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COMSTAR★
Ambulance Billing Service

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August 22, 2007

Comstar, Inc. is an ambulance billing service. We act as the authorized billing agent for over 200 municipal ambulance services through out the New England states.

On our clients behalf, Comstar welcomes this opportunity to comment on CMS-1385-P

Comstar and its clients 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, for a large percentage of encounters, the beneficiary is not in a condition to sign a claims authorization during the entire time the supplier is treating and/or transporting the beneficiary. Many beneficiaries are in physical distress, unconscious, or of diminished mental capacity due to age or illness. The very reason they need ambulance transportation often contraindicates the appropriateness of attempting to obtain a signature from the beneficiary.

However, Comstar and its clients believe strongly that the relief being proposed by CMS would have the unintended effect of increasing the administrative and compliance burden on ambulance services and on the hospitals. Accordingly, we urge CMS to abandon this approach, and to instead eliminate the beneficiary signature requirement for ambulance services entirely.

Please consider the following points and our sincere request that the beneficiary signature requirement be completely eliminated:

1) For the reason stated in my opening paragraph, our clients face extreme difficulties getting signatures in emergency and non-emergency situations.

2) Time spent attaining signatures increases the cost of the trip and reduces the crews availability to respond to another emergency call.

3) The signature is no longer needed for the assignment of benefits since assignment of Medicare benefits is mandatory for covered services.

H.I.P.
Santa Cruz County

Health Improvement Partnership of Santa Cruz County

1600 Green Hills Road ♦ Scotts Valley, CA 95066
(831) 430-5604 Telephone ♦ (831) 430-5858 FAX

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August 20, 2007

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

Re: Proposed reconfiguration of CA physician payment localities

The Health Improvement Partnership of Santa Cruz County is a public and private collaboration of local health care leaders dedicated to increasing access to care. We appreciate the opportunity to comment on the three options outlined in the proposed physician payment rule for 2008 with respect to reconfiguration of physician payment localities in California. We are once again calling for a locality reconfiguration in California that must include Santa Cruz County.

Santa Cruz County has been uniquely disadvantaged since the last reconfiguration in 1996 with respect to CMS physician payment localities. Not only has Santa Cruz County had the largest underpayment within Locality 99 in California each year since 1996, we have also had the largest boundary payment difference between our county and San Mateo/Santa Clara Counties, the largest of any adjoining counties in the nation. In contrast to the Locality 99 payment rate for our physicians, we have the highest Wage Index/Hospital GAF of any county in the nation. As a result we continue to lose local physicians who are drawn to practice in neighboring localities such that our Medicare beneficiaries are facing critical access issues.

The GAO has called for a national reform of the payment localities. They interviewed many providers in our county during the development of their report. We are concerned that only one of the three proposed options in the rule reflects the recommendations of the GAO. Neither Option 1 nor 2 includes an iterative reconfiguration of California's localities, which was the approach CMS used in 1996 and by the GAO.

We therefore support Option 3 which constructs six payment localities for California. CMS describes the application of a 5% floor for a given locality based upon the highest GAF of a county within that locality. CMS presented this option in past Federal Register proposals. However, we believe CMS miscalculated the designation of the new payment localities in California. We recommend that the text described in the proposed rule be accepted but that CMS should recalculate the county groupings accurately. We have attached a table showing this recalculation which would also move adjoining San Benito County into Locality 02 using actual data from the June 2007 GAO report on physician localities for San Benito County.

If CMS were to select Option 1 we strongly recommend that each county that is removed from Locality 99 (and Locality 03) be assigned into its own fee schedule areas. This is especially true given that the most likely eligible counties (Santa Cruz, Monterey, Santa Barbara, and San Diego) all currently exist as one county Metropolitan Statistical Areas in the Hospital GAF. Further, we recommend that an iterative 5% threshold be applied if you choose this option.

CMS must correct this problem this year. CMS must not defer the implementation of this long-awaited reform to a state medical society. Thank you for your attention to our comments and recommendations.

Sincerely,

Alan McKay
President, Board of Directors

Attachment

cc: The Honorable Sam Farr, US House of Representatives

Thomas Jefferson University Hospital
Jefferson Health System®

Department of Radiology

403

David C. Levin, M.D.
Emeritus Professor and Chairman
Department of Radiology
Thomas Jefferson University Hospital

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August 22, 2007

Thomas Jefferson University Hospitals

Thomas Jefferson University Hospital

Methodist Hospital

Jefferson Hospital for Neuroscience

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

Re: Changes to reassignment and physician self-referral rules relating to diagnostic tests (anti-markup provision), in-office ancillary services exception

Dear Mr. Kuhn:

The following are comments I wish to submit.

Imaging is the most rapidly growing physician service within the Medicare program. It is therefore of great importance that steps be taken to curb any possible inappropriate growth of this service. Much of the growth has been fueled by the acquisition in recent years of high technology scanners (such as MRI, CT, PET, or nuclear scanners) by nonradiologist physicians who install the units in their offices and are then able to self-refer their patients for those types of examinations. They have been able to be reimbursed for these examinations under the in-office ancillary services exception of the Stark laws.

In the CMS proposed rule on the Physician Fee Schedule, 42 CFR 409,410 et al, page 38181, you indicate that Congress's original intention was to create this exception to allow for the provision of certain services when necessary for the immediate diagnosis or treatment of the medical condition that brought the patient to the physician's office. You then give the example of some simple laboratory tests. You go on to say that today, however, services being provided under this exception are often not as closely connected to the physician's practice. This statement is clearly true, and it is exemplified by the acquisition of high tech imaging equipment by physicians who were not trained as radiologists, or even how to just oversee these specialized procedures. Radiologists are trained for at least 4 years and usually as many as 5 or 6 years to perform and interpret imaging studies. In their practices, they do not have the opportunity to self-refer. All their patients are referred to them by other unaffiliated physicians, who have no financial incentive to do so but are simply seeking assistance in diagnosing their patient's clinical problem. By contrast, nonradiologist physicians who operate their own imaging equipment or lease it from

of referring their patients to radiologists. It is difficult to justify the rapidly increasing use of invasive catheter angiography by vascular surgeons and cardiologists at a time when cheaper, noninvasive techniques are readily available.

These and many other studies have demonstrated that (1) purchase of expensive and sophisticated imaging equipment by nonradiologist physicians is a rapidly growing trend, and (2) when self-referral opportunities exist, imaging utilization will increase sharply. They highlight the urgency of revising the in-office ancillary services exception in ways that will substantially limit the opportunities for self-referral.

A variety of fixes have been proposed for this problem. One that has not been previously discussed widely is what might be called "the 75% rule". Under this rule, physicians and physician group practices would not be reimbursed by Medicare for imaging (either technical or professional components) unless at least 75% of all the allowable fees of that physician or entire physician group practice came from imaging. This rule would be fair in that physicians would not necessarily have to be radiologists to be paid for imaging. However, imaging would have to be the major component of that physician or physician group practice. This would ensure that any physicians being reimbursed for imaging would be doing it all or most of the time and would therefore presumably have the greatest expertise. Moreover, since imaging was the primary focus of their practice, the likelihood is that their equipment would be of higher quality and recent vintage. I hope you will consider incorporating this policy in the CMS final rule.

Thank you for your consideration of these comments. I would be happy to come to CMS and present our data in person if you wish. I can be reached by phone at 215-955-6271, or cell at 610-331-1877, or by email at david.levin@mail.tju.edu.

Sincerely,

David Levin

David C. Levin, M.D.

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NCSBN
National Council of State Boards of Nursing

111 E. Wacker Drive, Suite 2900
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312.525.3600
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August 21, 2007

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

RE: CMS-1385-P

Dear Sir or Madam:

On behalf of the National Council of State Boards of Nursing (NCSBN), I would like to submit comments regarding the proposed regulations in the Federal Register dated July 12, 2007. The National Council of State Boards of Nursing is composed of the 59 nurse licensing boards in all 50 states, the District of Columbia and four U.S. Territories.

CORF & Skilled Nursing Services:

The section that speaks to allowing skilled nursing services to be performed only by Registered Nurses (RN) does not fully articulate those skills which CMS does not feel at this time can be performed by a licensed practical/vocational nurse. The nursing services provided by either the RN or the LPN/VN should be determined by the legal scope of practice as outlined in state law by a state board of nursing.

Physical Therapy Qualifications

The proposal to allow for physical therapists to pass a national exam approved by the American Physical Therapy Association (APTA) and for foreign trained physical therapists requirement to undergo a credentialing process approved by the APTA is duplicative, unnecessary, and inappropriate. It is the purpose and function of state licensing boards to determine the qualifications of healthcare professionals. State licensing boards have a legal duty to protect the public by only licensing safe and competent healthcare professionals. This is a state right under the United States Constitution.

State healthcare licensing boards already approve national licensing examinations for assessment of competence for healthcare professionals including the evaluation of international applicants. It is inappropriate and a conflict of interest for a professional organization to be awarded approval authority when their mission is to protect and advocate for the profession versus the mission of a state licensing board which is to protect and advocate for the public.

CMS will be well served by the current national licensing examinations approved by state licensing boards and their evaluation of individual credentials.

Sincerely,

Kathy Apple, RN, MS, CAE
Chief Executive Officer
National Council of State Boards of Nursing

Cc: NCSBN, Board of Directors
Kristin Hellquist, Director of Policy & Government Relations

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Houston Metro Urology

Brian C. Powers, M.D.
Urology
Mark A. Sutton, M.D., F.A.C.S.
Urology
Ricardo R. Gonzalez, M.D.
Urology

August 20, 2007

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

Re: **Physician's Self Referral Provision**

Ladies and Gentlemen:

I am a urologist in Houston, Texas and I have been providing quality lithotripsy and other therapeutic services to Medicare patients through a urology joint venture. I am very worried by the apparent attack on legitimate physician joint ventures.

I understand that there is a proposal that CMS would prohibit a hospital from billing Medicare for any referrals made by a physician for a designated health service provided by the hospital if the service was provided to the hospital "under arrangements" by the physician or any entity in which the physician is an investor. I believe that CMS should limit the reach of Stark only those arrangements that are known to the abusive and that Congress intended to reach.

No one has ever shown any evidence of abuse by urology joint ventures that provide therapeutic services. 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 its 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 arrangement should not apply to services where the investor physician performs the professional portion of the procedure.

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For urological joint ventures the primary purpose of physician investment is to improve patient care. Hospitals refuse to purchase state of the art technology even if it is clinically superior because of the expense and the fact that rapidly changing technology makes today's "best" tomorrows "obsolete". Lithotripsy is a good example of this. 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 the ALS versus Thompson case the court held that extracorporeal shock wave lithotripsy is not a designated health service even though it is provided under arrangements at the hospital. It would be highly beneficial to patients and providers if CMS also exempted procedures that are not otherwise DHS from the proposed prohibitions to under arrangements.

To accommodate hospital's 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. Also, sometimes the patient will need a procedure that is less often performed and it is difficult to calculate this into the compensation arrangement. For example, a lithotripsy case that requires insertion or removal of a stent or ureteroscopy or cystoscopy.

Another way that a hospital avoids risks is to create arrangements where compensation is set as a percentage of reimbursement for the procedure. Certain third party payers provide lower imbursement while others reimburse more generously. Percentage compensation arrangements permit the physician joint venture to shoulder some of the risks, but at the same time receive a fair payment. Physicians are willing to take this risk.

The CMS proposal to have a hospital stand in the shoes of an ASC that it owns or controls will have the effect of turning hundreds if not thousands of procedures that are not of themselves DHS into DHS. Its proposal called stand in the shoes is finalized, physicians would likely withdraw from ownership in ASCs where hospitals are investors.

CMS wants the burden to be on their provider to prove that he did not violate the Stark clause even though CMS is the accuser in that situation and the one that wrote the rules that the doctor must follow. Such an effort to shift the burden from itself to the providers who are taking care of Medicare patients is unfair and outrageous and offends my sense of justice. Requiring a DHS entity or physician to prove lack of knowledge would create the impossible situation of having to prove a negative.

Urology joint ventures have enabled sharing of expensive capital technology such as lithotripsy between many hospitals that cannot afford to purchase a lithotripter by themselves or cannot justify such a purpose because of their limited case volume. Many rural areas are also served by the same shared service concept that Urology joint ventures have fostered. Because of this 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.

I ask you to accept the burden of proof that the law has historically placed upon the one creating the rules and to not shirk that responsibility. I would like to clarify that as a result of the ruling in the ALS versus Thompson lithotripsy would not be subject to the proposed under arrangements restriction. I would also ask that it would be clarified that 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 sites where they are delivered.

I would ask that you 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 share service model has created and I would ask that you clarify the stand in the shoes provision to accept possible 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 very much for considering my concerns.

Very sincerely,

Brian C. Powers, M.D.

BCP:mc

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*Steve Alexander, MD FACS
*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,

Hunter L. Brown, MD FACS

407-1

DEPARTMENT OF FIRE/RESCUE
DIVISION OF EMERGENCY
MEDICAL SERVICES

CITY OF
HALLANDALE BEACH
City of Choice

Phone (954) 457-1481
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August 22, 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:

Our organization provides emergency ambulance services to the communities which we serve. The proposed rule 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 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 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 authorizations 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 would have the unintended effect of increasing the administrative and compliance burden on ambulance services and the hospitals and would result in shifting the payment burden

to the patient if they fail to comply with the signature requirements at the time of 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, document 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 department and no registration desk. The same individuals responsible to providing medical care and transportation to the hospital are also responsible for fulfilling the administrative functions. All EMS encounters are emergency in nature and medically necessary ambulance transports in particular are stressful events on patients.

CMS has recognized this 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 patients signature even though the patient is under mental duress. The very reason they need 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 their behalf, while adding additional documentation requirements. Therefore, we believe that the new exception for emergency ambulance services set forth in proposed 42 C.F.R. §424.36(b)(6) should be amended to include only subsection (i), i.e. that no authorized person is available or willing to sign on the beneficiary's behalf.

It is important for CMS to realize that the first two requirements in the proposed sub-division (ii) are always met, as the ambulance crew will always complete a trip report that lists the condition of the beneficiary, the time and date of the transport and the destination where the beneficiary was transported. For this reason, we do not object to the 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 4 years from the date of service. However, we do not see any reason to include these in the Regulation, as they are already required and standard practice.

The Proposed Rule would add a requirement that an employee of the facility, i.e. hospital, sign a form at the time of transport, documenting the name of the patient and the time and date the patient was received by the facility. Our organization **strongly objects** to this new requirement as:

- Instead of alleviating the burden on ambulance providers and suppliers, an additional form would have to be signed by hospital personnel.
- Hospital personnel will often refuse to sign <u>any</u> forms when receiving a patient.
- If the hospital refuses to sign the form, it will be the beneficiary that will be responsible for the claim.
- The ambulance provider or supplier would in every situation now have the additional burden in trying to communicate to the beneficiary or their family, at a later date, that a signature form needs to be signed or the beneficiary will be responsible for the ambulance transportation.
- Every hospital already has the information on file that would be required by this Proposed Rule in their existing paperwork, e.g. in the Face Sheet, ER Admitting Record, etc.

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 date, time and 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 ABN's 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 ABN's 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 to or from a facility, i.e. a hospital or a skilled nursing facility. In the case of emergency ambulance transports, the ultimate destination will always be a hospital. These facilities typically obtain the beneficiary's signature at the time of admission, authorizing the release of medical records for their services *or any related services*. The term "related services", when used by hospitals and SNFs, can mean more than only entities owned by or part of the facility. 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 10 claims per month), ambulance suppliers must submit claims electronically. Thus, the beneficiary does not even sign a claim form. When submitting claims electronically, the choices for beneficiary signature are "Y" or "N". An "N" response could result in a denial, from some Carriers. That would require appeals to show that, while the signature has not been obtained, an alternative is accepted. As a result, many Carriers allow a "Y", even though the signature was not actually obtained, if one of the exceptions is met.

While this may be a claims processing issue, since you are now looking at the regulation, this would be a good time to add language indicating that the signature requirement will be deemed to be met if one of the exceptions to the requirement exists.

Program Integrity

It is important for CMS to realize that, for every transport of a Medicare beneficiary, the ambulance crew completes a trip report listing the condition of the patient, treatment, origin/destination, etc. AND the origin and destination facilities complete their own records documenting the patient was sent or arrived via ambulance, with the date. Thus, the issue of the beneficiary signature should not be a program integrity issue.

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 dual eligible patient (Medicare and Medicaid), the exception should apply in connection to a signature being on file with the State Medicaid Office.
- Amend 42 C.F.R. §424.36(b) (5) to add "or ambulance provider or supplier" after "provider".

In light of the foregoing, we urge CMS to forego creating a limited exception to the beneficiary signature requirement for emergency ambulance transports, especially as proposed, and instead eliminate the beneficiary signature requirement for ambulance services entirely if one of the exceptions listed above is met.

Thank you for your consideration of these comments.

Sincerely,

Alexander R. Baird, Division Chief EMS

408-1

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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 physician practicing in North Carolina, 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

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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.

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,

John D. Lasater, M.D.

409-1

UROLOGY HEALTH SPECIALISTS, LLC

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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,

Robert S. Charles, M.D.

Government Affairs Division

Baxter Healthcare Corporation
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Baxter

August 29, 2007

Herb Kuhn
Acting Deputy Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Department of Health and Human Services
Washington, D.C. 20201

RE: Medicare Program: Proposed Revision to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008 (CMS-1385-P)

Coding_payment for IVIG Add-on
Practice Expense and ESRD MCP and Quality

Dear Herb Kuhn:

Baxter Healthcare Corporation (Baxter) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed regulation, entitled "Medicare Program: Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008,"[1]("Proposed Rule") released July 12, 2007. Baxter is a global diversified healthcare company that develops products and therapies to make a meaningful difference in the lives of people with hemophilia, kidney disease, immune disorders and other chronic and acute conditions. The company operates in three segments: *BioScience* develops biopharmaceuticals, biosurgery products, vaccines and blood collection products and technologies. *Medication Delivery* provides intravenous solutions and specialty products used for fluid replenishment, anesthesia, nutrition, pain management, antibiotic therapy and chemotherapy. *Renal* develops products and services to treat end-stage kidney disease.

[1] 72 Fed. Reg. 38122 (July 12, 2007).

Preadministration Fee for IVIG

To ensure appropriate services to Medicare beneficiaries, we believe that Medicare payment policies should create incentives and not disincentives to provide the right treatment in the right place at the right time. In 2005, the Medicare Modernization Act (MMA) average sales price (ASP) provision was implemented to reimburse Part B drugs and biologicals in the physician setting and collided with patient treatment and the intravenous immune globulin (IVIG) market in the U.S., resulting in unintended negative consequences for patients. While the ASP methodology was not researched or tested prior to MMA enactment, we appreciate the outstanding work undertaken by the Office of the Inspector General[2] and the Department of Health and Human Services Assistant Secretary for Planning and Evaluation (ASPE)[3] to examine the IVIG reimbursement issues after the implementation of ASP. Baxter agrees with the OIG's report that states, "IVIG is a unique pharmaceutical product that presents payment and cost-related issues that may not be typical of other Part B covered drugs."

The HHS OIG report found that only 59 percent of IVIG sales to physicians by the three largest distributors occurred at prices below the Medicare payment amount in the third quarter of 2006. And this "positive" result still means that 41 percent of physician purchases to treat patients with IVIG were above ASP plus 6%. (Significantly, the OIG report states on page 9 that these data are only from 66 percent of physicians and do not include data from smaller distributors at noncontract prices, so we observe that the 41 percent may be too low.) As a result of the shortfall, the ASPE February 2007 report found that, within a year and a half of implementation, roughly 42 percent of the patients that had been receiving care in a physician office were shifted to treatment in a hospital setting.

For patients with primary immune deficiency diseases, IVIG is the standard of care. The switch to ASP payment for IVIG resulted in patients with compromised immune systems being forced to seek care out of the home and office settings into the hospital where they are surrounded by other patients with serious communicable diseases. The hospital outpatient is the least ideal setting, while the

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[2] Department of Health and Human Services Office of the Inspector General: Intravenous Immune Globulin: Medicare Payment and Availability – April 2007, OEI-03-05-00404.

[3] Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation: Analysis of Supply, Distribution, Demand, and Access Issues Associated with Immune Globulin Intravenous (IGIV)-February 2007

home is often the best place for immune deficient patients to receive treatment. ASPE reports that several physicians stated that patients died or were seriously impaired in the chaos surrounding the implementation of ASP.

Baxter Healthcare Corporation has tried to ameliorate the transitional problems by continually investing in patient-centric initiatives that help provide continued access to patients: first, through Gammagard Portability which is a program to help provide hospitals continued access to Gammagard irrespective of changes in their group purchasing organization affiliation; second, Low IgA/IVIG Intolerence program that provides patient access to special lots of GAMMAGARD S/D that has a lower content of certain immunoglobulins called IgA, for certain patients that experienced adverse reactions from other IVIG therapies. Baxter has announced the launch of the GARDian program, which is expected to start early next year, to further help provide continued access to Gammagard for patients even when there are changes to providers or sites of care.

But problems will continue because the OIG and ASPE reported data demonstrate that ASP plus 6% is not the market price for IVIG but, rather, it is a single market price in a continuum of prices paid by providers. There are at least three significant problems with ASP for IVIG:

1) ASP is derived from a formula capturing manufacturers' rebates and other factors. Many biologicals are distributed directly to providers by the manufacturers and thus, the manufacturers' price is fairly representative of the market. In the case of IVIG, the OIG reports that 34% of physician purchases were from smaller distributors at noncontract prices. The OIG report also states that noncontract prices may be higher than contract prices because they are subject to additional distributor markups. The ASP calculation rules do not reflect the non-contract prices to physicians and thus the aggregate ASP is understated, especially within the physician class of trade.

2) Given the statistical distribution of prices, the average is not the going rate for IVIG and simply covers a part of the variation in IVIG pricing. The OIG pricing data show that the market appears to be significantly

segmented and payment set at ASP plus 6% cuts off significant groups of providers. Given that the plus 6% is not empirically derived[4], is there any evidence to suggest that these prices above ASP plus 6% are not real market prices or not legitimate?

3) Most biologicals are in separate codes with separate average sales price amounts for each product. Until July, 2007, all the IVIG therapies were bundled into only two codes--a liquid code and a lyophilized code generating blended average sales price amounts for each of the two codes. The OIG report states, "each IVIG product is a unique brand drug, yet Medicare payment is based on a weighted average price of all products." While liquid IVIG brands now have separate ASPs, lyophilized products do not and this affects the ability of physicians to afford higher priced products within that single code and ASP. (Since it is an average, one product will always have a higher price than the other.)

For these reasons, Baxter believes that, for the sake of the patients, the Secretary needs to continue the preadministration fee for IVIG for physicians until each IVIG product can be in a separate ASP and the ASP formula or add-on revisited to cover a larger proportion of the actual market prices paid for IVIG by physicians. We are concerned about the continuing effects on clinical practice because, according to the OIG and ASPE data, the preadministration fee is not sufficient enough for a significant segment of physicians to make up for the failure of ASP plus 6% to adequately capture the non-normal statistical distribution of market prices paid for IVIG across different products. Baxter encourages the agency to reexamine the value of the preadministration fee in order to reestablish access in all sites of service. We respectfully disagree with the agency that the $71 fee might distort the market when data show that ASP has distorted the delivery of IVIG and forced care out of the lowest cost setting.

Policy for Home Dialysis Values for the Monthly Capitation Payment (MCP) for Patients 20 or older

In the 2003 Federal Register, Vol. 68, No 216, November 7, 2003, page 63219, the Centers for Medicare and Medicaid Services

[4] Government Accountability Office, End Stage Renal Disease, June 26, 2007, Page 3

decided to set the work values for the MCP for home patients 20 years of age or older at the same rate as the codes for other dialysis patients. CMS cited a desire to be consistent with the Social Security Act 1881(b)(3)(B) to provide an increased incentive for home dialysis. The two codes are G0318 (ESRD related services during the course of treatment for patients 20 years of age and over with 2 to 3 face-to-face physician visits per month) and G0323 (ESRD related services for home dialysis patients per full month, for patients twenty years of age and older). G0318 is reimbursed $10.61 more than the comparable G0323 home code due to a difference in the practice expense. Baxter is concerned that this differential reimbursement mitigates the incentives that CMS tried to establish in 2003 when they revised the Monthly Capitation Payments in order to improve physician oversight and care.

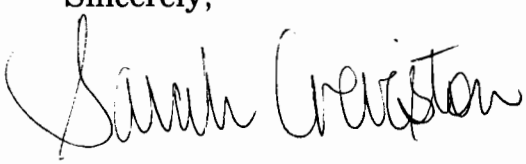
This issue was not raised directly in the proposed rule, but we recently uncovered several problems such as the reimbursement gap between codes and that there is no reference in the 2008 files for the practice expense values. Our concern is heightened, given the effect of the introduction of additional reimbursement for the MCP with 4 or more face-to-face visits. The MCP for 4 or more face-to-face visits is the highest volume MCP code with 1.9 million services reported compared to 0.7 million for MCP for 2 to 3 visits (2005 Medicare physician supplier procedure summary master file.) The MCP with 4 or more visits is reimbursed almost $60 dollars more per month than the home dialysis code for patients above 20 years of age. Thus, we believe it is a critical issue for patient care and choice that, at a minimum, CMS strengthen its 2003 policy position used in the MCP work values by using a consistent practice expense value for MCP codes G0323 and G0318. The preferred policy is that the home MCP amount would be a weighted average of the MCP amounts for the other dialysis patient G-Codes. We appreciate your attention to this urgent issue to remove a disincentive further for the use of peritoneal dialysis, which has a high level of patient satisfaction, lower medication costs, maintains oversight on patient compliance through cycler data, and has more favorable hospitalization profile (USRDS 2006).

Finally, we would like to bring your attention to the need to collect adequacy measures for PD patients on Dialysis Compare. We ask that CMS make the appropriate changes to the codes reported on the bill so that information on KT/V at the 2006 KDOQI standard can be provided on Medicare beneficiaries.

Conclusion

In conclusion, Baxter appreciates this opportunity to comment on the Proposed Rule. We recognize that to truly create an adequate, reasonable, and equitable payment for all IVIG products that it may take an act of Congress. Until that time, we appreciate the efforts that CMS has made as a first step to ameliorate the problems with ASP. In addition, we thank CMS for their attention to issues with renal patients over the years. If you have any questions, please contact me at 202 508-8210 or at sarah_creviston@baxter.com.

Sincerely,



Sarah Creviston

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Johnson & Johnson

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August 28, 2006

By Hand Delivery

Herbert Kuhn, Acting Deputy Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: CMS-1385-P—Comments on Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B—ASP Issues & CAP Issues

Dear Acting Deputy Administrator Kuhn:

Johnson & Johnson appreciates the opportunity to submit these comments on behalf of its pharmaceutical Operating Companies who manufacture products reimbursed under Medicare Part B. These comments are in response to the proposed rule published by the Center for Medicare and Medicaid Services' ("CMS") on July 12, 2007, regarding Revisions to Payment Policies Under the Physician Fee Schedule for CY 2007 and Other Changes to Payment Under Part B ("Proposed Rule").[1] In particular, these comments focus on the ASP and CAP issues raised in the Proposed Rule.

While we generally support the comments submitted by the Pharmaceutical Research and Manufacturers of America ("PhRMA"), the Biotechnology Industry Organization ("BIO") and AdvaMed, we find it necessary to supplement their comments in certain critical aspects. In particular, we provide comments on bundling, the threshold for comparing ASP to WAMP and AMP, and changes proposed to the CAP program. These comments are further supplemented by the submission made by Ortho Biotech Products, L.P., a Johnson & Johnson Operating Company, on a necessary exception to the proposed bundling rule for certain situations involving bundles with dominant drugs.[2]

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1 72 Fed. Reg. 38,122 (July 12, 2007).

2 *See* letter from Ortho Biotech Products, L.P., to Herb Kuhn dated August 27, 2007.

I. ASP ISSUES

As a general matter, Johnson & Johnson continues to advocate for certainty and clarity in the requirements for calculating and reporting Average Sales Prices ("ASPs") for Medicare Part B covered drugs. The need for clarity is underscored each quarter when representatives from our Operating Companies are required to certify the ASP submissions for their companies' Part B covered drugs at the risk of penalties of $10,000 per day for each incorrectly calculated ASP.

As a general proposition, we agree with CMS' goal of "ensur[ing] that the ASP is an accurate reflection of market prices for Part B drugs and that the treatment of bundled price concessions in the ASP calculation does not create inappropriate financial incentives." We believe that J&J Operating Companies have appropriately allocated the discounts and price concessions associated with bundled arrangements since the inception of the ASP reporting requirement. Nonetheless, it is plain from comments previously submitted to CMS on the issue of bundling and the concerns generated by the recently issued Medicaid bundling rule that CMS now proposes apply to ASP calculations, that manufacturers do not have a consistent understanding of what constitutes a bundled arrangement or what discounts must be reallocated if a bundled arrangement is determined to exist. For these reasons, we support CMS taking action to clarify the rules applicable to bundling in the ASP context, but we urge CMS to proceed cautiously in adopting the Medicaid bundling rule for the ASP calculations and to recognize that the Medicaid rule is not appropriate in all circumstances." Furthermore, as explained in detail in comments submitted separately by Ortho Biotech Products, L.P., the Medicaid bundling rule does not achieve CMS' goal where rebates/discounts on a product with virtually no competition (a "dominant drug") are conditioned in whole or in part on purchases of a drug (or drugs) with clinical alternatives ("competitive drugs."). In that situation, an exception to the proposed allocation methodology is necessary to ensure the accuracy and integrity of the reimbursement rates under the Part B program.

A. *Bundled Arrangements*

CMS has proposed to revise the methodology for determining the ASP for Part B drugs by "defining bundled arrangements and requiring that drug manufacturers allocate bundled price concessions proportionately to the dollar value of units of each drug sold under the bundled arrangement when reporting ASPs."[3] In essence, CMS has proposed that the definition and allocation methodology now included in the final Medicaid AMP rule be applied to the ASP calculations. CMS explained in its press release for the proposed rule that it expected this proposed approach would "help the ASPs to better reflect the true costs incurred by physicians when purchasing Part B covered drugs."[4]

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[3] CMS Press Release: *CMS Proposes Policy, Payment Changes for Physicians' Services in 2008,* July 2, 2007

[4] *Id.*

Before proceeding into the specifics of CMS's proposal, two underlying premises for this proposal should be revisited. The first relates to MedPAC's recommendation and the second relates to the purpose of allocating bundled discounts.

1. MedPAC Recommendation

CMS explains that its proposal on bundling is in response to MedPAC's January 2007 report to Congress. CMS correctly noted that MedPAC recommends, "the goal should be to ensure that ASP reflects the average transaction price for drugs."[5] CMS also correctly pointed out that MedPAC advised that the reporting requirements for allocating discounts should be clear and capable of being implemented in a timely fashion by manufacturers.[6] While MedPAC opined that application of the Medicaid bundling rule, with some adjustments, might be simpler to administer than an alternative that was considered, MedPAC did not recommend that the Medicaid bundling rule be applied to the ASP calculations in all situations. In fact, MedPAC specifically remarked that the Medicaid bundling approach "might not capture contingent discounts" and that an approach that allocated bundled discounts to reflect the contingencies in a contract would "more accurately reflect[] the transaction price of drugs when a discount for one drug or drugs is contingent in whole or in part on the purchase of another drug.[7]

The bundling rule that CMS has proposed to apply to the ASP calculations is basically the new Medicaid bundling rule with some minor tweaks, e.g., use of "bundled arrangements" in lieu of "bundled sales" as used in the Medicaid context. As explained further below, the new Medicaid bundling rule, without further clarification, is by no means simple to apply. While we support CMS' proposal to apply this rule as a general proposition, several adjustments are needed to make the rule appropriate for the ASP reimbursement context. These adjustments are in the nature of (1) clarification of the definition of "bundled arrangement," (2) exclusion of "non-contingent" discounts from the reallocation methodology required by the proposed bundling rule, and (3) a *limited* exception to the general rule for the particular instance where rebates/discounts on a dominant drug are conditioned in whole or in part on purchases of competitive drugs. Absent these adjustments, the proposed bundling rule could undermine the objective of ensuring that ASP reflects the average transaction price for drugs.

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5 72 Fed. Reg. 38,150 (July 12, 2007).

6 *Id.*

7 MedPAC 2007. *Report to Congress: Impact of Changes in Medicare Payments for Part B Drugs.* Washington, DC: MedPAC: page 9.

2. *Proposed Definition of Bundled Arrangement is Too Broad*

a. Rationale for Allocating Bundled Discounts

CMS states that its purpose for establishing a rule on when and how to allocate discounts associated with certain arrangements is "to better reflect the true costs incurred by physicians when purchasing Part B covered drugs." This is consistent with the OIG's expression of why bundled discounts need to be allocated. Looking back to the preamble of the 1999 clarifications to the discount safe harbor under the Anti-Kickback Act, in regards to bundled arrangements, OIG stated

> As a general rule, discounts for health care items and services are encouraged under the Federal Health Care programs so long as the Federal health care programs share in the discount where appropriate, and as appropriate, to the reimbursement methodology. Arrangements in accordance with which Federal programs get less than their proportional share of cost-savings on items or services payable by the program are seriously abusive.

64 Fed. Red. 63526 (Nov. 19, 1999).

OIG further clarified that

> in certain circumstances ... discounts on multiple items may qualify as a "discount" for safe harbor purposes where the reimbursement methodology for all discounted items or services is the same and where the discount can be fully disclosed to the Federal health care programs and *accurately reflected where appropriate and as appropriate, to the reimbursement methodology.*
>
> The most important aspect of the discount safe harbor is that the Federal health care programs share in the discount in proportion to the percentage the programs pay of the total cost.

64 Fed. Reg. 63529 (emphasis added.)

OIG said it was persuaded that in certain circumstances, "discounts offered on one good or service to induce the purchase of a different good or service" do not pose a risk of program abuse *"where the net value can be properly reported."* [8]

Collectively, the statements above make plain that the OIG anticipated there might be some situations involving discounts on multiple items where a reallocation of the

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[8] 64 Fed. Reg. 63530 (emphasis added.)

discounts *would not be appropriate*. They also make plain that the purpose of reallocation of discounts is to assure the net value of the discount is properly reported and the Federal health care program shares appropriately in any discounts. In other words, reallocation is necessary only when, and to the extent that, it more accurately reflects the "true" value of the transaction to the purchaser or to the Federal health care program. In contrast to this objective, the proposed bundling rule seeks to define bundled arrangements in a way that captures non-contingent discounts and requires re-allocation of non-contingent discounts. We contend that this imposes unnecessary complexity to the proposed bundling rule and in fact, causes the resulting ASPs to be *less reflective* of the true acquisition costs of the affected products.

b. The Scope of " Bundled Arrangements" Should Be Limited to Cross-Product Discounting Contingencies

Superficially it may seem simpler and less burdensome on manufacturers to apply the new Medicaid definition of bundling to the ASP calculations than another approach, but we do not agree that this is correct because the new Medicaid definition of bundled sales is over-inclusive and unclear. Accordingly, we object to the adoption of the Medicaid rule for ASP purposes until those concerns are addressed.[9]

More particularly, the definition of bundled arrangement that CMS proposes to adopt for ASP purposes—direct from the Medicaid final rule—is,

> an arrangement regardless of physical packaging under which the rebate, discount, or other price concessions is conditioned upon the purchase of the same drug, drugs of different types (that is, at the nine-digit National Drug Code (NDC) level) or another product *or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary)* or where the resulting discounts or other price concessions are greater than those which would have been available had the bundled drugs been purchased separately or outside the bundled arrangement. For bundled sales, the discounts are allocated proportionally to the total dollar value of the units of all drug sold under the bundled arrangement. For bundled sales where multiple drugs are discounted, the

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[9] CMS contends that its new definition of what constitutes a bundled sale is no change from the previous definition in the Medicaid Rebate Agreement; CMS further contends that the revised text is merely a clarification of that set forth in the rebate agreement. 72 Fed. Reg. 39159-39160 (July 17, 2007). While CMS may not have intended to revise the definition of bundled sale, the prevailing view of industry is that the new definition of bundled sale is considerably different than the prior definition, that it is confusing and vague, and that it could be construed to sweep in numerous prevailing contractual practices that previously would not have required a reallocation of discounts. Commenters raised these concerns in response to the proposed rule, yet the language of the final rule was not revised and CMS did not sufficiently address these concerns in the preamble to the final rule to quell industry's apprehension that this definition can be applied in a consistent, meaningful and practical manner.

> aggregate value for all the discounts in the bundled arrangement shall be proportionally allocated across all the drugs in the bundle.

72 Fed. Reg. 39240 (July 17, 2007) (Emphasis added.)
At least two aspects of the final Medicaid definition that is now proposed to be applied to the ASP calculations, are particularly troubling. The first is captured in the highlighted text above. CMS is now saying that a bundled "arrangement" is one for which the rebate, discount, or other price concessions may be conditioned upon "*some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary).*" We are concerned that this language may be construed too broadly.

We can certainly envision circumstances under which a formulary or market share contingency should be construed to create a bundled sale. For example, if a discount on product A is contingent on the customer putting Product B in a favorable formulary position, a bundled arrangement likely exists. In contrast, we do not agree that a bundled arrangement is created in every instance in which a formulary requirement exists in a contract. For instance, we do not believe that a requirement to not disadvantage a group of products vis-à-vis the purchaser's formulary creates a bundled arrangement. In our view, this does not create a purchase contingency that would meet the threshold for a bundled arrangement to exist. We believe that this type of condition simply assures access to the product but imposes no specific purchase contingency. Similarly, we would not consider the application of master terms and conditions to a portfolio contract to automatically invoke a bundled arrangement, absent a specific contingent discount being offered for meeting the master terms and conditions. In some cases, the latter might be referred to as an access discount.

In our view, the determination of whether a bundled arrangement exists should be made on a case-by-case basis after analysis to determine whether a purchase contingency exists--for example, whether Product A must be purchased, in any amount or percentage of market share, for the customer to receive discounts on Product B. When the discounts offered are determined solely on the performance of the product, we do not agree that a bundled arrangement exists, even when the product is included as part of a contract that contains master terms and conditions applicable to the entire agreement. A contrary interpretation could have the impact of converting all, or nearly all, multiple product contracts into "bundled arrangements". *In this regard, CMS should clarify that the scope of the "bundled arrangement" is limited to those situations where contingent discounts or price concessions are offered for meeting a specific purchase or other performance requirement of another product.* Furthermore, to the extent that certain non-contingent discounts might be offered on other products covered by the contract, e.g., if there was a Product C in the above example but the price for product C was not affected by performance conditions applicable to Products A and B, those discounts are not included in any reallocation because they are not part of the "bundled arrangement".

A second way in which the Medicaid bundling rule needs to be adapted for the ASP environment arises from language in the Medicaid AMP Rule preamble which indicates that CMS expects that certain volume share and/or market share arrangements should be allocated across periods, e.g. if the discount in the 2nd quarter is based on market share during the 1st quarter, then the additional discount earned for meeting certain market share requirements in the 1st quarter should be allocated across both periods. When applied in the context of Medicare ASP this would have the impact of requiring recalculation of the 1st Quarter ASP because the impact of the bundling allocation would not be known until subsequent to the time when the 1st Q ASP was filed. This scenario will be problematic when AMP is used as a basis for reimbursement as well. The lagged price concession methodology does not solve this issue.

Recommendation: **CMS should narrow and clarify, i.e., further adjust, the Medicaid bundling rule before extending its application to the Medicare ASP calculations. Specifically, CMS should (1) confirm that a "bundled arrangement" is limited to those situations where contingent discounts or price concessions are offered for meeting a specific purchase or other performance requirement on another product, (2) address with more specificity the meaning of certain language in the final Medicaid rule and (3) provide more meaningful examples of what is and is not a bundled sale within the context of the final rule definition.**

3. Allocation of Discounts under Bundled Arrangements: Contingent and Non-contingent Discounts

The proposed bundling rule, as explained by CMS in the context of the Medicaid final rule on bundling, anticipates that non-contingent discounts must be allocated when a bundled arrangement is deemed to exist. This plain does not make sense. This is best illustrated by an example. As explained above, commercial arrangements often involve a single contract covering a portfolio of products for which the discounts on each product are determined independently of the discounts and performance of other products covered by the contract. Under CMS' construction, a bundled discount that is "overlayed" (e.g., get an additional 5 percent on all purchases if an overall volume threshold is met) on top of other independently determined, non-contingent discounts could require an allocation not only of the additional 5 percent discount, but also of the independently determined individual product discounts. The result of such an allocation would be that all products in the contract would be subject to a single uniform discount percentage. The impact of an approach that would include "non-contingent" discounts in the scope of a "bundled arrangement" would be to flatten the discount percentage on products, causing increased ASP on some products and decreased AMPs and ASPs on others, and causing the ASP to be *less* of a reflection of the transactional cost to the purchaser. CMS' rationale for allocation of discounts and price concessions associated with bundled arrangements is more effectively achieved by requiring reallocation of the contingent discount(s) only, and including non-contingent discounts in the allocation base only to the extent that the non-contingent discounts impact the net sales amount used in determining compliance with the applicable contingency.

***Recommendation*: Any methodology imposed for reallocating discounts and price concessions attributable to bundled arrangements only apply to the contingent discounts.**

B. Widely Available Market Prices (WAMP) and AMP Threshold

CMS is proposing to continue use of a 5 percent applicable threshold percentage for purposes of comparing ASP to WAMP and AMP under Section 1987A(d)(3)(A) of the Act. This would mean that the Secretary *may* disregard the calculated ASP if it exceeds the AMP or WAMP for a particular drug or biological by 5 percent (or more.) The proposed 5 percent is the same threshold that was applied in the Secretary's discretion in CY 2006 and 2007.

Plainly, the AMPs for some drugs and biologics will be affected by changes made as a result of implementing the Deficit Reduction Act. Some of the changes theoretically will increase AMP and others will likely decrease AMP, but at this time we cannot foresee the overall impact for most drugs and biologics. Until sufficient experience has been developed with AMPs calculated pursuant to the DRA and its implementing regulations, the Secretary should apply a larger threshold for purposes of comparing ASP to AMP. A threshold that is too narrow could have unanticipated consequences. We propose that a 10% threshold be applied throughout CY 2008 to allow for sufficient experience to be developed with the new AMP metric. We support the continued application of a 5% threshold to the comparison of ASP to WAMP for CY 2008 based on our understanding that the method for determining WAMP has not changed since CY 2007.

In addition, we recommend that CMS establish the procedural and substantive safeguards that Congress intended when it established the provision allowing the Secretary to substitute WAMP or AMP for the calculated ASP. One such safeguard should be to allow the manufacturer with notice and a reasonable period of time to object, with explanation, prior to substitution of WAMP or AMP for the ASP-calculated reimbursement amount. In it's notice, CMS should be required to provide the data and methodology used for deriving the WAMP supporting its position. In addition, the substitution should be limited to a single quarter as there are many market dynamics that might skew WAMP or AMP for a particular, brief, period of time.

II. COMPETITIVE ACQUISITION PROGRAM (CAP) ISSUES

Since enactment of its original authorizing legislation, J&J has been a strong supporter of the CAP program. Our overarching goal with CAP is to ensure that Medicare beneficiaries have meaningful access to Part B medical therapies. We believe the CAP program has unfulfilled potential to expand patient access to important therapies while offering an alternative for physicians to the current and often complex "buy and bill" system.

Unfortunately, relatively few physicians have enrolled in the program to date for a variety of reasons. We have heard reports from physicians who view the program as overly burdensome, untested and have concerns with the general stability of this new program that has only one vendor. In order to improve current physician enrollment rates and enhance patient access to medications covered under Part B of Medicare, we encourage CMS to continue reforms in the program to make CAP a more viable, less burdensome and attractive alternative for physicians.

Our specific comments and recommendations follow. As requested by CMS, we have organized our comments consistent with the order they appear in the preamble to the proposed rule. We have also included recommendations on policy issues not addressed in the proposed rule. Specifically, we urge CMS to consider some of the reforms to CAP included in the Children's Health and Medicare Protection Act of 2007 (H.R. 3162). In most cases, these reform proposals are within the CMS' current legislative authority. We encourage the agency to consider moving forward with these additional recommendations, which we maintain are within the agency's legal authority. In the case of all of our comments below, we urge CMS to take action in this rulemaking cycle, rather than simply taking these comments under advisement for a later rulemaking. As mentioned above and as CMS is well aware, the enrollment results for the CAP program have been very disappointing. Accordingly, drastic, immediate changes are necessary to avoid even further erosion of the support for the program in the physician community.

A. Required Changes to CAP Claims Processing

***Recommendation:* CMS should withdraw the current requirement that physicians electing CAP must agree to file a claim within 14 calendar days of the drug administration.**

Even prior to this proposed rule, CMS began implementing section 108 of the MIEA-TRHCA which requires that payment for drugs and biologicals be made upon receipt of a claim for those products covered CAP. The legislation also requires CMS to establish a post-payment review process to assure that payment is make for a drug only if the drug has been administered to a beneficiary. Prior to this legislation, a CAP vendor could not get paid until the physician's drug administration claim was matched (e.g., a pre-payment review) with the claim for the drug submitted by the CAP vendor.

In the initial CAP final rule, CMS made clear that the basis of the 14-day billing requirement was to allow the CAP vendor to be paid timely for drugs it had shipped.[10] As TRHCA has now removed the claims match predicate to the CAP vendor's payment in favor of post-payment review, the underlying rationale for the 14-day bill submission requirement is no longer applicable. To make the program more workable, and therefore more appealing, for physician practices that do not customarily submit bills in this timeframe, we recommend that CMS withdraw this requirement for physicians electing the CAP program.

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[10] 70 Fed. Reg. 39022, 39050.

Recommendation: We recommend that CMS allow comments on the sampling process for post-payment review of CAP claims.

The proposed rule discusses the post-payment review process that will use statistical sampling to determine whether drugs were administered and if they were medically necessary.[11] We acknowledge this is a responsible element of program oversight. However, to ensure that the process is transparent and that stakeholders' input is obtained, we recommend that CMS make a detailed description of the sampling process available to the public prior to implementation and consider comments if possible. To promote consistency with other facets of the Medicare program, CMS can propose as a potential model the sampling process set forth in its Program Integrity Manual.[12] This model may need only minor adjustments to accommodate the needs of the CAP program.

Recommendation: CMS should reiterate and clarify expectations for documentation in medical records for patients receiving services under CAP.

