice the art of medicine again. We do not want politics in medicine. We only want to take care of our patients. Most physicians were just programmed that way.

If you would like to discuss my letter or if I can be of any further assistance, please do not hesitate to contact me directly. I have no hidden agenda. I truly want to be a part of the solution.

Sincerely,



Kenneth L. Perego, II, M.D.

LB. PHYSICAL THERAPY, INC.

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[redacted]

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, 24 2007

From: M. Baestaens, DPT

Re: **Physician Self-Referral Issues**

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 Sir,

Please find hereby my comments on the July 12 proposed 2008 Physician fee schedule, Specifically the issue surrounding Physician self-referral and the "in-office ancillary services" exception.

I am a practicing and teaching Physical Therapist for more than 20 years, and am co-owner of a Private Practice with locations in St Joseph, Coloma and Niles, Michigan. In our area there are several Physician Owned Practices who have besides their own consultation areas, also Physical Therapists working for them in their own locations, or locations owned by these Physicians, working on patients that are referred by these physicians, who hereby practice self-referring. They are mostly orthopedic surgeons.

In numerous occasions we have encountered problems with these Physicians and Physician practices:

Examples:

* At several occasions we referred our own patients (who were in treatment for issues and referred by other physicians) to these surgeons for consult on orthopedic matters related to the diagnosis for which we were treating the patient:

result the orthopedic surgeons never referred these patients back to us but told them that they had to come to their practice to continue physical therapy.

* The same thing happened for patients we referred for a different diagnosis to these orthopedic surgeons: we lost the patients because they had to stay with the physician owned physical therapy program of the orthopedic surgeon.

* Often we referred patients to these physicians who then as a result of our referral underwent surgery and then had to stay with the orthopedic surgeon owned physical therapy program.

* On several occasions patients came back to us with complaints that the orthopedic surgeon told them that if they would continue physical therapy with us, they (the orthopedic surgeons), would refuse to treat them any longer.

* Very often we see patients come back to us after having treatments at these physician owned practices with the complaints that the care they received was performed by technicians instead of PT's. (In our region one of these practices have 5 orthopedic surgeons who refer all their hip, knee and shoulder surgeries to their own practice where only one PT is employed and the therapy is being provided by techs or even front desk people.)

* We now are referring our patients to surgeons outside of our region (to South Bend) in which cases most of our patients return to our care because they don't want to drive 45 minutes a few times per week to get their care. However also those orthopedic surgeons try to do the same thing, and tell the patients to come to their therapy locations.

* Many people can testify about the bad quality of care that they received at these practices and insisted to be returned to our care afterwards.

* Right now our patient population has only a very small percentage of orthopedic post surgical patients because of these practices (knee, hip and shoulder surgeries):

* <u>Here is the reflexion of our yearly patient population numbers:</u>
(Referrals coming from other physicians)
Low back/back problems, with or without neurological implications: 40%
Cervical problems, with or without neurological implications: 15%
Foot/ankle problems, with or without neurological implications: 13%
Shoulder, knee and hip problems referred through family physicians: 10%
Neurological patients: 6%
Other indications: 16%
Patients referred by orthopedic surgeons from our region: 0-1%

Compared to the national average our referrals by orthopedic surgeons should be at least 15-20% (for treatments S/P knee- hip and shoulder surgeries)

The Physician-owned practices in our region are:

- Southwest Michigan Center for Orthopedics and Sport Medicine.
  183 Peace Blvd., St Joseph, MI 49085
  Dr. Edwards, Dr. Sohn, Dr. Burczak, Dr. Kolettis, Dr. Lisher,
  (Have their own PT practice with 1 PT and the rest are techs)
  (Physician group mentioned in "Examples")
- Dr. Grannell James:
  6 Longmeadow Village Drive, Niles Township
  (has one PT and one OT working for him, and is very insistent that his patients only come to his facility)
  (Physician mentioned in "Examples")
- South Bend Orthopedic Associates:
  53880 Carmichael Drive, South Bend, IN
  (8+ orthopedic surgeons, with their own huge PT practice)
  (Physician group mentioned in "Examples")

I believe that 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 (DHS) furnished under the in-office ancillary service 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 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 benefits laws to collect payment in order to circumvent "incident-to" requirements.

In writing these comments, I would like 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.

Dear Sir, I would like to thank you for your time and consideration of my comments.
Sincerely,

Dr. Margaretha Baestaens, DPT

Tuesday, August 28, 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
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 physical therapist in private practice for over twenty years, I would like to comment on the potential for abuse due to the inclusion of physical therapy services under the in-office ancillary exemption in the current Stark II regulations.

In the village where I practice, there are at least ten physical therapy offices owned and operated by physical therapists. Yet within the past four years, a significant number of physicians in the area have either opened a physical therapy office, or have hired a physical therapist to work in their office. I was told by a local physician that he had been approached on a number of occasions by "practice-management consultants" who told him they could set him up with a physical therapist and showed him the amount of additional profit he could make, just by referring his patients back to himself. I am sure you are aware of the OIG report noting the exceptionally high rate of inappropriate billing (greater than ninety per cent of claims) from physician-owned facilities.

The opportunity for over-utilization, fraud and abuse are self-evident in this type of business relationship. Our particular village is certainly well-served by physical therapist owned practices and as such, there is no clinical need for providing such services "in-house".

Patients who have returned to our office after being directed to the physician's physical therapist have reported the following:

-They were specifically directed to go to the physical therapy office that is owned by the physician. In some cases, the referral was sent directly to the office before the patient was consulted, or the physician walked the patient to the physical therapy area and delivered the referral.

-The patient was not informed that they could obtain treatment at a facility of their choice.

-After being treated at the physician-owned physical therapy office, our previous patients often returned to our office because they preferred the service we provided. Without an internal source of referrals, we succeed only by providing a level of care that maintains our reputation in the community.

I appreciate the enormous complexity of regulating physician self-referral over such a broad range of circumstances. One element remains consistent, however. The ability to self-refer for profit is without a doubt a potential conflict of interests for the physician. As such, the practice should be restricted as strongly as possible. One possible solution to the problem might be to remove the profit motive from the equation. If a physician legitimately feels that in-house physical therapy services are a necessity, then the service should be reimbursed at cost only. I am convinced that many, if not all of the physician self-referral practices would disappear under a cost-reimbursement payment methodology. Certainly, those physicians who feel strongly that providing such a service in-house is a clinical necessity for their patients should be willing to provide it at cost.

In our practice, we do not sell any items to patients for just this reason. We refer them to a variety of sources where they can obtain any item we might recommend. They may have to drive into town to pick something up, but we feel strongly that the absence of a profit motive for anything we recommend works best for the patient.

I would also point out that physical therapy services should not qualify for the exemption as the services are not required at the time of the physician's office visit. In those rare cases where therapy is felt to be urgently needed, immediate treatment can be arranged with a phone call to an independent physical therapy clinic.

I would also like to add a concern regarding non-specialist physicians operating physical therapy clinics. While medical training is certainly extensive, it does not cover physical therapy. In my practice I have treated many physicians, and their questions and concerns regarding their own physical therapy are often no different from those of a lay person, and show no greater insight into our profession or how it should be practiced. In many cases, they are very surprised at what we do. I doubt that a dermatologist or an ear nose and throat specialist would have any idea what the range of physical therapy practice might entail. Yet, they would legally be able to direct such a practice, not only for patients within their own scope of practice, but all others as well.

In summary, I would respectfully urge CMS to remove physical therapy as a designated health service (DHS) permissible under the in-office ancillary exception of the physician self-referral laws. The current exception is unnecessary clinically, and encourages cottage industries that supply therapists as revenue sources for doctor's offices. The patient and Medicare are not well served by this loophole.

I would like to thank you, Mr. Weems, for your consideration of these concerns.

Sincerely,
Name Withheld
Area code 11021

The Center for Physical Rehabilitation

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
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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 writing to you as a licensed physical therapist in Grand Rapids, Michigan. I am also one of the owners of The Center for Physical Rehabilitation. I have been in practice for 13 years and have been involved in legislative issues at the Michigan level for 5 years. I am the one responsible for the daily operations of our practice. My duties include overseeing that our practice is compliant in all phases of delivery of our physical and occupational therapy services. I spend one day a week working with our staff on correct documentation, correct billing, corporate compliance, and risk management issues, etc.

The Centers for Medicare and Medicaid Services have a chance to close the Stark Referral for Profit loophole that has clearly caused the explosion in over utilization and escalated costs in providing physical therapy services. The physician owned physical therapy services (POPTS) issue has significantly grown each year and can be eliminated with the correct action by CMS. This topic is clearly controversial and ultimately needs to be better defined to allow patients to have the highest in quality care at an affordable price. The data is there from the American Physical Therapy Association on the over utilization, lack of compliance and escalating costs when physicians are allowed to refer Medicare beneficiaries to entitities in which they have a financial interest. Where is the data that says otherwise? A verbal response from the physicians we know in our area that own and refer to their own entity is "I can keep better track of your care if you do the rehab in our PT clinic." In my 13 years of practice I have yet to meet a patient who said their doctor came over and checked on their care. Most of these clinics are owned by specialists, orthopedic surgeons and pain clinic doctors. They are too busy treating their scheduled patients to oversee the daily rehabilitation of their patients. I find it hard to believe that in today's technology era that my telephone, fax, e-mail, etc. is not an acceptable way to communicate to the referring physician as them referring to their own entity.

I have multiple examples of the inherent fraud and abuse that exists in this system. I have had patients write to our state legislators of their concerns regarding referral for profit. I have even had several medical professionals write of their concerns of the conflict of interest in this issue. In the last 8 years, we have been approached on 4 separate occasions to oversee and manage orthopedic and physician specialty practice physical therapy services. On each and everyone one of those discussions we proposed to lease space in their suite for fair market value, deliver our high quality rehabilitation services (which we feel is why we were approached in the first place by these practices) but to keep our services separate. Each discussion quickly ended when we clearly stated that as two separate businesses the profits from physical therapy would be separate. One entity opened their own clinic one mile from us after we declined to run their referral for profit clinic. Our referrals have dropped by over 70%, did our care change? Patients are not being told they have a choice on where they go nor are they told that the entity owns the physical therapy clinic; both are required by state law. Clearly this could be viewed as a monopoly. Is it in my best business and patient referral interest to raise these concerns to the insurance commissioner? We are physician referral state. Medicare requires a physician referral for payment eligibility. When physicians control the patient referral they should NOT have the opportunity to refer to themselves. They should refer based on who gives the patient the best access to care, cost and quality. We have been told:

1. "Frankly the ethical dilemma does not hold weight with us". The OIG report of 2004 would clearly dispute this.
2. "Don't worry you will still receive our scraps". Would that be the lower paying insurance patients? I did not know patients could be viewed as scraps.
3. "If I can make money off of keeping the referrals in house, why would I use your services?"

CMS needs to eliminate the referral for profit loophole. It was designed to help patients. I am still amazed that I spend time each week adhering to the compliance measures set forth by CMS but the physician owned services do not have anyone auditing their compliance and they get reimbursed more by most insurance companies.

In summary:

1. CMS needs to eliminate the ability for physicians to refer patients to entities in which they have a financial interest. This can be done by eliminating physical therapy as a designated health service (DHS) furnished under the in-office ancillary exception.
2. If the DHS rule continues because of rural care settings, then considering a rule for those in-office exceptions are valid in cases where there is no hospital PT, rehabilitation agencies or independent physical therapy clinic within 10 miles of the entity.

3. CMS has to implement an auditing accountability system for physician owned physical therapy services. It is very frustrating to hear how PT services/costs under CMS has significantly grown but there is no separate tracking of physician owned services. The physician owned services are categorized under independent physical therapy services (IPT). I still do not have a solid explanation of why this is.
4. Due to the frequency of needed PT visits, it is not convenient for the patient to receive services in the physician's office than an independent clinic.
5. Clearly physician direct supervision is not needed to administer the services and it is not currently being done in any setting I know of. In fact, an increasing number of POPTS clinics are using the reassignment of benefits laws to collect payment in order to circumvent "incident-to" requirements.
6. The American Physical Therapy Association has strongly advocated against POPTS, should not the national body of a profession be able to have the federal government enforce what they advocate?
7. The AARP has written a letter against POPTS, should not that organization's voice be honored?

Thank you for your time in this most important health care issue.

Sincerely,

Chris Nawrocki, PT, MS, OCS
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August 27, 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: CMS-1385-P
Physician Self-Referral Provisions
Services Furnished "Under Arrangements"

Dear Sir/Madam:

These comments are being submitted in response to 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* published in 72 Federal Register 38122 on July 12, 2007 ("Regulations"). In particular, this comment addresses the proposed changes to the **Physician Self Referral Provisions: Services Furnished "Under Arrangements."**

We have performed a thorough review and analysis of the proposed changes. The proposed revisions, especially those targeting the definition of "entity" at 42 C.F.R. § 411.351 and impacting the wide-spread, industry (and CMS) accepted practice of "under arrangements" relationships, are an over-reaction to the stated concerns. If implemented as proposed, the Regulations will have a far-reaching impact on many existing and mutually beneficial business relationships between physicians and hospitals. In an attempt to meet both regulatory constraints while remaining economically viable, many hospitals formed "under arrangements" relationships and relied on previous regulations promulgated and finalized by CMS. Many hospitals have come to rely on these relationships as a means of providing cost-effective health care services to patients.

Our experience with "Under Arrangements" relationships have been the opposite of the general concerns stated in the regulatory preamble. In particular, we address the application of the proposed

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August 27, 2007

CMS
Department of Health and Human Services
Attention: CMS-1385-P
Mail Stop C4-26-04
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Ladies and Gentleman:

I am a urologist who has been in private solo practice for 20 years. I have been involved with doing lithotripsy and other therapeutic services for Medicare patients using a joint venture. These ventures have all been carefully examined and particularly since they are therapeutic rather than diagnostic have been shown to be beneficial for the Medicare patients and access to modern treatment techniques. I am concerned because recent reevaluation of policy would make these ventures more difficult, which is the subject of this letter.

All of these factors seem to be chipping away at the ability to run such a venture without actually causing it illegal. This is contrary to the previous judicial ruling along this regard in reference to lithotripsy. It should also parallel other therapeutic type ventures.

First, the Under Arrangements Proposal, this should only come into play if there is a situation where there is an abuse potential, particularly with over ordering of diagnostic tests. There has been no such allegation with therapeutic treatment, such as lithotripsy, and this was the original intent of Congress. Other joint ventures involving advanced laser and cryotherapy are also new techniques, which hospitals are not interested in buying and are minimally invasive techniques, are beneficial once again to Medicare patients. Again, these are therapeutic treatments, and there have been no allegations of abuse. There should not be any parallels to this situation and the (per click) situation in an imaging center, which were designed to circumvent the regulations.

From urology joint ventures, the primary purpose is to improve patient care and allow them access to new technology. We have updated our lithotripter several times and have had excellent results with this. In the long run, this saves Medicare money by decreasing the number of repeat treatments necessary and also helps provide excellent patient care. I would think a good parallel would be a group of contractors coming together to contract with the U.S. Government to build a road. There would not be any prohibition in them all equally owning equipment, which would help them with that service. The Medicare patients or government are not charged a higher amount, and the services we provided. Some risk is taken by the investors, and the investors should be reimbursed.

Also, in the ALS vs. Thompson case, shockwave lithotripsy was defined as not a designated health service, even though it is provided under arrangements at the hospital. This was clearly defined in this legal case and should not be a factor at this point.

In reference to the "per click ban", urology joint ventures are of a benefit to Medicare patients because they will come together and purchase new equipment and will do this accepting click fee contracts. This allows the hospital to not have to buy expensive equipment that can be obsolete. It also allows the doctors to be able to get the best new equipment for their patients and spread it out over a larger geographical area. This also means that Medicare patients who are not immediately in the middle of the largest city can still have access to this type of treatment, which saves time and expense, as well as being excellent therapy.

In reference to the percentage fee prohibition, it is well known that many third party payers provide a wide range in reimbursement. Hospitals in general do not want to pay the vendor more for a procedure than the reimbursement provided on a long-term basis because it cannot predict how many procedures will be performed by any particular insurer. Percentage compensation arrangements allow the joint venture to shoulder some of this risk and receive a fair payment. This is a true business concept, and physicians (in this case urologists) have demonstrated willingness to take this risk.

Another issue is the so-called Stand and Choose Proposed Rule. This rule in effect would broaden Stark referrals as a referral to the hospital when it was usually a referral to an ambulatory center. This was not the initial intention of this, and it is an unnecessary additional burden. CMS has been concerned about physicians subverting rules. It seems to me this is just an attempt by CMS to subvert rules and the original intent of Congress. Burdensome interpretation of rules is being made concerning practices that have already been approved.

The Burden of Proof Rule would require providers to prove they did not violate Stark laws, even though CMS is the accuser and the ones who write and interpret the laws. I have mentioned this to several friends, and people are incredulous that the government can try anything so outrageous and offensive. If you were to ask this scenario to 100 people walking down the street, no one would agree that this was a fair situation, neither kindergarten children, nor experienced attorneys.

As to the issues of the DHS Entity Knowledge of Physician Ownership Market Value and Compensation being taken into account, based on volume or value of referrals, this is all difficult, if not impossible, to prove as well.

In summary, I would ask CMS to accept the burden of proof that the law has historically placed upon the entity creating the rules (CMS) and not try to shirk or hand off their responsibility. Also, I would ask that the ruling of ALS vs. Thompson be followed as the wishes of the court, another branch of the government, would show and clarify that this should not be subject to rules proposed under arrangements restrictions. Also, under Arrangements Provision it should be clarified to make certain that therapeutic services provided by urology joint ventures are not DHS services if they would be so only because of a sight where they are delivered. Additionally, I would ask CMS to drop any prohibition of "per click" or percentage fees as related to therapeutic joint ventures (again different from diagnostic joint ventures) in order to preserve the access and cost savings that the shared services have created time and time again and finally to clarify the Stand and Choose Provision to accept hospital ownership or control and ASC to clarify legitimate joint ventures. Not clearly abiding this would force many to abandon all ACSs that have any hospital participation. This would be adverse to patient care, particularly in remote areas.

Thank you for your time in reviewing these opinions.

Sincerely,

William C. Mitchell, M.D.

wcm/amr

300

HealthTrac
Medical Diagnostic Testing Services

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August 30, 2007

Herb Kuhn
Deputy Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1385P 7
Mail Stop: C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

RIN 0938-AO65

Dear Mr. Kuhn:

On behalf of HealthTrac and its affiliated companies, providing portable x-ray and ultrasound services in six northeastern states, I offer the following comments on the **"Proposed Revision to Payment Policies under the Physician Fee Schedule and Other Part B Payment Policies for CY 2008,"** as published in the July 12, 2007 federal register.

MALPRACTICE

The proposed rule requested information on malpractice insurance coverage for technical service providers. As a Portable X-Ray supplier and Independent Diagnostic Testing Facility (IDTF), we are considered a technical service provider. We do not employ physicians due to state prohibitions on the corporate practice of medicine. Our interpreting physicians have their own malpractice insurance coverage. We do not reimburse technologists for malpractice insurance. If they have coverage, it is paid by them personally and the cost to the company is considered part of their wages.

We have three components of our malpractice coverage:

- General Liability Insurance
- Professional Liability Insurance
- Umbrella coverage, providing coverage claims in excess of the aforementioned insurances.

Over the years, we have been advised to increase our coverage as the size of the average claim increases. The most cost effective way for us to do this has been to increase the umbrella component of our coverage.

There have been significant changes in the type and cost of malpractice insurance. Most notable are:

- Higher deductibles for each claim, $25,000 or more are typical. The deductible covers the first expenditures in defending against any claims.
- Tight insurance markets have limited the number of insurance carriers in local markets. This has the effect of lowering competition and increasing premiums.
- Many suppliers are opting for self-insurance. We have considered this option to be too risky.
-

We provide most of our services to nursing home residents. There is an increasing trend for lawyers and plaintiffs to name all service providers within an institution in an effort to have the claim "stick" to an insured party. We have had to defend ourselves on two occasions during the past three years. One claim has been dismissed and the second one is still open.

With regards to identifying sources for data to develop resource based costing for malpractice insurance, please refer to comments on IDTF Issues (Standard 410.33(g)(6)) listed later in this letter for our recommendation.

CODING – Code 93325 Doppler Echocardiography Color Flow Velocity Mapping

In principle, we agree with the recommendation. However, we are concerned with the accuracy of the "bundling" process. For example, has the RUC evaluated CPT-4 codes 93307 and 93320 incorporating the resources necessary to do the Doppler color flow mapping? How will the new RVU's for echocardiograms be compiled, by the RUC or by CMS? What is the basis for compilation?

IDTF Issues

Standard 410.33(g)(6) requires the IDTF to maintain comprehensive liability insurance coverage of at least $300,000 to be in effect at all times. CMS is proposing to enforce this standard by requiring IDTF's to list the Medicare contractor as a certificate holder on the policy. **This approach is burdensome and intrusive on the small business entities such as IDTF's.**

- I would recommend using a comparable approach to the one required of the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS), by having the IDTF provide a copy of the annual renewal of the insurance coverage for the IDTF to the Medicare contractor.

- The renewal package will contain information on coverage levels, as well as premiums paid. This approach may also serve as a source for resource data being sought by CMS on Malpractice insurance for technical service providers.

Standard 410.33(g)(8) requires the IDTF to "answer, document, and maintain documentation of the beneficiaries' questions and responses to their complaints at the physical site of the IDTF." This requirement is modeled after the standard imposed on DMEPOS. CMS should clarify this requirement to specifically state that this standard

relates to the provision of service complaints. Many of the beneficiary questions received by IDTF's relate to routine billing questions. It is my understanding that the DMEPOS are not obligated to document each billing question received from a beneficiary.

- Therefore, I would recommend clarification on this requirement to avoid unnecessary regulatory burden on small business entities.

Standard 410.33(b)(1) limits the number of fixed site IDTF's or Mobile units a supervising physician can oversee. The term "mobile unit" appears to be the combination of two different terms used by CMS in their instructions on the Form 855B, Mobile Facility and Portable Units.

The instructions on form 855B state:

"Mobile Facility and/or Portable Unit
A "mobile facility" is generally a mobile home, trailer, or other large vehicle that has been converted, equipped, and licensed to render health care services. These vehicles usually travel to local shopping centers or community centers to see and treat patients inside the vehicle.
A "portable unit" is when the supplier transports medical equipment to a fixed location (e.g., physician's office, nursing home) to render services to the patient.
The most common types of mobile facilities/portable units are mobile IDTFs, portable X-ray, portable mammography, and mobile clinics. Physical therapists and other medical practitioners (e.g., physicians, nurse practitioners, physician assistants) who perform services at multiple locations (e.g., house calls, assisted living facilities) are not considered to be mobile facilities/portable units."

The portable units transport the testing equipment to Medicare approved places of services such as physician offices, nursing homes and hospitals. Mobile facilities are not limited to Medicare approved places of service and are more difficult to regulate.

- I recommend the standard be revised to be consistent with the definitions contained in the instructions to form 855B.
- Additionally, I recommend treating fixed based sites and portable units on a comparable basis. The standard does not limit the number of devices or technicians a supervising physician can oversee within a fixed based IDTF. It simply limits the number of sites a supervising physician can oversee. Therefore, I recommend the standard be altered to limit the supervising physician to oversee three sites from which portable units are dispatched, conditionally that the portable units are only providing service in a Medicare approved place of service (physician office, nursing home, etc.).

I believe mobile facilities should be treated differently from portable units. First, there may be a number of diagnostic testing devices and technologists within the Mobile Facility. The Mobile Facility is a quasi-fixed site and should be treated as such. Second, Mobile Facilities pose the greater risk to Medicare Program Integrity as they may provide services at sites not traditionally approved by Medicare, such as motels or shopping centers.

- Therefore, I concur with the recommendation to limit supervising physicians to oversee up to three fixed based sites (including fixed based site from which portable units are dispatched) or three Mobile Facilities or a combination of both that total up to three separate places.

Standard 410.33(g)(15) prohibits the IDTF (fixed based site) from sharing space, equipment or staff or subleasing its operations to another individual or organization. This standard seeks to limit the opportunity to circumvent the requirements under sections 424.500 and 410.33. Although this standard applies to fixed based sites, CMS is seeking input on its potential application to "mobile units." In my previous comment, I recommended separating the definition of "Mobile Units" into "mobile facility" and "portable units," as they operate very differently. I am commenting on this standard as a "portable unit" supplier. HealthTrac is certified as both an IDTF and portable x-ray supplier, providing diagnostic imaging services to nursing homes and physician offices. It is one company, but Medicare rules require two certifications because we perform x-ray and ultrasound services. We believe the efficiency of sharing a call center, accounting, billing and vehicle maintenance functions outweighs the risk for sharing these services.

- Therefore, I recommend an exception to this standard for companies operating both an IDTF and portable x-ray supplier, as both are surveyed and subject to multiple standards under the Medicare Program.

PHYSICIAN SELF-REFERRAL PROVISIONS

In Section 414.50, CMS is proposing four changes:

- The PC of a purchased test be subject to an anti-mark-up provision;
- The anti-mark-up provision for the TC and PC apply to all arrangements not involving a reassignment from a full-time employee of the billing entity;
- The performing physician's or supplier's net charge be calculated exclusive of any charge that reflects the cost of space or equipment leased to the performing physician or supplier by the billing entity;
- The anti-mark-up provisions not apply to independent labs that have not ordered the PC.

As a portable x-ray provider and IDTF, we operate similarly to independent labs by meeting the purchased interpretation rules. Specifically, tests are ordered by a financially independent referring physician. The physician performing the interpretation does see the patient. We only purchase the interpretation when we perform the technical component of the test.

- My first recommendation on this section would be to provide an exception to the anti-mark-up for purchased interpretations for imaging suppliers meeting the purchased interpretation rules, reflected above.

The proposal includes a calculation of "net charge" for the purchased interpretations that is too narrow. The proposed rule only focuses on payments to the interpreting physician and ignores the additional costs incurred by the purchasing entity to facilitate the

interpretation. For example, the advances in the use of teleradiography have made it easier for physicians to acquire images to interpret. The cost of teleradiography should be completely allocated to the professional component as it directly relates to the interpretation of the image. However, the cost of teleradiography is usually borne by the technical component provider when an interpretation is purchased.

Additionally, the definition of professional component includes the production of a report. Again, the technical service provider may incur the cost of transcription when interpretations are purchased. This cost should be allocated to the professional component when analyzing the implications an anti-mark-up provision on a purchased interpretation.

- My second recommendation on this proposed rule is that the net charge include the costs incurred by the purchasing entity to facilitate the interpretation and are traditionally part of the professional component, specifically the cost of teleradiography to transmit images to the interpreting physician and the cost of producing a written report of the interpretation.

Collection and Recordkeeping Requirements

My recommendations for this category are as follows:

- **The preponderance of requirements in this proposed rule fall upon the IDTF's, which are mostly small business entities, with significant negative financial consequences. My recommendations on section 410.33 were directed to reduce the paperwork burden on the IDTF's. I would hope they are viewed with serious consideration to reduce the burden identified in this section of the proposed rule.**

- **If the proposed rule is not altered to reduce the financial burden on IDTF's, then CMS must consider an add-on for services rendered by IDTF's to be in compliance with the Small Business Administration rules and governing statutes.**

If you have any questions or need additional information, please contact me at 716-614-3260 ext. 120 or by e-mail at McDonnellD@healthTrac-inc.com

Respectfully submitted,

Daniel T. McDonnell
Executive Vice President/CFO

cc: William N. Parham, III, Office of Strategic Operations and Regulatory Affairs

Via UPS Overnight Deliver – 1Z 796 W49 13 9277 9385

August 31, 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

Regarding: Therapy Standards in Hospitals, rules related to Conditions of Participation and Other Proposed Revisions to Payment Policies Under the Physician Fee Schedule

Dear Sir/Madam:

On behalf of the thousands of specially trained lymphedema therapists serving the millions survivors of breast and other forms of cancer and sufferers of hereditary lymphedema, I am pleased to share the comments of the Lymphedema Stakeholders with the Centers for Medicare and Medicaid Services (CMS) on its proposed rules to limit the number and type of providers of all physical medicine and rehabilitation services in hospitals, hospital outpatient therapy clinics, the variety of rehabilitation facilities and rural health clinics. The proposed rules were published on July 12, 2007 and seeks to amend the regulations related to 42 Code of Federal Regulations Section Parts 409, 410, 411, 413, 414, 415, 418, 423, 424, 482, 484, 483, and 491.

Summary of Lymphedema Stakeholders' Position:
It is the position of the Lymphedema Stakeholders that CMS has violated the Federal Administrative Procedures Act and proceeded with proposing rules that will have a significant effect on the:

1) Safe delivery of quality lymphedema services to patients in the various types of therapy facilities mentioned in these rules
2) The health of patients by allowing unqualified physical therapists and others to provide lymphedema services
3) Economic balance of the lymphedema profession by causing thousands of therapists to lose their jobs
4) Hospital Conditions of Participation by removing the authority of medical staff to make staffing decisions based on local need, local workforce patterns, need to improve patient quality, need to control costs and other considerations
5) The ability of CMS to control costs because CMS has violated the Federal Administrative Procedures Act by not gaining an objective report from the Office of Management and Budget as to the economic impact of these proposed rules related to the physical medicine and rehabilitation medical specialty
6) creating a provider monopoly for physical therapists, physical therapy assistants, occupational therapists, occupational therapy assistants and speech-language pathologists and this is known to CMS staff
7) and finally, that these proposed rules will exacerbate an already significant allied health workforce shortage in hospitals, clinics, rural health clinics and other specialty rehabilitation facilities.

Discussion:

These proposed Hospital Conditions of Participation and similar rules will only exacerbate problems with access to quality rehabilitation services. There is a workforce shortage of all types of allied health care providers. The load of rehabilitation cannot and should not be borne by only physical therapists, occupational therapists, PT assistants and OT assistants. The Hospital Conditions of Participation and other staffing models are consistent with state law and the medical judgment of the facilities' staffs. It is unwise and unnecessary for CMS to interfere with state jurisdiction issues. Additionally, hospital staffing and quality standards are closely monitored by JCAHO and other similarly authorized organizations and agencies. This job is already being done and done well!

CMS has not provided any economic or patient safety justification for these sweeping changes to providers of physical medicine and rehabilitation in all types of hospital and clinic facilities. It has presented no reports or other evidence to indicate why these changes are proposed. In particular, the Hospital Conditions of Participation rules are not designed to achieve improvements in patient safety or service quality, their primary reason for existence.

These CMS changes are not demanded in order to improve access to services and, in fact, will have a detrimental effect on access. Without a doubt, the lymphedema therapist profession will suffer significant economic harm with these rules. The profession was first harmed by the 2004 Therapy-Incident to Rule when approximately one-third of the profession lost their jobs. We expect up to 50 percent of the remaining lymphedema therapists will be harmed economically.

CMS has not given any economic justification for these changes nor has it addressed the economic impact on either the hospitals or other rehabilitation facilities. We also believe that these rules will result in increased expenses to CMS, and these economic scenarios have not been properly considered by the Office of Management and Budget. In the case of rural health clinics, CMS appears to be creating a whole new set of services outside of statutory authority.

CMS states that it wants to develop a consistent definition for physical therapists and physical therapy assistants. CMS and that profession continue to attempt to redefine the physical medicine and rehabilitation specialty as "physical therapy." This is wrong at every level. Physical medicine and rehabilitation medicine is a much broader term than physical therapy—as stated by the American Medical Association—and many types of providers are qualified and capable of providing these services. The rules, as proposed by CMS, go well beyond a consistent definition of physical therapist or physical therapy assistant. The end result is that CMS is seriously limiting the ability of hospitals and other providers to hire appropriate staff for the delivery of physical medicine and rehabilitation services. If CMS wants to have a consistent definition of PTs and PTAs, it only needs to defer to state law, which fully defines these and all other professionals working in hospitals and rehabilitation facilities.

CMS has been working under Executive Order 12866 to reduce bureaucratic control in favor of allowing autonomy of hospital medical staffs. This is completely contrary to these Executive Orders. Similarly, early intervention can prevent costly and needless suffering among patients. When "prevention" is a key phrase at CMS, why is the agency restricting the ability of capable, qualified providers to deliver these services?

It is very curious, too, as to why CMS feels compelled to only restrict providers of physical medicine and rehabilitation services. Although repeatedly requested, no information has been provided as to why these services are singled out from, for example, radiology, pharmacology, chemotherapy or gastro-intestinal specialty services.

The Lymphedema Stakeholders and the member groups of the Coalition to Preserve Patient Access to Physical Medicine and Rehabilitation Services and their patients will all be harmed by these rules. Like lymphedema therapists, we estimate that thousands kinesiotherapists, athletic trainers, low-vision therapists and others will no longer be able to work in hospitals and other rehabilitation facilities. This will exacerbate workforce shortages and magnify access and quality problems across the U.S.

Creation of a Monopoly?

CMS, in collaboration with a professional organization, is once again attempting to establish a monopoly for PTs and PTAs for the delivery of physical medicine and rehabilitation services provided in various provider settings. This is particularly egregious because these typically Medicare Part A changes are buried in what is typically viewed as Medicare Part B sections of proposed rules. Is it CMS's goal to prevent any health professional other than a physical therapist from providing physical medicine and rehabilitation services? If this is the case, under what statutory authority has CMS pursued this objective? While only a small part of the rehabilitation provider community, lymphedema therapists are one of the many growing list of specialty providers. We are specially trained to efficiently and effectively provide care—rather than care being provided by the PT generalist who doesn't get any training in these specialty areas.

We believe it is irresponsible for CMS to propose what equates to a mandatory staffing requirement – a monopoly if you will – under Medicare Part A at a time of workforce shortages. Unlike Part B, where specific staffing requirements exist as a condition of payment (generally mandated by federal statute), Part A providers have traditionally been given wider latitude in staffing decisions because they take financial responsibility and liability. Staff who are not recognized under Part B as independent providers of care are able to see and provide services to patients being treated by a Part A provider. The Part A provider is given this staffing latitude because none of these professionals is seeking independent reimbursement. The professionals, however, are doing exactly the same tasks as a physician, physician assistant or nurse practitioner would be doing in this capacity. In this case, Medicare trusts the judgment of the hospital and physician—and state legislatures and health departments—to only use qualified personnel.

No Consultation with Public or Lymphedema Therapists

Although CMS states otherwise, there was no broad-based public or provider discussion on these revisions to our knowledge. No lymphedema provider or patient group was consulted prior to the publication of these proposed rules. Therefore, we must question whether this proposal has gone through any of the normal vetting process, either associated with the Hospital Conditions of Participation or other requirements related to quality. Additionally, there is no statutory deadline or requirement for these changes—it is as if they appeared out of thin air. CMS has only stated that it wanted to develop a "consistent" policy across provider types; it has reached well beyond that with these rules.

Inappropriate Placement of Federal Register Notice

The Lymphedema Stakeholders question whether these proposed regulations are more focused on delivering reimbursement to a selected group of providers than focused on delivering quality services to Medicare beneficiaries. We also do not understand why major revisions to Hospital Conditions of Participation were incorporated in a Physician Fee Schedule proposed rule, which is a Medicare Part B section. This has had a chilling effect on comments from those in the hospital community, which typically reviews regulations related to Medicare Part A. CMS recently published other rules for hospitals, so other more appropriate publication vehicles were available.

No Compelling Law or Employer Desire

While CMS cites a need to update standards for physical therapists and physical therapy assistants, there is no need for this The current standards contained in the Hospital Conditions of Participation, as well as outpatient clinic therapy standards, are consistent with state law and staff models of rehabilitation facilities for both Medicare Parts A and B. Employers—including hospitals—are concerned that the degree creep in the physical therapists profession (which moves PTs to a three-year clinical doctorate degree) only succeeds in increasing salaries and driving up costs. This degree creep also limits the current and future physical therapy workforce and supports the PT profession's primary agenda and stated goal of direct access, which is opposed by MedPAC.

There is no compelling law mandating these changes. These changes are not necessary to interpret the law and CMS has failed to identify any "compelling public need" for this change. In fact, the proposed changes in the physical therapy standards can best be described as a "solution in search of a problem." Even if there were a compelling reason, CMS has created a set of rules so complicated and convoluted that they are practically unenforceable. These rules would place significant burden on the hospitals, rural health clinics and other rehabilitation facilities with no return on investment in patient access or quality.

Loss of Access

For those hospitals and other providers unable to recruit or retain the physical therapists and physical therapy assistants necessary to meet patient demand, we will see facilities close or dramatically scale back service availability. A large number of clinics providing lymphedema services closed after the therapy-incident to rule, and now even more will close. Patients in need of physical medicine or rehabilitation services will simply have to go without services, suffering needless pain, or without the continuation of a treatable and costly if chronic condition, if hospitalized.

Proposed Rules Override State Law and Medical Staff Authority

These proposed standards clearly override State governments' authority to determine scopes of practice for health care professionals and license those professionals. Current Hospital Conditions of Participation (COP) for most providers provide staffing flexibility to the facility. For example, the COP stipulates that if rehabilitation services are provided, "The organization of the service must be appropriate to the scope of the services offered.

(1) The director of the services must have the necessary knowledge, experience, and capabilities to properly supervise and administer the services.

(2) Physical therapy, occupational therapy, or speech therapy, or audiology services, ***if provided, must be provided by staff who meet the qualifications specified by the medical staff, consistent with State law.***

Not all CMS-statutorily recognized health professionals are state licensed or certified. But when this occurs, CMS has typically established coverage standards in consultation with the appropriate professional associations representing those health professionals for both licensure and non-licensure states. This combination of deferring to state licensure requirements and consultation with all affected provider groups generally works well, especially in a time of workforce shortages. This also allows for the flexibility needed in local staffing models, and the growing demand for highly-trained specialty providers. CMS clearly did not consult with physical medicine and rehabilitation (PMR) physicians, specialty rehabilitation provider groups, hospitals or medical associations. It appears it only consulted the physical therapist lobby.

The current standard defers to the collective judgment of the medical staff and recognizes the authority of the state to determine the appropriate scope of practice for various health professionals. The Lymphedema Stakeholders is at a loss as to how an individual working at CMS could believe his or her judgment could realistically apply to every type of rehabilitation service in every type of hospital or facility in every urban, suburban, rural or medically underserved geographic area. Likewise, it is unreasonable to believe that the judgment of a CMS employee—or even a small team of employees—is superior to the collective judgments of the state legislatures, health departments and regulatory agencies throughout the United States who make these determinations for individual states. CMS employees generally are not clinicians practicing daily in physical medicine and rehabilitation.

Inappropriate Application of Statute

In proposing the current change, CMS perpetuates an incorrect—and we believe possibly illegal—application of outpatient therapy provider standards to the 2005 therapy-incident to rule. At the time that policy was under consideration by CMS, the Lymphedema Stakeholders and members of the Coalition to Preserve Patient Access to Physical Medicine and Rehabilitation Services repeatedly asked for data supporting CMS position and were repeatedly told that it was not necessary for the agency to engage in such justification because CMS was merely following what Congress mandated in Section 1862(a)(20).