In the proposed rule, CMS discusses the post-payment review process. Specifically, the rule notes that "When a claim is selected for review we notify the approved CAP vendor and request its records . . . [and] we will be requesting medical records from the participating CAP physician. . . ."[13] We believe this policy represents responsible program oversight when the needed information is not retrievable without obtaining the medical records. To make this process more efficient and less likely to create uncertainty for enrolled physicians, we ask that CMS reiterate, and clarify as needed, the standard data elements or information it expects to see in medical records to ensure that enrolled physicians have properly documented the appropriateness and medical necessity of services that will be subject to review. Moreover, we would appreciate it if CMS would confirm that the medical record is not needed in all cases in which a review is undertaken. For instance, the physician claim form may include both a CPT code confirming administration of the CAP drug, as well as an ICD-9 code, indicating the patient's diagnosis justifying the medical necessity of the drug administration. Thus, to alleviate the administrative burdens on both the enrolled physicians and the designated carrier, medical records should only be requested when claim form data does not suffice to verify drug administration and medical necessity. Importantly, all CMS relied on prior to the enactment of TRHCA was data in the physician's claim form, which was used to match data in the CAP vendor's claim form. It is unclear why, on a routine basis, CMS would now require medical records simply because the review is retrospective, rather than prospective.

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[11] 72 Fed. Reg. 38154 (July 12, 2007).

[12] Program Integrity Manual, § 3.10.

[13] Ibid.

***Recommendation:* CMS should clarify extenuating circumstances under which payment may still be made for CAP drug when medical records are not produced within 30 days.**

The proposed rule describes how payment to the CAP vendor will be denied if medical records to support a post-payment review audit are not made available by the administering physician to the carrier within 30 days of the request.[14] While we understand there is precedent for a 30-day rule in other parts of the Medicare program, this policy should be clarified to include extenuating circumstances under which the CAP vendor may still be paid if records cannot be produced within 30 days. For example, we recommend that CMS make provision for the following types of situations: death of the practitioner and resulting closure of the practice, bankruptcy or litigation that results in sudden closure of the practice, or destruction of records or disruptions of a practice due to fire or other natural disaster. In any event, for the reasons stated above, we request that CMS consider not requiring the submission of medical records in any instant where all necessary information is contained in the physician's claim form. Naturally, in all such cases, there should be no penalty associated with the failure to produce medical records, which would not be necessary to the determination of the propriety of payment to the CAP vendor.

***Recommendation:* CMS should allow physicians the opportunity for "short-term" enrollment periods (e.g., 30-60 days).**

Under current regulations, physicians electing CAP can disenroll over the course of the year under certain specific circumstances (e.g., vendor withdraws from program, physician leaves a group practice, relocation or other exigent circumstances). In the absence of these specified circumstances, the physician must stay enrolled in CAP for the entire annual period. Many physicians are reluctant to make a year commitment for a new program like CAP. CMS would likely encourage more physician interest in the program if it allowed physicians to withdraw "without cause." While we welcome that CMS has now proposed expanding the circumstances under which a newly-enrolled physician or physician group can withdraw from the program, we do not believe that CMS' proposal will likely affect enrollment significantly. As currently proposed, requests for termination must be channeled through the dispute resolution process, and disenrollment is contingent upon several layers of review, without any certainty that ultimately the request for termination will be granted. Most physicians considering enrolling in the CAP program will not find this unpredictable termination process to be a sufficient incentive to outweigh the uncertainties associated with trying an untested program. Therefore, at least until there has been widespread acceptance of the CAP program within the physician community, physicians should have unfettered discretion to terminate within 60 days of enrollment.

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14 Ibid.

15 Id. at 38156-38157.

Recommendation: ***CMS modify enrollment material to clarify that physicians or their authorized representatives sign the enrollment forms.***

There have been circumstances under which unauthorized employees of physician practices have signed and submitted CAP enrollment forms without the approval of the practice's physicians or key administrators. To help avert this problem in the future, it would be useful if CMS modified the CAP enrollment forms and materials to more clearly indicate, perhaps by separate attestation, that enrollment forms should be signed by either physicians or authorized representative of the physicians/practice.

B. Proposals Included in the Children's Health and Medicare Protection Act of 2007 (H.R. 3162)

Recommendation: CMS should permit continuous or more frequent open enrollment and selection of a CAP vendor.

Under current law and regulations, CMS traditionally allows one annual open enrollment for physicians to sign-up for the CAP program. However, CMS has recently made some exceptions to this policy to allow for additional enrollment opportunities over specified times to encourage participation in the program.
To allow for maximum flexibility for physicians, we recommend that CMS allow for continuous open enrollment in CAP. We believe this is well within CMS' legal authority. The requirements of the statute can be met as long as there is *at least* one annual enrollment period. There is no requirement in the statute that there be *no more than* one enrollment period.[17] CMS should use whatever discretion it has under the statute to seek to improve the appeal of the CAP program. Notably, this proposal would not likely create any real increase in the CAP vendor's administrative burdens, and would instead likely be welcomed as a means towards increasing enrollment.

Recommendation: CMS should specify that an election into CAP and the selection of a vendor would continue to be effective without the need for any periodic reelection or reapplication.

Under current CMS regulations and instructions, physicians must resubmit the annual CAP election form to CMS during the annual enrollment period. We have heard complaints from many physicians that this creates unnecessary administrative burdens. In some cases, physicians have actually forgot to re-enroll, but clearly intended to do so. This has prevented these physicians from gaining access to the CAP program for an extended period of time. CMS should allow physicians to enroll into CAP during the

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16 72 Fed. Reg. 38159 (July 12, 2007).

17 Social Security Act, § 1847B(a)(1)(A)(ii).

initial period and allow this selection to remain in effect until the physician proactively changed his election or CAP vendor decision. While perhaps there would be some logic to mandatory, annual enrollment if physicians were to be offered a number of choices of CAP vendors each year, right now they only have one. Therefore, the re-enrollment requirement serves no other purpose than to penalize the unwary with disenrollment. If CMS were concerned that some physicians will forget to terminate their CAP enrollment during the annual window, even though they wish to return to the "buy and bill" system, it could create a failsafe mechanism. CMS could determine that, for some period of time following the annual window, physicians continue to be allowed to terminate their CAP election on the basis that such termination is for "exigent circumstances."

Conclusion

We thank you for the opportunity to comment on these important regulations. The Johnson & Johnson family of companies strongly supports CMS' efforts to continue to develop meaningful guidance for manufacturers to follow in the development and submission of ASP data and to assure the continuity viability of the CAP program. We believe that only through this process of close collaboration with industry can the objectives of Congress be achieved by establishing meaningful ASP reporting requirements and reasonable reimbursement levels for providers that will generate access to drugs and biologics for Medicare Part B beneficiaries as Congress intended.

Respectfully,

Stephanie P. Gilson

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BY HAND

August 27, 2007

The Honorable Herb B. Kuhn
Acting Administrator
Centers for Medicare &. Medicaid Services
Department of Health and Human Services
Attention; CMS-1385-P
Room 445-G Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington. DC 20201

Re: Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008

Dear Mr. Kuhn:

On behalf of Ortho Biotech Products, L.P. ("Ortho Biotech"), a Johnson & Johnson company, I am pleased to submit these comments on the proposed rule: "Proposed Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008." published in the Federal Register on July 12, 2007 (Volume 72, No, 133. p. 38122). Ortho Biotech markets Procrit (Epoetin alfa), a manufactured form of a naturally occurring hormone erythropoetin that is given by injection to stimulate the bone marrow's production of red blood cells.

In this letter, we respond to the agency's request for comments on the methodology manufacturers should use for apportioning price concessions across Part B drugs sold under bundling arrangements for purposes of calculating average sales price (ASP). CMS's stated premise of its allocation methodology is its goal "to ensure that the ASP is an accurate reflection of market prices for Part B drugs and that the treatment of bundled price concessions in the ASP calculation does not create inappropriate financial incentives." We strongly support that stated goal, and submit that the specific proposal set forth herein is necessary to preserve that laudable objective.

I. INTRODUCTION

CMS has requested comments on its proposal to require manufacturers to allocate the total value of all price concessions on all drugs sold under a bundled arrangement proportionately

according to the dollar value of the units of each drug sold under the bundled arrangement for purposes of the calculation of the drugs' ASPs. In addition, CMS seeks comments on what it describes as an alternative approach for the treatment of bundled price concessions proposed by MedPAC. In its recent report to Congress, MedPAC proposed that manufacturers allocate all incentives on a drug that is "contingent" on the purchase of another drug(s) to the ASP(s) of latter drug(s).

We do not view the MedPAC approach as an *alternative* to CMS's proposed allocation rule. Rather, we view CMS's proposal to allocate incentives proportionately across all bundled drugs as a *general rule* applicable for most bundles. In contrast, and as MedPAC specifically illustrated in its report, the MedPAC proposal represents a limited *exception* required for the particular instance where rebates/discounts on a product with virtually no competition (a "dominant drug") are conditioned in whole or in part on purchases of a drug (or drugs) with clinical alternatives ("competitive drugs"). The general rule alone is insufficient to effectuate CMS's stated intent that incentives be allocated to the sales of those drugs that benefit from and are driven by the incentives paid. Instead, the general rule *and* limited exception are necessary corollaries to achieve CMS's stated goal of advancing the accuracy of the reported ASPs, which in turn will (i) mitigate the manipulation of the reimbursement regimen, (ii) promote fair competition and (iii) minimize costs for the Medicare program and its beneficiaries.

In the event the broader issues relating to the scope of the proposed general rule are resolved,[1] the allocation exception for bundles that contain dominant drugs is simple to state and can be implemented without undue burden on CMS or the manufacturers. Under the exception, manufacturers are required to allocate *all* incentives paid on dominant drugs to drive the sales of a competitive drug *entirely* to the competitive drug (or drugs, based on the relative sales of the competitive drugs). This allocation process is self-implementing, and utilizes the same data the manufacturer otherwise would generate to apply the general rule. Moreover, should a manufacturer fail to adhere to this patent directive, a straightforward protocol is available to allow interested parties (*e.g.*, CMS, beneficiaries, physicians, competitors) to challenge the manufacturer's compliance, and to afford the manufacturer an opportunity to respond before a final determination is made.

In the sections that follow, we clarify why an exception to the general allocation rule: (a) is required to ensure accuracy of ASPs in bundles with dominant drugs; (b) is consistent with MedPAC's recommendations; (c) can be implemented without imposing undue incremental administrative burdens; and, (d) will save Medicare and its beneficiaries hundreds of millions of dollars.

II. CMS GENERAL ALLOCATION RULE IMPROVES ACCURACY OF ASPS

CMS has proposed as a general allocation rule that incentives paid on bundled drugs be allocated to the ASPs of the bundled drugs based on the relative sales of those drugs. Where

[1] *See* the attendant letter from Ortho Biotech's parent Johnson & Johnson to Herb Kuhn, dated August 27, 2007.(the "Johnson & Johnson Letter").

there are therapeutic alternatives for the drugs included in the bundle, this general rule advances CMS's stated intent of ensuring that incentives paid are allocated to the sales that are driven by those incentives.[2] That is, the general rule reflects the proposition that it is the power of the aggregate incentives that drives the sales of the constituent drugs, rather than the market power of a particular drug within that package.

That proposition is valid, insofar as customers can purchase alternatives for each of the constituent drugs within the bundle (effectively aggregating a competitive bundle). The ability to do so ensures that the bundled drugs' ASPs properly reflect the competitive forces that should act to mitigate pricing in a competitive market. Accordingly, with the aggregate incentives offered driving the sales of the bundled competitive drugs, it is reasonable to allocate the incentives paid based on the constituent drug sales to accurately reflect those drugs that benefit from the incentives.

III. AN EXCEPTION IS REQUIRED TO ENSURE THE ACCURACY OF ASPS IN BUNDLES WITH DOMINANT DRUGS

CMS's proposed general allocation rule does not achieve its stated intent when applied to bundles that contain dominant drugs. That is, the general rule does not result in the alignment of incentives with the sales driven by the incentives. As MedPAC recently stated, *infra*, incentives typically are not paid on drugs that don't face therapeutic competition because the incentives are not necessary to drive sales. Consequently, where incentives are offered on such drugs in bundles with competitive drug(s), the incentives drive the sale of the competitive drug(s), not the dominant drug. To accurately reflect the incentives that drive their sales, therefore, the incentives paid on dominant drugs bundled with competitive drugs must be allocated entirely to the ASPs of the competitive drugs. As explained in detail below, this allocation process does not impose incremental administrative burdens on manufacturers or Medicare.

Absent such an exception, however, the inaccurate ASPs resulting from the application of the general rule has had – and will continue to have – unintended and significant adverse consequences. First, the general rule insulates the ASPs of competitive drugs bundled with dominant drugs from competition, allowing a manufacturer to drive sales solely by allowing the excess 'spread' derived from the difference between the inflated Medicare reimbursement and the acquisition costs of a drug to drive physician choice between equivalent drugs.

- This is exactly what has occurred with Amgen's bundle of white blood cell and red blood cell growth factors that is described below.

[2] We concur with the sentiment expressed in the Johnson & Johnson Letter that the proposed general bundle allocation rule may further the agency's stated intent of improving the accuracy of reported ASPs for drugs included in bundles in many instances, but we also reaffirm that the proposed amendments and clarifications specified in the letter must be adopted to ensure the application of the Medicaid bundling rule is appropriate in the ASP reimbursement context.

- This is exactly the inappropriate financial incentive CMS has stated that it seeks to avoid in adopting bundle allocation rules.

- This is exactly the issue that HHS has challenged in the context of the AWP allegations, and that the OIG arguably has construed to raise anti-kickback concerns.

Second, as discussed below, the inaccurate ASPs have caused – and will continue to cause absent an exception to the general rule – materially inflated Medicare and beneficiary costs. Simply put, applying the general allocation rule to bundles including dominant drugs does not adequately account for, and will materially distort, the appropriate reimbursement under an ASP-based reimbursement regimen. An exception to the general rule therefore is required to achieve CMS's stated goals and to protect the financial interests of Medicare and its beneficiaries.

IV. THE EXCEPTION IS CONSISTENT WITH MEDPAC'S ANALYSIS

The Medicare Modernization Act (MMA) of 2003 instructed MedPAC to evaluate the impact of the new ASP reimbursement system for Part B drugs on providers and patients and submit its findings in two reports to Congress. Med PAC submitted its second report to Congress on December 29, 2006. The report included findings and recommendations that are consistent with those set forth in this comment letter,[3] including the following:

- ASPs Should Reflect Drugs' Actual Transaction Prices: MedPAC recommended that, in establishing guidance, the "goal should be to ensure that ASP reflects the average transaction price for drugs." This goal seeks to ensure that, through transparency and the alignment of reimbursement and costs, Medicare derives the benefit of price competition under its ASP reimbursement system. The goal is thwarted, however, to the extent a drug's published ASP does not reflect the incentives paid to drive its sales.

- Discounts on Bundled Dominant Drugs Distort ASPs Absent Appropriate Allocation: MedPAC correctly recognized that "[i]t is very unusual to get a large discount on a drug that has no competition." That is, a manufacturer need not provide discounts on dominant drugs to drive their sales. But a manufacturer may provide large discounts on a dominant drug contingent on the purchase of a competitive drug in order to drive the purchase of the competitive drug. MedPAC correctly found that, without a rule requiring the allocation of the incentives of the dominant drug to the competitive drug, the drugs ASPs will not reflect their transaction prices: "Without guidelines for the allocation of bundled discounts, the bundling methodology undercuts the ASP payment method."

[3] The report makes one finding that is not consistent with Ortho Biotech's view of the impact of Amgen's bundle of white blood cell and red blood cell growth factors. The report states that "[i]n the short term, the bundling arrangement results in lower payment rates for all three drugs." The reality is that Amgen's bundle of white blood cell and red blood cell growth factors has curtailed price competition in the oncology clinic market, causing Aranesp and Procrit ASPs to be higher than they would have been if Amgen's bundle of white blood cell and red blood cell growth factors had not been implemented.

- Amgen's Coercive Bundle Restricts Clinical Choice: MedPAC recounts that "many interviewees'" described a bundling issue that "posed a problem for them." MedPAC describes this specific bundling issue as follows: "Currently, there are two drugs, we call Drug A and Drug B, similar products that compete for market share. Although the shift to ASP has resulted in lower payment rates for both products, volume and expenditures continued to increase in 2005. In this instance, the manufacturer of Drug A also makes Drug C, a lifesaving drug with no effective competition. It is very unusual to get a large discount on a drug that has no competition, but, in this case, the manufacturer provides a significant discount on Drug C to purchasers who buy Drug A instead of Drug B." Thus, without naming the drugs or parties, MedPAC describes a dominant drug bundle that has the same characteristics as Amgen's bundled contract. Specifically, Drug A corresponds to Amgen's Aranesp, Drug B corresponds to Ortho Biotech's Procrit and Drug C corresponds to Amgen's dominant WBCGF drugs. The Amgen arrangement is a problem because, as MedPAC finds, physicians "lose money'" on the drugs administered to Medicare patients unless they secure the large discounts on the bundled dominant Drug C by purchasing the competitive Drug A. MedPAC states that physicians indicated this economic coercion compromises their "ability to choose a product based on clinical factors." And MedPAC properly identifies the magnitude of the problem, concluding that without guidance, "[o]ther manufacturers of single source drugs might also use this method to increase their sales on products with competition."

- CMS Should Issue Regulatory Guidance to Close the Loophole: MedPAC correctly finds that CMS "could support the accuracy of the ASP methodology by clarifying rules about the way bundled discounts should be allocated under manufacturer reporting requirements." Thus, MedPAC recommends that "The Secretary should clarify average sales price (ASP) reporting requirements for bundled products to ensure that ASP calculations allocate discounts to reflect the transaction price for each drug." Moreover, MedPAC properly emphasizes that, while CMS's policy may need to change over time to reflect changing market practices, this "should not slow down action in this area." MedPAC further highlights the importance of the issue by making the appropriate allocation of discounts for bundled products the only policy recommendation in the entire 56-page report to Congress.

- The Guidance Should Require Allocation Contingent Discounts to Dominant Drugs: MedPAC proposed two allocation methodologies for bundled discounts. One "option is to allocate bundled discounts in proportion to the sales of each drug sold under the bundled arrangement. According to MedPAC, "[t]his option would parallel bundling requirements under Medicaid and be simpler to administer. However, this method might not capture contingent discounts." That is, the Medicaid allocation methodology is appropriate as a general rule, but a particular rule is required to ensure discounts on dominant drugs that are contingent on the purchase of competitive drugs are properly allocated to the competitive drugs for ASP calculations. To address the contingencies in the contractual arrangement described, MedPAC also proposes an "option reflecting the contingencies in the contract." Consistent with Ortho Biotech's proposed exceptions approach, MedPAC"s second option calls for a manufacturer to allocate

discounts contingent on the purchase of another drug to the sales of the drug that the discount is meant to increase. This would result in an ASP that more accurately reflects the transaction price of the drugs."

Thus, MedPAC recognized the need to close the loophole that enabled the manipulation and distortion of the published ASPs. The MedPAC report reinforces the need for CMS to clarify ASP reporting requirements for bundled products to ensure that ASP calculations reflect actual transaction prices and thus maintain the integrity of the reimbursement system.

V. THE EXCEPTION CAN BE IMPLEMENTED WITHOUT UNDUE INCREMENTAL COMPLEXITY OR ADMINISTRATIVE BURDENS

In the proposed rule, CMS cites several reasons for its proposal to adopt the proportional allocation approach over the alternative method recommended by MedPAC. First, the agency cites the potential complexity that may be introduced by the alternative approach, which it says could present complicated implementation and monitoring challenges. Second, it cites the possibility of additional computational complexity because it is unknown whether applicable data may be adequately known at quarterly reporting intervals for manufacturers to appropriately reflect the contingencies in purchasing contracts within their ASP calculations. We address each of these concerns in our comments that follow.

First, we do not believe that the implementation of an exception to the general bundle allocation rules would increase the burden or complexity for either CMS or the manufacturers. Specifically, our proposal:

- does not require manufacturers to collect or report data that is not already available for reporting under the basic allocation rules;
- is self-implementing in that it directs manufacturers to apply CMS's stated intent that incentives be allocated to the sales the incentives are paid to drive;
- does not require CMS to identify dominant drugs independently and proactively;
- has limited application with only one known example to date (Amgen's bundle of red cell and white cell growth factors);
- will discourage the creation of coercive bundles with dominant drugs, reducing potential future workload; and,
- affords manufacturers the opportunity to rebut an assertion that they are offering incentives on a dominant drug to drive sales of a competitive drug in the unlikely scenario that there is any legitimate dispute in that regard.

The following is a step-by-step of the process we recommend.

1. Under our proposal, manufacturers of bundles with dominant drugs shall be required to report discounts based on good faith interpretation of whether the incentives they

pay on their drug(s) not subject to competition are offered to drive the sales of competitive drug(s). There should be no legitimate ambiguity as to when this scenario arises. With respect to the extant Amgen bundle, for example, Amgen cannot legitimately dispute that it has paid and is paying incentives on its monopoly WBCGF drugs to drive the sales of its competitive drug Aranesp. A good faith adherence to the stated rule, therefore, should not require proceeding beyond this first step.

2. In the event interested parties (*e.g.*, CMS, medical providers, beneficiaries, and manufacturers) conclude that a manufacturer is not adhering to the rule, such parties may submit a complaint to the agency particularizing their concerns.

3. Upon receipt of the complaint, the agency shall make an assessment whether the preponderance of the evidence demonstrates that the manufacturer is in fact paying incentives on the drug not subject to competition to drive the sales of the competitive drug(s). In reaching its determination, the agency may, among other relevant steps:

   (a) request the manufacturer to specifically attest to whether it has paid incentives on its dominant drug to drive the sales of the competitive drug, and therefore, whether the ASPs competitive drugs accurately reflect the incentives granted to drive their sales;

   (b) assess whether the allegedly dominant drug's introduction into the bundle is driving sales of the competitive drug(s) by evaluating the sales volume of the competitive drugs after the dominant drugs introduction;

   (c) assess whether the allegedly dominant drug's introduction into the bundle is intended to drive sales of the competitive drug(s) by determining whether incremental incentives were provided on the drug after, relative to before, it was introduced into a bundle;

   (d) evaluate the approved indications and risk profile of the dominant drug (relative to other approved drugs and therapies) to determine whether (i) there are viable alternatives to the allegedly dominant drug, or conversely, (ii) the dominant drug is a necessary therapy, which renders particularly valuable the incentives offered thereon;

   (e) review the Medicare expenditures on the drug relative to any purported alternatives to corroborate that the drug is viewed as a valuable and necessary course of therapy without viable alternatives;

   (f) consider whether the allegedly dominant drug's market share is sufficiently large such that the incentives offered on the dominant drug likely drive the sales of the competitive drugs; and

   (g) determine whether the allegedly dominant drug is a single source drug (versus multi-source) and patent protected, which, again, would factor into whether the

incentives offered on the drug conditioned on the purchase of the competitive would serve to drive sales of the competitive drug.

4. After making its initial assessment, CMS will post on its website the possible dominant drug and the supporting rationale for its identification as a dominant drug. Thereafter, a 30-day comment period will be provided during which the manufacturer and other parties may provide comments and evidence to rebut or support the preliminary determination that a particular drug in a bundle is dominant.

5. Following the close of the comment period, CMS will make its final decision regarding whether a drug is found to be dominant in a bundle, and if so, the drug will be identified in the quarterly release of the ASP prices.

6. Manufacturers of bundles with a drug identified as dominant will follow the general allocation rule for all drugs except the incentives paid on the dominant drug. The incentives on the dominant drug will be allocated to any drugs in the bundle (based on relative sales) that have purchase requirements to the payment of such incentives. No incentives on the competitive drugs in the bundle will be allocated to the dominant drug.

We believe the ASP calculations for bundles with dominant drugs described above are straightforward and based on data readily available to manufacturers.

VI. THE EXCEPTION WILL SAVE MEDICARE AND BENEFICIARIES HUNDREDS OF MILLIONS DOLLARS

In comments on last year's proposed rule for 2007, Ortho Biotech identified three elements of savings to Medicare and beneficiaries that would result from the implementation of the proposed exception. First, Ortho Biotech estimated that the proposed exception would generate $50 million in immediate savings to Medicare as a consequence of the allocation of incentives from Amgen's WBCGF drugs to Aranesp, because ASP is a per unit reimbursement amount and a much larger percentage of the total Aranesp sales volume is reimbursed by Medicare than Amgen's WBCGF drugs. Second, Ortho Biotech estimated that Medicare could have saved at least $177 million in 2005 alone by allowing the competitive forces back into the market place and, thereby, eliminating the dose premium paid for Amgen's drug Aranesp (*i.e.*, Medicare pays a huge premium for Aranesp relative to Procrit). Third, Ortho Biotech noted that by leveling the competitive playing field for Aranesp and Procrit, the proposed apportionment rule would foster price competition, which in turn will reduce the drugs' acquisition costs and ASPs, generating savings to Medicare and beneficiaries on a going-forward basis. *See* Johnson & Johnson's submission dated September 28, 2006, attached as Appendix A.

The elements of those cost savings remained largely unchallenged during the comment period. Indeed, Amgen was constrained in its ability to do so because Ortho Biotech subsequently submitted the then recently unsealed evidence and testimony from a pending dispute between the parties that conclusively demonstrated the current allocation rule has enabled Amgen to maintain a significant cost premium over Procrit. *See* Johnson &

Johnson's submission dated January 2, 2007, attached as Appendix B. Specifically, the documents obtained from both parties' files, the parties' expert data analysis, and the evidence elicited under oath in that case conclusively demonstrated that ***all*** data regarding relative costs of the parties' drugs based on doses ***actually administered in practice*** in oncology clinics shows Aranesp is by far the more costly drug to Medicare and beneficiaries. *Id.*

We have updated and refocused our prior analysis to model the estimated future savings to Medicare and beneficiaries that will inure from the adoption of the proposed exception. We have integrated into one model the effect of the three elements of the costs savings (*i.e.*, the allocation of incentives from the whites to the reds, the elimination of the dose premium, and the drop in ASPs resulting from the reemergence of competitive market forces into RBCGF drug oncology clinic market), and included as an offset the contemplated immediate increase in reimbursement expenditures on Amgen's WBCGF drugs as a consequence of the shift of incentives from their ASPs to the Aranesp ASP.[4] Utilizing conservative estimates, we project that cost savings to Medicare and beneficiaries will amount to $151 million in 2008 alone and $943 million over the five-year period 2008 through 2012. Taking into account both Part B coinsurance and monthly premium savings, beneficiaries can expect to receive savings of $60 million in 2008 and $416 million over the five-year budget window. Overall, net savings to the government would be $90 million in 2008 and $526 million over five years as result of this policy.

The materials savings to the Medicare program and beneficiaries do not include the savings that will result from deterring similar bundles in the future, or more precisely, from the proper allocation of incentives if and when such bundles are created.

CONCLUSION

The implementation of the proposed exception to the general rule unequivocally accomplishes, and indeed is required to achieve, CMS's stated goals of ensuring the accuracy and integrity of the ASP reimbursement regimen. From a payment perspective, moreover, the nominal administrative burdens and the significant savings for patients and Medicare call for the implementation of the exception policy. Finally, absent its adoption, the unintended inequity and abuse of the reimbursement system will continue and likely escalate. For all the foregoing reasons, we respectfully request that CMS adopt the proffered proposal.

Respectfully submitted,

Cathleen M. Dooley /WGW

Cathleen M. Dooley
Executive Director, Federal Affairs

[4] Although, from an economic perspective, one would expect the WBCGF drug ASPs to return to the lower ASPs since the net prices of those drugs likely currently are at their monopoly pricing, to be conservative the model utilizes the higher ASPs.

Appendix A

SEP 29 2006

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BY HAND

September 28, 2006

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P
445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B

Dear Dr. McClellan:

On behalf of Ortho Biotech Products, L.P. ("Ortho Biotech"), a Johnson & Johnson company, I am pleased to submit comments on the proposed rule: "Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment under Part B," published in the *Federal Register* on August 22, 2006 (Volume 71, No. 162, p.48982). Ortho Biotech markets Procrit (epoetin alfa), a manufactured form of a naturally occurring hormone (erythropoietin) that is given by injection to stimulate the bone marrow's production of red blood cells.

In this letter, we respond to the agency's request for comments on the methodology manufacturers should use for apportioning price concessions across Part B drugs sold under bundling arrangements for purposes of calculating average sales price (ASP). At the outset, we wish to express our strong support for the stated CMS goal "to ensure that the ASP is an accurate reflection of market prices for Part B drugs and that the treatment of bundled price concessions in the ASP calculation does not create inappropriate financial incentives".

We also support the CMS statement that manufacturers of drugs reimbursed by Medicare Part B are expected to "comply with all applicable laws, regulations, and legal decisions including, but not limited to the Stark law, other relevant anti-kickback laws, antitrust laws, and laws governing fair trade practices". However, CMS should not rely on the application of these laws to address the issue of drug pricing under the ASP payment

methodology for Part B drugs that was established by the Medicare Modernization Act of 2003 (MMA).

In the sections that follow, we respond to the specific CMS requests for comments on the effect bundling arrangements may have on the ASP calculation, on beneficiary access to high quality, appropriate care (including access to drugs that may not have clinical alternatives), and on costs to the Medicare program and its beneficiaries. In addition, we recommend a specific methodology for apportioning price concessions across Part B drugs sold under bundling arrangements.

Need for Guidance on Apportioning Price Concessions across Part B Drugs Sold under Bundling Arrangements

For the purposes of calculating ASPs, clear guidance for the apportionment of bundled incentives across Part B drugs is essential. The enforcement community has repeatedly made plain its expectation that manufacturers appropriately identify and allocate bundled discounts. In its Final Guidance to the Pharmaceutical Industry, the OIG advised that "any discount, price concession, or similar benefit offered on purchases of multiple products should be fairly apportioned among the products (and could potentially raise anti-kickback issues.)" 69 Fed. Reg. 23,832 (May 5, 2003). In the next breath, the OIG warned manufacturers to "pay particular attention to ensuring they are calculating [AMP and Best Price] accurately and that they are paying appropriate rebate amounts for their drugs," implying that the fair apportionment is expected in connection with government pricing calculations. Elsewhere, the OIG has explained that they expect bundled drug discounts to be properly and fairly allocated down to the individual line item. See Corporate Integrity Agreement between the HHS OIG and Abbott Laboratories, Page 7, Paragraph (c), dated July 22, 2003.

While perhaps clear in purpose, the agency and OIG guidance has lacked the level of specificity needed to ensure consistent practices among manufacturers. Absent explicit guidelines, pharmaceutical companies are thus at risk that their apportionment methodologies will be construed to contravene CMS's caution that they must comply with relevant laws, legal decisions and regulations, including "the Stark law, other relevant anti-kickback laws, antitrust laws, and laws governing fair trade practices." An explicit uniform methodology, moreover, best serves CMS's stated objective of ensuring ASPs incorporate the incentives derived from full and fair price competition. Explicit guidance is, therefore, essential and should be issued as soon as possible.

Definition of a "Bundle"

CMS has solicited comments concerning the appropriate methodology to apportion incentives among drugs in bundled sales arrangements, including bundles that include drugs that have no clinical alternatives. As CMS recognizes, a threshold question in determining how to allocate bundled incentives is to define what constitutes a "bundled sale". While there are myriad contractual arrangements for the sale of multiple drugs, not all should qualify as "bundled sales" for ASP reimbursement purposes. It is our view that

arrangement for the sale of multiple drugs should be deemed a "bundled sale" if it involves the payment of incentives on (at least) one drug that are expressly contingent or calculated in whole or in part based on the actual purchases of (at least one) other drug.

This definition of a bundle is clear, relatively easy to implement, and captures the bundled incentives that may and should be subject to apportionment to individual drugs. It provides consistency with what qualifies as a bundle under the Medicaid Rebate program, the Anti-Kickback Discount Safe Harbor and arrangements on which the OIG has provided guidance through the Advisory Opinion process.

By adopting this clear and concise definition of a "bundle", CMS need not, and should not, itemize specific business arrangements that are bundles for which the discount must be apportioned. It is not possible to itemize all such arrangements or to foresee all types of bundled arrangements that may exist in the future. A listing of arrangements deemed "bundles" may be construed as an implicit pronouncement that the omitted arrangements are not subject to the apportionment rules.

Bundles Containing Drugs with No Clinical Alternatives

CMS also has recognized that any proposed apportionment rule must account for bundles that include "drugs that may not have clinical alternatives," which we term "dominant drugs" for ease of reference. Bundles with dominant drugs have the potential to result in unfair competitive advantage to the detriment and cost to the public health system and Medicare. These adverse consequences result where large incentives are paid on the dominant drug (or drugs) to drive sales of a competitive drug (or drugs) in the bundle.

In such circumstances, the general Medicaid apportionment rule will not achieve the requisite reallocation of incentives to the drugs that benefit from the incentives paid. If that rule were to be applied, incentives paid solely to drive sales of the competitive drugs wrongly would be allocated to the dominant drug. The apportionment, therefore, would decrease the ASP for the dominant drug (which does not face competition) and increase the ASPs for the competitive drugs, thereby exacerbating the perverse incentives of such bundles by affording the competitive drugs an artificial competitive advantage. Absent an appropriate alternative apportionment rule to allocate the bundled incentives to the drugs that benefit from the incentives, the drugs' published ASPs will not reflect - and will be insulated from - competitive market forces. We appreciate the agency's recognition of the problems associated with this particular class of drugs and agree an alternative rule is required to ensure the Federal reimbursement system is not manipulated to the detriment of competition or at a cost to the Medicare program.

i. the approved indications and risk profile relative to other approved drugs and therapies;

ii. whether the drug is a single source product;

iii. whether the drug is patent protected;

iv. the drug's market share;

v. the incentives provided on the drug after, relative to before, it was introduced into a bundle; (a dominant drug historically has a minimal discount; if/when a dominant drug is bundled with a drug that has competition and a significant discount is placed on the dominant drug, there is a strong inference that such incentive is used to drive sales of another product in the bundle);

vi. the effect of the introduction of the drug into the bundle on the sales volume of the other bundled products; (a significant increase in the sales of the competitive drugs following the introduction of the dominant drug into the bundle is indicative of the power of, and lack of alternatives for, the dominant drug); and

vii. the relative Medicare expenditures on the drug (e.g., large Medicare expenditures for the dominant drug relative to any purported alternatives is evidence the dominant drug is the only viable alternative).

It will be fairly self-evident in virtually every instance that a dominant drug exists and the manufacturer would be expected to report the incentive discounts based on its good faith interpretation of whether these guidelines apply. We recognize, however, that certain manufacturers may object to the imposition of an apportionment rule addressing bundles with dominant drugs unless afforded an opportunity to present their views as to whether there are viable clinical alternatives to such drugs. As discussed further below, we propose the adoption of a notice and response period to provide manufacturers with that opportunity to be heard with respect to the determination of dominant drugs. There should be minimal incremental administrative demands on the agency as a consequence of this protocol because, once the rule is adopted, there likely will be few instances that a dominant drug is bundled to drive the sales of competitive drugs.

Guiding Principles for Bundle Apportionment

With bundles and dominant drugs defined, CMS can promulgate apportionment rules to allocate the bundled incentives to individual drugs in such a way to ensure ASP-based reimbursement reflects (rather than distorts) the drugs' market prices and, in turn, that bundles are used to further the efficient (rather than coercive) sale of drugs.

As noted previously, CMS explicitly stated that the goal of its contemplated guidance is to ensure ASP "is an accurate reflection of market prices for Part B drugs and that the treatment of bundled price concessions in the ASP calculation does not create inappropriate financial incentives." Moreover, while CMS has given no specific guidance to date, the existing precedent provides two guiding precepts that should be respected in fashioning the appropriate apportionment rules. First, CMS has indicated that manufacturers' apportionment practices must be consistent with the general

requirements and intent of the Social Security Act and applicable Federal regulations, which would include, most notably, the Medicaid Drug Rebate Program. As a practical matter, this means that, as a general rule, manufacturers offering bundled arrangements should allocate incentives proportionally among the products, as suggested by the Medicaid rebate agreement. Second, through the discount safe harbor, various Advisory Opinions addressing bundled arrangements, and its Final Compliance Program Guidance for pharmaceutical manufacturers, the HHS OIG has consistently stated that discounts associated with bundled arrangements must be appropriately and accurately reflected in reported discounts. See e.g., 42 C.F.R Section 1001.952(h)(5)(ii); OIG Advisory Opinion 99-3; 69 Fed. Reg. 23832 (May 5, 2003).

The clear purpose of this requirement is to assure that the Federal pricing programs, including the ASP-based regimen under Medicare Part B, receive the proper benefit from any such discount arrangements and to assure there is no inappropriate inducement to purchase certain products so as to increase the cost to the Federal program. To comply with these directives as applied to the ASP reimbursement regimen –which is premised on a fair and accurate reporting by the manufacturer of its drugs acquisition costs– bundled incentives must be allocated to the drugs whose sales are driven by such incentives.

In most instances, the Medicaid bundle rule, which allocates incentives on the basis of sales, achieves that end. In the limited instances where bundles include dominant drugs, however, an alternative rule is required to ensure the Federal reimbursement system is not manipulated to the detriment of competition or at the cost to the Medicare program.

Proposed Apportionment Methods

Two apportionment rules are required to achieve the legal and regulatory requirement that bundled incentives be allocated to the drugs that derive the benefit of the incentives for the ASP calculation: (i) a general rule encompassing most bundled sales; and (ii) an exception for bundled sales that involve discounts/rebates on dominant drugs.

First, for bundled sales that do not contain dominant drugs, the bundled incentives should be allocated proportionally to the dollar value of the units of each drug sold under the bundled arrangement. This approach aligns the incentives with the sales generated thereby. This general rule is consistent with the Medicaid bundling principles.

Second, for bundles that contain dominant drugs, incentives granted on such drugs that are conditioned in whole or in part on purchases of a drug (or drugs) with clinical alternatives ("competitive drugs") should be allocated to the competitive drug (or drugs, based on the relative sales of the competitive drugs). For dominant drugs there is no clear economic incentive to offer large incentives, and thus, there is a strong inference the payment of such incentives actually are intended to be an incentive on other competitive drugs within the bundle. This proposed apportionment approach for bundles that include dominant drugs therefore appropriately reflects the price concessions or incentives created by such bundles.

By requiring the allocation of bundled incentives to drugs that derive the benefit of the incentives, the two proposed apportionment rules achieve CMS's stated goals that the guidance ensure ASP "is an accurate reflection of market prices for Part B drugs and that the treatment of bundled price concessions in the ASP calculation does not create inappropriate financial incentives."

Amgen's Bundle

This propriety of the proposed apportionment rule for incentives on bundled dominant drugs is illustrated through the use of an existing example from the field of medical oncology and the bundling arrangements of Amgen Inc. The products involved are red blood cell growth factors (RBCGFs) and white blood cell growth factors (WBCGFs).

The RBCGFs are epoetin alfa sold by Ortho Biotech under the brand name Procrit and darbepoetin alfa sold by Amgen Inc. under the brand name Aranesp. RBCGFs are used to treat severe anemia that is commonly seen in patients undergoing chemotherapy. Chemotherapy can destroy red bloods and depress the production of erythropoietin, the human hormone that stimulates red blood cell creation. Ortho Biotech and Amgen are the only two competitors for the sale of RBCGF drugs to treat chemotherapy-induced anemia in the United States. Ortho Biotech's drug Procrit is an exact replicate of the naturally produced erythropoietin molecule; Amgen's drug Aranesp is a modified version of erythropoietin molecule.

The WBCGFs are filgrastim and pegfilgrastim sold by Amgen under the brand names Neupogen and Neulasta, respectively, and sargramostim sold by Berlex Laboratories Inc. under the brand name Leukine. The WBCGFs are used to treat neutropenia, a severe white blood cell deficiency that is potentially life threatening. WBCGF drugs stimulate the production of infection-fighting white blood cells known as granulocytes. These cells are reduced or destroyed during many kinds of cancer chemotherapy. White blood cell counts become dangerously low in some cancer patients, leaving them vulnerable to life-threatening infections. WBCGF drugs lessen patients' chances of infection and reduce their need for antibiotics and hospitalization, resulting in a significant improvement in their quality of life. Neupogen was Amgen's initial WBCGF product. In 2002, Amgen introduced Neulasta, a drug modified version of Neupogen that, according to Amgen, may be administered less frequently than Neupogen.

Amgen dominates the sales of WBCGF products, which have become the recognized standard of care for the treatment of neutropenia. Although Berlex's product has been on the market for many years, unlike Amgen's drugs, it (i) not indicated for the treatment of neutropenia, (ii) has a significantly higher risk profile than Amgen's drugs, and (iii) must be administered intravenously, which is a longer and more costly process than the subcutaneous injection process employed with Amgen's drugs. As a consequence, Berlex's drug has a *de minimis* share of WBCGF sales and Amgen's WBCGF products are undisputedly the dominant drugs.

Virtually all oncology clinics administer both RBCGFs and WBCGFs to patients. These clinics must buy their WBCGF drugs from Amgen and, therefore, Amgen need not offer large competitive incentives on its WBCGF drugs to make those sales. But Amgen nevertheless offers large discounts and/or rebates to oncology clinics on the condition that these facilities reach certain volume purchase requirements for Amgen's RBCGF and WBCGF drugs (individually and in aggregate). That is, Amgen's bundle conditions the grant of rebates for its WBCGF drugs on the purchase of large volumes of its competitive drug Aranesp (darbepoetin alfa).[1] As a consequence, oncologists and oncology clinics must buy less Procrit (arguably a superior alternative) and more Aranesp in order to get access to both the WBCGF and RBCGF rebates.

Oncologists who accede to Amgen's demands to purchase Aranesp in lieu of the competition (Ortho Biotech's Procrit) earn significant incremental back-end rebates on Amgen's WBCGF drugs. Oncologists who fail to purchase the large volumes of Aranesp, however, are denied the rebates on Amgen's WBCGF drugs required to break even on the WBCGF drugs administered to Medicare patients (i.e., because of the back-end rebates that are awarded, the WBCGF drugs' ASP reimbursement is lower than their acquisition prices, net of any available discounts).

Thus, the rebates Amgen provides on its WBCGF drugs are intended to drive Aranesp purchases. But Amgen allocates the rebates to its WBCGF drugs for its ASP calculations to keep the WBCGF drugs ASPs low and the Aranesp ASP high, thereby creating an artificially high ASP that overpays Aranesp and is a net cost to Medicare. As a consequence, the Amgen drugs' ASPs (i) do not reflect their market prices and (ii) are used wrongly by Amgen to induce oncologists to purchase Aranesp in circumstances where they otherwise might purchase Procrit.

Our proposed ASP calculation methodology corrects this inequity and achieves CMS's stated goals. By requiring bundled incentives offered on dominant drugs to be allocated to the competitive drugs, the new apportionment rule would require Amgen to report pricing on Aranesp that reflects the economic reality of its offering by stating its ASP at an amount that reflects the incentives that drive its sales, thereby forcing it to compete on a level playing field with Procrit. And the methodology would remove Amgen's ability to force oncologists to incur losses on its WBCGF drugs administered to Medicare patients by increasing their ASPs to an amount that reflects the actual incentives attributable to the drugs.

The proposed policy also would mitigate opportunities to distort Medicare reimbursement rates and any resulting inducement to purchase Medicare Part B covered products with overstated reimbursement rates. In turn, this would foster meaningful competition and lead to reduced drug acquisition costs and ASPs. Thus, the proposed apportionment rule ensures the drugs' ASPs do in fact represent the drugs' market prices and would allow the competitive marketplace to operate, which would benefit patients and Medicare.

[1] This condition is effectuated through the imposition of minimum Aranesp purchase requirements, and the structure of contract's rebate schedule which requires large Aranesp purchases to earn higher incentives on Neulasta.

Proposed Policy Generates Savings for Medicare and its Beneficiaries

The proposed policy will generate immediate savings for the patients and Medicare. The allocation of incentives from Amgen's WBCGF drugs to Aranesp decreases the Aranesp ASP and increases the WBCGF drugs' ASPs. However, ASP is a per unit reimbursement amount and a much larger percentage of the total Aranesp sales volume is reimbursed by Medicare than Amgen's WBCGF drugs. That is, Medicare reimburses more units of Amgen's Aranesp than Amgen's WBCGF drugs. Consequently, even though the proposed policy would result in increased ASPs for Amgen's WBCGF drugs, the lower Aranesp ASP generates immediate cost savings to Medicare. We estimate those savings to approximate $50 million.

Currently, Medicare pays a "dose premium" for Aranesp compared to Procrit. A dose premium is the difference in reimbursement costs for comparable doses of two different drugs used for the same clinical indications. In the case of Aranesp and Procrit, the existing Amgen bundle forces oncologists to purchase Aranesp, which is by far the more costly drug to private payors and Medicare due to the high doses of Aranesp administered relative to Procrit.[2]

We estimated the dose premium on Aranesp cost Medicare an excess $177 million in 2005 alone. At the 20% coinsurance rate, the excess costs to the Medicare beneficiaries was $35 million.

These cost estimates were derived from two studies of the comparable doses of Procrit and Aranesp administered in oncology clinics. The first is an independent study conducted by Oncology Therapeutics Network (OTN) of its proprietary database, which provides the relative average weekly doses of Aranesp and Procrit administered in oncology clinics.[3] The second is an analysis of the average cumulative dose data from the Medicare Standard Analytic Files.[4] Both sets of data – the first from the providers and the second from the payor – yielded the same ratio of Procrit to Aranesp doses administered on average to oncology patients in 2005: 266:1. That is, on average 266 International Units of Procrit were administered for every microgram of Aranesp administered. (The two drugs are packaged by Amgen in different units.)

[2] Private payers (e.g., Blue Cross Blue Shield of Georgia and Virginia) have recognized this dose premium and begun to take the extraordinary step of paying much greater per unit reimbursement amounts for Procrit relative to Aranesp to offset the Aranesp dose premium.

[3] OTN is a leading specialty distributor of drugs and supplies to more than 2,400 office-based oncology practices. OTN provides practices integrated point-of-care drug dispensing and tracking systems. These systems also can provide summary data on the amount of a particular drug provided to patients across all practice locations.

[4] These Medicare data files contain claims for a 5% random sample of Medicare beneficiaries and are commonly used to study diseases in elderly patients.

At the published reimbursement rates for 2005, this dose ratio translates to a 22.4% dose premium for Medicare (and a 37.2% dose premium for private payors).[5] Applying the dose premium percentage to the total Medicare allowed charges for Aranesp – derived from the National Procedure Summary Data File as of August 17, 2006 produces an excess Aranesp dose premium to Medicare of $177 million based on the August 2006 report.

Absent action by the agency, Medicare will continue to incur an Aranesp dose premium as oncology clinics are coerced to purchase Aranesp in lieu of Procrit. Indeed, our studies show that the Aranesp dose premium has increased dramatically in 2006, corresponding with the approval of Amgen's new dosing regimen.[6] The proposed apportionment rule would alleviate the coercive nature of the bundle, allowing oncologists to purchase Procrit and thereby generating savings to patients and Medicare.