While we disagreed then and continue to disagree with CMS's 2005 interpretation (as opposed to the agency's interpretation of the intent of Section 1862 (a)(20) published in both 2001 and 2003), we can't help but note that when Congress enacted Section 1862(a)(20), it DID NOT apply that policy to 1861(p) of the Social Security Act nor did it apply the language of 1862(a)(20) to other providers of services. Therefore we believe that adoption of this proposal, absent specific Congressional directive and absent any compelling health or safety concerns, is unwarranted and unauthorized.

Summary:

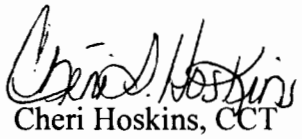
The Lymphedema Stakeholders and the patients it serves strongly object to these proposed rules. The effect of these proposed rules, under the guise of a consistent definition, is a mandate and monopoly for physical therapists and physical therapy assistants in all types of physical medicine and rehabilitation Medicare Part A and B facilities. This is inappropriate and unwise from patient access, quality and economic standpoints. The proposed rules are inconsistent with Congressional intent, state law, and long-standing medical authority on staffing decisions. The proposed rules are contrary to Executive Order 12866 allowing more local control and latitude by facilities to provide health care in a safe and effective manner.

Recommendations:
We strongly urge CMS to:

1. Immediately withdraw all proposed changes related to Therapy Standards and Requirements (physical medicine and rehabilitation) in all facilities mentioned in this Federal Register publication.
2. Request that the Office of Management and Budget thoroughly conduct a review of the economic impact and access impact of any proposed rules prior to a Medicare transmittal or similar instruction or public comment period.
3. Convene a working group with representation of the range of providers furnishing rehabilitation services, as well as the health professionals working in rehabilitation departments, to discuss with CMS: workload, staffing, personnel qualifications and scope of services delivered, and attempt to achieve a policy via consensus. CMS must acknowledge that, in the make up of this working group, others in the commercial health provider market are affected by its rules and seek to include providers not currently covered by CMS provider lists. This must include lymphedema therapists, athletic trainers, kinesiotherapists and others.
4. Separately, the Lymphedema Stakeholders will recommend that Congress conduct an inquiry into CMS's creation and proposal of these rules and its apparent attempt to create and support a provider monopoly.

Thank you for the opportunity to voice the Lymphedema Stakeholder's concerns. We look forward to receiving information on the CMS decision after the comment period. If you need any additional information or would like clarification of any of Lymphedema Stakeholder's points, please contact me directly at 972-231-6511 extension 11, or email cheri@healthtronix.com.

Sincerely,



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THE DECLAIRE
KNEE & ORTHOPAEDIC
INSTITUTE

August 15, 2007

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Minimally Invasive Knee Replacement

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Leslie Norwalk
Centers for Medicare & Medicaid Services
P.O. Box 8018
7500 Security Boulevard
Baltimore MD 21244-8018

RE: CMS-1385-P Reimbursement for Office Based Arthroscopy

Dear Ms. Norwalk:

Thank you for this opportunity to comment on the 2008 proposed Medicare Physician Schedule. I am a practicing physician in Rochester Hills, Michigan and the founder of the DeClaire Knee and Orthopaedic Institute. I am also a member of the American Medical Association, the American Academy of Orthopaedic Surgeons, the Arthroscopy Association of North America, and the American Orthopaedic Society for Sports Medicine. In 1997, I was awarded the Outstanding Physician of the Year Award by Governor John Engler.

I wish to comment on the discussion on page 38135 of the Federal Register regarding non-facility practice expense (PE) relative value units (RVUs) for arthroscopy and to express my **support for extending Medicare reimbursement to physicians who perform arthroscopy in the office setting.**

As a board certified and fellowship trained orthopaedic surgeon who has been practicing for more than 18 years, I am very familiar with this issue. In my opinion, Medicare's reimbursement policy for arthroscopy procedures needs to be revisited and updated. Physicians are currently reimbursed for arthroscopies performed in a hospital outpatient department or in an ambulatory surgical center, but not when the same procedure is performed in their office. In 2007, this distinction is illogical and interferes with the medical community's ability to offer the best possible treatment to our patients.

Arthroscopy is no less safe when performed in the physician's office; nor is arthroscopy less effective when performed in the "non-facility" setting. Physicians choose (or would choose if there were payment) to perform arthroscopy in their office in order to receive important data faster and to avoid extra appointments in unfamiliar settings for their patients. There are several peer reviewed articles that support office-based arthroscopy, some of which date back to the early 1990s, and my colleagues and I have many years of experience performing these procedures.

Accordingly, I recommend that CMS establish non-facility practice expense RVUs for arthroscopy procedures.

Sincerely,

Jeffrey H DeClaire, M.D.

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UAB SCHOOL OF MEDICINE

Department of Surgery

August 20, 2007

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: Proposed Revisions to the Physician Fee Schedule for CY 2008;
Recommendation for Improved Reimbursement for Arthroscopy Procedures Performed in Physician Offices

Dear Administrator Norwalk:

Diagnostic arthroscopies performed in the physician office setting are safe and effective procedures appropriate for reimbursement under the Medicare Physician Fee Schedule ("MPFS"). They are also clinically feasible, cost-effective, and often preferred by the patient.

Unfortunately, Medicare has not assigned non-facility practice expense ("PE") relative value unit ("RVU") amounts to diagnostic arthroscopy procedures. Because my fellow orthopaedic surgeons are not adequately reimbursed for the significant practice expenses associated with providing arthroscopies in their office, patient access to these important procedures and technology is limited. Doctors substitute more expensive MRI tests for the arthroscopies and in that way tie up hospital outpatient resources. Furthermore the information obtained on the MRI is often not as complete as that obtained by directly visualizing the pathology using the arthroscope.

As Professor and Director of Orthopedic Surgery at the University of Alabama, Birmingham I oversee orthopaedic surgery throughout our large health care delivery system and as Surgeon-in-Chief at UAB Highlands Hospital I monitor closely resource utilization and quality of care. I specialize in the treatment of hand, wrist, and elbow disorders and I am a member of the American Academy of Orthopaedic Surgeons, the American Orthopaedic Association, the American Society for Surgery of the Hand, and the American Association for Hand Surgery to name just a few.

In my practice, I have carefully investigated the efficacy of diagnostic arthroscopy and I have found the procedure extremely effective and beneficial for patients. Consequently, I am writing to voice my strong support for establishing non-facility PE RVUs for arthroscopy procedures in the final 2008 MPFS rule.

I appreciate your attention to this critical issue and thank you for the opportunity to comment on the matter.

Sincerely,

Thomas R. Hunt, III, M.D.

Professor and Director of UAB Orthopaedic Surgery

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August 8, 2007

Leslie Norwalk
Centers for Medicare & Medicaid Services
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Baltimore, MD 21244-8018

Re: **CMS-1385-P**

Dear Ms. Norwalk:

I am writing to express my **support for extending Medicare reimbursement to arthroscopy procedures performed in the physician's office.** I understand that the Centers for Medicare & Medicaid Services (CMS) solicited comments on this subject in the recently published proposed 2008 Medicare Physician Fee Schedule Rule.

I am an orthopedic surgeon and Professor of Orthopedic Surgery at the State University of New York – Upstate Medical University where I specialize in wrist and hand disorders, with a particular interest in carpal tunnel syndrome, rheumatoid and degenerative arthritis, and ligamentous injuries of the wrist. Since April 2002, I have also sponsored the Cazenovia Health Care Symposium, a community outreach/education program that deals with various health problems and their treatments.

I frequently see patients in my office who complain of hand or other joint pain. While I can usually make a tentative diagnosis, I often must refer the patient to another facility for a diagnostic arthroscopy. In the past, these procedures were perhaps not medically appropriate for the physician's office, but today it is economics not science holding us back. It has been clear for a number of years that in-office diagnostic arthroscopy is safe, that such procedures produce useful data, and that both patients and physician prefer the convenience of immediate results. Nevertheless, Medicare does not reimburse physicians for these procedures when they are performed in the office-setting.

CMS is right to reevaluate this dated policy. I strongly believe that in 2007 payment should be available for diagnostic arthroscopy performed in both outpatient departments and physician offices. While there may be important medical reasons to choose one location over another, reimbursement considerations should not play a role.

Sincerely,

Andrew Palmer, 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)

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Pain and Spine Specialists of Connecticut, LLC

David C. Levi, MD

August 29, 2007

Kerry Weems
Administrator Nominee
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1385-P

Dear Mr. Weems:

I would like to thank you for the opportunity to comment on the Proposed Rule CMS-1385-P, "Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008" (the "Proposed Rule") published in the *Federal Register* on July 12, 2007

I am one of the approximately 7,000 physicians practicing interventional pain management in the United States. As you may know physician offices, along with hospital outpatient departments and ambulatory surgery centers are important sites of service for the delivery of interventional pain services.

After having experienced a severe cut in payment for our services in 2007, interventional pain physicians are facing additional proposed cuts in payment; cuts as much as 7.8% to 19.8% in 2008 alone. This will have a devastating affect on my ability to provide interventional pain services to Medicare beneficiaries. I am deeply concerned that the continued underpayment of interventional pain services will discourage physicians from treating Medicare beneficiaries unless they are adequately paid for their practice expenses. I urge CMS to take action to address this continued underpayment to preserve Medicare beneficiaries' access to appropriate care.

I recommend that CMS modify its practice expense methodology to appropriately recognize the practice expenses of all physicians who provide interventional pain services. Specifically, CMS should treat anesthesiologists who list interventional pain or pain management as their secondary Medicare specialty designation, along with the physicians that list interventional pain or pain management as their primary Medicare specialty designation, as "interventional pain physicians" for purposes of Medicare rate-setting. This modification is essential to ensure that interventional pain physicians are appropriately reimbursed for the practice expenses they incur.

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RESOURCE-BASED PE RVUs

I. CMS should treat anesthesiologists who have listed interventional pain or pain management as their secondary specialty designation on their Medicare enrollment forms as interventional pain physicians for purposes of Medicare rate-setting.

The practice expense methodology undervalues interventional pain services because the primary Medicare specialty designation for many of the physicians providing interventional pain services is anesthesiology. Many interventional pain physicians received their medical training as anesthesiologists and, accordingly, clinically view themselves as anesthesiologists. While this may be appropriate from a clinical training perspective, their Medicare designation does not accurately reflect their actual practice and associated costs and expenses of providing interventional pain services.

This disconnect between the Medicare specialty and their practice expenses is made worse by the fact that anesthesiologists have the lowest practice expense of any specialty. Most anesthesiologists are hospital based and do not generally maintain an office for the purposes of rendering patient care. Interventional pain physicians are office-based physicians who furnish evaluation and management (E/M) services and also perform a wide variety of interventional procedures such as nerve blocks, epidurals, intradiscal therapies, implant stimulators and infusion pumps. Therefore the interventional pain physician has practice expenses that are similar to other physicians who perform both E/M services and surgical procedures in their offices.

Furthermore, the utilization rates for interventional pain and pain management specialties are so low that they are excluded from Medicare rate-setting or have very minimal affect compared to the high utilization rates of anesthesiologists. The following table illustrates that anesthesiologists are reported as the primary specialty providing interventional pain services compared to interventional pain physicians

CPT Code	Anesthesiologists - 05 (Non-Facility)	Interventional Pain Management Physicians - 09 (Non-Facility)
64483 (Inj foramen epidural l/s)	59%	18%
64520 (N block, lumbar/thoracic)	68%	15%
64479 (Inj foramen epidural c/t)	58%	21%
62311 (Inject spine l/s (cd))	78%	8%

The high utilization rates of anesthesiologists (and their extremely low practice expenses) drive the payment rate for the interventional pain procedures, which does not accurately reflect the resource utilization associated with these services. This results in payment rates that are contrary to the intent of the Medicare system in which physician payment is intended to reflect resources used in furnishing items and services to Medicare beneficiaries.

I urge CMS to make a modification to its practice expense methodology as it pertains to interventional pain services such that its methodology treats physicians who list anesthesiology as their primary specialty and list interventional pain as their secondary specialty designation as interventional pain physicians for rate-setting. This pool of physicians should be cross-walked to "all physicians" for practice expenses. This will result in payment for interventional pain services that is more aligned with the resources and costs expended to provide these services to a complex patient population.

I urge CMS not to delay implementing our proposed recommendation pending the results of the Physician Practice Information Survey ("Physician Practice Survey"). While I believe the Physician Practice Survey is critical to ensuring that physician services are appropriately paid, I do not believe that updated practice expense data will completely resolve the current underpayment for interventional pain services. The accurate practice expense information for interventional pain physicians will continue to be diluted by the high utilization rates and associated low practice expenses of anesthesiologists if the current methodology is not restructured.

II. CMS Should Develop a National Policy on Compounded Medications Used in Spinal Drug Delivery Systems

We urge CMS to take immediate steps to develop a national policy as we fear that many physicians who are facing financial hardship will stop accepting new Medicare beneficiaries who need complex, compounded medications to alleviate their acute and chronic pain. Compounded drugs used by interventional pain physicians are substantially different from compounded inhalation drugs. Interventional pain physicians frequently use compounded medications to manage acute and chronic pain when a prescription for a customized compounded medication is required for a particular patient or when the prescription requires a medication in a form that is not commercially available. Physicians who use compounded medications order the medication from a compounding pharmacy. These medications typically require one or more drugs to be mixed or reconstituted by a compounding pharmacist outside of the physician office in concentrations that are not commercially available (*e.g.*, concentrations that are higher than what is commercially available or multi-drug therapy that is not commercially available).

The compounding pharmacy bills the physician a charge for the compounded fee and the physician is responsible for paying the pharmacy. The pharmacy charge includes the acquisition cost for the drug ingredients, compounding fees, and shipping and handling costs for delivery to

the physician office. A significant cost to the physician is the compounding fee, not the cost of drug ingredient. The pharmacy compounding fees cover re-packaging costs, overhead costs associated with compliance with stringent statutes and regulations, and wages and salaries for specially trained and licensed compounding pharmacists borne by the compounding pharmacies. The physician administers the compounded medication to the patient during an office visit and seeks payment for the compounded medication from his/her carrier. In many instances, the payment does not even cover the total out of pocket expenses incurred by the physician (*e.g.*, the pharmacy fee charged to the physician).

There is no uniform national payment policy for compounded drugs. Rather, local carriers have discretion on how to pay for compounded drugs. This has lead to a variety of payment methodologies and inconsistent payment for the same combination of medications administered in different states. A physician located in Texas who provides a compounded medication consisting of 20 mg Morphine, 6 mg Bupivicaine and 4 mg Baclofen may receive a payment of $200 while a physician located in Washington may be paid a fraction of that amount for the exact same compounded medication. In many instances, the payment to the physician fails to adequately cover the direct cost of the drug, such as the pharmacy compounded fees and shipping and handling. Furthermore, the claim submission and coding requirements vary significantly across the country and many physicians experience long delays in payment.

We urge CMS to adopt a national compounded drug policy for drugs used in spinal delivery systems by interventional pain physicians. Medicare has the authority to develop a separate payment methodology for compounded drugs. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (the "MMA") mandated CMS to pay providers 106% of the manufacturer's Average Sales Price ("ASP") for those drugs that are separately payable under Part B. The language makes clear that this pricing methodology applies only to the sale prices of manufacturers. Pharmacies that compound drugs are not manufacturers, and Congress never contemplated the application of ASP to specific drug compounds created by pharmacies. Accordingly, CMS has the discretion to develop a national payment policy.

We believe that an appropriate national payment policy must take into account all the pharmacy costs for which the physicians are charged: the cost of the drug ingredient(s), the compounding fee costs, and the shipping and handling costs.

III. CMS Should Incorporate the Updated Practice Expense Data from Physician Practice Survey in Future Rule-Making

I commend CMS for working with the AMA, specialty societies, and other health care professional organizations on the development of the Physician Practice Survey. I believe that the survey data will be essential to ensuring that CMS has the most accurate and complete information upon which to base payment for interventional pain services. I urge CMS to take the

appropriate steps and measures necessary to incorporate the updated practice expense data into its payment methodology as soon as it becomes available.

IV CMS Should Work Collaboratively with Congress to Fix the SGR Formula so that Patient Access will be preserved.

The sustainable growth rate ("SGR") formula is expected to cause a five percent cut in reimbursement for physician services effective January 1, 2008. Providers simply cannot continue to bear these reductions when the cost of providing healthcare services continues to escalate well beyond current reimbursement rates. Continuing reimbursement cuts are projected to total 40% by 2015 even though practice expenses are likely to increase by more than 20% over the same period. Reimbursement rates have not kept up with the rising cost of healthcare because the SRG formula is tied to the gross domestic product that bears no relationship to the cost of providing healthcare services or patient health needs.

Because of the flawed formula, physicians and other practitioners bear the cost of providing health care to Medicare beneficiaries. CMS should work collaboratively with Congress to create a formula that bases updates on the true cost of providing healthcare services to Medicare beneficiaries.

***

Thank you for the opportunity to comment on the Proposed Rule. My fear is that unless CMS addresses the underpayment for interventional pain services today there is a risk that Medicare beneficiaries will unfairly lose access to appropriate treatment for pain care from interventional pain physicians who have received the specialized training necessary to safely and effectively treat and manage their complex acute and chronic pain. We strongly recommend that CMS make an adjustment in its payment methodology so that physicians providing interventional pain services are appropriately and fairly paid for providing these services and in doing so preserve patient access.

Sincerely,

David C. Levi MD
Pain and Spine Specialists of CT
67 Sandpit Road, Suite 308
Danbury, CT 06810

306

UROLOGY ASSOCIATES
OF FREDERICKSBURG
A Division of Mid-Atlantic Health Alliance, Inc.

Peter O. Carey, M.D. F.A.C.S.
Daniel M. Hoffman, M.D. F.A.C.S.
Elmore J. Becker, M.D.
Scott M. Sell, M.D.

Gregory R. Szlyk, M.D. F.A.C.S.
Matthew D. DuMont, M.D.
C. Ralph Beamon, M.D. (Retired)
F. Brad Gray, M.D. (Retired)

August 27, 2007

VIA FEDERAL EXPRESS OVERNIGHT

Center for Medicare and Medicaid Services
Department of Health and Human Services
Attn.: CMS-1385-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: JULY 2, 2007, MEDICARE PHYSICIAN FEE SCHEDULE PROPOSED REGULATIONS

Dear Sir or Madam:

I am a practicing urologist in Fredericksburg, Virginia. For the past eight years, I have been an owner in a joint venture partnership that provides lithotripsy services, as well as other therapeutic services including laser therapy, for benign prostatic hypertrophy. I believe there are many beneficial effects secondary to joint ventures including the fact that mobile physician vendors provide greater access to patients in remote locations and also provide access to underserved areas that are unable to afford the latest technologies. In my experience, hospitals are reluctant to purchase new technologies and, oftentimes, encourage the use of outdated equipment, which may not be in the patient's best interests. Oftentimes, the volume, for example, of lithotripsies performed at our hospital in Fredericksburg, would not justify the purchase of our own lithotriptor. Once again, mobile physician vendors lower overall costs by sharing expensive equipment among many hospitals. I understand that CMS is concerned about possible over-utilization of services secondary to physician ownership. Lithotripsy and benign prostatic hypertrophy laser services are therapeutic interventions and are not diagnostic procedures. Patients are referred for lithotripsy due to the fact that they have symptomatic renal or ureteral stones and, similarly, patients are referred for laser treatments due to the fact that they have prostatic obstruction. The notion that I would send a patient for one of these interventions simply because I was a participant in a joint venture is insulting. Obviously, sending a patient for an intervention that was not needed is, in my mind, medical malpractice.

Once again, I am extremely concerned that the proposed changes to the physician self-referral provisions will hurt physicians, specifically urologists, and also Medicare patients. Our hospital does not have the volume of patients to justify the purchase of a freestanding lithotriptor. Our joint venture enables patients to be treated on a timely basis with excellent quality of care. If CMS finalizes these proposed changes, I believe, they will do a great disservice to Medicare patients and practicing urologists.

Although I completely understand and support efforts by CMS to prevent abuse, I believe, the current proposals will ultimately prevent very valuable services such as mobile laser technology and mobile lithotripsy.

Sincerely,

Elmore J. Becker, Jr., M.D.

EJB:plc

D: 08/27/07
T: 08/28/07
J: 0827-256

PHOTOPHERESIS OF NEW JERSEY
182 South Street, Morristown, New Jersey 07960 (973) 292-1358

August 27, 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

Subj: RESOURCE-BASED PE RVUs FOR PHOTOPHERESIS (CPT 36522)

Dear Centers for Medicare and Medicaid Services:

In the interest of improving safety and accessibility for our Medicare patients and reducing overall costs to the Medicare program, I ask that you revisit the cost of photopheresis therapy, and take whatever steps are needed to increase practice expense RVUs to a level where your payment approaches my costs for this procedure. As the proposed 37.04 RVUs in the July 12 Federal Register notice falls at least 20% short of our overall costs, I will be forced to give up on my goal of providing photopheresis therapy in our office setting.

I have provided photopheresis therapy (CPT 36522) for the palliative treatment of skin manifestations of cutaneous T-cell lymphoma (CTCL) since 1988, when this procedure was approved by the FDA for this use. In 1990, I was among the first physicians to move the procedure to the hospital outpatient setting; previously, all patients requiring this treatment were hospitalized for their treatments. Nearly two decades of experience have proven that photopheresis is a very safe procedure. Medicare covers photopheresis in the physician office setting under the supervision of a physician.

In January 2003, I provided photopheresis therapy for the first patient – a Medicare patient – in our new office-based photopheresis suite. I established this service in my clinic despite my knowledge that I would at least temporarily incur financial losses due to inadequate valuation of the procedure at that time. Despite continuing losses, I have continued to do so on a limited basis because there are a number of important advantages – for non-hospitalized patients and for myself – in providing photopheresis in the office setting instead of the hospital.

First, photopheresis patients are physically debilitated by their underlying disease. Most require treatment on a recurring basis to control their disease manifestations. The office setting is far more convenient and easily accessible than large urban hospitals, where, for historical reasons, most photopheresis programs were started and still exist today. It is much safer to receive treatment in the non-hospital setting from the standpoint of serious infection risk: these patients are usually maintained on powerful immunosuppressive drugs which make them susceptible to methicillin-resistant staphylococcus and other serious pathogens that are commonplace in the hospital setting.

Second, since most of my overall patient caseload is seen in our office-based dermatology practice, providing photopheresis in this setting also reduces my travel and time costs. As more procedures have moved out of the hospital in recent years, it has become logistically more difficult to remain at the hospital to oversee the treatment phase of photopheresis procedures, each of which requires several hours to complete.

Finally, appropriate payment for this procedure in the office-based setting should be appreciably less costly than paying for it to be provided in a hospital outpatient department. I don't have direct access to the Medicare reimbursement rate for photopheresis at Morristown Memorial Hospital here in New Jersey, but my office manager has learned that it is about $2,400 per procedure, and is expected to increase next year.

I had hoped that by now photopheresis would be appropriately valued and I could expand its availability to more patients now being treated at the hospital. Below is detailed information about my practice expenses in the hope that CMS can upwardly adjust its "fully transitioned" practice expense RVUs for photopheresis, and I can finally realize my goal of providing this critical service for my patients. Should the valuation not increase appreciably – roughly 20% – to more closely approximate our costs, I will be forced to discontinue offering this service, even on the current very limited basis.

With a valuation that covers costs, I am certain that patient access to photopheresis in the non-hospital setting will improve, as more physicians no longer are deterred by the serious financial disincentive that currently prevails.

Photopheresis: Direct Costs and Operating Overhead for Photopheresis of New Jersey

Cost Description	Amount
Photopheresis procedural kit[1]	$1,013.00
Other supplies and UV light source[2]	$26.00
UVADEX methoxsalen (10 ml vial)	$60.00
RN Specialist (3.5 hours @ $45/hr) + RN benefits/payroll taxes (30%)	$205.00
UVAR XTS Equipment Amortization[3]	$65.00
TOTAL DIRECT COSTS:	**$1,369.00**

[1] UVAR XTS system. Manufacturer: Therakos Inc.

[2] Heparin 10,000 u/ml (1 ml vial); lidocaine 1% or 2% (no epinephrine); oxygen canister/nasal cannula or mask; NaCl (500 ml bags x 2); plastic hemostats (3-6/treatment); underpad (17 x 23 Chux); Terumo AVF fistula needles (17 gauge); 10 cc syringes; 3 cc syringes; 20 gauge needles, 1 inch; 4 x 4 pads; 2 x 2 pads; Sof-Kling 2 inch x 3.5 yd; alcohol wipes; 1 inch tape; specimen bags; non-sterile gloves; UV light source ($1,650/175 procedures).

[3] $65,000 per device; 200 procedures/device/year x 5 year service life

Indirect procedural overhead costs[4]	$480.00

TOTAL DIRECT AND INDIRECT COSTS: **$1,849.00**

I hope it is evident from this breakdown of costs that photopheresis is very resource-intensive. Our cost for the disposable procedure kit now exceeds $1,000 per kit; if we don't purchase a large specified quantity of these kits, the manufacturer's price increases to $1,100 per kit. A specially trained nurse specialist is dedicated to the procedure from start to finish; this is a half-day procedure including the set-up and post-treatment activities. I must pay these nurses $45 per hour, plus benefits, to retain them.

If helpful, I would be happy to provide invoices and any other documentation of supply- and equipment-related costs that you might need. I also invite you to visit my practice and observe a photopheresis procedure first-hand.

At present, Medicare's payment is covering little more than my direct costs of nearly $1,375 for this procedure.

I appreciate your attention to this matter. I hope that you will take corrective measures to make photopheresis financially viable for physician providers, and more broadly accessible to our patients in the office-based setting.

Please do not hesitate to contact me or my office administrator, Robert Lombardi, at (973) 292-1358, if we can offer any additional assistance.

Sincerely,

Emilio Bisaccia, M.D., F.A.C.P.
Medical Director, Photopheresis of New Jersey
Professor of Clinical Dermatology, Columbia University College of Physicians & Surgeons

EB/rl

[4] Administrative and clerical wages, benefits and payroll taxes; allocated clinic floor space cost; UVAR XTS equipment service contract; inventory financing costs; office supplies; utilities; telephone; postage; computer supplies/maintenance; training/educational expenses; and misc. expenses.

SSM HEALTH CARE

August 28, 2007

Department of Health and Human Services
Attention: CMS-1385-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Subject: Computer Generated Fax e-Prescribing requirements

Dear Sirs:

As one of the largest Catholic health care systems in the country - touching the lives of over 1.3 million Americans annually - SSM Health Care welcomes the opportunity to comment on the proposed rule that would eliminate the exemption for computer generated faxes from the Medicare Part D e-Prescribing requirements.

We believe that e-prescribing is the safest and most secure method for communicating prescriptions to pharmacies, and we support the push to make electronic prescriptions the standard for the country. However, we believe that eliminating the ability to fax prescriptions by January 2009 is too soon. A date of January 2010 would remove undue hardship on our system-wide initiative for planning and implementing the electronic health record system that will serve as our primary ePrescribing platform.

SSM Health Care is in year-two of a nine year project that will bring a seamless electronic health record to all of our facilities. This new system will eventually include standard electronic prescription writing capabilities, however, the full implementation of that technology is not trivial. Planning and implementing an electronic prescription solution takes months of time and we must ensure we are using the appropriate software versions to take advantage of the technology. Upgrading to those versions can often take as much or more time than the implementation of those new features.

While January 2010 would still be a challenge to our overall implementation, it is a challenge that could be met. January 2009 would be too soon. This would mean that many of our providers who currently very successfully fax prescriptions to pharmacies today would have to revert to paper prescriptions after the proposed rule takes effect. This would be a very unfortunate consequence of a premature date: computer-generated faxes are in almost all cases safer, more secure, and more convenient than printed prescription.

Furthermore, the electronic prescribing network may not currently be ready for full electronic prescribing standards in many of the markets served by SSM Health Care. Third-party

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intermediaries required for robust electronic prescription communications, such as SureScripts and RxHub, often have inaccurate or missing data about local pharmacies because they rely on the pharmacies themselves to provide this information. This inevitably results in failed ePrescribing transactions. Also, not all pharmacies - particularly those in some of the more rural markets served by SSM Health Care facilities - have implemented the receiving side of the ePrescribing solution. We remain skeptical that these and other gaps could be completely eliminated in the short timeframe allowed in the proposal.

Finally, those health systems who do currently use certified ePrescribing standards to communicate prescriptions, report that in a significant number of cases, ePrescription transactions fail for a variety of reasons. In these situations, computer-generated faxing has been an invaluable back-up mechanism. Eliminating faxing as a back-up would result in delayed and missed prescriptions, which presents an unnecessary risk to patient safety. We recommend that even after the final ePrescribing requirement date that computer-generated faxing still be allowed as a back-up for communicating prescriptions in the event that the fully electronic system fails for any reason for a particular transaction.

Two years ago, President Bush set a national goal to have most Americans using electronic health records within ten years. He asked that the privacy and security of those records be protected. SSM Health Care is working toward this goal, however, we must move forward in a systematic fashion to realize the full potential of this new technology and ensure the integrity of the systems that will eventually support ePrescribing.

Thank you for your consideration of these recommendations. We look forward to a time in the near future when patients have the safety, security, and convenience benefits that fully electronic prescription writing promises.

Sincerely,

Tom Langston
President, SSM Integrated Health Technologies
CIO SSM Health Care
(314) 768-5160
tom_langston@ssmhc.com

TL/nr

UROLOGY HEALTH SPECIALISTS, LLC

410 Plymouth Road, Suite 120
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Centers for Medicare Services
Dept of Health & Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

File code: CMS-1385-P
Issue Identifier: Physician Self-Referral Provisions

To Whom It May Concern:

As a member of a urology group practice, I read with extreme concern the proposed changes to the anti-markup provision. Physicians who have invested in in-office ancillary services have followed the historic guidelines set out by CMS. To change those rules at this point in time to limit the provider of the professional component of services to a full time employee is arbitrary. There are many providers of service who choose to work part time for personal health or family care needs. In addition, the Internal Revenue Service's rules regarding the classification of an employee v. an independent contractor would conflict with the proposed changes. The IRS will require the part time physician to be treated as an employee with W-2 income. Yet, the proposed change would contradict this application by treating them as an independent contractor who would normally receive a 1099. The economic cost and role of the part physician is clearly that of an employee and not that of a contract physician. As such, your proposed change would penalize practices and physicians. It seems much more reasonable to apply the fair market value rule to the payment of staff physicians providing the professional component of DHS services. In fact, if a fair market value rule is not applied, it seems to me that CMS is creating a situation in which it is explicitly favoring large corporate laboratories. These large laboratories do not always provide the highest level of care available. Big labs have an incentive to hire the cheapest physician labor to churn out the high volume of services. Conversely, in-office DHS services that are integral to the effective evaluation and management of the patient, must be of the highest quality whether they are provided by a full time or a part time employee. Medicare should judge these services on the medical necessity of the order for that service – whether it is to an in-office ancillary service or an independent lab performed service. If the physicians then makes some money on the transaction, you must understand that they are also taking risk by providing the services. They have a distinct incentive to provide high quality care when the malpractice risk also is in-office.

As an example, a urologist who relies on the accurate and timely diagnosis of a prostate biopsy specimen to effectively treat their patient in clinical practice will be much better able to evaluate the skills of the DHS provider, and to weed out those who do not provide the highest level of care. In fact, it is in their best interest to have the highest quality of care. We believe the interaction between the urologists in a group practice and a dedicated pathologist (whether full time or part time) in that practice will lead to better

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outcomes. While we understand the concern for an increase in volume of diagnostic tests ordered, the current malpractice system creates far more incentive for unnecessary tests than in-office ancillary services do. We respectfully ask that you regulate the ancillary services usage based upon medical necessity guidelines and fair market value of services provided.

Thank you for your thoughtful consideration of my comments.

Sincerely,

John M. Rodgers MD

Mark & Kambour
PATHOLOGY ASSOCIATES
5000 University Drive
Coral Gables, FL 33146
305-669-3471

August 29, 2007

Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850
Attention: CMS-1385-P

RE: Physician Self-referral Provisions

To Whom It May Concern:

This letter is in regard to 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. My group practices in South Florida as part of a group of pathologists providing both hospital based pathology services and independent reference lab services

This issue is having significant impact in our community and my group as a whole is grateful to the CMS for beginning the process of eliminating the many abusive self-referral practices in the billing and payment for pathology services.

We have witnessesed already a number of scenarios where overutilization of pathology testing has become apparent when urologists sent two bottles to our facility if certain insurances where not accepted in their own pod lab arrangement, however, they performed 12 jar biopsies when submitting to their physician group "laboratory".

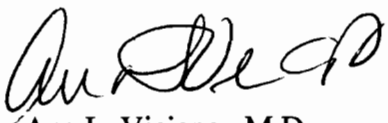
Some checks need to be put into place to ensure that arrangements are appropriate such as additional requirements for the pathologist employed by the group such as:. 1) The pathologist should not be allowed to work for more than one physician clinical practice group. 2) The pathologist should not be allowed to also work for or have any other arrangement with independent reference laboratory. (This would

eliminate the possibility that a reference laboratory could provide a pathologist in return for receiving the technical component billing.) 3) Medical liability insurance for the pathologist should be paid by the physician clinical practice.

I am also concerned that if there are single pathologists, appropriate or optimal quality assurance will not take place. As a group practice, we have guidelines that all malignancies are reviewed by at least two board-certified pathologists.

The Medicare program should play a role to ensure that providers furnish care in the best interests of their patients. It is my concern that these pod labs will not provide the best care or serve the best interest of the patient.

Sincerely,



Ana L. Viciana, M.D.

Sent by Fed Ex

NASW
National Association of Social Workers

...the power of social work

August 30, 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:

I am writing to you on behalf of the National Association of Social Workers (NASW) and its 150,000 members. The oldest and largest professional social work organization in the United States, NASW promotes, develops, and protects the practice of social work and social workers.

NASW appreciates 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 Calendar Year 2008," published in the Federal Register dated July 12, 2007. Our comments are listed below.

TRHCA-SECTION 101 (b): PQRI

Proposed 2008 PQRI Quality Measures
NASW supports the following three proposed non-physician quality measures that were developed by Quality Insights of Pennsylvania:
(1) Screening for Clinical Depression
(2) Screening for Cognitive Impairment
(3) Patient Co-development of Treatment Plan

We recommend that clinical social workers have access to two AMA/PCPI measures listed in Table 17, 72 Fed. Reg., 38201, as part of the bonus incentive program. They are:
(1) Patients who have Major Depression Disorder who meet DSM-IV Criteria
(2) Patients who have Major Depression Disorder who are assessed for suicide risks

These two measures also fall within the scope of clinical social work practice.

MEDICARE TELEHEALTH SERVICES §410.78(b)

NASW supports the expansion of telehealth services, which are critical to rural Medicare beneficiaries. Because clinical social workers are unable to seek reimbursement for the neurobehavioral status exam, we recommend that CMS also expand the telehealth services to include the new CPT Code 96125, "Cognitive Performance Testing." The CPT Editorial Panel approved this code in 2007 for non-physician practitioners who did not have access to the neurobehavioral status exam but who performed similar services.

RESOURCE BASED PE RVUs

This is the second year that clinical social workers will receive cuts due to the practice expense formula's change in methodology. NASW continues to oppose the new methodology, which negatively affects clinical social workers as mental health practitioners.

Social workers incur limited practice expenses due to the nature of their services. We continue to advocate for the adoption of an alternative practice expense methodology that would provide a practice expense balance for those in health care and mental health care or an exemption for mental health providers from the new practice expense methodology for calculating costs.

CORF ISSUES

CORF Social and Psychological Services

NASW supports the use of Health and Behavior Assessment Codes in Comprehensive Outpatient Rehabilitation Facilities (CORFs). The family is a very important part of treatment. Situations may arise that require a meeting with a family member without the beneficiary present.

For example, sensitive rehabilitative barriers to treatment may exist, which require an interview with the family only, especially when the family may have problems adjusting to the rehabilitation plan. Therefore, we recommend the addition of 96155 - whose descriptor reads, "family (without the patient present)" - to the proposed list of CPT codes 96150-96154.

§410.100

Social workers perform social work services, not "social services" or "social" services. We recommend that CMS change:

(1) All references to "social services" to "social work services"
(2) All references to "social" services" to "social work" services.

The phrase "social work services" adequately describes the depth and breadth of social workers' skills and expertise.

§410.100(h)

NASW finds the proposed definition for social and psychological services restrictive. Therefore, we recommend that the definition include social work, biopsychosocial functioning, and discharge plans.

The recommended definition should read:

> Social work and psychological services include the assessment and treatment of an individual's biopsychosocial, mental and emotional functioning and the response to and rate of progress as it relates to the individual's rehabilitation plan of treatment and discharge plans.

§485.70

Additional information is required in order for NASW to make an informed recommendation regarding the qualifications of social workers who work in CORFs. The social work profession recognizes several levels of social work education and licensure for social workers.

If the proposed definition increases the required skills of social workers in CORFs, it may be appropriate to advance the qualifications to the level of "Master of Social Work." However, if the proposed definition does not expand the skills of social workers in CORFs, it seems appropriate for the qualifications to remain at the educational level of the "Bachelor of Social Work."

Thank you for the opportunity to offer comments on the proposed rules. We look forward to the final rule in November 2007. Meanwhile, please contact me at 202-336-8200 if you have any questions about any of NASW's comments.

Sincerely,

Elizabeth J. Clark

Elizabeth J. Clark, PhD, ACSW, MPH
Executive Director

INSIGHT IMAGING

312

August 30, 2007

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

RE: Proposed 2008 Physician Fee Schedule
File Code CMS–1321–P

To Whom It May Concern:

The purpose of this letter is to comment on CMS' July 2nd 2008 Medicare Physician Fee Schedule Proposed Regulations that, among other topics, address IDTF Performance Standards, Purchased Test Provisions and Reassignment Rules.

Insight Imaging, LLC provides a diagnostic ultrasound service in five (5) states in the Southeast. Insight Imaging is owned by businessmen and has no physician owners. The Company's service is provided with technologically advanced equipment and highly qualified and experienced technologists in many areas where the quality of diagnostic services is inferior and/or access is limited. Unlike CT, PET and MRI imaging technologies, ultrasound is a much lower cost, portable technology that may be effectively and efficiently offered in the physician practice suite and supervised by the treating / ordering physician.

In-office ultrasound suppliers like Insight Imaging provide services in physician practices, many of which are located in rural, non-metropolitan areas in which the quality and convenience of diagnostic ultrasound is not available or limited.

Insight Imaging provides ultrasound service in the physician's practice facility under the direction, control and supervision of the on-site physician and physician staff. For Medicare beneficiaries, the convenience of on-site service is very important in determining whether the patient ultimately receives the ultrasound imaging study. In certain markets, alternative service outlets (e.g. hospital outpatient imaging departments and fixed imaging centers) may entail drives beyond a twenty (20) mile radius for patient treatment. In other markets, service delays of 10-14 days for the scheduling of an exam are not uncommon. These lengthy drive times and scheduling delays do not exist with on-site, imaging services.