Moreover, by leveling the competitive playing field for Aranesp and Procrit, the proposed apportionment rule would foster price competition, which in turn will reduce the drugs' acquisition costs and ASPs. Thus, our proposed bundle apportionment policy ensures the drugs' ASPs do in fact represent the drugs' market prices and would allow the competitive marketplace to operate, which would benefit patients and Medicare.

Implementation of Bundle Apportionment Policy

Guidance should be issued immediately through program instruction or other guidance (consistent with the authority under section 1847A(c)(5)(C) of the Act) on the methodology manufacturers must use for apportioning price concessions across Part B drugs sold under bundling arrangements.

For bundled sales that do not contain dominant drugs, the bundled incentives should be allocated proportionally to the dollar value of the units of each drug sold under the bundled arrangement. Because this general rule is consistent with the Medicaid bundling principles, we view its implementation as straightforward.

For bundles that contain dominant drugs, we believe it will be self-evident to the manufacturer in virtually every instance that such a drug exists and compliance with the apportionment policy could be done voluntarily. However, before any manufacturer is required to modify their ASP reporting for bundles with dominant drugs, we believe it should be provided the opportunity to respond to a finding by the Secretary that the apportionment policy for dominant drugs applies to their bundle.

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[5] The Medicare premium percentage was derived using the average of the published ASPs for Procrit and Aranesp in 2005. The private payor premium percentage was derived using the average published list prices for 2005, the assumption being that payors reimbursed Aranesp and Procrit at the same discount off of AWP (which in turn was set at for the two drugs at the same fixed markup over WAC).

[6] In March 2006, Amgen secured approval for its new regimen that allows dosing of up to 500 micrograms every three weeks.

We recommend that the 2007 final rule for the physician fee schedule include a finding by the Secretary that Amgen's bundle of Neupogen/Neulasta with Aranesp is subject to the apportionment policy for bundles with dominant drugs. Such a finding should be apparent based on the information provided in this comment letter and the fact that Amgen readily concedes in its public filings that its white blood cell growth factor drugs Neupogen and Neulasta are monopoly products without viable competitive alternatives. However, Amgen should be provided 30 days to provide evidence to rebut the finding that its bundle includes a dominant drug before they are required to comply with the ASP reporting requirements.

As other bundles with dominant drugs are identified, the Secretary would be required to make an initial determination followed by an opportunity for the manufacturer to rebut the finding during a 30-day comment period.

Harm Will Increase if the Bundle Apportionment Policy is Not Adopted

Amgen has exploited the absence of clear guidance to pursue its anticompetitive bundle to the detriment of oncologists, patients, and the healthcare system. The rule is required to prevent Amgen's approach from becoming the norm in each instance that a dominant drug may be bundled with drugs for which there are clinical alternatives ("competitive drugs").

CMS may be aware of an antitrust lawsuit that has been filed by Ortho Biotech over Amgen's bundling practices. We urge CMS not to accept arguments that that this lawsuit obviates the need for any action by the agency. It is not sufficient to rely on the judiciary to prevent or alleviate the costs and harm from bundles containing unique therapies. A judicial determination that a bundle does or does not violate the antitrust laws involves a different standard and analysis than involved in assessing the appropriate allocation methodology for reimbursement purposes. The proposed bundle apportionment rule for dominant drugs is required to achieve CMS's stated goal of ensuring that drugs' ASPs reflect market prices and do not create inappropriate financial incentives.

Conclusion

We support the CMS goal of ensuring that the ASP is an accurate reflection of market prices for Part B drugs and that the treatment of bundled price concessions in the ASP calculation does not create inappropriate financial incentives. We believe specific guidance is needed and we recommend the following:

1) For bundled sales that do not contain dominant drugs, the bundled incentives should be allocated proportionally to the dollar value of the units of each drug sold under the bundled arrangement. This general rule is consistent with the Medicaid bundling principles.
2) For bundles that contain dominant drugs, incentives granted on such drugs that are conditioned in whole or in part on purchases of a drug (or drugs) with clinical alternatives ("competitive drugs") should be allocated to the competitive drug (or

drugs, based on the relative sales of the competitive drugs). The methodology for applying discounts/rebates is as follows:

a) Determine the total incentives paid on the dominant drug;
b) Determine the amount of incentives paid on the dominant drug that are conditioned in whole or part on the purchase of another bundled product;
c) Allocate the incentives determined in step (b) to the other competitive products in the bundle;
d) Allocate the difference between the amounts determined in step (a) and (b), if any, to the dominant drug; and
e) Apportion the incentives on the competitive products, including those amounts allocated in step (c), based on the dollar value of the units of each drug sold. .

Guidance should be issued immediately through program instruction or other guidance (consistent with the authority under section 1847A(c)(5)(C) of the Act) on the methodology manufacturers must use for apportioning price concessions across Part B drugs sold under bundling arrangements. Amgen's WBCGFs should be identified as dominant drugs in a bundle and Amgen should be given 30 days to rebut this finding before the new ASP reporting requirements are implemented for the drugs in their bundle.

In addition to eliminating inappropriate financial incentives, the guidance we have recommended would generate savings for the Medicare program and its beneficiaries and it would foster price competition, which in turn would reduce the drugs' acquisition costs and ASPs.

Thank you for your consideration of our comments and recommendations. If you have any questions, please contact Cathleen Dooley, Executive Director, Federal Affairs at 202-589-1008 or by e-mail at cdooley@obius.jnj.com.

Sincerely,

Cathleen M. Dooley
Executive Director, Federal Affairs
Johnson & Johnson

Appendix B

Johnson & Johnson

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January 2, 2007

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Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
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445-G, Hubert H. Humphrey Building
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Re: Medicare Program; Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B

Dear Ms. Norwalk:

On behalf of Ortho Biotech Products, L.P., a Johnson & Johnson Company, I am pleased to submit comments on the "Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B" published in the *Federal Register* at Volume 71, No. 231, p. 69624 as a final rule with comment period on December 1, 2006. Of the many provisions on which CMS has solicited further comment, we confine our remarks to one issue related to the calculation of the average sales price or ASP for reimbursement of drugs and biologics under Part B. Specifically, we convey newly available information that demonstrates the pressing need for a rule governing the allocation of incentives paid on dominant drugs bundled with competitive drugs.

During the comment period for the proposed rule, Ortho Biotech and its competitor Amgen Inc. submitted conflicting views regarding the propriety of an allocation rule for bundles containing dominant drugs. The parties agreed that Amgen pays oncology clinics large rebates on its dominant white blood cell growth factor (WBCGF) drugs (Neupogen and Neulasta) contingent on the clinics' purchase of large volumes of Amgen's competitive red blood cell growth factor (RBCGF) drug (Aranesp) in lieu of Ortho Biotech's competitive RBCGF drug (Procrit). They also agreed that Amgen does not allocate to Aranesp for its ASP calculation the incentives Amgen pays on its dominant drugs to drive Aranesp sales. Where the parties differed was with

respect to the effect of Amgen's bundling practices on the drugs' ASPs and the public healthcare system.

The supplemental information conveyed below reveals that Amgen's own data demonstrate what it has consistently denied, i.e., Amgen's bundling practices have caused and are causing significant harm to Medicare and its beneficiaries. Unless addressed, the use of dominant drugs (such as Amgen's WBCGF drugs Neupogen and Neulasta) to drive the purchase of competitive drugs (such as Amgen's RBCGF drug Aranesp) will continue to distort the reported ASPs and harm the public healthcare system. For these reasons, we renew our recommendation that CMS adopt a rule that requires manufacturers to allocate the incentives paid on their dominant drugs that are calculated based on the sales or market share of their competitive drugs to such competitive drugs for the purposes of their ASP calculations.

Consistent with Ortho Biotech's position, the Medicare Payment Advisory Commission (MedPAC) unanimously recommends – in its recent report to Congress titled "Impact of Changes in Medicare Payment for Part B Drugs" (January 2007) – that CMS issue regulatory guidance clarifying the appropriate methodology for the allocation of discounts afforded on bundled products. In the report (summarized below) MedPAC recognizes that bundles involving dominant drugs can lead to distortions in ASP reimbursement rates in the event the bundled discounts are not allocated so as to accurately reflect the drugs' transaction prices. To maintain the integrity of the ASP system, MedPAC proposes that CMS clarify ASP reporting requirements for bundled products to ensure that ASP calculations allocate discounts to reflect the transaction price for each drug. This recommendation is designed to ensure that discounts paid on bundled drugs that are contingent on the purchase of competitive drugs are allocated to the competitive drugs that derive the benefit of the incentives. As the MedPAC report reflects, the issue before CMS is not whether Amgen's bundle is illegal or whether bundling is appropriate, but whether the existing payment methodology is accurate, fair, and minimizes costs to Medicare and beneficiaries. CMS has the authority to implement rules to ensure a fair and accurate ASP reimbursement system for Part B drugs, and we respectfully agree with MedPAC that CMS should act quickly to achieve these goals.

I. BACKGROUND

On August 22, 2006, CMS issued a proposed rule that solicited comments on the methodologies manufacturers should use to apportion price concessions across Part B drugs sold under bundling arrangements for purposes of calculating the drugs' ASPs. CMS explained that the goal of the contemplated guidance is to ensure a drug's ASP "is an accurate reflection of market prices for Part B drugs and that the treatment of bundled price concessions in the ASP calculation does not create inappropriate financial incentives." CMS recognized that any proposed apportionment methodology must account for bundles that include "drugs that may not have clinical alternatives," which we term "dominant drugs" for ease of reference.

Without appropriate regulatory guidance, bundles with dominant drugs can undermine the integrity of the ASP reimbursement system, may impair competition and impose undue costs on the public healthcare system. These adverse consequences result where a manufacturer pays large incentives on a dominant drug to drive sales of a competitive drug but does not allocate the

incentives to the competitive drug for the ASP calculations. In such circumstances, the ASP of the competitive drug is insulated from price competition and does not reflect the incentives paid to drive its sales.

A. Ortho Biotech's Comments: In its September 28, 2006 comments on the proposed rule Ortho Biotech proposed methodologies for the allocation of incentives on bundled drugs. Consistent with CMS's stated goal that the published ASPs reflect drugs' true market prices, Ortho Biotech recommended that the incentives paid on a dominant drug to drive sales of a competitive drug be allocated to the competitive drug for the ASP calculations. Moreover, to illustrate the inequity and the distortion of ASP payment rates resulting from a manufacturer's failure to appropriately allocate incentives on dominant drugs, Ortho Biotech itemized the harm to competition and Medicare program as a result of Amgen's bundled offering to oncologists known as the Amgen Portfolio Contract ("APC").

To review, the APC encompasses Amgen's WBCGF drugs (Neupogen and Neulasta) and Amgen's RBCGF drug (Aranesp). Neupogen and Neulasta are dominant drugs, together accounting for approximately 98% of the sales of WBCGF drugs to oncology clinics. Amgen's drug Aranesp, in contrast, competes with Ortho Biotech's drug Procrit in the oncology clinic RBCGF drug market. Under its APC, Amgen pays large incentives on Neupogen and Neulasta (its dominant drugs) contingent on the oncology clinics' purchase of large amounts of Aranesp (Amgen's competitive drug) in lieu of Ortho Biotech's drug Procrit. That is, oncologists are denied lucrative rebates on Amgen's life saving WBCGF drugs unless they purchase large amounts of Aranesp. Without those rebates, moreover, the oncology clinics actually lose money on the WBCGF drugs administered to Medicare patients. Thus, the APC undermines the integrity of the market-based ASP reimbursement system by pitting the margin on Amgen's three drugs against the margin on Ortho Biotech's one drug, thereby rendering futile any effort to price compete against the bundle.

Ortho Biotech identified in its comments the significant immediate and long-term savings for patients and Medicare that will result from the adoption of Ortho Biotech's proposal to require the allocation to Aranesp of the incentives paid on Amgen's dominant drugs:

- First, the allocation of incentives from Amgen's WBCGF drugs to Aranesp will decrease the Aranesp ASP and increase the WBCGF drugs' ASPs. The realignment of ASPs will generate immediate savings because a much larger percentage of Medicare's payments for the drugs included in the APC are for Aranesp than for Amgen's WBCGF drugs.
- Second, by requiring the Aranesp ASP to reflect the incentives paid to drive its sales, the proposed allocation will level the competitive playing field and afford oncologists the option to purchase Procrit as their drug of choice. The use of Procrit in lieu of Aranesp will generate significant costs savings for the ultimate payors (i.e., patients, private insurers and Medicare) by eliminating the significant Aranesp "dose premium" currently incurred. That is, the volume of Aranesp administered during a course of therapy, in absolute terms and relative to Procrit doses administered, has increased dramatically since Aranesp was introduced in 2002. As the data Ortho Biotech submitted showed, at the doses actually administered in oncology clinics, Aranesp is by far the more costly drug to payors.

- Third, by leveling the competitive playing field for Aranesp and Procrit and thereby fostering price competition, the proposed rule will reduce the drugs' acquisition costs and ASPs.[1] Thus, the proposed bundle apportionment policy ensures the drugs' ASPs do in fact represent the drugs' market prices and allows the competitive marketplace to operate, to the benefit of Medicare and its beneficiaries.

B. Amgen's Comments: Amgen submitted comments to the proposed rule on October 10, 2006. Amgen did not dispute that its APC offers oncology clinics large rebates on its dominant WBCGF drugs contingent on the clinics' purchase of large volumes of Aranesp. Nevertheless, Amgen opposed any rule calling for the allocation of incentives paid on its dominant WBCGF drugs to Aranesp as "unnecessary". Amgen made a series of specious assertions in support of that proposition that are summarily addressed in Appendix A.

More relevant to these supplemental comments, Amgen also asserted that adopting an allocation rule for bundles with dominant drugs "could" increase Medicare costs. Amgen correctly noted that allocating to Aranesp the incentives on its WBCGF drugs likely would shift market share from Aranesp to Procrit (because the allocation will mitigate the coercive nature of the APC). (p. 10). But Amgen argued that the resultant increase in Procrit share could increase Medicare reimbursement because the per unit ASP for Procrit is higher than the per unit ASP for Aranesp. (pp.10-11). What Amgen ignored is that total reimbursement is a function of the per unit cost and the actual doses administered. It is worth noting that Amgen's comments did not address at all the total relative costs of the drugs at the doses actually administered in oncology practices.

C. CMS's Final Rule: CMS published its final rule on December 1, 2006 (71 FR 69624). With respect to the treatment of bundled incentives for the ASP calculation, CMS began by reiterating that "our goal is to ensure that the ASP is an accurate reflection of market prices for Part B drugs and that the treatment of bundled price concessions in the ASP calculation does not create inappropriate financial incentives" (71 FR at 69673). CMS noted, however, that conflicting comments had been submitted by the parties (Id. at 69764). Without a clear consensus, CMS elected to defer the implementation of allocation rules until it obtains more information (Id. at 69765). CMS advised that it would "continue to monitor this issue" and encouraged constituents to submit "additional information or concerns to us on this issue as they may arise." Moreover, CMS provided explicit notice that it "may provide more specific guidance in the future through rulemaking or through program instruction or other guidance . . . if we determine it is warranted" (Id.). Finally, CMS noted that "MedPAC has indicated it will be studying this issue in the upcoming year, and we look forward to its work in this area" (Id.).

D. The Antos and King Paper: In an effort to influence the debate, Amgen funded and submitted to CMS and other parties a paper prepared by Joseph R. Antos, Ph.D. and Roland (Guy) King, F.S.A., M.A.A.A. titled "Competition and Bundled Pricing in Medicare's Part B Drug Market", dated December 1, 2006 (the "Antos and King paper"). While largely a

[1] Moreover, the actual price of the WBCGF drugs Neulasta and Neupogen should not increase as a consequence of the allocation of incentives under the proposed rule. The WBCGF drugs are dominant products that can be priced without much regard for competitive drugs. Thus, the WBCGF drugs likely are priced at the level the market will bear and a Medicare allocation rule directing Amgen to accurately report Aranesp ASPs should not affect the net prices of the WBCGF drugs.

reiteration of Amgen's talking points, the paper supplemented Amgen's earlier submission with two findings concerning the effect of the allocation of the WBCGF drug incentives to Aranesp. First, the paper states that "shifting back to Aranesp discounts offered on the white cell agents would encourage physicians to purchase J&J's competing anemia product Procrit" (p.1). That finding is significant. The recognition that market share will shift to Procrit if an allocation rule is implemented affirms that the incentives on Amgen's dominant WBCGF drugs are driving Aranesp share. The finding also confirms that any model assessing the cost of the proposed rule must assume, as Ortho Biotech has, that Aranesp share will shift to Procrit. Second, the paper concludes that the allocation rule "would increase spending in Part B and would substantially raise the cost of administering the program without improving patient care." Thus, in contrast to Amgen's initial submission which focused solely on per unit ASPs, the paper analyzes the cost of the program by comparing the total relative costs of the parties' drugs.

In the Antos and King paper, however, no analysis whatsoever was presented of the relative costs of the parties' drugs as actually administered in oncology clinics. Rather, the paper merely adopted the "dose conversion ratio" of 330:1 adopted by CMS in 2004 for reimbursement under the functional equivalence standard of the Outpatient Prospective Payment System (OPPS) (pp.7, 9). That dose conversion ratio was set as a prospective conversion rate based, in large part, on Amgen's representations to CMS that a dose ratio of 400:1 accurately reflected the relative doses of Procrit and Aranesp actually administered in oncology clinics. (Ortho Biotech took the position that a dose ratio of 260:1 more accurately reflected the actual dosing at that time.) In proffering the larger ratio, Amgen did not submit to CMS the data from its own files – disclosed for the first time below – that demonstrates Amgen knew full well that its 400:1 ratio did not accurately account for the doses of Aranesp actually administered in oncology clinics. Amgen apparently also failed to provide that data to the authors of the Antos and King paper, since they were equally silent with regard to that newly available information.

One final omission from the Antos and King paper is worthy of note. The paper asserts that Aranesp and Procrit's ASPs have decreased since 2005 in the "broad oncology market," implying that the APC has fostered price competition in the oncology clinic market[2] (p.8). What the paper does not disclose or address, however, is the pricing pattern of the parties' drugs in oncology clinics before the implementation of the explicit minimum Aranesp purchase requirements on January 1, 2005, which would demonstrate that the APC effectively ended price competition in the oncology clinic setting.

E. The MedPAC Recommendation: The Medicare Modernization Act (MMA) of 2003 instructs MedPAC to evaluate the impact of the new ASP reimbursement system for Part B drugs on providers and patients and submit its findings in two reports to Congress. MedPAC submitted its second report to Congress on December 29, 2006. The recent report makes

[2] Amgen's APC was and is offered only to oncology clinics. The published ASPs incorporate incentives paid to other markets, such as hospitals. It is misleading therefore to reference changes in the published ASPs for Procrit and Aranesp as a basis for conclusions regarding the impact of the APC on competition.

findings and recommendations that are consistent with those set forth in this comment letter,[3] including the following:

- ASPs Should Reflect Drugs' Actual Transaction Prices: MedPAC recommends that, in establishing guidance, the "goal should be to ensure that ASP reflects the average transaction price for drugs." This goal seeks to ensure that, through transparency and the alignment of reimbursement and costs, Medicare derives the benefit of price competition under its ASP reimbursement system. The goal is thwarted, however, to the extent a drug's published ASP does not reflect the incentives paid to drive its sales

- Discounts on Bundled Dominant Drugs Distort ASPs Absent Appropriate Allocation: MedPAC correctly recognizes that "[i]t is very unusual to get a large discount on a drug that has no competition." That is, a manufacturer need not provide discounts on dominant drugs to drive their sales. But a manufacturer may provide large discounts on a dominant drug contingent on the purchase of a competitive drug in order to drive the purchase of the competitive drug. MedPAC correctly finds that, without a rule requiring the allocation of the incentives of the dominant drug to the competitive drug, the drugs' ASPs will not reflect their transaction prices: "Without guidelines for the allocation of bundled discounts, the bundling methodology undercuts the ASP payment method."

- Amgen's Coercive APC Restricts Clinical Choice: MedPAC recounts that "many interviewees" described a bundling issue that "posed a problem for them." MedPAC describes this specific bundling issue as follows: "Currently, there are two drugs, we call Drug A and Drug B, similar products that compete for market share. Although the shift to ASP has resulted in lower payment rates for both products, volume and expenditures continued to increase in 2005. In this instance, the manufacturer of Drug A also makes Drug C, a lifesaving drug with no effective competition. It is very unusual to get a large discount on a drug that has no competition, but, in this case, the manufacturer provides a significant discount on Drug C to purchasers who buy Drug A instead of Drug B." Thus, without naming the drugs or parties, MedPAC describes a dominant drug bundle that has the same characteristics as Amgen's bundled contract. Specifically, Drug A corresponds to Amgen's Aranesp, Drug B corresponds to Ortho Biotech's Procrit and Drug C corresponds to Aranesp's dominant WBCGF drugs. The Amgen arrangement is a problem because, as MedPAC finds, physicians "lose money" on the drugs administered to Medicare patients unless they secure the large discounts on the bundled dominant Drug C by purchasing the competitive Drug A. MedPAC states that physicians indicated this economic coercion compromises their "ability to choose a product based on clinical factors." And MedPAC properly identifies the magnitude of the problem, concluding that without guidance, "[o]ther manufacturers of single source drugs might also use this method to increase their sales on products with competition."

[3] The report makes one finding that is not consistent with Ortho Biotech's view of the impact of Amgen's APC. The report states that "[i]n the short term, the bundling arrangement results in lower Medicare payment rates for all three drugs." As explained in Appendix A, Amgen's APC has curtailed price competition in the oncology clinic market, causing Aranesp and Procrit ASPs to be higher than they would have been if the APC had not been implemented.

- CMS Should Issue Regulatory Guidance to Close the Loophole: MedPAC correctly finds that CMS "could support the accuracy of the ASP methodology by clarifying rules about the way bundled discounts should be allocated under manufacturer reporting requirements." Thus, MedPAC recommends that "The Secretary should clarify average sales price (ASP) reporting requirements for bundled products to ensure that ASP calculations allocate discounts to reflect the transaction price for each drug." Moreover, MedPAC properly emphasizes that, while CMS's policy may need to change over time to reflect changing market practices, this "should not slow down action in this area." MedPAC further highlights the importance of the issue by making the appropriate allocation of discounts for bundled products the only policy recommendation in the entire 56-page report to Congress.

- The Guidance Should Require Allocation of Contingent Discounts to Dominant Drugs: MedPAC proposes two allocation methodologies for bundled discounts. One "option is to allocate bundled discounts in proportion to the sales of each drug sold under the bundled arrangement." According to MedPAC, "[t]his option would parallel bundling requirements under Medicaid and be simpler to administer. However, this method might not capture contingent discounts." That is, the Medicaid allocation methodology is appropriate as a general rule, but a particular rule is required to ensure discounts on dominant drugs that are contingent on the purchase of competitive drugs are properly allocated to the competitive drugs for ASP calculations. To address the contingencies in the contractual arrangement described, MedPAC also proposes an "option reflecting the contingencies in the contract." Consistent with Ortho Biotech's proposed approach, MedPAC's second option calls for a manufacturer to allocate discounts contingent on the purchase of another drug "to the sales of the drug that the discount is meant to increase. This would result in an ASP that more accurately reflects the transaction price of the drugs."

Thus, even without the benefit of the newly available information disclosed below, MedPAC recognized the need to close the loophole that enabled the manipulation and distortion of the published ASPs. The MedPAC report, in addition to the newly available information summarized below reinforces the need for CMS to clarify ASP reporting requirements for bundled products to ensure that ASP calculations reflect actual transaction prices and thus maintain the integrity of the reimbursement system.

II. NEWLY AVAILABLE INFORMATION REGARDING THE RELATIVE COSTS

Following Ortho Biotech's submission of its initial comments on the proposed rule, additional information has become available that confirms Ortho Biotech's representations – and squarely refutes Amgen's representations – concerning the relative costs of Aranesp and Procrit to patients, Medicare and private insurers. This information is derived from the recently unsealed testimony and exhibits presented during the June 2006 hearing in the pending antitrust litigation between Ortho Biotech and Amgen. The evidence submitted under oath in that hearing establishes the significant incremental costs imposed on the public healthcare system by Amgen's payment of incentives on its dominant drugs to drive the purchase of Aranesp in lieu of Procrit. That proof is further corroborated by studies and data concerning the relative dosing and costs of the parties' drugs obtained after the hearing, as well as recent developments in private

insurer reimbursement for Aranesp and Procrit. Indeed, current data pertaining to the adoption of a new Aranesp dosing regimen shows that, without immediate action, the excess costs to Medicare and patients already documented will escalate dramatically.

A. Recently Unsealed Testimony and Exhibits: Starting on June 6, 2006, the United States District Court for the District of New Jersey held a week-long hearing to address Ortho Biotech's request that the Court issue a preliminary injunction to stop Amgen from using its APC until the case is tried to the jury. The issue before the Court (i.e., whether Amgen's APC violates the antitrust laws) is distinct from, and involves a different standard than, the issue before CMS (i.e., whether existing guidelines effectuate a payment methodology that is accurate, fair, and minimizes costs to Medicare and beneficiaries). The Court ultimately concluded that the harm Ortho Biotech incurs as a consequence of Amgen's conduct could be remedied by money damages and, therefore, the parties could proceed to trial on the merits without an injunction. Of relevance here, during the course of the hearing evidence was submitted and testimony was heard regarding the relative costs of the parties' drugs to patients, Medicare and private payors.

All the testimony and documents admitted at the hearing concerning oncology clinics' actual administration of the parties' drugs – including both parties' internal analyses – proved that Aranesp was far more costly than Procrit to the ultimate payors. That is, regardless of the time period examined or the information reviewed, the evidence uniformly showed that the relatively large doses of Aranesp administered in oncology clinics render the drug more costly to payors under both AWP-based and ASP-based reimbursement regimens. Thus, the evidence belies Amgen's assertions that the relative costs of the parties' drugs should be assessed at a dose conversion ratio of 330:1 (at which Procrit would be more costly). Rather, as Amgen was well aware, the data of actual doses administered yield a range of significantly lower dose ratios, all of which reveal a large Aranesp cost premium.

The Court unsealed that evidence by order dated December 12, 2006, thereby enabling Ortho Biotech to make this submission to CMS. To that end, following is a summary of the categories of evidence admitted at the hearing concerning the actual dosing and costs of the parties' drugs, with citation to the pages of the annexed transcripts and trial exhibits:

- Ortho Biotech's expert analyses: Ortho Biotech's expert Dr. Pierre Cremieux of the Analysis Group analyzed two large databases of private insurer reimbursement claims data[4] to determine the average weekly doses of Aranesp and Procrit actually administered in oncology clinics (Tr. 478-575, at 482-488; PD 64-65).[5] At the doses actually administered, Aranesp was 32% to 51% more costly than Procrit under an AWP-based

[4] Reimbursement claims data are insurers' records of the "claims" submitted by oncologists for the reimbursement of drugs actually administered in their offices. Health insurers and other industry participants rely on claims data to conduct analysis of drugs' relative costs (Tr. 427).

[5] References to "Tr. ___" are to the page number of the hearing transcript attached as Appendix B. References to "PD___" are to the numbers of the cited plaintiffs' demonstratives attached as Appendix C. References to "PX___" are to the numbers of the cited plaintiffs' exhibits attached as Appendix D.

reimbursement regime, and from 19% to 33% more costly under an ASP-based reimbursement regime[6] (Id.).

- Ortho Biotech's internal dosing data analyses: In the regular course of business Ortho Biotech tracks the average weekly doses of Aranesp and Procrit actually administered in oncology clinics (Tr. 491-92; PD 66). The data obtained from Ortho Biotech's files showed that, for 2005, Aranesp was 47% more costly than Procrit under an AWP-based reimbursement regime and 33% more under an ASP-based reimbursement regime (Tr. 492).

- Ortho Biotech's internal cost analyses: Ortho Biotech also calculates in the regular course of its business the relative costs of Aranesp and Procrit based on doses of the drugs actually administered in oncology clinics (Tr. 493-495; PX 528 at 291634-35). Ortho Biotech calculated that the Aranesp cost premium grew from 36% in 2004 to 45% in 2005 (Tr. 493-94).

- Amgen's internal dosing data analyses: Like Ortho Biotech, Amgen tracks the average weekly doses of Aranesp and Procrit in the regular course of its business (Tr. 496- 499; PX 350; PD 67). At the doses specified in Amgen's internal reports, Aranesp was from 25% to 34% more costly than Procrit under an AWP-based reimbursement regime, and from 13% to 21% more costly under an ASP-based reimbursement regime (Id.).

- Amgen's internal cost analyses: Amgen also calculated the relative costs of Aranesp and Procrit in the regular course of its business (Tr. 500-02; PX 434 at 92451-52). In 2004, for example, Amgen concluded from its own data that the Aranesp cost premium was 28% (Tr. 500; PX 434 at 92452).

- Amgen's expert analyses: Amgen did not offer an independent expert to testify regarding the relative costs of the parties' products. Instead, Amgen had its own Vice President Dr. Joshua Ofman offer an opinion on that issue. Amgen submitted through Dr. Ofman analyses of reimbursement data conducted by two third party vendors (Tr. 893-.897). As Dr. Ofman conceded at the hearing, both vendors' initial analyses of the relative costs of the parties' drugs demonstrated that Aranesp was more costly than Procrit (Id.). And as was explicitly stated in one vendor's report, Amgen thereafter directed the vendors to alter their analysis in an effort to show the drugs were at cost parity (Tr. 897; 516-517).

- Independent third party payor analyses: Wellpoint is the nation's largest private health insurer. Wellpoint Vice President Dr. Randy Axelrod testified that the insurer determined that Aranesp was far more costly than Procrit based on analyses of its own claims data conducted in the regular course of its business (Tr. 411-477, at 464-68). Dr. Axelrod explained that, based on those analyses, Wellpoint attempted to encourage oncologists to administer Procrit by offering more favorable reimbursement for Procrit. That is, Wellpoint revised its fee schedule to afford reimbursement for Procrit at ASP plus 35% and Aranesp at ASP plus 6% (Tr. 464-65, 468). Wellpoint reasoned that, due to the large Aranesp dose premium, it could reimburse Procrit at a significant premium to Aranesp and still save money if oncologists switched from the higher cost Aranesp (Id.).

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[6] The dosing disclosed in the two databases Dr. Cremieux analyzed yielded dose ratios of 248:1 and 276:1.

The evidence also proved that, while asserting to CMS that Aranesp was less costly, Amgen at the same time deliberately withheld from CMS the analyses Amgen conducted that showed Aranesp to be the more costly drug.

- Amgen Vice President Dr. Joshua Ofman admitted that Amgen has represented to CMS, since the introduction of Aranesp in 2002, that CMS should evaluate the relative cost of Aranesp and Procrit based on an assumed Aranesp weekly dose of 100 micrograms (or 200 micrograms every other week).[7] Dr. Ofman also conceded that in 2002, before oncologists had much clinical experience with Aranesp, Amgen submitted to CMS analyses of reimbursement claims data that purportedly showed that Aranesp actually was administered at an average weekly dose of 100 micrograms (Tr. 871-872).
- Amgen's internal records revealed that, following its initial submission in 2002, Amgen learned from its own claims data analyses that oncologists were administering increasingly larger doses of Aranesp relative to Procrit (PX 434 at 92452; Tr. 873). Dr. Ofman agreed that steep Aranesp "dose escalation" resulted in increased Aranesp costs relative to Procrit from 2003 forward (Tr. 874). Amgen's internal recognition of Aranesp's dose escalation was consistent with disclosures oncologists made to Amgen in 2004 (Tr. 877-880; PX 50; PD 607).
- Dr. Ofman admitted that Amgen did not disclose to CMS its post-2002 internal analyses of reimbursement claims data that disclosed the dose escalation (and therefore escalating costs) of Aranesp (Tr. 875). Rather, Amgen has withheld from CMS the reimbursement claims data analyses Amgen has conducted each year since 2002.
- In fact, Amgen affirmatively instructed its employees not to provide Amgen's internal analyses to CMS after determining the extent of the Aranesp dose escalation. Specifically, in the cover e-mail to its September 2004 monthly claims data report, Amgen determined that the average weekly dose of Aranesp administered was increasing at a far more rapid rate than for Procrit (PX139; Tr. 874-875). Dr. Ofman admitted that Amgen did not disclose that finding to CMS (Tr. 875). Instead, Amgen added to the cover of the October 2004 claims data report a large warning that instructed its employees that the information contained therein was not to be included in Amgen's CMS submissions (PX 156; Tr. 876-77). Consistent with that direction, Amgen has not disclosed to CMS any of its subsequent claims data analyses, including is detailed survey of average weekly doses in October 2005 discussed above (Tr. 496- 499; PX 350; PD 67).
- Further still, at the same time it has been advising CMS that it should evaluate the relative costs of Aranesp and Procrit based on an assumed average weekly dose for Aranesp of 100 micrograms every week (or 200 every other week), Amgen admittedly has been recommending to oncologists in the United States and throughout the world that they should be administering twice that amount[8] (Tr. 573; 859-866; PD 602). Dr. Ofman

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[7] This purported 100 microgram per week Aranesp dosing regimen is the premise of the 400:1 ratio Amgen consistently proffered to CMS as the appropriate dose conversion ratio for reimbursement under the hospital Outpatient Prospective Payment system.

[8] That is, while Amgen has consistently represented to CMS that the appropriate dose conversion ratio is 400:1 (at which Aranesp is the less costly alternative), Amgen has represented to oncologists throughout

conceded that, at the doses Amgen has been recommending to oncologists, Aranesp is more costly than Procrit. (Tr. 863).

Finally, the evidence demonstrates that Aranesp dose premium likely will increase significantly with the adoption of Aranesp's new dosing regime. In March 2006, Amgen secured approval for the administration of Aranesp at an initial dose of 500 micrograms once every three weeks. While noting that the data pertaining to the new regimen was not available before the hearing, Ortho Biotech's expert Dr. Cremieux anticipated that the new regime likely would increase the dosing and costs of Aranesp relative to Procrit. (Tr. 507). The data now available validates Dr. Cremieux's predictions.

B. Recent Dose and Cost Studies: The revelations in the unsealed hearing evidence are corroborated by recent studies and analyses of the relative doses and costs of Aranesp and Procrit administered by oncologists in actual practice. Regardless of the data sets used, the studies demonstrate a significant Aranesp premium, which is growing even more rapidly since March 2006, when Amgen secured approval for its new 500 microgram dosing regimen.

- Lefebvre Study: On July 18, 2006 the peer-reviewed journal Current Medical Research and Opinions published an analysis of private insurer reimbursement data similar to, and effectively endorsing, that presented at the hearing by Ortho Biotech's expert Dr. Cremieux. See Lefebvre, Patrick, et al., "*Dosing patterns, treatment costs and frequency of physician visits in adults with cancer receiving erythropoietic agents in managed care organizations*," Current Medical Research and Opinions, 22(9): pp. 1623-1631 (July 18, 2006), annexed as Appendix E. The Lefebvre study examined the actual doses of the drugs administered in oncology clinics reported in the database, which contained "the complete medical history for over 30 million managed care lives from over 35 health care plans, covering all the census regions of the United States" (Id. at 1684). The study found that the average cumulative doses of the drugs actually administered yielded a dose ratio of 236:1, i.e., 236 International Units of Procrit were administered for every microgram of Aranesp. At that relative dosing, and using the drugs' wholesale acquisition costs as a proxy for the private insurer reimbursement,[9] the study concluded that Aranesp was 52% more costly to payors than Procrit. Using the drugs' most current published ASPs (1st quarter 2007), the Aranesp dose premium at the 236:1 dose ratio is 41%. The actual cost premium to Medicare likely is larger under Aranesp's new dosing regimen given that the dosing of Aranesp has increased since the study was conducted.
- Harley Study: Another recent study of private insurer claims data reaching similar conclusions was presented at the December 2006 meeting of the American Society of Health-System Pharmacists. See Harley, C. et al., *Comparison of Utilization Patterns, Resource Use and Treatment Costs Among Cancer Patients Treated with Epoetin alfa or*

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the world that the appropriate dose conversion ratio is 200:1 (at which Aranesp is by far the more costly drug).

[9] The use of wholesale acquisition cost ("WAC") as a proxy for private insurer is based on the assumption that the insurers reimbursed oncologists at the same percentage of the drugs' published Average Wholesale Prices or AWPs, which are set at fixed markups over the WAC. The assumption is conservative in that the AWP for Aranesp generally has been set at 25% above its WAC while the AWP for Procrit is set at 20% above its WAC. Thus, the actual Aranesp cost premium likely is greater.

Darbepoetin alfa. Poster presented at the 41st American Society of Health-System Pharmacy (ASHP) Midyear Clinical Meeting and Exhibition December 3-7, 2006; Orange County, California, annexed as Appendix F. The study "was conducted using medical claims data from a large United States health plan from January 1, 2002 through May 31, 2005" (Id. at p.1). Based on the doses actually administered in oncology clinics and reimbursed by the health plan, the study found a mean cumulative treatment dose of Procrit and Aranesp were 308,791 International Units and 1134 micrograms, respectively, for a dose ratio of 272:1. Based on the actual reimbursement allowed by the health plan, moreover, the study found Aranesp to be reimbursed at a 32% premium over Procrit (Id.). Using the published ASPs for the most recent quarter to determine the relative costs to Medicare, the Aranesp dose premium at the 272:1 dose ratio is 22%.

While demonstrating the significant dose premium associated with Aranesp administration, the data analyzed in the Lefebvre and Harley studies did not encompass doses administered in oncology clinics since March 2006, when Amgen secured approval for its new 500 microgram dosing regimen. To assess the incremental impact of the new Aranesp dosing regime, Ortho Biotech sponsored an independent consultant to manage a registry of Aranesp and Procrit doses administered by oncology clinics in 2006. The findings from the limited data available to date are alarming. That is, the data shows that the new Aranesp regimen drives Aranesp doses – and therefore its costs – to new heights.

- D.O.S.E. Registry: The research and consulting firm Abt Associates manages a registry of Aranesp and Procrit doses administered by oncology clinics in 2006 referred to as the "Dosing and Outcomes Study of Erythropoiesis-Stimulating Therapies" or "D.O.S.E." registry. The D.O.S.E. registry tracks real-world practice patterns of more than 1,500 patients from 61 oncology practices. As of December 22, 2006, the treatment of 168 patients (145 Procrit, 23 Aranesp) initiated at approved fixed doses during 2006 has been monitored longitudinally through the course of their treatment. Only those Aransesp patients whose treatment was initiated with the new dosing regimen were included in the analysis. The mean cumulative doses of Procrit and Aranesp administered to the patients were 305,241 IUs and 1,665 mcgs, respectively, which equates to a dose ratio of 183:1. At that dose ratio and the most current published ASPs, the Aranesp dose premium is 81%. This data indicates that the large starting doses called for by the new Aranesp dosing regimen are not being reduced over the course of the patient's therapy, resulting in large incremental costs for Medicare and patients.

In summary, the recent data concerning the doses and costs of Aranesp and Procrit actually administered in oncology clinics corroborates the conclusions derived from the recently unsealed evidence. That is, at the doses actually administered, Aranesp is far more costly than Procrit and that cost premium is increasing rapidly under Aranesp's new dosing regimen.

C. Recent Private Insurer Restrictions on Aranesp Reimbursement: The evidence elicited at the hearing also is corroborated by recent developments in private insurer reimbursement. As noted above, Dr. Axelrod testified at the hearing that the large health insurer Wellpoint implemented in 2006 a differential reimbursement schedule to encourage the administration of Procrit in lieu of Aranesp to address the large Aranesp cost premium. Wellpoint's implementation of a differential reimbursement schedule for drugs administered in oncology

clinics and reimbursed under the medical benefit was virtually unprecedented. For a variety of reasons, insurers historically have been reluctant to impose formulary or utilization controls for physician-administered drugs (in contrast to self-administered drugs reimbursed under the pharmacy benefit, which are routinely subject to formulary management). The dramatic cost premium of Aranesp over Procrit, however, has forced insurers such as Wellpoint to reconsider their options.

Another plan that has elected to implement a different reimbursement schedule is CareFirst Blue Cross Blue Shield, the largest health insurer in the mid-Atlantic region. Effective January 1, 2007, CareFirst will implement a fee schedule that provides reimbursement for Procrit at significant premium over the reimbursement afforded for Aranesp. CareFirst implemented the differential reimbursement after determining, based on the analysis of its own claims data, that it could provide a large reimbursement premium for Procrit and still reduce reimbursement costs if oncologists switched from Aranesp. The same economic rationale militates that CMS adopt a bundle allocation rule that will eliminate that artificial impediment to competition afforded by the current reimbursement that provides the incentive for oncology clinics to purchase the more expensive drug Aranesp in lieu of Procrit.

III. PAYMENT IMPLICATIONS

The supplemental data and disclosures set forth in the preceding sections substantiate Ortho Biotech's positions in its initial comments concerning the costs savings to Medicare resulting from the adoption of the proposed allocation rule. As noted above, Ortho Biotech identified three components of savings resulting from application of an allocation rule that requires Amgen to accurately state the ASPs on its drugs. The largest short-term savings arise from the second component, i.e., the savings from a shift in market share from Aranesp to Procrit. To illustrate the magnitude of those savings, Ortho Biotech calculated that, under the proposed rule, Medicare would have reduced RBCGF drug reimbursement for 2005 alone in the amount of $177 million, assuming a dose ratio of 266:1. The supplemental submissions demonstrate that the assumptions of Ortho Biotech's model are accurate for the prior-year analysis, and conservative for the purpose of estimating the annual costs to Medicare going forward without the proposed guidelines.

The two fundamental assumptions of Ortho Biotech's cost model are that (i) the new rule will result in a shift in share from Aranesp to Procrit, and (ii) the shift in share properly is measured by a dose ratio of 266:1. As discussed, Amgen and its consultants readily concede the first assumption, but challenge the second, asserting without analysis that the 330:1 dose conversion ratio adopted in 2004 for the OPPS program should govern. The supplemental submissions demonstrate that (i) the 330:1 ratio was set without the benefit of full disclosure by Amgen and, more conclusive, (ii) all the data concerning the doses of the parties' drugs actually administered in oncology clinics offices is consistent with a dose ratio of 266:1. That is, the studies cited above show that, prior to 2006, the dose ratios ranged (depending on the data set) from 236:1 (the Lefebvre study) to 248:1 or 276:1 (Dr. Cremieux's analysis for trial). Consequently, Ortho Biotech's adoption of a dose ratio of 266:1 to determine the potential savings for 2005 is eminently reasonable and conservative.

The supplemental submissions also demonstrate that going forward, as the oncology clinics adopt the new Aranesp dosing regimen, the excess costs of maintaining the status quo will increase dramatically. That is, if the same cost model is run at the dose ratio generated by the D.O.S.E. registry (183:1), the costs savings are $621 million. Recognizing that the available data currently is limited, the D.O.S.E. registry findings are directional and demonstrate that, absent new guidelines, Medicare's and patients' costs will increase dramatically.

IV. PROPOSED RULE GOVERNING THE ALLOCATION OF INCENTIVES IN BUNDLES CONTAINING DOMINANT DRUGS

The supplemental information presented above confirms that the absence of an explicit rule governing the allocation of incentives in bundles containing dominant drugs is imposing significant excess costs on Medicare and patients. CMS should implement such a rule to (i) curtail those excess costs, (ii) achieve CMS's stated goal of ensuring drugs' ASPs reflect the incentives afforded to drive their sales, and (iii) allow for an equitable payment system that does not foster anti-competitive conduct. The requisite rule is relatively straightforward, involving a process for identifying "dominant drugs" and a simple allocation methodology. In truth, merely stating the rule likely will inspire the appropriate practices.

A. Defining Dominant Drugs: In its proposed rule, CMS correctly noted that there is a class of "drugs that may not have clinical alternatives" that, when bundled, may drive the sales of the other bundled drugs. The Secretary may readily identify such drugs without having to go so far as to render economic or clinical findings regarding the dominant or functional status of the drugs. For payment purposes, the Secretary may weigh a number of factors to determine whether a drug may reasonably be viewed as dominant in its therapeutic class. As we noted in our original comments, these factors include, but are not limited to:

- the approved indications and risk profile relative to other approved drugs and therapies;
- whether the drug is a single source product;
- whether the drug is patent protected;
- the drug's market share;
- the incentives provided on the drug after, relative to before, it was introduced into a bundle; (a dominant drug historically has a minimal discount; if/when a dominant drug is bundled with a drug that has competition and a significant discount is placed on the dominant drug, there is a strong inference that such incentive is used to drive sales of another product in the bundle);
- the effect of the introduction of the drug into the bundle on the sales volume of the other bundled products; (a significant increase in the sales of the competitive drugs following the introduction of the dominant drug into the bundle is indicative of the power of, and lack of alternatives for, the dominant drug); and
- the relative Medicare expenditures on the drug (e.g., large Medicare expenditures for the dominant drug relative to any purported alternatives is evidence the dominant drug is the only viable alternative).

We maintain that it will be fairly self-evident in virtually every instance that a dominant drug exists and the manufacturer would be expected to report the incentive discounts based on its good faith interpretation of whether these guidelines apply. Consequently, the protocol for assessing dominant drugs should impose minimal incremental administrative demands on CMS.

B. Allocation Rule for Dominant Drugs: The appropriate allocation rule for bundles that contain dominant drugs is simple to state and implement. Under the rule, the incentives granted on dominant drugs that are conditioned in whole or in part on purchases of a competitive drug should be allocated to the competitive drug (or drugs, based on the relative sales of the competitive drugs). This allocation ensures the drugs' published ASPs appropriately account for the price incentives offered in bundled arrangements involving dominant drugs.

Ortho Biotech respectfully submits that guidance should be issued immediately through program instruction or other means (consistent with the authority under section 1847A(c)(5)(C) of the Act) regarding the methodology manufacturers must use for allocating price concessions across Part B drugs sold under bundling arrangements. Amgen's WBCGF drugs should be identified as dominant drugs in a bundle.

Thank you for your consideration of our supplemental comments and recommendations. If you have any questions concerning this submission, please contact me at 202-589-1008 or by e-mail at cdooley@obius.jnj.com.