We appreciate the opportunity to provide commentary on the following rules as proposed by CMS:

WCSR 3722551v2
1901 Roxborough Road, Suite 200, Charlotte, NC 28211 704.525.7005 704.525.6250 fax insightimagingllc.com

I. IDTF Performance Standards

A. Liability Insurance – § 410.33(g)(6)

The liability insurance requirement made effective January 1, 2007 is a positive standard that raises the quality bar for all IDTFs. We support CMS' proposals to: i) delete the requirement that the liability policy list the serial numbers of all diagnostic equipment as this will increase administrative burden on IDTFs and MACs, and (ii) clarify that the liability policy must provide coverage at each location of at least $300,000 "per incident". We recommend that liability policy details be reflected in the 855B Medicare Enrollment Application and that material changes to this policy would require notification to the MAC according to the same thirty (30) day notice period as that required for changes in ownerships, location, general supervision, and adverse legal actions rather than adopting the requirement for the MAC to be a named certificate holder. We expect that insurance underwriters will be reluctant to add MACs as certificate holders as it may raise questions regarding government indemnification or payment rights that are not warranted.

B. Enrollment Changes – § 410.33(g)(2)

We agree with CMS' proposal to require that changes in ownership, changes of location, changes in general supervision, and adverse legal actions must be reported to the designated fee-for-service contractor on the Medicare enrollment application within thirty (30) calendar days of the change and that all other changes to the enrollment application must be reported within ninety (90) days.

C. Beneficiary Questions & Complaints – § 410.33(g)(8)

We do not agree with CMS' proposal to expand performance standard # 8 to require not only that the IDTF answer beneficiaries' questions and respond to their complaints but that the IDTF create and maintain on file at the physical site of the IDTF (or home office for mobile units) documentation of these interactions with beneficiaries. This documentation provision will place additional administrative and enforcement burdens on IDTFs and MACs, respectively, which will likely decrease the services available to program beneficiaries by the IDTFs.

D. Supervising Physician - § 410.33(b)(1)

We agree with CMS' proposal to delete the existing, very broad requirement that the supervising physician is responsible for "the overall administration and operation of the IDTFs... and for assuring compliance with applicable regulations." We believe that the supervising physician should be responsible for quality-related oversight where he/she is more capable of positively impacting the operation of the IDTF.

§ 410.33(b) Supervising physician. We recommend that CMS move to a diagnostic equipment threshold limit instead of an IDTF site limit since, as proposed – "Each supervising physician must be limited to providing supervision to no more than three IDTF sites." -- portable/mobile providers would be unfairly treated relative to fixed

WCSR 3722551v2

five different groups. Therefore, the machine is available for use "at the hospital" twice a month. Medicare patients must wait for the services of

the lithotripsy, even though it is provided in the community every week. Now, you speak of taking this option away completely. Patients will be vulnerable to costly procedures in the hospital, and the potential for adverse outcomes.

The proposed "under arrangement" rule, will prohibt the provision of IMRT, laser or any other ownership interest that are very beneficial to the patients. The prohibition of per click payments for space and equipment rentals will prohibit the availabilty of services to patients because not everyone has the resources to purchase the equipment out right, and then provide the service.

The sweeping changes to the Stark regulations and the reassignment and purchased diagnostic test rules go far beyond what is necessary to protect the Medicare program from fraud and abuse. The rules should be revised to only prohibit those specific arrangements that are not beneficial to patient care or work to limit the availability of services.

Thank you for your consideration.

Debbie Klauka
Administrator

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August 30, 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: Comments to Proposed Revision to Physician Fee Schedule for Calendar Year 2008: CMS-1385-P

To Whom It May Concern:

Uropath, L.L.C. ("**Uropath**") submits the following comments to the Centers for Medicare and Medicaid Services ("**CMS**") published File Code [CMS-1385-P], *Medicare Program: Proposed Revisions to the Payment Policies Under the Physician Fee Schedule, and other Part B Payment Policies for Calendar Year 2008* (the "**Proposed Rule**").

I. GENERAL COMMENTS

Uropath provides managerial and operational expertise and efficiencies which permit a physician group practice to provide superior pathology services and better patient care. All services are provided by employees and contracted physicians in a group practice's own facilities, utilizing solely the individual group practice's CLIA certified laboratory, equipment, and supplies, all in accordance with the group practice's policies and procedures. The structure under which these services are provided is completely consistent with applicable anti-markup provisions, limitations on the billing for purchased services, the Stark Law, and all other applicable law and regulations.

During 2005, the Office of the Inspector General's Office of Audit Services conducted audits of laboratory services claimed by a group practice that owned pathology laboratories in each operational location that Uropath serves. A Medicare Program Safeguard Contractor reviewed medical records to determine whether pathology services provided were reasonable, medically necessary and supported by adequate documentation. In July, 2007, the OIG posted audit reports for each of these three audits. In each case, the Medicare Program Safeguard Contractor determined that the Practice's claims for pathology services complied with Medicare medical necessity and documentation requirements. None of the audits contained any reports of deficiencies, recommendations, or any other adverse findings.

Uropath met with CMS representatives in Maryland to explain in detail exactly how Uropath managed labs are structured and operate. There is no data to support the accusation that these labs facilitate the generation of medically unnecessary biopsies. Clinical indications for prostate biopsy are not subject to manipulation. Internal data generated by group practices that operate Uropath-managed pod labs actually show a higher positive incidence of prostate cancer than before they owned their own laboratories.

There exists no substantive evidence to support the accusation that Uropath-managed pathology laboratories cause over-utilization of services, the provision of unnecessary medical services, kickbacks, fee-splitting, or any other program abuses. Uropath data and group practice data confirm no over-utilization or other program abuse is occurring. Uropath and Uropath managed labs recognize that these labs generate permitted self-referrals which are subject to intense regulation, so Uropath-managed laboratories are vigilant of all changes in Medicare laws, rules and regulations that apply to the provision of pathology services.

The Proposed Rule, like the 2007 proposed rule before it, seeks to eliminate pod labs. Uropath-managed pod labs are vital to the accurate detection and treatment of prostate cancer, and do not expose Medicare to undue risk of program abuse. Rules intended to eliminate pod labs simply because they are pod labs, without any evidence of program abuse, are bad public policy and lower the quality of health care provided to Medicare beneficiaries.

II. PHYSICIAN SELF-REFERRAL PROVISIONS

A. The Reassignment Provision; 42 CFR § 424.80

CMS proposes to amend 42 CFR § 424.80 to provide that if either the technical component ("**TC**") or the professional component ("**PC**") of a diagnostic test is billed by a physician or medical group pursuant to a contractual reassignment from a provider who is not a full time employee of the billing group, the following conditions must be met:

(i) the payment to the group, less applicable deductibles and coinsurance, may not exceed the lowest of: (1) the provider's net charge to the group, which must be determined without regard to any charge intended to cover the cost of equipment or space leased to the provider by the billing group; (2) the billing group's actual charge; or (3) the Medicare fee schedule payment for the service provided;

(ii) the billing group must identify the provider that performed the PC or the TC and indicate their net charge as a condition of reimbursement; and

(iii) in order to bill for the TC of a service, the group must directly perform the PC of the same service.

CMS assumes that physicians who financially benefit from referring patients for health care services will unnecessarily refer patients for those services at the expense of the Medicare program. Uropath does not agree with this premise but acknowledges CMS's mandate to safeguard the Medicare program. The Stark Law and its regulations are the proper place for rules aimed at curbing perceived physician self-referral abuses. This is a reassignment provision which is not limited to self-referrals.

This proposed rule would prohibit a group practice from profiting from the provision of the PC of a diagnostic test unless the PC was performed by a full time employee of the group. It penalizes physicians who are unable or prefer not to work full time, regardless of the reason, and penalizes group practices who choose to utilize these pathologists to provide professional services on their behalf.

1. The Rule Penalizes Part-Time Physicians

This proposed rule applies to any situation in which the billing group is entitled to bill for a PC due to a reassignment received from a less than full time physician. It would apply to a part time employee of a single specialty pathology group practice. It would apply to a part time physician working for an independent diagnostic testing facility. It would apply to physicians who seek part time work from group practices who do not generate enough test volume to hire full time physician employees to provide PCs. In each of these cases, a billing group would be unable to collect from Medicare one penny more than the group paid a part time diagnostic physician.

Medicare is a significant payor for most diagnostic providers, which makes sense given the demographics of Medicare beneficiaries. Career opportunities for part time diagnostic physicians would dwindle. Single parent physicians, physicians who work two jobs to pay off educational loans or to earn more money, or even physicians who simply value time more than money would find part time work difficult if not impossible to find. These physicians deserve the same quality of life opportunities other citizens enjoy.

There is no rational basis for applying this rule only to part time employees. As a self-referral measure, the rule suggests that CMS believes group practices that generate smaller amounts of diagnostic tests present more risk of program abuse. There is no basis for asserting that a large group practice with a sufficient volume of diagnostic tests to hire a full time diagnostic physician is on that basis less likely to engage in program abuse. As an example, Uropath-managed labs, which operate less than 40 hours per week, have never engaged in any form of Medicare abuse, and OIG audits of Uropath-manage labs confirm the labs operate in a

compliant manner. Even if self-referral for low volume providers was proven, this rule is not limited to self-referrals. It refers to any reassigned PC.

2. The Net Charge Inappropriately Excludes Employer Costs

Under the proposed rule, the actual cost of office space, equipment, and other overhead allocable to a part time diagnostic physician cannot be recouped by the employing group. As a result, a group practice would necessarily incur a net loss from employing a part time diagnostic physician to provide PC services on the billing group's premises. CMS believes that if a group loses money from in-housing its own PC it will ultimately cease providing the PC and thus eliminate self-referral risk. But this perspective completely ignores the benefits to a part time physician of providing services on another entity's premises.

Uropath-managed laboratories provide their less than fulltime pathologists with a completely equipped, maintained and supplied laboratory. The pathologist is not responsible for hiring and firing of staff, or tending to any administrative burdens related to the facility and its operation. The pathologist does not have to negotiate managed care contracts or contracts with other vendors and suppliers. The pathologist does not have to bill and collect for her work, and assumes no risk for the non-payment for services. The pathologist gets paid regardless of whether the group is reimbursed for services. The pathologist does not have to generate business and does not have the anxiety associated with whether business will continue to exist.

CMS recognizes the cost and expense associated with these aspects of a professional medical practice. CMS specifically states in the Proposed Rule at page 38125 that Congress has required that CMS develop resource-based practice expense relative value units ("**PE RVUs**") which consider relative categories of expenses such as office rent, wages of personnel, and other overhead. The PE RVU is typically the largest of the three RVU components that CMS uses to calculate Medicare reimbursement for covered services. Despite this, CMS refuses to consider any of a group's practice expense in determining a part time physician's net charge to the group.

Uropath strongly urges CMS to eliminate the limited application of 42 CFR § 424.80 to less than full time employees. There is no basis for discriminating against part time physicians, and this will permit part time physicians to continue to pursue career opportunities that balance with their other obligations and desires. In addition, Uropath urges CMS to permit employers to include in the calculation of a provider's net charge the lower of (i) a reasonable practice expense component derived from its own PE RVUs, or (ii) the actual and demonstrable overhead costs attributable to the provider. This will permit a group to utilize part time diagnostic physicians without financially penalizing the employer, while at the same time safeguarding against artificial overhead costs which could unnecessarily tax the Medicare program. Alternatively, Uropath urges CMS to eliminate application of 42 CFR § 424.80 in situations where the physician provides the PC on the premises of the billing entity. This will permit legitimate operators of part time diagnostic providers to continue to provide services at a profit while eliminating the ability of providers to profit off of other suppliers' services through a mere paper reassignment.

3. Definition of "Directly Perform"

Proposed 42 CFR § 424.80 includes a requirement that "to bill for the technical component of the service, the physician group must directly perform the professional component of the service." Please confirm that this billing restriction refers only to a TC billed pursuant to a reassignment. Further, please define the term "directly perform." Specifically, if a group practice utilizes a less than full time physician to provide a PC on the group's premises, and the group bills for the PC pursuant to a reassignment, has the group "directly performed" the PC? Uropath believes that it has, and this interpretation is consistent with the Stark Law Physician Services Exception in recognizing that services provided by a less than part time physician on the premises of a group practice and billed for by the group practice are services provided by that group practice.

B. The Purchased Diagnostic Test Provision; 42 CFR § 414.50

The Proposed Rule amends 42 CFR § 414.50 to provide, among other things, that if a group practice bills for the technical component or professional component of a test that was performed by an "outside supplier," the payment to the medical group may not exceed the lowest of: (1) the supplier's net charge to the group, which must be determined without regard to any charge intended to cover the cost of equipment or space leased to the outside supplier by the billing group; (2) the billing group's actual charge; or (3) the Medicare fee schedule payment for the service if the supplier had billed directly. The Proposed Rule also adds a section 42 CFR § 414.50 (a)(3), which states that "an outside supplier is someone other than a full-time employee of the billing physician or medical group." This new section suggests that if a group practice uses a part time technician, or an independent contractor technician, to help provide the technical component of services in a group practice's facility using a group practice's equipment under the supervision of the group practice's physicians in accordance with the group practice's policies and procedures, CMS may still deem that the test was purchased by the group and not provided by the group merely because the technician was not a full time employee.

Historically, CMS has applied the purchased diagnostic test rules to determine whether the technical component of a diagnostic test was purchased rather than provided by a group practice. This rule could be read as overriding the purchased diagnostic test rules when a technician is a less than full time employee. In conversations with David Walczak of CMS which occurred after publication of the Proposed Rule, Mr. Walczak advised that it was not the intention of CMS to do so. Mr. Walczak stated that if a group practice provided and not purchased the technical component of a service under the purchased diagnostic test rules prior to adoption of the Proposed Rule, the Proposed Rule was not intended to change that result. Uropath respectfully requests that CMS make this clarification in writing when it issues a final rule with respect to this rulemaking.

C. Anti-Markup on TC Performed in a Centralized Building

In the Proposed Rule, CMS proposes to apply an anti-markup on the TC of a diagnostic test performed by a leased employee of a group practice in a centralized building. CMS believes this rule is necessary because its current anti-markup proposal does not address such a situation. Without proposed regulation text to review, it is difficult to analyze such a proposal, and Uropath respectfully requests that any such final rule be preceded by a proposed rule that proposes the regulation for public review and comment. This has proved productive in prior rulemakings.

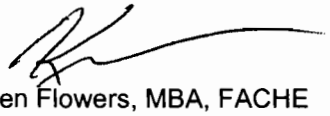
Uropath has met with CMS and explained in great detail how Uropath-managed labs utilize the centralized building prong of the In-Office Ancillary services exception to permit group practices to economically provide their own superior pathology services. We asked and CMS could provide no rational basis for concluding that the incentive to self-refer patients for diagnostic tests is greater when the tests are performed in a centralized building than when performed in the "same building" where the provider provides other clinical services. There is none.

Groups utilize leased employees to economically provide diagnostic services in "same building" business models for the exact same reasons. To the extent that this proposal is specifically aimed at a "pod lab" model, we would ask that you consider our labs' collective compliance history, lack of any evidence of program abuse despite three OIG audits, and superior pathology services in reaching a decision on such a proposal.

III. CONCLUSION

Thank you for your consideration of Uropath's comments regarding the Proposed Rule. Uropath understands and appreciates CMS's mandate to protect the integrity of the Medicare program. Uropath believes it can continue to assist group practices in providing world class urologic pathology services without undue risk of program abuse. If you have any questions or concerns about the comments we have submitted, we would be happy to discuss them with you.

Sincerely,



Ken Flowers, MBA, FACHE
Chief Executive Officer

Kf/dd

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Colorado Springs CO 80907
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August 27, 2007

VIA FEDERAL EXPRESS

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 writing on behalf of the Vascular Center of Colorado ("VCC") as a supplemental submission to the letter written by Tom Crane of the law firm Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C. We write this letter to express our objection to CMS's proposed changes to the Stark regulation related to under arrangement services that would have the effect of creating an impermissible physician ownership in a DHS entity. We offer the following comments to give our unique perspective of the history, operation, and compliance measures of VCC.

VCC is a Colorado Limited Liability Company owned one-half by fourteen (14) physicians who specialize in cardiology, and one-half by the local hospital. VCC has twenty two (22) non-physician employees including nurses, registered cardiovascular invasive specialists, clerical and administrative workers. VCC has a six (6) person Board of Managers, three of whom are cardiologists appointed by the cardiologist owners, and three of whom are appointed by the hospital. One of the hospital's Board appointees is also the Chief Medical Officer of the hospital system. The Board meetings are generally focused on clinical activities and improvements. I am the VCC Medical Director and am supported by an Administrative Manager, and a Clinical Director. Together we manage the company on a day-to-day basis.

The Vascular Center of Colorado, LLC

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VCC commenced operations in September, 2005, and has operated continuously since that time providing a full range of cardiac cath lab services to patients of our local hospital under arrangements with the hospital. Services we provide currently include diagnostic cardiac catheterization, percutaneous coronary interventions such as balloon angioplasty and stent placements, diagnostic and therapeutic electrophysiology procedures, and implantation of permanent pacemakers and implantable cardioverter defibrillators.

VCC is located on the campus of the hospital, in a building that is immediately adjacent and connected to the hospital. Patients are transferred between VCC and the hospital by gurney. The building that houses VCC's clinical space is owned by the hospital, and rented to VCC for its exclusive use by long term lease at market rates.

The vast bulk of the services are provided to the hospital based on flat fees for specific categories of service that include the full costs for these services (personnel, medical supplies and devices, equipment, space, etc.). Thus, VCC assumes the risk of all costs of providing the service, including the costs of medical supplies and implantable devices, the capital costs of x-ray, hemodynamic monitoring, and related accessory equipment, the capital and operating costs of the real property used by VCC, and the labor costs for all clinical and administrative employees.

The agreed-upon fees with the hospital are exhaustively reviewed. VCC has developed proprietary software to benchmark all costs of providing services, and to identify best practices for the delivery of care. In addition, all fees are reviewed periodically by a third-party valuation company to assure that such fees are fair market value. Each party fully understands this legal obligation.

Physician ownership and participation in management of VCC has resulted in a business focused on clinical excellence. Prior to the VCC, the hospital had not yet submitted Cath or PCI Registry data to the American College of Cardiology ("ACC") where quality data is routinely reported and benchmarked to national results. Within a few months of commencement of operations, the VCC filed quarterly reports retroactively and prospectively. In addition the VCC: 1) was an early participant in the ACC's new ICD Registry; 2) participates in routine clinical performance improvement activities of the hospital; 3) has been inspected by JCAHO as part of its routine review of the hospital, with no Request for Improvement (RFI) noted; 4) has developed a Cardiac Alert program to treat acute myocardial infarctions; 5) has developed and followed up on several clinical initiatives, for example, to reduce vascular complications, or to reduce door to balloon times; and, 6) was an early participant in the Colorado ACC's Door-to-Balloon ("D2B") initiative.

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This history demonstrates why our arrangement with our local hospital provides clinically-driven, cost-effective services. CMS would advance no legal or policy interests if it implements the changes it proposes.

If I may assist in providing additional information or perspective in this regard, please do not hesitate to contact me.

Respectfully submitted,

Robert A. Cadigan, M.D., FACC
Medical Director and Vice Chair

316-

Colorado Springs Cardiologists, P.C.
DIAGNOSTIC AND INTERVENTIONAL CARDIOLOGY
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Robert A. Cadigan, M.D., F.A.C.C.
Shannon L. Richardson, PA-C
Cynthia Brown, ANP-C

Christopher R. Cole, M.D., F.A.C.C.
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Richard W. Moothart, M.D., F.A.C.C.
Christian M. Simpfendorfer, MD
David Brunk, PA-C

August 29, 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 physician with Colorado Springs Cardiologists, P.C., and 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 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,

D Albrecht MD

David W. Albrecht, MD

c: Tom Crane

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Hand Surgery and Orthopaedic Surgery
STEVEN A. BARRINGTON, M.D.
Joint Replacement and Orthopaedic Surgery

CHARLES W. HARTZOG, JR., M.D.
Sports Medicine and Arthroscopic Surgery
G. DEXTER WALCOTT, JR., M.D.
Sports Medicine and Arthroscopic Surgery
MICHAEL E. DAVIS, M.D.
Spine Surgery and Orthopaedic Surgery
RONALD P. O'NEAL, MPH, CHE
Administrator
JEFF SENFT, CMPE
Controller

August 29, 2007

Center for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8018
Baltimore, MD 21244-8018

Dear Sirs,

Subject: CMS 1385-P In Office Ancillary Services Exemption

Thank you for the opportunity to comment regarding whether changes are needed concerning Physician self-referral rules. I see no reason to change or alter the In Office Ancillary Services Exemption.

Our sub-specialized orthopaedic surgery medical practice has seven orthopaedic surgeons. We have a physical therapy department we established three years ago complying with the In Office Ancillary Services Exemption under the "Stark" regulations as a part of the continuum of care we provide. This department sees only our patients. Stated differently; the patients treated in our Physical Therapy department must be under the care of one of our orthopaedic surgeons.

We view the addition of physical therapy as part of a comprehensive treatment plan with continuous physician oversight affording more cost effective care. We give our patients a choice of where they want to have their services provided. Many choose the convenience of having their physical therapy in our office due to enhanced communication, personalized care and timely initiation of treatment.

These arrangements do not encourage abuse but promulgate better access, preserve the arena of competition hence enhancing the range of patient choice.

Respectfully,

Ronald P. O'Neal

Ronald P. O'Neal, MPH, CHE
Administrator

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August 27, 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 **Inland Cardiology** and our 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.

Inland Cardiology was established in 1981 and serves patients in Eastern Washington, Northern Idaho and Northeastern Oregon. Our outpatient catheterization lab serves as an important component of the care we provide to our patients. This lab was established in April of 2003 in an attempt to provide our patients and physicians with access to a facility that would allow us to perform elective procedures more efficiently. Prior to offering this service thru our own cath lab, patients often had to wait for their procedure and would often be "bumped" to the end of the day or rescheduled to make room for more emergent cases. We feel our facility provides a more consistent, convenient and cost effective alternative to our patients, while also maintaining a high level of patient care. Our commitment to quality is evident in our voluntary accreditation thru the Accreditation Association for Ambulatory Health Care (AAAHC).

Inland Cardiology is a founding 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 find it troubling that while these cuts could result in the closure of our lab, the local hospitals will actually receive an 11.19% increase for providing the exact same service.**

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 cost the Medicare program more in direct APC payments **and** Medicare patients more in higher deductibles and co-insurance. Even more troubling may be the limited access to care that will imposed on the patients we serve.

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

Sincerely,

William S. Murphy, MD

President, Inland Cardiology

Donald B. Canaday, MD

Medical Director, Cardiovascular Services of Spokane

Joel R. Galloway, MD

Medical Director, Inland Cardiology

ACADIANA UROLOGY
ADULT & PEDIATRIC UROLOGY

SAMUEL H. SHUFFLER, M.D.
Certified, American Board of Urology

WILLIAM B. ROTH, M.D.
Certified, American Board of Urology

August 21, 2007

Center of Medicare and Medicaid Services
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Re: July 2, 2007 Medicare Physician Fees Scheduled Proposed Regulations

To Whom It May Concern,

My name is Samuel H. Shuffler, M.D. and I practice urology in Lafayette, Louisiana. I am a co-owner in a joint venture partnership that provides lithotripsy services as well as many other therapeutic services to aid with the care of my patients and other patients in our area. By being a partner in such a venture, I truly believe that my patients and others have benefitted. The particular lithotripsy machine of which I am a co-owner travels around the state and provides access in a timely fashion in a professional and easy way. Before this partnership existed, patients would have to travel to other cities and would have to wait for weeks in order to have such care. There are new suggested provisions/regulations that, if finalized, could materially negatively affect the operations of our lithotripsy limited partnership. This in turn could negatively benefit the care of my patients. As it stands, the current situation works well and I believe it is fair for both the patients and for the physician. Two provisions that I am particularly concerned about are the "under arrangements proposed rule" and the "peri-procedure proposed rule".

Our limited partnership arrangement contract is quite helpful as it is a physician owned entity. This is important because physicians constantly read medical literature. With this in mind, we are able to "keep up" and buy the latest advancements in our field in order to improve the quality of care of our patients. Our goal is simply to provide quick, up to date, excellent care. If my patients do well, I do well. Hospitals, on the other hand, often use outdated equipment based on cost considerations. To hospitals, "the bottom line" is the

primary concern, and all too often the patient suffers because of this. Whether we like it or not, hospitals are "for profit" and decisions are made based on hospital desire to cut costs and survive in a competitive "for profits" world. Our current venture is a mobile lithotripsy unit and because this unit is mobile, we are able to provide greater access to patients in rural and under-served areas around our state. I live in South Louisiana and there are multiple communities that would not receive the type of care that we are talking about unless the care is provided by our machine. Interestingly, mobile physician vendors lower hospital costs by sharing expensive equipment among multiple hospitals. It makes sense to continue allowing a venture such as the physician owned lithotripsy venture of which I am a member.

It is my understanding that CMS is concerned that physician "under arrangement" contracting results in over-utilization and higher costs to the Medicare Program. This is absolutely not true. Please note that lithotripsy and BPH laser services are therapeutic, they are not diagnostic. The underlying medical condition can be objectively determined (i.e. kidney stone or enlarged prostate can be identified via CT scans, ultrasound, etc), and so there is no risk of over-utilization. In short, problems exists and we take care of it. There is no way to over-utilize something that is so obvious. If the problem exists, it is fixed. If it does not, there is no way for over-utilization to occur. Please note that lithotripsy and BPH laser use are not like diagnostic testing with its higher risk of over-utilization based on the subjective judgement of the physician ordering the tests. While I also believe that certain diagnostic tests should continue to be used by physicians, i.e. in-office ultrasound, post void residual checks, etc. because these too aid with patient care, please note that any rule pertaining to lithotripsy should only apply to potentially abusive diagnostic tests. In-office ultrasound performed by a trained urologist makes absolute sense because urologists perform biopsies, need to know about certain characteristics associated with the prostate gland, kidney, etc. and having the convenience of maintaining an office-based ultrasound is good for my patients. Regardless, any new rule from CMS should only apply to potentially abusive diagnostic tests and not beneficial therapeutic and diagnostic tests performed by well trained, caring, compassionate physicians. Please note that Stark Legislative History indicates Congress clearly intends, under "arrangement contracting," to only require compensation exception and not an ownership exception. I can list multiple examples of improved patient care based on my access to superior technology. When a patient has an obstructing stone or a stone which causes pain, easy access and direct ownership of my lithotripsy unit has allowed me to make therapeutic choices, which were good for my patients and eased their pain and suffering.

The next item of which I am very concerned is the "Peri-procedure fee prohibition". As we all know, hospitals are risk adverse. Hospitals often do not appreciate the benefits of new technology. As I stated above, the hospital's bottom line is financial and often, purchasing the best new equipment or entering into a fixed monthly lease over a term of one or more years are capital risks that hospitals do not want to accept, particularly when they cannot predict procedure volume. As above, physicians understand the benefits of new technologies as new technologies point to improvement of patient care. Historically, physicians have been willing to accept the capital risks inherent in a peri-procedure lease to a hospital. My involvement in our lithotripsy program has allowed our lithotripsy machine to be sent to rural hospitals where procedure volume may be too low to allow for a fixed monthly rental

of technology. This too could reduce access to the latest innovative technologies in poorer markets. Please note that Congress clearly wishes to preserve peri-procedure fees in the Stark Legislative History. CMS cannot contradict congressional intent through a prohibition of such fee arrangement. This is highly important. It is my hope that I can receive confirmation from CMS that the peri-procedure payment prohibition will not apply to the Stark Indirect Compensation arrangement exemption relied upon by our partnership.

My current situation is a hospital/co-owned hospital venture with physicians. The Medicare Ambulatory Surgery Center approved procedure list does not allow for reimbursement of Stark DSH procedures so Stark should not be implicated by a physician partnership contracting with an ASC. Ambulatory Surgery Centers are lower cost providers of services. Physician owned ventures should not be encouraged to contract with ambulatory surgery centers regardless of their ownership if it results in savings to the Medicare Program. This prohibition will deter physicians from joint venturing with hospitals to form ambulatory surgery centers. Instead, physicians would develop only wholly owned ambulatory surgery centers and this is clearly not as good for the patients.

Finally, although I have no association with anatomical pathology, CT imaging, or IMRT within my office practice, I think that in-office ancillary services should not be discontinued. Please note that the fact that physicians are allowed currently to participate in such ventures enhances patient access and convenience and allows primary physicians, i.e. the urologist, to control and influence the entire episode of care. This is helpful and good for patients, as there is direct sharing of information between urologist and other specialists, i.e. radiologist, pathologist, radiation oncologist, etc. that are integrated into the episode of care. This is clearly good for the patients. Urology ancillary services such as IMRT and CT are truly integral to a urology professional practice and directly benefit patient care. On more than one occasion have I had the opportunity to directly discuss cases with the pathologist and/or radiologist who is caring for my patient. If this ancillary care were a part of my practice, it would be much easier to discuss and share information, which is helpful towards our ultimate goal of providing the highest quality care for our patients. Of note, Congress clearly indicated that DHS services were excluded from the exception (e.g. DME), and what DHS were to be included, CMS cannot issue regulations and contradiction of Congressional intent! Revisions to the Stark Statute are not necessary to address perceived over-utilization abuses that may occur within that exception. Over-utilization abuse concerns should be directly addressed through more diligent enforcement of the federal anti-kickback statute!

As a urologist, I have seen first hand the beneficial affects that joint ventures have had for the health care system. I truly believe that I provide quality care to my patients. I have been involved with providing my patients lithotripsy and other cutting edge therapies for urologic disease that would not have been widely available to my patients, including Medicare beneficiaries, unless physician joint ventures had provided the services. Some physicians in my area do not provide care to Medicare patients. I think that is a crime as well. Their feelings are that the cutbacks in Medicare reimbursement and the rules and regulations that Medicare provides make practicing medicine unsavory. I personally feel that it is my duty to provide care to anybody that comes into my office. I hope to continue providing quality care to all patients. I hope to continue accepting the risk of providing costly services when

hospitals refuse to do so. Urology joint ventures have greatly expanded patient access to worthwhile and effective treatments. The proposals in your 2008 Physician Professional Fee Schedule attack the substance of the varied joint ventures that, by all accounts, have saved Medicare millions of dollars and increased beneficiary access to effective treatments. I believe that CMS should address its concerns in a much less intrusive manner. The goal of medicine is to provide quality and compassionate care. I intend to do so with my whole heart. I do not believe that physicians should work solely for the benefit of profit and clearly, my practice would indicate that this is not what I have set out to do. I do however, believe that physician ownership and partnership within the ancillary services to which they participate makes the entire experience a more personal and worthwhile endeavor. My entire life has been geared toward the practice of medicine. I went to college, medical school, a prolonged residency and am now in the early stages of a long and hopefully fruitful medical practice. I will not become rich from medicine, but I hope to continue to enjoy the personal and professional success that I have been experiencing for the last five years. The proposed Medicare changes need to be reviewed, as it will negatively impact my career, my happiness in medicine, and the great care that I believe that I provide to my patients.

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 CMS that the urology community's therapeutic joint ventures have broadened access to new technology for Medicare patients, brought new efficiency to the market, and simultaneously saved hundreds of millions of dollars to the Medicare program. As CMS tries to stop abusive arrangements, it would be a great mistake to jeopardize time tested improvement models. Please do not hesitate to contact me should you have any questions or concerns.

Sincerely,

Samuel H. Shuffler, M.D.

SHS/cc

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Urology Consultants, PC

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Linda Jackson, NP-C

August 29, 2007

Centers for Medicare and 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 Centers for Medicare and Medicaid Services,

I am a practicing physician in Pueblo, Colorado specifically in Urology. I am quite concerned by your recent proposal called: Under Arrangement: per Click Fee, Percentage Fee Arrangements, Standard Issues, And Burden of Proof.

My goal in medicine is to deliver the most cost effective services using state of the art equipment. Your current proposal will jeopardize my ability to deliver that care in a timely manner maintaining high quality.

I personally am involved in two joint ventures one for the PVP Laser and the other for Lithotripsy.

Both of these joint ventures allow delivery of otherwise unattainable services to my patients at a variety of locations. The fact that these services are mobile and the equipment is supplied by the venture allows us to perform these procedures at several small local hospitals. These include services as far away as Alamosa, La Junta, Trinidad, and Canon City hospitals. If these joint ventures were not available we would not be able to have these procedures performed at these local hospitals. The hospital could not afford the equipment for the relative small number of cases performed. These services help maintain healthy small hospitals in relatively small communities.

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This proposal would also impact negatively the elderly Medicare population and the disabled Medicaid population in terms of increasing distance in travel arrangements to receive these procedures. They would be forced to travel long distances to receive what historically their local communities offered. This for the disabled is truly a hardship.

Currant Stark requirements appear to me to be adequate to control abuse. This proposal extends reach beyond Congressional intent. Particularly in view that no abuse for these therapeutic services has been uncovered. Our country has a long history of "innocent until proven guilty." The requirement for the physician to prove they are in compliance is in direct violation of that constitutional mandate.

Under our current arrangements therapeutic services such as PVP Laser and Litho, which we supply through joint ventures are not DHS services. You would be making them a DHS service bases solely on location of delivery. This has not been the intent of Congress.

I strongly recommend that CMS reconsider this proposal in detail. The objective is to deliver healthcare economically to the population in a timely fashion. Curtailing any joint venture, which is the only way the physician can do this in many instances, will greatly restrict the delivery of this care.

Thank you for your consideration.

Sincerely,

Dana J Weaver-Osterholtz

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August 27, 2007

Centers for Medicare and Medicaid Services
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Dear Sirs or Madam,

I am a practicing Urologist in Pueblo, CO. I have been practicing here for about fifteen years. I believe that the 2008 proposed physician fee schedule as proposed will be detrimental to my practice. I understand that the efforts as the rational behind this proposal is to prevent abusive practices. I support those efforts in general, however current proposals stand above and beyond the intended abuse prevention and would hamper viable and legitimate joint venture arrangements. Years ago when I first moved to Pueblo, we sent all our lithotripsy patients that required stone treatment with lithotripsy up to Denver because the two hospitals in town did not want to purchase the equipment to perform lithotripsy. Both hospitals have had experiences where physicians request expensive medical equipment that has been purchased that yet underutilized, therefore are costly to the scarce resources that the hospital may have. In order to address this problem, I was instrumental in setting up a lithotripsy partnership. The partnership that exists today, is therefore because of my efforts, and this partnership services all of the hospitals in Southern Colorado south of Colorado Springs. Pueblo, Canon City, Alamosa, Walsenburg, Trinidad, and La Junta all benefit because of physicians banded together bought costly equipment and now provide this equipment to hospitals that would not be able to afford them. Literally five years ago, I felt that cyro therapy for Prostate Cancer was a great patient benefit, but once again hospitals did not want to purchase the equipment that would allow us to perform the procedure so another physician partnership was formed. Once again patients, particularly our Medicare patients are a great beneficiary of these services that are instigated by the physicians getting together in order to provide these services for our communities.

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Let me tell you what I am very concerned about regarding this proposed legislation.

1. The burden of proof. Apparently CMS proposes that the provider should bare the burden of proving that referrals were not made in violation of Stark and any appeals of denial of payment on that basis. This would seem to put the physician in an unattainable position in trying to prove a negative. Furthermore, the cost of legal representation for this type of legal proceedings is prohibited. Therefore I feel that CMS should accept the burden of proof that the law has certainly placed upon one creating the rules and you should not shirk your responsibility in this matter.
2. Per Click payments. Currently most lithotripsy ventures are paid on a per Click payment that is currently based on a fair market evaluation of that service. Specifically I believe CMS is concerned with the per click lease agreements involved with designated health services. In my experience when new legislation is set forth, all things seem to get lumped together. Certainly the ruling of ALS vs Thompson the underlying results in that are that lithotripsy are not designated health services. Specifically for that matter I believe I think this should be specifically noted in this legislation that lithotripsy and cryo thereapy would not come under this ruling. I believe per click arrangements for lithotripsy and cryoblation should continue. Percentage based fee arrangements I believe should also be allowed.

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Furthermore I feel that distinction between therapeutic and diagnostic DHS (designated health services) should be differianted. The proposals are so broad they would ban legitimate non-abusive arrangement for therapeutic services that are not otherwise DHS except for the fact they are performed in the hospital settings. These services include laser procedures along with cryotherapy.

In summary, I would like the ability to continue to practice urology as I have and be fairly compensated not only for my fee for service, but services provided as an entrepreneur who has brought innovated services to our community and guardian of the quality of care of these services. You will not find the commitment to excellent health services among hospital administrators as you will find among physicians. Too often our administrations are under the pressure to increase their profit margin and decrease their operating loses and it has been my observation that value judgments based on these things are not consistent with decisions based on quality of care.

Thank you for your consideration.

Sincerely,

Dr. Alan Bickel

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BRIAN W. FRYE, PA-C

August 29, 2007

Center for Medicare and Medicaid Services
Department of Health and Human Services
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Ladies and Gentlemen:

I am an urologist who practices in Cheyenne, Wyoming. I am an owner at a joint venture partnership that provides primarily lithotripsy services but also other therapeutic services including laser for benign prostatic hyperplasia. I think that are many Healthcare benefits that are able to be provided through the partnerships that otherwise would not be available particularly in rural areas. Of primary importance is the access to quality medical care and advance technologies that otherwise would not be available to our patients.

I am concerned that new provisions if enacted would adversely affect Healthcare in our area. The benefits of the partnerships under arrangement contracts include the ability for the physicians to have a strong input into the equipment that is used utilized and to have the most advanced technology available for our patients. The mobile units provide access to the patients in rural areas that would otherwise not be available to this group of patients. The equipment is very expensive and through utilizing mobile units and sharing these among hospitals overall cost is reduced while maintaining the best care.

It is clear that from the American Lithotripsy Society vs. Thompson case that lithotripsy is not a designated health service under Stark and thus the Partnership should not be considered to be performing a DHS or causing a claim to be submitted for a DHS.

I think that lithotripsy with BPH laser services there should not be the concern for over utilization in view of the fact that these are therapeutic and not diagnostic procedures. There is objective criteria that is necessary in order to perform these services and again they are not diagnostic and therefore there is not the risk of overutilization. I am concerned about the Per Procedure Fee Prohibition hospitals often do not appreciate the benefits of new technology. Rural Hospitals can not afford newer technology because of the costs and the low utilization. Physicians do understand the benefits of new technologies and the benefits of patient care and are willing to accept the capitol risks of this. The desire of Congress has clearly been to preserve Per Procedure Fees in Stark legislative history and this should not be changed.

This could potentially restrict partnerships ability to contract with Ambulatory Surgery Centers. Ambulatory Surgery Centers often offer a lower cost of services and therefore should be encouraged rather than discouraged. Although I do not currently utilize multiple in office ancillary services there is a significant potential benefit of this. Services such as Anatomical Pathology CT Imagining IGRT/IMRT allows for good control and continuity of care as well as patient access and convenience.

I appreciate your careful consideration in this matter.

Sincerely,

John F. Bryant, M.D.