Respectfully submitted,

Cathleen M. Dooley
Executive Director, Federal Affairs
Johnson & Johnson

APPENDIX A

Response to Amgen's Assertions that an Allocation Rule is "Unnecessary"

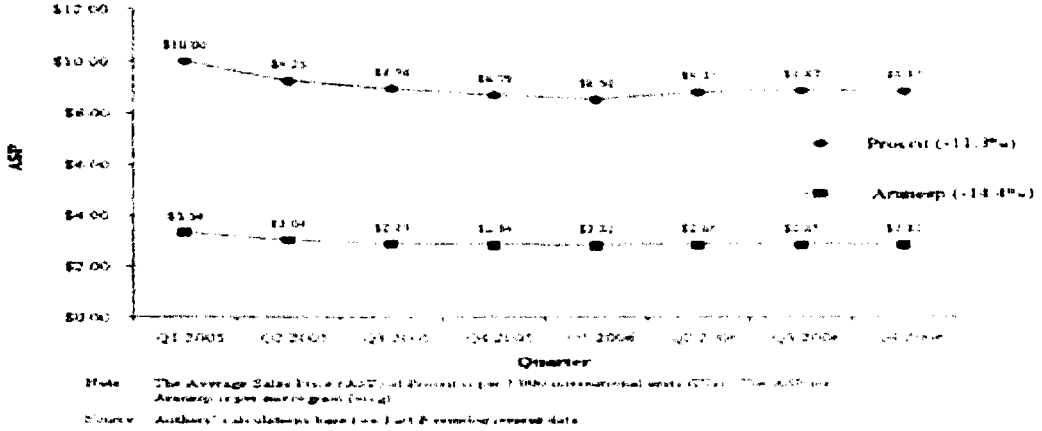
In its October 10, 2006 comments to CMS's proposed rule, Amgen made a series of assertions as to why an allocation rule for bundles containing dominant drugs is unnecessary. Following are Amgen's assertions and succinct responses thereto.

Assertion 1: Amgen asserts that incentives already "are properly disclosed in the quarterly ASP submissions (pp.5-6).

Response: The fact that the published ASPs for Amgen's WBCGF drugs incorporate the large incentives Amgen pays on those drugs to drive Aranesp purchases is undisputed and irrelevant to whether an allocation rule should be established. That is, Amgen's pricing program need not be secret to be coercive.

Assertion 2: Amgen claims that Ortho Biotech's challenge to its bundled arrangement is an attempt to avoid price competition. (p.6.)

Response: To the contrary, Ortho Biotech's preposed allocation rule will level the playing field – and facilitate competition – by ensuring the published ASPs reflect the incentives paid to drive their sales. Amgen and its consultants argue that the Aranesp and Procrit ASPs, which are depicted in the following chart from the Antos and King paper, evidence a downward trend in ASPs consistent with vigorous price competition under the APC. Of note, the ASPs in the chart are not the CMS published ASPs but rather the "authors' calculations based on Part B reimbursement data."



The more objectively reasonable interpretation of this chart is that the ASPs for the two drugs have been relatively flat in 2005 and 2006. Also, the more appropriate economic analysis of the impact of the Amgen bundle is to compare the trend in pricing of the competitive drugs before and after Amgen first implemented the APC in March 2004 and before and after the imposition of the explicit minimum purchase requirements effective January 1, 2005. Amgen has not come

forward with data concerning its ASPs – or more squarely net prices in the oncology clinics from 2002 to 2005. That data likely tells an entirely different story.

Assertion 3: Amgen argues CMS should not implement a bundle allocation rule because the judiciary may determine the legality of Amgen's APC (pp. 6-7).

Response: The issue before CMS is not whether Amgen's APC is illegal but whether the existing payment methodology is accurate, fair, and minimizes costs to Medicare and beneficiaries. CMS has the authority to implement rules to ensure the fair and accurate reimbursement under Medicare Part B, which is what the proposed allocation rule accomplishes.

Assertion 4: Amgen claims the incentives paid on its dominant WBCGF drugs contingent on large purchases of Aranesp are not intended to drive Aranesp sales, but instead to offer the best deal to the best customers (p.7).

Response: The Amgen APC does not offer the best deal to the best customers of its WBCGF drugs and, in any event, whether it does is irrelevant. Amgen offers the largest incentives on its WBCGF drugs to those customers that purchase large amounts of Aranesp, and penalizes those that do not. There is no economic rationale for Amgen to pay incentives on its dominant drugs – and in particular, back-end rebates conditioned on the purchase of Aranesp – other than to drive Aranesp sales.

Assertion 5: Amgen contends clinics can choose to disregard its APC and purchase Procrit (p.8).

Response: Amgen's contract presents clinics with an economically untenable choice: The clinics can participate in the contract (i.e., purchase Aranesp in lieu of Procrit) and make large margins on Amgen's WBCGF drugs, or alternatively, the oncology clinics can elect to lose money on Neulasta administered to Medicare patients. That is no choice at all.

Assertion 6: Amgen argues that clinics do not have to participate in its APC because they can purchase Neupogen or Berlex's drug Leukine instead. (p. 8.)

Response: Neupogen is encompassed by the APC and Leukine accounts for just 2% of clinic purchases (and is not indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs, which is the primary indication of Amgen's dominant WBCGF drugs). Again, oncology clinics have no viable alternative.

Assertion 7: Amgen claims it provides "some" incentives on its WBCGF drugs independent of Aranesp purchases (p.8).

Response: Amgen claims that oncology clinics that do not accede to its demands to buy Aranesp can earn "some" incentives merely highlights that the incentives the clinic can secure absent the purchase of Aranesp are *de minimis* and insufficient to breakeven on Neulasta administered to Medicare patients, who comprise the large percentage of Medicare patients treated by the

oncology clinics. Indeed, as the Court in the antitrust action recently stated in its decision, "the Medicare reimbursement rate for these drugs is an important factor in health care providers' decision to use one RBCGF drug over another" (Decision, p.3).

Assertion 8: Amgen asserts that oncologists can participate in the Competitive Acquisition Program rather than purchasing its drugs under the APC (p.9.)

Response: Amgen seeks to obfuscate the fact that its APC encourages oncologists to purchase Amgen's drugs rather than participate in CAP by affording large reimbursement to the detriment of Medicare and beneficiaries.

APPENDIX B

Unsealed Transcripts from Ortho Biotech v. Amgen Antitrust Action

APPENDIX C

Plaintiffs' Demonstratives or "PDs" from Ortho Biotech v. Amgen Antitrust Action

APPENDIX D

Plaintiffs' Exhibits or "PXs" from Ortho Biotech v. Amgen Antitrust Action

APPENDIX E

The Lefebvre Study

APPENDIX F

The Harley Study

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August 28, 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 Physician Fee Schedule, and Other Part B Payment Policies for CY 2008

Dear Mr. Kuhn:

On behalf of the members of the Cardiovascular Outpatient Center Alliance (COCA), we appreciate the opportunity to submit these 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 proposed 2008-2010 PE RVU's established for non-facility outpatient cardiac catheterization procedure codes and the significant negative impact on the practices and patients of our members that would result if these RVU changes are implemented.

COCA is a national non-profit organization representing over 60 medical cardiology practices and organizations and more than 1,000 cardiologists that own and operate non-hospital outpatient cardiac catheterization facilities. As will be described below, the impact of the CMS proposed PE RVU changes would be devastating to cardiovascular outpatient cardiac catheterization centers, with the potential to force these facilities to exit the market. As a result, Medicare beneficiaries would be denied access to high quality, convenient cardiovascular services at a reasonable cost and the overall cost to the Medicare program for these services would increase dramatically.

Background
Cardiac catheterizations are an important and sophisticated tool for diagnosing heart disease that were traditionally performed in hospitals until the 1980's. Since then an increasing number of catheterizations are now performed in non-facility (i.e. non-hospital) cardiovascular outpatient centers because they offer patients greater convenience, higher

quality, and lower costs – factors that have led payers, including CMS, to encourage their development. Non-facility cardiovascular outpatient catheterization labs can be organized as part of a cardiology group practice or an independent diagnostic testing facility (IDTF). The cardiology group practice can bill a global fee for both the professional and technical components, while the IDTF bills only the technical component. Medicare's payments for the technical component, either as part of the global payment billed by the cardiology group or the separate technical component billed by an IDTF, are intended to reimburse solely for the technological and other support services that enable physicians to perform catheterizations. Medicare calculates payments for the technical component through the same fee schedule methodology used to pay physicians. This methodology seeks to identify a "relative value" that reflects the resources needed to provide each service. Because Medicare has been unable to capture complete cost information for the technical services associated with certain non-facility services such as cardiac catheterizations, the program for several years used a special estimation method to calculate values for the practice expenses associated with these technical services, which involved the use of the non-physician work pool (NPWP) in a "top-down" methodology.

In the June 29, 2006 Proposed Notice regarding *Proposed Changes to the Practice Expense Methodology*, CMS stated its intent to replace the "top-down" methodology with a "bottom-up" approach that would result in payment levels that it believed would more accurately reflect the relative costs of certain services. The Proposed Notice described two changes to the PE RVU methodology. The first change was to replace the "top-down" methodology with a "bottom-up" methodology for developing resource-based RVU's for the practice expenses associated with discrete physician services. The second change was the elimination of the NPWP. These changes were implemented for most CPT codes in the 2007 Physician Fee Schedule; however, most outpatient cardiac catheterization procedure codes were not included in this change. COCA and other cardiology advocacy organizations submitted formal written comments, and after discussions with COCA representatives, CMS acknowledged in their December 1, 2006 Final Rule that *"We currently do not have direct cost input data for the non-facility setting for these services. Until we are able to obtain such data, we will carrier-price the cardiac catheterization codes."* (Federal Register/Vol. 71, No. 231/ page 69642). CMS went on to state in the same section that *"We urge interested parties to continue to work with the RUC to develop direct cost inputs for these services in the future."*

Based on this CMS request, COCA members proactively engaged Medicare carriers throughout the country to present direct and indirect cost data. We understand that carriers also received informal guidance from CMS regarding this issue. The result was that Medicare reimbursement to non-facility outpatient cardiac catheterization centers in 2007 was equal with 2006 reimbursement (with some minor adjustments resulting from the Five Year RVU review).

AMA RUC/PERC Participation

In addition to their comments in the December 1, 2006 Final Rule, CMS representatives verbally requested that COCA participate with the American College of Cardiology (ACC) in providing direct cost data for non-facility outpatient cardiac catheterization centers to the RUC to establish appropriate PE RVU's. COCA readily agreed and conducted a detailed

study of these direct costs. The preliminary results were presented to CMS in COCA's formal comments to the August 22, 2006 Proposed Rule for the 2007 Physician Fee Schedule. The final report was presented to you on May 3, 2007 at a meeting organized by representatives from the Florida Congressional delegation.

COCA Direct Cost Study

The COCA direct cost study was managed by staff from Epstein Becker and Green, P.C. and the cost information was based on the median value reported for the clinical time in the pre-, intra-, and post- procedure phases of the procedure. The Bureau of Labor Statistics hourly compensation was used to calculate the clinical labor cost associated with each phase of activity. Similarly, the clinical supplies and equipment costs reflect the median values. With regard to equipment, the cost estimate is based on the same assumptions regarding useful life, utilization rate and financing that CMS used in the June 29 2006 Notice.

The study reveals that the major problem associated with the 2006 RUC estimate of direct costs for non-facility outpatient cardiac catheterization was that the list of direct patient care activities was inadequate and that the total estimates of clinical time were so low as to lack credibility. COCA learned that some under-reporting of time was due to an assumption that clinical staff performs services related to patients who are undergoing other procedures. This allocation of time to other procedures is inappropriate because non-facility cardiovascular outpatient catheterization centers focus on diagnostic catheterizations and all of the clinical labor activities and time should be allocated to these procedures alone.

Participation in 2007 RUC Process

In direct response to CMS' requests, COCA members and physicians committed extensive time and resources from September 2006 through April 2007 in a good-faith effort to provide accurate direct and indirect cost data to the Practice Expense Review Committee (PERC) of the AMA's RUC. Unfortunately, this process did not allow a significant portion of COCA's data to be considered and resulted in PE RVU recommendations to CMS that severely undervalued the direct and indirect costs of providing these procedures to its members' patients. There are many reasons for this failure, but they primarily involve two areas:

1) arbitrary definitions established by the RUC/PERC that unfairly penalize highly specialized procedures performed by physicians that require equipment and supplies for patient safety, and

2) the underlying politicizing of the RUC process that pits medical specialties against each other and forces them to consider the political implications of each request as opposed to simply presenting the complete data set for discussion.

Two examples of our experience will help explain why the final RUC recommendations to CMS severely underestimated the costs associated with non-facility outpatient cardiac catheterization procedures:

1) Arbitrary definitions
The RUC has established a definition that automatically disallows direct costs that are essential to patient safety in a cardiac catheterization lab. Specifically, the RUC will only count staffing, equipment, and supplies that are used in a "typical" case and they arbitrarily define "typical" as a case where these items are used at least 51% of the time. This definition disallows patient safety devices and equipment that are infrequently used, but are essential to quality patient care (e.g., "crash carts" with defibrillators and essential pharmaceuticals, and expensive wound closure devices).

2) Politicized process
COCA was fortunate to work collaboratively with the American College of Cardiology, allowing COCA physician members to present non-facility cardiac catheterization cost data to the PERC as part of the ACC/COCA team. However, the presentation data only included a portion of COCA's actual direct cost data instead of the full report. This is because the nature of the current RUC process forces the medical specialty societies to balance their various constituents' requests instead of simply presenting data to be evaluated on their own merits. There is a strong perception that if the gap is too wide between the preexisting RUC data base and the new data being presented for clinical time, equipment or supplies, the new data is often considered suspect and rejected. In this specific case, the preexisting RUC data base for cardiac catheterization clinical staff time primarily reflected hospital data with little relationship to actual direct cost data for dedicated outpatient cardiac catheterization facilities, resulting in tremendous disparity.

Proposed Rule PE RVU Impact
It appears from the July 2, 2007 Proposed Rule that CMS has accepted the 2007 PERC/RUC direct cost recommendations for outpatient cardiac catheterization codes without considering the more accurate direct cost information that COCA provided to CMS in May 2007. As a direct result, the July 2, 2007 Proposed Rule would result in draconian cuts in reimbursement for cardiac catheterizations performed in medical cardiology practices and IDTF locations. If the 2007 conversion factor is applied to the technical components of the primary three CPT codes for a Left Heart Catheterization (93510TC, 93555TC, and 93556TC) the reimbursement in 2008 would be reduced from the 2007 rate by 32.18%, and when fully implemented in 2010 the total reimbursement reduction would be 49.0%. These severe cuts would undoubtedly result in the closing of the majority of non-facility outpatient cardiac catheterization labs in the country forcing Medicare patients who now benefit from improved access and lower costs into more acute and expensive hospital settings.

The inappropriateness of the current rate setting process becomes self-evident when the proposed negative changes for outpatient diagnostic cardiac catheterization codes listed in the 2008 Physician Fee Schedule are compared with the proposed 2008 APC rate increase of 11.18% for APC 0080 "Diagnostic Cardiac Catheterization" published in the August 2, 2007 Federal Register (CMS-1392-P). It is clear that the RUC recommendations concerning the cost of performing these procedures are dramatically at odds with those that CMS determined for the same procedures performed in facility-based

outpatient cardiac catheterization centers. This comparison is set out in the following chart:

Comparison of Payment Rates by Site of Service for Family of Diagnostic Catheterization Codes (PFS 93510 TC, 93555 TC, 93556 TC and APC 0080)

	Actual 2007	Proposed 2008	Proposed 2010	% Change	2008 PFS as % of 2008 APC	2010 PFS as % of 2008 APC
APC Rate	$2,283.55	$2,539.00		11.19%		
PFS Rate	$2,138.56	$1,450.34		-32.18%	57.12%	
PFS Rate	$2,138.56		$1,090.69	-49.00%		42.96%

COCA's Request

COCA requests that CMS review the additional cost data provided by COCA and revise the current proposed PE RVU's for outpatient cardiac catheterization procedures to values that more reasonably reflect the direct and indirect costs of providing these services. An additional solution would be to recognize the difficulty in determining direct and indirect costs for non-facility outpatient cardiac catheterization centers utilizing RUC criteria and tie reimbursement for these procedures to a reasonable percentage of the hospital APC rate for the same family of procedure codes.

As COCA stated both in our 2006 written comments and during our August 12, 2006 meeting with you and your senior staff, the costs of performing these services in facility and non-facility locations are remarkably similar based on actual experience from COCA members who administer both facility and non-facility cardiac catheterization centers. We view APC payment levels as a reasonable benchmark when accurately evaluating the Medicare Physician Fee Schedule payment methodology for outpatient cardiac catheterization procedures where the technical component can be billed separately.

Conclusion

We believe that you have no interest in supporting a flawed process that would drive non-facility cardiac catheterization centers out of business. We base this belief not only on our face-face discussions, but also on the statement CMS made in the July 2 Proposed Rule when expressing concern with service furnished under arrangement with a hospital because it *"not only costs the Medicare program more, but also costs Medicare beneficiaries more in the form of higher deductibles and coinsurance"* (CMS-1385-P, pages 349-50). This concern about increased Medicare program and beneficiary costs must also apply to other services...which is exactly the point we have expressed about

non-facility outpatient cardiac catheterization centers from our first formal written comments about the proposed reimbursement cuts in 2006.

We thank you for the opportunity to describe our concerns about the proposed rule, specifically as it relates to payment for cardiac catheterization-related procedures and the development of standards for centers that perform these procedures on an outpatient basis.

We look forward to meeting with you and your staff after the comment period is over and before CMS finalizes the 2008 Physician fee Schedule. If you have any questions, please do not hesitate to contact me at (615) 776-1810.

Sincerely yours,

Steve Blades
President

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August 29, 2007

Herb Kuhn, Acting Deputy Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
ATTENTION: CMS-1385-P
Post Office Box 8018
Baltimore, Maryland 21244-8018

Dear Mr. Kuhn:

Please accept this letter as the comments of the Medical Association of the State of Alabama (hereinafter MASA) to the proposed changes to the physician fee schedule rules that were published on July 12, 2007 that concern the Stark self-referral and the reassignment and purchased diagnostic test rules.

MASA is composed of approximately 7500 physicians licensed to practice medicine in the state of Alabama. Our membership includes physicians from all types of medical specialties, many of whom will be directly and adversely impacted by the proposed changes. More importantly, several of the proposed changes to the physician self-referral rules will needlessly and unjustifiably harm Medicare patients and providers. While, we understand and support the efforts by CMS to prevent abusive practices, we firmly believe that the current proposals will extend beyond this goal and restrict and possibly prohibit valuable and legitimate joint venture arrangements.

The beneficial effects that joint ventures have brought to the health care system in the United States cannot be denied. Cutting edge therapies, services and medical procedures would not have been available on a wide scale basis to patients, including Medicare beneficiaries, unless physician joint ventures had provided these necessary services. By accepting the risks of providing these costly services when hospitals have frequently refused to do so, physician joint ventures have greatly expanded patient access to worthwhile and effective treatments. However, the proposals in the 2008 Physician Professional Fee Schedule attack the substance of the very joint ventures that by all accounts have saved Medicare millions of dollars and increased beneficiary access to effective treatments.

There are several "anti physician ownership" proposals that, if adopted, will have a negative effect on the health care system and the quality of medical care provided to all patients, including Medicare patients. First, CMS proposes that a provider bear the burden of proving that referrals are not made in violation of Stark in any appeal of a denial of payment on this basis. Such logic is inherently wrong in that it requires providers to basically prove a negative, i.e., that a prohibited arrangement leading to a referral did not exist. This flawed reasoning, coupled with the fact that most Stark exceptions require payments to be made at fair market value and in a manner that does not affect the volume or value of referrals or other business between the parties, creates an extremely unfair situation for the physician provider. In addition, the proposal will result in CMS or its contractors becoming both judge and jury over such complex matters in which even their own experts may offer varying opinions, all with the burden of proof being wrongly placed on the provider.

CMS also proposes to prohibit time based or unit of service based arrangements of payments for space and equipment leases. However, Congress, as recognized by CMS in its Phase I rulemaking, specifically intended for such arrangements to be valid and permissible. Consequently, CMS should not prohibit arrangements that Congress has previously allowed and intended to permit.

CMS proposes to adopt a blanket prohibition on percentage-based fee arrangements. Clearly, such arrangements have allowed for new treatments and technologies to be offered to more beneficiaries. Moreover, these arrangements are not abusive per se. Percentage based arrangements allow the apportionment of the risk of low or no volume for new or costly therapeutic modalities. Typically, any person or entity bringing a service to a hospital should be compensated for those services on an proportional basis. Such an arrangement may more accurately reflect the value of the efforts provided by the person or entity than would a flat fee arrangement. Consequently, the adoption by CMS of a blanket prohibition of percentage based fee arrangements would result in unintended consequences.

The proposed changes to the Stark regulations regarding services furnished under arrangements appears to prohibit physician joint ventures from contracting with hospitals to provide diagnostic Designated Health Services (DHS). These proposals are overly broad and if adopted would result in the prohibition of legitimate, non-abusive arrangements for therapeutic services that are not otherwise DHS except for the fact that they are performed in a hospital setting. The therapeutic services that would obviously be affected include those utilized by various specialties such as urology. CMS commentary indicates the mistaken view that physicians who invest in these joint ventures do so at the expense of good patient care. We would submit that just the opposite is true and that the primary focus of physician investment is to improve patient care.

It should also be pointed out that with new technologies and innovations constantly being introduced into the health care system, the maintenance of these state of the art techniques and the purchase of equipments is expensive. Hospitals are often reluctant to undertake the expense and the risks involved. Physicians, on the other hand, are willing to and frequently choose to undertake those risks. The result is that physicians, wanting a better treatment for their patients, have taken it upon themselves to form joint ventures and have assumed the risks inherent in the purchasing and implementation of innovative and effective new technologies. The health care system, including CMS, benefits from such arrangements because technology otherwise unavailable is brought to both urban and rural settings by physicians and the cost is spread among several providers.

There appears to be a concern on the part of CMS that the prohibition of services under arrangements where there is physician ownership is necessary because of the threat of questionable diagnostic imaging arrangements. However, CMS fails to identify any overuse or improper referrals for many therapeutic services. Simple fairness would indicate that such arrangements should not be prohibited for services that would not be DHS but for being furnished in the hospital.

MASA is deeply concerned and strongly challenges the characterizations articulated in the "in office ancillary exception" portion of the proposed rule. CMS refers to "hundreds of letters from physical therapists and occupational therapists that the in-office ancillary services exception encourages physicians to create and physical and occupational therapy practice." However, CMS fails to elaborate on any impropriety of this alleged activity. The advantages of physician owned physical and occupational therapy practices to physicians, therapists, and most importantly, to patients, have been well documented and acknowledged. These practices provide better, more cost effective care than do independent physical therapy practices because of the continuous physician oversight and supervision. These practices give patients more places to choose from in which to obtain physical therapy services and in some cases, it is more convenient to obtain such services at their physician's offices. We respectfully request that CMS elaborate on its concerns in this area and remind CMS that the fact that letters received by physical therapists alone is not indicative of the gravity of the issue or the need for correction. We also feel that CMS should engage in discussions with physicians on this issue given the obvious importance of physician expertise, patient needs, clinical quality and the appropriate use of Medicare resources in the area of physical therapy. At a minimum, physicians should be given an opportunity to address whatever specific concerns CMS may have on such an important matter.

In summary, MASA feels that the sweeping changes proposed by CMS to the Stark regulations and the reassignment and purchased diagnostic test rules go far beyond what is necessary and appropriate to address the issue of fraud and abuse in the Medicare program.

Sincerely,

James G. Chambers, III, M.D.
President

JGCIII:skf

THE ALLIANCE FOR PATIENT ACCESS

August 27, 2007

Kerry Weems
Centers for Medicare & 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 Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; CMS-1385-P

Dear Mr. Weems:

As chairman of the Alliance for Patient Access (AfPA), a national network of physicians whose mission is to ensure and protect patient access to approved medical treatments in the U.S., and as a neurologist who has been practicing in an academic setting for 13 years, I am pleased to submit comments on the Proposed Physician Fee Schedule Update for 2008, particularly on the agency's proposal concerning drug compendia and request for comments concerning CAP issues.

DRUG COMPENDIA

AfPA thanks CMS for recognizing and proposing solutions to resolve the problems that could arise if Medicare contractors are left with only one compendium on which to make off-label use coverage determinations. Although AfPA recognizes that Medicare law refers to the compendia specifically for coverage of Part B cancer chemotherapy drugs, we likewise recognize that Medicare contractors generally refer to these same compendia when making off-label determinations for most Part B drugs.

While we generally applaud CMS for developing a process to permit listing of additional compendia, we are nonetheless concerned that the process CMS is proposing may be overly restrictive to allow timely adoption of new compendia. The process outlined by CMS likely would take applicants more than a year to clear, and may actually be too high a hurdle for some useful compendia. Patients need access to drugs that treat their conditions. If there are too few compendia covering the drugs most commonly used by patients, and those that are available are not updated quickly enough as new therapies are approved or as new uses of existing therapies are reported in the clinical literature, access could be impacted. We urge CMS to develop a process for adoption of new compendia that is flexible and that focuses on adoption of new compendia that are accurate and timely in their updates.

Additionally, we urge CMS to immediately recognize *DrugPoints*® as the successor publication to the USP-DI, so that Medicare contractors have at least two compendia available to support coverage decisions while CMS reviews requests to adopt additional compendia.

CAP ISSUES

As physicians who frequently administer complex biologicals, we are concerned that CMS may be considering loosening CAP regulations in a manner that might permit CAP vendors to repackage complex biologicals that require special handling. Many complex biologicals require special handling, such as constant refrigeration at specified temperatures, utilization within a specified period after reconstituting and special refrigeration after reconstituting. Unless CAP vendors are specifically trained in these handling techniques, and abide by them, the safety and efficacy of the product furnished could compromised. Even if CAP vendors are specially trained, we as physicians could not vouch for the safety and efficacy of a product that has been opened and manipulated after leaving the manufacturer.

AfPA encourages CMS to consider carefully any changes that would allow CAP vendors to offer compounded *drugs*. AfPA strongly discourages CMS from allowing CAP vendors to compound or open in any manner complex biologicals. AfPA specifically recommends that CMS continue to require that CAP vendors ship complex biologicals only in "unopened vials or other original containers as supplied by the manufacture."

Thank you for your consideration of our comments.

Sincerely yours,

David Charles, MD
Chairman

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Lake Region Urology

William H. Foresman M.D., P.C.
Board Certified, Adult & Pediatric Urology

192 Genesee Street • Auburn, NewYork 13021
Phone (315) 258-5253 • Fax (315) 258-0202

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

Regarding: Physician Ownership/Joint Venture proposal

To Whom it May Concern,

I am writing in response to the recent CMS proposals involving physician ownership in medical procedure entities. I am a Urologist, and provide ESWL services in my office under arrangement with United Shockwave Therapies, in addition to prostatic photovaporization procedures at Auburn Memorial Hospital under United Prostate Centers. I hope to provide this procedure at my office when able/appropriate.

I am worried about the prospect of losing my ability to provide these services due to the recent Medicare proposals to limit physician Joint Ventures and the associated reimbursement provided under these arrangements. Just as with ESWL, which has been deemed an exemption to the Stark II regulations, the laser procedure and other procedures provided under arrangement with various vendors are extremely important services that Urologists provide. I believe it is the very nature of the Joint Venture agreements that allows us to most effectively provide these services, thereby providing the best possible care for our patients.

In the current climate of declining reimbursements in the face of rising overhead/staff costs related to electronic medical records and other complexities of office management, as well as rising malpractice coverage costs, I feel that any measure to disallow physician Joint Venture agreements as they currently stand woud be detrimental to my practice and that of physicians in general.

Thanks for your time, and please strongly consider supporting physician ownership/Joint Venture agreements as they stand, or at least considering certain exemptions to allow us to continue to provide top-quality care under proper reimbursement arrangements.

Sincerely,

W H Foresman MD

cc: Senator Michael Nozzolio

Wilson Urology, P.A.

James B. Rounder, M.D., F.A.C.S.
Jobe C. Metts, III, M.D.
Urology & Urological Surgery

August 24, 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

Dear Ladies and Gentlemen:

My name is James B. Rounder, Jr., M.D. and I am a urologist who has been in practice in Wilson, North Carolina since 1990. I am a limited partner in Carolina Lithotripsy, a joint venture LLC, that has provided lithotripsy service to our small community over the past 17 years. Before moving to Wilson in 1990, there was no lithotripsy service to this area. Being able to provide lithotripsy service in Wilson County has greatly improved patient access and the quality of care.

Carolina Lithotripsy has a contract with both the free-standing surgery center and our local community hospital, Wilson Medical Center. We have been able to provide affordable service to the community by reducing hospital costs and have acquired the latest advancements in equipment. Our mobile unit services the greater part of rural eastern North Carolina and travels with a dedicated registered nurse and registered radiation technologist thus providing extremely good continuity of care.

Although we see a large volume of stone patients in eastern North Carolina, we do not have the patient volume to have a free-standing lithotripsy unit with dedicated technicians. The contract status between Carolina Lithotripsy and Wilson Medical Center and our local surgery center has worked out well over the past 17 years, but lithotripsy is a therapeutic procedure and not diagnostic and not at high risk for overutilization. If you compare the number of stone cases that we treat in relation to lithotripsy vs. endoscopic procedures, you will see that overutilization is not a problem.

I understand the nature of the Stark legislation set forth by Congress was intended to deal with a compensation exception and not ownership exception. It is my understanding that Congress purely wished to preserve the per procedure fee in the Stark legislation and I would hope CMS would keep this in mind with the new proposed regulations.

This prohibition could potentially restrict Carolina Lithotripsy's ability to contract with our ambulatory surgery center. We have a system that has worked well in eastern North Carolina over the last 15-20 years providing good patient access and excellent quality of care.

Thank you for taking time to review my letter and your consideration is greatly appreciated.

Sincerely,

James B. Rounder, M.D., F.A.C.S.

JBR/ab

AMERICAN COLLEGE OF CHEST PHYSICIANS

The leading resource for the improvement in cardiopulmonary health and critical care worldwide

August 31, 2007

Herb B. Kuhn
Acting Director
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
7500 Security Blvd., Mail Code C5-01-14
Baltimore, MD 21244-1850

Re: **CMS-1385-P** Medicare Program; Proposed Revisions to Payment Policies under the Physician Fee Schedule for Calendar-Year 2008

Dear Mr. Kuhn:

I am submitting these comments on behalf of the American College of Chest Physicians (ACCP). The ACCP's membership is comprised of over 16,700 physicians and allied health professionals whose everyday practice involves diseases of the chest in the specialties of pulmonology, cardiology, thoracic and cardiovascular surgery, critical care medicine, sleep and anesthesiology. These health care professionals practice in virtually every hospital in this country, and many of the physicians head major departments in these hospitals. As a multidisciplinary society, the ACCP offers broad viewpoints on matters of public health and clinical policy in cardiopulmonary medicine and surgery.

We appreciate the opportunity to submit comments to CMS on the proposed rule for the Medicare Physician Fee Schedule.

SUSTAINABLE GROWTH RATE (SGR) AND PROPOSED -9.9% Cut

ACCP continues to believe that the SGR formula is seriously flawed and must be replaced. We are very concerned about the 9.9% across the board cut to the conversion factor announced in this proposed rule due to this flawed formula. The yearly negative updates to the Medicare Physician Fee Schedule, fixed at the last moment, continue to be a serious problem.

CMS underestimates the impact of National and Local Coverage Decisions on increased spending on physician services under Medicare. Additional money needs to be added to the MPFS for all the ancillary costs associated with new preventive benefits. CMS must use its discretionary authority to remove the costs of Medicare-covered physician-administered drugs from the SGR calculation. These costs have increased from $1.8 billion in 1996 to $8.1 billion in 2005 and an estimated $8.5 billion in 2006. The medical community continues to comment on this issue and remains frustrated that at the very least, this SGR adjustment to the Medicare physician fee schedule has not yet been made.

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www.chestnet.org

AMERICAN COLLEGE OF CHEST PHYSICIANS

BUDGET NEUTRALITY/FIVE-YEAR REVIEW WORK ADJUSTOR

ACCP agrees with the AMA and other medical specialty societies that the negative 11.8% work adjustor be eliminated. Such budget neutrality adjustments should be made in the conversion factor.

EQUIPMENT USAGE PERCENTAGE ASSUMPTIONS

ACCP recommends that the 50% utilization rate for all equipment be increased based on the ABT studies showing that the utilization rate for equipment to be 70%.

EQUIPMENT INTEREST RATE ASSUMPTIONS – COST OF CAPITAL ASSUMPTIONS

CMS uses an interest rate of 11% in pricing medical equipment. We support the AMA RUC letter that the utilization rate is reviewed frequently and that CMS spell out exactly the assumptions made in assigning a utilization rate.

PRICING OF HIGH COST DISPOSABLE MEDICAL SUPPLIES

ACCP also supports the AMA RUC comment letter recommending that the 50 medical supplies priced at or above $200.00 be reported separately with a J-code, or individually identified within the payment bundle and re-priced annually.

PHYSICIAN PRACTICE INFORMATION SURVEY DATA

ACCP agrees with the AMA RUC position that CMS be consistent in utilizing recent and reliable practice expense data for all specialties and health care professionals. We are most concerned that the American College of Radiology (ACR) presented information to CMS after a published deadline recommending that CMS alter its practice expense methodology for radiology by weighting the survey data to account for practice size. Based on this recommendation, CMS proposed to revise the practice expense per hour (PE/HR) associated with radiology using the survey data weighted by practice size. Although we applaud CMS for being amenable to altering its methodology to more accurately reflect practice expenses, the ACCP believes that this action is unfair, as this weighting methodology has not been applied for all specialties. The ACCP also requested to survey after the deadline and was denied.

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AMERICAN COLLEGE OF CHEST PHYSICIANS

TRHCA-SECTION 101(b): PQRI

ACCP encouraged its members to participate in the 2007 PQRI. However, we are concerned that the 1.5% incentive does not cover the costs for medical practice participation.

Pulmonary medicine has eight measures on the 2007 list of performance measures: two each for COPD and Asthma, and four for Pneumonia. ACCP is pleased to see Inquiry regarding Tobacco Use, and Advising Smokers to Quit on the Table 20-Additional AQA Starter-Set Measures on the list for 2008, especially with the transitioned G0375, G0376 codes into CPT for smoking cessation counseling beginning January 1, 2008. We continue to encourage our membership to be aware of these smoking cessation-counseling codes and to consistently use them to encourage patients to stop smoking.

ACCP appreciates the opportunity to comment on the proposed rule under the Medicare Physician Fee Schedule. Should you or your staff have any questions, please do not hesitate to contact me, or Lynne Marcus at lmarcus@chestnet.org. Her telephone number is 847-498-8331.

Sincerely,

Mark J Rosen

Mark J. Rosen, MD, FCCP
President, American College of Chest Physicians

Cc: Kenneth Simon, MD, CMS
Edith Hambrick, MD, CMS
ACCP Practice Management Committee
Diane Krier-Morrow, ACCP Consultant

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418

August 29, 2007

By Overnight Mail

Herb Kuhn, Acting Deputy 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: 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:

Abbott welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services' ("CMS") proposed rule on Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2008 and Other Part B Payment Policies (the "Proposed Rule").

Abbott is a global, broad-based health care company devoted to discovering new medicines, new technologies and new ways to manage health. Our products span the continuum of care, from nutritional products and laboratory diagnostics through medical devices and pharmaceutical therapies. The company employs 65,000 people and markets its products in more than 130 countries.

Our comments focus on the following sections of the Proposed Rule: (1) CMS's proposed changes in average sales price ("ASP") policy, (2) proposed provisions related to the establishment of payment amounts for new clinical laboratory tests, and (3) new Physician Quality Reporting Initiative ("PQRI") measures.

I. SUMMARY OF ABBOTT RECOMMENDATIONS

A. Average Sales Price ("ASP") Issues

We agree with CMS that the agency should proceed with care when considering adjusting Medicare reimbursement amounts for drugs and biologicals based on Office of Inspector Generals reports comparing ASP and average manufacturer price ("AMP"), since there are a number of differences between the AMP and ASP methodologies that could impact the price comparisons reported by OIG. Moreover, since many market factors and methodological issues could temporarily impact the relationship between AMP and ASP, CMS should not substitute a lower payment amount for a drug based on the OIG's findings related to pricing in a single quarter. Instead, CMS should examine pricing trends that point to a sustained, meaningful differential between AMP and ASP before considering changing the payment basis for a drug.

B. Clinical Laboratory Issues

With regard to gapfill payments, we support a number of reforms for establishing clinical laboratory payments through the gapfill process. First, CMS should include only those local contractors with sufficient experience with the new test in the determination of the national limitation amount. Second, CMS should establish more explicit instructions to carriers on the methodology for determining gapfilled payment amounts that reflect a variety of cost, time, technological innovation, and value considerations. Third, carrier-specific amounts and the rationale for these amounts should be made public. Finally, CMS should consider creating an advisory committee to provide advice to CMS regarding payments for new test codes.

CMS also proposes establishing a reconsideration process for clinical laboratory payment determinations. While we support a reconsideration process to address payments that are not appropriate, particularly when payments do not reflect the technological innovations of a new test, CMS should establish additional safeguards before adopting its proposed policy. In particular, CMS should propose consistent, substantive, and transparent criteria for assessing both the basis of payment and the actual payment amount, based on the factors that apply to contractor determinations. In addition, CMS should make public its detailed rationale for any payment changes. Likewise, in assessing the appropriateness of carrier payment amounts, CMS should consider whether carriers have followed CMS instructions for determining payment amounts. In addition, rather than providing that reconsideration decisions are final, as CMS has proposed, CMS should establish an expedited comment period on any payment changes CMS proposes adopting through the reconsideration process.

C. Physician Quality Reporting Initiative (TRHCA—Section 101(b): PQRI)

Abbott commends CMS for promoting the use of quantifiable quality measurements in the Medicare program. We have several PQRI recommendations that are designed to conform to established clinical guidelines and consensus measures in order to improve the quality of care for Medicare beneficiaries with coronary artery disease ("CAD") and diabetes. In particular, we recommend:

1. Adding a new CAD clinical measure titled "Lipid Profile in Patients with CAD" (CPT category II Code 3011F), as developed and supported by the American Medical Association ("AMA"), the American College of Cardiology ("ACC"), the American Heart Association ("AHA"), and the Physician Consortium for Performance Improvement ("PCPI");

2. Renaming PQRI Measure #2 (Low Density Lipoprotein Control in Type 1 or Type 2 Diabetes Mellitus) to state "Complete Lipid Testing and LDL Control in Type 1 and 2 Diabetes Mellitus"; and

3. Adopting additional measures to capture complete lipid control in future updates to the PQRI measures.

II. DETAILED COMMENTS

A. Average Sales Price ("ASP") Issues

Section 1847A(d) of the Social Security Act requires the Secretary and the Office of the Inspector General ("OIG") to monitor market prices for drugs and biologicals to determine the widely available market price ("WAMP"), which is defined as the price that a prudent physician or supplier would pay for the drug or biological. If the OIG determines that the ASP for a drug or biological exceeds the WAMP or the applicable percentage of the average manufacturer price ("AMP"), the Secretary may disregard the ASP and base reimbursement on WAMP or AMP. Under the statute, the applicable threshold percentage was 5 percent in 2005 and the percentage designated by the Secretary in subsequent years.

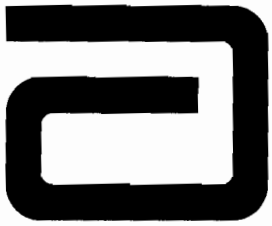
In the Proposed Rule, CMS proposes to continue the 5 percent threshold in 2008. CMS states, however, that it will "proceed cautiously in this area," since "[t]here are complicated operational issues associated with potential payment substitutions" based on the OIG's findings that the ASP exceeds the WAMP or AMP by more than the established threshold. CMS also states its intention to provide impacted stakeholders with adequate notice and input opportunities regarding changes to this policy.

We agree that CMS should proceed with care when considering adjusting Medicare reimbursement amounts for drugs and biologicals based on the OIG's reports comparing ASP and AMP. There are a number of differences between the AMP and ASP methodologies that could impact the price comparisons reported by OIG, including:

- ASP and AMP use different methodologies to account for price concessions.
- ASP is based on all non-government direct sales, while AMP is based on the price realized for drugs distributed to the retail pharmacy class of trade.
- ASP is calculated at an NDC-11 level, while AMP is reported at an NDC-9 level.
- ASPs may not be restated, while AMPs can be restated retroactively.

CMS should take these differences between the ASP and AMP methodologies into account before imposing any price adjustments in response to the OIG's findings.

Moreover, given that many market factors and methodological issues could temporarily impact the relationship between AMP and ASP, it is imperative that CMS not substitute a lower payment amount for a drug based on the OIG's findings related to pricing in a single quarter. There are too many factors that could influence pricing comparisons at one particular moment in time; such quarterly fluctuations should not form the basis for setting aside the regular statutory payment methodology for the product. Indeed, a premature payment adjustment based on a single quarter's data could result in skewed payment amounts and undermine reimbursement accuracy. Instead, CMS should examine pricing trends that point to a sustained, meaningful differential between AMP and ASP before considering changing the payment basis for a drug.



B. Clinical Laboratory Issues

In the Proposed Rule, CMS solicits comments on reforms to the gapfilling process through which carriers establish prices for clinical laboratory tests. CMS also proposes establishing a reconsideration process for determining the basis for and amount of Medicare payment for a clinical laboratory test for which a new or substantially revised HCPCS code is assigned on or after January 1, 2008.

1. Gapfill Reforms

We appreciate CMS's interest in reforms to the gapfill process. We share the concerns of many in the clinical laboratory community that the current carrier gapfill process lacks clear standards, is not transparent, and allows carriers with limited claims experience with a new test to impact CMS's national payment determination. We offer the following recommendations for reform.

First, we believe the gapfill process could be improved by including only those local contractors with sufficient experience with the new test in the determination of the national limitation amount ("NLA"), recognizing that all new tests are not performed in every region. We therefore would support CMS specifying that it has the discretion to include only those contractors with claims activity for the new test meeting or exceeding an established threshold.

Second, CMS should establish more explicit instructions to carriers on the methodology for determining gapfilled payment amounts. Such instructions should reflect:

- Charges for the test and routine discounts to charges;
- Costs of acquiring the equipment and supplies and resources required to perform the test, including any necessary quality controls;
- Staff expertise and skill required to perform the test;
- The time associated with performing the test;
- The potential value of the test in the diagnosis, treatment, and management of Medicare patients;
- Technological innovations in the test (such as enhanced sensitivity or specificity) that improve the quality of diagnostic information and the quality of care;
- Payment amounts determined by other payers;
- Charges, payment amounts, and resources required for other tests that may be comparable or otherwise relevant; and

- Other sources of information as appropriate, including clinical studies and information provided by clinicians practicing in the area, manufacturers, or other interested parties.

Third, we believe that carrier-specific amounts and the rationale (including data) for these amounts should be made public to facilitate assessment of whether carriers have followed CMS instructions. We are pleased that CMS has proposed posting the carrier-specific amounts on the CMS web site, which would be followed by a public comment period, and we encourage CMS to include this provision in the Final Rule. We also believe that CMS should expand this requirement to include posting of the carrier's detailed rationale for its payment determinations.

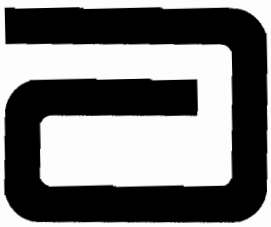
Finally, we recommend that CMS consider creating an advisory committee to provide advice to CMS regarding whether a new test code should be gapfilled or cross-walked to an existing test code, and the development of the NLA for a new test code. This advisory committee would participate in the annual meeting CMS holds to determine whether to crosswalk or gapfill a new test, and it would be in a position to fully analyze the various recommendations made at the meeting, as well as consider additional data related to new tests. This advisory panel would help ensure that CMS has the benefit of advice from clinical laboratory test experts in making payment determinations, and promote an evidence-based consensus on behalf of physicians, laboratories, manufacturers, and patients.

2. Reconsideration Process

CMS proposes establishing a reconsideration process for clinical laboratory payment determinations regarding (1) whether a new or substantially-revised laboratory test code should be crosswalked or gapfilled, and (2) the payment amount for the clinical laboratory test.

We agree that a reconsideration process should be established to address clinical laboratory test payments that are not appropriate, particularly when payment amounts do not reflect the technological innovations of a new test. Such a process should ensure that consistent criteria are applied in a transparent manner. However, the Proposed Rule does not set forth the actual standards CMS will use in the reconsideration process. Instead, CMS simply provides that after considering public comments, it may establish a new payment basis or amount using any criteria, and its decision would not be subject to challenge. As a result, under the Proposed Rule there would be no regulatory protections against changes in payment amounts for a particular test.

We therefore recommend that CMS set forth additional safeguards before adopting its proposed clinical laboratory payment reconsideration policy. In particular, CMS should propose consistent, substantive, and transparent criteria for assessing both the basis of payment and the actual payment amount, considering the same factors that apply to contractor gap fill determinations. In addition, CMS should make public its detailed rationale for any changes adopted through the reconsideration process. Likewise, in assessing the accuracy and appropriateness of carrier payment amounts, CMS should consider whether carriers have followed CMS instructions for determining payment amounts. If CMS determines that a carrier followed CMS instructions, CMS should accept the carrier-established amount or provide a detailed rationale explaining why the payment amount



otherwise is not appropriate. If, on the other hand, CMS determines after review of the public comments that the carrier did not follow CMS instructions, CMS should not include the carrier's amount in setting the NLA.

Under the Proposed Rule, CMS might adopt under the reconsideration process a payment amount that is very different from the initial determination, but affected parties would have no opportunity to present additional information. Rather than providing that reconsideration decisions are final and not subject to review, we believe that public policy would benefit from a comment period on any payment changes CMS proposes adopting through the reconsideration process. This would be consistent with other Medicare payment determinations (including physician payment amounts that typically are considered "interim" during a first year, and subject to update in subsequent years). We recommend that CMS adopt an expedited (i.e., 30 day) comment period on its reconsideration determinations to give the public an opportunity to provide additional data to CMS before prices are finalized.

C. Physician Quality Reporting Initiative (TRHCA—Section 101(b): PQRI)

The Proposed Rule includes a number of proposed PQRI measures for 2008. Abbott commends CMS for this initiative to promote the use of quantifiable quality measurements in the Medicare program. We have several recommendations involving the proposed PQRI measurements that are designed to conform to established clinical guidelines and consensus measures in order to improve the quality of care for Medicare beneficiaries with coronary artery disease ("CAD") and diabetes, as discussed below.

1. Add a New CAD Clinical Measure Entitled "Lipid Profile in Patients with CAD" (CPT Category II Code 3011F)

CAD is the leading cause of mortality in the US, accounting for almost 1 in 5 deaths, and resulting in a total annual cost of approximately $130 billion.[1] In order to promote quality of care for patients with CAD, the AMA PCPI, the ACC, and the AHA jointly have adopted a Chronic Stable Coronary Artery Disease measure that specifically recommends performance of a complete lipid panel.[2] (See Appendix A.)

Adding this widely-used CAD measure to the 2008 PQRI would ensure that uniform clinical quality standards are applied to address CAD within the Medicare Program. Further, adding the AMA PCPI/ACC/AHA complete lipid profile measure for CAD will support CMS's goal of cardiovascular disease prevention in CAD patients and Centers for Disease Control ("CDC") heart disease prevention policies and programs in 33 states.[3] Moreover, this measure is already supported by CPT II Code 3011F (lipid panel results documented and reviewed),[4] and thus would require no new technical specifications for either CMS or physicians.

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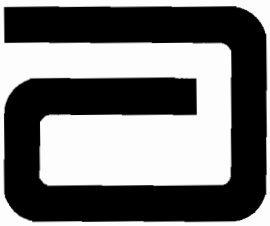
[1] American Heart Association. *Heart Disease and Stroke Statistics – 2003 Update*. Dallas, Texas: American Heart Association; 2002.
[2] AMA-PCPI. Clinical Performance Measures: Chronic Stable Coronary Artery Disease. Available at: http://www.ama-assn.org/ama1/pub/upload/mm/370/cadminisetjune06.pdf.
[3] Centers of Disease Control. Division for Heart Disease & Stroke Prevention. Available at: http://www.cdc.gov/heartdisease/.
[4] AMA-PCPI. Appendix H: Alphabetical Index of Performance Measures by Clinical Condition or Topic. Available at: http://www.ama-assn.org/ama1/pub/upload/mm/370/cadcptcodes706.pdf.



We therefore request that CMS add a new CAD clinical measure entitled "Lipid Profile in patients with CAD" in the 2008 PQRI update.

2. Clarify Proposed PQRI Measure 2 to State "Complete Lipid Testing and LDL Control in Type 1 and 2 Diabetes Mellitus"

In Table 16 of the Proposed Rule, CMS lists the second proposed 2008 PQRI measure as "Low Density Lipoprotein Control in Type 1 or Type 2 Diabetes Mellitus." We recommend that CMS clarify this measure to fully capture other lipid measures besides low density lipoprotein, or LDL. Note that there already is a performance measure that would enable reporting of the expanded quality measure encompassing complete lipid testing.[5]

Strong clinical support for a complete lipid profile in the diabetes patient population is well established through evidenced-based guidelines and recommendations from organizations including the PCPI, the ACC and AHA,[6] [7] the American Association of Clinical Endocrinologists ("AACE/ACE"),[8] and the American Diabetes Association ("ADA").[9] All of these organizations recommend that a complete lipid panel be performed annually to evaluate cardiovascular disease ("CVD") risk for diabetes patients.

In addition, the most prominent national guidelines for lipid control -- promulgated by the National Cholesterol Education Program ("NCEP") (managed by the National Heart, Lung and Blood Institute) in its "Third Report of the Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III, or ATP III) – stresses the importance of complete lipid testing in managing patients at high risk of CVD, including those with diabetes.[10]

Moreover, the NQF and AQA -- two nationally recognized consensus organizations CMS relies on to validate measures for the 2008 PQRI -- support conducting a complete lipid panel to assess CVD risk in diabetes patients. (See Appendix B.) The National Diabetes Quality Improvement Alliance ("NDQIA"), comprised of 13 national organizations including CMS, the Agency for Healthcare Research and Quality, and the AMA, also has developed a

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[5] Lipid Management – Whether or not patient received at least one LDL-C test (CPT codes 3048F, 3049F, 3050F, 80061, 82465, 83700, 83701, 83704, 83721).

[6] Gibbons RJ, Chatterjee K, Daley J, et al. ACC/AHA/American College of Physicians-American Society of Internal Medicine: "Guidelines for the management of patients with chronic stable angina: a report of the ACC/AHA task force on practice guidelines (Committee on the Management of Patients with Chronic Stable Angina)". J Am Coll Cardiol. 1999; 33:2092-2197 and Brunwald E, Antman EM, Beasley JW, et al.

[7] ACC/AHA guidelines for the management of patients with unstable angina and non-ST-segment elevation myocardial infarction. "A report of the ACC/AHA task force on practice guidelines (Committee on the Management of Patients with Unstable Angina)". J Am Coll Cardiol. 2000; 36:970-1062.

[8] The American Association of Clinical Endocrinologists: "Medical Guidelines for Clinical Practice for the Diagnosis and Treatment of Dyslipidemia and Prevention of Atherogenesis." 2002 Amended Version. Endocrine Practice. March/April 2000;6(2).

[9] Clinical Practice Recommendations 2002. "Standards of Medical Care for Patients with Diabetes Mellitus (Position Statement)". Diabetes Care. 2002; 25(suppl 1): 33-49.

[10] NCEP. Third Report of the Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (ATP III Final Report). 2002. Page III-6. Available at: http://www.nhlbi.nih.gov/guidelines/cholesterol/atp3full.pdf.

performance measurement set for adult diabetes that includes complete lipid management. Recognizing that persons with diabetes are at increased risk for CVD, NDQIA recommends a performance measure for quality improvement that assesses the percentage of patients receiving at least one lipid profile (or all component tests).[11]

In light of the strong evidence in support of complete lipid testing for individuals with diabetes, and the availability of a performance measure that would enable reporting, we urge CMS to include as a 2008 PQRI measure "Complete Lipid Testing and LDL Control in Type 1 and 2 Diabetes Mellitus."

D. CMS Should Adopt Additional Measures to Capture Complete Lipid Control in Future Updates to the PQRI Measures

While including in the PQRI a complete lipid panel that measures high density lipoprotein cholesterol ("HDL-C"), non-HDL-C, fasting triglycerides, and low density lipoprotein cholesterol ("LDL-C") levels in the management of dyslipidemia for patients with CVD, diabetes, and chronic kidney disease is an important step in improved patient care, we believe *outcomes* measures also ultimately should be incorporated in future PQRI measures.

The NCEP guidelines specifically describe the need to control both LDL-C and non-HDL-C as a specific target. Non-HDL-C (the sum of very low-density lipoproteins and LDLs) is highly correlated with apolipoprotein B, the primary atherogenic lipoprotein.[12] Serum total apo B has been shown to have a strong predictive power for severity of coronary atherosclerosis and coronary heart disease events.[13] The NCEP specifically recognizes non-HDL-C as a secondary target for cholesterol-lowering therapy and notes that "existing data actually favor use of non-HDL cholesterol over LDL cholesterol in clinical evaluation of risk.[14] NCEP Guidelines further note "a stronger correlation with coronary mortality for non-HDL cholesterol than for LDL cholesterol".[15] Future PQRI measures therefore should consider control of all lipids.

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[11] NDQIA. National Diabetes Quality Improvement Alliance Performance Measurement Set for Adult Diabetes, Approved January 21, 2005. Page 3. Available at: http://www.nationaldiabetesalliance.org/Final2005Measures.pdf.

[12] NCEP at 11-8, citing Vega GL, Grundy SM. Does measurement of apolipoprotein B have a place in cholesterol management? *Arteriosclerosis* 1990; 10:668-71, and Abate N. Vega GL, Grundy SM. Variability in cholesterol content and physical properties of lipoproteins containing apolipoprotein B-100. *Arteriosclerosis* 1993; 104:159-71.

[13] NCEP at 11-8, citing Tornvall P, Bavenholm P, Landou C, de Faire U, Hamsten A. Relation of plasma levels and composition of apolipoprotein B-containing lipoproteins to angiographically define coronary artery disease in young patients with myocardial infarction. *Circulation* 1993; 88 [part 1]: 2180-9 and others.

[14] NCEP. Third Report of the Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (ATP III Final Report). 2002. Page II-8. Available at: http://www.nhlbi.nih.gov/guidelines/cholesterol/atp3full.pdf, citing Frost PH, Havel RJ. Rationale for use of non-high density lipoprotein cholesterol rather than low-density lipoprotein cholesterol as a tool for lipoprotein cholesterol screening and assessment of risk and therapy. *Am J Cardiol* 1998; 81: 26B-31B.

[15] NCEP at 11-8, citing Cui Y, Blumenthal RS, Flaws JA, Whiteman MK, Langenberg P. Bachorik PS, Bush TL. Non-high-density lipoprotein cholesterol level as a predictor of cardiovascular disease mortality. *Arch Intern Med* 2001; 161: 1413-9.

* * * * *

We appreciate your consideration of our comments. Please feel free to contact me if you have any questions or if you need additional information.

Sincerely,

Virginia Tobiason

Virginia Tobiason
Senior Director,
Corporate Reimbursement

Attachments

APPENDIX A

American College of Cardiology, American Heart Association, and Physician Consortium for Performance Improvement Chronic Stable Coronary Artery Disease Physician Performance Measurement Set[8]

	Clinical Recommendations	Clinical Performance Measures Per Reporting Year	
Blood Pressure Measurement	A blood pressure reading is recommended at every visit.[7] Recommended blood pressure management targets are ≤130 mm Hg systolic (Class I Recommendation, Level-A Evidence)[7] and ≤85 mm Hg diastolic in patients with CAD and coexisting conditions (eg, diabetes, heart failure, or renal failure) and <140/90 mm Hg in patients with CAD and no coexisting conditions.[7,11]	**Percentage of patients who had a blood pressure measurement during the last office visit** **Numerator** – Patients who had a blood pressure measurement during the last office visit **Denominator** – All patients with CAD	
		Per Patient: Most recent systolic and diastolic blood pressure measurement[9]	*Per Patient Population:* Percentage of patients who had a blood pressure measurement during the last office visit Percentage of patients with last blood pressure measurement: <140/90 mm Hg Distribution of most recent blood pressure values by range (mm Hg):[9] Systolic: <120, 120-129, 130-139, 140-149, 150-159, 160-169, 170-179, ≥180, undocumented Diastolic: <75, 75-79, 80-89, 90-99, 100-109, ≥110, undocumented
Lipid Profile	A lipid profile is recommended and should include total cholesterol, high-density lipoprotein cholesterol (HDL-C), low-density lipoprotein cholesterol (LDL-C), and triglycerides.[7,9] (Class I Recommendation, Level-C Evidence)[7]	**Percentage of patients who received at least one lipid profile (or ALL component tests)** **Numerator** – Patients who received at least one lipid profile (or ALL component tests) **Denominator** – All patients with CAD	
		Per Patient: Whether or not a lipid profile was obtained Most recent total cholesterol, HDL-C, LDL-C, and triglycerides test results	*Per Patient Population:* Percentage of patients who received at least one lipid profile (or ALL component tests) Distribution of percentage of patients with the most recent test results in the following ranges: Total cholesterol: ≥240, 200-239, <200, undocumented LDL-C: ≥160, 130-159, 100-129, <100, undocumented HDL-C: <40, 40-49, 50-59, ≥60, undocumented Triglycerides: ≥400, 200-399, <200, 150-199, <150, undocumented
Symptom & Activity Assessment	Regular assessment of patients' anginal symptoms and levels of activity is recommended.[7] (Serves as a basis for treatment modification)	**Percentage of patients who were evaluated for both level of activity and anginal symptoms during one or more office visits** **Numerator** – Patients evaluated for both level of activity and anginal symptoms during one or more office visits **Denominator** – All patients with CAD	
		Per Patient: Whether or not patient's level of activity and anginal symptoms were evaluated during office visit	*Per Patient Population:* Percentage of patients who were evaluated for both level of activity and anginal symptoms during one or more office visits
Smoking Cessation	Smoking status should be determined and smoking cessation counseling and interventions are recommended.[7-10] (Class I Recommendation, Level-B Evidence)[7]	**Percentage of patients who were queried one or more times about cigarette smoking** **Numerator** – Patients who were queried one or more times about cigarette smoking **Denominator** – All patients with CAD **Percentage of patients identified as cigarette smokers who received smoking cessation intervention** **Numerator** – Patients who received smoking cessation intervention **Denominator** – All patients with CAD identified as cigarette smokers	
		Per Patient: Whether or not patient was queried one or more times about cigarette smoking Whether or not patient identified as cigarette smoker received intervention for smoking cessation	*Per Patient Population:* Percentage of patients who were queried one or more times about cigarette smoking Percentage of patients identified as cigarette smokers who received intervention for smoking cessation

APPENDIX B

NQF has endorsed and AQA has adopted two complete lipid profile measures for patients with CAD and diabetes. The charts below summarize the measures that have been endorsed and adopted by the NQF and AQA respectively regarding the clinical imperative to perform a complete lipid profile in these populations.

CAD: Endorsed by NQF in May 2006[16], adopted by AQA in April 2006[17]

CAD: lipid profile	Patients who received at least one lipid profile (or ALL component tests) during the reporting year CPT Laboratory Codes for lipid testing: 80061, 83721, 83716, 82465, 83718, 84478; or LOINC Codes for lipid testing: 24331-1, 13457-7, 18262-6, 18261-8, 22748-8, 2093-3, 14647-2, 2085-9, 14646-4, 18263-4, 2571-8, 14927-8, 1644-4, 3043-7, 3048-6, 30524-3	All patients with CAD ³18 years of age Patient selection: ICD-9-CM Codes for CAD: 414.00-414.07, 414.8, 414.9, 410.00-410.92, 412, 411.0-411.89, 413.0 413.9, V45.81, V45.82; or CPT Diagnosis Codes: 92980-92982, 92984, 92995, 92996, 33140, 33510-33514, 33516-33519, 33521-33523, 33533-33536; and Patient's age is ³18 years	AMA PCPI/ ACC/AHA

*The intellectual property (IP) owner maintains the most current specifications.

Diabetes: Endorsed by NQF in September 2006[18], adopted by AQA April 2006[19]

Diabetes: Percentage of patients receiving at least one lipid profile (or ALL component tests), per patient population : lipid profile	Patients with at least one lipid profile (or ALL component tests) during the measurement period. CPT laboratory codes for lipid testing: 80061, 83721, 83716, 82465, 83718, 84478; LOINC Codes for lipid testing: 24331-1, 13457-7, 18262-6, 18261-8, 22748-8, 2093-3, 14647-2, 2085-9, 14646-4, 18263-4, 2571-8, 14927-8, 1644-4, 3043-7, 3048-6, 30524-3	A systematic sample of patients 18-75 years old who had a diagnosis of diabetes (type 1/2) Diabetes include: ICD-9-CM Codes 250, 357.2, 362.0, 366.41, 648.0; DRGs 294, 295 Outpatient/non-acute inpatient: CPT Codes 92002-92014, 99201-99205, 99211-99215, 99217-99220, 99241-99245, 99271-99275, 99301-99303, 99311-99313, 99321-99323, 99331-99333, 99341-99355, 99384-99387, 99394-99397, 99401-99404, 99411, 99412, 99420, 99429, 99499; UB-92 Revenue Codes 019X, 0456, 049X-053X, 055X-059X, 065X, 066X, 076X, 077X, 082X-085X, 088X, 092X, 094X, 096X, 0972-0979, 0982-0986, 0988, 0989 Acute inpatient/emergency department: CPT Codes 99221-99223, 99231-99233, 99238-99239, 99251-99255, 99261-99263, 99281-99285, 99291-99292, 99356-99357; UB-92 Revenue Codes 010X-016X, 020X-022X, 0450, 0451, 0452, 0459, 072X, 080X, 0981, 0987	AMA PCPI

*The intellectual property (IP) owner maintains the most current specifications.

[16] NQF. National Voluntary Consensus Standards for Ambulatory Care: An Initial Physician-Focused Performance Measure Set. Page A-20. Available at: http://www.qualityforum.org/pdf/reports/ambulatory_care.pdf.

[17] AQA. AQA Endorsed Starter Set for Cardiology. Page 2. Available at: http://www.aqaalliance.org/files/AQAProposedStarterSetforCardiologymay2006.doc.

[18] NQF. National Voluntary Consensus Standards for Adult Diabetes Care: 2005 Update. Measure 18, Page B-14. Available at: http://www.qualityforum.org/pdf/reports/diabetes_update.pdf.

[19] AQA. Recommended Starter Set Clinical Measures For Physician Performance. Measure 16, Page 2. Available at: http://www.aqaalliance.org/files/RevisedStarterSetApril2006.doc.

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August 28, 2007

VIA FIRST CLASS MAIL

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

Re: Comments on CMS-1385-P, Obstetrical Malpractice Insurance Subsidies

To The Addressee:

This letter is written on behalf of St. Mary's Hospital of St. Mary's County, Maryland.[1] St. Mary's Hospital is pleased to have the opportunity to comment on the Obstetrical Malpractice Insurance Subsidies stated in CMS-1385-P, Section II, M, 4, 72 Fed. Reg. 38123, 38182 (July 12, 2007).

Medical malpractice insurance premiums have increased significantly, which has decreased significantly the number of obstetricians available to rural communities. Although each area of the country is different, obstetricians in St. Mary's County have seen their medical malpractice insurance premiums increase by approximately 150% from 2003 to 2007, from approximately $40,000 to $100,000.

On the other hand, obstetrician reimbursement from federal health care programs and other payors has remained relatively flat. The payment for labor deliveries remains in large part a fixed sum per labor delivery, approximately $1,500 per delivery on average in St. Mary's County (reimbursement from Medicaid and other federal health care programs is typically less than $1,000). As a result, approximately one-quarter (1/4) of every dollar paid for a labor delivery in Maryland is now actually used to pay malpractice insurance premiums, leaving only 75¢ out of every dollar to cover rent, utilities, employee salaries and benefits, as well as some

[1] St. Mary's Hospital is a § 501(c)(3) tax-exempt hospital located in Leonardtown, Maryland.

compensation for the obstetrician. ($1,500 per delivery x 250 deliveries = $375,000 of revenue per year.)[2]

In light of the foregoing, it is not surprising why so many obstetricians are fleeing the practice or practicing in urban areas with higher reimbursement rates. Many obstetricians are also restricting their practices to gynecology, inasmuch as obstetricians pay three to four times more, on average, in malpractice insurance premiums than gynecologists. For example, St. Mary's County has lost nearly one-half of the people who used to perform labor deliveries in the County during this most recent malpractice insurance crisis.

The rising medical malpractice insurance premiums and decrease in the number of available obstetricians impacts significantly rural communities. In some urban areas, several hospitals provide emergency room services in the community, and occasionally within city blocks of each other. The failure of one hospital to provide adequate obstetric care can be overcome by other hospitals located in the same area.

Unlike urban area hospitals, rural community hospitals are often the sole source of emergency labor deliveries. Alternate emergency care is not several blocks away but dozens of miles away and in the next community or county. For example, St. Mary's Hospital is the only emergency labor delivery and emergency care facility in a thirty mile radius. Because there are no interstate highways in the County, the next closest facility is approximately a fifty (50) minute drive from St. Mary's Hospital.

Unfortunately, St. Mary's Hospital and many other rural hospitals cannot make use of the Stark law exception, 42 C.F.R. § 411.357(r) (2006) (the "Obstetrician Exception"), and anti-kickback statute safe harbor, 42 C.F.R. § 1001.952(o)(2)(2006), because these regulations require a subsidizing hospital and a subsidized obstetrician's patients to reside in a primary care health professional shortage area (HPSA). In fact, St. Mary's Hospital is prohibited by the Stark law from subsidizing the medical malpractice insurance premiums of its remaining obstetricians because neither the Hospital nor St. Mary's County is designated a primary care HPSA. 42 C.F.R. § 411.357(r); 42 C.F.R. § 1001.952(o)(2).

The flawed underpinnings of these exceptions are twofold. First, is their reliance on primary care HPSA. A primary care HPSA counts five types of primary care physicians: general practitioners, internists, pediatricians, gynecologists, and obstetricians. Areas served by hospitals may not be primary care HPSAs because of an abundance of pediatricians, internists, gynecologists, and general practitioners—yet that same area may be underserved by obstetricians. Accordingly, one must ask the question, why is the *Obstetrician Exception* to the

[2] Obstetricians in St. Mary's County average an abnormally high number of labor deliveries per year; obstetricians, on average, perform approximately 140 labor deliveries per year. "Average" obstetricians would pay almost 50% of their collections to pay for medical malpractice insurance ($1,500 x 140 = $210,000).

Stark law linked to a metric that measures *non-obstetricians* in an area? Also, why not base the *Obstetrician Exception* on the number of *obstetricians* in the area?

The second flawed underpinning of the existing exceptions is that obstetricians in rural communities have no alternative but to send labor deliveries to the local rural community hospital, whether or not the hospital is subsidizing the obstetricians' medical malpractice insurance premium.

Accordingly, St. Mary's Hospital suggests two alternative changes to the current obstetrical malpractice insurance exception. CMS could: i) define and rely upon an Obstetrical Shortage Area instead of a HPSA; or ii) alter the definition of "compensation arrangement" to exclude obstetrical malpractice subsidies in areas where there is no alternative for labor deliveries.

Set forth as enclosure 1 to this letter is suggested language defining an Obstetrical Shortage Area, and attached to this letter as enclosure 2 is suggested language effectuating a change in the definition of compensation arrangement.

St. Mary's Hospital believes that it is perfectly appropriate to slightly expand the Obstetrician Exception to accommodate the special circumstances of rural hospitals. It should be remembered that the obstetric specialty is different from other specialties that refer patients to hospitals. Obstetricians have no power to increase the number of labor deliveries they perform, because the volume of deliveries is, of course, determined by the number of pregnancies in the area, and not based on the therapy choice of the physician. In comparison, the risk of program abuse from other physician specialties is significant; other physicians that wish to increase their revenue may do so by increasing the number of procedures they perform.

As you move forward, if we can be of any assistance, please feel free to contact us. Thank you for your consideration of our suggestions.

Best regards,

Barry F. Rosen

Christopher P. Dean

Enclosures

617119.2
8/28/2007
13050/094167

cc: The Honorable Steny Hoyer
Lisa M. Ohrin, Esquire
Linda P. Howard, Esquire
Ms. Christine Wray

617119.2
8/28/2007
13050/094167

ENCLOSURE 1

PROPOSED OBSTETRICAL SHORTAGE AREA

The current Obstetrical Malpractice Insurance Exception requires patients to reside within a primary care health professional shortage area (HPSA) or medically underserved area. That exception should be expanded to include a patient residing within an Obstetrical Shortage Area as described below:

Obstetrical Shortage Area

A. *Criteria for Obstetrician Shortage Area.*

A geographic area will be designated as having a shortage of obstetricians if the following criteria are met:

1. The area is a rational area for obstetrician services; and

2. The ratio of full-time equivalent (FTE) obstetricians to the population of females between the ages of 15-49 within a rational area[1] is greater than 1:4,500; or

3. The ratio of FTE obstetricians to the population of females between the ages of 15-49 within a rational area that has unusually high needs for obstetricians services is greater than 1:4,000.

B. *Methodology*

1. *Rational Areas.* A rational area shall be determined in accordance with 42 C.F.R. Appendix A to Part 5, Part I, Subpart B, Paragraph 1.

2. *Population Count.* Population shall be counted in accordance with Appendix A to Part 5, Part I, Subpart B, Paragraph 2.

3. *FTE Obstetrician Count.* The number of obstetricians within a rational area shall be counted in the following manner:

a. All licensed or otherwise state certified non-federal obstetricians will be counted as one (1) FTE.

b. Interns and residents of obstetrician programs will be counted as 0.1 FTE.

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[1] A rational, and publicly available, metric for "labor delivering population" would be the number of women aged 15-49 in the area. The United States Census Bureau provides this information on its website, www.census.gov. The Bureau counts the population every decade and estimates periodically the population in areas in between censuses.

c. Obstetricians who are semi-retired, who operate a reduced practice due to infirmity or other limiting conditions, or who provide patient care services to the residents of the area only on a part-time basis will be discounted through the use of full-time equivalency figures. A 40-hour work week will be used as the standard for determining full-time equivalents in these cases. For obstetricians working less than a 40-hour week, every four (4) hours (or 1/2 day) spent providing patient care, in either ambulatory or inpatient settings, will be counted as 0.1 FTE (with numbers obtained for FTE's rounded to the nearest 0.1 FTE), and each obstetrician providing patient care 40 or more hours a week will be counted as 1.0 FTE. (For cases where data are available only for the number of hours providing patient care in office settings, equivalencies will be provided in guidelines.)

d. Hospital staff obstetricians involved exclusively in inpatient care will be excluded.

4. *Determination of Unusually High Needs for Obstetrician Services.*

An area will be considered as having unusually high needs for obstetrician services if at least one of the following criteria are met.

a. The area has more than 200 live births per year per FTE obstetrician in that area.

b. The area has more than 100 births per year per 1,000 women aged 15-49.

c. The area has more than 20 infant deaths per 1,000 live births.

d. More than 20% of the population (or of all households) have incomes below the poverty level.

ENCLOSURE 2

COMPENSATION ARRANGEMENT EXCEPTION

42 C.F.R. § 411.354 (e)

(e) Compensation Arrangement Exception

The term compensation arrangement does not include an obstetrical malpractice insurance subsidy where the designated health services are provided at a hospital that:

(1) is exempt from taxation pursuant to section 501(c) (3) of Title 26;

(2) is located within any rational area that is a rural area and does not include an urban area or any portion of an urban area; as defined in section 1395ww of this title;

(3) owns and operates an emergency room facility within that rational area; and

(4) that emergency room facility is the only emergency room facility within that rational area and is otherwise open and admits all patients regardless of the ability to pay.

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MERCER PATHOLOGY ASSOCIATES, P.A.
446 BELLEVUE AVENUE
TRENTON, NEW JERSEY 08607

August 23, 2007

Department of Health & Human Services
P.O. Box 8018
Baltimore, MD 21244-8018

ATTN: CMS-1385-P

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".

To Whom It May Concern:

I appreciate this forum as opportunity to express my views referable to the provision of pathology services as impacted by 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, member of the College of American Pathologists, as well as, a member of the New Jersey Society of Pathologists, and have been in practice within the City of Trenton, Mercer County, New Jersey since 1984. I am a member of a group practice comprised of three full-time and one part-time pathologists, primarily practicing in a hospital-based setting.

I commend CMS for taking steps to end abuses in regard to self-referral in the billing and payment for pathology services. I am aware of physician practice arrangements in my geographic area that enable medical groups to share in the revenues generated from pathology services, as ordered and performed for individual patients of these groups. I believe such arrangement to represent an abuse of the Stark law prohibition against physician self-referral. I support revisions in the interpretation of Stark law which would close the loopholes that currently permit physicians to profit from pathology services. I believe that such revisions will keep good faith with the intent of the Stark law, and promote direct payment to physicians who actually perform professional services in the caring of patients.

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 provisions of pathology services, unless the physician is capable of personally performing, or supervising the service.

Captive pathology arrangements of this type are primarily based on self-interest and do not enhance patient care. Furthermore, I believe that such practices corrupt and injure the practice of pathology as a profession in general. I believe that restriction on physician self-referral is an important safeguard to ensure that good medical practice and clinical decision making is determined solely on the basis of the highest of professional standards and quality, in providing healthcare for the best interest of patients under the Medicare program. The proposed revisions to payment policies (CMS-1385-P) will not adversely impact the availability or delivery of pathology services, however, will help to eliminate sources of financial conflict of interest that would compromise the integrity of the Medicare program.

Sincerely,

Robert H. Wood, M.D., FACP

RHW:jab

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 As requested, I have limited my comments to the issue identifiers in the Proposed Rule.

There are approximately 7,000 physicians practicing interventional pain management in the United States we are included in this statistic. 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.

I appreciated that effective January 1, 2007, CMS assigned interventional pain and pain management specialties to the "all physicians" crosswalk. This, however, did not relieve the continued underpayment of interventional pain services and the payment shortfall continues to escalate. 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. This will have a devastating affect all physicians' 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. **There are many Pain Management Practices who currently only accept cash payments for services as a result of such measures- just call one in NYC to confirm.**

The current practice expense methodology does not accurately take into account the practice expenses associated with providing interventional pain services. 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.

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.

Effective January 1, 2007, interventional pain physicians (09) and pain management physicians (72) are cross-walked to "all physicians" for practice expenses. This cross-walk more appropriately reflects the indirect practice expenses incurred by interventional physicians who are office-based physicians. The positive affect of this cross-walk was not realized because many interventional pain physicians report anesthesiology as their Medicare primary specialty and low utilization rates attributable to the interventional pain and pain management physician specialties.

The practice expense methodology calculates an allocable portion of indirect practice expenses for interventional pain procedures based on the weighted averages of the specialties that furnish these services. This methodology, however, undervalues interventional pain services because the Medicare specialty designation for many of the physicians providing interventional pain services is anesthesiology. Interventional pain is an inter-disciplinary practice that draws on various medical specialties of anesthesiology, neurology, medicine & rehabilitation, and psychiatry to diagnose and manage acute and chronic pain. Many interventional pain physicians received their medical training as anesthesiologists and, accordingly, clinically view themselves as anesthesiologists. While this may be appropriate from a clinically training perspective, their Medicare designation does not accurately reflect their actual physician 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 not only furnish evaluation and management (E/M) services but also perform a wide variety of interventional procedures such as nerve blocks, epidurals, intradiscal therapies, implant stimulators and infusion pumps, and therefore have 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. CMS utilization files for calendar year 2007 overwhelming report anesthesiologists compared to interventional pain physicians and pain management physicians as being the primary specialty performing interventional pain procedures. The following table illustrates that anesthesiologists are reported as the primary specialty providing interventional pain services compared to interventional pain physicians

CPT Code	Anesthesiologists -	Interventional Pain

III. 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. The 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 disproportionately bear the cost of providing health care to Medicare beneficiaries. Accordingly, many physicians face clear financial hardship and will have to make painful choices as to whether they should continue to practice medicine and/or care for 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 be unfairly lose access to 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,

Susan Brienza Gordon RN, BSN, MBA
Director of Operations
New York Pain Management, PLLC
711 Troy Schenectady, Road Suite 207
Latham, NY 12110

Alliance of Specialty Medicine
Sound Policy. Quality Care.

200,000 Physicians Strong

Gordon Wheeler, Chair
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August 20, 2007

Herb B. Kuhn, Acting Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Attention: CMS-1385-P

RE: Medicare Program; Proposed Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2008

Dear Mr. Kuhn:

On behalf of the undersigned members of the Alliance of Specialty Medicine, a coalition of 11 medical societies representing more than 200,000 specialty physicians in the United States, we appreciate the opportunity to provide the Centers for Medicare & Medicaid Services (CMS) with our comments on the proposed rule for physician payment for 2008 that was published in the Federal Register on July 12, 2007.

The Alliance was founded in 2001 to serve as a strong voice for specialty medicine. Its mission is to improve access to quality medical care for all Americans through the unified voice of specialty physicians promoting sound federal policy. A fee schedule that adequately and fairly accounts for the costs of furnishing medical services to Medicare beneficiaries indisputably affects access to and the quality of care for our nation's elderly citizens, and thus, is of paramount concern to us.

Impact

After seven years of reimbursement cuts, freezes, or updates that were less than the rate of inflation, physicians are now faced with the largest payment reduction ever (- 9.9%). The nation's physicians are not impervious to continuing growth in costs of staff, liability premiums, equipment, and other expenses of running their medical practices. In response to shrinking practice revenues, physicians may not completely drop out of the Medicare program, but they will in many cases be forced to explore other means to limit their exposure to continuing losses, which in turn may unfortunately have an adverse effect on beneficiary access.

Each year, we work with the Administration and Congress to urge rescinding of the SGR and replacing it with a formula that recognizes reasonable inflationary costs, similar to all of the other Medicare payment systems. This proposal has been repeatedly recommended by the Medicare Payment Advisory Commission (MedPAC) and other policy experts as well.

TRHCA – Section 101(d)

While the largest challenge is on Congress to act, CMS has done nothing to ameliorate the growing cost of the SGR fix and has repeatedly refused to take drugs out of the SGR pool while also under estimating the costs of new Medicare benefits. This year, CMS proposes to take the $1.35 billion that Congress set aside in the TRHCA legislation of 2006 and use it for the physicians' quality reporting initiative which will benefit a limited number of participating physicians, rather than as a down payment for a longer term payment fix that would be of direct benefit to all participating physicians.

The Alliance strongly supports use of the $1.35 billion available in the Physician Assistance and Quality Improvement Fund to buy down the deleterious effects of the 9.9 percent payment cut. We believe the proposal to apply these funds to the PQRI is counter to the intent of Congress and MedPAC's recommendation. CMS should and can overcome the "legal and operational" problems associated with applying the funds to the negative update, as the dire situation posed by the harmful cuts surely prevails over the potential obstacles. Use of these funds to ameliorate the severe reduction to the fee schedule will have a more positive impact on all physicians than a reporting program whose value has not yet been demonstrated.

Budget Neutrality Adjustment

We were disappointed by CMS' decision to make the budget neutrality adjustment to the physician work values for 2007, particularly after the large majority of physician specialties asked CMS to make this adjustment to the conversion factor. From 1998 to 2006, CMS achieved budget neutrality requirements by adjusting the Medicare conversion factor, so clearly CMS supported this policy. Further, as CMS has never satisfactorily explained the rationale for the 2007 decision, the Alliance again urges the Agency to make any budget neutrality adjustment for 2008 to the conversion factor, rather than impose a nearly 12 percent reduction to the work values.

Publishing Relative Value Units (RVUs) for Non-covered Services

We reiterate our request that CMS publish services for CPT codes that remain non-covered by Medicare. Since many other payers look to CPT codes, we strongly support CMS publishing relative values for all services, regardless of Medicare's coverage policies. It is our understanding that CMS can include a table in the final rule for New and Revised CPT codes.

TRHCA –Section 101(b) Physician Quality Reporting Initiative (PQRI)

The Alliance members have been engaged in significant efforts to develop performance measures, and are working closely with external stakeholders to develop measures that will help us provide even better care for our patients. However, we are concerned that the process for developing the 2008 PQRI is advancing while the 2007 PQRI just began July 1. This timeframe leaves scant opportunity to evaluate the most basic elements of the 2007 PQRI program, such as impact on patient care, physician participation rates, and implementation costs before moving forward. While we understand that CMS is required by TRHCA to implement the 2008 program, we urge the agency to use its discretion to closely evaluate the 2007 program before moving ahead, and support provisions included in S. 1519/ H.R. 2749, the Voluntary Medicare Quality Reporting Act. Specifically, we urge CMS to work with medical specialties to identify gaps in care for which quality measures are genuinely needed and to ensure that any Medicare quality program for physicians remains voluntary. Further, we believe that any incentives linked to such a quality program should be paid with new funds.

In addition, we believe that the requirement that measures for the 2008 program be developed "through the use of a consensus-based process" is too broad. For any reporting system to improve quality, the measures must be

meaningful to clinical care and relevant to practicing physicians. Therefore, direct physician involvement in the development, testing and implementation of quality measures is the only way to ensure measures are appropriate and clinically relevant. While we appreciate that the proposed rule recognizes the American Medical Association's Physician Consortium for Performance Improvement (the Consortium) as a source for the development of quality measures eligible for inclusion in PQRI 2008, we urge CMS to go further and consider the Consortium as the only entity appropriate for the development of physician-level quality measures. The Consortium process is consensus-based and physician-led. This characteristic will ensure physician buy-in on measures which is essential for an effective quality reporting program. Further, tasking the Consortium as the only group for developing physician measures significantly reduces the risk of duplicative or contradictory measures and ensures measure harmonization.

As CMS seeks to make refinements in the program, the Alliance asks that measures used for PQRI be coordinated with measures in use by other CMS programs, e.g., the Hospital Compare program and the Surgical Care Improvement Project (SCIP). For example, in the case of SCIP, measure VTE-1 (also referred to as the National Quality Forum Consensus Standard for Prevention and Care of Venous Thromboembolism) and the CMS PQRI Voluntary Reporting Measure #23, Perioperative Care: Venous Thromboembolism (VTE Prophylaxis) are incongruent. PQRI rewards individual physicians for the use of certain treatments for all common inpatient surgical procedures, while SCIP rewards hospitals for a narrower set of treatments for a limited set of procedures.

In the case of the Hospital Compare program, measure AMI-6, Beta Blocker at Arrival for Acute Myocardial Infarction (AMI), rewards hospitals for administration of beta blocker within 24 hours after hospital arrival, while the PQRI Measure #29: "Beta-Blocker at Time of Arrival for Acute Myocardial Infarction (AMI)" rewards individual physicians for documenting receipt of beta blocker within 24 hours before or after hospital arrival.

CMS should review all of its quality initiatives and work with measure developers in a transparent and inclusive process to ensure that performance measures throughout the different programs, though operating separately, are compatible and are not in conflict in order to avoid confusion and unduly burdensome reporting.

The Alliance asks CMS to clarify how the reporting requirements indicated in the 2008 PQRI program apply across the seven categories of proposed measures—including clinical, process and structural measures and how successful reporting may be achieved. The Alliance urges CMS to take a very flexible approach in its consideration of the use of electronic means of reporting measures. Such consideration should include registry, electronic health record and other means of electronic reporting, and we urge that CMS ultimately adopt quality reporting mechanisms that allow all providers to effectively report.

Physician Self-referral Provisions - Alternative Criteria for Satisfying Certain Exceptions

The Alliance commends CMS on its attempt to bring rationality to the strict enforcement of inadvertent form violations of the self-referral regulations. However, the Alliance also believes that CMS should amend the proposal so as not to be so unilateral in its enforcement. The proposed rule states that whether the criteria have been met will be determined "at the sole discretion" of CMS and that decisions will not be "subject to further administrative or judicial review." Surely, CMS can preserve its authority while simultaneously ensuring that those who are subjected to this rule and exception are able to access the benefits of it.

The Alliance of Specialty Medicine appreciates the opportunity to comment on these important issues affecting Medicare beneficiaries and the physician community. Please contact Barbara Marone, Director Federal Affairs, ACEP, at bmarone@acep.org (202) 728-0610, or Anne Marie Bicha, Director of Regulatory Affairs, AGA, abicha@gastro2.org (240) 482-3223 if you have any questions regarding our comments and recommendations.

American Academy of Dermatology Association
American Association of Orthopaedic Surgeons
American Association of Neurological Surgeons
American College of Emergency Physicians
American College of Obstetricians and Gynecologists
American Gastroenterological Association
American Society of Cataract & Refractive Surgery
American Urological Association
Congress of Neurological Surgeons
National Association of Spine Specialists

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CMS-1385-P/14 MPFS

Submitter : Ms. Deborah Peterson **Date:** 08/16/2007

Organization : Ms. Deborah Peterson

Category : Physical Therapist

~~ASC~~

Issue Areas/Comments

Physician Paymen Services Provided in ASCs

Physician Paymen Services Provided in ASCs

Re: proposed 2008 physician fee schedule rule. Why physical therapy services should not be allowed under the in-office ancillary services exception:

I have been a physical therapist for over 30 years, and practiced in a rehabilitation center, acute care hospitals, a sports physical therapy clinic, and in three different private practices. Currently, I am the owner of a small private practice that was established 19 years ago. From my perspective, the problem of physician self-referral for physical therapy has never been worse than now. Physical therapy services should not be allowed under the physician in-office ancillary services exception.

Years ago, I worked at a private practice that was owned by a physical therapist. Under pressure, she subsequently sold part interest to the orthopedic surgeons across the street. I was in a direct position to see the difference in the amount of PT referrals that were made, once the physicians had part ownership. Business increased dramatically. Many times, patients did not need treatment, but were nonetheless sent to us. Other times, we recommended discontinuing treatment as the patient no longer required PT, but the doctor sent them back.

In my current situation, a large group practice of physicians in our town has created three physical therapy clinics. Despite a state law requiring physicians to identify ownership in the clinics they refer to, this is not being done. Many of our long term patients, who have requested to return to our clinic, have been told by physicians that they want the patient to go to THEIR therapist. Very few patients feel comfortable telling their physician they don't want to do what the doctor recommends! In one instance, a doctor refused the patient's request for a written prescription for PT (which she wanted to bring to our clinic) and told her instead that he would call THEIR clinic with the referral information. These same physicians, however, readily refer patients with poor insurance coverage to other clinics. I have no doubt that if I did an audit of referrals for PT from this physician group prior to their owning PT clinics, and compared their referrals to AFTER their ownership, that the insurance case-mix is quite different. They cherry pick the patients with good insurance, and send out those with poor or no insurance.

We have also had patients return to our clinic (by request) after attending the doctor's physical therapy clinic, and tell us that the treatment provided by the doctor's clinic was not of the same quality and the patient got less direct care than they receive at our clinic. This may simply represent a difference in approach to patient care among therapists, but it is a comment we have heard more than once.

I have also done work in the past as a reviewer of physical therapy documentation for an insurance company. Although I have no direct knowledge (only anecdotal comments), it is my impression that physician office physical therapists do not have a good understanding of Medicare requirements / documentation standards. I personally attend continuing education events and professional courses to be sure I am meeting the rigorous requirements of Medicare. I see many of my colleagues in independent practice at these seminars, and there are ongoing communications among us. In POPTS (Physician Owned Physical Therapy Clinics), because the therapists are employed by physicians, who are busy being physicians, I suspect that adherence to Medicare requirements in those physician-owned settings may be sketchy. I may be wrong: an audit of various clinics by ownership would be informative in this regard.

The Florida study done years ago shows what kind of abuse that self-referral of PT can create. The nature of the beast has not changed since then. I strongly recommended that physician self-referral of physical therapy not be permitted by law. Thank you for considering my opinion.

Dana (2)
Carol
Alberta

424

Dr. Joseph N. Macaluso, Jr.
c/o ***Health Care Excellence***
3101 St. Charles Avenue, #12
New Orleans, LA 70115

August 25, 2007

Mr. 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

RE: Proposed changes to the physician fee schedule rules that were published on July 12, 2007, which concern the Stark self-referral rule and the reassignment and purchased diagnostic test rules.

Dear Mr. Kuhn:

I am a retired urologist (due to medical disability) who practiced for 22 years in New Orleans in a large, single specialty urology practice (Urologic Institute of New Orleans, www.uino.org). This practice serves a large Medicare population and provides the full scope of urologic services to patients. Though retired from active practice, I remain a gratis ad-hoc advisor to UiNO as well as other urologists and healthcare providers. 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 on the way urologists and other physicians 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.

This exemption to the Stark law was created for a specific reason – to allow physicians to make decisions that were in the best interests of their patients and practices – and since they were the implementers at financial risk, either by direct provision of services or via contracted service provisions, it was felt that only arrangements that made sense on all levels would proceed. This has clearly been the case under this in office ancillary services exemption.

This exemption has also allowed in many, many cases for patients to receive local access to services that would NOT be provided if left solely to the discretion of local hospitals. This has been the case in a myriad of situations, where hospitals make decisions regarding provision of new technology or specific services completely on volume and revenue generation considerations. Without joint ventures, contracted services and mobile provider access, patients would often be traveling long distances, or be inconvenienced by having to access services in other geographic locations of metropolitan areas, when those services could easily, safely and effectively be provided in a single location.

It is important for patient care that urologists 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. Additionally, imaging services should not be made more difficult for Medicare beneficiaries to access by limiting the ability of a practice to provide for these services.

The proposed changes to the reassignment and purchased diagnostic test rules will make it difficult, if not impossible for urologists and other physicians to provide efficient, timely and accurate test results to patients. These tests can include PSA as well as biopsy results and in other cases a wider array of laboratory testing.

The proposed "under arrangement" rule, will prohibit the provision of many services including, but not limited to, laser services, cryotherapy services, IMRT and other radiation oncology related services, as well as newer services such as TUMT and TUNA which are more often than not performed in the office.

The prohibition of per click payments for space and equipment rentals will prohibit physicians from creating ease of access to services for many patients, particularly the elderly. By limiting these types of services CMS is creating hardships by forcing patients to make multiple stops, at multiple locations for services that can often be provided in a single location.

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.

Most significantly, the in office ancillary services exemption, as well as the common billing ID unified practice exemption should be left intact and in fact, strengthened to prevent future attempts by vested interest competitors from undermining this vital tenant in the Stark rules, which were designed to truly allow physicians to make vital decisions for the common good of their patients and practices.

Thank you for your consideration,

Joseph N. Macaluso, Jr., M.D., F.A.C.S.

Joseph N. Macaluso, Jr., M.D., F.A.C.S.
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Roger H. Tall, M.D.
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(208) 529-0633

August 27, 2007

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

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

Dear CMS:

I am writing to express by concerns regarding certain proposals in the recently released 2008 Proposed Physician Fee Schedule. As a physician practicing in Idaho Falls, I fear that several of the proposed changes to the physician self-referral rules will needlessly and unjustifiably harm Medicare patients and providers. Although I understand and support the efforts by CMS to prevent abusive practices, I believe the current proposals will extend beyond this worthy goal to hamper valuable and legitimate joint venture arrangements. I believe that CMS could address its concern in a much less intrusive manner.

As a urologist, I have seen firsthand the beneficial effects that joint ventures have had for the healthcare system. I have been involved with providing my patients lithotripsy and other cutting edge therapies for urological disease that would not have been widely available to my patients, including Medicare beneficiaries, unless physician joint ventures
had provided the services. By accepting the risk of providing these costly services when hospitals refused to do so, urology joint ventures have greatly expanded patient access to worthwhile and effective treatments. Yet the proposals in your 2008 Physician Professional Fee Schedule attack the substance of the very joint ventures that by all accounts have saved Medicare millions of dollars and increased beneficiary access to effective treatments.

It appears to me that the reason CMS wants to ban services under arrangements where there is Physician ownership is because it has heard of questionable diagnostic imaging arrangements. CMS does not identify any overuse or improper referrals for therapeutic services such as laser services and other urological procedures. Simple fairness would dictate that under arrangements should not be prohibited for services that would not otherwise be DHS but for being furnished in a hospital.

The incentive to over utilize present in diagnostic imaging services is not present for most other services furnished under arrangements where the referring physician also performs the professional portion of the referred procedure. Where urologists perform therapeutic
procedures, the referring physician receives a professional fee and the professional fee is greater than the distributions for any particular referred procedure that the physician will earn from his investments interest in the joint venture. The portion of the technical fee that he will earn in distributions from his investment in

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August 25, 2007

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

Dear Administrator:

As a member of the American Association of Nurse Anesthetists and a provider in a Critical Access Facility, I write to support the CMS proposal to boost the value of anesthesia work by 32%. Under CMS's proposed rule Medicare would increase the anesthesia conversion factor by 15% in 2008.If adopted, CMS's proposal would help to ensure that Medicare beneficiaries would continue to have access to anesthesia services provided by CRNA's as Medicare Part B providers.

Medicare currently under-reimburses for anesthesia services. MedPAC studies clearly demonstrate that Medicare Part B reimburses for most services at approximately 80% of third party payers, but reimburses for anesthesia services far below this at about 40% of third party rates.

Americas's CRNA's provide some 27 million safe anestheticts in the U.S. annually, and are the predominant providers to rural and medically underserved populations. Medicare patients and healthcare delivery depend on our services. The availability of anesthesia services depends in part on fair Medicare payment for those services. 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.