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August 29, 2007

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Subj: RESOURCE-BASED PE RVUs – THERAPEUTIC PLASMA EXCHANGE

Dear Sir or Madam:

I am writing to you to express my concerns about the looming reductions in reimbursement for therapeutic plasma exchange (TPE, CPT 36514). Medicare proposes a valuation of 10.41 RVUs for TPE by the year 2010. This amounts to approximately $400 per procedure based on the Medicare rates for Portland, Oregon. I am deeply concerned that these reimbursement reductions would make it impossible for our practice to provide TPE in an office based setting. I strongly believe that CMS needs to significantly increase the valuation of the plasma exchange procedure so that it is feasible to offer it in an outpatient clinic.

Plasma exchange is a life-saving procedure for a variety of medical conditions spanning multiple sub-specialties. It has been validated for many diseases by peer-reviewed clinical trials, and has been used clinically for decades. It is considered vital first-line therapy for a variety of neurological, renal and hematological disorders. Like all other extra-corporeal therapies however, it is expensive to perform.

A reimbursement of $400 per plasma exchange procedure is simply not enough to cover the costs involved. I have tried to estimate some of the expenses below:

- The disposable supplies alone cost approximately $250 per treatment. This is almost two-thirds of the total proposed reimbursement!
- The nurse specialists that provide the treatment are highly trained and it takes approximately 3 hours of their time for each procedure. This includes the machine setup, monitoring during the treatment, and post-procedure work. The nurse cannot be involved in any other activities during this period and the TPE takes up their entire time. Using the salary and benefit packages that we offer our nurses, I estimate that the labor cost is approximately $50/hr or $150 per procedure.
- There are other direct out-of-pocket costs including amortization of the machine and the cost of a maintenance contract ($5,000/Spectra machine/year) which amount to about $40 per treatment.
- Obviously, there are the usual overhead expenses including rent, administrative staff, utilities and insurance. It is important to point out that the provision of

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plasma exchange in the outpatient setting requires a considerable amount of clinic floor space which cannot be used for any other purpose.

As you can see, the multiple costs involved in providing the plasma exchange procedure greatly exceed the proposed $400 in reimbursement per treatment. I frankly don't understand how the new RVU formula was calculated for TPE given the above-mentioned costs. It is critical that CMS appropriately increase the reimbursement for TPE so that it can continue to be offered in the outpatient setting.

I strongly believe that Medicare should encourage physicians to provide plasma exchange in the office-based setting rather than deter them with Draconian reimbursement cuts. There are also very important patient-oriented factors to consider in the discussion of office-based apheresis treatments.

Many apheresis patients require regularly scheduled treatments a few times a week similar to outpatient hemodialysis. When these patients come to an acute care hospital for their treatments, they always risk unforeseen delays due to emergencies that often arise. They are virtually immune from these delays if the procedures are electively scheduled in an outpatient clinic. The inpatient environment also tends to be very hectic, and it is undoubtedly a much more pleasant and calming experience for the patient to come to an outpatient clinic than an inpatient hospital ward. The diseases that require TPE tend to be very morbid and are significantly burdensome to the patients. These individuals are invariably anxious about coming in for their treatments, and the acute inpatient environment does little to soothe their fears.

In our hospital Medicare patients are required to present to the admitting department before each plasma exchange procedure (which can be up to three times a week). They are assigned a different account number each day and are essentially admitted to the hospital for a few hours while they are undergoing the procedure. This is obviously very inconvenient for the patients, and requires them to waste a lot of time waiting to be admitted and then discharged. Since I am not involved in hospital billing, I do not know how much the hospital charges Medicare for each procedure. However since our hospital performs TPE as an inpatient treatment, I have no doubt in my mind that it is a substantially higher cost setting than an office-based clinic. I believe that office-based plasma exchange is more cost-effective from a Medicare standpoint than hospital-based treatments.

All patients undergoing plasma exchange treatments are immunosuppressed because of the obligate loss of infection-fighting immunoglobulins from the procedure. We are very concerned about infections in these patients and routinely advise them to minimize their exposure to sick contacts. We currently provide hospital-based TPE in our acute dialysis unit and there are numerous hospitalized patients undergoing hemodialysis with active infections. I feel that if we direct our immunocompromised TPE patients to an office based setting instead of the hospital, we would potentially reduce their risk of exposure to virulent nosocomial pathogens that could result in life-threatening infections.

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NEPHROLOGY
HYPERTENSION

TRANSPLANT
MEDICINE

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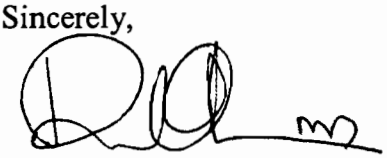
In summary, I believe the proposed reimbursement cuts for TPE will make it impossible to provide these treatments in the outpatient setting. Office-based plasma exchange improves the quality of the patient experience and is more cost-effective than hospital based treatments. CMS should re-evaluate the costs associated with providing this valuable extracorporeal therapy and significantly increase reimbursement in the outpatient setting.

Thank you very much for your consideration in this very important matter. If you require any additional information or have any questions, please do not hesitate to contact me.

Sincerely,



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Center for Medicare Services
Department of Health and Human Services
P.O. Box 8018
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8/18/2007

http://www.hhs.gov/eRulemaking

Comments on CMS- 1385-P: Proposed 2008 Medicare Physician Fee Schedule Rule

Current Rules: In June of 2004, Congress passed law regarding shared facilities for separate medical practices in the same building. These rules, promulgated by CMS are the basis for the "Medical office building (MOB)" exemption for providing and billing for designated health care services (DHS) by physicians in the same office building.

Many physician practices have relied on these rules to plan and move forward on facilities as well as purchasing and leasing of equipment to provide these services for patients. These projects are very expensive and rely on extensive legal review of current rules and law. The current proposed rule, CMS- 1385-P puts the practicing physician in financial jeopardy and the Medicare patient in danger of loss of access to vital health care services and care.

The current state of Medicare's treatment of practicing physicians is difficult, to put it mildly. The E and M reimbursement barely covers overhead for most internists and internal medicine specialists. Most of these physicians have relied on in office ancillary DHS, including laboratory, ultrasound and X ray requiring the purchased services of pathologists and radiologists, to make ends meet. Many physicians acted on the 2004 MOB exemption and have taken on large, if not huge obligations to comply and to provide superior services for the patient. Is it fair to turn the current rules upside down?

Medicare patients are often frail and have difficult access to transportation. They consistently prefer to have DHS provided by their personal physician's practice where they are familiar to the staff and facility. Outside of the physician's office there is almost always a delay and often tests are not performed because patients have difficulty finding or getting to outside hospitals or IDTFs. These delayed or missed tests are a significant risk to the patient and increase the inefficiency and cost to Medicare.

As far as the potential for abuse from the current MOB exemption is concerned, the proposed rule will limit competition and provide a monopoly by pathologists and radiologists. The proposed rules seem tailor made to protect the income and control of radiology services and laboratory tests by these two specialties.

Who drives the utilization and expense of these DHS? I would like to provide some real life examples for your consideration.

The physician orders a chest X ray at an IDTF. A vague density is seen on the film (as a board certified pulmonologist, my review showed that this was clearly calcium in a healed rib fracture, i.e.; nothing!)

A CAT scan is requested by the radiologist and then ordered by the primary care physician (the radiologist is not available to review the films and in this climate of medical liability the doctor would be at risk if the CT is not ordered!) An incidental finding of a tiny 3mm nodule is found. The best care is rendered when the radiologist and ordering physician can review the findings together. This is almost impossible in an IDTF or an impersonal hospital based radiology department.

The current standard of care promulgated by the radiology societies is to follow a minimal abnormality such as this with serial CT scans at three-month intervals to assure stability for two years. Six to eight CT scans for nothing. Clearly, the radiologist is at least as responsible as the primary referring physician for driving utilization and cost in this common scenario.

As a pulmonologist, I perform bronchoscopy and often refer patients for surgery. Specimens are always sent to pathology (hospital only in my practice.) Although precise diagnosis is enhanced by the skill of the pathologist, sometimes expensive special stains are requested, not by the pulmonologist, but by the pathologist. I am concerned that the pathologist may in some instances recommend unnecessary procedures or special stains. Again, the cost and "referrals" are driven by the pathologist as are the procedures done by the radiologist.

There is a privately owned radiology company in South Florida that is currently being investigated by the OIG for fraud and abuse regarding recruitment of referring physicians. I suspect that there has really been no violation of Medicare rules, however, this is an example of a radiologist owned center possibly increasing the number and cost of procedures billed to Medicare.

These three real life examples show that eliminating competition and giving one specialty monopolistic control over laboratory and radiology procedures will only exacerbate the potential for abuse. Conversely, there is no data presented that a "per click" arrangement nor the employment of part time radiologists or pathologists have resulted in over utilization of services nor otherwise threatens program integrity.

The centralized medical office building (MOB) exception to the Stark law has made it more financially feasible for physicians working in separate practices in the same building to provide additional services to their patients. The expense of building out a clinical laboratory or imaging department, purchasing the needed equipment and hiring qualified staff that is prohibitive for a small practice becomes a manageable expense under the MOB exception where physicians can share these expenses. Physicians have been developing these arrangements in good faith and at great expense.

CMS is proposing to no longer allow per-click or per-use agreements which is a reversal from CMS current position. No data has been presented that "per click"

arrangements, or the employment of part-time radiologists or pathologists has resulted in over utilization of services or otherwise threatens program integrity.

The proposed anti-markup provision to the technical and professional component of diagnostic services specifically disallows operational costs incurred from part-time employment of a physician to provide the professional component of a diagnostic service. This defies logic. No serious argument can be made that a practice does not have legitimate expenses for scheduling and billing at the very least. The centralized medical office building (MOB) exception to the Stark law has made it more financially feasible for physicians working in disparate practices, but in the same building, to provide additional services to their patients. The expense of building out a clinical laboratory or imaging department, purchasing the needed equipment and hiring qualified staff that is prohibitive for a small practice becomes a manageable expense under the MOB exception where physicians can share these expenses. Physicians have been developing these arrangements in good faith, often after having obtained, at considerable expense, a legal opinion to help ensure that they remain in compliance with the rules and laws.

CMS is proposing to no longer allow per-click or per-use agreements which is a reversal from what CMS has so recently ruled. No data has been presented that "per click" arrangements, or the employment of part-time radiologists or pathologists has resulted in over utilization of services or otherwise threatens program integrity.

The proposed anti-markup provision to the technical and professional component of diagnostic services specifically disallows operational costs incurred from part-time employment of a physician to provide the professional component of a diagnostic service. This defies logic. No serious argument can be made that a practice does not have legitimate expenses for scheduling and billing at the very least.

CMS is concerned about the "existence of certain arrangements that we believe are not within the intended purpose of the physician self-referral rules, which permit physician group practices to bill for certain services furnished by a contractor physician in a "centralized building."

CMS is proposing to apply the anti-markup provision "irrespective of whether the billing physician or medical group outright purchases the PC or the TC, or whether the physician or other supplier performing the TC or PC reassigns his or her right to bill.... (Unless the performing supplier is a full-time employee of the billing entity)." In fact, there is no substantive difference between employing a fulltime physician (which enables the employer to keep the "mark up" on the professional component) and engaging a physician on a fair market basis on a part-time basis and billing globally (again enabling the price to keep the "mark up"). In either scenario, the program costs are the same. No data is presented to support the need for these restrictions, only a "concern" that abuse is possible.

The restrictions contemplated in CMS-1385-P leaves one with the impression that CMS has been influenced by a conflict between radiologists and pathologists as opposed

patients is required. Therefore, prior to enacting these rules, CMS should review the potential for abuse with the present versus the proposed payment methodology for histology, pathology and laboratory services in that the pathologist has control over doing multiple expensive stains on the same specimen.

Likewise, CMS should review the potential for abuse by radiologists and IDTFs in the current versus the proposed changes.

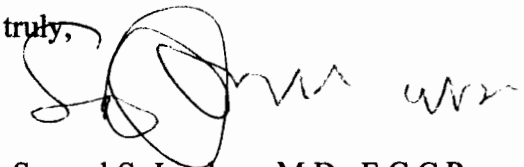
My personal analysis is that with the proposed CMS- 1385- P, monopolistic radiology and pathology services will increase costs, decrease healthy competition and make appropriate tests inconvenient for Medicare patients. Along with declining Medicare reimbursement, the proposed rules potentially will limit access of Medicare patients to not only diagnostic testing, but for physician services as well. The current rules will, on the other hand, will not impact radiologists or pathologists adversely and will help preserve Medicare program integrety.

Keeping the current rules for the MOB exemption and purchased tests provide Medicare beneficiaries high quality choices for testing including those tests done in their own physician's office building. The proposed rules, I believe, will adversely affect Medicare beneficiaries by forcing many physicians to limit or cease caring for Medicare patients.

Keep in mind that many physicians, having relied on the current rules have already committed to leases and contracts with five or more years duration. Therefore, CMS needs to exempt projects in progress or delay implementation of rule 1385-P for at least five years.

In closing, CMS has high expectations for physicians to live up to the demanding rules already in place. I believe that CMS is obligated to abide by it's own policies on which physicians have relied on as a valid basis for legitimate projects in progress. Pulling the rug out from practicing physicians with 1385-P is, at this time unacceptable at best, and truly a threat to not only the physician; but to the Medicare patient, as well.

Yours truly,



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URORAD HEALTHCARE

The Pioneer of Urology and Radiation Oncology Practice Integration ...

August 29, 2007

Herb B. Kuhn
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-1385-P
PO 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 (CMS-1385-P)

Dear Mr. Kuhn:

We thank you for the opportunity to provide comment on *the "Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008, and other Part B Payment Policies for CY 2008*" published in the Federal Registry on July 12, 2007. Our comments focus on the issue of physician self-referral as it applies to radiation therapy. In particular, we want to address concerns that have been expressed by groups representing radiation oncologists regarding the reliance on the in-office ancillary services exception by medical groups developing comprehensive prostate cancer treatment centers.

As you may know, multi-specialty medical groups are increasingly incorporating radiation therapy into their service offerings. In some cases, the group employs a wide range of physicians from different specialties, and radiation therapy constitutes a very small portion of the services rendered by the group. In other cases, the group focuses largely on the treatment of prostate cancer by employing only urologists and radiation oncologists who specialize in this area. In either case, contrary to the allegations of certain radiation oncology professional associations, the arrangement provides numerous benefits to patients and is not prone to abuse.

A urologist is typically the first physician to diagnose prostate cancer. Once such a diagnosis has been made, urologists desire to treat the cancer with the modality that offers the highest probability of cure and minimizes morbidity, based on the progression of the patient's cancer and the patient's preference. These treatment modalities range from robotic surgery, radiation therapy (i.e. IMRT-IGRT), brachytherapy, cryosurgery etc. When appropriate, watchful waiting is yet another option presented to the prostate cancer patient. Urologists have referred prostate cancer patients for radiation therapy for the past 30 years. They have managed all of the patient morbidity problems associated with the older forms of radiation treatment delivery. With the advent of modern advanced forms of radiation delivery, urologists are now embracing radiation therapy as an equal treatment modality to surgery with significantly less morbidity.

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Some urology and multi-specialty groups have elected to develop their own capacity to deliver radiation therapy treatment rather than refer patients in need of radiation therapy to other medical groups. This enables the group to offer the full range of treatment options available to prostate cancer patients. The capacity to deliver comprehensive prostate cancer treatment is extremely beneficial to patients.

In developing radiation therapy treatment capacity, urologists work with radiation oncologists who may be owners, employees or independent contractors of the group. In many cases, an employee is on a partner track to become a shareholder. This arrangement creates a bona fide multi-specialty group whose core competency is comprehensive prostate cancer treatment. Many groups have "sub-specialists within specialties," meaning some physicians specialize in prostate robotic surgery, incontinence, pediatric urology, laparoscopic surgery, urologic oncology, etc. The radiation oncologist functions as a member of this multi-disciplinary team.

Contrary to the suggestions of radiation oncology professional associations, a medical group's focus on comprehensive prostate cancer treatment will improve rather than undermine the quality of care. Medical groups that focus on treating particular diseases tend to be better educated about the dynamic clinical issues and treatment options relating to that disease. They are more likely to have state-of-the-art equipment. Proven clinical and physics protocols are implemented in these groups that have incorporated radiation therapy, marrying the best in technology with the latest clinical research. This approach has led to greatly enhanced cure rates for prostate cancer patients. In addition, patients are treated in a group that, due to its focus, has experienced virtually every variation of prostate cancer "behavior."

Integrated prostate cancer treatment centers allow patients to be treated in an environment that is conducive to healing. These patients share the experience with other men who have the same anxiety, fears, and concerns regarding their cancer and their lives. These centers tend to spawn prostate cancer support groups where extraordinary relationships are formed, among patients as well as staff.

In contrast to a general radiation oncology practice, integrated groups are also more likely to retain the type of sub-specialists referenced above, who are in the best position to provide the most sophisticated and appropriate care. Moreover, bringing urologists and radiation oncologists together within a single medical group leads to tighter integration and coordination of medical care involving both specialties, such as brachytherapy or radiation therapy, following surgery.

Rather than being used abusively, the multi-specialty radiation oncology/urology integrated practice model has been responsible for bringing advanced community-based prostate cancer care to many areas of the country which previously did not have access to this type of service. In addition, because of this integrated model's economies of scale, and intense focus on the second leading cause of male cancer deaths in the United States, it offers invaluable opportunities for clinical research.

It is misleading to allege that an integrated group skews physician treatment decisions in a way that is inconsistent with optimal patient care. In a Balkanized treatment environment, where radiation oncologists and urologists practice in separate groups, each specialty tends to favor its own form of treatment. In an integrated group, the physicians can collectively determine the appropriate course of care in consultation with the patient, without facing the prospect that a particular treatment decision will cause the care to be provided by another medical group. If anything, integrating the practices of urologists and radiation oncologists minimizes the impact financial considerations may have on treatment advice.

The integration of urologists and radiation oncologists in comprehensive prostate cancer treatment centers is part of a broader trend in the health care industry toward the creation of large multi-specialty medical groups. These groups tend to enhance the level of specialization of their physicians and improve the continuity of care. There is nothing unique about radiation therapy that would support a policy prohibiting the service from being delivered by a multi-specialty group. The only rationale for such a policy would be protecting the interests of radiation oncologists by restricting medical groups that include other types of physicians from offering radiation therapy services.

For all of the reasons set forth above, we feel strongly that prostate cancer patients are receiving better care within integrated radiation oncology and urology and broader multi-specialty groups than in other settings, and that such groups minimize rather than exacerbate the impact of financial considerations on treatment decisions. As a result, we believe the current in-office ancillary services exception is serving its purpose and should not be amended in any way that creates an impediment to the continued success of comprehensive prostate cancer treatment centers.

Thank you for the opportunity to comment on the proposed rule. Should you have any questions regarding the issue discussed within this communication, please do not hesitate to contact us at 956.682.9894.

Sincerely,

Mark L. Harrison, MD
Diplomate, American Board of Radiology
Chairman & Chief Executive Officer

Steven R. Carrales
President & Chief Operating Officer

TUCKER ARENSBERG
Attorneys

J. Kent Culley 412.594.5520
kculley@tuckerlaw.com

VIA FEDERAL EXPRESS

August 27, 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/Madam:

We have had the opportunity to review the above proposed physical therapy rule published at 72 Federal Register 38230-28231 (July 12, 2007) and we submit the following comments:

Initially, you should understand that this firm, through its healthcare practice, has extensive background relating to the practice of physical therapy in all facets including education, testing, licensure and the regulatory aspects of physical therapy practice. For example, we have been involved over a number of years in assisting some 25 state physical therapy professional or licensing entities in the promulgation of state licensing standards and/or regulations pertaining to the state activities in regulating the practice of physical therapy. We also have regularly assisted numerous physical therapy private practices and rehabilitation facilities or entities relating to both federal and state laws and regulations regarding the professional practice of physical therapy. In all our background and experience, it has always been the individual states that are empowered to establish and adopt appropriate testing and licensure standards for the various health professions, not the federal government. These proposed regulations above stated, however, appear to cause the federalization of the practice and testing standards for licensure as a physical therapist. This action, seemingly unique, makes no practical sense and is contrary to the traditional state authority to continue to regulate the testing standards leading to a license for physical therapists.

This proposed rule, among other things, totally ignores the fact that there already exists a National Physical Therapy Examination ("NPTE") developed and maintained by the Federation of State Boards of Physical Therapy ("FSBPT"). Further, the NPTE has been adopted by all fifty (50) state physical therapy licensing agencies, the District of Columbia and two (2) U.S. territories, as the test that is approved and utilized by these agencies. The attempt, by this proposed rule, to introduce another layer of (federal) regulatory approval and use as a test "approved by the American Physical Therapy Association" ("APTA") will unnecessarily create confusion in the regulatory field of licensure for physical therapy practice for both the states and individual candidates

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seeking licensure as a physical therapist. As such, this action would be wholly counterproductive to the existing uniform national examination already in use through the United States, the District of Columbia and U.S. territories, the NPTE.

For CMS to now attempt to establish the APTA as the approval entity for a "National Examination" for U.S. and foreign-trained applicants for physical therapy licensure, as well as for the physical therapy assistant, would create a significant conflict of interest for the APTA. The APTA is the body that represents and promotes the profession! By contrast, the FSBPT is the organization that concerns itself only with the licensure of physical therapists through the development and maintenance of the NPTE, adopted and utilized by all state physical therapy licensing agencies. The APTA already has control over the Commission on Accreditation in Physical Therapy Education ("CAPTE"). For CMS to now propose that the APTA should approve the National Examination, puts complete control of both the education and testing for licensure process into the entity that is established as the trade association for the profession and as such, we believe is a significant conflict of interest.

Historically, the APTA prior to the late 1980's, had developed a licensure examination for physical therapy practice which it sought to become national in scope. Because it was realized that control over this aspect of licensure was a conflict of interest since the APTA also controlled CAPTE, the APTA sold the NPTE development and maintenance through a Transfer Agreement in 1989 to the newly created and independent organization, the FSBPT. Since that time, the FSBPT has spent considerable money and effort to continuously upgrade, improve and appropriately maintain the NPTE for its member jurisdictions and the licensing agencies of these United States. The effect of the NPTE has been to establish a highly regarded testing vehicle and has created uniformity in the testing field for physical therapy licensure, greatly expediting, among other things, the free flow of candidates from state to state depending on their choice of a practice residence.

The Medicare Benefit Policy Manual, among other laws and regulations of the Social Security law, makes it clear that a physical therapist, as a "Qualified Professional", is licensed by the state to perform therapy services. It is clearly recognized and established that licensure and, therefore, all aspects of licensure, is a state function, including the state's authority under law to approve and adopt the licensure examination it chooses. This proposed rule, however, usurps the state's authority to so act and attempts, by federal mandate, to place the approval process for the physical therapy examination in the hands of an advocacy group, the APTA.

It is well settled in the physical therapy regulatory area that there already exists a uniform National Physical Therapy Exam which has been adopted by all U.S. licensing agencies for physical therapy. To rule that now an advocacy group like the APTA must approve a "National Examination", is a conflict of interest for the APTA, is very confusing to the states licensing physical therapy and individuals seeking licensure as a physical therapist, is an unnecessary additional cost burden to the states and these individuals and, in fact, is unnecessary.

For the reasons stated above, we, therefore, strongly urge CMS not to enact the above-mentioned proposed rule, particularly subsection (1)(i)B and (1)(ii)B regarding physical therapists and subsections (1)(ii) regarding the physical therapist assistants. Alternatively, we urge that such rule should at least be postponed for CMS to have the opportunity to fully understand the examination and licensing process that exists at this time for physical therapists in the United States.

Thank you for the opportunity to provide these comments.

Very truly yours,

TUCKER ARENSBERG, P.C.

J. Kent Culley

JKC:dms

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Colorado Heart Institute

1455 S. Potomac, #101 • Aurora, CO 80012 • (303) 369-7565

August 27, 2007

VIA FEDERAL EXPRESS

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 writing on behalf of the Colorado Heart Institute ("CHI") as a supplemental submission to the letter written by Tom Crane of the law firm, Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C. We write this letter to express our objection to CMS's proposed changes to the Stark regulation related to under arrangement services that would have the effect of creating an impermissible physician ownership in a DHS entity. We offer the following comments to give our unique perspective of the history, operation, and compliance measures of CHI.

CHI is a Colorado Limited Liability Company owned by fourteen (14) physicians who specialize in cardiology, a twenty six (26) physician cardiology group, and one (1) non-physician manager of the facility. CHI has twenty seven (27) non-physician employees including nurses, registered cardiovascular invasive specialists, clerical and administrative personnel. CHI has a five (5) cardiologist-physician Board of Managers, a Medical Director, an Administrative Manager, and a Clinical Manager who manage the company on a day-to-day basis.

CHI commenced operations in November, 1987 and has operated continuously since that time providing a full range of cardiac catheterization laboratory services to patients of our local hospital under arrangements with the hospital. Services we provide currently include primarily diagnostic cardiac catheterizations, percutaneous coronary interventions such as balloon angioplasty and stent placements, diagnostic and therapeutic electrophysiology procedures, and implantation of permanent pacemakers and implantable cardioverter-defibrillators. Prior to CHI, the hospital did not have a catheterization laboratory, and such services were not otherwise available in our community.

CHI is located on the campus of the hospital, in a medical office building that is immediately adjacent and connected to the hospital. Patients are transferred between CHI and the hospital by gurney. The building that houses CHI's clinic space is owned by the hospital, and rented to CHI for its exclusive use by long term lease at fair market rates. CHI has paid significant tenant improvement costs at its own expense, utilizing its own capital.

The vast bulk of the services are provided to the hospital based on flat fees for specific categories of service that include the full costs for these services (personnel, medical supplies and devices, equipment, space, etc.). Thus, CHI assumes the risk of all costs of providing the service, including the costs of medical supplies and implantable devices, the capital costs of x-ray, hemodynamic monitoring, and related accessory equipment, the capital and operating costs of the real property used by CHI, and the labor costs for all clinical and administrative employees.

The agreed-upon fees with the hospital are exhaustively reviewed. CHI has developed proprietary software to benchmark all costs of providing services, and to identify best practices for the delivery of care. In addition, all fees are reviewed periodically by a third-party valuation company to assure that such fees are fair market value. Each party fully understands this legal obligation.

Physician ownership and participation in management of CHI has resulted in a business focused on clinical excellence. CHI participates in routine clinical performance activities of the hospital, such as: In its many routine JCAHO inspections that are part of its review of the hospital, CHI has never received a Request for Improvement (RFI). CHI and the hospital participate in the American College of Cardiology's Cath, PCI, and ICD Registries where quality data is routinely reported and benchmarked to national results. In addition, CHI has participated in new, innovative clinical developments that were later adopted around the country by other similar programs. For example, CHI's Cardiac Alert program which was written up in trade journals and recognized as a leading new patient treatment for acute myocardial infarctions; and participated in clinical trials of TAXUS drug eluting stent devices. CHI is recognized in the Metro Denver area as a leading provider of clinically advanced cardiac catheterization laboratory services. CHI and the hospital were recognized as one of four cardiac Centers of Excellence from a hundred fifty seven (157) hospitals within a national hospital system.

This history demonstrates why our arrangement with our local hospital provides clinical-driven cost-effective services. CMS would advance no legal or policy interests if it implements the changes it proposes.

Respectfully submitted,

Dennis J. Battock, MD

Dennis J. Battock, M.D., FACC
Medical Director and Executive Manager

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The Sleep Wellness Institute Inc.

Ron Baake

Mark Stoiber

Don Harden, MD
Gary J. Leo, DO

- *Sleep apnea*
- *Insomnia*
- *Narcolepsy*
- *Parasomnias*
- *Snoring*
- *Hypersomnia*
- *Restless legs syndrome*

- *Insurance accepted and filed*
- *Flexible payment options*
- *Major credit cards accepted*
- *Fast results*

August 28, 2007

VIA FEDERAL EXPRESS

Leslie V. Norwalk
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: IDTF ISSUES
Comments on Proposed Rule, 72 Fed Reg. 38122, July 12, 2007
File Code CMS–1385–P

Dear Administrator Norwalk:

We are submitting comments on the new performance standard prohibiting an independent diagnostic testing facility ("IDTF") from sharing space and equipment with other entities. The rule proposed by CMS on July 12, 2007 states that an IDTF may not "share space, equipment, or staff or sublease its operations to another individual or organization" at 42 CFR § 410.33(g)(15). The preamble discussion states that CMS believes it is inappropriate for a fixed-base IDTF to commingle space, equipment or staff with another individual or organization because of the difficulty in ensuing that each physical IDTF site establishes and maintains IDTF billing privileges consistent with Medicare rules and meets performance standards and other IDTF requirements. We are requesting that CMS not promulgate § 410.33(g)(15) as a final rule because it severely restricts the use of an IDTF's property and places unnecessary limitations on the entity. The prohibition as written is vague, and could be interpreted to prohibit any number of business arrangements that do not impact the IDTF's functioning, or that even improve the IDTF's services. Further, to the extent there may be anti-kickback concerns with respect to the co-location of Medicare suppliers, existing lease and personal services safe harbors and Stark exceptions are sufficient to protect Medicare from inappropriate arrangements.

This letter provides the Sleep Wellness Institute, Inc.'s ("Sleep Wellness") comments on three possible scenarios under the proposed performance standard: 1) an entity enrolled as an IDTF that is also enrolled as a multi-specialty clinic; 2) physicians providing services to patients in the space owned by the IDTF entity and leased to the physicians, where the physicians submit their own bills, rather than reassigning billing to the IDTF entity; and 3) an IDTF-enrolled entity owning or leasing to an unrelated business. We

(414) 336-3000 • 2356 S. 102nd Street • West Allis, WI 53227 • Fax: (414) 336-1015 • www.sleepwell.org

believe that CMS's intent is to keep IDTFs from leasing their facilities in a way that would allow others to bill for the IDTF's services in a manner that circumvents applicable requirements, and reduces the IDTF's level of control over its own operations. These examples show that CMS has proposed a broad, sweeping standard that prohibits a whole host of uses of facilities owned by entities enrolled as IDTFs, and therefore demonstrates that CMS should not finalize the proposed rule.

The first scenario describes our current operations. Sleep Wellness owns a medical office building, which is suitable for a variety of medical and other uses. It is enrolled with Medicare as both a multi-specialty clinic and an IDTF. The IDTF and clinic are not separate legal entities, and share space in the same building. IDTF activities are performed in one portion of the space, and physician office services in another, with shared lobby, hallways, reception, parking and administrative services. Sleep Wellness works with two supervising physicians who use the offices within the Sleep Wellness clinic space to provide services to patients; they keep corresponding medical records in those offices. These physicians reassign their right to bill for these services to Sleep Wellness and are compensated by Sleep Wellness at a rate that does not exceed fair market value for their professional and supervising physician services. The physicians are assisted by Sleep Wellness administrative and clinical staff, including nurses and mid-level practitioners, to perform their clinic services. We believe that this arrangement is not prohibited by the proposed rule, since the clinic operations are not "another individual or organization," but rather operated by the same entity that is also the IDTF. If CMS implements § 410.33(g)(15) as part of the final rule, we request that CMS confirm in commentary to the final rule that this situation does not violate the proposed regulation as currently drafted. That is, it will remain acceptable for an entity to be enrolled as both a clinic and an IDTF, and for portions of the space and staff to be used for both clinic and IDTF activities.

The second scenario described above would be for independent physicians who are also the supervising physicians to lease the clinic offices. Here, the physicians would submit their own bills, rather than reassign their right to bill to Sleep Wellness. Sleep Wellness would continue to provide fair market value compensation in accordance with applicable requirements for supervision services; the IDTF's operations would continue to be enhanced by the proximity and availability of the supervising physicians. The physicians would not be leasing the diagnostic capabilities of the IDTF, only office space and perhaps limited administrative or clinical support services that would further the physicians' performance of professional services to their patients. This arrangement is acceptable under current law, but would have to be revisited if the proposed regulation is implemented as drafted. It would appear that the IDTF would be sharing space with another individual, which would be prohibited. We submit that prohibiting this beneficial arrangement is not a positive outcome, and would limit the effectiveness of Sleep Wellness and other IDTFs desiring to have appropriate and available supervision while allowing the physicians to maintain their practices.

The third scenario demonstrates the extent to which the proposed rule prevents an IDTF from putting its property to its best and highest use. As currently drafted, the proposed

The Sleep Wellness Institute Inc.

regulation seems to prohibit the sharing of space with other unrelated businesses within the IDTF-owned space, such as a physician with an unrelated practice, or even a coffeeshop. We are concerned that the proposed rule prohibits an IDTF from participating in any type of leasing arrangements and from using its own property and space in the most effective manner. The proposed regulation means that common models involving IDTFs would be disallowed, and would prohibit lease arrangements that satisfy all of the elements of the lease safe harbor under the Anti-Kickback Statute and the Stark lease exception. Practically speaking, the proposed rule would create considerable challenges and transaction costs by requiring restructuring of previously permitted arrangements.

We believe that allowing an IDTF to share space would not lead to circumvention of billing rules or performance standards. In keeping with the current performance standards, the IDTF would remain open to inspection and unannounced site visits to verify that it operates in compliance with all applicable federal and state licensure and regulatory requirements.

Thank you for considering our comments. If you have any questions regarding this letter, please feel free to contact us.

Very truly yours,

Vernon R. Baake
CEO / Owner

20788685_3.DOC

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MIDWEST
STONE
MANAGEMENT

1885 County Road C West ■ Roseville, Minnesota 55113 ■ Phone (651) 633-9414
Fax (651) 633-9403

August 29, 2007

Center 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: July 2, 2007 Medicare Physician Fee Schedule Proposed Regulations

Ladies and Gentlemen:

I am the manager of a lithotripsy and laser service provider operating at more than 60 locations in seven Upper Midwest states. We own and operate 18 lithotripters and four lasers that are used at either fixed sites or on mobile routes. We began our service in 1986 and over the past 21 years we have treated more than 75,000 patients. We are committed to providing the highest quality service and as such we maintain a comprehensive quality improvement program. Over the years we have published numerous articles in peer reviewed medical journals using the data collected in that program. This year alone we have had three articles published in the Journal of Endourology. These articles have, know doubt, improved the quality of care for lithotripsy patients well beyond our own region. We are organized as a partnership of more than 100 urologists who are both owners and users of our services. The proposed regulations would very seriously disrupt the care of patients in our region if it is determined that the regulations apply to organizations such as ours. Of most concern to us are the proposed rules related to "Under Arrangement Contracting" and "Per Procedure Fees."

Our mobile services are provided to facilities that could not justify having a full-time machine on site. In that sense we are creating a very cost effective method for those facilities to have a service that they otherwise would not be able to offer to their patients. We charge the hospital for our service on a per procedure basis. Therefore, the hospital can be very efficient in only paying for what they use without having to expend precious funds for underutilized equipment. In 2006 at our 54 mobile lithotripsy sites the average caseload for the year was 41.17 and the median was 24. It is quite clear that the charge per procedure is essential for these facilities to maintain this service. While we could charge on a unit of time basis many of these facilities would choose not to offer the service as they averse to the risk of paying when services are not used. The fact that we are owned by urologists means that we are willing to take on the risk of uncertain caseload. The urologists are motivated by the desire to treat their own patients and not by the profit from the technical charge to the hospital. In many locations, if we were to do a

careful cost accounting, it is doubtful that we are profitable. Clearly, in all locations the professional fee the urologist receives per case is greater than any profit from incremental cases. We know that non-physician owned lithotripsy companies will not offer service to the expanse of locations that we cover because it is not profitable for them to do so. They do not have the same motivation as our urologist owners do.

Our company is not strictly a mobile provider. We have placed fixed lithotripters and lasers at some very large facilities that undoubtedly could buy their own machines. Because we specialize in lithotripsy and laser our staff is highly trained and these facilities have found that better care is provided to their patients by using our service. As evidence of this we have had two hospitals that after first using our mobile service then decided to acquire their own lithotripter and staff it themselves. After much dissatisfaction with the service provided by their own staff these sites reverted to having us provide equipment and staffing. We do a better job because we respond to the needs and desires of our owners, the urologists who use the equipment to treat their patients. I do not believe the same could be said of those companies that are not urologist owned.

Shared services owned by urologists are economical and reduce costs for hospitals and the healthcare system in general. This is true for lithotripsy and laser and based on my experience it is true for other types of medical technologies as well. As an example of what happens without a shared service I would like to point to our experience in this area regarding a robotic assisted surgery device, a very expensive piece of medical equipment. We tried persistently to form a shared service venture with this device but met absolute resistance from the manufacturer. We had the commitment of several hospitals in the Minneapolis/St. Paul region to use our service because of the economics. They felt public pressure to have the device but saw that purchasing was not in their economic best interest. In the end we were unable to overcome the resistance from the manufacturer. The result was a technology war among the hospitals with all of them purchasing this device despite the resultant underutilization and financial losses. This was a waste of precious resources and adds costs to the system that would not have happened had there been a doctor owned shared service. Fortunately, with respect to lithotripters and lasers, we have created a system of high quality patient care in a most economical fashion.

While we believe that the proposed regulations do not apply to organizations such as ours due to legislative intent and previous legal rulings we do need clarification that this understanding is correct. It would be extraordinarily disruptive in our region and indeed nationally to have these proposed regulations apply to lithotripsy and laser doctor owned ventures. If there are abuses in the system of referrals to providers causing over-utilization then I believe the tools already exist to remedy such abuses. Physician owned joint ventures in lithotripsy and laser services are not abusive and it is in the best interest of Medicare beneficiaries that these arrangements be protected.

Sincerely,

Charles A. Nystrom
Chief Operating Officer

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BOARD CERTIFIED UROLOGISTS

Lakeside Urology

Continence Center

John E. Bannow, M.D., F.A.C.S
Board Certified Urologist

Peter J. Bridges, M.D.
Board Certified Urologist

David W. Terhune, M.D., F.A.C.S
Board Certified Urologist

Benjamin, R. Stockton, M.D.

August 29, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Mail Stop C4-26-06
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Ladies and Gentlemen:

I am a Urologist practicing in a small Michigan community. I have been providing services to Medicare patients through a Urology Joint Venture. These services include Lithotripsy for kidney stones and Cryotherapy for prostate cancer. **Prior to the initiation of these joint ventures our patients routinely traveled 2 hours, or more, for Lithotripsy and at least 4 hours for Cryotherapy.** Patient care and access to needed treatment have improved dramatically through these joint ventures.

There are multiple points that I would like to make:

1. I am unaware of any abuse history in any Urology joint venture.
2. Without these arrangements our patients **would have no access** to these treatments locally just like in the past.
3. **Community hospitals cannot afford the "latest" technology** as the number of cases in a community hospital does not support the investment.
4. Our patients have been well served by having access to technologies that they had **no access to previously.**
5. Without access to these procedures, **Urologists will not be willing or able to practice in small communities like ours.**
6. Urology joint ventures accept risk in obtaining equipment and assuming that the equipment will be needed. **Community hospitals will not take these risks.**
7. The idea of the proposed "Burden of Proof" would shift the burden to providers to show no Stark violation. This makes no sense whatsoever. It is unfair to providers who are trying to bring unavailable technology to patients.
8. We have received **countless expressions of gratitude from patients** who no longer need to travel to receive their kidney stone treatments. Our community hospital has also benefited by being able to provide the service to patients even though they could not themselves justify the purchase of a lithotripter.