Most Sincerely-

Michele Hannon

Michele Hannon, CRNA
890 Mount Eustis Road
Littleton, NH 03561

August 26, 2007

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

Re: CMS-1385_P

Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

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

Most people do not understand the value of a good anesthesiologist; they are the ones that keep you alive! You can have a bad surgeon and survive if you have a good anesthesiologist. Chances are slim if that is in reverse. I know many doctors who do not want to take Medicare patients because they are underpaid in comparison to other specialties. It is simply not fair when you calculate the risk that is involved with anesthesia. We need the very best to take care of us because we are elderly and generally have multiple illnesses and risks that they must be liable for. They need to be paid at the same level as the surgeons. I am shocked that this has gone on for so long.

Your serious consideration of this serious matter would be greatly appreciated.

Thank you very much,

Margaret Abdo Karam

August 26, 2007

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

Re: CMS-1385_P

Anesthesia Coding (Part of 5-Year Review)

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Your serious consideration of this serious matter would be greatly appreciated.

Thank you very much,

Teresa Sammiguel

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August 26, 2007

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

Re: CMS-1385_P

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Your serious consideration of this serious matter would be greatly appreciated.

Thank you very much,

Emily V. Ellis

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August 21, 2007

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

Re: Medicare Program; Proposed Revisions to Payment Polices under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Rule

I am a concerned citizen and Physical Therapist Assistant. I have been practicing Physical Therapy under a Physical Therapist for 21 years. I worked for a major hospital in Ohio for 19 years, and I am currently working for a privately owned clinic.

I am fearful that Physician Owned Physical Therapy Services will not only negatively impact the practice of Physical Therapy for Physical Therapy Providers who are hospital based or privately owned, but also Medicare patients and the Medicare Program itself.

The potential for fraud and abuse exists whenever physicians are able to refer Medicare beneficiaries to services in which they have a financial interest.

The potential for over-utilization of Physician Owned Physical Therapy Services for financial gain is great.

Eliminating Physical Therapy as a designated Health Service under the In Office Ancillary Services Exception will reduce abuse and over-utilization of Physical Therapy Services which will save money for the Medicare Program and enhance the quality of care for the Medicare beneficiary.

Thank you for your consideration in this matter.

Sincerely,

Catherine DeBerti PTA

Catherine DeBerti, PTA
Northern Physical Therapy Services

APMA
American Podiatric Medical Association

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August 29, 2007

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:

On behalf of the American Podiatric Medical Association (APMA), the national association representing more than 11,000 podiatric physicians and surgeons, I am pleased to submit comments on a variety of issues addressed in the proposed rule published July 12, 2007, which proposed changes to the Medicare physician fee schedule (PFS) and other Medicare Part B payment policies.

Additional Codes from the 5 Year Review of Work RVUs

As discussed in the CY 2007 PFS final rule with comment period, CMS deferred for one year the decisions on proposed changes to the work RVUs for 58 codes from the 5 Year Review, either because they had not yet received the RUC recommendation or because CMS suggested that the RUC re-evaluate the original recommendation. These additional codes are still considered part of the 5 Year Review. CMS proposes to accept all but one of the RUC recommendations, an acceptance rate of 98 percent. We believe the high acceptance rate is a reflection of the RUC's competence in determining the value of physician work through a deliberative and equitable process that involves all specialties, including podiatric medicine. We are proud to be a part of this process and we commend CMS for recognizing the RUC's value in the ongoing maintenance of the physician fee schedule.

Included in the list of additional codes from the 5-year review are seven codes that describe initial nursing facility care, subsequent nursing facility care and an annual nursing facility assessment (CPT codes 99304-99310). Included in this family of codes are services that are commonly performed by podiatrists. We strongly recommend acceptance of the RUC recommendations in the final rule for these and other codes for which CMS proposes to accept the RUC's recommendations.

Proposed Conversion Factor Update for 2008

We continue to be concerned about the impact of the sustainable growth rate (SGR) formula on payments for services under the fee schedule. Ironically, any increases in work RVUs for the codes described above will be largely offset by the proposed -9.9 percent update of the conversion factor for 2008. While we do not have evidence of a significant increase in the number of podiatrists who have placed limits on new Medicare patients, we are concerned that could change if payments for all services are reduced nearly10 percent across the board in 2008. Clearly, if a reduction of this magnitude is put into place, beneficiary access to physicians' services will be adversely affected.

We urge CMS to use its 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 because 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. 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.

Budget Neutrality/Five-Year Review Work Adjuster

The Medicare statute requires that increases or decreases in relative value units (RVUs) for a year may not cause the amount of expenditures for the year to differ by more than $20 million from what expenditures would have been in the absence of these changes. In 2007, CMS created a new "work adjuster" to ensure budget neutrality following the implementation of the improved work RVUs from the 2005 Five-Year Review of the RBRVS, despite the vigorous opposition of virtually every specialty society. For 2008, again CMS proposes to apply a work adjuster (0.8816 or -11.8 percent) to all work RVUs to maintain budget neutrality rather than adjust the conversion factor.

We are opposed to the use of a work adjustor for the following reasons:

- It adds an extra element to the physician fee schedule payment calculation that creates confusion and questions among the public who have difficulty using the RVUs to determine a payment amount that matches the amount actually paid by Medicare
- Adjusting the work RVUs affects the relativity of services. For example, if the work RVUs are adjusted as proposed, it will disproportionately affect codes with physician work that are commonly performed by podiatrists, such as E/M services and surgical procedures.
- Adjusting the work RVUs has an adverse impact on other payers who use the Medicare RVUs and their own conversion factors.

We recommend elimination of the work adjustor and an adjustment of the conversion factor to maintain budget neutrality.

American Podiatric
Medical Association, Inc.

Physician Self-Referral Provisions

APMA believes the Stark law exists to eliminate incentives to make referrals for services to the Medicare program. Congress authorizes CMS to create exceptions so that the typical and desirable practice of medicine doesn't trigger a Stark violation. APMA encourages CMS to remember that some arrangements improve patient care or the efficiency of health care delivery more than they might create a risk for improper referrals. APMA is concerned that CMS will restrict practices that benefit patient care and health care delivery at a much greater level than they create a risk for incentivizing referrals. If CMS knows of outliers abusing the system with referrals, then CMS should use education and intervention first and, if necessary, then turn to criminal or civil law enforcement, to address the individual problem. CMS shouldn't change the rules merely on the theory that there could be abuse.

Therapy Standards and Requirements

CMS proposes updated qualification requirements for physical therapists (PTs), occupational therapists (OTs), physical therapy assistants (PTAs) and occupational therapy assistants (OTAs). CMS also proposes an expanded grandfathering policy under which PTs, OTs, PTAs or OTAs who meet their respective State qualifications (or have received State recognition as PTs, OTs, PTAs or OTAs) before January 1, 2008 would not have to meet these updated qualifications.

In the proposed rule, CMS states that "It is not our intention to modify the policy that requires physical therapy, occupational therapy, and SLP services furnished incident to a physicians service to meet all the standards and conditions (except licensure) that apply to therapists, as this policy is based on the section 1862(a)(20) of the Act. Rather, it is our intention to assure that Medicare payment is made only for physical therapy, occupational therapy, and SLP services provided by personnel who meet qualifications, including consistent and appropriate education and training relevant to the discipline, so that they are adequately prepared to safely and effectively treat Medicare beneficiaries."

We appreciate this clarification and support the proposed changes related to education and training. We also support the proposal to replace the current 30-day recertification requirement for outpatient therapy with a 90-day recertification requirement. The 30-day recertification requirement is an unnecessary burden that has not been shown to limit therapy services.

Percentage Change in the Medicare Economic Index (MEI)

The Medicare Economic Index (MEI) is a measure of the cost of providing medical care. The MEI values a "market basket" of inputs to the price of health care (salaries, equipment, services, etc) to assess annual changes in the price of health care. The MEI is used, in conjunction with the Sustainable Growth Rate formula to update the Medicare physician fee schedule on an annual basis. The proposed rule includes a preliminary estimate of the expected MEI update for CY 2008. The forecasted increase in the MEI is 1.9 percent, which includes a forecasted 1.5 percent productivity offset.

We object to the proposed 1.5 percent productivity offset which we believe is significantly overstated. The expansion of Medicare reporting requirements for PQRI (and other CMS initiatives) has reduced productivity in physicians' offices. As described below, we support the Physician Quality Reporting Initiative (PQRI). However, successful reporting requires a significant new commitment by physicians and their office personnel. We ask that CMS consider the adverse impact of the CMS reporting requirements on physician productivity when the final MEI is calculated for 2008 and reduce the size of the productivity offset.

Physician Quality Reporting Initiative (PQRI)

In Part II, Section T(c)(vii) of the proposed rule, the Centers for Medicare & Medicaid Services (CMS) proposes to include measures in the final 2008 Physician Quality Reporting Initiative (PQRI) quality measures selected from those listed in Table 22 that are currently under development by the American Podiatric Medical Association (APMA) and that achieve National Quality Forum (NQF) endorsement or American Quality Alliance (AQA) adoption by November 15, 2007:

- Diabetic Foot and Ankle Care, Peripheral Neuropathy: Neurological Evaluation
- Diabetic Foot and Ankle Care, Peripheral Arterial Disease: Ankle Brachial Index (ABI) Measurement
- Diabetic Foot and Ankle Care, Ulcer Prevention: Evaluation of Footwear.

Diabetes is the leading cause of lower extremity amputations, which are detrimental to a Medicare beneficiary's quality of life as well as expensive for the Medicare program. Despite widespread agreement among public health and medical experts that an amputation could be prevented if a patient with diabetes receives quality foot and ankle care, the number of amputations continues to rise. The three quality measures developed by the APMA would encourage physicians and other practitioners to evaluate diabetic patients for possible peripheral neuropathy, measure the ABI of diabetic patients for possible PAD, and evaluate footwear of diabetic patients to prevent ulceration. The evaluations and measurement can identify diabetic patients who have a particularly high risk of lower extremity complications. The identification of patients who need appropriate foot and ankle care would help address a gap in care that has allowed the number of amputations to increase. Thus, the APMA believes that these three quality measures should be included for reporting in the 2008 PQRI, and encourages CMS to facilitate approval of all three measures by the NQF or the AQA prior to November 15, 2007.

The proposed rule lists the measures in Table 22 as "Podiatric Measures." We respectfully request that the title be revised to "Diabetic Foot and Ankle Measures" so that other practitioners who treat diabetic patients will immediately recognize that these clinically important measures are available to them under the PQRI.

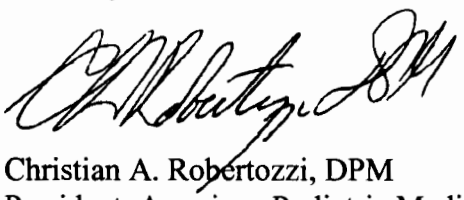
We greatly appreciate CMS' recognition of the APMA work in this area. We also commend the CMS staff who have worked closely with us to refine the measures and to have them considered for endorsement by the relevant organizations.

American Podiatric
Medical Association, Inc.

Conclusion

The APMA appreciates the opportunity to offer these comments. If you require additional information, please contact Rodney Peele, Assistant Director for Health Policy and Practice, at (301) 571-9200, extension 230.

Sincerely,



Christian A. Robertozzi, DPM
President, American Podiatric Medical Association

ETMC EMS

East Texas Medical Center
Regional Healthcare System

August 23, 2007

Leslie Norwalk, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
P. O. Box 8012
Baltimore, Maryland 21244-8012

Re: CMS-1385-P, Beneficiary Signature requirements
Title 42, Chapter IV, Part 424, Section 424.36

Dear Ms. Norwalk:

East Texas Medical Center Emergency Medical Service provides ambulance services to 17 counties covering over 17,000 square miles in rural and urban East Texas. We transport approximately 100,000 patients per year. We appreciate the opportunity to submit comments on the proposed rule. It would have a direct, significant impact on our operation.

With emergency transports, the patient is not in a condition to sign a claim authorization during the time the supplier is treating and/or transporting them. Many are in physical distress, unconscious, or of diminished mental capacity due to age or illness. Current rules allow us to submit claims on emergency transports as long as we document that the patient was unable to sign, the reason, and that no one could sign for the patient.

The proposed rule adds the additional requirement of 'a signed contemporaneous statement from a representative of the facility that received the beneficiary, which documents the name of the beneficiary and the date and time the beneficiary was received by that facility'. Though we believe the intent was to provide relief, it will actually impose an additional requirement that will be a difficult administrative burden with which difficult to comply.

A record of medical treatment, including the time and destination is completed by ETMC EMS at the time of transport. Every hospital already has the information on file that would be required by this proposed rule in their existing paperwork as well. Hospital personnel often refuse to sign and are involved in more pressing activities to sign a form when receiving a patient.

We request that the additional requirement for a facility signature be removed and that the requirement for any signature at the time of an emergency transport be eliminated entirely.

Thank you for your consideration of these comments.

Sincerely,

Anthony J. Myers
Vice President / Chief Operating Officer

P.O. Box 387 • Tyler, Texas 75710 • 352 S. Glenwood • Tyler, Texas 75702
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NorthSound
PHYSICAL THERAPY

"Your regional physical therapy provider of choice"

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

Dear Mr. Weems:

We are writing today to comment on the proposed 2008 Physician Fee Schedule Rule, published July 12, specifically the issues surrounding physician self-referral and the "in-office ancillary services" exception. Particularly, we want to express our sincere conviction that physical therapy must be removed from the "in-office ancillary services" exception to the federal physician self-referral laws.

As physical therapists, we are concerned with providing the best possible care for our patients, while considering the unique and individual needs of each. The company we work for in turn has demonstrated the same level of commitment and responsibility by striving to continue to provide a local service, with a high quality of care amid the ever growing presence of referral for profit centers and physician owned clinics. We recognize that our profession needs to continue to work towards autonomous practice settings where physical therapist owned clinics exist in order to meet the needs of the communities they serve.

Our objection to physical therapy being included in the "in-office ancillary services" is quite simple: it is bad business practice, and it is bad for the patient.

First, allowing physicians to refer to a service in which they have a financial interest creates a huge potential for over-utilization and, potentially, fraud. With financial incentives for referral, decisions cannot be made objectively and in the best interest of the patient. When the situation where profit is a motivating factor for referral is eliminated, the potential for fraud and over-utilization is eliminated.

Secondly, the current situation frequently places undue stress on the patient by forcing them to travel out of his/her way for treatment. Due to the frequent and repetitive nature of physical therapy services, convenience is paramount to the patient's recovery. Self-generated referrals by physicians to their own physical therapy clinics forces the patient to travel to locations, which are frequently in larger metropolitan areas, thereby avoiding the more convenient and local physical therapy providers. This is sometimes complicated by patient conditions that are negatively impacted by spending extra time traveling to physical therapy appointments, for example, lower back disc injuries. We have personally heard many stories from patients who have been asked to commute to other communities so they could attend physical therapy sessions at a physician-owned clinic.

Finally, this loophole reduces the quality of the service provided. Physical therapist-owned clinics stay in business by working to produce the best possible treatment and service options available. They

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Phone (425) 315-9500
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Lake Stevens ❑
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Everett, WA 98205
Phone (425) 334-1122
Fax (425) 334-1188

Marysville ❑
9516 State Avenue, Suite B
Marysville, WA 98270
Phone (360) 658-8857
Fax (360) 659-8296

Smokey Point ❑
3405 172nd Street NE, Suite 10
Arlington, WA 98223
Phone (360) 651-8880
Fax (360) 651-9975

Stanwood ❑
27500 102nd Avenue NW, Suite 1
Stanwood, WA 98292
Phone (360) 629-9768
Fax (360) 629-6487

work to recruit the best clinicians and employees to support their service goals. This system results in the best possible option for patients in need of physical therapy services, if they are given the freedom to select where they receive their care. If physical therapy remains an "in-office ancillary service" physicians will continue to have a captive referral base, and the service they provide will be based more around profit than quality. This system is more likely to result in a decreased level of service, less skilled clinicians, over-utilization of care, and the possibility that care will be provided by under-qualified providers.

In closing, Mr. Weems, we would like to thank you for your judicious consideration of these comments. All of us at NorthSound Physical therapy 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. If you should have any questions regarding this, please contact us at your convenience. Thank you.

Best regards,

Bart Hawkinson, DPT	Marty Stanton, PT	Karl Hedeen, PT
John Bielser, PT	Becky Rice, MS, PT	Sarah Ridley, DPT
Jenefer Mills, PT	Sheila VonBergen, MPT	Tracy Hartley, MPT
Stephanie Korfanta, DPT	Chancellor Norris, DPT	Janie Hett, DPT
Tony Johns, MPT	Victoria VanHorn, MS, PT	Gwen Gentes, PTA
Bonnie Spivey, PTA	Stacey Killian, PTA	Sue Pendleton, PTA
Amber Wright, PTA, LMP	Dan McBride, PTA	Miki Hatano, PTA

GYN PATH
Services, Inc.

August 27, 2007

Attn: CMS-1835-P
Centers for Medicare & Medicaid Services
P.O. Box 8018
Baltimore, MD 21244-8018

RE: Comments on Provisions of CMS-1385-P

To Whom It May Concern:

Thank you for the opportunity to submit comments on the 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 am in practice in El Paso, Texas, operating as an independent pathology laboratory.

RESOURCE-BASED PE RVUs: The only solution I will support at this time is a nationwide legislative solution that would provide additional funding for fair and equitable payment to Medicare participating physicians in every State.

GEOGRAPHIC PRACTICE COST INDICES (GPCIs): The only solution I will support at this time is a nationwide legislative solution that would provide additional funding for fair and equitable payment to Medicare participating physicians in every State. I do not support providing GPCI changes and/or increases solely for California.

PHYSICIAN SELF-REFERRAL PROVISIONS: I applaud CMS for undertaking this important initiative to end self-referral abuses in the billing and payment for pathology services. I am aware of arrangements in my practice area that give physician groups a share of the revenues from the pathology services ordered and performed for the group's patients. I believe these arrangements are an abuse of the Stark law prohibition against physician self-referrals and I support revisions to close the loopholes that allow physicians to profit from pathology services.

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

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

PERCENTAGE CHANGE IN THE MEDICARE ECONOMIC INDEX (MEI): The only solution I will support at this time is a nationwide legislative solution that would provide additional funding for fair and equitable payment to Medicare participating physicians in every State.

Respectfully,

Philip A. Miles, M.D., FACOG, FCAP
Medical Director

EASTON PHYSICAL THERAPY & SPORTS CARE

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

August 28, 2007

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).**

Dear Mr. Weems,

My name is Thomas J. Yoviene, Sr., my wife Michele and I own and operate 14 Outpatient Physical Therapy Offices in Maryland and Delaware. My wife has been a Physical Therapist for 18 years and I have been a Physical Therapist Assistant for 16 years. The biggest challenge and number one threat to my profession and livelihood is the issue of physician self-referral and the "in office ancillary services" exception provided by Stark II.

I live in the beautiful town of Easton, MD where I operate Easton Physical Therapy & SportsCare. Two years ago, the only orthopedic group in town decided to open their own Out-Patient Physical Therapy Center in a small corner room of their office. I immediately noticed a significant drop in patient referrals to my Easton office and needed to make staffing changes in order to maintain profitability and combat boredom. I began to spend a great deal of money on advertising in an effort to educate the public that they do have a choice of physical therapy providers. I spoke to the Primary Care Physicians in an effort to educate them on what was going on and that if they referred a patient to the orthopedic group that the patient will most likely not be referred to us if they needed Physical Therapy. The Orthopedic group would refer the patient to their own Physical Therapy. Then the patient complaints began. We live in "Small Town America" where everyone knows everyone. I received many phone calls at my home from past patients who stated," the MD told me to go to their place, they did not give me a choice". One patient told me that the MD stated "we don't work with that group anymore" I instructed the patients who called me that they had a right to choose their Physical Therapy provider and that they could switch. Unfortunately, it is not that simple. The patient looks at the MD as if they are GOD and listens to whatever the MD

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❑ 640 Shoal Creek Mall, Suite 2 • Cambridge, Maryland 21613 • 410.228.5100 • Fax 410.228.7479

says. The MD instructs the patient to go down the hall and schedule Physical Therapy immediately after the visit with the MD is finished. The patients felt uncomfortable asking the MD if they could switch providers after the fact because they felt as though they were questioning the MD. I have discussed this issue with one of my State Representatives who informed me that she had a bad experience with the same group however it had to do with her having an MRI at the Orthopedic groups office and not being given a choice of other MRI providers until after she had the MRI and a scheduling nightmare.

The Orthopedic Group has recently expanded their building for the sole purpose of housing a new in-office ancillary services physical therapy center. I will represent that there are 4 different Out-Patient Physical Therapy Centers including mine less than ¼ mile from the Orthopedic Groups office. Never once has one of the MD's expressed a concern to me regarding quality of care issues, lack of communication issues, billing issues, convenient appointment times or facility issues. Why then with all of those quality Physical Therapy providers in the area did the Orthopedic Group decide to open their own Out-Patient Physical Therapy Office?

Stark laws have unfortunately been misconstrued by many and created a thriving environment for fraud and abuse. Stark laws have opened the doors for physicians to profit from owning ancillary services thus limiting consumer choice, driving up health care costs, creating an anti-competitive market and causing unnecessary hardships for private practitioners.

As Arnold Relman, MD, editor emeritus of the New England Journal of Medicine, said, "Medicine is a profession and should remain so. In the practice of medicine it is unprofessional and unethical to make money from services not directly provided or supervised." Please read the quote again, the quote says it all!

I strongly support any effort to eliminate abusive financing arrangements under the Stark law that was created solely for profit without regard to the best interest of the Medicare beneficiary. I strongly request that CMS removes Physical Therapy as a designated health service (DHS) permissible under the in-office ancillary exception of the federal physician self referral laws.

Thank you for your consideration of my comments, if you have any questions or comments, please do not hesitate to call.

Sincerely,

Thomas J Yoviene, Sr., PTA, Owner

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VBS Vaughn, Buchanan, Shelley & Associates,
Physical Therapists, Inc.

August 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

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:

As a licensed physical therapist in South Carolina for the past 36 years and a provider of physical therapy under the current Medicare Program, I am writing to express my concerns with regards to the Physician Self-Referral Issues.

It is my personal observation that over-utilization of physical therapy services occurs when physicians are allowed payment by Medicare for designated health services (DHS). Physician owned physical therapy services, in my opinion, provide the potential for fraud and abuse.

During the past 15 years, I have, as a principal in a physical therapist owned practice, seen our patient census decrease as much as 50% in a particular clinic due to an orthopaedic group practice who decided to open their own physical therapy clinic. These physicians, who previously indicated that they preferred to send patients to our clinic because of the quality of care, suddenly refer 95% of their patients to their own clinic. Moreover, patients whom we have provided care for in our clinics previously no longer have a choice as to where to be treated; they are simply referred to the physician owned clinics. Competition in the market place is eliminated.

In South Carolina, the code of law governing the practice of Physical Therapy was recently amended to prohibit a physical therapist from being employed by a physician which has been helpful in eliminating some of the potential problems with referral for profit.

The Medicare "in-office ancillary services exception" or designated health services (DHS), which is so broadly defined, has created a loophole for the expansion of physician owned physical therapy arrangements.

Therefore, please consider eliminating physical therapy as a designated health service furnished under the in-office ancillary services exception. In my opinion, eliminating physical therapy as a DHS would reduce program abuse through over-utilization of physical therapy services under the Medicare program. More importantly, the quality and efficiency of care for the Medicare beneficiary will improve.

Thank you for your consideration of my comments oN this very important matter.

Sincerely,

Fred S. Buchanan, PT, ECS
SC License #199

FSB/bsm

Richmond Lenox E.M.S.
Ambulance Authority

34505 32 Mile Road
Richmond, Michigan 48062
(586) 727-2184

Centers for Medicare and Medicaid Services

Department of Health and Human Services

Attn: CMS-1385-P

PO Box 8018

Baltimore MD 21244-8018

On July 12, 2007, the Centers for Medicare and Medicaid Services (CMS) issued a Proposed Rule regarding Medicare patient signature requirements for ambulance services. The Proposed Rule is actually contained in a much larger document that also contains changes to the Physician Fee Schedule.

The Proposed Rule would allow ambulance providers to submit a claim to Medicare without an "assignment of benefits" signature from the patient when the patient is unable to sign, provided that: (1) no other authorized signer was available or willing to sign; and (2) the ambulance service maintains documentation in its files for a four-year period including:

(i) a "contemporaneous statement" from an employee of the ambulance service that none of the authorized signers were available or willing to sign;

(ii) a "signed contemporaneous statement from a representative of the facility that received the beneficiary, which documents the name of the beneficiary and the date and time the beneficiary was received by that facility"; and

(iii) Documentation with the date and time the beneficiary was transported, and the name and location of the facility that received the beneficiary.

While items (i) and (iii) appear more than reasonable, there is little doubt that the second requirement - a signed statement from a representative of the facility that receives the patient - will generate a great deal of hardship for EMS Agencies. Therefore as a local Township owned EMS Provider Richmond Lenox EMS would request, you reconsider this requirement.

Thank you for your consideration of our comments,

Jeffery R. White

Chief of Emergency Medical Services

438

August 17, 2007

The Honorable Senator Jim Bunning
316 Hart Senate Office Building
Washington, D.C. 20510

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

Dear Senator Bunning:

I have been treated for skin cancer with Mohs Micrographic Surgery, a specialized procedure that has the highest cure rate of all treatments for skin cancer. Since I have already had one cancer, I have a 40% chance of another new cancer within the next 5 years. As such, I have become concerned that, in view of a recent change proposed by Medicare, in the future it will no longer be cost effective for my doctor to perform other procedures such as biopsies on the same day as Mohs surgery or to treat more than one cancer per patient per day. It is my understanding that a proposal to remove Mohs surgery from the list of procedures exempt from the Multiple Procedure Reduction Rule will result in a 50% reduction in reimbursement for procedures performed on the same day as Mohs. In many cases, such a reduction would not cover the costs of providing the additional procedures, making it difficult for my doctor to perform more than one procedure for me on the same day.

Such a change would represent a costly inconvenience for skin cancer patients such as me. The need for a biopsy before surgery, which is currently often done on the same day as Mohs, would require an additional trip to the doctor. Also, as many as 10% of skin cancer victims have two or more skin cancers diagnosed at the same time; while currently treated on the same day, in the future two or more trips would be required, delaying treatment and increasing risk. Obviously, the cost in transportation, personal time, and time off work for multiple visits is considerable, not to mention the added inconvenience and risk.

Please consider these extra and unnecessary burdens on Medicare patients that this recent Medicare proposal would cause. On behalf of more than one million skin cancer patients per year across the United States, I respectfully request that you do everything possible to reverse this proposal which restricts my access to cost effective and timely care for my cancer. It is my understanding that the contact person at CMS for this issue is Mr. Terrence Kay (Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244-1850, toll-free telephone: 877-267-2323).

Sincerely,

B. Franklin Simpson 8/30/07
Signature Date

B. Franklin Simpson
Name (print)

/ Teacy Lane
Street Address Apt. #

Williamstown, Ky. 41097
City State ZIP +4

859-824-4627
Phone

Bradley J. Thomas, M.D.
PO Box 2509
Truckee, CA 96160

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

Dear CMS:

I strongly support the proposed rule to boost the anesthesia conversion factor for Medicare payment. As an anesthesiologist, I have been frustrated for many years over the dramatic undervaluation of my medical services by CMS. Medicare patients are aware of this situation as well. (Please read the enclosed typical letter from one of my patients.)

While I am sensitive to the serious funding challenges faced by the Medicare program, I believe our senior citizens would support this modest and long overdue increase. As a practicing anesthesiologist, I believe it is certainly the right and fair thing to do.

Respectfully,

Bradley J. Thomas MD

Bradley J. Thomas, M.D.

439
attachm

Dr Bradley J. Thomas, MD
P. O. Box 34120
Reno NV, 89533-4120

January 20, 2005

Dear Doctor Thomas,

You may recall that you were the attending anesthesiologist when Doctor Dodd repaired my broken femur bone on February 6, 2004. My injury was sustained from a skiing accident earlier that same day. You and I met prior to the surgery, and you may remember me because I mentioned that I did not want a spinal tap.

I understand the surgery lasted for over three hours and, while routine in nature, it was still a serious surgery because of the specific kind of injury and the fact that I had been under the influence of blood thinners for atrial fibrillation.

Throughout the entire surgery procedure you attended to me and, quite frankly, my life was in your hands.

Subsequent to your medical care for me, you submitted a bill to Medicare for $910. As it turned out, Medicare only approved $245.23 for your services.

I write you this letter because I truly believe your compensation by Medicare was incredulous! The skill you performed on my behalf was worth far more than $245.23.

To put matters into perspective, had you been a plumber and called to the hospital to make a four hour plumbing repair, you would have been paid much more than $245.23.

While I realize nothing can be done at this juncture, I wanted to let you know my feelings about this matter and express my gratitude for a job well done.

Regards,
Dave Stoner

588 Trumbull Court
Sunnyvale, CA 94087

cc: Medicare

KEYSTONE
REHABILITATION
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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: Physician Self-Referral Issues

Subject: July 12 proposed 2008 physician fee schedule rule and the in-office ancillary services

To Whom It May Concern:
I am a Physical Therapist Assistant in the state of Ohio. My experience in 7 years has been in a variety of settings. I am currently the Facility Director in an outpatient clinic. Since the start of self-referrals and "in-office ancillary services" we have seen a decline in our patient caseload. As physical therapists we strive to provide quality care for each individual and achieve functional goals to improve the quality of life for that patient.

In speaking with numerous clinicians they have witnessed overuse of therapy services beyond what is necessary for a particular diagnosis. 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. The care continuum offered in the outpatient setting is far more advanced and equipped to provide advanced care for a variety of conditions and in an efficient time frame. This type of care reduces health care costs to the payor and demonstrates their best interest in the patient rehabilitation for long term benefits. 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. 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. I firmly believe that all therapists pride themselves in the ethical administration of health care and this type of practice lacks consideration of ethical standards.

I would like to thank you for your consideration of our concern in this matter.

Sincerely,

Erin Quinlan PTA

Erin Quinlan, PTA

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YORK UROLOGIC ASSOCIATES

JOEL CORNFIELD, M.D. JOHN KRITSAS, M.D.
SAMUEL KRENGEL, M.D. JAY HWANG, M.D.

950 NORTH YORK ROAD, SUITE 208
HINSDALE, ILLINOIS 60521
(630) 887-0580

August 22, 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

To Whom It May Concern:

I am a board certified urologist and have been in private practice in Hinsdale, IL for the last 19+ years. I also have clinical teaching appointments at the University of IL- Chicago and Midwestern University in Downers Grove IL. Over that time, I have been involved in a number of joint ventures, all of which have complied with the burgeoning Stark regulations.

Needless to say, I am somewhat disturbed by the recent CMS proposals regarding changes in these regulations.

It is my understanding that CMS would prohibit a hospital from billing Medicare for any referrals made by a physician for designated health care service provided by the hospital if the service is provided to the hospital under arrangement by the physician or an entity in which the physician is an investor. This will effectively prevent hospital and physician joint ventures. Yet, such joint ventures have been able to offer valuable state of the art services to the community at large while both lowering costs and improving care. There seems to be an assumption implicit in these proposed changes that physicians and hospitals are intrinsically dishonest, functioning only in a fashion that one would anticipate from a heartless market.

Nothing could be further from the truth.

Further, I understand that the burden of proof as to whether or not there has been a violation of Stark laws will fall on the accused as opposed to the accuser. This offends my sense of justice and appears to represent a potential civil rights violation.

I understand and am sympathetic to the fact that there have been abuses of Medicare, Medicaid patients and indeed the general public in the past. However, I believe that enforcement efforts should be focused on weeding out those people who are indeed bad actors as opposed to preventing basically altruistic attempts at providing services at relatively inexpensive prices and very high quality from taking place.

YORK UROLOGIC ASSOCIATES

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It is with great and heartfelt despair that I see these regulations being foisted upon us, the unintended consequence of which will make access to care more difficult, time consuming and furthermore enable those individuals who are not physicians, who do not have the patient's interest at heart and who operate solely through the rules of capitalism to enjoy the fruits of both physician and hospital labor.

I would strongly urge that these new regulations be aborted and in fact, that the Stark regulations as a whole be revisited.

Sincerely,

Joel Cornfield, M.D.
JC:hss/jw

Cc: Senator Dick Durbin
Senator Barack Obama
Representative Judy Biggert
Representative Mark Kirk

PHYSICIAN SELF-REFERRAL ISSUES

I am addressing this issue as a patient, not a therapist. I have been concerned for several years as some physicians whom I have seen, prescribed physical therapy to be given at facilities that they or their medical groups owned.
This is obviously a major conflict of interest and is creating a tremendous drain of funds on Medicare and Medicaid.
Therefore, I deem it of utmost importance that Physical therapy be removed from the "in office ancillary services" exception to the federal physicians self-referral laws.

Please consider this confidential I do not want my name used in any way.

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Center for Urologic Care
a division of
Delaware Valley Urology, LLC
www.dvullc.com

Randy B. Ackerman, MD
Michael R. Bernstein, MD, FACS
Robert J. Biester, MD, FACS
Rajen P. Butani, MD
Karl H. Ebert, MD
Mark L. Fallick, MD, FACS
Louis L. Keeler III, MD, FACS
Evan B. Krisch, MD, FACS
Thomas C. McNamara, MD, FACS

August 21, 2007

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

RE: Physicians Self-Referral Provisions
CHART#:

Ladies and Gentlemen:

I am a practicing urologist in Southern New Jersey and part of a recently formed Integrated Medical Group, Delaware Valley Urology. It has come to my attention that CMS is considering revising the Stark Law, and I am certainly supportive of ending abuses that are not in the best interest of the patient or the Health Care System, but in doing so, there are many beneficial arrangements that should not be affected. I think you need to look at lithotripsy arrangements as a model so what should be done. Our Lithotripsy Center in South Jersey is composed of multiple urologists most of who are in large groups. It is quite clear what patients need lithotripsy and what patients do not. There is an internal quality assurance program to look for abuses. Profits from the Center are distributed to the physician independent of cases performed or referrals to the Center. This is an arrangement which benefits patients and hospitals. There are a number of smaller hospitals that cannot afford to provide this service if they were not on a per case basis. There may be arrangements, which result in abuse and overuse, but lithotripsy is not one of them. Going forward, I hope you look at the participation in the Ancillary Services, such as laboratory and radiation therapy that large groups such as ours is considering as not increasing the overall dollars spent on Health Care. We are attempting to garner some of the financial benefit that a third party (CMS) derives the profit. I know there are a number of issues, which the details I do not qualify to discuss. I hope you understand that the majority of Urologists in Private Practice are honest and decent individuals and treat our patients as we would treat our family. A fair profit is reasonable, but abuse and fraud is certainly not acceptable.

Sincerely yours,

Karl H. Ebert, M.D.
KHE/prb/soy/KE 0078

Centennial Medical Center
502 Centennial Blvd., Suite 2
Voorhees, NJ 08043
(856) 751-7772
Fax (856) 751-5328

301 White Horse Pike
Haddon Heights, NJ 08035
(856) 547-1115
Fax (856) 547-0283

Woodbury Medical Center
17 W. Red Bank Ave., Suite 204
Woodbury, NJ 08096
(856) 845-6655
Fax (856) 845-5170

The Health Center at Sicklerville
485 Williamstown Rd
Sicklerville, NJ 08081
(856) 237-8035
Fax (856) 237-8039

Submitter : **Miss. Krista Scronce** **Date: 08/27/2007**

Organization : **NATA**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

I am a senior Athletic Training Major at UNC-Charlotte.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Krista Scronce

Submitter : **Mr. Bryan Voracek** **Date: 08/27/2007**

Organization : **Mr. Bryan Voracek**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

My name is Bryan Voracek. I am a Certified Athletic Trainer with 8 years of experience working in the health care field. I have a 4-year bachelor's degree plus over 240 hours of continuing education. I work in an outpatient rehabilitation clinic and at the local high school.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Bryan Voracek, ATC

Submitter : **Date: 08/28/2007**

Organization :

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Physician owned physical therapy practices are taking over in my town of Columbus, Ohio. The most recent group to go in house is a group of over 25 physicians. I have spoke with managers and therapists that are working at the POPS facility. I am told about over utilization of services, increased referrals from physicians who previously did not believe in therapy, an use of unlicensed staff.

I know of another group of local family physicians that also decided to have in house therapy. They will only send to out consults to orthopedic physicians that will send the patient back to them for their physical therapy.

Stark laws need revision to correct this loophole. It is affecting patients, healthcare costs and utimately my profession.

CMS-~~3188-NC-4~~ 1385-P

Submitter : Mr. Jay Mellette **Date:** 08/28/2007

Organization : Cirque Du Soleil

Category : Other Health Care Professional

Issue Areas/Comments

Background

Background

Dear Sir or Madam:

My name is Jay Mellette. I am a Certified Athletic Trainer and the Health Services Manager for Cirque du Soleil. As a medical practioner I am blessed to be employed by a company that values the professional services I offer as an Athletic Trainer. I manage a team of 20 full time Athletic Trainers and Physical Therapists; and the high level of medical care provided by from Allied Health professions is extraordinary. This model, of equally employing both sets of medical professionals, Athletic Trainers and Physical Therapists, brings great diversity and strength to the rehabilitative medicine and services we provide our patients.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,
Jay D Mellette, ATC

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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

2606 Creek Ridge Lane
Chapel Hill, NC 27514

August 27, 2007

Dear Administrator:

The shortage of nurses is one of our nation's most serious health care problems today, and it threatens to grow even worse. For many years now, low pay and long hours have deterred many young people from entering this noble profession.

On behalf of America's 36,000 Certified Registered Nurse Anesthetists of which I am one, I urge you to support the Centers for Medicare & Medicaid Services (CMS) proposal to increase the value of anesthesia work by 32%. Adoption of this proposal will ensure that nurse anesthetists as Medicare Part B providers can continue to provide Medicare beneficiaries with access to skilled, high quality anesthesia services.

If this proposed change is not enacted, the vital services rendered by nurse anesthetists will be degraded 17% below 2006 payment levels. This would not only affect the availability of anesthesia services for Medicare patients, but would further exacerbate nurse pay levels and discourage others from entering the profession. In addition, consider the fact that while Medicare Part B reimburses for most health care services at approximately 80% of private market rates, it has seen fit to reimburse nurse anesthesia work at 40% of private market rates.

As a proud member of the nursing profession for more than 15 years, I urge you to approve the proposed 15 percent increase in 2008, thereby putting nurses on an equal value level with other health care providers and taking a step forward in making nursing a more attractive career option.

Very Truly Yours,

Shirley Sue Sopko, BSN, MSN, CRNA

CGFNS INTERNATIONAL
3600 Market Street, Suite 400, Philadelphia, Pennsylvania 19104-2651 U.S.A.
Phone: 215.222.8454 • Web: www.cgfns.org

VIA EXPRESS MAIL

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

RE: COMMENTS ON PROPOSED RULE CMS-1385-P

Dear Ms. Norwalk:

CGFNS International submits the following comments on the Proposed Rule CMS-1385-P, which was published on July 12, 2007 in the Federal Register at Volume 72, at page 38160, on the subject of "Proposed Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Changes to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008, and the Proposed Elimination of the G-Prescribing Exemption for Computer-Generated Facsimile Transmissions".

Our comments are focused specifically on the provisions of section 484.4 of the Proposed Rule, regarding "Personnel Qualifications." Our comments may be briefly summarized as follows:

- The regimen proposed in section 484.4 for establishing the credentials of the five categories of healthcare professionals covered by section [illegible] is duplicative and needlessly complex;
- For persons educated within the United States, presentation of a state license provides sufficient documentation of the individual's credentials and qualifications;
- For persons educated outside the United States, licensed by the US military, the regulation should be revised to include the individual's state license and presentation of [illegible] in accordance with the requirements of Federal immigration law by either CGFNS (for all covered professions), or NBCOT (for occupational therapists) or the PCC (for physical therapists). These three organizations have been specifically approved to provide this credential-verification function in regulations published by the Department of Homeland Security.

As we will describe in greater detail below, Federal immigration law has already established a process by which the credentials of foreign healthcare professionals are reviewed, verified and certified before these professionals may be granted authorization to enter the United States on an occupational visa. We

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believes that this verification and certification process, which is carried out by CGFNS International and the other "equivalent" organizations named above, can be effectively utilized in this context to eliminate duplicative and/or multi-tiered requirements and satisfy the certification of professional qualifications that Section 484.4 is seeking to ensure.

The Regimen Proposed in Section 484.4 duplicative and needlessly complex; For Persons Educated within the United States, presentation of a valid State License should be sufficient.

CGFNS will not make its own arguments in support of this point, as we believe that other commenters will make the same or a similar point in considerable detail. It would not serve a useful purpose to duplicate the comments that we expect others will offer on this point. We note only that we offer our support for the point of view that a valid state license should be sufficient in the occupations of occupational therapist, physical therapist and speech-language pathologist. A valid state license should also be sufficient in the occupations of OT assistant and PT assistant, if licenses are granted in those fields.

In the case of persons educated outside the United States or trained by the U.S. military, Section 484.4 should require a state license and a CGFNS VisaScreen certificate, or similar certificate issued pursuant to the immigration laws at 8 U.S.C. 1182(a)(5)(C).

B. CGFNS International Has Thirty Years of Experience in Evaluating the Credentials/Qualifications of Foreign Healthcare Professionals, Has been Designated by Congress and the Department of Homeland Security to Examine, Verify and Certify the Credentials of Foreign Professionals Coming to Work in the U.S.

CGFNS International is a not-for-profit corporation based in Philadelphia, PA, which has for the past 30 years examined, verified and certified the credentials of foreign-educated health care professionals. CGFNS International (formerly known as the "Commission on Graduates of Foreign Nursing Schools" and hereafter referred to as "CGFNS") has been statutorily designated in Federal immigration law to certify the credentials of foreign health care professionals (other than physicians) who are seeking to enter the United States to work as health care professionals in the United States. Its jurisdiction under this statutory mandate (8 U.S.C. Section 1182(a)(5)(C)) includes the professional categories of nurse, occupational therapist, physical therapist, speech language pathologist and audiologist, physician assistant, medical technologist (also known as "clinical laboratory scientist") and medical technician (also known as "clinical laboratory technician").

The Federal immigration statute requires that before a foreign (i.e., non-U.S. citizen) healthcare professional in any of the seven specified occupations can be granted a work visa or work authorization as a Lawful Permanent Resident ("green-card holder"), CGFNS (or an equivalent organization, see "B" below) must review that individual's credentials and certify that:

"(i) the alien's education, training, license and experience –

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(II) meet all applicable statutory and regulatory requirements for entry into the United States under the [employment] classification specified in the application;
(III) are comparable with that required for an American health-care worker of the same [employment] classification; and
(IV) are authentic and, in the case of a license, unencumbered [by disciplinary or similar action];
(ii) the alien has the level of competence in oral and written English . . . appropriate for the [employment] of the kind in which the alien will be engaged . . .; and
(iii) if a majority of States licensing the profession in which the alien intends to work require a test predicting the success on the profession's licensing or certification examination, the alien has taken such a test or has passed such an examination."

In carrying out these statutory requirements, CGFNS:

- Obtains direct from the source a copy of the foreign health care worker's transcript of professional education;
- Verifies that that education is comparable to that required of an American health care worker in the same field;
- Requests and obtains verification of licensure from the foreign licensing authority, and determines whether the individual's license is authentic and unencumbered;
- Obtains proof of the applicant's English language proficiency as tested by designated tests of English language proficiency approved by the Department of Homeland Security and the Department of Health and Human Services, with advice from the Department of Education;
- In the case of nursing applicants, CGFNS requires evidence of passage of either the NCLEX Qualifying Exam or the NCLEX-RN exam.

Once an applicant has met these requirements, the International Commission on the Healing Professions ("ICHP"), a division of CGFNS, issues a "VisaScreen"™ certificate. The VisaScreen certificate is valid for a period of five years from date of issuance.

Federal Regulations issued by the Department of Homeland Security outlining CGFNS International's authority and responsibility under this legislation can be found at 8 Code of Federal Regulations 212.15.

C. Other Organizations Have also Been Authorized to Certify the Credentials of Occupational Therapists and Physical Therapists.

The Department of Homeland Security ("DHS"), in the Federal Regulations cited immediately above, has also authorized the National Board for Certification in Occupational Therapy ("NBCOT"), in addition to CGFNS, to conduct the credentials review and certification in the field of occupational therapy. DHS has also authorized the Foreign Credentialing Commission on Physical Therapy ("FCCPT"), in addition to CGFNS, to conduct the credentials review and certification in the field of physical therapy.

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In the case of nurses and the four other healthcare professions covered by the [illegible] requirement and listed above, CGFNS is the sole certifying authority. (8 CFR 212.15(c))

Comments on Section 484.4 "Personnel Qualifications" of the Proposed Rule.

CGFNS believes that this process for the review, verification and certification of the credentials of non-U.S. citizen healthcare professionals, already well established in the Immigration and Nationality Act (the nation's immigration law), offers to CMS a useful tool for establishing and documenting the credentials of healthcare professionals educated outside the United States, as CMS is seeking in Section 484.4 of the Proposed Rule.

Section 484.4 deals with five occupations: Occupational therapist; occupational therapy assistant; physical therapist; physical therapy assistant; and speech-language pathologist.

CGFNS issues VisaScreen certificates for three of those occupations: occupational therapist, physical therapist, and speech-language pathologist. Federal immigration law does not authorize CGFNS to issue VisaScreen certificates for OT assistants or PT assistants. CGFNS has the capacity, however, to examine the credentials of such workers and verify whether they are comparable to the credentials of a US-trained worker in these professions, if that is the desire of CMS.

Federal immigration law requires CGFNS to issue its VisaScreen certificates to non-U.S. citizens, regardless of whether they received their professional education outside or inside the United States. In the context of Section 484.4, however, CGFNS believes that the most important and best use of the VisaScreen certificate is to require that it be presented by all persons educated outside the United States, if those persons began their U.S. practice on or after January 1, 2003. The Department of Homeland Security issued its Final Rule designating CGFNS and the other named organizations to examine, verify and certify the credentials of non-U.S. citizen healthcare professionals in this rule, which took effect on this date. This rule is found at 8 C.F.R. 212.15.

CGFNS believes that its VisaScreen certificate provides reliable and Federally-mandated documentation of precisely the sort of information that CMS is seeking to obtain from healthcare workers educated outside the United States or trained by the U.S. military. To be specific, requiring that such a worker present a VisaScreen certificate would establish, for both the worker and CMS, the following facts:

- That CGFNS has obtained, examined and assessed documentation regarding the worker's education, training, license and experience, and has determined that the worker's education, training, license and experience–

a) meet all applicable statutory and regulatory requirements for entry into the United States under the appropriate employment classification;

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- [illegible] comparable with that required for an American health-care worker of the [illegible]
- [illegible] authentic and, in the case of a license, unencumbered by disciplinary or similar [illegible]
- That the worker has a work-appropriate level of competence in oral and written English, as established by the worker's scores on standardized English language proficiency tests designated by the Secretary of Health and Human Services in consultation with the Department of Education.

Those are the critical facts which the VisaScreen (or equivalent) certificate establishes. We believe that requiring such a VisaScreen certificate from a healthcare professional educated outside the U.S. is a simple and ideal way to establish the worker qualifications that CMS is seeking to establish in Section 484.4.

CGFNS therefore proposes that that CMS inserts at the appropriate place in the Proposed Rule that a worker educated outside the United States [illegible] by the U.S. military presence [illegible] possess and:

> "an authentic VisaScreen certificate in the [illegible] (occupation) [illegible] five years by the International Commission [illegible] Healthcare Professions, a division [illegible] International, under the authority of 8 U.S.C. [illegible](5)(C), or an equivalent [illegible] by a credentialing organization authorized [illegible] Department of Homeland [illegible] statutory authority of 8 U.S.C. 1182(a)(5)(C)."

B. Federal Law Mandates that Healthcare Credentialing Organizations be "[illegible] no conflicting interests.

Federal regulations require that uncertified [illegible] health care workers be certified [illegible] or an equivalent "independent credentialing organization." (See 8 U.S.C. Code section [illegible]. To qualify as a credentialing organization under federal [illegible] regulations, certifying organizations must be "independent of any organization that functions as a representative of the occupation or [illegible] question or serves as or is related to a recruitment [illegible] organization." (See 8 C.F.R. [illegible] (k)(1)(ii) (A) -(D)).[2] Furthermore, the rule provides that "the DHS shall not approve an [illegible]

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[1] The comparability of Philippine Nursing licenses to U.S. licenses has recently proved important to [illegible] patient safety. Pursuant to CGFNS's actions, it was determined that over 4,000 Philippine nurses had improperly passed a Philippine exam that had been marred by exam fraud.

[2] (k) Standards for credentialing organizations. . . . . All organizations will be reviewed, including CGFNS, to ensure that they continue to meet the standards required of all credentialing organizations, under the following:

[illegible] is unable to render impartial advice regarding an individual's qualifications regarding training, experience, and licensure."

The purpose of this immigration rule is to avoid vesting the accreditation or certification process in a U.S. trade and professional organization that would have an economic interest in keeping foreign trained individuals out of the profession. In addition, professional and trade organizations have conflicting interests to protect and serve its members, *and* service the interests that are extrinsic to the purposes and aims of CMS. Therefore, these organizations would not be able to render "impartial advice" as required by federal regulations.

The proposed CMS rule appropriately vests accreditation authority for occupational therapists in the World Federation of Occupational Therapists, and credentialing authority in the National Board for Certification in Occupational Therapy (NBCOT), both independent organizations for occupational therapists that are not directly connected to a professional or trade association of occupational therapists.

However, the proposed rule inappropriately grants certifying authority for physical therapists to the American Physical Therapy Association (APTA), an organization that is *not* independent for purposes of the federal regulations. The APTA is the leading national professional organization representing physical therapists in the United States. The APTA website notes that the APTA has more than 66,000 members and that its "goal is to lead advancements in physical therapy practice, research, and education." Furthermore, its website states that the APTA is "the principal membership organization representing and promoting the profession of physical therapy."[3] Clearly, the organization "functions as a representative of the occupation" and therefore, cannot be [illegible]

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(1) Structure of the organization. (i) The organization shall be incorporated as a legal entity. (ii)(A) The organization shall be independent of any organization that functions as a representative of the occupation or profession in question or serves as or is related to a recruitment/placement organization.

(B) The DHS shall not approve an organization that is unable to render impartial advice regarding an individual's qualifications regarding training, experience, and licensure.

(C) The organization must also be independent in all decision-making matters pertaining to evaluations and/or examinations that it develops including, but not limited to, policies and procedures; eligibility requirements and application processing; standards for granting certificates and their renewal; examination content, development, and administration; examination cut-off scores, excluding those pertaining to English language requirements; grievance and disciplinary processes; governing body and committee meeting rules; policies about qualifying for a certificate and its renewal; setting fees for application and all other services provided as part of the screening process; funding, spending, and budget authority related to the operation of the certification organization; ability to enter into contracts and grant awards; ability to demonstrate adequate staffing and management resources to conduct the program(s) including the authority to approve selection of, evaluate, and initiate dismissal of the chief staff member.

(D) An organization whose fees are based on whether an applicant receives a visa may not be approved.

[3] See American Physical Therapy Association (APTA) website at http://www.apta.org/AM/Template.cfm?Section=About_APTA&Template=/TaggedPage/[illegible]41&ContentID=23725

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[illegible] credentialing authority. Furthermore, APTA has an economic interest to [illegible] physical therapists do not enter the profession and has a conflict of interest in [illegible] and serving the interests of CMS. Therefore, the APTA does not qualify as an [illegible] credentialing organization under federal immigration law, and it would be unwise to provide [illegible] such authority for Medicare or Medicaid payment purposes.

CGFNS therefore proposes that the appropriate independent organizations within the [illegible] therapy profession be referenced in the Proposed Rule as follows:

1. Proposed changes in the language re Physical Therapists

(I) Requirements for individuals beginning [illegible] practice on or after January 1, 2008.

(ii) If educated outside the United States or trained by the United States military--

(A) Graduated after successful completion of an education program that, by a credentials evaluation process approved by the Federation of State Boards of Physical Therapy or its credential subsidiary, the Foreign Credentialing Commission on Physical Therapy, or the International Commission on Healthcare Professions, a division of CGFNS, as allowed under 8 C.F.R. §212.15 (e)(1), is determined to be comparable to a United States physical therapist entry level education program in the United States; and

(B) Passed the National Examination approved by the Federation of State Boards of Physical Therapy or its credential subsidiary, the Foreign Credentialing Commission on Physical Therapy, as allowed under 8 C.F.R. §212.15(e)(1).

Conclusion

Our proposed amendments are necessary to help CMS and the foreign healthcare workers establish the credentials that CMS has required in section 484 and to maintain the [illegible] impartiality of independent credentialing authorities.

Sincerely,

Barbara Nichols

Barbara L. Nichols
Chief Executive Officer
[illegible]

450

Centers for Medicare and Medicaid Services :
Attention: CMS-1385-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 221244-1850

8/29/07

Ladies and Gentlemen:

As a practicing urologist in the counties of Camden and Gloucester, NJ, I am writing to you to express my concern about certain proposals made by CMS regarding Medicare, that will unduly and unnecessarily harm patients and physicians and have a detrimental effect on our healthcare system.

Proposed revisions would dramatically alter the ability of physicians to form partnerships that own medical equipment and provide services to their patients through arrangements with local hospitals. CMS's rationale for the proposed changes is that physician ownership is "corrupting medical decision-making". This rationale is what I find most insulting to the ethic standards of my profession. I have been providing lithotripsy services to all my patients, including Medicare beneficiaries, for whom it is medically indicated regardless of my financial arrangement, because it is the most effective, safe, and cost-efficient method. It is not available at my hospital and it receives patients from all of southern New Jersey.

Proposals are so broad that they would ban legitimate arrangements for therapeutic services that are not otherwise designated health services only because they are performed in a hospital setting. It seems CMS takes the view that physicians who invest in these ventures do so at the expense of good patient care. I believe that, at least for the urologic joint ventures, the primary purpose of physician investment is to improve patient care, and access to care. The costs of these procedures don't change but the profit shifts to the physician, instead of to a for-profit company whose bottom line is strictly making money. Partnerships with physicians would insist upon the highest standards of quality patient care. These joint ventures also diffuse the risk of obsolescence of the modern techniques and expense of the start-up, etc. due to rapidly changing technology. Some hospitals would not invest in new capital ventures that would lessen the use of other services that they currently provide.

Moreover, a single hospital often doesn't have the volume of cases to justify the expenses of the most up-to-date technology. Physicians who want to provide the most current treatments for their patients are willing to invest in a joint venture with other physicians who may practice at other facilities and hospitals to purchase the technology. It can then be brought to the various facilities on a rotation to save costs and provide the care to all, benefiting urban and rural patients.

When urologists refer patients for therapeutic procedures that the urologist performs, the professional fee he receives is greater than the incremental increase in his distributions from his investment in the venture. The distribution is not likely to induce

referring physicians to refer patients for the procedure. Remember, in addition to our ethics, any unnecessary medical procedures put the doctor at risk of malpractice and loss of his license. CMS SHOULD NOT PROHIBIT SERVICES UNDER ARRANGEMENTS WHERE THE INVESTOR PHYSICIAN PERFORMS THE PROFESSIONAL PORTION OF THE PROCEDURE.

Physicians, who invest in joint ventures to bring new, innovative therapeutic technology to my community, are willing to take the risk of failure. The hospitals are comfortable with us bearing the risks of low volume and welcome "per click" arrangements.

In regards to ambulatory surgical centers, CMS seems to prefer as many procedures be performed there where the reimbursement will be lower, saving Medicare dollars. However, if a referral to a center owned or controlled by a hospital is viewed as a referral to the hospital, it would become difficult for legitimate physician joint ventures to provide services at those centers. Doctors will likely withdraw from hospital-owned centers and build their own, with attendant costs and the demise of the current methodology.

Finally, I strongly disagree with the burden of proof on the provider in cases of Stark violations. I would have to prove my actions were legal rather than the government agency which writes the law proving my actions as illegal. This is contrary to our justice system. It's enough persecution of physicians who have dedicated our lives to the health, and care of our patients.

In summary, I ask CMS to separate those beneficial therapeutic joint ventures which are not DHS, from the abusive and questionable diagnostic ventures that physicians and hospitals may have propagated. Certainly the urologic community's ventures have broadened access to new technology for Medicare patients and others, brought needed efficiency to the market, and simultaneously saved CMS hundred of millions of dollars. It would be a huge mistake to jeopardize such a time tested and proven model.

Sincerely,

Mitchell N. Kotler, M.D., F.A.C.S.
11 CAMEO DR.
CHERRY HILL, NJ 08003

Washington University Physicians
Washington University School of Medicine in St. Louis

Children's HOSPITAL • ST. LOUIS

The Edward Mallinckrodt Department of Pediatrics
The David Goldring Division of Cardiology

August 20, 2007

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

RE: File Code: CMS-1385-P, Coding- Additional codes from 5-year review.

Dear Sir/Madam;

We are writing regarding the proposed change to bundle CPT 93325 into CPT codes 76825, 76826, 76827, 76828, 93303, 93304, 93307, 93308, 93312, 93314, 93315, 93317, 93320, 93321, 93350 when provided together.

As pediatric cardiologists, this is of particular concern to us because we do not believe that the appropriate process has been followed. The American College of Cardiology and the American Society of Echocardiography have interacted with the CPT editorial panel to recommend a new code be established that would bundle the 93325 with the 93307 by January 1, 2009. The CPT editorial panel did not recommend that the list of the above echo codes be bundled with the 93325.

A new code in 2009 would address any outstanding issues relative to Medicare utilization of the 93307, and has been analyzed in length by appropriate national medical societies, the CPT editorial panel, and the RUC.

Because the actions of CMS are contrary to the normal process for such changes and the resultant compressed timeframe, the specialty societies have not been able to effectively work with their membership to evaluate the proposed change in a reasoned, methodical manner.

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.

With respect to CPT code 93325, pediatric echocardiography is unique in that it is frequently necessary to use doppler flow velocity mapping for diagnostic purposes and it

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forms the basis for subsequent clinical management decisions. CPT Assistant in 1997 references the uniqueness of the 93325 for the pediatric population stating that doppler

color flow velocity is "...even more critical in the neonatal period when 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.

In conclusion, we strongly urge CMS to withdraw the proposed change with respect to bundling 93325 with other pediatric cardiology echocardiography codes until such time as an appropriate review of all related issues can be performed, working with the prescribed process and timeframe, in order to achieve the most appropriate solution. Importantly, there is no proposed change to increase the RVUs of the codes with which the 93325 will be bundled.

Thank you in advance for your consideration to this important issue.

Sincerely,

Dr. Achi Ludomirsky

Dr. David Balzer

Dr. Charles E. Canter

Dr. Susan Foerster

Dr. R. Mark Grady

Dr. Patrick Jay

Dr. Mark C. Johnson

Dr. Angela Sharkey

Dr. Gautam Singh

August 25, 2007

Ms. Leslie Norwalk, JD
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8018
Baltimore, MD 21244–8018

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

Dear Ms. Norwalk:

As a member of the American Association of Nurse Anesthetists (AANA), I 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,

Gerry Herriges, MS, CRNA
3854 Turtle Road
Minnetrista, MN 55375

PHYSICAL THERAPY & SPORTS INJURY CENTER

THE DOCTOR'S CHOICE FOR PERSONALIZED CARE.

August 24, 2007

Kerry N. Weems,
Administrator-Designant
Centers for Medicare and Medicaid Services
US Dept. Of Health and Human Services
Attn: 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 CY2008: Proposed Rule

Purpose: Physican Self-Referral Issues

Dear Mr. Weems:

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

I am a physical therapist with 30 years experience and owner of a private practice for the last 26 years in the York, PA, area. Over the years there has been numerous physician-owned practices providing physical therapy services and we have seen little to no referrals from those physicians. Also, several years ago an orthopedic practice which referred quite heavily to our office merged with a practice who had their own physical therapy services and statistics immediately showed a significant reduction in orthopedic referrals from that time onward. This has significantly impacted our number of referrals from orthopedic practices and we have needed to branch out to other services and physicians.

I have heard comments from our patients when seen in these practices that they were not given a choice as to where they desired to receive physical therapy services. If these patients did not know us personally or from past experiences I highly question if they would be able to come to our office for treatment. It appears that the potential for fraud and abuse does exist with physicians who own their own practice, specifically for financial interest. By eliminating physical therapy as a designated health service furnished under the in-office ancillary services exception, CMS would reduce a significant amount of programatic abuse, over-utilization of physical therapy services under the Medicare program and enhance the quality of patient care.

F. Robert Kolanko, PT
President
B.S. P.T. Ithaca College
Member-APTA, PPTA
Orthopedic, Private Practice & Sports Medicine Sections

Holly H. Potter, PT
Vice President
B.S. P.T. University of PA
Member-APTA, PPTA
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Steffen Abrahamsen, PT
B.S. Biology,
City College of NY
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Long Island University

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78 Wyntre Brooke Drive, York, PA 17403 • Tel: 717-741-4818 • Fax: 717-741-5593

Thank you for taking the time to consider these comments.

Sincerely,

F. Robert Kolanko, P. T.

FRK/clm

454

627 Highland Ave.
Little Falls, NJ 07424

August 27, 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 Policies for CY 2008; Proposed Rule

RE: **Physician Self-Referral Issues**

Dear Sir:

I am a physical therapist licensed in New Jersey and have been practicing in outpatient orthopedics since I graduated in 2002. I have only worked in and will continue to work only for physical therapist- owned private practices. I have directly experienced the negative impact of physician-owned P.T. practices on our patients and would like to comment on the July 12 proposed 2008 physician fee schedule, specifically the issue surrounding physician self-referral and the "in-office ancillary services" exception.

I have treated patients who have come to see me after having prior physical therapy with misconceptions that physical therapists aimlessly prescribe a set of exercises without giving "personal attention" because he/she was seeing about 5-6 people at one time. Unfortunate to say, but many of these patients are coming from physician-owned P.T. practices who were "lured" by their doctors to see the physical therapist that happens to be in the same building. Naïve to what physician self-referral is and assuming doctors are prescribing what is in the best interest of their patients, most people simply do what their doctor says. I find myself constantly educating my patients that they have choices as to where they can go for physical therapy and that physical therapy should be attentive to an individual's disability and personal goals. Physician-owned physical therapy practices are not opening up to better serve their patients but to simply generate more profit from every aspect of healthcare that their patients need. This loophole is creating a false pretense that patients don't have choices when it comes to their healthcare and that their outcomes solely rely on what their doctor says.

I am thanking you, Mr. Weems, for your attention to my opinions regarding physician self-referral issues.

Sincerely,

Jane Vilches, MSPT

Jane Vilches, PT, MSPT

DOWN EAST MEDICAL ASSOCIATES, P.A.

306 Medical Park Court • Morehead City, North Carolina 28557 • (252) 247-2013 • FAX (252) 247-7299

Internal Medicine
TERRENCE L. GOODMAN, M.D.
WILLIAM T. WALKER, JR., M.D.
LARRY D. LAWRENCE, JR., M.D.

HELEN C. GOODMAN, NP

Internal Medicine & Endocrinology
MARY KATHERINE LAWRENCE, M.D.

Dermatology
GLORIA F. GRAHAM, M.D.

August 27, 2007

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

RE: CMS-1385-P Proposed Revisions to payment policies under the physician fee schedule and other Part B payment policies for CY 2008

Comments:

The Physician Work RVU-CPT 77080 (DXA)

The Direct Practice Expense RVU for 77080 (DXA)

Indirect Practice Expense for DXA and VFA

Deficit Reduction Act

Dear Mr. Weems:

I appreciate the opportunity to offer general comments on the proposed rule regarding changes to the Medicare physician fee schedule CMS-1385-P.

As a provider of DXA and/or VFA services, I request CMS to reevaluate the following:

a. The Physician Work RVU for 77080 (DXA) should be increased from 0.2 to 0.5, consistent with the most comprehensive survey data available;

b. The Direct Practice Expense RVU for 77080 (DXA) should reflect the following adjustments:
   - the equipment type for DXA should be changed from pencil beam to fan beam with a corresponding increase in equipment cost from $41,000 to $85,000;

- the utilization rate for preventive health services involving equipment designed to diagnose and treat a single disease or a preventive health service should be calculated in a different manner than other utilization rates so as to reflect the actual utilization of that service. In the case of DXA and VFA, the 50% utilization rate should be changed to reflect the utilization rate for DXA to 12%.

c. The inputs used to derive Indirect Practice Expense for DXA and VFA should be made available to the general public, and

d. DXA (77080) should not be considered an imaging service within the meaning of the section 5012 (b) of the Deficit Reduction Act of 2005 because the diagnosis and treatment of osteoporosis is based on a score and not an image.

Sincerely yours,

Terrence L. Goodman MD.

Terrence L. Goodman, MD

8/28/07

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. 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 a physical therapist in Illinois who has actively practiced for the last 8 years and have first hand experience working within private practice and physician-owned physical therapy clinics with "fee splitting" arrangements currently allowed under the Stark laws.

First and foremost, because physicians have a vested interest within physician-owned clinics or similar arrangements, there is the potential for abuse and over-utilization of physical therapy services. For instance in a physician-owned or similar "fee splitting" arrangement, the physician often becomes the gate-keeper for termination of physical therapy services. Many times, patients are sent back to physical therapy despite the physical therapist documenting and recommending discharge based upon a lack of *"functional"* progress. It has been my experience that physicians would often *demand* that a patient continue therapy with little to no justification while physical therapists are put in an unfortunate morale dilemma of seeing the patient or risk the chance of termination (or loss of contract).

Second, I have treated patients within our private practice clinics, who have stated that they were instructed, by their physician, to go to therapy in which the referring physician had a financial relationship. I have also spoken to rehabilitation patients who have driven over 40 miles for therapy when there were several clinics within his or her hometown because, "my physician wanted me to go there"! This is completely ridiculous and an injustice to our patients.

Third, there has been a huge influx of physician-owned physical therapy clinics within my own and nearby communities resulting limited consumer access and choice for physical therapy services. More specifically, the "in-office ancillary services" exception has created a loophole which has resulted in the expansion of physician-owned arrangements that provide physical therapy services. In my own community and state where a referral for physical therapy treatment is unfortunately necessary, this has prevented me from being able to my own clinic and forced many independent physical therapy companies to form some type of legal physician-owned arrangement in order to compete and stay in operation. This loophole needs to be closed!

Finally, the argument that "direct supervision" is needed to administer physical therapy services is invalid. 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.

For reasons stated above, I am strongly requesting that CMS eliminate physical therapy as a designated health service (DHS) under the current list of in-office ancillary services within current Stark regulations. I would like to thank you for your consideration of these points as CMS continues to debate this issue.

Sincerely,

Aaron Fuerst PT, DPT.

Aaron Fuerst PT, DPT.
Flexeon Rehabilitation
Director of Clinical Operations

August 25, 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 a Urologist practicing in Bradenton, Florida. My practice is a single specialty practice of six Urologists all of whom have been in practice over 10 years. As is true for most Urology practices in Florida we have a very high Medicare patient population. At our last evaluation, 85% of our practice was Medicare patient based.

I am writing to comment on the recently proposed changes to the physician fee schedule rules that were published on 12 July 2007 that concern the Stark self-referral and the reassignment and purchased diagnostic test rules.

The changes make little or no sense to me. In an arena where quality of care is paramount and efficiency of care is one of the cornerstones, it seems counterintuitive to me to restrict my patients' access to the very type of care paradigms CMS urges all physicians and surgeons to adopt.

To unduly restrict my ability to directly provide, oversee and coordinate very exacting and highly technical care for which I am uniquely qualified by skills honed over a lifetime of education is counterproductive and illogical. It will ultimately lead to the unintended outcome of increased fractionation of care, decreased efficiency of care, poor oversight of care and ultimately result in cost increases system wide.

The ability to provide lab, radiographic and cancer care treatments in a single geographical location, under the steady and watchful eye of the ordering physician makes ultimate sense. Who better to ensure the quality of the results than the surgeon responsible for the care of the patient?

As the owner of the entire process, I can ensure that the patient gets the correct test the first time, that there is minimal duplication of services, and that the care is handled efficiently and in many cases on a same day basis. This type of efficiency cuts costs by decreasing the need for ancillary resources to transport the patient to a myriad of service locations with disparate quality measures over multiple days and ultimately avoids unnecessary delays in diagnosis and treatment. Who wouldn't want care like this?

The current proposed "under arrangement" rule will prohibit the establishment of these types of care efficiencies for pathology, specialized equipment services, radiography and specialized cancer treatments such as IMRT for my patients. This is unfortunate for my patients and for the Medicare system. It is a step backwards.

The ability to provide these services to our patients has had another beneficial, yet unexpected, outcome. It has led to unprecedented cooperation between otherwise competing physicians and surgeons. Why, because there is a mutually beneficial end. In this case, better services to our patients, improved efficiencies for the involved physicians, and decreased duplication of services for the community. These are noble ends affected with noble means. You don't see to many win-win-win situations anymore, but this is certainly one of them. So I am mystified by the rule changes.

If we are always looking for fraud, we will certainly find it. Unfortunately, that search has blinded us from seeing the real benefits of the current market force induced changes in medicine.

Please help physicians and surgeons continue to take positive steps towards improving the services provided to the patients under their care.

Respectfully,

Alan Miller, MD, FACS
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Bradenton, Fl 35205
a.miller@urology-partners.com

458

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OF CENTRAL VIRGINIA

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F:434.847.7715

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F:434.352.9559

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F:434.376.3773

Hurt Practice
527 Pocket Road
Hurt, VA 24563
P:434.324.9750
F:434.324.9796

August 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:

My name is Melanie Conner and I am a physical therapist practicing in Lynchburg, Virginia, in an outpatient private practice setting for the past 10 years. I have continued my education by completing my clinical doctorate in May of this year in addition to having completed certification as a sports certified specialist from the Board of Clinical Specialities of the American Physical Therapy Association since 2003.

The intent of this letter is to comment on physical self-referral issues and the potential for abuse by physicians who have a financial interest in physical therapy services under their ownership and/or employment. In Virginia, physical therapy services are almost exclusively by physician referral only. There are few exceptions. We rely on physician referral for our access to patients. Allowing physical therapy services to remain an exception to the "in-house ancillary services" could impact not only my livelihood, but also create the potential for abuse by physicians who face decreased reimbursement as all of us in healthcare delivery do.

I urge you to suggest that CMS remove Physical Therapy as a designated health service under the "in-office ancillary" exception to the federal physician self-referral laws.

Thank you for your time and consideration of this matter.

Sincerely,

Melanie C. Conner, P.T., D.P.T., S.C.S.
MCC/lp

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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 in a group practice in Pittsburgh, Pa with a very large Medicare population. 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 on 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 that urologists 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. If the limitations in this proposal are enacted, I will not be able to provide my patients with the immediate diagnostic studies and therapeutic interventions that are needed by patients with kidney stones, cancer or other urologic diseases. The proposed "under arrangement" rule, will prohibit the provision of laser surgery commonly used to treat cancer, enlarged prostate and other conditions. Not providing these services will be severely detrimental to patient care and cause a serious hardship for my Medicare 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,
Signature

MD

David A. Corral, MD, FACS

Valley Urological Group

dcorral@valleyuro.com

Ph: 412-741-8025

Fax: 412-741-2102

John C. Byrne, M.D., FACS
Diplomate of the American Board of Urology

460

175 Memorial Highway
New Rochelle, NY 10801

August 25, 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.

Re: July12 Fed Register proposed changes

Dear Mr. Kuhn:

I have been a solo practicing Urologist in Westchester County, New York since 1973. About half my Patients are covered by Medicare.

Before the current regulations covering in office lab services I performed urine cultures, organism identification and antibiotic sensitivity for acutely ill patients with urinary tract infections. I would know within 24 to 36 hours whether the patient was getting appropriate antibiotic treatment. The regulatory requirements forced me to discontinue this service and send out all urine cultures to major laboratories. The turnaround time is now 5 days so effectively I'm back to guessing which antibiotic is best and this has had a significant effect on the quality of care I can provide. I don't expect the clock to be turned back so I cite this only as an example of the unintended consequences of new regulations.

Physician owned outpatient services such as laser and microwave thermal treatment of prostatic obstruction have substantially improved my ability to treat BPH. The alternative is the standard TURP requiring hospitalization for two to three days and considerably more morbidity. These outpatient services exist only because they cater to the physician and provide unparaleled efficiency as compared with hospital based treatment. Hospitals are at a disadvantage because they are drowning in regulations and leveling the playing field by destroying the physician owned services is not the answer. So long as these services are physician owned they will remain efficient but if you destroy them with new Stark interpretations Medicare patients will be the losers.

Sincerely,

John C. Byrne, M.D.

Assistant Clinical Professor – Cornell Medical Center
Attending Urologist – New York Presbyterian Hospital
Chief of Urology – Sound Shore Medical Center

SOUTHEAST
UROLOGY
NETWORK

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 practices in Memphis, Tennessee. 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 on the way my group, ***Southeast Urology Network***, practices 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 to 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.

Cooperation and investment by urologists has in the past led to the introduction of many new and improved technologies for our patients. Many of these technologies would not have been made available if we were dependent on hospitals to provide such services.

The proposed "under arrangement" rule, will prohibit the provision of in office TUMT, hospital based cryoablative surgeries and laser procedures that were financed by urologists to provide cost effective care for their patients. Again, these services were not provided by our hospitals, until urologist took an active and financial role in their introduction.

The prohibition of per click payments for space and equipment rentals will prohibit readily access to CT imaging, enabling us quick and accurate diagnosis of our patient's ailments. To limit the access on new and improving technology to physicians in their office, not only serves to delay diagnosis and increase health care costs, but fosters a direction of limiting the progress of medicine in the United States.

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,

A. Michael Alabaster, M.D.

East Memphis Office
995 S. Yates
Suite 1
Memphis, TN 38119
901.527.7100
901.527.7124 FAX

Southaven Office
7420 Guthrie Drive, North
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UAB SCHOOL OF MEDICINE

Department of Pediatrics

Tuesday, August 21, 2007

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

Re. File Code: CMS–1385–P, CODING—ADDITIONAL CODES FROM 5-YEAR REVIEW

To CMS:

I am writing regarding the proposed change to bundle CPT 93325 (which describes Doppler color flow velocity mapping) into CPT codes 76825, 76826, 76827, 76828, 93303, 93304, 93307, 93308, 93312, 93314, 93315, 93317, 93320, 93321, 93350 when provided together. As a pediatric cardiologist, this is of particular concern to me because of several reasons:

I do not believe the appropriate process has been followed with respect to this change. After significant interaction between the RUC and the appropriate medical specialty societies, the CPT editorial panel recommended that a new code be established to bundle 93325 with 93307, to be implemented on January 1, 2009. This new code is fully expected to address any outstanding issues relative to Medicare utilization of 93307. The panel did not recommend that the list of above echo codes be bundled as well with 93325.

However, as a result of this proposed regulatory action by CMS, contrary to the normal process for such changes, we are faced with resolving, in an accelerated timeframe of less than two months.

The analyses to set the work RVUs for echo codes used by pediatric cardiologists were performed more than 10 years ago. As a result, particularly regarding 93325, the RVUs reflect a focus on the cost of the technology and not the advances in care that have been developed as a result of the technology. 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.

RVUs for procedures that are common to both adult and pediatric patients are established exclusively using adult patients as the basis; the work and expense associated with providing care to pediatric patients is often not considered. 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 clinical management decisions. It is an essential medical service being provided to pediatric patients with congenital and non-congenital heart disease.

This proposed change would adversely impact access to care for pediatric cardiology patients. It will result in an increase in the need for subsidies from already resource-challenged children's hospitals and academic programs, or a significant increase in Medicaid reimbursement for the proposed bundled services, in order for pediatric cardiology patients to have the same access to care and resources that they do today.

I strongly urge CMS to withdraw the proposed change with respect to bundling 93325 with other pediatric cardiology echocardiography codes until such time as an appropriate review of all related issues can be performed, working within the prescribed process and timeframe, in order to achieve the most appropriate solution. Thank you for your consideration of this serious matter.

Sincerely,

Walter H. Johnson, Jr., M.D.
Associate Professor of Pediatrics
Division of Pediatric Cardiology

Division of Pediatric Cardiology
320 New Hillman Building
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205.934.3460
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The University of
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Mailing Address:
NHB 320
619 19TH ST S
BIRMINGHAM AL 35249-6852

463-1

New York Pain Management
PLLC

Charles F. Gordon III, M.D.
Medical Director
Board Certified - Pain Management
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711 Troy-Schenectady Road, Suite 207
Latham, NY 12110
08/22/07

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 As requested, I have limited my comments to the issue identifiers in the Proposed Rule.

There are approximately 7,000 physicians practicing interventional pain management in the United States I am included in this statistic. 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.

I appreciated that effective January 1, 2007, CMS assigned interventional pain and pain management specialties to the "all physicians" crosswalk. This, however, did not relieve the continued underpayment of interventional pain services and the payment shortfall continues to escalate. 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 and all physicians' 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.

The current practice expense methodology does not accurately take into account the practice expenses associated with providing interventional pain services. 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.

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.

Effective January 1, 2007, interventional pain physicians (09) and pain management physicians (72) are cross-walked to "all physicians" for practice expenses. This cross-walk more appropriately reflects the indirect practice expenses incurred by interventional physicians who are office-based physicians. The positive affect of this cross-walk was not realized because many interventional pain physicians report anesthesiology as their Medicare primary specialty and low utilization rates attributable to the interventional pain and pain management physician specialties.

The practice expense methodology calculates an allocable portion of indirect practice expenses for interventional pain procedures based on the weighted averages of the specialties that furnish these services. This methodology, however, undervalues interventional pain services because the Medicare specialty designation for many of the physicians providing interventional pain services is anesthesiology. Interventional pain is an inter-disciplinary practice that draws on various medical specialties of anesthesiology, neurology, medicine & rehabilitation, and psychiatry to diagnose and manage acute and chronic pain. Many interventional pain physicians received their medical training as anesthesiologists and, accordingly, clinically view themselves as anesthesiologists. While this may be appropriate from a clinically training perspective, their Medicare designation does not accurately reflect their actual physician 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 not only furnish evaluation and management (E/M) services but also perform a wide variety of interventional procedures such as nerve blocks, epidurals,

intradiscal therapies, implant stimulators and infusion pumps, and therefore have 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. CMS utilization files for calendar year 2007 overwhelming report anesthesiologists compared to interventional pain physicians and pain management physicians as being the primary specialty performing interventional pain procedures. 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—physician payment reflects 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 a 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 to see if the updated practice expenses information from the Physician Practice Information Survey ("Physician Practice Survey") will alleviate the payment disparity. 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.

II. CMS Should Incorporate the Updated Practice Expenses 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.

III. 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. The 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 disproportionately bear the cost of providing health care to Medicare beneficiaries. Accordingly, many physicians face clear financial hardship and will have to make painful choices as to whether they should continue to practice medicine and/or care for 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 be unfairly lose access to 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,

Charles F. Gordon III, MD
Medical Director NY Pain Management

464-1

The Urological Center, P.A.

Adult &
Pediatric
Urology

Diplomates,
American Board
of Urology

H.J. Talton, M.D., F.A.C.S.
W.A. McWilliams, M.D., F.A.C.S.
P.J. Dennis, M.D., F.A.C.S.
K.C. Hackett, M.D., F.A.C.S.
M.R. Chaudhry, M.D., F.A.C.S.

D.J. Lamont, PA-C, C.U.P.A

August 10, 2007

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

Dear Mr. Kuhn:

We are a group of urologist who practice in Hagerstown, Maryland. Our business is made up of approximately 45% of Medicare beneficiaries. We are the only urology group providing services at the local hospital. 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 on the way we 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 urologist to work with radiation oncologists in a variety of ways to provide radiation therapy to patients.

The proposed changes to the reassignment and purchased diagnostic test rules will make it difficult, if not impossible for me to provide imaging services to my patients. Patients have the convenience of coming to our office for their ultrasounds, and then seeing the physician following the test. This enables the patient to limit their trips to an office for services. Otherwise, the patient will have to make multiple trips for services. Also, we provide services for the treatment of beneign prostatic hyperplasia with the use of "Green Light Laser." Without the exception, this service will not be available to the patient, and therefore requiring the patient to have a more extensive surgery in the hospital for this very problem.

11110 Medical Campus Rd.
Suite 228
Hagerstown, MD 21742
301-733-0022
1-888-326-0022
301-733-3461 (Fax)

There is also the concern of the availability of lithotripsy to the elderly. As it stands now, Medicare patients can only receive the treatment at the hospital. This has created a situation where our patients have limited access to this service. Our hospital has not invested the resources into purchasing the equipment. therefore a joint venture of a regional group of urologist purchased the equipment. The equipment must be shared with five different groups of urologist. Therefore, the machine is available for use "at the hospital" twice a month. Medicare patients must wait for the services of 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 more costly procedures in the hospital, and the potential for adverse outcomes.

The proposed "under arrangement" rule, will prohibit 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 availability 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 you consideration.

M Chaudhry

Mohammad R. Chaudhry, M.D.
Physician

WCHQ
Wisconsin Collaborative *for* Healthcare Quality

465

Thursday, August 30, 2007

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

RE: "TRHCA - - Section 101(b): PQRI"

Dear Mr. Kuhn,

As one of the six (6) regional quality coalitions serving as pilot sites for the "Better Quality Information for Medicare Beneficiaries" (BQI) program sponsored by the Center for Medicare and Medicaid Services (CMS), the Wisconsin Collaborative for Healthcare Quality (WCHQ) is a stalwart supporter of the Department's various initiatives designed to improve the quality and cost-effectiveness of healthcare services for all Americans. A key component of this multi-pronged effort is the "Physician Quality Reporting Initiative" (PQRI) which was officially implemented in July of this year. While WCHQ is broadly supportive of the goals of the PQRI, we believe there are numerous opportunities to enhance the design of the program and ensure a greater alignment with other CMS initiatives, notably the BQI. In that spirit, we offer the following comments on the "Proposed Revisions to Payment Policies under the Physician Fee Schedule, and other Part B Payment Policies for CY 2008" as published in the Federal Register on July 12.

1. Strengthen the link between the BQI and PQRI by functionally integrating the two initiatives. As noted above, WCHQ is serving as one of six (6) pilot sites for the BQI initiative. This program - - initially conceived by the AQA in late 2005 and officially launched by CMS in January of 2007 - - is designed to test methods of increasing the availability of comparative performance information on servicesphysicians for the benefit of Medicare beneficiaries. Despite the fact that the BQI is striving toward exactly the same goals as the PQRI, there appears to be little operational coordination between the two initiatives. While this is understandable when considering that the genesis of the two programs is different, the perpetuation of programmatic "silos" represents a lost opportunity for strategic and operational synergies that would enhance both programs. To correct this, there are two concrete actions we would recommend to achieve this goal:
   a. Ensure complete alignment between the performance measures reported under each initiative.

b. Allow medical groups and practitioners that report performance information through the BQI pilot sites to receive their full or substantial "pay for reporting" incentive under the PQRI through participation in the BQI.

2. Allow the WCHQ to serve as a demonstration site for a data submission model under "Option 3" in 2008. In today's environment, healthcare organizations are presented with requests or demands to participate in a number of measurement and reporting initiatives, each of which represent legitimate and important opportunities to improve the quality and cost-effectiveness of healthcare services. While virtually all are well intentioned, these initiatives are frequently uncoordinated and thus introduce complexity and competition for the proportion of organizational resources that can be devoted to measurement, reporting, and improvement. We view the PQRI as an important opportunity for organizations to assess the quality of care on an individual physician level of their Medicare beneficiaries. The WCHQ proposes to demonstrate that the methods we have developed for our membership can offer a streamlined approach that integrates the work that our member medical groups are doing for WCHQ with the efforts for PQRI, thus giving greater recognition and value to both measurement and reporting initiatives.

   In order to demonstrate how this would work, the following paragraphs describe our measurement model in more detail.

   The WCHQ's current method of reporting involves submission of a numerator and denominator for each corresponding measure to the data tool found on our website. Members use their own programmers internally to write the code to apply the measurement specification, collect the data and prepare for data submission. The data is made available for preview for one week prior to being posted live at www.wchq.org in order to allow member organizations to check their work and confirm that all of the data is accurate before it is made public. Of the options listed in the proposed rule, Option 3 most closely matches the process currently in use by WCHQ members.

   Our vision is that members of WCHQ will submit their data, stratified by payer to allow for identification of the Medicare population. Once this population has been isolated, numerators and denominators will be factored through the data tool for individual physicians and then submitted to CMS via a web upload. The data would be identifiable to individual physicians according to their National Provider Identifier (NPI). No beneficiary level information would be made available publicly so as to avoid compromising HIPAA laws.

   Our member organizations would submit data based on WCHQ's distinctive, "all patient, all payer" measurement methodology. Our measures have been designed using HEDIS as a template and applying a three-question algorithm that is integral to determining which patients actually belong to the medical group and in the measurement denominator. This method has numerous advantages, with one of the

most important being the fact that the emphasis on construction of an accurate denominator results in the generation of a ready-made patient registry for the condition being measured. The accuracy and utility of the patient lists that are downloaded from these measurement specifications have created a significant degree of support and engagement from both clinical leaders and practitioners. We believe that piloting this methodology in the PQRI will give CMS a representative view of the performance of any given physician submitted under WCHQ's process while providing CMS with a richer data set (both administrative and clinical data) on the measures we currently report.

The benefits of this approach are significant. First, physicians will be more supportive of this data than of other measures that might be reported, especially at the individual physician level. Second, the process of complying with PQRI would be less cumbersome as the organizations will fulfill the obligations for preparing data to be submitted for WCHQ.

These are a number of important questions yet to be resolved in the design and implementation of this model. These include HIPAA regulations on storage of confidential patient information, understanding of the CPT-II modifier codes and how they will be implemented into our current measurement process, and development of a data tool to be used for a web upload. Overall, however, this process is one that will allow the members of WCHQ - - representing approximately 50% of the state's primary care physicians - - to submit data for PQRI giving the Centers for Medicare and Medicaid Services a broader picture of the care that is being given to their beneficiaries.

3. Include WCHQ's performance measures, and the detailed specifications, on the list of approved measures for 2008. The WCHQ fully supports the need for the adoption and use of a consistent set of performance measures as a critical component of a national quality strategy. At the same time, it is important to recognize that the United States has relatively little experience with the development and deployment of measures that accurately portray the performance of medical groups in managing a population ("all patient, all payer") of patients. The WCHQ stands alone in achieving a level of sophistication in ambulatory performance measurement that has generated a high degree of physician engagement. The WCHQ uses performance measures - - listed in the attachment - - that are either AQA or NQF endorsed and has developed, tested, deployed, and gained acceptance of detailed measure specification that marry administrative and clinical data at a population level. While these measure specifications vary from those developed by the AQA and NQF, WCHQ formulated the numerator according to current HEDIS specifications. Our algorithm for calculating the denominator has been endorsed by our physician leadership and members as a significant enhancement to HEDIS due to the fact that our model generates highly accurate, population-based measure results. Our confidence in the reliability and accuracy of our specifications has led us to initiate discussions with NCQA regarding the potential relationship to their "Physician HEDIS" measures; we plan similar discussions with NQF regarding our denominator algorithm. The

WCHQ would like the opportunity to demonstrate the potential for our community level measures to serve as a model for broader adoption in the United States. In view of these considerations, we believe that our proposal to use these measures in conjunction with the PQRI in 2008 will present CMS with a valuable demonstration of the utility of this measurement methodology and specifications, and is consistent with the latitude CMS has for "selecting measures for PQRI based on a lesser degree of consensus where necessary to meet CMS' programs needs . . .".

We appreciate the opportunity to comment on the proposed rules and look forward to joining with CMS to demonstrate our commitment to furthering the goals of PQRI in 2008.

Sincerely,

President/CEO

CQ/trc

Ambulatory Care Performance Measures

Preventive Care Specifications
Breast Cancer Screening
Colorectal Cancer Screening
Cervical Cancer Screening

Episodic Care
Postpartum Care

Chronic Care
Diabetes Care
- Blood Sugar Testing Annually
- Blood Sugar Control
- LDL Cholesterol Testing Annually
- LDL Cholesterol Control
- Annual Nephropathy Screening/Treatment or Diagnosis of Kidney Disease
- Blood Pressure Control

Controlling Uncomplicated Hypertension

In Development
Cholesterol Management of Patients with Cardiovascular Conditions (*to be reported in 2008)*
- LDL Cholesterol Testing
- LDL Cholesterol Control

Pneumovax

4060

August 23, 2007

Re: Physician Self-Referral Provisions

To Whom It May Concern:

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 pathologist in training and a member of the College of American Pathologists. I am a resident in Evanston, Illinois as part of Northwestern University's McGaw Center for Medical Education at Evanston Hospital.

As someone about to enter the field of pathology, I applaud CMS for undertaking this important initiative to end self-referral abuses in the billing and payment for pathology services. I am aware of arrangements in my practice area that give physician groups a share of the revenues from the pathology services ordered and performed for the group's patients. I believe these arrangements are an abuse of the Stark law prohibition against physician self-referrals and I support revisions to close the loopholes that allow physicians to profit from pathology services.

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

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

Sincerely,

Megan E. Sullivan, M.D.
Chief Resident in Pathology
Evanston Hospital
2650 Ridge Ave.
Evanston, IL 60201

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;

I am writing this letter to express my trepidation regarding the in-office ancillary service arrangements that have impacted the delivery of appropriate Physical and Occupational Therapy.

Since the opening of physician owned outpatient Physical and Occupational Therapy offices in our community we have seen the following:

- Therapists are not allowed to contact or market to physicians in a physician group that have physical and occupational therapy services.
- The doctors do not give patients a choice of where to receive treatment, even if a non-physician owned clinic would be closer to the patients home or just more convenient for the patient.
- The "in-office ancillary services" exception has created a loophole which has resulted in many physician-owned arrangements where physicians have a financial incentive to potentially exploit the use of physical and occupational services.

Thank you for considering these comments.

Sincerely,

Mark Reed PT

Mark Reed, MPT

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

468

333 N. Texas Avenue
Webster, TX 77598
26 August, 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 wish to express my support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule.

In an effort to rectify a huge payment disparity for anesthesia care, the RUC recommended that CMS increases the anesthesia conversion factor to adjust for a calculated 32% work underevaluation - a major step in correcting the underpayment of excellent anesthetic care of patients. The Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC's recommendation.

Anesthesia care providers work diligently to provide optimal care for our patients. In order to continue this, please approve the anesthesia conversion factor increase as recommended by the RUC.

Thanking you for your consideration,

Verna J. Yancy, MD

469-1

OREGON HEALTH & SCIENCE UNIVERSITY

Department of Anesthesiology and Peri-Operative Medicine
Oregon Health & Science University, School of Medicine
3181 SW Sam Jackson Park Road,
Mailcode: UHS-2
Portland, Oregon 97239
503.494-7641~ Fax: 503.418-0884

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

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

Dear Ms. Norwalk:

Thank you for the opportunity to comment on the proposal to adjust the anesthesia payments under the 2008 Physician Fee Schedule to a more appropriate level. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to rectify this complicated issue.

As you know, anesthesia is the only specialty that is outside of the RBRVS system. When the decision was made to allow anesthesia to continue to use a separate unit system that included base, time, and modifier units, the payment rate initially established per unit by CMS was inappropriately calculated, creating a huge payment disparity for anesthesia care compared to other physician services paid according to the RBRVS methodology. While other specialties are paid about 70% of their average commercial payments by Medicare, anesthesia continues to receive about 32% of their average commercial payments. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services averages just $16.19 per unit nationally, and this rate is even lower in the Portland area at $15.47. The latest ASA survey shows the average commercial payment at $51.04 per unit. The Medicare payment amount does not cover the cost of caring for our nation's seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

As an academic institution we face additional challenges with the Medicare payment system. We serve a higher portion of the Medicare population and are greatly impacted by the teaching rule and the concurrence penalty. This results in even lower payments and a greater burden of teaching and providing tertiary care.

If this situation is not rectified it could decimate academic anesthesia practices when combined with the pending SGR cuts. While we recognize that CMS must implement the SGR, this will compound the issues with our already low paid specialty and make it more difficult to recruit and retain qualified physicians to train the next generation of physicians.

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,

Teresa Liao, M.D.
Assistant Professor

cc: The Honorable Darlene Hooley, Darlene@mail.house.gov
The Honorable David Wu, david.wu@mail.house.gov
The Honorable Greg Walden, greg.walden@mail.house.gov
The Honorable Earl Blumenauer, earl@mail.house.gov
The Honorable Peter DeFazio, peter.defazio@mail.house.gov
The Honorable Earl Blumenaur, write.earl@mail.house.gov

August 17, 2007

The Honorable Senator Mitch McConnell
361-A Russell Senate Office Building
Washington, D.C. 20510

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

Dear Senator McConnell:

I have been treated for skin cancer with Mohs Micrographic Surgery, a specialized procedure that has the highest cure rate of all treatments for skin cancer. Since I have already had one cancer, I have a 40% chance of another new cancer within the next 5 years. As such, I have become concerned that, in view of a recent change proposed by Medicare, in the future it will no longer be cost effective for my doctor to perform other procedures such as biopsies on the same day as Mohs surgery or to treat more than one cancer per patient per day. It is my understanding that a proposal to remove Mohs surgery from the list of procedures exempt from the Multiple Procedure Reduction Rule will result in a 50% reduction in reimbursement for procedures performed on the same day as Mohs. In many cases, such a reduction would not cover the costs of providing the additional procedures, making it difficult for my doctor to perform more than one procedure for me on the same day.