Sincerely,

Peter J. Bridges, M.D.

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815 St. Joseph Dr.
St. Joseph, MI 49085
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NILES OFFICE
24 St. Joseph St., Suite F
Niles, MI 49120
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WATERVLIET OFFICE
Medical Park Dr., Suite 400
Watervliet, MI 49098
(269) 463-3733

Re: File Code CMS-1385-P
Physician Self-Referral Provisions
Section II.M.3; In-Office Ancillary Services Exception

Dear Sir or Madam:

I am an Occupational Therapist, working for an organization that provides rehab services, within a physician practice. Working within this model has proven to be very patient-centered. My past work experiences include the U.S. Public Health Service, out-patient rehab within a hospital, and private practice out-patient rehab. Of all of the settings, this one provides the most frequent guidelines, to the therapists, concerning quality patient services, cost containment, and the monitoring of standards of care.

Located within the same physical space as the physicians enables me to have frequent contact with them, concerning individualized treatment plans and case management to facilitate timely return to activities of daily living. The accessibility to physicians, nurses, medical records, and financial records enables me to provide more comprehensive care to my patients and to provide it with cost-containment as a priority.

The patient satisfaction survey scores from the facility in which I work, are very high. Our patients disclose that they have input into treatment and discharge planning; that they are cared for in a supportive and knowledgeable environment; and that they receive a high quality of care for their health care dollars. This results in lower costs, as compared to privately owned rehab practices, which are profit driven.

Compared to the other settings in which I have worked, this model, of in-house PT & OT, represents good stewardship of resources. In today's world of shrinking resources for health care needs, criteria of good stewardship should prevail. The in-house PT/OT model holds both partners accountable to best practice principles concerning patient care and cost-containment. As a rehab provider, I ask for your continued support of this model. The partnership between the physicians and the therapists sustains a positive stress, to provide quality care in a cost efficient manner. The collateral scrutiny between partners, to execute best practices, benefits the patients and the health care system at large.

Sincerely,

36093

332

Mark & Kambour
PATHOLOGY ASSOCIATES
5000 University Drive
Coral Gables, FL 33146
305-669-3471

August 28, 2007

Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850
Attention: CMS-1385-P

RE: Physician Self-referral Provisions

Dear Sirs:

I am writing this letter in regard to 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 Miami, Florida as part of a group of pathologists providing both hospital based pathology services and independent reference lab services

I want to thank CMS for beginning the process of eliminating the many abusive self-referral practices in the billing and payment for pathology services.

We know the practice has become more sophisticated than just "pod labs". Many arrangements now attempt to portray the pathologist as a "member or employee" of their practice. I believe your proposal that the pathologist has health insurance and their pension with the clinical practice group is very good. Additional requirements would beneficial to help assure that the self-referral abuses are curtailed.

I suggest three other requirements which would enhance and strengthen the above. 1) The pathologist should not be allowed to work for more than one physician clinical practice group. 2) The pathologist should not be allowed to also work for or have any other arrangement with independent reference laboratory. (This would eliminate the possibility that a reference laboratory could provide a pathologist in return for receiving the technical component billing.) 3) Medical liability insurance for the pathologist should be paid by the physician clinical practice.

Opponents to these proposed changes assert that their captive pathology arrangements enhance patient care. On the contrary, the opposite occurs with these

self-referral arrangements. For example, we received a biopsy on a urologist physician who routinely sent his patient's biopsies to his physician group's "employed pathologist" in a self-referral arrangement. But when a prostate biopsy was performed on him, the biopsy was not sent to the solo pathologist "employed" by his group. He sent his own biopsies to our pathology reference laboratory which he knew included a team of pathologists highly experienced and knowledgeable in interpreting prostate biopsies. What was good enough for his patients was not good enough for him.

Over utilization of pathology testing is a reality in these self-referral arrangements. I know of more than one urologist who routinely submitted prostate biopsies in two bottles (left and right). When their physician group "employed" their own pathologist they switched to twelve bottles. This was a six fold increase. In these self-referral situations it is clear that more bottles/specimens per patient are submitted which results in a higher cost for the Medicare system.

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,

Thomas M. Mark M.D.

Sent by Fed Ex

Physiotherapy
Associates

August 29, 2007

Mr. Kerry N. Weems
Administrator-Designate
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1398-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 Administrator-Designate Weems:

I am submitting the comments below on behalf of Physiotherapy Associates, Inc. and Benchmark Medical, Inc., two national outpatient rehabilitation companies which recently merged to become a single company ("Physiotherapy"). Physiotherapy owns and operates approximately 800 outpatient rehabilitation centers located in 34 states throughout the United States.

Physiotherapy appreciates the opportunity to comment regarding the Physician Self-Referral provisions in the 2008 Proposed Physician Fee Schedule Rule. Specifically, Physiotherapy would like to applaud CMS for seeking comments to limit the in-office ancillary services exception. Physiotherapy believes that the in-office ancillary services exception should not encompass physical therapy services. As stated by CMS, the in-office ancillary services exception was created to permit physicians to perform tests and procedures essential to the immediate diagnostic or treatment needs of their patients, not to self-refer for medical services that could (and should) be provided at lower costs[1] and with better results by specialists dedicated to the specific medical service at issue. The legislative history supports CMS' interpretation. Testimony by Congressman Stark, when the in-office ancillary services exception was created, specifically states, "The exception would most commonly apply to in-office lab tests or x-rays. The exception reflects a judgment that there is often a clear need for quick turn-around time on crucial tests." 135 Cong. Rec. H240-01 at 6 (Feb. 9, 1989).

By allowing the in-office ancillary services exception to include physical therapy services, physicians who provide such services as part of their practice benefit financially each time they order therapy services. These physicians, however, have little to do with the therapy services being provided and the therapy services have little relationship to the physicians' need to

[1] *See*, Scott E. Mitchell JM, *Physician Ownership of Physical Therapy Services,* 1992 # 268 JAMA 2055,2055-2059 1992. (Noting the higher costs associated with physical therapy provided in so-called "joint venture clinics" in the state of Florida).

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diagnose or develop a treatment plan for their patients at the time of the initial office visit. Physical therapy services, unlike other ancillary services, are not intended to assist physicians in their diagnostic work and generally treatment is not provided by a physician. Physical therapy is instead intended to rehabilitate patients over multiple visits according to a long-term treatment plan, which generally does not involve physician participation. Patients do not receive an added convenience when their physical therapist's office is located in their physician's office since physician visits are not generally provided each time physical therapy is provided. Physical therapy, accordingly, should not be considered a service that is "ancillary" to a physician's diagnosis or immediate treatment of a patient during an office visit.

Additionally, physical therapy services do not require the involvement of a physician. The in-office ancillary services exception requires supervision of services by a physician in the group, but only to the extent required under Medicare coverage and reimbursement rules. 42 C.F.R. 411.355(b)(1)(iii). Unless the services are provided "incident to," however, the reimbursement rules do not require any physician supervision for physical therapy services. Medicare Benefit Policy Manual Transmittal 5 (January 9, 2004). Accordingly, physical therapists properly provide such services without needing any supervision of the physician. This "loophole" has led to some fairly obvious examples of physicians stretching the boundaries of what can be considered "ancillary." The OIG's recent evaluation and inspection letter on physical therapy services provided in physician offices (OEI-02-09-0200), for instance, described a physician who bills Medicare for an average of 51 "ancillary" physical therapy sessions per day. It is difficult to imagine that this particular physician encounters an average of 51 patients per day whose diagnosis or care depend upon his ability to immediately provide physical therapy.

As the above example indicates, the current in-office ancillary services exception has the distinct potential to misalign physician incentives with respect to physical therapy services. Physicians who are responsible for both ordering and billing for services that they have not personally provided may allow their financial interest to affect their medical judgment. The fear that the provision of physical therapy services in a physician office may lead to overutilization (or fraud and abuse) is more than theoretical; a 1992 study of the California Workers' Compensation system found that physical therapy was initiated 2.3 times more often by physicians in self-referral relationships than by those referring to independent practices.[2] An OIG recent evaluation and inspection report echoed this concern, noting that 91% of the physical therapy billed by physicians in the first 6 months of 2002 did not meet program requirements. Similarly, according to the OIG's 1994 report on the same topic (OEI-02-90-00590), four out of five physical therapy claims reported from physician offices failed to provide medically necessary services or failed to properly record treatment plans or goals. In contrast, the same report noted that nine out of ten physical therapy providers (not working in physician offices) provided appropriate therapy services in conjunction with all necessary documentation. Essentially, allowing physicians to bill for physical therapy services that are provided by therapists in their own offices permits the physicians to be their own "gatekeepers" – a situation that the Stark regulations have taken great pains to avoid. This potential conflict of interest seems antithetical to the general intent of the Stark law and its growing regulatory framework.

[2] A. Swedlow et. al, Increased Costs & Rates of Use in the California Workers' Compensation System as a Result of Self Referral by Physicians, 327 New Eng. J. Med. 1992, 1502-1506 (1992)

Physical therapy is a professional service regulated in every state and provided by licensed and experienced providers who have dedicated their careers to a specific physiological understanding of the mechanics of the human body. Physical therapists bring their specific knowledge regarding body mechanics and physiology to bear in providing patients with explicit treatment plans designed to restore mobility or function in an otherwise damaged body part within a specific time frame. As a medical specialty practiced by dedicated and knowledgeable professionals, physical therapy can serve an essential role. As an "ancillary" service, physical therapy poses an unnecessary risk of fraud and abuse while providing little added benefit to beneficiaries. CMS should recognize that there is no reason to treat physical therapy any differently than other medical specialties; physical therapy should not be provided as an "ancillary" service anymore than surgery should. Accordingly, Physiotherapy recommends that physical therapy be removed from the list of designated health services that can be provided by physicians under the in-office ancillary services exception.

Physiotherapy appreciates this opportunity to comment. Please do not hesitate to contact the undersigned if the Physiotherapy organization can be of any further assistance to CMS.

Sincerely,

Richard S. Binstein
Physiotherapy Associates
Executive Vice President
And General Counsel

HEALTHCARE

August 29, 2007

VIA FEDERAL EXPRESS/Morning Delivery

Honorable Herb B. Kuhn, Deputy and Acting Administrator
Center for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1385-P, Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: IDTF Issues: Comments on IDTF Provisions of Proposed Revisions to Regulations Regarding Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY2008; File Code CMS-1385-P

Dear Administrator Kuhn:

e+ healthcare, llc ("*e*+") thanks you for the opportunity to comment on the proposed Physician Fee Schedule Rule, as published by CMS in *The Federal Register* on July 12, 2007 (the "Proposed Rule"). *e*+ is commenting on the portions of the Proposed Rule concerning independent diagnostic testing facilities ("IDTFs"). *e*+ operates imaging centers that are enrolled in the Medicare program as IDTFs. *e*+ would like to comment on the so-called "anti-sharing" portions of the Proposed Rule.

Prohibition on Sharing.

The Proposed Rule would add a new performance standard to the existing IDTF performance standards. This new standard would prohibit an IDTF from sharing space, equipment or staff with, or subleasing its operation to, another individual or organization.

In the commentary to the Proposed Rule, CMS indicates that the purpose of the anti-sharing portions of the Proposed Rule is to insure that an IDTF's operations are distinct from the operations of other entities, thereby allowing CMS to make a determination that the IDTF is operating in compliance with applicable Medicare regulations. Further, CMS noted that it was concerned that sharing arrangements are subject to abuse and might violate the federal self-referral and anti-kickback statutes. *e*+ agrees that certain sharing arrangements could be subject to abuse, but requests that CMS reconsider the blanket anti-sharing prohibition for the reasons described below.

Sharing of Non-Clinical Space, Equipment and Personnel

Certain sharing arrangements do not raise the concerns that CMS has noted in the comments to the Proposed Rule. Specifically, *e*+ is aware of arrangements whereby minimal

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non-clinical space, equipment and personnel is shared between an IDTF and an adjacent facility. For example, adjacent imaging and radiation therapy centers could share a common waiting room and entrance, a common reception desk, and a common receptionist. Although "per click retail sale" or "block lease" arrangements represent situations where CMS could raise objections based on the polices underlying the anti-referral and anti-kickback laws, the innocuous sharing of non-clinical space with adjacent providers does not offer the same potential for abuse. Such activities would not intermingle the operations of the IDTF with another provider's operations to the extent that CMS would have difficulty determining whether the IDTF was in compliance with CMS's performance standards. Further, sharing of such nominal space an other items serves the positive goal of reducing the costs of both the IDTF and the adjacent provider. To the extent that CMS uses cost data in setting rates, the sharing of non-clinical space, equipment and personnel will ultimately allow providers to report lower costs to CMS in various cost surveys used to set rates.

Sharing Space Between a Group Practice and Its Own ITDF

The anti-sharing rule is overly broad in one other respect. The anti-sharing rule, as currently drafted, might arguably prohibit a physician practice enrolled as an IDTF from "sharing" space with the IDTF. Some Medicare contractors require physician practices that accept a certain level of outside work to enroll as an IDTF. Further, Chapter 10, Section 4.19.1 of the Medicare Program Integrity Manual requires a physician practice to enroll as an IDTF when, among other factors, a substantial portion of the group's business involves the performance of diagnostic tests. In fact, the Program Integrity Manual allows a practice to enroll as both a practice and as an IDTF; the practice uses two different supplier numbers depending on the patient source:

> ....the physician or group can be enrolled as a physician or a group practice of physicians, but must also enroll as an IDTF. The physician or group can bill for professional fees and diagnostic tests they perform on their patients using their billing number; the practice must bill as an IDTF for diagnostic tests furnished to Medicare beneficiaries who are not patients of the practice. The carrier shall advise the entity how to bill for physician office tests versus IDTF tests, and shall advise claims personnel of the dual enrollment. Id.

These practices may enroll either directly through the entity which operates the practice (such as a professional corporation), or through a wholly-owned subsidiary. In either case, the practice is not, in any meaningful sense, "sharing" the IDTF -- the practice is simply using its own facilities to treat patients referred from outside the practice. It is not clear from the existing draft of the Proposed Rule whether a practice sharing an IDTF with -- essentially -- itself, would violate the new standard.

To take into account the two concerns addressed above, *e+* suggests that the applicable standard be revised to read as follows:

(15) Does not share space, equipment or staff with or sublease its operations to another individual or organization. An IDTF wholly-owned by a physician practice, whether through the practice itself or through a wholly-owned subsidiary, will not be deemed to be sharing space, equipment or staff with or subleasing its operations to another individual or organization. An IDTF sharing non-clinical space, equipment and personnel with another entity (such as a reception area, a registration desk and a receptionist) will not be deemed to be sharing space, equipment or staff with or subleasing its operations to another individual or organization.

Application of Anti-Sharing Rule to Non-IDTFs.

e+ urges CMS to adopt an anti-sharing rule similar to the one proposed above applicable to physician practices, hospitals and other providers. The opportunity for abuse of the self-referral and anti-kickback laws noted in the preamble of the Proposed Rule is present regardless of whether the facility sharing its facilities or leasing its operations is an IDTF, a physician practice, a hospital or any other sort of provider. Limiting anti-sharing restrictions to IDTFs will simply force sharing arrangements out of the IDTF context and into, for example, the physician office context. Further, the lack of uniformity of the application of an anti-sharing rule will create an unlevel and unfair playing field for IDTFs, which will be forced to compete with other organizations not subject to an anti-sharing rule for the business of referring physicians.

For all the foregoing reasons, *e+* hereby respectfully requests that CMS modify its "anti-sharing" provisions of the Proposed Rule as described above.

Sincerely,

Timothy M. Petrikin
President and CEO

SOMERSET SKIN CENTRE

August 28, 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: Resource-based PE RVUs for photopheresis (CPT 36522)

For my treatment-refractory cutaneous T-cell lymphoma patients with serious debilitating skin manifestations, extracorporeal photopheresis therapy is highly effective, and enables the patient to return to a more normal, productive life.

Unfortunately, because of the current and proposed reimbursement rates, I continue to be unable to treat these patients in my office, despite the fact that it is more convenient and poses less risk for infection than in a hospital setting. The direct cost for disposable supplies and drugs used for each procedure is more than $1,200; the cost of the procedural kit alone is $1,100. Add to this the cost for a nurse specialist to administer this 3 ½- to 4-hour procedure, and I am faced with the fact that that the current practice expense reimbursement of about $1,320 scarcely covers my direct cost only. There is no compensation for any overhead costs, which include not only office overhead but equipment service costs and the requirement to purchase a back-up photopheresis machine. At the proposed 37 RVUs for practice expense, I could provide this service only at a substantial loss.

Currently, there are only two hospitals that offer photopheresis therapy that I can refer my patients to; both of these hospitals are in the city of Detroit, a minimum of 20 miles for those patients in the closer surrounding suburbs. This creates a significant added burden for patients who require periodic scheduled treatments, who must travel many miles, especially older patients not familiar with the area.

By encouraging physicians to provide photopheresis in their offices, not only would the quality of the patient experience be greatly improved, I assume that Medicare expenses would very likely be reduced as opposed to the hospital-based treatment setting. Therefore, CMS needs to significantly increase the valuation or reimbursement of photopheresis to make it feasible to offer this important treatment in a physician office or clinic.

If you have any questions regarding this important subject, please do not hesitate to contact me.

Sincerely,

George J. Murakawa, M.D., Ph.D.

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August 29, 2007

Herb Kuhn
Acting Director
Centers for Medicare and Medicaid 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 Optometric Association (AOA) 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 Fee Schedule for calendar year 2008. The AOA represents more than 34,000 optometrists in the United States. Doctors of Optometry are independent primary health care professionals who examine, diagnose, treat, and manage diseases and disorders of the visual system, the eye and associated structures. Optometrists are the nation's largest eye care profession serving patients in nearly 6,500 communities across the country, where in more than 3,500 of these communities; they are the only eye doctors accessible.

"TRHCA – Section 101(b): PQRI"

The AOA has worked closely with CMS to ensure active participation by optometrists in the 2007 Physician Quality Reporting Initiative and will continue to provide guidance and education to our membership for 2008 participation. We are pleased that CMS will continue to work with measures that have been endorsed by a consensus organization such as the National Quality Forum. The AOA appreciates CMS's support for inclusion of multi-stakeholders, including non-MD clinicians, in the measure development process. The AOA has requested to be a part of the development of eye care measures through the AMA Physician Consortium for Performance Improvement. This has not occurred as of the submission of these comments however, we will continue to seek opportunities to provide comment and clinical expertise as the 2008 eye care measures are developed this fall.

Table 16 of the proposed rule lists 2007 PQRI measures that CMS proposes to use for the 2008 reporting period. The AOA is concerned that Measure 14: Age-Related Macular Degeneration: Dilated Macular Examination is omitted from this list. It is our understanding that this measure was endorsed by the NQF in May 2007, and optometrists are reporting this measure currently in the 2007 PQRI reporting period. We see no reason why it should not be used for the 2008 reporting period. We anticipate the development of additional eye care measures to be submitted to the NQF this fall for inclusion in the 2008 PQRI program and optometry is expecting to be included in discussions to finalize the development of these measures.

The AOA agrees with the relevance of including the "dilated eye exam in diabetic patient" from the AQA Starter-Set Measures and this measure should be reportable by optometrists. Diabetes mellitus is a chronic disease with long-term complications, including diabetic retinopathy. Approximately 80 percent of blindness in persons 20-74 years of age is related to diabetic retinopathy. At least 50,000 Americans are legally blind from this condition and diabetes is responsible for 10 percent of the new cases of blindness reported annually. According to the *Optometric Clinical Practice Guideline – Care of the Patient with Diabetes Mellitus*, all diabetic patients should have routine eye examinations to reduce the risks of vision loss in patients with diabetes through timely diagnosis and appropriate referral and intervention. The examination should include all aspects of a comprehensive eye exam, with supplementary testing as indicated to detect and thoroughly evaluate ocular complications.

"Coding – Additional Codes from the Five-Year Review"

We thank CMS for accepting the RUC's recommendations for Eye Exams (92002, 92004, 92012, and 92014) for the recent Five Year Review submission. We truly appreciate CMS's review of this data and implementing them in a timely fashion.

"Coding- Reduction in TC for Imaging Services"

CMS has determined that certain ophthalmological procedures meet the Deficit Reduction Act (DRA) definition of imaging procedures, but were not included in the original list of imaging services subject to the Outpatient Prospective Payment System (OPPS) cap. Therefore, CMS is proposing to add CPT codes 92135, 92235, 92240, 92250 and 92285 to the list of procedures subject to the OPPS cap effective January 1, 2008. The AOA feels that 92250 and 92285 do not meet the requirements for Current Procedural Terminology (CPT) and alpha-numeric Healthcare Common Procedure Coding System (HCPCS) codes that fall within the scope of "imaging services" defined by the DRA provision, CMS states that "imaging services provide visual information regarding areas of the body that are not normally visible, thereby assisting in the diagnosis or treatment of illness or injury". CPT codes 92250 and 92285 are true photography codes (traditional picture taken). These two codes take images (OPPS, pictures) of parts of the eye that "are normally visualized" (contrary to the CMS definition) with the naked eye. These structures are seen via ophthalmoscopy and slit lamp evaluation. Their main purpose is for documentation of a pathological condition and monitoring it for change or progression.

Therefore, CPT codes 92250 and 92285 are not "imaging" of a structure which cannot be seen in a clinical exam and, therefore, should be excluded from the OPPS cap.

We appreciate this opportunity to comment on the proposed rule. If additional information is needed, please contact Ms. Kelly Hipp, Director of Professional Relations. Ms. Hipp can be reached at 703 837-1346 or via email at KHipp@aoa.org.

Sincerely,

Kevin L. Alexander OD, PhD

Kevin L. Alexander, OD, Ph.D

CMS Proposed Rule- Medicare Physician Fee Schedule
File Code: CMS-1385-P
Re: PHYSICIAN SELF-REFERRAL ISSUES

We laud CMS attempts to address self-referral issues that are undoubtedly a leading cause of overutilization of imaging services. We have some comments and concerns about specific provisions in the Proposed Rule:

1. **Changes to Reassignment and Physician Self-Referral Rules Relating to Diagnostic Tests (Anti-Markup Provision)**

a) We strongly urge you to impose an anti-markup provision for the TC of medical imaging services. It appears that the best way to do this is with a simple regulation that prohibits billing Medicare for any amount in excess of what was paid by the billing entity. (As you point out in the Proposed Rule, you will need to make the language somewhat more complex to prohibit those who would "game" the system with rent kickbacks and the like.) This removes all profit-motivated incentives to purchase TC. Such a regulation, working in unison with "Stark" prohibition on referral of patients to an entity in which an ownership position is held, would appear to preclude the referring physician from profiting from referrals except by way of the in-office exception.

b) You are proposing in §414.50 that – …."(2) the anti-markup provision for the TC and PC apply to all arrangements not involving a reassignment from a ***full-time employee*** of the billing entity;

Our concern here is with the use of the phrase "*full-time employee*", particularly without defining the term. The term "full-time" can mean many different things to many people and can be twisted in a fashion to skirt the rules.

Ours is a professional radiology practice. We have a number of employed radiologists who are not considered to be full-time employees. Some work as little as 12 hours each week and others work only a few weeks per year. We do not believe it is your intent to disqualify them from being able to reassign their benefits to our incorporated practice, simply because they are nearing retirement or because they are women who choose to work partial schedules while rearing children. We suggest that you alter the proposal to ***exclude only TC and PC furnished by providers who are employed to provide services exclusively to the billing entity***. Thus, you would establish that: (a) the provider must be an employee of the billing entity, and (b) the provider cannot be producing services for more than one billing entity. This accomplishes your purpose, without imposing unwanted constraints on how the physician labor force is contracting for work in the free market.

There is an additional facet to this issue that is somewhat unique to radiology practices, since they are not in a position to refer patients. Many professional

radiology practices have entered into joint venture business arrangements with hospitals to own and operate outpatient medical imaging centers. This is an important trend to allow, since the profits generated by the ventures give financial stability to community hospitals that would otherwise see these revenue streams evaporate entirely as outpatient imaging continues to migrate out of the hospital walls. Due to the corporate practice of medicine doctrine, these joint ventures do not directly employ physicians, but they typically contract with the professional radiology practice to provide the PC for these services. Clearly, the radiologists in the professional practice group are neither "*full-time employees*" nor "*exclusively employed*" by the imaging center to whom they are currently reassigning their benefits for providing these services. Therefore, you need to allow an exception for enterprises located outside of hospital walls, that are jointly owned by radiologists and hospitals, and to which the partial-owner radiologist physicians are exclusive providers of the professional services.

3. **In-Office Ancillary Services Exception**
Your statement that "In sum, these types of arrangements appear to be nothing more than enterprises established for the self-referral of DHS." is right on the mark!

In response to your solicitation of comments, we offer the following possible solution, modeled after the logic of the supervision rules for medical imaging tests. Divide DHS into three or more categories. Possible categories are:

- Assign to one category those services that are of a non-complex nature. (e.g. simple tests exempt from CLIA) These services are eligible for billing to Medicare when provided anywhere.
- Assign to the next category those services that require interpretation by a trained physician, but that do not require patient preparation, do not require expensive equipment (i.e. cost <$250,000 when purchased new) or complex evaluation. (e.g. a CBC or a chest x-ray) These services are eligible for billing to Medicare when provided by a licensed physician in a centralized building.
- Assign to the highest category those services that are most complex and require patient preparation, and/or that do require expensive equipment (i.e. cost >$250,000 when purchased new) and where board certification in a medical or surgical specialty is considered a standard for interpreting the examination.

5. **Unit-of-service (Per-Click) Payments in Space and Equipment Leases**
Your concerns are warranted, as the types of arrangements cited are abusive in nearly every setting. If someone owns equipment, then he needs to compete in the marketplace and try to make a profit. If he is unable to do so, he should not be saved by a false demand that rewards the referring physician financially for having requested a service for his patient. The corollary is that if a referring

physician wants to make profits on imaging, he should do as others have done and be at risk for a capital investment. He should not be rewarded with profits for intermittent referrals when he has no capital at risk.

a) Absolutely, you should prohibit unit-of-service payments to a physician lessor when patients he refers receive services on the equipment that is subject to such a lease.
b) And yes, you need to promulgate a rule whereby it is illegal for a physician to lease equipment from a hospital lessor for use on a patient that the physician has referred. Since we should anticipate that some physicians and attorneys might scheme with a hospital to set up "cross-referral" arrangements, the only sure mechanism to prevent abuse is to entirely prohibit unit-of-service lease arrangements for physicians who are either lessors or lessees directly, or indirectly as owners of a lessee or lessor entity.

6. Period of Disallowance for Noncompliant Financial Relationships

Generally, you could consider setting up two alternatives for defining the period of disqualification, which period should begin within 6 months of the publication of the Final Rule:

a) No trailing period of disqualification- When the parties sign a document setting forth their belief that the arrangement had an appearance of non-compliance, AND they revise the financial arrangement substantially.
b) Trailing three year period of disqualification- Many contracts for services, lease space and equipment leasing have terms of 3 to 5 years. If the parties do not select option a), above, then they must be willing to live with a period of disqualification of three years from the effective date of the options.

11. Services Furnished "Under Arrangements"

We have witnessed in our own local market what we believe to be the type of abusive arrangement described in the Proposed Rule. Referring physicians were invited to invest in a "Services Company" that purportedly leased employees and equipment to an imaging center and provided management services to the center. By virtue of a sliding scale of compensation, the Services Company had more profit to distribute with increased referrals.

Rare would be circumstance that a hospital or a free standing imaging center would need the capital of referring physicians to finance its operations, if it has a solid business model and provides good services. All such arrangements should be considered thinly disguised forms of kickbacks and need to be banned entirely.

Submitted by: Philip J. Russell, South Texas Radiology Group
San Antonio, TX 78229

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ENID
THERAPY CENTER
Physical Therapy & Hand Rehabilitation

08/24/2007

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

Dear Mr. Weems,

I am writing this letter to express my concern regarding the in-office ancillary service arrangements that have impacted the delivery of quality Physical and Occupational Therapy.

- The in-office ancillary services exception has created a loophole which has resulted in many physician-owned arrangements that provide physical and occupational services.
- Patients do not realize they have the right to go to any facility to receive therapy. Rather physicians insist their patients use their facility for therapy, which is obviously a conflict of interest.
- The facilities I am familiar with are understaffed. This leads to group therapy secessions and no time for skilled manual treatments. All resulting in a decrease in the quality of care the patient is receiving and poor outcomes.
- Allowing the in-office ancillary services hurts our practice by significantly limiting the referrals we receive. When we do finally have a referral from one of these facilities, it is the patient with the "poor outcome" we are seeing. The patient is now faced with a much longer rehab due to the poor care received initially.

Thank you for considering these comments.

Sincerely,

Gabrielle Nightingale

Gabrielle Nightingale, PTA

Lynelle E. Fleming P.T., C.H.T.
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GAINESVILLE
PHYSICAL THERAPY
& REHABILITATION SERVICES, INC.

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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 23, 2007

Regarding: **Physician self-Referral Issues.**

Dear Mr. Weems,
I was forced to reduce my hours of practice. I could not pay myself for six months last year and not at all this year due to *the reduction in referrals as a result of the arrival of physician owned clinics.*

Please remove physical therapy from the "in-office ancillary services" exception to the federal physician self-referral laws.

For 21 years I have been in practice in Gainesville, Florida, as a Medicare provider of physical therapy in my community. I bought an existing practice when I let my then employers (two physicians) know that I could not continue to work an employee in a clinical setting where referral for profit might be suspected. The practice was under my control and referrals not medically necessary were accepted. As my employers were not exploiting their clinic, but rather celebrated the quality of care available in a small practice and did not wish to lose my services to the community, they gave me the option to purchase their clinic while one physician retired and the other moved to a rehabilitation center.

I was on my own with no referral base, but over the first decade I successfully practiced my skill and earned a solid reputation as a therapist whose services were sought by word of mouth of patients and by physician recommendation. My practice became a valued alternative to the hospital clinics.

My practice is still a highly valued part of my community. But the birth of physician owned therapy clinics and physician owned corporate entities who have established physical therapy clinics have markedly reduced my opportunity to deliver services. The pressures on younger physicians who have joined forces with group practices are directed to NOT refer patients anywhere but to their in-house facility. We know as a young administrative assistant at a social reception inadvertently blurted out that a particular M.D. who had just joined his office would no longer be allowed to send us patients. We used to see all of his patients.

It means that patients unaware of their freedom of choice to seek physical therapy feel pressured to attend the clinic in which the physician has an economic interest. I am forced to reduce my hours of practice as I hired a young therapist 4 years ago. There was no longer sufficient referrals to keep us both working. I opted to transfer my business to the young man whose future I bright but only if he is able to meet the unfair competition created by the potentially abusive practice of self referral.

Please help keep independent physical therapists practicing. We get only raving reviews and praise from our patients for the quality of services we provide in a setting that is more efficient and welcoming to the community we serve. Please let us continue to deliver quality Physical Therapy.

Sincerely,

Vibeke Vala P.T.

Vibeke Vala, P.T. • David C. Lower, M.P.T. • 1234 N.W. 14th Avenue Gainesville, Florida 32601 • (352) 376-6300 • Fax: (352) 372-0661

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Piedmont HealthCare

August 20, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
PO Box 8011
Baltimore, MD 21244-1850

To Whom It May Concern:

I am a practicing cardiologist at Davis Regional Medical Center and Iredell Memorial Hospital in Statesville N. C. and I use echo contrast agents.

If separate payment for echo contrast agents is eliminated for hospital outpatients I believe it will reduce patient access to echo contrast agents.

Thank you for your time.

John J. Allan, M.D., F.A.C.C.

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August 16, 2007

Mr. Kerry N. Weems
Administrator/Designate
Center for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attn: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Dear Mr. Weems:

I am writing to provide clinician insight on the proposed revisions to payment policies under the Physician Fee Schedule and other Part P payment policies for 2008 Fiscal Year.

I am a physical therapist and upon learning the limitations of this proposed program, I have strong concerns. In particular, my primary concern revolves around in-office ancillary service utilization. In-office ancillary services is so broadly defined in the regulations that abuse of referral arrangements have been and will continue to be created. This loophole provided economic incentive for physicians to own physical therapy practices and subsequently an exorbitant number of these types of practice arrangements have been created. Due to Medicare's referral requirements, physicians presently and will continue to have a captive referral base of physical therapy patients that are Medicare subsidiaries. The real concern with this is that many of these Medicare beneficiaries could be receiving inadequate care or at the very least traveling further than necessary to get to the care that they require. Additionally, the in-office ancillary services exception has not required direct physician supervision and subsequently many physician-owned physical therapy clinics are using the reassignment of benefits laws to collect payment in order to circumvent the "incident-to" requirements.

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I have strong opposition to this and I am concerned about this language moving forward as it was outlined on the July 12, 2007, proposed 2008 Physician Fee Schedule rule. I, along with my partners, who own a private practice in physical therapy would strongly encourage you to take any measures necessary to limit the continued physical therapy abuse of in-office ancillary services.

Sincerely,

Joshua A. Bailey, P.T., D.P.T., O.C.S., C.S.C.S., C. Ped.
Lic. # 2305006068
Co-Owner, Rehab Associates of Central Virginia, Inc.
Site Manager, Timberlake Office

JAB/pat

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UROLOGIC SURGEONS OF NEW ENGLAND, P.C.

STEVEN I. COHEN, M.D., F.A.C.S.
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of Surgery and Urology
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Diplomat, American Board of Urology

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HOWARD I. MILLER, M.D.

SHARON M. FORSMO, PA-C

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

August 21, 2007

RE: Physician Self-Referral Provisions

Ladies and Gentlemen:

As a physician practicing in a state of Rhode Island, 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 patient's lithotripsy and other cutting edge therapies for urologic diseases and other services that would have not been widely available to the Medicare beneficiary without the involvement of urology joint ventures that dramatically expanded patient accessed 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.

The State of Rhode Island, which has absolutely minimal funding for health care for its citizens, cannot afford to fund the technologies of today to deliver quality health care services. It is only through physician consortiums and joint ventures that have shared the fiscal responsibility have we been able to provide quality care of the standards of 2007 to our patients. Rhode Island, being one of the poorer states in reimbursement, the fiscal healthcare climate being extremely poor, the state needing to balance its own budget by further taxation to certain groups of physicians, will not be able to provide quality health care to our citizens currently or in the future.

I implore you not to modify the current Stark Laws any further, as this will have serious and deleterious effects for the citizens of the State of Rhode Island, and I could foresee the same for many other states within this great nation.

Sincerely,

Steven I. Cohen,M.D.,F.A.C.S.

125 Corliss Street, Providence, Rhode Island 02904 • 333 School Street, Suite 208, Pawtucket, Rhode Island 02860 Phone: 401-274-6565 Fax: 401-331-2370
20 Cumberland Hill Road, Room 202, Woonsocket, R.I. 02895 Phone: 401-769-9170

UROLOGY, INC.

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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 C. Carroll, M.D.

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1030 PRESIDENT AVENUE • FALL RIVER, MA 02720 • (508) 646-0066

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6100 Harris Parkway Suite 265
Fort Worth TX 76132
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Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
PO Box 8018
Baltimore MD 21244-8018

August 22, 2007

Dear Sir or Madam,

I am a Urologist in Fort Worth, Texas and am very concerned about certain proposals in the 2008 Physician Fee Schedule. I believe these proposals concerning the physician self referrals will be detrimental to the quality of care I can provide for my Medicare patients. My group raised its own capital to purchase a Da Vinci robot and lithotripsy machine when the hospitals refused our requests to buy them. We believe and studies confirm, that these ventures are more beneficial to the patient's health and healing. Without these joint ventures, we would be unable to offer the best, cutting edge care. Our group has provided these costly services when hospitals refused to do so. What is most important to me, is being able to take care of my patients in the best possible way. If the hospital will not purchase devices that offer the latest and most advanced therapies, then I, and my group, feel it is not just a right, but a duty, to purchase them ourselves. I carry all the liability when a patient comes to me for care, so I feel it is unfair that I would be prevented from offering them better alternatives for therapy with higher success rates than what is offered through the hospital.

I truly believe these anti-physician ownership proposals will have a negative effect on the healthcare system if adopted. These ventures have given Medicare recipients access to effective treatments they otherwise would not have had. I hope you consider what I have written and ponder how your own healthcare would be affected.

Sincerely,

Mark A. McCurdy, M.D.

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

Subject: Medicare Program; Proposed Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Rule

RE: **Physician Self-Referral Issues**

Dear Sir,

I am a licensed Physical Therapist Assistant working in Bergen County, NJ. I have been practicing for 14 years. The past three years I have been working for a physical therapist-owned outpatient clinic. Over the past two years I have also been marketing for this company, which has given me a negative prospective on physician-owned physical therapy.

I have been going around to physicians in Bergen County, NJ and Rockland County, NY marketing for my company and have some examples of what I have heard regarding physician-owned physical therapy clinics. Many of the employees in these physician's offices comment on how their doctors will not "give up any of their physical therapy patients" and "they want to keep them all because the doctors are complaining that their physical therapy is slow, we would love to send patients to your company but are told we can not".
I asked a large orthopedic group if I could come in and meet with the doctors to review my company, locations and benefits. I was told they were not allowed to have other physical therapy companies come in anymore because when we do their physical therapy numbers drop. There is a doctor that has his name and physical therapy under it as if he were the treating therapist which he is not. I currently work with many fantastic physical therapists that do not get the opportunity to help these patients that need it secondary to referral for profit situations.

Thank you for taking the time for my comments on physician-owned physical therapy.

Sincerely,

Laura O'Dea PTA

Laura O'Dea, PTA

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cross creek
physical therapy

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: *Physician Office PT/OT Services*

Dear Mr. Weems;

I am writing this letter to express my concern regarding the in-office ancillary service arrangements that have impacted the delivery of quality Physical and Occupational Therapy. I operate a stand alone practice just south of Memphis, TN. A large number of my patients are referred by specialists in the Memphis area.

- I have seen a recent explosion of in-office ancillary clinics in the Memphis area, in the past few years. The majority of these clinics are not convenient to the patient. They also are typically less equipped staffing, space, and equipment wise than a stand alone PT clinic. I know of two offices in Memphis, where the PT is no bigger than a MD exam room, and the patients receive gait training in the hallway of the billing office. Often these patients are post surgical, and rely on transportation by others to get to these offices.
- Over this time period I have been informed by many prior and current patients about the difficulties they had to overcome by having to return to the Doctor's office for PT services. I have seen and heard the over-utilization that occurs. I also know that patients are often not aware of their right to seek PT services elsewhere or are influenced by their physician to see their in-house

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services so the doctor can keep a "better eye on things." I have been doing this for 9 years and I have never had a case that required immediate MD attention or that could not be taken care of with a phone call.

I truly believe that this is one the most detrimental things in my realm of practice to offering our community access to quality PT services performed by quality clinicians. Referrals to PT should be based on what is best for the patient, not what is in the financial interest of the referrer. As PT's we strive to operate under the ethical guidelines by the American Physical Therapy Association which prevents us from accepting referrals from a source that has an incentive to refer other that the patient's best interest. I think these in-house services allow MD's to take advantage of the trust that the patients place in them.

Thank you for considering these comments.

Sincerely,

Dano Napoli MPT

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August 21, 2007

Mr. Kerry N. Weems
Administrator – Designate
Centers for Medicare and Medicaid Services
US Dept. 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:

My name is Matt Strayer and I am a Physical Therapist practicing in Bryan, Ohio. I would like to comment on the proposed 2008 Physician Fee Schedule Rule, specifically the "in-office ancillary services" exception as it relates to physical therapy.

I have been employed as a Physical Therapist for 17 years. The first 16 years I worked in a hospital setting including in-patients, but primarily dealing with out-patient orthopedics. One year ago I took a position as Director of a Physical Therapy Department located within a multi-specialty physician group practice. Having practiced in both settings, I feel that I can provide some insight into the working relationship and standards of both types of practices.

I have been solicited by the American Physical Therapy Association (APTA), of which I am a member, requesting that I offer comments on the pending legislation. My opinion, however, differs from that of the APTA. The APTA supports removal of Physical Therapy as a designated health service permissible under the in-office ancillary exception of the federal physician self-referral laws. I would argue for the opposite.

Several factors lead to my position. The presence of the Physical Therapy Department in the same proximity/location of the physician's office allows for the therapist to collaborate more easily with the physician regarding individual patient cases and the economics of consolidating costs allow for services to be provided at lower costs than if those individual services were provided at separate locations. Also, the combined resources of this medical clinic have allowed us to provide a dedicated therapeutic pool, a service that was previously not available in this community. All of this is directed at producing the best quality of care in the best interest of the Medicare beneficiary.

I disagree with the APTA's insinuation that abusive financial arrangements are inherent to physician owned physical therapy services. In fact, there are oversights and policies in place to prevent such practices. From my perspective, privately owned physical therapy practices are as likely to attempt to defraud the system.

All patients have the right to receive treatment at the location of their choice. Competition among providers is what keeps costs under control and motivates therapists to provide better service. We offer a quality service and patients have elected to come here for therapy for that reason. They should not be denied the opportunity to choose where they want to receive services. This then becomes discriminatory against those of us who work in clinic environments.

Sincerely,

Matthew L. Strayer, PT

MLS:rkm

cc: Congressman Paul E. Gillmor
American Physical Therapy Association

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HARADA Physical Therapy & Rehab Services Inc., P.S.

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August 22, 2007

Mr. Kerry N. Weems
Administrator – Designate
Centers for Medicare and Medicade Services
U.S. Department of Health and Human Services
Attn: CMS-1385-P
PO Box 8018
Baltimore, MD 21244-8018

Physician Self-Referral Issues

To Whom It May Concern:

I am a physical therapist in the State of Washington and am concerned about the loophole in the Stark law concerning physical therapy services as an in-office ancillary service. The way it is currently interpreted, a physician may own a physical therapy practice and refer patients to it if it is in their same office. This allows the physician to bill physical therapy under their fee schedule.

At first glance, this does not seem to be a problem. However, since the physician can determine the number of visits and frequency a physical therapy patient is seen, there is a possibility of over utilization to make more profit with more visits. Also, physicians can insist on the patient coming to see their therapist even though there is a more convenient clinic closer to the patient's home. This happened to my friend who had a total hip replacement and she felt obligated to go to his therapy clinic over 55 miles away twice a week.

I do not believe most physicians would do the above but I hope you can see the conflict of interest that presents itself. Please support the removal of physical therapy services being used as an in-office ancillary service.

Thank you for your attention to this matter.

Sincerely,

Steve N. Harada, PT

Urology Associates of Wisconsin S.C.
Scott C. Kolbeck, M.D. • Omar Atassi, M.D. • Matthew S. Anderson, M.D.
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August 22, 2007

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

RE: July 2, 2007, Medicare Physician Fee Schedule Proposed Regulations

To Whom It May Concern:

I am a urologist in private practice in Wisconsin. I practice mainly at Theda Clark Medical Center in Neenah, Wisconsin, and New London Family Medical Center in New London, Wisconsin. I am an owner in a joint-venture partnership that provides lithotripsy services and also am an owner in another joint-venture partnership that offers benign prostatic hyperplasia treatment with a laser. I have been involved with the lithotripsy service for about ten years and with the laser service for about two years. I found this to be very beneficial in providing quality of medical care and approved patient access to our patients including Medicare patients. Quality assurance and outcomes data are available and appreciated. These services have been especially valuable at New London Family Medical Center, which is a rural hospital that would not otherwise have this technology available. Prior to these joint ventures, my patients would have to be transferred to a larger hospital for treatment. I am quite concerned about the new provisions that are being proposed. In particular, I am concerned about the Under Arrangements Proposed Rule and the Per Procedure Proposed Rule.

Our partnership's contract with the area hospitals allow us to treat patients close to home and allow us to keep up with the ever-changing technology that is available. As a joint venture, we are able to upgrade and change technology as it becomes available which would be less likely to occur should a hospital invest significant capital in equipment that could quickly become outdated. In addition, the joint venture allows us to have technicians available that have excellent experience and this experience could not be gained if the equipment was owned by the hospital, as the volume would be significantly less for the technician to acquire the experience necessary to perform his job in an efficient and competent manner. The mobile vendors are especially crucial in providing great access to patients in rural settings, such as New London. In this way, they lower the hospital costs by sharing expensive equipment among many hospitals.

Because of the American Lithotripsy Society vs Thompson case, lithotripsy is not a designated health service (DHS) under Stark, and thus our Partnership cannot be deemed to be performing a DHS or causing a claim to be submitted for a DHS. Also, I believe it should be clarified that services that are not DHS when performed outside of a hospital, (e.g., lithotripsy and BPH laser), likewise cannot be DHS service if they are deemed directly performed by our Partnership. Thirdly, CMS is concerned that physician-under-arrangement contracting results in over utilization and higher cost to the Medicare program. I believe that these services are therapeutic and not diagnostic. The underlying medical condition can be objectively determined, such as a kidney stone or large prostate with symptoms so there is no risk of over-utilization. Finally, lithotripsy and

BPH laser treatments are not like diagnostic testing with its higher risk of over-utilization based on the subjective judgment of the physician ordering the tests. A new rule should only apply to potentially abusive diagnostic tests and not beneficial therapeutic ventures with no risk of over-utilization. It should be noted that Stark legislative history indicates congress clearly intended under their arrangement contracting to only require a compensation exception and not an ownership exception.

The Per Procedure Fee Prohibition proposal would also have a negative effect on the health care system. Hospitals are risk averse and they don't often appreciate the benefits of new technology and are not willing to take the risk of purchasing new equipment or leasing them over the long term. This is especially true in smaller hospitals where volume is an issue. As physicians, we understand the benefits of new technology and are willing to accept that risk. Congress clearly wished to preserve Per Procedure Fees in the Stark legislative history and CMS should not contradict congressional intent through a prohibition of such fee arrangements.

In summary, I ask the 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. Our joint ventures I have been associated with concerning lithotripsy and laser prostate surgery have broadened access to new technology for the Medicare patients in my community, brought needed efficiency to the market, and have no doubt, saved the CMS money in the long run. For example, what used to be a two to three day stay in New London Hospital for prostate surgery is now an outpatient procedure. As CMS tries to stop abusive arrangements, it would be a great mistake to jeopardize such time-tested and proven models that have benefitted hospitals and patients.

Thank you for your consideration.

Sincerely,

Scott C. Kolbeck, MD

SCK/jdk

Madison-Scott Physical & Occupational Therapy

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Mr. Kerry N. Weems,
Administer – Designate
Centers for Medicare and Medicaid Services
US Department of Health and Human Services
Attention: CMS-1385-P
PO BOX 8018
Baltimore, MD 21244-8018

Tuesday, August 21, 2007

Dear Mr. Weems,

I am a physical therapist who has been in private practice in NY and NJ since 1997. In that time, I have had the opportunity to treat and speak with thousands of patients, in and out of the Medicare system, with regards to various changes in the healthcare system.

Our physical therapists provide a significant value in our services to patients in that we make every effort to make the patients self reliant, accountable for their self care and independent in function as soon as they can safely do so. The 2 comments that I hear most often from patients is that we provide 'true individualized physical therapy' as opposed to a one size fits all rehab program. Second is that they were able to limit the number of visits as compared to prior experiences.

Lately, however, patients have not even had the opportunity to test out our services because of an increase of physician owned physical therapy practices. Physicians who own physical therapy practices, or who employ PT's in their facility, will not allow patients to go elsewhere for their care. In the past 7 months alone, I have had more than 12 incidences where a physician either withheld a referral, threatened that they will not follow up with the patient if they go outside the physicians office for therapy, or provide services such as 'free massages' camouflaged as physical therapy, all for financial gain for the doctor.

While we can argue who provides "better" therapy or medically appropriate therapy, we cannot argue that if a patient requests to go to a specific physical therapist because of a recommendation, prior experience, or simply geographical convenience, they should be allowed to do so.

Because of Medicare referral requirements, physicians have a captive referral audience of patients in their office. Patients are never given the opportunity to be evaluated by independent practitioners. Physical therapists are highly educated and trained in identifying musculoskeletal dysfunctions. Almost all of the recent graduates are earning doctoral degrees and many past graduates are continuing their education at the doctorate level. Physician direct supervision is not needed to administer physical therapy. New

Madison-Scott Physical & Occupational Therapy

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York State became the 43rd state in the union to allow direct access to physical therapists for 10 visits or 30 days, whichever is least, where patients can eliminate the time and expense of going to their pcp to simply get a referral for physical therapy. An increasing number of physician owned physical therapy clinics are using the re-assignment of benefits laws to collect payment in order to circumvent 'incident - to' requirements.

Thank you kindly for allowing me the opportunity to express my experience of the changes and impact that physician owned physical therapy offices have had on our patients and our community. Lets end this potential for fraud and abuse close the loopholes in the physician self-referral, and improve the quality of patient care.

Sincerely,

Mark

Comprehensive Physical Therapy & Rehabilitation Services

PRAMOD BHANTI, P.T., C.Ped.
Clinical Director

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Telephone: (631) 878-1771
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August 22, 2007

Mr. Kerry N. Weems, Administrator-Designate
Center 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 independent practice since 1987. After working in a reputable Rehab Center and two major Tertiary Care Centers for ten years, I started my own state of-the-art practice in Center Moriches, New York in 1993. Due to my dedication towards my profession I designed a custom built facility to provide excellent care to the residents of my community. I can claim with certainty about my practice being the most modern in Eastern Long Island.

I am sending this letter to you because of my serious concerns over the Physician Self Referral Issues. As an independent physical therapist for past 20 years, I have seen the paramount fraud and abuse going on where the physicians are able to refer the Medicare beneficiaries to entities in which they have financial interest, especially in the case of the physician-owned physical therapy services. In my small town of Center Moriches in past few years I have seen physicians have opened offices with in yards of my facility only to refer patients to them. These are the physicians who never had any referral for physical therapy for as long as I have known them. Because of Medicare referral requirements, physicians have a captive referral base of physical therapy patients in their offices. There is no need for physician's direct supervision to administer physical therapy service. In fact, an increasing number of physician-owned physical therapy clinics are using the reassignment of benefits law to collect payment in order to circumvent "incident to" requirements. In past year alone I have seen more than fifty percent decline in my patient load and now I am finding it hard to survive. I feel by eliminating physical therapy as a designated health service furnished under 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.

Thank you very much for your consideration.

Sincerely,

Pramod Bhanti, PT

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Jackson State
COMMUNITY COLLEGE
A Tennessee Board of Regents Institution
2046 NORTH PARKWAY JACKSON TN 38301-3797

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 Sir:
I am writing in regard to **Physician Self-Referrel Issues**. I am a physical therapist in Jackson, TN. As an educator, a clinician, a member of the Board of Directors of the Tennessee Physical Therapy Association, and a concerned citizen I am writing to comment on the July 12 proposed 2008 physician fee schedule rule. I am specifically interested in the physician self-referral issue and the "in-office ancillary services" exception. I feel that the current state related to both of these is abusive of physical therapy services and I strongly support the removal of physical therapy services from the permitted services under the in-office ancillary exception.

I have lived and worked in the rural West Tennessee area for many years. I have seen the problem related to physician owned physical therapy services grow to a point of significant compromise of patient autonomy in this area. I personally have had patients removed from my services by their physicians insisting that their physical therapy care be provided by the therapy services within that physician's office. The patients in this geographical area, unknowing or unsure of their freedom of choice, most often follow this dictation of their referring physician compromising insurance coverage, travel constraints, and, often unfortunately, therapy outcomes. I feel that CMS must address this issue and finalize the Stark Phase III regulations.

I praise CMS for recognizing the abusive practice related to the current physician self-referral laws and encourage you to take further actions for the sake of the patients' rights.

Sincerely,

Jane David

Jane David, PT, DPT TN #PT930
PTA Program Director

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August 21, 2007

Mr. Kerry N. Weems
Administrator – Designate
Centers for Medicare and Medicaid Services
US 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 of Letter: Physician Self-Referral Issues

Dear Mr. Weems,

I am a board certified orthopedic physical therapist, and I have been in private practice for the past 14 years. I obtained my undergraduate degrees (BS, PT) from Cleveland State University and my clinical doctoral degree from Andrews University of Michigan. Additionally, I am certified in orthopedic manipulative therapy.

I am proud of the fact that my partners and I have refused to participate in physician owned physical therapy opportunities. Clearly, numerous scientific studies have demonstrated that such arrangements have resulted in increased costs and at the same time decreased quality while additionally limiting rehabilitation options to the Medicare consumer. Throughout the past four years, our company has declined at least 7 such opportunities. Prior to 2003, we were not approached once, but the loopholes in the existing in-office ancillary services exception to the physician self-referral laws has created a thriving environment for such arrangements.

In fact, it would appear that there are nearly no circumstances in which a physician can have ownership in his own physical therapy clinic. On July 20, 2004, several colleagues and I had contacted the Office of Inspector General (OIG) when a local Orthopedic Physician group had appeared to be in obvious violation of the building requirements described by phase I and Phase II of the Stark Regulations. This group practice opened their own physical therapy center, which was located off site. There was no active number at the externally located office and the physicians were never on-site.

We were quite impressed when an OIG investigator had contacted us for an interview that was performed on September 15, 2004. Throughout the next 2+ years we had corresponded with the investigator who thought this was an obvious violation, but ultimately the physicians were exonerated of all charges subsequent to the exceptions created in the physician self-referral laws.

Since the opening of the physician owned therapy center, the physician's practice has demonstrated a gross neglect of their patient's rights. We have been informed by numerous

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patients that they were not given the option of receiving services off site. In fact, several patients have informed us that they had actually requested our services, but were denied the privilege. Prior to the physicians opening their center, 18% of our referrals were from this group. Since the physician's opened their center, their percentage has declined to less then 1% (patients who have been treated by us in the past and who are adamant about receiving therapy at our center). Regardless of the fact that we offer services for substantially less then the physician's office, and our staff is far more qualified offering certified Hand, Manipulation, Lymphedema, McKenzie services, and our centers are open from 7am to 8pm with weekend services while the physician's office is closed at 5pm with ½ days on Fridays and Tuesdays, we will not receive one referral from the group unless the patient insists on our services.

As you know, most patients place their trust in their physician and are very concerned with offending their physician; hence, the great majority will follow their doctor's advice. Subsequently, such arrangements will have a negative impact on competition and quality of care. As important, costs for therapy services will continue to rise as competition is eliminated.

Would you please consider removing physical therapy as a designated health service (DHS) permissible under the in-office ancillary exception of the federal physician self-referral laws.

Thanks very much for the consideration given to my request.

Sincerely,

Michael Martinez, PT, DScPT, OCS, CMPT, COMT

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August 17, 2007
Re: Physician Self-Referral Laws

Mr. Kerry N. Weems
Administrator Delegate
CMS
US Dept. of Health Services
Attn: CMS-1385-P
PO Box 8018
Baltimore, MD 21244- 8018

Mr. Weems,

I would like to echo the concern by the American Physical Therapy Association and Illinois Physical Therapy Association regarding referral-for-profit situations in physical therapy (as well as in other diagnostic and laboratory situations). As a member of both organizations and staunch supporter of the physical therapy profession, I believe that physician-owned therapy clinics have led to significant adverse issues within the physical therapy field and are a threat both to the consumer and insurance industry. I also believe that referral for profit relationships undermine the profession of physical therapy by asserting a controlling influence over the physical therapist by restricting job availability and independent practice.

Over the past 10 years of practice I have witnessed every major orthopedic practice as well as many large podiatry/family practice clinics open their own physical therapy sites. Each clinic has taken a stance of prioritizing a referral to their own clinic with occasional oblivion to several key issues typically critical to the consumer. It is this disregard to patient welfare and rights, along with the concern for the physical therapy profession as a whole, which prompts this letter.

There are many items of concern to the patient seeking physical therapy but of immediate concern is convenience (hours and location) as well as clinical expertise. When the patient is offered no choice where to attend therapy, patients are often obliged to travel longer distances (at a higher personal cost) to therapy appointments while there are other in-network providers much closer to home.

In addition, many physician-owned clinics in our area are not open at hours convenient to the patient but instead convenient to the physician staff. Therefore, the patient often has to carve time out of work to attend therapy. Many physician practices no longer provide the patient either a list of potential clinics in their area or a list of clinics accepting their insurance so that they may make an independent decision. Therefore, it is expected that the patient will attend therapy at the only clinic suggested by the physician: the physician-owned-physical therapy clinic. Often, there is less than full disclosure that the referring physician has a financial investment in the therapy clinic.

Ultimately, we all want the best available healthcare possible. When the patient is given direction to only attend therapy at a physician-owned clinic, clinical expertise does not necessarily factor into the decision. Ultimately, when referral "capture" is not in question, it largely benefits the physician practice to lower salary costs with less skilled care. The most skilled and experienced therapists, whom often do not work for the physician, instead rely on referrals based on patient satisfaction and outcomes over a long period of practice. Unless the therapist is prepared to endure the risk associated with continued employment in a private practice, hospital or company operated outpatient site, the safer employment haven is in a physician-owned practice. This is directly related to the control wielded by the physician in directing referrals to their own therapy clinic.

In some ways, I believe referral-for-profit threatens a free market society where the consumer and the physical therapist are able to choose based on their own inherent values and needs. The right to choose a provider is largely taken away from the consumer when a treating physician specifically indicates their own clinic as the preferred or only choice for physical therapy. The physical therapist is backed into a corner in selecting a position with the referral for profit clinic due to job stability and a shrinking job pool.

Many patients are afraid to speak up or are unaware of their rights to seek physical therapy wherever they wish. In addition, many are unaware of the financial incentive for the physician to suggest care at a particular clinic. Most patients would be unable to champion the cause of eliminating physician-owned-physical therapy practices without further grasping the inherent threat to the physical therapy profession and consumer cost. Most physical therapists are reluctant to speak up about referral for profit for several potential reasons: forfeiture of job security as an employee of this type of practice, fear of physician backlash as the physician ultimately directs the referrals.

What is the real danger in physician-owned-physical therapy clinics? The price of healthcare services is potentially driven higher by several issues: increased and unecessary referrals, higher cost per service, and extended visits/referral to physical therapy. I believe it to be self-explanatory that there is always the potential for impropriety in unnecessary referrals to physical therapy, laboratory, or diagnostic sites where the physician has a vested financial interest. The higher cost per service issue is fairly simple to understand as well and not dissimilar from any other market. When the number of choices for a service is diminished, the cost for the same service can be driven up. This cost is carried to the patient and insurance industry for the benefit of – you guessed it – the referring physician. Ultimately, either the physical therapist or physician should be able to determine whether the patient has met a point of maximal improvement with rehabilitation. When the check and balance system is eliminated (as is the case when a physical therapist garners a salary, bonus incentive or profit sharing plan from the referral source) there is the potential for extending therapy beyond what is truly needed.

I have seen and heard many points of rebuttal from the AMA and physicians regarding the effectiveness and legitimacy of referral for profit clinics. These have included, among others, greater control over the quality of care rendered to the physician's patient and direct oversight of the treatment rendered (as the physician is theoretically on-site).

In this region, this greater control is characterized by greater utilization of support staff including physical therapy assistants and certified athletic trainers rather than more educated physical therapists.

In a landscape without referral for profit clinics, the physician would still have the ability to monitor quality of care rendered through patient outcomes, patient feedback and direct communication with the clinic where the patient was referred. This would be no different than the methodology utilized when a physician chooses to refer a patient to a physician specialist (i.e. family practice referral to neurologist). The referring physician, although lacking direct control over the care rendered by the specialist, always has the option of discontinuing future referrals if dissatisfied.

Physicians often argue that direct oversight of the treatment is a key benefit to the patient attending a physician-owned clinic. This argument is pure fantasy. The physician offices are often down a different hallway, on a different floor or, more recently, at an off-site location. One can romanticize that the physician will make multiple trips into the therapy clinic each day to check on the progress of the patient or speak personally to the therapist each week. This simply does not happen. Under the current Stark self-referral law, physicians are even opening physical therapy clinics in locations where they do not see patients. In this case, billing is set under the therapist name but then benefits are assigned back to the physician in ownership control. I would believe to be difficult to directly oversee patient care when you do not even have an office in the same town.

I must recognize that there are many good physicians who operate therapy clinics and there are many physicians who have passed on the golden opportunity to capitalize on the Stark law loophole. That is truly not the point. The potential for fraudulent practice through unnecessary referrals and higher health care costs, the restriction of trade, and the lack of concern for patient welfare is the point! I do not truly fault physical therapists that work in this environment. When your employment is dictated by physician referral, there are many less positions available outside of the physician-owned-practice. I truly believe that many of these therapists would enjoy greater career advancements, autonomy, and financial remuneration if able to pursue endeavors independently. When held to the ethical standard of choosing the most appropriate care for the patient, one would have to assume that the physician would direct the patient to the same physical therapy clinic or therapist no matter the circumstances of finances. I believe this ethical standard is being breached with regularity.

The vision of the American Physical Therapy Association is of autonomous practice for all physical therapists. Truly autonomous practice, even for a profession with doctorate-level education and advanced clinical degrees or certifications, is a virtual impossibility in the current landscape of referral-for-profit clinics. As long as physicians can direct referrals for personal benefit, the careers and jobs of all physical therapists (no matter the current place of employment) are at risk. Therefore, the greatest threat to the physical therapy field may be the same physicians in which each patient places trust to direct their physical therapy treatment. Despite the ongoing advancement of the field of physical therapy, the individual physical therapist has become less of a health care partner and

more of a servant to the physician's financial portfolio in the presence of the referral-for-profit physical therapy concept.

Although my personal concern is related largely to referral for profit as it impacts the field of physical therapy, one must also examine diagnostic and laboratory services. Recently, referral for profit irregularities were raised by Illinois Attorney General Lisa Madigan for several MRI centers in Illinois. These irregularities were brought to the forefront by multiple articles in the Chicago Tribune. I truly believe that these improprieties should shed light on the potential for suspicious behavior in other referral-for-profit venues such as physical therapy.

Coincidentally, I heard of a recent report of AMA opposition to physician practice within large chain stores due to the potential referral for profit to the pharmacy at the same location. How can the AMA stand on both sides of the referral for profit issue? Simply put, AMA opposition stops when the physician is pocketing the potential profit.

As a final illustration, I would propose that we present the following scenarios for consideration to the typical consumer and draw parallels to the current exception to the federal physician self-referral laws.

- Ford Motors collaborates with an individual oil company (ie BP) forcing the consumer to buy gasoline and receive maintenance at only these locations. As the consumer has no other options, the cost of gasoline and maintenance services escalates without competition. Other car manufactures and oil/car maintenance companies rush to ally themselves similarly thereby forcing established mechanics to work for the motor companies rather than depend on their previous reputation and quality of work.
- A patient is referred to a specialist well away from her home. Upon seeing the specialist, a physical therapy referral is generated but the physician office writes this on a prescription pad for the physician-owned clinic. The referral coordinator tells the patient that she should go to therapy where the doctor suggests, knowing full well that it is a one hour commute each way for 3 visits/week. After several weeks, the patient calls her insurance company to enquire about a clinic close to home and transfers. When the patient sees the physician again for a follow-up appointment, the physician expresses discontent that the patient is not attending therapy at the first clinic and suggests she transfer back.

Ultimately, I feel that each physical therapist should be able to freely choose the nature of their employment whether it be private practice, hospital based or other environment without worry that a fellow professional will potentially undermine their employment or career opportunities or place their profession in such turmoil. Finally, the patient should be able to freely choose a provider for medical treatment such as physical therapy by what means they see fit: convenience, expertise or prior experience. This freedom should not be inhibited in any way.

As you may realize, I have very strong feelings regarding how referral-for-profit impacts physical therapy. On three separate occasions, I have spurned offers from physician-owned practices that would have afforded me greater job security at the cost of my personal views regarding ethics in physical therapy practice and my belief in autonomous practice. Despite my strong feelings, I can not truly indicate my practice affiliation nor sign this document. I dare not personally affix my name due to the fear of negative backlash within the local physician community. Threatening behavior was described during the recent legislative efforts by physical therapists in South Carolina and there is no reason to believe that there would be a different reaction in Illinois. Such vehement and threatening responses should indicate how much revenue physicians stand to lose from forfeiting a self-directed revenue stream. Sadly, it also indicates how many physicians believe they should **control** the practice of physical therapy and the careers of physical therapists.

A concerned physical therapist
McHenry County, Illinois

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August 22, 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
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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 American Association of Physicists in Medicine (AAPM) is pleased to submit 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.

AAPM's mission is to advance the practice of physics in medicine and biology by encouraging innovative research and development, disseminating scientific and technical information, fostering the education and professional development of medical physicists, and promoting the highest quality medical services for patients. Medical physicists contribute to the effectiveness of radiological imaging procedures by assuring radiation safety and helping to develop improved imaging techniques (e.g., mammography CT, MR, ultrasound). They contribute to development of therapeutic techniques (e.g., prostate implants, stereotactic radiosurgery), collaborate with radiation oncologists to design treatment plans, and monitor equipment and procedures to insure that cancer patients receive the prescribed dose of radiation to the correct location. Medical physicists are responsible for ensuring that imaging and treatment facilities meet the rules and regulations of the Nuclear Regulatory Commission and various State Health Departments. AAPM represents over 6,700 medical physicists.

AAPM recommends that CMS more closely examine the impact of all 2008 Medicare Part B payment policies for radiation oncology, including medical physics services. Continued reductions for some practice expense relative value units (RVUs) combined with the forecasted decreases in the annual update factor could have a major impact on the provision of radiation oncology and related procedures to Medicare beneficiaries in the freestanding radiation oncology center setting.

Resource-Based Practice Expense Relative Value Units (PE RVUs)—Methodology & Impact to Medical Physics Codes

Major changes to the practice expense methodology for 2007 were discussed in the June 29, 2006 proposed notice and December 1, 2006 final rules. CPT 77336 Continuing Medical Physics Consult has significant practice expense RVU reductions under the new "Bottom-Up" practice expense methodology. CPT 77336 has an additional 18.3% reduction from 2007 to proposed 2008 practice expense RVUs and a 62.2% reduction in 2010 practice expense RVUs at the end of the transition period (see Table 1).

Table 1 Practice Expense Reductions in Medical Physics Codes

CPT Code	2006 PE RVU	2007 PE RVU	2008 Proposed PE RVU	2010 Proposed PE RVU	2007-2008 PE RVU Percent Change	2006-2010 PE RVU Percent Change
77336 Continuing medical physics consult	2.99	2.52	2.06	1.13	-18.3%	-62.2%

The current practice expense inputs for the medical physics consultation code 77336 are outdated and incorrect. This code was last reviewed by the PEAC/RUC in 2002 and the practice standard has changed significantly. For example, the intraservice work described in the weekly medical physics consultation code (CPT 77336) describes only the medical physicist work of reviewing medical charts. Today, the intraservice work of a medical physicist includes review and analysis of medical physics aspects of changes to the treatment regime, consultation on patient setup and treatment modifications, verification of dose calculation data, accuracy of the current data record, including review of patient specific therapist treatment and technical notes, and patient radiation safety. The work effort is ongoing throughout the week and the entire course of therapy. The complexity and time requirement of the work has increased significantly as the complexity of radiation therapy has increased, as the consistent precision of daily patient positioning has become critical and as the target doses have increased more closely to the tolerance level of adjacent normal tissue.

Further, the one-year impact of all the CMS Physician Fee Schedule proposals results in a 25% reduction of payment for CPT 77736 Continuing Medical Physics Consult in 2008 (see Table 2). A large decrease in RVUs leads to significant reductions in reimbursement, which could result in the disastrous end effect of poorer quality and safety of treatments for those cancer patients undergoing radiation therapy.

Table 2 Total Reduction in 2008 Payment for Medical Physics Codes

CPT	2007 Payment	2008 Proposed Payment	2007-2008 Proposed Percentage Change
77336 Continuing medical physics consult	$101.57	$75.80	-25.4%

Although there is medical physics work implicitly included in the valuation of 28 other CPT codes in the 77XXX series in radiation oncology, the work described in 77336 is a separate, distinct and necessary service provided to individual patients. Appropriate valuation of the cost of these services is essential to assuring that patients who are undergoing cancer therapy will continue to receive the complete process of care for this disease. If the value of these codes continues to drop significantly as they are slated to do under the new practice expense methodology, staffing levels of medical physicists will drop proportionately. If medical physics work is not adequately compensated, the cost of hiring Qualified Medical Physicists will be difficult to recover by freestanding facilities.

Shortages of Qualified Medical Physicists will result in decreased availability for consultations with radiation oncologists on many of the new, complicated procedures for the precision delivery of radiation therapy, such as intensity modulated radiation therapy (IMRT), image guided radiation therapy (IGRT), stereotactic radiosurgery (SRS), and stereotactic body radiation therapy (SBRT). Some cancer clinics may have to delay or forgo such high-tech therapies.

Further, the "unintended consequences" of reducing the value of medical physics CPT codes may be an increase in the misadministration rate of radiation therapy doses to cancer patients in this country since there will not be adequate Qualified Medical Physicists to intervene for prevention of these errors.

The ultimate victim of this payment policy is patients needing quality care for their cancer treatment. Qualified Medical Physicists are responsible for accurate delivery of radiation dose to patients to be consistent with the radiation oncologists' prescription. Our patients will suffer, and the cost of correcting for misadministrations of radiation therapy will drive up health care costs, if quality medical physics services are not available.

AAPM recommends that CMS review and refine the direct practice expense inputs for the Continuing Medical Physics Consult code 77336 so that accurate salary and time data for medical physicists can be assigned to these codes for 2008.

Resource-Based PE RVUs—Equipment Usage Percentage & Interest Rate

In the 2008 proposed rule, CMS acknowledges that it does not have sufficient empirical evidence to justify a change from its current assumption of a 50% utilization rate for imaging equipment. Some analysts cite a 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. The MedPAC survey was not nationally representative and did not examine all types of equipment usage, only CT and MRI.

AAPM supports CMS's decision to maintain the usage assumption at 50% until sufficient empirical evidence justifies an alternative proposal.

In addition, CMS states its intention to maintain the interest rate on equipment at 11%, following their analysis of revised Small Business Administration data. AAPM concurs with the use of this data for verifying assumptions about the actual interest rates faced by physician offices and freestanding radiation oncology centers.

AAPM supports CMS's decision to retain the interest rate assumption used in the calculation of equipment costs at 11%.

Malpractice

Malpractice RVUs are reviewed by CMS at 5-year intervals. CMS notes that there are some technical services that have assigned malpractice RVU values that have never been part of the review process. Consequently, the malpractice RVUs assigned to these technical services have not been revised since their initial assignment. CMS states that the reason these services have never been reviewed is directly linked to a lack of suitable data on the cost of professional liability insurance for technical staff or imaging centers. CMS states that more information is needed from the affected community to ensure that any changes made to malpractice RVUs are resource-based.

Medical physicists, due to their key role in the design and quality assurance of high-risk radiation therapy procedures, have a significant liability exposure, and so liability insurance is normally carried by the medical physicist's employer or by the medical physicist if self-employed. Typical policies are valued at $1Million Individual / $3Million Aggregate coverage.

The AAPM Insurance Committee is studying this issue and would be happy to provide data to CMS later this year, upon request. It is important that the cost of medical physicist's professional liability insurance be captured in the resource-based malpractice RVUs for technical services.

AAPM supports CMS's decision to obtain more information and data from the affected community before proposing changes to the malpractice RVUs for technical services.

Impact—Sustainable Growth Rate

The proposed rule indicates that payment rates for all 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.

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 not viable 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 patients. Further, the current formula does not account for the costs and savings associated with new technologies. The current SGR formula must be replaced with one where payment updates keep pace with practice cost increases.

CMS should 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 and take into account Medicare Part B savings associated with new technologies.

Further, CMS had the option of using the $1.35 billion Physician Assistance and Quality Initiative Fund to help offset the negative 9.9% update but chose to use the funds for the Physician Quality Reporting Initiative. Financing for quality reporting should come from a distinct, separate financing mechanism that is outside of the budget neutrality provision and focused solely on the improvement of health care quality.

AAPM supports the use of the $1.35 billion Physician Assistance and Quality Initiative Fund to help offset the negative 9.9% annual update for 2008.

Conclusion

Appropriate payment for radiation oncology procedures and medical physics services is necessary to ensure that Medicare beneficiaries will continue to have full access to high quality cancer treatment in freestanding radiation oncology centers. The effect of multiple proposals on the technical component and global payment for radiation oncology procedures could be devastating to freestanding radiation oncology centers that provide cancer care to Medicare beneficiaries.

We hope that CMS will take these issues under consideration during the development of the 2008 Physician Fee Schedule Final Rule. Should CMS staff have additional questions, please contact Wendy Smith Fuss, MPH at (703) 534-7979.

Sincerely,

James Hevezi

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Chair,
Professional Economics Committee

James Goodwin

James Goodwin, M.S.
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August 23, 2007

Herb Kuhn
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Department of Health and Human Services
Attention: CMS-1385-P
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Re: July 2, 2007 Medicare Physician Fee Schedule Proposed Regulations

Dear Mr. Kuhn,

I am the President of a 21 Urologist Single Specialty Group practice in Lexington, KY. We have a very large Medicare and Medicaid population in our practice as our patients come from not only the prosperous central Kentucky area but the extreme poverty areas of rural eastern Kentucky and Appalachia as well. We treat all patients in our practice regardless of insurance status. The proposed changes to the physician fee schedule rules published on July 2, 2007 that relate to the Stark self-referral rule and the reassignment and purchased diagnostic rules if implemented will have a devastating effect on our patients and our practice.

As you may recall, I have met with you in your office in the Hubert Humphrey Building in the past on other issues concerning urology. I write to you as one who has participated positively in the evolution of the Medicare system through 10 years as a member of the AMA RUC committee. I have met with MedPac staff on several occasions in an honest and open way and worked with them trying to fix problems with the Medicare system. I was deeply distressed to read the proposed new regulations. Over the years I have practiced medicine in many settings including the United States Navy (Viet Nam), the Veterans Administration, University Hospitals and for the majority of my professional life in the private practice setting here in Kentucky.

I and my partners are owners in joint venture partnerships that provide lithotripsy services and laser benign prostatic hypertrophy services. We have "fixed site" lithotripsy services here in Lexington and in addition we provide mobile lithotripsy services to patients in rural eastern Kentucky hospitals. Through these services we provide high quality advanced technologic care to all patients – regardless of type of insurance coverage.

My comments follow:

1. **Under Arrangement Contracting**:
Our partnership uses the latest technology. We recently purchased a new lithotripter to take advantage of new technology – we did not have to replace an older unit, we chose to do so, we wanted the latest and the best. Mobile services provide greater access to under-served areas and our practice is a vivid example of providing the latest technology to areas that cannot afford this technology. Our mobile partnership provides lower hospital costs by sharing very expensive cutting edge equipment among many hospitals.

Please clarify for me the following:

- Because of the *American Lithotripsy Society vs Thompson* case, lithotripsy is not a designated health service (DHS) under Stark, and therefore my Partnership cannot be deemed to be performing a DHS or causing a claim to be submitted for a DHS. Is this correct?
- As I understand, services that are not DHS when performed outside of a hospital (e.g. Lithotripsy), cannot be DHS services if they are deemed directly performed by our Partnership. Is this correct?

CMS is concerned that "physician under arrangement contracting" results in over utilization and higher costs to the Medicare program.

- Lithotripsy and BPH laser services are *therapeutic and not diagnostic*. The underlying medical condition can be clearly identified (e.g. kidney stone, enlarged obstructive prostate), therefore there is no risk of over utilization. In fact, in our lithotripsy partnership we carefully monitor utilization, number of repeat treatments etc.
- We care greatly about quality and strive to adhere strictly to the Kidney Stone Practice Guidelines of the American Urological Association. Because we are the owners of the partnership we have full control of quality monitoring and are proud of our track record. Urologists know about how to treat stones, and about the best (not necessarily the "cheapest") equipment.

- Lithotripsy and BPH services are not in any way similar to diagnostic testing with its possible risk of over utilization.

2. Per Procedure Fee Prohibition:

- Small rural hospitals don't like to take chances on new equipment. They cannot always afford new technology. Physicians are constantly fighting to get new technology that results in less morbidity and better results. Rural hospital procedure volume is too low to allow for a fixed monthly rental of technology. *These proposals if enacted will reduce access to the latest innovative technology in much of the area that we service.*

- I have been involved in "Stark" issues for many years. Congress clearly wished to preserve "per procedure fees" in the Stark legislative history, and ***CMS cannot contradict Congressional intent through a prohibition of such fee arrangements***. I request you to personally confirm to me that the per procedure payment prohibition would not apply to Stark indirect compensation arrangement exemption which my partnership relies on.

3. Percentage Fee Prohibition.

- The percentage fee prohibition is contained in the definition of "set in advance" that is a requirement of many Stark exceptions, but it is not in the indirect compensation arrangement exception relied upon by my Partnership. Again, I would like you to confirm to me that the percentage fee prohibition not apply to indirect compensation arrangements.
- Lithotripsy reimbursement rates may increase or decrease and payer mixes may change. Percentage fee arrangements allow hospitals and equipment vendors to share in the market risks, and are often preferred by hospitals. These arrangements ensure that a hospital will never make an equipment rental payment in an amount greater than what it collects for the service from even the lowest cost insurer. How does this not make sense?

4. Stand in the Shoes:

- This prohibition may restrict my Partnership's ability to contract with ambulatory surgery centers (ASCs) owned or controlled by hospitals. As CMS is aware, ASCs provide services at a lower cost than hospital in-patient and out-patient facilities.
- The Medicare ASC Approved Procedure List does not allow for reimbursement of Stark DHS procedures, so Stark should not be implicated by a physician partnership contracting with an ASC.

5. <u>In-Office Ancillary Services Exception:</u>

- There are many benefits to our patients associated with providing services such as imaging (CT, US, traditional X-ray) and laboratory testing in the office setting. For example, my practice has a late model GE CT-Scanner. The availability of CT scanning in our office allows us to offer rapid diagnosis (and therefore treatment) of kidney stones. Instead of going to a hospital and waiting in an emergency room, and then in a radiology waiting room for several hours to get a CT scan to diagnose a stone our patients receive prompt and accurate diagnosis of stones. Although as urologists we read our CT scans to make a diagnosis (without charge), however all of our scans are officially read and billed by a radiologist not associated with our group. This is clearly cost efficient medicine that follows to the letter the Practice Guidelines of the American Urological Association. This is an integral part of our practice just as "plain X-ray" and "kidney x-rays" were in the past. To go back to the way things were 10 years ago makes no sense.

In summary, it seems to me that revisions to the Stark Statute are unnecessary and if implemented will absolutely lead to a step back in the care of our patients here in Kentucky. I have worked hard for many years to have a positive influence on the health care system in the United States and am deeply distressed by these proposed new regulations. If you have questions I am happy to talk or meet with you, Dr. Ken Simon or anyone else in the Agency. Thank you for the opportunity to comment.

I have taken the liberty of copying my Congressman, the Hon. Ben Chandler (KY-6) as I know he cares deeply about bringing the best and most up to date medicine to all residents of Kentucky, not only in our large population centers but in the far reaches of Appalachia as well. The proposed regulation will in my opinion, if implemented, have a negative impact on our patients here in Kentucky.

Sincerely,

William F. Gee

William F. Gee, M.D., F.A.C.S.
President
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Cc: Hon. Ben Chandler
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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

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. As a therapist of 18 years, I had the opportunity to see the abuse in this self referral pattern in the early 1990's and applauded the restriction of this practice in the mid 1990's.

Unfortunately a "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.

Here are some of the reasons that I feel that self referral should be banned:

- Self referral presents an obvious financial opportunity for physician practices to utilize therapy in excess of expected durations and for conditions which frequently would previously not received a referral for therapy. Previously there was a check and balance system as the physician made the decision as to physical therapy utilization without any financial incentives which may influence their decision.
- Patients are frequently pressured that they must receive therapy at their physician's office and fear retaliation if they do not. They fear that they may not received their medications and/or necessary paperwork for work and insurance. Patients frequently do not know their right to choose a provider.
- Several physicians have stated to me that their referrals are tracked by the practice and they are often reprimanded if they do not refer the majority of their patients to their practice's therapy regardless of whether this creates any hardship for the patient.
- I have personally spoken with therapists who have worked at physician offices and stated that some patients are pressured to drive 1-1 ½ to attend therapy at the physicians office when therapy services are available close to their home. This creates undue time and expense for the patient and often causes a patient to decline therapy services from which they would significantly benefit.

- Therapists are less likely to express concerns regarding treatment that may not be warranted or contraindicated if the physician is their employer.
- Physicians who do have not financial ties to therapists will likely refer to the best therapists in the community rather than a less skilled therapist who is employed by the physician.
- Physicians and their therapist employees realistically have little to no communication to which they site as being a major benefit.

The "in office-ancillary service" has exploited patients and therapists and does not serve the public and the taxpayers appropriately. I appreciate CMS asking for input regarding this issue.

Sincerely,

"ACT"

"A concerned therapist"

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August 17, 2007

Kerry Weems
Acting Administrator
Center for Medicare and Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Room C5-15-12
Baltimore, MD 21244-1850

***Re: CMS-1385-P: Comments on 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;* Proposed Rule, 72 Federal Register 38122, July 12, 2007**

Dear Mr. Weems:

The American Health Care Association (AHCA) appreciates the opportunity to comment on the above referenced proposed rule, in particular on the section eliminating the e-prescribing exemption for computer-generated facsimile transmissions.

AHCA is the nation's leading long term care (LTC) organization. AHCA and its membership are committed to performance excellence and Quality First, a covenant for healthy, affordable and ethical long term care. AHCA represents more than 10,000 non-profit and proprietary facilities dedicated to continuous improvement in the delivery of professional and compassionate care provided daily by millions of caring employees to more than 1.5 million of our nation's frail, elderly, and disabled citizens who live in nursing facilities, assisted living residences, subacute centers, and homes for persons with mental retardation and developmental disabilities.

On June 29, 2007, the Centers for Medicare & Medicaid Services (CMS) issued a proposed rule that would establish new policies and payment rates for physicians and other providers who are paid under the Medicare physician fee schedule. Included in the proposed rule is a provision that would eliminate the exemption for computer generated faxes from the e-prescribing standards. AHCA does not believe that the elimination of

the exemption has any applicability to LTC facilities (skilled nursing facilities and nursing facilities) since e-prescribing itself does not as yet apply to LTC facilities. We ask, therefore, that CMS confirm AHCA's conclusion that both e-prescribing and the exemption that CMS proposes eliminating has no bearing on the tripartite prescribing system now in place in LTC and that therefore there will be no disruption of the prescribing and distribution of drugs to LTC residents.

Background

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the MMA) established a program for electronic transmission of prescriptions and related information under the new prescription drug benefit (Medicare Part D) and required the Secretary to adopt standards for these transmissions. While there is no requirement that prescribers or dispensers implement e-prescribing, those who do (for Part D-covered drugs prescribed to eligible beneficiaries) are required to comply with the e-prescribing standards. Prescription Drug Plan (PDP) sponsors, Medicare Advantage organizations offering Medicare Advantage-Prescription Drug Plans (MA-PDs), and other Part D sponsors must also comply with the standards.

Through a final rule published in November 2005, the Secretary adopted e-prescribing standards for use by physicians and suppliers in connection with prescriptions under Medicare Part D, effective January 1, 2006.[1] The standards included a SCRIPT standard for communications between physicians and pharmacies regarding prescription information. The rule provided that entities that transmit prescriptions via computer-generated faxes (i.e., faxes generated by a prescriber's computer and sent to a dispenser's fax machine) were exempt from using the SCRIPT standard. Absent this exemption, entities using e-prescribing software that generated faxes would either have been required to comply with the SCRIPT standard or revert to paper prescribing.

CMS expected that entities using computer-generated fax software would adopt the use of the SCRIPT standard over time, but this has not occurred to date. With improved and more readily available standards-based e-prescribing products, CMS believes that eliminating the exemption will encourage e-prescribers and dispensers to move as quickly as possible to using the SCRIPT standard.

Long Term Care Prescribing Environment

Many providers and members of AHCA have expressed concern over the elimination of the exemption, fearing that it would apply to LTC and wreak havoc with the current prescribing process used in this environment. AHCA has assured providers that while AHCA is extremely supportive of e-prescribing, the elimination of the exemption is not relevant to LTC because LTC is not covered by e-prescribing.

Indeed, in the proposed rule[2] prior to the November 9, 2005 final rule referred to above,[3] AHCA had explained the current inability of the LTC environment to e-prescribe and CMS had responded very thoughtfully. CMS agreed that the proposed foundation

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[1] 70 Federal Register 67568, November 7, 2005.

[2] Proposed rule published at 70 Federal Register 6256, on February 4, 2005

[3] See 70 Federal Register at 67582-67583.

standards did not support the complexities of the prescribing process for patients in LTC facilities. CMS itself explained that, while the standard outpatient prescribing process involves a prescriber and a pharmacy, prescribing in the LTC setting also involves the facility itself and its nursing staff. CMS concluded that the nursing home industry standard practice is not conducive to early application of prescribing standards. Therefore it did not require Part D plans to support e-prescribing when a facility, such as a LTC facility, is involved in the prescribing process in addition to the prescriber and the dispenser.

We therefore ask, as noted above, that CMS confirm AHCA's conclusion that both e-prescribing and the exemption that CMS proposes eliminating has no bearing on the tripartite prescribing system now in place in long term care and that therefore there will be no disruption of the prescribing and distribution of drugs to LTC residents.

Long Term Care Facility Support for E-Prescribing

It is, however, important for AHCA to note that in the same comments to the February 4, 2005 proposed rule where we explained the inability of the LTC environment to utilize e-prescribing at this time, AHCA was also adamant that the benefits and enhancements to the quality of pharmacy care which would derive in great part from advancements such as e-prescribing, must be provided to LTC residents as well as Part D beneficiaries who do not reside in LTC facilities. We said that such application would constitute advancement in -- and become a fundamental and integral part of -- the quality of care in LTC facilities. We asked that the 2006 pilot project include LTC facilities, and that the three-way prescribing communication between facility, physician, and pharmacy be tested using the standards.

We are very appreciative that CMS agreed to the request and that CMS did test e-prescribing standards specifically in the LTC environment. CMS conducted a five-site pilot project in 2006 to test additional e-prescribing standards, including transactions that can communicate formulary and benefit and medication history information to the prescriber at the point of care. Findings from the pilot evaluation were released in a Report to Congress in April 2007.[4]

AHCA members were involved in the pilot testing of initial electronic prescribing standards. We were delighted to part of the pilot that found the use of e-prescribing in long term care can, with appropriate modifications be successful using current standards. Achieve Healthcare Information Technologies, LP conducted the study with Benedictine Health System and others in Minnesota. Achieve has suggested that there is a need to provide for increased awareness of the study among all provider groups, including doctors, and that further pilot work is warranted in key areas.

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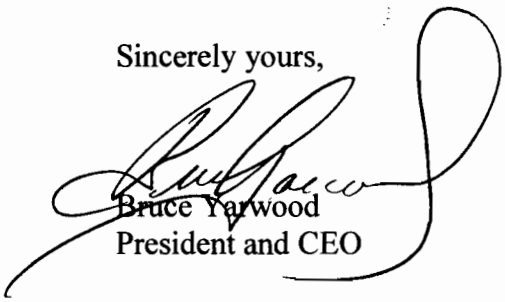
[4] Pilot Testing of Initial Electronic Prescribing Standards – Cooperative Agreements Required Under Section 1860D-4 (c) of the Social Security Act as Amended by the Medicare Prescription Drug, Improvement, and Modernization Action (MMA) of 2003, Michael O. Leavitt, Secretary of Health and Human Services, 2007.

AHCA is ready, willing and able to assist CMS in moving e-prescribing in LTC to the next level. Thank you again for having included the LTC sector in this important study.

Sincerely yours,



Bruce Yarwood
President and CEO

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Office of the Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8018
Baltimore, MD 21244-8018

August 20, 2007

RE: CMS-1385-P (BACKGROUND, IMPACT)
ANESTHESIA SERVICES

Dear Administrator:

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,

Edward Schmitt CRNA

Edward Schmitt, C.R.N.A.
RR # 3 Box 34
Towanda, PA 18848

CASCADE PHYSICAL THERAPY & SPORTS CLINIC
HAROLD VON BERGEN, P.T.
RICK SCHAFER, M.P.T.

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August 21, 2007

Mr. Kerry N. Weems
Administrator Designate
Centers for Medicare and Medicaid Services
US Dept of Health and Human Services
Attn: CMS 1385P
PO 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 CY2008 Proposed Rule.

Dear Mr. Weems:

As a physical therapist who has been in practice for nearly 40 years and in private practice 25 years, I am appealing to you regarding the issues surrounding the physicians self referral and the "in-office ancillary services" exception to the Stark law. I am appealing to you to stop the potentially abusive nature of physician owned physical therapy services and to support physical therapy services removal from the permitted services under the 'in-office ancillary" exception to the federal physician self-referral laws.

I have personally seen evidence of over utilization in the physician owned practices and even more troubling to me as a small practice owner is the practice of "cherry picking" where patients with excellent insurance are kept in the physician owned practices while patients with less desirable insurances are allowed to choose whomever they want for their physical therapy services.

The in-office ancillary services exception creates a loophole, which has resulted in the expansion of physician owned arrangements to provide physical therapy services. Because of Medicare referral requirements, physicians have a captive referral base of physical therapy patients for their offices. Patients are directed to physician owned physical therapy practices even though more convenient therapy is available locally if the patient had been given a choice.

In a physical therapy practice direct supervision by a physician is not needed to administer the services. In fact, an increasing number of physician owned physical therapy clinics are using their re-assignment of Medicare laws to collect payment in order to circumvent "incident to" requirements.

By eliminating physical therapy as a designated health service 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.

Thank you for your consideration of these comments.

Sincerely,

Harold Von Bergen, PT

210 FERRY STREET SEDRO WOOLLEY, WA 98284 (P) (360) 856-4216 (F) (360) 856-4217

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T. Harrop Miller, MD, FACS
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ABILENE
Physicians Group

August 21, 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

To Whom It May Concern:

If CMS is bent on destroying the American healthcare system, congratulations. You are on the brink of success. I refer to the recently released 2008 Proposed Physician Fee Schedule. I have practiced urology in Abilene since 1978 and for two years prior to that at Fort Hood as an Army officer. I have had the privilege to serve as president of my county medical society and the Texas Urological Society.

I am currently a limited partner in a lithotripsy partnership. It is my understanding that this venture is threatened by your proposals. When I started practice, we set our fees, our patients paid us, and our collection rate was close to 100%. Our patients considered our charges fair and reasonable. I am sure my income would double or triple if you allowed me to do the same now. Your current reimbursement rate and those of private insurers which are all based upon it, now just about cover my overhead. I could not practice were I not employed by a hospital.

I have been unable to supply LHRH agonists such as Lupron since January 1, 2005 when you reduced reimbursement below my costs. My patients have to buy their own unless they have a drug plan which will cover it. We have resumed performing bilateral orchiectomy (castration) in select patients with advanced prostate cancer. If lithotripters become unavailable, we can resume performing open stone surgery also. It would be another huge step backward. What would you prefer for yourself or a loved one?

I do not understand many of the terms and phrases in the CMS proposal enough to comment on those such as Under Arrangements, Stand in the Shoes, etc. I do know that my friend, the late Roberto Olivares, MD, who practiced urology in Sherman, Texas was

in a hearing room when none other than the infamous Pete Stark agreed that lithotripsy should be made an exception because it really just cannot be abused. You have to have a patient with a stone!

Surely CMS must realize that for years now physicians have been scrambling to find additional sources of income so that we can continue to practice medicine under increasingly reduced reimbursement schedules. You have taken away Lupron income and now lithotripsy income is threatened. Many urologists will not be able to continue to practice on reimbursement for services alone and will retire or change careers away from patient care. One of my colleagues, Dr. Dan Riesenberg, just did just that.

I implore CMS to consider carefully the unintended but easily predictable consequences of the 2008 Proposed Physician Fee Schedule.

Sincerely,

T. Harrop Miller, MD, FACS

CENTER FOR UROLOGIC CARE

OF BERKS COUNTY, PC

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BARRY S. SHULTZ, M.D., F.A.C.S.
JOSEPH V. LEONI, M.D., F.A.C.S.
JAY B. MILLER, M.D., F.A.C.S.
JOHN M. HENRY, M.D., F.A.C.S.
STEPHEN A. SIHELNIK, M.D., F.A.C.S.

ALAN N. FLEISCHER, M.D., F.A.C.S.
CONSTANTINE F. HARRIS, M.D.
JUNG P. LEE, M.D., F.A.C.S.
DEBORAH T. CASTELLUCCI, C.R.N.P., Ph.D.

August 21, 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 physician practicing in Wyomissing, PA at Center for Urologic Care of Berks County, PC, I am acutely aware of both the clinical and cost issues that are important to 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.

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. Nothing could be further from the truth.

Indeed, hospitals often balk at buying state of the art technology, 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 hospital would not. Sometimes hospitals will not invest in 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 Physicians wanted a better and less invasive treatment for their patients.

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 these 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 references in your commentary. 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 other arrangements should not be banned because of concerns over diagnostic imaging.

Where urologists perform therapeutic procedures, 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. 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 not prohibit services under arrangements where the investor physician performs the professional portion of the procedure.

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.

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.

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. 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 differentiate beneficial <u>therapeutic</u> joint ventures which are not of themselves DHS from the questionable <u>diagnostic</u> 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,

Joseph V. Leoni, M.D.
President

1320 Broadcasting Road
Suite 200
Wyomissing, PA 19610

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MOMENTUM
THERAPEUTICS

Mr. Kerry N. Weems
Administrator – Designate
Centers for Medicare and Medicaid Services
U.S. Dept. of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD. 21244-8018

8/20/07

Physician Self-Referral

Dear Mr. Weems,
It has come to my attention that physician-owned-physical therapy practice arrangements are being reviewed by CMS. This seems to be a perfect time for me to get my 2 cents in regarding this issue. My name is Frank Marrapese. I am a physical therapist in private practice in Greenville and Hermitage Pennsylvania. I opened my practice in 1984, in a more innocent time, when Orthopedic Surgeons did surgery and referred their patients to a P.T. clinic based on quality of care. My practice steadily grew because we offered a high-quality product. Over the years, Orthopedic Surgeons have become hospital employees with referral obligations to their employer, or have opened their own P.T. practices "in-house". Needless to say, my practice has been shrinking (not your problem).

I can't comment on the quality of the care patients are receiving or the appropriate utilization of therapy services because, frankly, I don't know. What I do know is that it establishes an unfair environment for competition and that it reduces a patient's options. Patients aren't forced to go to the "in-house" facility, but the patient is expected to follow their physician's advice. We do see an occasional patient from physicians with "in-house" therapy practices. These tend to be patients with unfavorable insurance.

Patients should have an opportunity to go where they can best be treated as opposed to the facility that is the best financially connected.

Sincerely,

Frank Marrapese, P.T.

41 Sixth Avenue
Greenville, PA 16125
724/588-3330 △ 800/545-1093 ▲ 724/588-1338 fax

2500 Highland Road, Suite 101
Hermitage, PA 16148
724/981-7303 ▲ 724/981-7305 fax

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 18, 2007,

Dear Mr. Weems:

My name is Christine W. Meelia, P.T., and I am a physical therapist with fourteen years of experience in Columbus, Ohio. 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."

I work in an outpatient orthopedic facility that is located inside a building owned by a group of nineteen Orthopedic Surgeons. The physicians also own the surgical facilities and three MRI centers located inside this same building. In the fall of 2005, after several years of cultivating a relationship of mutual respect and open communication with the group of surgeons, we were surprised to learn that the physicians wanted to force out the company running our therapy center, and own their own physical therapy practice. In fact, they shared with our clinic director the surprising information that every private insurance company would actually pay them more than we were being reimbursed for the same therapy procedures.

We did not want to work for the physicians, as the referral for profit business has high potential for fraud and abuse. So the physicians began to openly boycott the use of our clinic, persuading their patients to use other therapy clinics, in an effort to put us out of business. Despite the threat that they would not send one patient to our clinic unless we sold the business to them, we were able to remain open. So, in December of 2006, the group of surgeons opened their own physical therapy clinic across the street from our building. This seems to be in conflict with the regulation that "in-office ancillary services" are provided in their office and not in a building across the street.

In an effort to capture all the physical therapy business, and to prevent patients walking into our center across the hall from their offices, the physicians started scheduling the physical therapy appointment directly from their office. I began to hear my co-workers say their patients were being sent to the physician owned therapy clinic across the street instead of being given the choice to come back to our clinic and be treated by someone who had treated them before.

In February of 2007, a former patient I had seen for several different injuries over a period of two years, walked into our clinic and said she was recovering from hip surgery. She told me she was ready to start physical therapy, but her surgeon was sending her to a new therapist in the clinic he owned across the street. She asked me if she could some back and see me. I told her that she absolutely had a choice in who provides her therapy services. She then walked back over to the physician's office and asked to return to physical therapy with me as her therapist. She was told no, "I want you to go across the street," by her physician.

Another former patient came to our clinic for therapy on her shoulder to increase range of motion prior to a rotator cuff repair. In April of 2007, after her surgery, she was scheduled to see a physical therapist at the physician owned clinic across the street. She felt so uncomfortable telling her physician she did not want to see his physical therapist that she waited until the initial therapy evaluation in the physician owned clinic to tell that person she wanted to return to our clinic for care. She told me this after returning to see me.

There have been many instances of fraud and abuse I have heard from patients, co-workers, and the physicians themselves. Most recently, one physician from this group who was still sending us patients told us his peers planned to cut his pay if he didn't comply with supporting their own physical therapy center.

Because of these circumstances, I urge you to eliminate physical therapy as a designated health service furnished under the in-office ancillary services exception of the Stark Law. I believe it would reduce a significant amount of programmatic abuse, overutilization of physical therapy services under the Medicare program, and enhance the quality of patient care.

Thank you for your consideration in this matter.

Sincerely,

Christine W. Meelia, P.T.
7121 Timberview Dr.
Columbus, OH 43017

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NORTH HILLS
ORTHOPEDIC AND SPORTS PHYSICAL THERAPY

DIRECTOR
Steven A. Hoffman, PT, ATC, SCS
Board Certified Sports Clinical Specialist

THERAPISTS
Christopher J. Hughes, PT, Ph.D., OCS
Gordon Riddle, PT, ATC
Omar A. Ross, PT, ATC

August 22, 2007

Mr. Kerry N. Weems
Administrator-Designate
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attn: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

RE: Physician Self-Referral Issues

Dear Mr. Weems,

I have been working as a Physical Therapist Assistant in a free-standing, Outpatient Orthopedic Clinic for the past eleven years. My experience and the reason I continue to work there is because I feel so strongly about the level of care that we provide. We never had quotas to meet or had financial incentives "dangled" before us based on the number of patients treated per day. Instead, we feel that our clinic provides our patients with the most knowledgeable, skilled, hands-on practitioners in the northern Pittsburgh area. Because of the reputation of our clinic, we have had a large referral base from several orthopedic groups in the area. This was a true statement up until this last year. All of a sudden we are no longer "the best P.T. clinic in the area", but rather another clinic that patients can go to if they do not choose their physicians "owned" clinic.

It is so disturbing to hear from our patients that either their physician or a member of their staff has tried to convince them to choose their "physician owned" clinic over one that may be closer to their home or work. We have been told that the physicians and their staff are telling the patients that it would be "so much more convenient to attend P.T. down the hall from their offices". Since when is it more convenient to say drive to the doctor's office 3 times per week than to a P.T. clinic that is 5 minutes from your house? Unfortunately, we have had two of our Physical Therapists and one PTA accept employment in one particular orthopedic-owned P.T. clinic. We have heard that the physicians have actually tried to persuade OUR patients to switch to their clinic because part of our staff (from the former "best P.T. clinic in the area") was now working for them. This is appalling behavior that needs to be addressed.

I am calling on CMS to remove physical therapy from the "in-office ancillary services" exception to the federal physician self-referral laws. If this continues, the days of free-standing P.T. clinics, owned by honest, hard-working people will be a thing of the past. Instead we will have "orthopedic malls", or one-stop shopping that includes everything from consultations, to physical therapy, to chiropractic care and maybe even a coffee shop, all for your convenience.

In closing, I would like to thank you for taking the time to listen to my concerns and for your consideration of my comments.

Sincerely,

Deborah M. King, PTA

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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 23, 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 Physicians Fee Schedule, and Other Part B Payment Policies for CY 2008: Proposed Rule.

Re: Physicians Self Referral Issues

Dear Mr. Weems:

I am contacting you in regards to the "in-office ancillary services" exception to the Stark Law that has provided physicians to own practices to provide physical therapy services on a self referral basis. I am currently a physical therapist working in an outpatient orthopedic private practice. I have now been working in the field for 2 years and primarily provided care to orthopedic and sports related injuries. In the brief period that I have been working as a physical therapist there has been a noticeable decrease in referrals from orthopedic surgeon groups who own physical therapy practices. There have been several patients that have been established in our practice who following doctors appointments did not return for continued services because they are unaware of the opportunity to seek physical therapy services from institutions other than the physician owned practice. There has been an obvious "funneling" of patients to these physician owned physical therapy practices for the sole reason of profit. This does directly affect us as physical therapists practicing in a private practice atmosphere but more importantly there is a conflict of interest of physician self referral for profit. This provides an environment for problematic abuse and over-utilization of physical therapy services under the Medicare program. Quality of patient care may also be jeopardized with self referral due to the patient's inability or lack of knowledge and awareness to seek physical therapy and ancillary services outside of the physician owned network.

There is a high potential for fraud and abuse whenever physicians are able to refer Medicare beneficiaries to entities in which they have a financial interest specifically with physician owned physical therapy services. Due to this financial interest there is an increased risk of over utilization for financial reasons. In fact an increasing number of physician owned physical therapy clinics are using the reassignment of benefits laws to collect payment in order to circumvent the "incident to" requirements. I as a physical therapist and a member of The

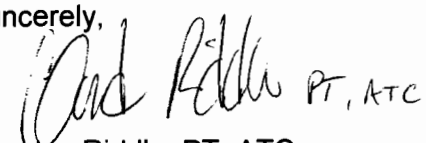
American Physical Therapy Association (APTA) believe that by eliminating physical therapy as a designated health service (DHS) furnished under the in-office ancillary services exception, CMS would reduce a significant amount of these problematic issues such as over-utilization of physical therapy services and this would help to enhance quality of patient care.

Working as an independent practitioner in physical therapy allows a natural checks and balances giving the patients the ability to choose where they receive their physical therapy services. Currently the in-office ancillary services exception is defined so broadly that regulations that facilitate the creation of abuse of referral arrangements. This exception also has created a loop-hole that is resulting in an expansion of physician owned arrangements that provide physical therapy services. Due to Medicare referral requirements, this places physicians with the captive referral base to physical therapy patients in their own offices. Due to the frequency and the repetitiveness of physical therapy services this is no more convenient for the patient to receive services in the physician's office than in an independent physical therapy clinic. There may be more benefit to the patient seeking independent physical therapy services having the choice to choose their physical therapist rather than be funneled into physician owned services.

The APTA proposed in vision 2020 to increase the autonomy of physical therapists as health care providers. By doing this they are instituting a doctor of physical therapy degree (DPT) that is providing more comprehensive education to physical therapists. Physical therapy education programs are well ahead of meeting the 2020 goal to provide all graduating physical therapists with the DPT. We are experts in the field of neuromuscular and musculoskeletal rehabilitation and highly trained in performing examinations and evaluations of patients to determine the appropriateness for physical therapy service. In addition to determining the appropriateness we also are proficient in providing a plan of care and progressing this plan of care in improving the patients quality of life and rehabilitating them to independence in activities of daily living. Due to the advances in the profession of physical therapy, physician directed supervision is not needed to administer physical therapy services. Prior to physician owned practices we as physical therapists did not require physician directed supervision. We can achieve quality safe care with open communication between the referring physician.

Thank you for your time and consideration on these issues at hand and for taking the time to understand my point of view this is truly a pressing issue for physical therapists, the APTA, and CMS.

Sincerely,



Gordon Riddle, PT, ATC

GR/fah

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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.

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 Kevin Rausch, and I am the owner and sole physical therapist of Rausch Physical Therapy, INC in Laguna Niguel, California. My practice currently provides rehabilitation services for people of all ages and athletic abilities. I currently see 1-2 patients per hour and provide the highest level of quality care possible. In fact, patients tend to seek me out because of my method of treatment.

However, the majority of physician practices in my area already own their own physical therapy practices. This has caused a major shortage of patients and has obviously made it difficult for me to begin my practice. That having been said, the true problem is the quality of patient care. In these "physician owned practices", most PT's see 4-5 patients per hour and are simply running the patients through a home exercise routine. Physical therapy practices should not be about the bottom line, which in the physician owned practice is always the case. I am sympathetic to physicians who are now struggling to make a living due to the decreasing rates of reimbursements of insurance companies. And in the long run, I suppose this whole situation could be blamed on poor insurance reimbursement across the board.

Returning to my main topic, physician owned PT practices will eventually put me out of business and create an overall poor physical therapy experience for our patients. Please help remedy this situation and keep physical therapy in the hands of physical therapists.

Thank you for your understanding.

Sincerely,

K Rausch MPT, CSCS

Kevin Rausch, MPT, CSCS

Ms. Leslie Norwalk
Centers for Medicare and Medicaid Services

Aug. 23, 2007

Re: CMS-1385-P
Anesthesia Coding

Dear Ms. Norwalk;

I wish to express my support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule.

There is currently a large disparity in payments for anesthesia care when compared to payments for other physician services, and I appreciate the fact that you are addressing this issue. The $4.00 increase proposed by the RUC will help to correct the current undervaluation of anesthesia services.

I would appreciate it if you would follow the recommendation of the RUC and implement the increase in the conversion factor for anesthesia services.

Thank you.

Sincerely,

Gayle Whitaker

Gayle L. Whitaker
1791 Kerr Gulch Road
Evergreen, CO 80439

When a physician refers for those services and has no financial stake in the service provider, there is little if any question that the services are in fact needed as the physician would be taking tremendous financial risk (under current Medicare rules) to do otherwise. But when referring to service providers in which the physician holds a financial stake, the physician gains financially on that referral; a strong incentive to generate unnecessary referrals and thereby take unfair advantage of Medicare and it's beneficiaries.

It is my understanding that the spirit of the exception concept is to improve efficiency of care and to minimize the burden of care on the client by providing "one stop shopping" for needed ancillary services. Due to the multi-visit nature of physical therapy services, there can be no expectation on the physician's part of gaining immediate information on which to base diagnostic decisions. Nor can there be any "one stop shopping" advantage to the beneficiary who, regardless of provider will be making multiple visits over days, weeks or even months. Further, a referring physician may or may not be closer to or farther from a beneficiary's home resulting in cases where a beneficiary travels farther for services.

Physical therapists are educated, licensed professionals who routinely make patient care decisions and monitor patient response to treatment. We routinely maintain open lines of communication via written, electronic and verbal means with physicians. During physical therapy, no direct, onsite physician monitoring is called for. Nor is there any financial arrangement between physicians and physical therapists, therefore, each profession is free to conduct their practice without fear of reprisal for care decisions they conclude are appropriate for the client but may cause a reduction in revenue for their employer.

In closing let me again express my concerns in regard to the July 12 proposed physician fee schedule rule as it pertains to physician self-referral and the "in-office ancillary services" exception. Please remove physical therapy as an excepted service.

Thank you for considering my comments on this matter.

Sincerely,

Mark A. Colkitt, P.T., M.S.P.T.

MAC/lab

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American Society of Echocardiography

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.

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[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,

/s/ *Thomas Ryan, MD/by DSM*

Thomas Ryan, MD
President
ASE

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.

CY 2007

CPT/ HCPCS	Description	CI	SI	APC	Relative weight	Payment rate	*Indicates a Change
93308	Echo exam of heart		S	0697	1.60	98.18	
93304	Echo transthoracic		S	0697	1.60	98.18	
93320	Doppler echo exam, h	CH	S	0697	60	98.18	
93321	Doppler echo exam, heart		S	0697	60	98.18	
93325	Doppler color flow add-on		S	0697	1.60	98.18	
93303	Echo transthoracic		S	0269	3.22	197.64	
93350	Echo transthoracic		S	0269	3.22	197.64	
93307	Echo exam of heart		S	0269	3.22	197.64	
93312	Echo transesophageal		S	0270	6.25	384.21	
93313	Echo transesophageal		S	0270	6.25	384.21	
93314	Echo transesophageal		N				
93315	Echo transesophageal		S	0270	6.25	384.21	
93316	Echo transesophageal		S	0270	6.25	384.21	
93317	Echo transesophageal		N				
93318	Echo transesophageal intraop		S	0270	6.25	384.21	

Proposed 2008

93350	Echo transthoracic	CH	S	0697	4.8072	306.18	
93308	Echo exam of heart		S	0697	4.8072	306.18	
93304	Echo transthoracic		S	0697	4.8072	306.18	
93303	Echo transthoracic		S	0269	6.5908	419.79	
93307	Echo exam of heart		S	0269	6.5908	419.79	
93312	Echo transesophageal		S	0270	8.42	536.30	
93313	Echo transesophageal		S	0270	8.42	536.30	
93314	Echo transesophageal		N				
93315	Echo transesophageal		S	0270	8.42	536.30	
93316	Echo transesophageal		S	0270	8.42	536.30	
93317	Echo transesophageal		N				
93318	Echo transesophageal intraop		S	0270	8.42	536.30	
93320	Doppler echo exam, h	CH	N				
93321	Doppler echo exam, h	CH	N				
93325	Doppler color flow add	CH	N				

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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:

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.

Michael G. Hernandez, M.D.

August 27, 2007

VIA FEDERAL EXPRESS

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: File Code CMS-1385-P
Physician Self-Referral Provisions
Section II.M.3; In-Office Ancillary Services Exception

Dear Sir or Madam:

I am a Physical Therapist, working for an organization that provides rehab services, within a physician practice. My past work experiences include out-patient rehab within a hospital, and private practice out-patient rehab, and nursing home services. This environment has proven to be the most effective, in my personal experience, at providing high levels of care while allowing for professional development within my area of practice. This patient centered model has proven to be extremely beneficial to our patient population and also to my maturation within my profession.

My choice to practice in this environment was greatly influenced by the high level of care this setting allows. The communication level between therapist and physician is a factor that enhances the quality of care given a patient. This setting allows for excellent communication between all parties involved and provides for more expedient modification of the plan of care as warranted. The convenience of on site therapy services often increases patient compliance, and as a result our patients typically see a 40% reduction in the number of visits required for rehab services.

As health care costs rise, patients are becoming more proactive in seeking out ancillary services. The in-house provision of therapy services provides an effective way to provide quality care in an environment that fosters a holistic, team approach to patient care. This environment also allows for accountability within the practice to insure that over utilization of services does not occur.

As a provider of health care services for the past 14 years, I ask for your continued support of the physician in house therapy service model. I truly believe it is in the public's best interest that this service is allowed to continue.

Registered Physical Therapist
35601

Barberton Anesthesia Care, Inc.
P.O. Box 341
Hudson, Ohio 44236-0341
Fax: 330-615-3626
330-573-9641

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

RE: Title: CMS-1385-P - Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;

Dear Sir or Madam:

This letter is to strongly encourage adjustment of Medicare's payment scale for anesthesia services. At present, the scale does not reflect the true cost of providing service and is jeopardizing the provision of care to patients.

I respectfully request that the payment scale be adjusted to more accurately reflect the costs and intensity of anesthesia service.

Sincerely,

James D. Cantoni, M.D.

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Barberton Anesthesia Care, Inc.
P.O. Box 341
Hudson, Ohio 44236-0341
Fax: 330-615-3626
330-573-9641

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

RE: Title: CMS-1385-P - Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;

Dear Sir or Madam:

This letter is to strongly encourage adjustment of Medicare's payment scale for anesthesia services. At present, the scale does not reflect the true cost of providing service and is jeopardizing the provision of care to patients.

I respectfully request that the payment scale be adjusted to more accurately reflect the costs and intensity of anesthesia service.

Sincerely,

Qiwen Zhang

Qiwen Zhang, M.D.

North Florida Radiation Oncology

1021 NW 64th Terrace
Gainesville, Florida 32605
Phone 352-331-1550
FAX 352-331-1558

August 20, 2007

Kerry N. Weems
Administrator Designee
Centers for Medicare & Medicaid Services
Dept. of Health and Human Services
Attn: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: Comments to Proposed Rules (File code: CMS-1385-P)

Dear Administrator Weems:

It is my pleasure to write you in response to the proposed rule (file code: CMS-1385-P). My name is Cherylle A. Hayes, M.D. and I practice at North Florida Radiation Oncology where I provide image guided robotic stereotactic radiosurgery. I am a member of the Cyberknife Coalition.

I welcome the opportunity to comment on CMS-1385-P RIN 0938-A065 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 1060"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-dimensiona; conformal radiation (3D-CRT) and image guided irradiation (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 irradiation (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 skul 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 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 RVUs 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. We 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.

North Florida Radiation Oncology

1021 NW 64th Terrace
Gainesville, Florida 32605
Phone 352-331-1550
FAX 352-331-1558

In summary, we 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,

Cherylle A. Hayes

Cherylle A. Hayes, M.D.

North Florida Radiation Oncology

1021 NW 64th Terrace
Gainesville, Florida 32605
Phone 352-331-1550
FAX 352-331-1558

August 20, 2007

Kerry N. Weems
Administrator Designee
Centers for Medicare & Medicaid Services
Dept. of Health and Human Services
Attn: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: Comments to Proposed Rules (File code: CMS-1385-P)

Dear Administrator Weems:

It is my pleasure to write you in response to the proposed rule (file code: CMS-1385-P). My name is Gail L. Suarez and I am Director of North Florida Radiation Oncology where we provide image guided robotic stereotactic radiosurgery. Our facility is also a member of the Cyberknife Coalition.

I welcome the opportunity to comment on CMS-1385-P RIN 0938-A065 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 1060"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-dimensiona; conformal radiation (3D-CRT) and image guided irradiation (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 irradiation (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 skul 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 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 RVUs 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. We 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.

North Florida Radiation Oncology

1021 NW 64th Terrace
Gainesville, Florida 32605
Phone 352-331-1550
FAX 352-331-1558

In summary, we 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,

Gail L. Suarez, MSHSA, RT (R)(T)
Director

CMS-1357-P

MPFS 380 AO ✓

Submitter : Dr.

Date: 07/19/2007

Organization : Dr.

Category : Physician

Data ASC

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 those three options will create huge ACCESS TO CARE issues in our practice at Wolfson Clinic as it will across the country.

Furthermore, as we all know reimbursements from Medicare are heavily 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.

Anita (2)
Carol
Alberta
Dana (2)

Pitman Creek Physical Therapy, P.C.

700 Alma, Suite 135

Plano, Texas 75075-8807

972-424-5840 • Fax 972-423-9427

381

August 15, 2007

Mr. Kerry N. Weems, Administrator – Designate
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
ATTN: CMS-1385-P
P.O.Box 8018
Baltimore, MD 21244-8018

RE: **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 would like to comment on the July 12 proposed 2008 physician fee schedule rule, especially as it relates to physician self-referral and the "in-office ancillary services" exception. I have been a physical therapist for 28 years, and have worked in a variety of settings, but have owned my own private practice for the past 19 years. I have certainly seen the negative impact of physicians being able to provide "physical therapy" services either out of their own offices, or through their ownership of a clinic.

I am also familiar with the independent studies done by the Florida Legislature state Health Care Cost Containment Board in 1989, which demonstrated that in situations where physicians owned health care businesses to which they refer patients, "there is a significantly higher utilization of services and higher charges to consumers". Additionally, in response to the argument that physician owners can "better monitor quality", this was demonstrated not to be the case.

In my own experience, I have seen a mushrooming of physical therapy facilities in our area since the Stark laws were weakened. I am content to compete on a "level playing field", because we are excellent orthopedic manual physical therapists...but when the physician controls the referral **and** can own and refer to his own therapy, there is no competition. We survive by being the best, but there is inherently less pressure to be the best in a physician-owned environment, because there is a huge financial incentive to put out the volume. Many, if not most, of our patients have already received treatment in at least one other facility before arriving at ours. I frequently hear that they never received even near the level of care that they receive here...which is, logically, why they did not get better at the other facility / facilities.

The "in-office ancillary services" exception has created a devastating loophole that has encouraged abusive referral arrangements. Frequently we see patients who were provided "physical therapy" at the physician's office by a lesser qualified provider, who would not meet the Medicare requirements in an independently owned clinic. If these requirements are indeed necessary, then shouldn't that be universally so? With regards to physician direct supervision, I must point out the irony that when I lectured to residents at a Medical school in our state, my 2-1/2 hours of instruction was most of what they received related to physical therapy. How do you propose that they be clinically prepared to provide "direct supervision" of physical therapy services? But even so, I am aware that these other providers are **not** receiving supervision. The frustration expressed by patients is two-fold: they didn't receive the same level of care from these other non-PT providers, **and** it used up insurance benefits, affecting their ability to receive adequate physical therapy from a PT.

In my opinion and experience, if you are looking to curb abusive financial arrangements, reduce costs, and provide better quality of care for Medicare beneficiaries, these "referral for profit" situations should be eliminated—especially including the "in-office ancillary services" exception, as it is much more easy to disguise.

Thank you for your concern and consideration.

Sincerely,

Patti L. Schwartz, PT

382

ISR Physical Therapy

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Richard W. Bunch, Ph.D., P.T.
Trevor D. Bardarson, P.T., OCS
Marc D. Cavallino, P.T., OCS
Jeanne Liner, PTA

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Harahan, LA 70123
Tel: (504) 733-2111
Fax: (504) 733-5999

Toll Free: 1-866-902-6385

Website
www.isrphysicaltherapy.com

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 15, 2007

Trevor Bardarson PT, OCS
Clinic Director

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

Dear Mr Weems;

I am a physical therapist who practices in Houma Louisiana. I have been in practice for the last 13 years. We provide great orthopedic care to the community and are well known for our high success rate.

I would like to comment on the July 12th proposed rule concerning physician self referral and the "in office ancillary services exception." I am very concerned about the potential for abuse in this situation. The physician is able to refer to his own practice which creates a monetary award for his referral. In essence, you have to be concerned if the patient actually needs that service or is it solely for the benefit of the physician? If a physician was to receive a percentage of each medicine he prescribes I think everyone would agree that this is a serious conflict of interest. It is my position that the referral to in house therapy services is no different.

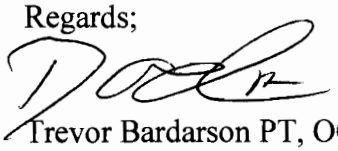
It also creates and anti-trust situation. Medicare does not allow a physical therapist to treat without a prescription. We are unable to get the prescription because the physician chooses to refer to his own practice. In essence they have a monopoly over the physical therapy they prescribe and won't refer outside their practice for their financial benefit. This type of monopoly is not in the best interest of patients who may prefer to work with someone they already know or with a therapist closer to

to their home.

As a result I recommend support PT services removal from permitted services under the in-office ancillary exception.

Please contact me if further clarification is required or if you have any recommendations;

Regards;



Trevor Bardarson PT, OCS
Physical Therapist
Board Certified Orthopedic Specialist

Rascal Creek Physical Therapy
A Professional Corporation

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Merced, CA 95348

209/722/1030

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August 17, 2007

Mr. Kerry Weems
Administrator-Designate
Centers for Medicare and Medicaid Services
US Dept of Health and Human Services
ATTN: CMS – 1385-P
PO 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.

PHYSICIAN SELF-REFERRAL ISSUES

I am a physical therapist in private practice in a community in the middle of California. I have been a PT for over 25 years and in private practice for over 20 years. I am writing to address my support the fight against the abusive nature of the self-referral loophole that physicians can use to profit from their referrals to their PT offices.

In the Merced area, I have been approached at least once every five years about forming a partnership with the local orthopedic surgeons or requests to purchase my business outright. I have resisted this referral-for-profit effort because I think it represents a serious conflict of interest. In my business, the patient comes first. I don't think I could maintain that personal mandate if the referring physician was my boss.

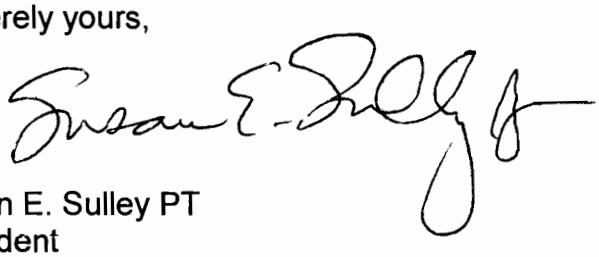
I have frequently seen a "dumping" of patients into the PT practice, often inappropriately, in order to either move a difficult patient out of their office or to make it look like something could be done but not by them. With the separation of PT and Dr. offices here, I am able to discontinue therapy when it becomes obvious that there is not going to be a long-term benefit from continued PT. With the therapist working for the doctor, the option to discontinue treatment may not exist.

We are lucky to live in a community where each of the private practice PT's has maintained a professional distance from the referring physician. In other Central Valley cities, there are physicians who have been able to offer "the big bucks" to attract new graduates of PT programs. With the high cost of education, these PT's often take jobs offering the highest compensation to pay off high student loans. And how does the physician manage to offer the highest pay? Certainly, the possibility of abusive self-referral would make it easier for that doctor to profit *and* pay the therapist above and beyond the going salary.

Please add my vote to support the removal of PT services from the permitted services under the in-office ancillary exception rule.

Thank you for your attention to my comments. I look forward to hearing more about your actions with regards to the issue later this year.

Sincerely yours,



Susan E. Sulley PT
President

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Physician Self-Referral Issues

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

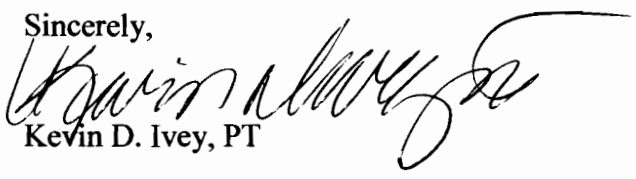
Re: Medicare Program; Proposed Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Rule

Dear Mr. Weems,

I am writing to you today 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 the owner of a small clinic in a rural community. The county in which I live and work has a very high number of retired folk given the pleasant climate and beautiful surroundings. Since opening my office in 1998, I have seen a moderate amount of growth and accommodated my office space for the change. Not long afterwards, though, a local doctor practicing as a PM&R specialist decided to open his own office and included Physical Therapy within his office. Up to that point we had been seeing his patients regularly and he had expressed his satisfaction with the care his patients had received and the progress they had made. It did not take long for things to change. Not only did we stop getting referrals from him, but soon we found that patients that had been coming to us for therapy, and were referred to him for "consultation" by their primary care physicians, were being told to discontinue their therapy with us and to go to the Physical Therapist he had hired to work in his office. This did not happen only once or twice, but numerous times. I found myself warning my patients that when they saw him, they should be prepared to be told to change therapists. Some of them declined to change while others did not want to "make the doctor mad", and switched. I spoke with him and expressed my concern that people were being shuffled unnecessarily and he could not respond to it, but has not ceased to do this.

This is just one example of the pitfalls of allowing self referrals to continue. I have witnessed countless other examples while practicing in Las Vegas, NV as well. I urge you to close this loophole and remove PT services from permitted services under the in-office ancillary exception.

Sincerely,



Kevin D. Ivey, PT

385

Rehab In Motion
Physical Therapy, Ltd.

Rehab In Motion & Physical Therapy, Ltd.
6360 W. 159th St., Suite C
Oak Forest, IL 60452
Phone 708-535-6100
Fax 708-535-6111

August 16, 2007

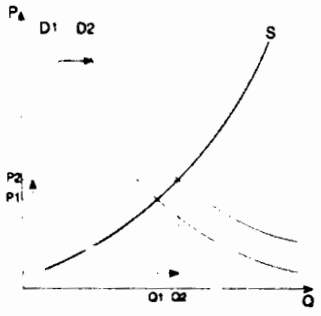
Mr. Kerry N. Weems
Administrator - Designate
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018.

Re: 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,

As a practicing physical therapist for over ten years and recent private practice owner, I am alarmed at the proliferation of physician (sole or coordinated group practice) owned physical therapy clinics. Not withstanding the various counter assertions, the central creation in such a structure is a cartel that diminishes patient choice and the feed forward mechanism of self incentive overutilization for the primary purpose of enhancing revenue streams. A cartel can also be operationally defined as a centralized institution set up to partially coordinate the actions of *several independent* providers.

I also want to present this evergrowing concern not in terms of my interests in private practice solely, though this letter is partially motivated the by desire to provide the best care for my clients. Rather, **this is limitation of supply and demand**. The model predicts that in a competitive market, price will function to equalize the quantity demanded by consumers and the quantity supplied by producers, resulting in an economic equilibrium of price and quantity. The model incorporates other factors changing such equilibrium as reflected in a shift of demand or supply.



The price P of a product is determined by a balance between production at each price (supply S) and the desires of those with purchasing power at each price (demand D). The graph depicts an increase in demand from D_1 to D_2, along with a consequent increase in price and quantity Q sold of the product.

With respect to physician self-referral issues, removing patient choice effectively removes the demand for other providers and the D is removed from this graph, left with only an escalating supply related to quantity and price or episode of care.

I see, hear and experience this removal in demand every day. Referral to independent physical therapy providers diminishes as stories of episodes of care spiral up. The issue surrounding physician self-referral and the "in-office ancillary services" exception is great. Please consider the abusive nature of physician-owned physical therapy services and support PT services removal from permitted services under the in-office ancillary exception.

Sincerely,

Art Lubinski PT,OCS
Clinic Director

amcno
THE ACADEMY OF MEDICINE OF CLEVELAND & NORTHERN OHIO
formerly known as AMC/NOMA

August 15, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Department of Health and Human Services
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244

Re: Physician payment localities in Ohio

Dear Ms. Norwalk:

As the Vice President of Legislative Affairs for the Academy of Medicine of Cleveland & Northern Ohio (AMCNO), a regional organization representing more than 4,400 physicians in the Northern Ohio area, I am writing to you on behalf of the organization to provide our comments about the payment localities in Ohio.

Due to the fact that our membership base encompasses mainly the Northern Ohio area, our organization is concerned about the geographic areas used to adjust physician payments in Ohio. The AMCNO physician leadership recently commented on the CMS proposed rule CMS-1385-P (copy enclosed.) As you can see from our letter, the AMCNO is of the opinion that payment locality changes should be considered in Ohio.

As a part of our review of this matter, the AMCNO physician leadership evaluated a copy of the recent GAO Report GAO-07-466. Your response to this report indicated that CMS has looked for support from an impacted state, such as from a State medical association, before proposing to make changes to payment localities in a state. The AMCNO has commented on this and other issues of concern to us in the attached letter to CMS. In addition, your response to the GAO report indicated that CMS "will consider payment locality issues when concerns are raised by interested parties." Please consider this letter and the attached response to the proposed CMS rule as areas of concern raised by an interested party – specifically the physicians from Northern Ohio and the members of the AMCNO. I look forward to your response.

Sincerely,

John A. Bastulli, M.D.
Vice President of Legislative Affairs

Enclosures

Cc: Mr. Herb Kuhn, Director, CMS Center for Medicare Management

amcno
THE ACADEMY OF MEDICINE OF CLEVELAND & NORTHERN OHIO
formerly known as AMC/NOMA

386
attachment

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)

cac
CERTIFIED
ANESTHESIA
CARE

August 17, 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 member of the American Association of Nurse Anesthetists (AANA), I am sure you have received many letters from our members regarding this proposal, and the fact that reimbursement has actually fallen behind the rate of inflation since 1992.

I wish to add my name to the list of CRNA's requesting your consideration in this matter.

The importance to the health of our profession and to the care of the ever increasing retirement age population is at stake in rural Minnesota and elsewhere.

If you have questions please feel free to call me at the number below, and Thank you.

Sincerely,

John Strandell, CRNA
7330 State Highway 7
Excelsior, MN 55331-7304

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August 27th, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1385-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD, 21244-1850

Re: Physician Self-Referral Provisions

Ladies and Gentlemen:

I am a practicing Urologist for North Dallas Urology Assos. in Plano, Texas. Since 1990, my associates and I have been involved with joint ventures to provide services that would not have been available to patients in our community. These patients would have had to travel elsewhere or elect other treatment modalities. Lesser options mean more invasive techniques, longer hospital stay, more medication for pain, more time off from the workplace, higher morbidity and mortality. Lithotripsy for Stone Disease, Cryosurgery for Prostate Cancer, Laser Surgery for Benign Prostatic Hyperplasia to name a few were technologies that hospitals felt were risky investments. We had the foresight as patient advocates to provide these new modalities that are now mainstream therapies.

It is my opinion that CMS will have to answer for their serious misguided decisions that will jeopardize patient care, creating a system of rationed care. There is a huge difference between a therapeutic joint venture as described above and a diagnostic joint venture such as an imaging center. To jeopardize a time tested entity will no doubt create tiered and rationed treatment for patients.

Sincerely,

Stephen J. Lieman MD
North Dallas Urology Assos.
5300 W. Plano Pkwy
Ste 200
Plano, Texas, 75287

Medical & Surgical Specialists, L.L.C.

834 N. Seminary St. Suite #502
Galesburg IL 61401
Phone: 309/343-2262 Fax: 309/343-2081

John W. McClean, M.D. *Hematology/Oncology*
Thomas H. Patterson, M.D. *Urology*
Matthew G. Baker, PA-C *Urology*
Alfred W. Mazur, M.D. *Urology*
Gina Riner, A.P.N. *Internal Medicine*

August 22, 2007

Re: Physician Self Referral Provisions

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

To Whom It May Concern:

As a Physician practicing in Illinois, Knox County, which is a rural area I am acutely aware of the cost issues and clinical care issues that are incumbent upon the Federal Government to provide Medicare beneficiaries appropriate services. These of course are a mandate for CMS. Because of my long term status in our community I've been here nearly 27 years I have found that more and more I need to be an advocate for my patients particularly as nearly 55% of my practice is Medicare. My patients as they live longer and are aging are far less able to sit in hospital radiography areas or travel distances for more sophisticated imaging. As such I have placed a CT Imaging Device in my office and I would like to comment on the proposals that would impact that imaging for the patients who have entrusted their care to me. Having practiced in Urology for more than a quarter century the technology is overwhelming and has accomplished a major change certainly management of stones, tumors and cystic and solid renal masses. Over the last ten years we have moved from utilizing IVP's which we typically did in our office as well as images to look for stones in the kidneys with plane filming. With the advent of CT Scanning and review of possible metastatic disease for our tumor patients it is becoming valuable and is certainly the imaging mainstay of urology. The utilization of CT Scans for our office have not changed compared to the CT Scans that we would send our patients to hospitals to obtain. My clinical judgement determines whether or not the patient would be helped in having a CT Scan if the clinical condition demanded imaging. The Scanner which we have purchased in our office is new. It's not a refurbished unit and we chose to purchase this because of the technology available to us and our offices interestingly that has software that as of yet is not available for the CT Scans even the 32 slice scanners that our local hospital utilizes. The Scanner that we chose provides us with excellent imaging and it is a two-slice (dual scanner). We chose this for many reasons the first of which is we don't do large volume work and as such the multiple slice scanners have been developed for speed, we do not need same. However with the multiple slice scanners significant radiation exposure and scatter is more prominent. With the scanner in my office that is being utilized for urology diagnostic purpose I rarely will need to utilize hospital based scanning or a wide multi-slice field. The dual slice scanner in truth is ideal for my typical patient population. In addressing your anti-markup provision proposal the images that my CT Scan produces can either be viewed Real Time on the monitor or remotely transmitted to monitors in other

locations in our office or through rapid broad band type lines to our Consultant Radiologist who reads our Scans. Clarification of this would be important as in-office scanners may not be fully operational for full office days immediately. Please clarify. The final area of concern the question has been raised as to which type of doctors should be eligible to place a scanner in their office. My own personal feeling is that if the challenges of new technologies and particularly within urology and oncology the reliance on CT Scanning has been paramount that none of these specialities should be excluded from this. Over utilization of CT Scans because they are within the office to me would be abhorrent from an ethical standpoint. We do not anticipate increased number of CT Scans in the office than we have previously done. What we do anticipate is that much of the burden that has been done with IVP's will be carried by the newer software of CT scanning where identification of intrarenal tumors, ureteral tumors and bladder neoplasms can be identified readily with the newer software that reconstructs these areas and in fact in the larger picture Medicare and CMS probably will see fewer multiple imaging procedures to identify this as this software becomes more and more sophisticated with each year. Please identify that the Radiologist complaints about doctors putting scanners in their office is in fact quite confusing to me because the Radiologist will read the Scans regardless of the location where they are done. In a sense this will be cost neutral to CMS and the clinical quality will rise.

For the Medicare beneficiary particularly all the aging patients who require assistance coming to and from the office and in our area many times will have hire someone to bring them to the office and return them home. The opportunity to be able to have their urologic services and imaging and Real Time discussion of the findings will save them inconvenience and expense and will certainly expedite the care that we are trying to provide. In our area it's not unusual with the burdens and the hospital Radiology Department for our elderly patients to be scheduled for procedures after eight o'clock at night. Many of them can't drive after dark. This is not unique to our area but Urologists all over the country as we meet share these same concerns. In conclusion please address clarification of anti-markup provision sections mentioned above and understand that the value of these imaging services to my Medicare patients is paramount both from an economic standpoint, convenience and comfort. The unit that we utilize in no way diminishes our abilities to image, diagnose, treat and certainly the trend towards timeliness is continuing to benefit everyone.

Thank you for your consideration.

Sincerely,

Thomas H. Patterson, M.D., F.A.C.S.

THP/bln

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CLIN-PATH ASSOCIATES, P.C.

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August 17, 2007

Re: 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."

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 dermatopathologist, a member of the College of American Pathologists, and a member of the American Academy of Dermatology. I live and practice in metropolitan Phoenix, AZ as part of medical group of 25 pathologists that serves several hospital systems and innumerable physicians' offices.

I am pleased that CMS is looking into this important issue to end self-referral abuses in the billing and payment for pathology services. I believe these arrangements are an abuse of the intent 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 that they neither performed nor supervised.

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 actually personally performing or supervising the service. Thank you for your efforts to abolish this disappointing behavior.

Sincerely,

Rich Bernert, M.D.
Clin-Path Associates, P.C.
Medical Director of Anatomic Pathology
Sonora-Quest Laboratories
1255 W. Washington Street
Tempe, AZ 85281-1210
602-685-5211

PRACTICE LIMITED TO UROLOGY

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A. and S. Gawande, M.D.s, Inc.
A. S. Gawande, M.D., F.A.C.S.
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August 23, 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:

I am writing this letter to explain my position regarding lithotripsy.

I am a urologist in Athens, Ohio and practicing urology for the last 33 years. I have been **providing quality lithotripsy** and other therapeutic services to medicare patient through a urology joint venture. I am concerned and worried by CMS apparent attack on legitimate physician joint ventures.

If these services discontinued, this little hospital, O'Bleness Hospital and Athens community will suffer.

I would request CMS to limit the reach of STARK to only those arrangements that are known to be abusive. **This American kidney stone management venture is a professional and quality service and follows protocols and standards established by American Urological Association.**

I know no one has ever shown any evidence of abuse by urology joint ventures that provide therapeutic services.

Joint ventures that offer services such as laser prostate ablation, cryotherapy are providing valuable services 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 abusing.

The urology joint ventures' primary purpose is to give opportunity for physicians t to improve the patient care.

O'Bleness Hospital is a small hospital and they cannot afford the latest newest technology like lithotripsy unit which is because of the expense and the fact that rapidly changing technology makes today's "best", tomorrow's "obsolete". I know that hospital is not in capacity to invest in technology if it is constantly changing.
Lithotripsy is a good example of this. Physicians wanted a better and less invasive treatment for their patients and that is why the physicians are forming joint venture to buy lithotripsy because hospital could not afford to buy such expensive equipment and the latest equipment.

Through the urology joint ventures, we have been able to improve clinical care and take that risk of obsolescence.

O'Bleness Hospital does not have enough volume to justify the expense of purchasing lithotripsy unit. Our hospital cannot spend money on the capital investment like this which may become obsolete in short time. Because of the joint venture of the physicians, they are able to shoulder some of the risks but at the same time to receive a fair payment and physicians like me are willing to take that risk. I would like to tell CMS that such an effort to shift the burden from itself to the providers who are taking care of patient is unfair and outrageous and offends my sense of justice.

Urology joint ventures enables sharing of the expensive capital technology, like lithotripsy, but in many hospital that cannot afford to purchase lithotriptor by themselves or cannot justify such purchase because due to their case volume and O'Bleness fits into that kind of category because we are not having large volume. *We cannot afford to have a lithotripsy unit purchased by the hospital. This is because it is a rural area.*
Finally, I just like to say to CMS that I am coming from a rural area serving rural population of Athens and has a small hospital of 50-60 beds which are often not filled and this hospital cannot afford to buy lithotripsy unit that means the services are to be out sourced somewhere else and it will be hard on my patient and me to travel.

Thanking you,

Atmaram S. Gawande, MD

Primacare
Rehabilitation
Physical Therapy

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Physician Self-Referral Issues.

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

Sir,
I am a Licensed Physical Therapist practicing in the state of Georgia. I have graduated from physical therapy since the last 21 years. I have my private practice since the last 4 years employing 4 other Physical Therapist. We provide outpatient physical therapy to the local community in Gwinnett County, Georgia. We are extremely proud of the services we provide and the results we get for our patients.

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. My 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.

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 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 utilization of physical therapy services under the Medicare program, and enhance the quality of patient care.

Abuse of this in house physical therapy is inherent. Physicians have a financial incentive to refer more patients to their own physical therapy who may not need the therapy. Physicians will continue with physical therapy even after the patient has reached maximum rehabilitation potential. If any part of the business brings in income, it is

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Christopher B. Dennis, CRNA, MS
318 North 160th Street
Omaha, NE 68118

August 17, 2007

Ms. Leslie Norwalk, JD
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8018 **RE: CMS–1385–P (BACKGROUND, IMPACT)**
Baltimore, MD 21244–8018 **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,

Christopher B. Dennis, CRNA, MS

Christopher B. Dennis, CRNA, MS

CARDIOVASCULAR ASSOCIATES P.S.C.

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Robert R. Goodin, M.D.
Richard D. Allen, M.D.
Jerome P. Lacy, M.D.
David A. Dageforde, M.D.
Janet L. Smith, M.D.
James M. Kammerling, M.D.
Kenneth J. Kral, M.D.
Joseph A. Lash, M.D.
C. Gregory Henes, M.D.
Wm. Martin Skaggs, M.D.
Ponnattu K. Cherian, M.D.
Brian T. Beanblossom, M.D.
William R. Schmidt, II, M.D.
Anthony C. Pearson, M.D.
John M. Mandrola, M.D.
William C. Dillon, M.D.
'Rodney M. Miguel, M.D.
James Patrick Donovan, M.D.
David E. Mann, M.D.
Vincent S. DeGeare, M.D.
Divyesh R. Bhakta, M.D.
Robert A. Schwartz, M.D.
Vipul R. Panchal, M.D.
John S. Harris, M.D.
Ravi Srivastava, M.D.

August 17, 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 CardioVascular Associates (CVA) and our 25 individual 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.

CardioVascular Associates provides comprehensive cardiology care to over 80,000 active patients in the greater Louisville, Kentucky area and surrounding service area. Almost 50% of our patients are Medicare eligible. We provided over 1000 diagnostic cardiac caths in our office cath lab in 2006.

CVA 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

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,

Timothy J. Higgins
Practice Administrator

James H Nelson, MD
Community Urology
1451 Yauger Rd
Mount Vernon, OH 43050

August 25, 2007

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

Sirs and Madames:

I am a urologist practicing in a rural community in north central Ohio. I am employed by my local hospital, Knox Community Hospital, and provide General Urology services including Lithotripsy, Laser Lithotripsy, etc. My hospital contracts for these services with a company, Fortec Medical Inc. This company is NOT physician-owned and managed, *would that they were!* The service is marginal, with no quality control, poor equipment, and the company is notorious for shady business practices (allegedly offering enticements to contracting facilities and practicing physicians to chose their services). The competing service in my area **is** physician-owned, but for reasons not disclosed to me, the hospital chose the "bottom feeder." I am a member of the physician joint venture, its former medical director, and I am well aware of the superior services that they offer and provide. Your apparent attack on this legitimate physician joint venture (as determined by Rep. Peter Stark himself) is very worrisome to me as a physician.

I am very aware of the clinical and cost issues that concern the Medicare beneficiary and CMS. I have been intimately involved in providing lithotripsy and other up to date urology services to may patients for 30 years. Many of these services would never have been available to my patients without physician joint venturing, as the technologies are often too expensive and changeable for hospitals to afford. The few non-physician corporations providing these services are totally and completely profit-driven with little or no regard for quality issues, price containment, etc. The physician joint venture model of providing

technology and service has saved Medicare millions of dollars over the 20 years of its existence under the Stark law.

I would like to address the individual issues put forth in the recent 2008 Physician Professional Fee Schedule proposal.

1- Under Arrangements:
Physician joint ventures are to be banned from contracting with hospital to provide therapeutic services that are DHS *only because* they are provided in a hospital setting. Included are a variety of laser procedures for prostate disease and cryotherapy for cancer of the prostate. The logic is that physician investors do so at the expense of good patient care. On the contrary, physicians do this because small to medium hospitals lack the financial resources to commit to these rapidly changing technologies for fear that their investment will be obsolete before it is paid off. Larger hospitals might be able to afford the technologies, but still balk at them preferring to contract the service or to leave it to regional referral hospitals when the services are much needed locally. Urologists investing in joint ventures are able to take on the shared risk collectively and see to it that the services are delivered where and when needed. This not only improves clinical care, but ensures that patients and families aren't inconvenienced by long trips away from home and jobs to get the care that they need.

The physicians can see to it that the service is provided over a large area and is completely up to date. The physicians themselves are driven to train and learn the most up to date techniques, because they know that their organization will see to it that they all get access to the necessary hardware. Hospitals benefit, because they keep their patients locally and don't have to give up routine procedures to regional centers unnecessarily. Everyone benefits.

2- Per Click Fee
The CMS proposal to ban per click fees is contrary to the intent of Congress. While CMS is concerned with per click arrangements for DHS, the proposed rule would apply the ban more broadly to all Physician owned services. Patients may sometimes need ancillary procedures that were not foreseen. For example, a patient having lithotripsy may need a stent placed or removed or a ureteroscopy to push a stone into a more treatable position. Neither the hospital nor the service provider can predict the occurrence or frequency of such procedures. The risk can only be balanced by per click fees. The per click fee is essential to bringing on the technology, because risk averse hospitals could afford to pay the risk taking physician joint venture.

3- Percentage Fee Reimbursement

The same problem that created the value of the per click fee arrangement created the percentage fee arrangement, apportionment of the risk for failure of adoption or low volume of new treatment modalities. Unless CMS understands the benefits of this type of risk minimizing reimbursement, new therapies will become increasingly difficult to access for Medicare and Medicaid patients, especially in poor neighborhoods, and rurally.

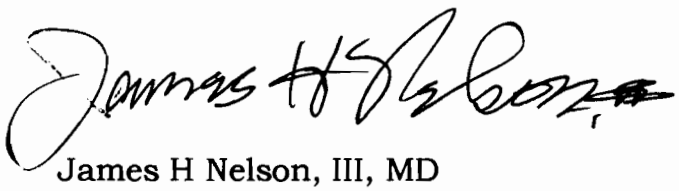
4- Stand in the Shoes

The move to view many ASC's owned by hospitals as part of the hospital itself, will limit the ability of the physician owned joint venture to provide services to those facilities. This will drive physicians to build more ASC's, withdrawing from the hospital-owned ASC's, in order to contain cost and achieve better reimbursement.

5- Burden of Proof

This proposal is truly based on a slippery slope of contradictory logic. It puts the burden of proof on the provider that his referrals were NOT in violation of the Stark laws. Logically and legally, it would seem more correct for the enforcer to prove that a violation had been committed. I take care of the health of the Medicare beneficiary at prices set by CMS. I now face the onus proving that my actions are legal.

I hope that CMS will distinguish between *therapeutic* joint ventures, which are not DHS, from *diagnostic* ventures. Our urology ventures have opened access to new technology for Medicare and Medicaid patients, improved efficiency in the market, and, over the years, saved CMS many millions of dollars. The loss of this time tested and proven model for health care delivery would be shameful. Though CMS's motive, to eliminate some bad behavior, may be well-intentioned, it is far too broad and draconian.



James H Nelson, III, MD
Mount Vernon, OH

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August 17, 2007

Leslie Norwalk, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attn: CMS-1385-P
PO 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,

Our organization provides emergency and non-emergency transports to the members of the communities we serve. We currently attempt to get patient signatures at the time of transport and always follow-up via US Postal mail by forwarding an Authorization Consent Form and Receipt of Privacy Policy Notice for any patient who did not have a previous signature on file. With said mailing we also enclose a self-addressed stamped envelope for the patient to return said form.

While the proposed rule as indicated above attempts to address the difficult issue we as an ambulance service face in obtaining patient signatures, it fails to recognize that many of the patients we transport do not understand the importance of signing and returning an authorization form. Despite the explanation provided on the signature form they receive, which is highlighted in bold that "we can not bill for the services rendered without an authorization on file and that a failure to sign will result in the patient being billed directly", many forms are never returned.

Furthermore requiring a patient's signature does not in-fact guarantee that CMS will avoid paying fraudulent claims. If an agency is going to transport a patient and leave him in a cornfield (or not transport a patient at all) but report that the patient was transported to the hospital, requiring a patient signature is not going to stop them from submitting a fraudulent claim. The agency could simply indicate on the claim that the signature was on file when it really was not. In either case, the fraud would not be detected unless some other outside action was taken (an audit, etc.) The only real way to guarantee claims are not being filed fraudulently is for CMS to cross check with the receiving and/or sending facility that the patient was transported as the ambulance company claimed. In addition, if a claim for services is paid for by Medicare the patient would presumably receive easily comprehended documentation from CMS that would indicate the ambulance company had been paid for services and consequently the patient would notify CMS if the services were not actually received.

From my perspective, the perspective of many other ambulance company administrators I have spoken with, as well as nearly every ambulance service crew member in this industry, the requirement for a signature is a costly and unnecessary requirement that in the end does not benefit CMS, the Ambulance Service, nor the patient. As for the proposal as it reads now, the assumption that busy emergency room staff would be willing or available to sign on a patient's behalf is very likely to be a false assumption. Obtaining a signature of medical necessity proves to be difficult enough.

Given the points I address in this letter as well as the opinions of most people who work in the "real world" that is the emergent and non-emergent transport of ill patients, I fail to see that the proposal as written will benefit the majority and at best will benefit a slight minority of the parties involved. That said, I respectfully request that the requirement for patient signatures be totally eliminated and that CMS consider meaningful options at the expense of CMS to deter and prevent fraudulent ambulance billing as opposed to asking the ambulance service who strives to provide top-notch services at inadequate reimbursement rates to comply to guidelines that in the end do nothing to prevent nor detect fraud and abuse.

Respectfully,

Pamela Rexford Scott
Finance Manager

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August 6, 2007

THE CLEVELAND CLINIC FOUNDATION
LORAIN

Leslie Norwalk
Acting Administrator
Centers for Medicare & Medicaid Services
P.O. Box 8018
7500 Security Boulevard
Baltimore, MD 21244-8018

Michael C. Kolczun II, M.D.
DEPARTMENT OF ORTHOPAEDIC SURGERY
(440) 985-3113 or (800) 860-3310 • (440) 985-3117 Fax

Attn: CMS-1385-P / Office Based Arthroscopy Procedures

Dear Administrator Norwalk:

Thank you for this opportunity to submit comments on the 2008 Medicare Physician Fee Schedule. I am writing to support CMS' proposal (on page 38,135) to reimburse physicians for certain arthroscopic procedures performed in their office.

Your staff may recall that I met with Carolyn Mullen and Pam West approximately a year ago to discuss non-facility ("office") practice expense relative value units ("RVUs") for certain diagnostic arthroscopy procedures. At that time, I explained that arthroscopy procedures are surgical procedures in which physicians examine the internal structure of a joint for diagnosis (or treatment) using a tube-like viewing instrument called an arthroscope. Arthropscopy has been available for many years and is both safe and effective. Procedures typically last 40 to 45 minutes (excluding pre-operative and post-operative care).

As I discussed with Ms. Mullen and Ms. West, today a significant number of physicians perform arthroscopy in the "non-facility setting", and an even larger number of physicians would perform these procedures in their office if reimbursement were available. The procedure is highly accurate, and diagnosis at the point of care is associated with better patient management. Furthermore, patients can generally walk out of their doctor's office after the procedure because only local anesthetic is used.

Medicare, though, does not reimburse physicians for arthroscopies performed in the office. This forces physicians to alter their medical decision making – either needlessly sending patients to the hospital outpatient department for the procedure or ordering other tests such as an MRI. While office-based arthroscopies are not appropriate for all patients, many Medicare beneficiaries would benefit from a change in CMS policy, and I urge the agency to finalize its proposal.

KOLCZUN & KOLCZUN ORTHOPAEDIC ASSOCIATES
DCLIB-513358.1-RJKAUFMA 8/23/07 11:26 AM
5800 Cooper Foster Park Road • P.O. Box 396 • Lorain, OH 44052-0396
LORAIN • ELYRIA • AVON LAKE • OBERLIN • NORWALK

Also attending the 2006 meeting with Ms. West and Ms. Mullen were representatives from Arthrotek, Inc., a manufacturer of arthroscopy products. I understand that Arthrotek has analyzed some of the expenses associated with in-office arthroscopy and concluded that relative value units equivalent to $1,300 should be assigned to the procedure. This number sounds approximately correct, and I recommend that CMS adopt it.

Thank you for your attention to this important matter. I was pleased to see that CMS continues to look for ways to improve the Medicare system and to respond to physicians' concerns. I hope that you will now finalize the proposal to establish payment for non-facility arthroscopy procedures.

Sincerely,

Michael Kolczun, 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)

398-1

CAPE GIRARDEAU
UROLOGY ASSOCIATES, INC.
ADULT AND PEDIATRIC UROLOGY

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J. RUSSELL FELKER, M.D., F.A.C.S.
JOHN PAUL HALL, D.O., F.A.C.S.
PAUL D. THOMPSON, M.D., F.A.C.S.
DONALD L. GENTLE, M.D., F.A.C.S.
GREGG S. HALLMAN, M.D., F.A.C.S
JAMES E. OUTMAN, D.O., F.A.C.S.

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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

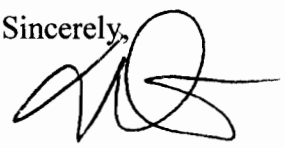
Ladies and Gentlemen:

As a practicing urologist in Cape Girardeau, Missouri, I am deeply concerned about certain proposals in the recently released 2008 Proposed Physician Fee Schedule. While I am acutely aware of both the clinical and cost issues affecting the Medicare beneficiary and CMS, I believe these proposals will unnecessarily harm patients and physicians, as well as the entire healthcare system. Although I support CMS efforts to prevent abusive practices, I believe CMS could address its concerns in a manner less detrimental to legitimate joint venture arrangements.

Practicing as a urologist, in a city of less than 36,000, I have seen firsthand the beneficial effects that joint ventures have had for the healthcare system. Joint ventures have allowed me to provide my patients lithotripsy and other cutting edge therapies, for urological disease, that would otherwise not have been available. Often hospitals refuse or are unable to purchase this state of the art technology. Through these urology joint ventures, physicians have been able to improve clinical care and take that risk of costly services, when hospitals would not. Ultimately, I want to provide my patient with the highest quality healthcare available in an efficient manner, as I am sure is your goal also. Therefore, I ask you to reconsider the anti-physician ownership proposals such as "Under Arrangements", "Per Click Fee", "Percentage Fee Reimbursement", Stand in the Shoes", and "Burden of Proof". If adopted, in the order in which they were presented in the proposed rule, they will have a negative effect on the healthcare system.

In conclusion, I would ask CMS to differentiate between beneficial therapeutic joint ventures, which are not of themselves DHS, from the questionable diagnostic ventures that physicians and hospitals may have propagated. Undoubtedly, 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 saved CMS hundreds of millions of dollars. As CMS tries to stop abusive arrangements, it would be a mistake to jeopardize such time tested and proven models.

Sincerely,



William C. Collyer, M.D.

399-1

Christopher Chaprnka, OTR
Hand Therapist, Director

Cheryl A. Reed, MS, OTR, CHT
Certified Hand Therapist

Amy Scarlett, PT
Physical Therapist

Liza Corzo, MPT
Physical Therapist

Donna Hasbrouck, MS, OTR/L
Hand Therapist

Amanda Stoker, OTR/L
Hand Therapist

Clinic Specialities
- Hand & Upper Extremity Rehabilitation
- Wound Care
- Splint Fabrication
- Orthopaedic/Sports/Work Related Injuries
- Back Rehabilitation
- Vestibular / Balance

Rehabilitation

August 23, 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 Office PT/OT Services*

Dear Mr. Weems;

I am writing this letter to express my concern regarding the in-office ancillary service arrangements that have impacted the delivery of quality physical and occupational therapy.

The "in-office ancillary services" exception has created a loophole which has resulted in many physician-owned arrangements that provide substandard physical and occupational services.

Physicians are in a position to refer Medicare beneficiaries to in-office physical and occupational services in which they have a financial interest. There is an inherent financial incentive to overutilize services under the in-office ancillary services exception.

Therapy treatments are repetitive in nature. Patients receiving outpatient physical and occupational therapy can just as easily return to a therapy clinic as to the physician office.

Thank you for considering these comments and eliminating this "in-office ancillary services".

Sincerely,

Louis Shapiro, DPT, ATC, LMT

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400

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 cautiously optimistic about the proposal to increase anesthesia payments in the 2008 Physician Fee Schedule. Anesthesia services for Medicare patients have been grossly undervalued for far too long.

Anesthesiologists complete twelve years of rigorous education and training in order to practice one of the most demanding, stressful, and important occupations in the country. This training requires huge sacrifices as it encompasses nearly all waking hours. In my case, I also had to join the military to pay for medical school. This added three additional years before I could begin my practice.

As you are aware, we act as the patient's advocate pre-operatively – assuring that their health issues have been optimized to minimize their risk of surgical complications (death, heart attack, stroke, etc.).

During surgery, we function as the patient's cardiologist, internist, pulmonologist, nurse, ER physician, psychiatrist, and all else necessary to keep them alive and well while surgeons dissect their hearts, livers, brains, etc.

Postoperatively, we serve as their pain specialist while continuing to address their individual medical needs.

With all these functions and responsibilities comes extraordinary stress (and lawsuits).

It is unfair that our hourly wage for these efforts is less than mechanics, plumbers, or even nurses working in the same OR. It's about one fifth of our lawyer's hourly fee.

Our senior patients require the best and brightest anesthesiologists to achieve optimal outcomes. However, Medicare's absurdly low reimbursement to anesthesiologists has resulted in many good anesthesiologists choosing to work in Medicare-free locations.

As the Chairman of our Anesthesiology Department, I observe with dismay as excellent anesthesiologists leave our hospital (where their skills are critically needed) and practice in less demanding settings where they are reimbursed fairly. Some have left the field of anesthesiology entirely for occupations that contribute significantly less to our society.

It is obvious that the present formula used to establish anesthesia conversion rates is grossly flawed. I encourage you to implement the anesthesia conversion factor increase as recommended by the RUC as soon as possible!

Sincerely,

David Gwyn Woodward M.D.