Such a change would represent a costly inconvenience for skin cancer patients such as me. The need for a biopsy before surgery, which is currently often done on the same day as Mohs, would require an additional trip to the doctor. Also, as many as 10% of skin cancer victims have two or more skin cancers diagnosed at the same time; while currently treated on the same day, in the future two or more trips would be required, delaying treatment and increasing risk. Obviously, the cost in transportation, personal time, and time off work for multiple visits is considerable, not to mention the added inconvenience and risk.

Please consider these extra and unnecessary burdens on Medicare patients that this recent Medicare proposal would cause. On behalf of more than one million skin cancer patients per year across the United States, I respectfully request that you do everything possible to reverse this proposal which restricts my access to cost effective and timely care for my cancer. It is my understanding that the contact person at CMS for this issue is Mr. Terrence Kay (Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244-1850, toll-free telephone: 877-267-2323).

Sincerely,

B. Franklin Simpson — Signature
8/23/07 — Date
B. Franklin Simpson — Name (print)

/ Tracy Lane — Street Address
Apt. #
Williamstown, Ky 41097 — City / State / ZIP +4
859-824-4627 — Phone

August 17, 2007

The Honorable Congressman Geoff Davis
1108 Longworth House Office Building
Washington, D.C. 20515

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

Dear Congressman Davis:

I have been treated for skin cancer with Mohs Micrographic Surgery, a specialized procedure that has the highest cure rate of all treatments for skin cancer. Since I have already had one cancer, I have a 40% chance of another new cancer within the next 5 years. As such, I have become concerned that, in view of a recent change proposed by Medicare, in the future it will no longer be cost effective for my doctor to perform other procedures such as biopsies on the same day as Mohs surgery or to treat more than one cancer per patient per day. It is my understanding that a proposal to remove Mohs surgery from the list of procedures exempt from the Multiple Procedure Reduction Rule will result in a 50% reduction in reimbursement for procedures performed on the same day as Mohs. In many cases, such a reduction would not cover the costs of providing the additional procedures, making it difficult for my doctor to perform more than one procedure for me on the same day.

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Sincerely,

B. Franklin Simpson 8/30/07
Signature Date

B. Franklin Simpson
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Thomas Jefferson University | Jefferson University Physicians

Jefferson Urology Associates

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August 20, 2007

Center for Medicare and Medicaid Services
Department of Health & Human Services
Attn: CMS-1385-P
P.O. Box No: 0818
Baltimore, Maryland 21244-8018

To Whom It May Concern:

My name is Perry Weiner and I am a practicing urologist here in Philadelphia. Additionally, I serve as the Vice Chairman of the department responsible for clinical affairs and I am board certified in Quality Assurance & Utilization Review. As a result of my experience, I am aware of the clinical and financial considerations concerning lithotripsy with respect to both your organization and my patients. However, the views I express in this letter are those of mine alone and do not represent those of my employer.

Increasingly, cost constraints limit the ability of hospitals to invest in cutting edge treatment, which benefits patients and ultimately translates into better outcomes. This also results in increased patient's safety with the effect to positively impact on disease management. Joint ventures such as lithotripsy allow the private sector to perform these services, which I believe, ultimately benefits our Medicare and Medicaid population.

I am very concerned about your recent stand regarding these joint ventures and believe if they are enacted, patients ultimately will suffer.

As written, your proposal will eliminate joint venture programs between a physician and a hospital currently providing therapeutic services only because they are performed in a hospital setting. Some of these procedures include not only lithotripsy, but BPH-related procedures as well. My particular area of interest is that of BPH and I will assure you that my ability to provide these services to my patients allows them to receive the most up to date and safe treatment, otherwise limiting patient choices. These choices often would result in a prolonged hospitalization and increased cost. Most certainly, this would also increase patient discomfort and raise the risk of hospital-associated complications.

Procedures such as those described above are of sufficiently low volume that a single institution may not be able to invest sufficient dollars because the volume of services performed is not cost effective. Joint ventures allow physicians to spread the cost of equipment among several hospitals reducing overall capital costs and allowing these procedures to be delivered to a larger patient population.

With respect to shockwave lithotripsy, the courts have demonstrated that lithotripsy is not a designated health service and it would seem apparent to me that similar outpatient procedures performed in the ambulatory setting would be viewed in a like fashion.

The CMS proposal to ban "Per-Click" fees is directly opposite of that which is intended by Congress, and I believe that your position would directly oppose what has already been stated to be a permissive service.

I would urge you to reconsider your position for the benefit of our patients.

Sincerely yours,

~~Dictated, not signed~~

Perry R. Weiner, DO

PRW/ar/hs

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RIDGEFIELD PHYSICAL THERAPY

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Ridgefield, WA 98642

(360) 887-7147

WORK AND SPORTS INJURY CENTER

PETE BARTEL, P.T.

08/27/07

Mr. Kerry N. Weems
Administrator-Designate
Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services

ATTN: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Dear Mr. Weems,

I am writing regarding to CMS-1385-P, specifically in regards to physician self-referral issues in relationship to physical therapy. I have been a physical therapist in Washington State for 32 years and practiced in a variety of settings, including hospital in-patient, outpatient, nursing home, home health, and in private practice. I served a total of 11 years on the Board of Directors of The Washington State Physical Therapy Association. Since the 1980s I have been concerned about physician ownership of physical therapy services where the physician may self-refer for PT. I believed the Stark legislation would resolve this problem, but as we all know, it has not.

I have heard from a number of therapists in a variety of settings who have complained of abuses with physician ownership of therapy practices. This includes instances where physicians refused to refer outside their own physical therapy business. Although I believe the majority of physicians are ethical individuals, I believe with physician owned PT there is great potential for abuse and it also eliminates any marketplace competition. The problem with the physician as gatekeeper of medical care occurs when the only gate that he opens leads to his or her own PT business. Without this market dynamic, there is no incentive to hold down cost or improve care.

I will relate two specific instances of which I am aware that highlight some of the current problem of physician ownership. The first incident happened to a friend of mine who was employed by 2 physicians in Olympia. She had worked for them for over a year when one of the physicians told her he was going to refer all patients to PT since "the numbers were down." She replied that she could only see those patients that truly needed physical therapy and it would be unethical to see the others. He replied "You didn't hear me. I am sending all patients to physical therapy." She again restated that her contract specifically required her to operate in an ethical manner. The following week she was fired on the grounds of "inability to communicate." When I suggested she file a complaint, she said her contract specifically prohibited her from speaking about any of her conditions of employment if she was terminated.

The second example came from my direct experience dealing with a large group of physicians with multiple offices in our county. One of their clinics was directly across the street from mine and I enjoyed a cordial relationship with them for over 10 years. They frequently expressed their pleasure and approval of my services as a physical therapist for their patients. They even referred a great many of their capitated patients to me. I had been told by one of their insurance

managers that they would never drop me from their capitated program because my charges were much less than they could provide with their own physical therapist.

However in 2003 this changed as they added more therapists in more locations. I had been seeing an average of nearly 40 referrals per month from them in 2002 and it almost instantly dropped to less than 15 referrals per month.. I had several former patients who live 5-10 miles north of my clinic relate that they had been instructed to drive to the main clinic in Vancouver. This made them almost literally pass my clinic to go another 10 miles to the physicians' clinic. Several patients reportedly complained and eventually they added a part time therapist at the clinic across the street from my office. Although I have a well established 3,500 square foot clinic with 4 physical therapists who average over 20 years of experience, suddenly most of the patients were going to the doctors' therapist who was a new grad seeing patients 3 days a week in a small, converted exam room with minimal equipment.

I had close friends working at the doctors' clinic, including medical assistants and their referral coordinator. They relayed to me that at the staff meetings their supervisor told them to encourage patients to see the clinic's physical therapists as this was "better for the bottom line." I had seen some of their bills which ranged from $120 and $160 a visit and at the time our average visit charge was $80. The referral coordinator told me that they booked patients first at the clinic before referring to outside sources. This is particularly true of the physicians at the main clinic in Vancouver. Although I had treated many of their patients from a variety of specialties, I saw this drop to virtually nil. A couple of providers at the local clinic still regularly send me patients despite this arrangement, but overall after 4 years, we now see only 11 new referrals/month from these physicians. This is in spite of a huge population growth throughout our county over the past 5 years.

Again I stress that not all physicians involved were necessarily operating in an unethical manner. However, I cannot see how it is to the benefit of our patients or Medicare, when they are required to drive farther for care with less experienced therapists in small facilities at a much higher visit charge. Since the majority of the clinic doctors had frequently proclaimed our praises over the years, it appears fairly obvious that financial incentives are a driving force rather than concerns about the best and most appropriate care for their patients. If physicians can receive profit from every patient that they self refer, it makes it nearly impossible to compete, even if I provide the care for free.

I apologize for the length of this letter, but wanted to give a clear representation of two incidents that clearly illustrate one of the problems of physician self referral to physical therapy. Even under the best of circumstances, this creates an avoidable conflict of interest for both the physician and the therapist to uphold the fiduciary responsibility to patients. I urge you to consider tightening and eliminating this loophole that gutted much of the original Stark legislation.

Sincerely,

Pete Bartel, P.T.
PB/eb

SKIN AND LASER SURGERY ASSOCIATES

AARON K. JOSEPH, M.D.,P.A.

Diplomate of the American Board
of Dermatology
Fellow of the American College of Mohs
Micrographic Surgery and Cutaneous Oncology

August 22, 2007

The Honorable Herbert Kuhn
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Washington, DC 20201

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

Dear Acting Administrator Kuhn:

As a dermatologist specializing in the treatment of skin cancer with Mohs Micrographic Surgery, I want to convey my concerns about proposed Centers for Medicare and Medicaid Services (CMS) coding and payment guidelines for skin cancer surgeries. I worry that these changes will have a negative effect on access to timely care of skin cancers for senior citizens and organ transplant patients.

I would like to call your attention to section II.E.2 (P-122) of the 2008 Medicare Fee Schedule Proposed Rule. This proposal would change sixteen years of prior CMS guidelines exempting Mohs surgery codes from multiple procedure reductions (modifier -51 exemption). Because of the unique nature of each tumor treated, the intra-service work effort, limited pre- and post- service time these CPT codes, 17311-17315, and their predecessors 17304-17310 have been exempt from payment reductions when multiple tumors are treated on the same day or when combined with a separate reconstruction.

Changing this longstanding rule in 2008 will decrease reimbursement for physicians to the point that the cost of performing the procedure is not even covered. This will result in decreased access to comprehensive skin cancer care for seniors and transplant patients as fewer tumors will be treated in a timely manner.

SKIN AND LASER SURGERY ASSOCIATES

AARON K. JOSEPH, M.D.,P.A.

Diplomate of the American Board
of Dermatology
Fellow of the American College of Mohs
Micrographic Surgery and Cutaneous Oncology

August 22, 2007

I respectfully request that you review the comments made on behalf of the American College of Mohs Surgery by the College President, David Brodland, M.D. His letter to you dated August 2, 2007 provides a very detailed description of all of the pertinent issues. Thank you for your time and consideration.

Sincerely,

Aaron K. Joseph, M.D.

cc: Senator Kay Bailey Hutchison
Senator John Cornyn
Representative Nick Lampson

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

August 27, 2007

Dear Mr Kuhn:

I am a private practice urologist in a suburban Chicago area that services a large number of Medicare patients. I am writing in regard to the proposed changes to the physicial fee schedule rules that were published on July 12, 2007. Specificaly the ones that concern the Stark self-referral rule and the reassignment and purchased diagnostic test rules.

The proposed changes in these rules will have deleterious consequences of limiting access in our area for multiple urologic services...specifically radiation therapy (both brachytherapy and IMRT), lithotripsy, and many in-office procedures like thermal ablative procedures for prostate obstruction....all of which have been innovations designed to improve quality and convenience for our elderly patients. These many in-office services have come into existence due to hospitals either not having the market share that would allow these services to be done in fiscally responsible way, or the capital or human resources to initiate these innovative outpatient procedures.

I found the enclosed article in the Wall Street Journal on July 19 , 2007 particularly pertinent to this discussion.

If the proposed changes to the reassignment and purchased diagnostic test rules go into effect, it will be difficult if not impossible to provide these services to the many elderly that we serve.

Sincerely,

George G. Moran, MD
5201 S Willow Springs Road
LaGrange, Illinois 60525

George Moran MD

475 attachment

Where Are the Innovators in Health Care?

By Regina E. Herzlinger

No sector of our economy is more in need of innovation than health care, yet its many regulations handcuff entrepreneurs. A consumer-driven health-care system will unlock these shackles to bring about a much-needed entrepreneurial revolution.

Health care's $2.2 trillion of costs (17% of GDP), breaks the backs of U.S. firms that compete with companies in countries spending, at most, 12% of GDP on health care. Yet, despite this torrent of cash, more than 40 million Americans lack health insurance, mostly because they cannot afford it. Although some claim we have the world's best health-care system, where are the quality outcome metrics to back this up? Don't try that one on the loved ones of the 300,000 people killed by hospital "medical errors" in the past few years.

In almost every sector of our economy, brilliant, effective innovators have forced sluggish U.S. industries to become more productive. Sam Walton's exquisitely detailed supply chain management, coupled with his daring decision to locate Wal-Marts in rural areas, kick-started the boom in retailing, while Bill Gates, Steve Jobs and Michael Dell drove productivity in the IT sector. These entrepreneurs, and so many others, have fundamentally improved our economy by making goods and services better, cheaper and more accessible.

But can you name any innovators in our bloated, inefficient health-care system? While there is innovation in the medical technology and health-insurance sectors, when it comes to health services, the 800-pound gorilla of our system, entrepreneurs are nowhere to be found. And their absence has enabled the status quo providers to get fat and sloppy.

One analysis showed that hospital activities accounted for $400 billion of the excessive costs of U.S. health care while all too many quality measures have worsened. Patients learn— sometimes the hard way—to bring along an assertive, intelligent loved one to protect them during a hospital stay.

Entrepreneurs avoid health-care delivery because status quo providers, abetted by legislators and insurance companies, have made it virtually impossible for them to succeed. Unlike any other U.S. industry, consumers do not set prices, yet they provide all the money through taxes for government programs and foregone salaries for employer-provided benefits. A third party—a government or an insurance company—not only sets the prices but goes so far as to specify procedures and even the kinds of patients to be covered.

Lately, payers are even telling doctors how to practice medicine—and those who follow their recipes get paid more. The recipes are devised through an innovation-killing "peer review" process. The history of medicine is filled with shameful stories of "peers" who used their powers to suppress innovations: Judah Folkman, the brilliant scientist whose anti-angiogenesis theory forms the basis for many important new cancer drugs, for example, had difficulty obtaining peer-reviewed government research funds for nearly a decade.

Third parties' lock-hold on reimbursement punishes innovators. When the Duke University Medical Center's innovative new program for people with congestive heart failure so substantially improved patients' health that hospital visits and usage plummeted, the perverse nature of the payment system meant Duke couldn't benefit from saving its patients' money—nearly $8,000 per person. In only one year, the program had reduced costs by 40%, yielding the kind of do-good returns that would normally earn kudos from Wall Street and Main Street. But, because the third parties pay providers only for treating sick people, they penalize innovators who make people healthy.

Non-market based payment is but one of many barriers to innovation that plague the health-care industry. Insurance entrepreneurs who confront mandated benefits and "community pricing" can neither design nor price their innovations. Technology entrepreneurs must clear massive hurdles before securing the "coding" and "coverage" decisions that open the door to reimbursement. And health-service entrepreneurs must comply with tens of thousands of pages of regulations.

Time and again the regulatory status quo blocks entrepreneurship. Consider the round-the-clock coverage, offered by Washington's Dr. Garrison Bliss, that will be available to middle-class and uninsured people at a price of only $70 a month. Attempts by insurers to characterize Dr. Bliss as an insurance company—with the attendant massive capital reserves and regulatory hurdles—have required his small start-up to hire a full-time lobbyist. No wonder the 20 or so doctors enrolled in my class "Innovating in Health Care" at Harvard Business School are ruefully driven to earn MBAs once they realize they can innovate in medicine better as an entrepreneur than as a doctor.

Luckily there is a solution, but there is only one: consumer-driven health care. Let's take back our $2.2 trillion from the entrepreneur-suppressing status quo and allow consumers to reward those entrepreneurs who lower costs by improving health. With us in charge, not only would Duke University Medical Center have flourished, but other entrepreneurs would introduce similar cost-reducing programs for the other chronic diseases, like diabetes, and disabilities like bad backs, that account for nearly $1.8 trillion of expenses.

Until we control our own health-care system, the entrepreneurs who could reform it—and make our lives better—will continue to look elsewhere for opportunities. Who can blame them?

Ms. Herzlinger is a professor at Harvard Business School, a senior fellow at the Manhattan Institute and the author of "Who Killed Health Care?" (McGraw Hill, 2007).

Wall Street Journal
July 19, 2007

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Administrative Office
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kitsap physical therapy
AND SPORTS CLINICS

Mike Danford, PT, OCS, MTC
Jackie Foss - Admin. Assistant
Amy Dyers - Billing Mgr.
Wendy Robbins - Billing Clerk

August 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.

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 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. 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 am a physical therapist that has been practicing for 32 years with the last 30 of those years spent operating my own private practice in a rural community on a peninsula in the Puget Sound area of Washington. My practice started when most doctors didn't even know what physical therapy was and we have grown along with the population growth in the area to the point where we now have 6 sites, 25 FT physical therapists, 14 PTA's, and about 24 other staff for reception, billing, administration, clinical aides, and cleaning. In the last several years, the ugly face of this problem has been rapidly expanding. I will give you 4 examples of situations we have encountered:

1. There is a group of occupational medicine doctors that were our biggest supporters for many years. They even encouraged us to grow and expand – saying that they had confidence in the work we did and wanted it to be more available throughout the county so that it would be more convenient for their patients. We did many projects with them and thought we had a close, quality based working relationship. When the rules changed to allow them to open their own PT service, they hired 2 of their own PT's to keep their referrals "in-house" and cut us off completely. They even had patients living in outlying areas drive past one or two of our offices just so that they could keep the business even though we have better facilities and more highly trained staff at our offices. When asked about it, they said it wasn't anything personal or about our skills, it was just a business decision based on what would be best for them. The PT's they hired had significantly less experience in orthopedic care than any of our staff (we know this because one of them later applied to work with us saying she was frustrated with

the situation because she felt she was being taken advantage of [worked too hard] just to make the doctors bigger profits).

2. The next experience was with the largest organized group of doctors in the county – they have over 100 physicians including 6 orthopedists. This group opened a new large office in the main town at the center of the county. We were excited because 2 years ago they opened a new large "main" office on the lot right next to our office. Up until this time, this group of doctors was by far our main source of referrals with 7 of our top 10 referrers being from this group. Up until this point, this group had been doing things what we considered to be "the right way". By this I mean that they used a referral form that had the request for PT with pertinent information on one side and they had a list of all the PT offices in the region on the back of it (a list of more than 20 offices). They also had been willing to meet with us periodically during the year to discuss mutual topics related to the work they were doing and what treatment we were doing to support that care. Basically, they challenged us (and other PT offices) to "prove to us why we should recommend you to our patients". They challenged local PT offices to "earn" recommendations by providing better locations, better hours, better equipment, more advanced training/skills for staff, and outcomes showing better results in less visits/lower costs. We always were concerned about providing the best program we could to stay as good as or better than other choices in the area. It has been very frustrating to us that, when they opened the new office right next to us, they also opened a physical therapy office as part of it. As of that day, they cut off all referrals to us (and other local PT offices) and also stopped using the referral papers that show their patients that there are any other options other then themselves. They offer shorter hours of operation, have staff with less years of experience and less advanced training/certifications, have much less equipment, and have lower quality spaces (they only have cheap curtained areas for "rooms" while we have more rooms and they all have real walls and doors. Additionally, since one of their surgeons is a hand specialist and we had the only certified hand therapist in the area, they called her up and told her that they wanted her to come and work with them – and if she didn't, they would bring in a new CHT and would no longer be allowing any patients to go out to her. As a result, she felt she had not choice but to leave and go to work for them. Additionally, the typical referral we got from the orthopedists in this group was for treatments 2x weekly for 4 weeks. We have been told by many sources that the standard now is for 3x weekly for 6-8 weeks. This group had originally told us that they would only have 1-2 physical therapists, but within a year they had expanded to 5 full time PT's. This has been devastating for my office and has caused us to relocate some of our staff to other offices due to the resulting drop-off in business at that site. An additional example of the problem here is that a PT at a different clinic in a town 10 miles away was telling me that he was at a restaurant there in a booth next to where one of the orthopedists from this big group clinic was talking to a family practice doctor about this "great way to make extra money" with his PT office. He was giving the sales pitch to the family practice doctor asking him to send any of his patients needing PT to this new clinic and he would get some kind of compensation. At the end of the lunch, as they were leaving, he said "are we all on-board now?" and the other doc said it "sounded good". As an added side note, 3 of our independent PT clinic competitors have already

had to close due to their loss of business. Also, we used to have periodic meetings with some of the doctors in this group, but we have been told by the doctors that their corporate CEO has told them they are no longer allowed to have meetings with "outside" PT groups because it is a "conflict of interest" to their corporate goals (since they have their own PT service). I thought they were at least supposed to pretend that they were open to using other PT clinics to reduce the perception that there is a conflict of interest. We have also been told that they routinely have 2-3 week long waiting lists for patients to get in while we guarantee that new patients get started within 24 hours of them calling us. We do this by being willing to pay staff OT to get this done rather than make a patient in pain wait; the physician offices are not willing to pay OT and have it reduce their profit. In the last several months we were surprised that this group has started sending us some patients again. We are happy about this because we need the business, but we have found that the reason is that, due to complaints from patients about having to wait, they are sending out their Medicare and DSHS patients to us so that they will keep a higher percentage of private pay patients. We have always had a policy of taking everyone without bias to their insurance, but the physician owned offices will use their gatekeeper position to skim off the patients with lower reimbursements and let them go to others while not allowing the private pay group the same options.

3. The next example is another orthopedic group in our county has been formed in the last year. This is a group of 6 orthopedics that had been practicing in 5 different groups, but they said that they are following the "standard" set by the group described in case #2 above to come together as a group and they are also opening their own PT clinic where they intend to have all their patients go for the PT. This group just completed their reorganization in Aug of 2007, but have not opened their PT office yet because they had trouble finding PT's. As of this week we heard they finally have hired 2 PT's but they are having them take some orthopedic classes since they have only worked in nursing homes and do not have any experience in outpatient orthopedic settings. The frustrating thing here is that most of our PT's are Certified Orthopedic Specialists (board certified orthopedic specialists) and all of them are required to take several classes every year for continued advanced training. It is going to take these "new-to-orthopedics" PT's many years to gain the level of knowledge and experience our staff already has. These doctors have been utilizing us regularly for many years and have repeatedly been telling us how happy they are with the depth of knowledge and skill of our staff, yet they will now funnel all their business to PT's with clearly much lower levels of skill and experience -- just so that they can make additional profit for themselves off of the physical therapy side of the treatment. They are not doing this for the benefit of patient quality of care; they are doing it for their own financial gain.

4. The last example is the only physiatrist (physical medicine and rehabilitation doctor) in the county. He has ownership in a rehab clinic that specializes in stroke, spinal cord, head injury, MS, and Parkinson's type problems. They do have a good reputation with those problems, so we have no problem with the quality of the work they do for this group of patients, but their PT's have little or no experience with orthopedic problems. When this doctor does occasionally get an orthopedic patient, he sends them to his

clinic even if there are other more convenient clinics or clinics with more qualified PT's that would be better for the patient. When a doctor has financial gain from things, it does create a bias that effects the decisions that he makes for the patients.

As you can see from my examples coming from just the county where I practice, the proliferation of the referral-for-profit situations has grown very rapidly and all because of the incentive for a physician to make extra profit off of physical therapy services. The reason for these doctors to offer these services has nothing to do with any desire for providing better quality of care or more convenience to customers because in all of my examples none of this happened. In actuality, it has resulted in a decrease in quality of care received by the customer and the only gain was financial gain to the referring physician. Many patients that live in outlying areas are being pressured by the physicians to drive significant distances (past many capable, quality clinics) to come to the clinic that the physician profits from even though these same physicians used to recommend these clinics when they didn't have any conflict of interest created by ownership in a PT service. Additionally, this situation has significantly compromised the business I have spent 30 years building based on a "quality of care comes first" standard. Because the physician's financial gain has come at our expense, it has caused us to be more "defensive" in our business practices. We have historically reinvested a much higher percent of our revenue back into our business (staff bonus', continuing ed, equipment, and community support/involvement, etc) because this is also an investment in our professional career. To the physicians, the PT business in just an investment and there is no reason for them to do it other than to make more money for themselves off of it. The quality programs are already here in the community and they already offer a higher standard of PT skill, equipment, facilities, and hours than the programs the physicians are creating. Physicians are not doing the programs because there is a lack of quality already.

Allowing these programs to continue has in fact resulted in a lower quality of care for many patients and has taken away the "competition incentive" from the marketplace. I am convinced that this has resulted in higher utilization, higher costs, and less convenience for patients. Physicians are no longer challenging us to provide a better program to earn their referral; they actually no longer care at all about what programs we have and are not willing to send patients to a better program if it means loss of revenue to them. Physician's without the bias of financial gain are a much better advocate in looking out for the best interest of the patient, while physician's with the bias of receiving financial gain will allow their personal financial gain to influence not just where the patient goes, but also how much they go there. It is not a healthy environment.

Thank you for consideration of my comments.

Sincerely,

Mike Danford PT

Mike Danford, PT, OCS, MTC

Kitsap Physical Therapy **www.KitsapPT.com**
Silverdale Fitness **www.SilverdaleFitness.com**

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Mountain Land.
PHYSICAL THERAPY
& REHABILITATION

Rick Lybbert, PT
Jason Lobb, PT
Kerry Tuttle, OTR/L, CLT
Mark D. Anderson, PT
Jenny R. Elton, MPT, CLT

August 17, 2007

Attention: 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

Dear Mr. Weems,

It is my understanding that the laws relating to Physician Self Referral are being reviewed and I would like to offer my personal experience with this subject as it relates to physical therapy services.

I am a physical therapist of 11 years and a partner of Mountain Land Physical Therapy, a physical therapy private practice across the street from St. Marks Hospital in Salt Lake City, Utah. My practice has steadily grown over the years, as we have become known amongst referring physicians for our high quality of patient care. This growth trend took a sharp dive last year when Salt Lake Orthopedic, the large orthopedic practice who referred the majority of their patients to us decided to hire their own physical therapists. I lost 9 of my top 10 referring physicians and 30% of my new patient referrals in a matter of a couple of months.

While this occurrence obviously had negative impact on the business aspects of my practice, I also believe that it possibly had negative impact on patients being referred for physical therapy services. Changes in referral patterns of this magnitude were clearly driven by financial gain, and arguably not with the best interest of the patient in mind.

I can offer numerous specific examples of incidents where I believe patients received lower quality of care due to financially driven referrals to the physician owned physical therapy practice. However, I believe citing these examples would be of little value due to the subjective nature of scrutinizing a physician's referral to one physical therapy clinic versus another.

Rather, I believe this issue needs to be evaluated from a larger perspective. It is no secret in America that money is a big motivator. In my experience, personal financial gain is the most influential motivator for most physicians when considering where a patient is

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Clay N. Boyd, M.D.
Urology
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Ph: (985) 652-6700 Fax: (985) 651-0540

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

27AUG2007

Dear Mr. Kuhn:

I am an ex-military urologist who has since been in an individual private practice setting near New Orleans, having experienced the onslaughts of Hurricanes Katrina and Rita. I have had a large Medicare population and have treated large numbers of displaced patients and families, caring for people with problems ranging from urinary calculi, to genitourinary cancer, to complicated injuries and infections. 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 on the way urologists 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 that urologists 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 cancer patients. Other complex tests such as lab testing or specialty services such as mobile ultrasound might be limited if the definition of an in-office ancillary service was limited to those tests and services that are needed to immediately diagnose or treat a patient. The limitation of such services would have deleterious effects on patient care, examples being costly hospital admissions for urologic studies currently performed more efficiently in the office. The proposed changes to the reassignment and purchased diagnostic test rules will make it difficult, if not impossible for me to provide various types of services that I currently provide in my office that are provided by part-time employees or independent contractors or for which I purchase services other than on a per service basis, i.e., pathology services. Not being able to provide that service will be detrimental to patient care, causing disruption of diagnostic testing and delay of treatment under the proposed "under arrangement" rule. These arrangements have brought positive outcomes for patients. Without a joint venture, these services would not have been available in our community. The prohibition of per click payments for space and equipment rentals will prohibit current mobile ultrasound arrangements paid for on a per service basis. Prohibiting such arrangements is detrimental to patient care.

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,

Clay N. Boyd, M.D.

Ronald L. Van Nest, CRNA, MA

1306 Anglesey Drive

Davidsonville, MD 21035

August 28, 2007

Ms. Leslie Norwalk, JD
Acting Administrator
Centers for Medicare and Medicaid Services
PO Box 8018
Baltimore, MD
21244-0818

Re: CMS-1385-P (Background, Impact) Anesthesia Services

Dear Ms. Norwalk,

I am a Certified Registered Nurse Anesthetist and member of the American Association of Nurse Anesthetists. I am writing to you in support of CMS's proposal to boost the value of anesthesia work by 32%. Anesthesia services have historically been under valued and have not kept up with inflationary adjustments.

Sincerely,

Ronald L. Van Nest

NCUA

Marc D Benevides, M.D.
H. Kenneth Leatherman, Jr., M.D.
Douglas C. Leet, M.D.
Jerome P. Parnell, II, M.D. F.A.C.S.
Stevphen F. Shaban, M.D.
Steven J. Stafford, M.D.
Lawrence A. Blelloch, PA-C

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North Carolina Urological Associates, Inc.

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226 Ashville Ave., Ste. 40 Cary, NC 27511 919-851-5482 Fax 852-5127

August 27th 2007

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

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

Dear Ladies and Gentlemen:

My name is Marc Benevides and I'm a Urologist in Cary, NC. I am an owner is a joint venture LLC that provides lithotripsy services. We provide excellent quality of care that has improved patient access to an advanced technology. We have a quality assurance program with excellent clinical outcomes. I was not able to provide rapid care to patients before joining the lithotripsy venture. There was only one existing entity that provided sporatic and expensive care. We have been able to provide less expensive quality care.

The new provisions that concern me are as follows: Under Arrangement Contracting, Per Procedure Fee, Percentage Fee and the Stand in Shoes.

The benefit of having physicians involved is the fact that physicians are closer to patients and technology that rapidly changes. Hospitals often continue to use outdated equipment. Our lithotripsy LLC serves area that are remote and can't afford the technology. Mobile units also lower the cost by sharing the expensive technology. Also, under American Lihtotripsy Society v. Thompson, lithotripsy is not a designated health service under Stark. Can it be deemed a DHS? Please also note that lithotripsy is a therapeutic service not diagnostic service. Any new rules should apply only to diagnostic testing, not therapeutic interventions. It is already known that these patients have stones.

It is a common fact that hospitals are risk adverse. Patients often suffer because local hospitals refuse to purchase new equipment especially if they can't predict procedure volume. Small communities, which we service, often can't afford lithotripsy technology. Our LLC services many such small/poorer communities.

Congress clearly wished to preserve per procedure fees in Stark legislative history. CMS seems to be contradidicting congressional intent through a prohibition of such fee arrangements. Could you please confirm that the per procedure payment prohibition would not apply to the Stark indirect compensation arrangement that sustains our LLC. Another thought to try and lower costs is to use ambulatory surgery centers which have been proven to lower costs.

I appreciate you taking the time to read this letter. Especially in regards to the service we provide to under served areas.

SINCERELY,

Marc Benevides MD

MARC BENEVIDES MD

Diplomates of The American Board of Urology

PROCare
PHYSICAL THERAPY

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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

RE: Medicare Program; Proposed Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY2008; Proposed Rule; Physician Self-Referral Issues.

O8/27/07

Dear Mr. Weems;

I am a self-employed physical therapist who owns a small private practice in Greenfield, Wisconsin. I made the decision four years ago to start my own practice so I could provide a better service of care to my community in the means of rehabilitation. Over the past few years I have seen more Physician-Owned Physical Therapy Services (POPTS) open their doors taking business away from private practitioners by keeping patients in-office.

The potential for fraud and abuse exits, and I have seen this first hand. Whenever physicians are able to refer Medicare beneficiaries to entities in which they have a financial interest, especially in the case of POPTS. 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.

I am very concerned about the July 12 proposed 2008 physician fee schedule rule, specifically the issues surrounding physician self-referral and the "in-office ancillary services" exception. As in the past, I foresee an even more abusive use of Medicare dollars under this ruling. There has been many loopholes in the Stark physician self-referral law resulting in the expansion of physician-owned arrangements that provide physical therapy services and because of Medicare referral requirements, physicians have a captive referral base of physical therapy patients in their offices.

The "in-office ancillary services" exception is defined so broadly in the regulations that it facilitates the creation of a thriving environment for fraud and abusive referral arrangements. 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. We all know

6520 W. Layton Avenue • Greenfield, WI 53220 • Phone: 414.282.9590 • Fax: 414.282.9348

Medicare is in need of further reform to keep the program solvent and by changing these laws it will be a major step in helping save Medicare and to protect physical therapy services as Congress had originally intended.

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 to all Medicare beneficiaries.

Please consider my comments on this urgent subject matter and I thank you for your time.

Sincerely,

David Tranchita MA,PT,OCS,CSCS

David Tranchita MA,PT,OCS,CSCS
CEO/President of PROCare Physical Therapy

August 23, 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

RE: Physician Self-Referral Issues

Dear Sir:

I am a practicing physical therapist of 13 years for a not for profit hospital based orthopedic outpatient department. 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 physician –owned physical therapy services" exception.

There are 3 large orthopedic surgical groups in this suburban town in which I practice. In 2002, my manager left our clinic to manage a physician owned clinic. My manager at the time told me that the physicians had been very pleased with the care that our hospital based clinic had given the patients, and that this acquirement of their own physical therapy department was strictly based on financial gains. Our referrals from that clinic decreased drastically as was expected. Three hospital employees left to work at the physician owned clinic and 2 have returned to work for the hospital this year citing they received a bonus the first year based on how many units of service that were billed. The following years, that benchmark was set even higher, so high, in fact that they did not receive the bonus. They also cited that they were being required to see up to 8 patients at one time and were billing each patient as if they were receiving one-on-one care. They were also strongly "encouraged" to use as many modalities as possible (electrical stimulation and ultrasound) even when the patient no longer needed these passive modalities in order to increase the billed units of service. We have in fact had numerous patients that were bold enough to discontinue their therapy at that physician owned clinic stating that they were just left to do exercises on their own while their therapist yelled across the room telling them what to do next. I know this because these were the testimonies of numerous patients that came to our clinic where they stated that the care was much better because the therapist only saw one patient at a time. I know that many of my former patients that I have come in contact with later were told to now go to the physician owned clinic when they needed physical therapy. The patients stated that they did not know that they could go where they wanted and stated that the doctor wanted them to go to his clinic where he could "keep a close eye on them". Many patients are intimidated by the physician and sincerely believe that the doctor has his or her best interest in mind. They do not consider that the financial gains are many times the driving factor. The former employees of this physician owned clinic stated that the physicians never set foot in the physical therapy clinics that they owned.

When therapists are encouraged to see as many patients as possible, even the very best therapist cannot provide quality care. The patient suffers, the profession suffers, and we all suffer financially as a result of abuse of the insurance companies.

I am strongly opposed to the continuing existence and growth of these physician owned clinics. I believe that even the best and most morally strong individuals do not need to have the temptation of monetary gains based on self –referral, abuse of billed units of service and abuse of patients by not giving them the individualized care that they deserve.

Thank you for your consideration of my comments.

Medical Plaza Urology Associates

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Jonesboro, AR 72403
870-932-2926
870-932-1560 FAX

Ladd J. Scriber, M.D.
J. Cranfill, M.D.
Joseph C. Kueter, M.D.

August 22, 2007

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

Dear Ladies and Gentleman:

I have read, with utter dismay, the 2008 proposed physician fee schedule and write at this time to express my concerns and opposition.

I have been practicing urology in Jonesboro, AR since 1975. Jonesboro, AR is a city of roughly 50,000 people with a trade area of roughly 300,000 people. While our hospital is cutting edge, there are technologies that, simply due to economies of scale, the hospital cannot provide.

In the mid 80s when lithotripsy services came to the United States, these services were only available in larger metropolitan areas. At that time, my patients had to be referred hours away for these needed services.

With the advent of limited partnerships and physician driven joint ventures to provide mobile lithotripsy service, I was able, as a practicing urologist, to provide those services to my patients in a timely manner in my own community. This arrangement has been most beneficial to my Medicare and non-Medicare patients since 1990.

Since its inception, that lithotripsy service has provided very timely and up to date quality control data for the entire partnership and each individual physician regarding patients treated. One of the allegations of the proposed changes concerns possible inappropriate referral of patients to a physician. Suffice it to say that with regards to lithotripsy, there could hardly be an opportunity for abuse. Only patients with well documented renal or upper ureteral stones are typically treated in this manner. I think that our quality control data would safely corroborate this contention. Also, as newer technologies have become available for management of stone disease, the number of patients actually being treated with extracorporeal shockwave lithotripsy has seemingly diminished.

Continued on Page 2 . . .

I am keenly aware of the abuses and fraud that have been inflicted on the Medicare program through the years. I applaud the efforts of CMS in seeking out and abolishing abusive practices of the program. I, however, believe strongly in the joint ventures with which I have been affiliated and support our fellow physicians in objecting to the proposals by CMS.

Sincerely,

Ladd J. Scriber, M.D.

LJS/pdp

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Sports Plus Rehab Centers

An affiliate of West Tennessee Healthcare

Dear Sirs,

I have been practicing Physical Therapy in the state of TN since 1997 at a hospital based outpatient P.T. Clinic. 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. I have lived in this mid sized community all my life and I have always felt our health care system has served this community with excellent high quality health care with 2 hospitals and multiple physician Clinics that take care of practically any health issue. However over the last few years a dark cloud has settled over our community in the form of contracted Physical Therapy Clinics that have aligned with physician groups with the primary purpose of monetary gain despite all the well thought out advantages they would lead one to believe. This is the first time I have ever written a letter of this type but I have become so discouraged and appalled at the abusive practices of Physician Owned P.T. Clinics in our community that I feel I must express my concerns in hope that you will take necessary steps to stop the injustice to patients, insurance companies, and the physical therapy profession. Our community supports several Orthopedic Clinics that have recently contracted with outside Physical therapy agencies that are obviously running a business with financial gain as the priority while good patient care is being neglected. These reports are coming to me directly from patients who were coerced by their physician to stay at the "in house" P.T. Clinic because the physician would be available to monitor their progress, which patients' state never happens. They also state that the treatment they received was sub standard due to the high patient volume and were often instructed to lay on a mat with several other patients and perform exercises with very minimal supervision and usually received no "hands on" care. This strongly speaks of over utilization of PT services for financial gain. Also I have spoken personally with more than one Physical Therapist who was lured to these Clinics due to higher wages and later resigned due to being unable to adequately treat such high volumes of patients or provide one on one quality care the patient is entitled and their insurance is paying for. They also became concerned over ethical issues when forced to charge for services the patient did not need or write notes about a patient's progress when they were unable to spend any quality time with the patient. One would hope integrity would reign over greed but the potential for fraud and abuse is so apparent that action must be taken to stop this harmful practice. I strongly urge you to remove physical therapy as a designated health service permissible under the in-office ancillary exception of the federal physician self-referral laws. I want to thank you for your careful attention to this matter for the future of good quality healthcare in our community and our state.

Thank You,

Benny Harper PT, #5082

Benny Harper, PT

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August 23, 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

Re: Physician Self-Referral Issues

Dear Sir:

Few challenges facing physical therapists (PTs) and physical therapist assistants (PTAs) have been as frustrating and tough to deal with as those involving financially motivated practice arrangements in which physicians derive significant profit by using their own referrals to steer patients into physical therapy practices they own. I am writing this letter to ask you to remove physical therapy from the in-office ancillary services exception to the federal physician self-referral laws. I have several patients who have shared some of their personal therapy stories at other clinics that were physician owned clinics. I would like to share one situation in particular with you, federal and state policymakers in order to paint a picture of the myriad problems created by arrangements based on referral of physical therapy services for profit: A recent patient of mine was sent to our clinic after 4 weeks of therapy at a local physician owned physical therapy clinic where she was not making much progress for a minor, common injury. She complained that she did not know she could attend therapy at any clinic of her choice-she was not informed of her rights. Furthermore, she underwent treatment there for a month with very little time spent on one-on-one individual treatment with the pt noting how the staff was "too busy" to help due to the number of patients they were seeing at that clinic at the same time as my patient was attending therapy. As a result she saw a specialist following no significant gains and after 3 weeks at our clinic is 75% functionally improved with no pain as compared to the initial treatment my patient received at the other clinic. My patient has commented several times on the amount of money that "was wasted" at the other clinic at insurances expense. This is only one of several patient testimonials I have heard regarding patient experiences at physician owned physical therapy clinics. Again, I urge you to take action now and remove physical therapy from the "in-office ancillary services" exception to the Stark Referral for Profit Loophole. Please help us prevent referral of physical therapy services for profit for patient benefit, ethical standpoint, and fraud and abuse prevention. Thank you for your time and consideration.

August 16, 2007

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

RE: **Physician Self- Referral Issues**

Dear. Mr. Kerry:

I am a physical therapist and an owner of a private practice in Tennessee. I am deeply concerned by the potential for fraud and abuse that exists with the current status of physical therapy being an in-office ancillary service. I have witnessed first hand the changes in referring practices of local physicians.

When we are trying to get Medicare spending under control, why would we allow more opportunity for abuse? A neurosurgeon in my town once told me that, "Physical therapy is for "stroke patients only. Once I operate on a patient they are well." When he and his partners hired a physical therapist to work in their office, he began sending his patients for pre-op education and a minimum of two post-op visits for exercise instruction. In addition, I have never received an initial order from that office for more than six sessions of physical therapy. With extreme circumstances, I could get four more visits from them if the patient had not met their goals. I have treated many of their patients for other diagnoses. In reviewing their history, I would learn that they had received therapy at the physician's office. I have made it a habit to ask how long their were in therapy. It is not unusual to hear 6-8 weeks, three times per week.

I am not saying that all physicians would abuse this system, but why give them the temptation? Please help to change the current system to reduce the likelihood of fraud and abuse by removing physical therapy from the in-office ancillary services.

Sincerely,

Name Withheld
Tennessee, 37221

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The Meridian Anesthesiology Group, P.A.

2107 North Hills Street
Meridian, Mississippi 39305

David T. Batarseh, M.D.
John C. Braun, D.D.S., M.D.
W. Harry Gibson, M.D., Ph.D.
Ben M. Grimes, M.D.
Gail E. Rasmussen, M.D.
Michael T. Salman, M.D.

Telephone (601) 485-6325
Facsimile (601) 485-3061

August 24, 2007

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

RE: Medicare Pay Increases for Anesthesia Services

Dear Sir:

We 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 we may, we would like to make one last comment. We 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 than 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.

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

Respectfully,

David T. Batarseh, MD
David T. Batarseh, M.D.

John C. Braun DDS MD
John C. Braun, D.D.S., M.D.

W. Harry Gibson
W. Harry Gibson, Ph.D., M.D

Ben M. Grimes MD
Ben M. Grimes, M.D.

Gail E. Rasmussen MD
Gail E. Rasmussen, M.D.

Michael T. Salman MD
Michael T. Salman, M.D.

To: Center for Medicare and Medicaid Services
Department of Health and Human Services

From: Daniel Zapzalka, MD
Department of Urology
Park Nicollet Health Services
St. Louis Park, MN 55416

Ladies and Gentleman,

I am writing you today in regards to the recent proposed plan to change the regulations to outlaw the current structure in medicine whereas physician joint ventures currently contract with hospitals to provide therapeutic services. I am a urologist working in Minneapolis, Minnesota. I work very, very hard trying to provide the best that I can for both my patients as well as for the multi-specialty group for which I work. The work isn't easy and the days aren't short, but I love what I do. The reason that I am writing you is not to go over all the 5 different parts of these proposed rule changes; I am sure that you have received more than enough of those letters written by lawyers who are much better than me at laying out their arguments for why we (the medical community) so strongly oppose these changes. No, my reason of writing you is one of a more personal appeal. We live in very difficult times in the health care profession. More and more is asked of us as doctors and nurses, all of which is supposed to be done more efficiently with zero mistakes. We gladly accept the challenge not because we necessarily like it, but we do it for the sake of the patients and their families, and for the profession. My real one deep reason for writing is to try and make you in the

administrative side of the health care field have some empathy for those of us on the other side of the bench.

We live in a world that expects, no...demands, the absolute best that the world of medicine has to offer. Yet, when it comes to finding the resources to purchase the equipment to make this happen, cash strapped hospitals tell us they don't have the money for our capital purchase requests. Just look at the world of urology as an example. In the last 2 years, we have gone from treating enlargement of the prostate (BPH) with traditional transurethral resection of the prostate and prostate cancer with open prostatectomy, to now treating BPH with laser treatment and cancer with robotic laparoscopic prostatectomy. This has been revolutionary for our patients. They recover much faster, with less pain and complications and return to a normal life much quicker. One would think that we would be rewarded for these achievements. But no, the reimbursement by CMS is actually less for laser treatment of BPH than old fashioned TURP and the payment for robotic prostatectomy is the same as open surgery even though it takes much longer to do. However, the acquisition cost for the laser is $150,000 and the surgical robot is $1,700,000. So, who pays for the capital expenditures for us to take pay cut. The hospitals don't want a part of it, they can't afford it. As a result, for the SAKE OF THE PATIENT AND OUR PROFESSION, physicians have banned together to "go in" on purchasing the machines to make medical progress happen ourselves. We do it in spite of the pay cut to help the patients recovery quicker and actually in return save CMS and the hospitals money by shorting hospital stays and complications. Now, CMS wants to even put an end to this!!! How can you not expect

Bone & Joint Specialists

G. Blake Chandler, M.D., ABOS
Michael D. Calfee, M.D., ABOS

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August 27, 2007

Administrator Leslie Norwalk
Centers for Medicare & Medicaid Services
P.O. Box 8018
7500 Security Boulevard
Baltimore, MD 21244-8018

Attn: CMS-1385-P

Dear Administrator Norwalk:

I write as a practicing physician in Paris, Tennessee and a member of the American Academy of Orthopaedic Surgeons to **support CMS' proposal to reimburse physicians for arthroscopy procedures performed in their office.**

Both the clinical literature and my own practice show that in-office diagnostic arthroscopy is a safe and highly accurate procedure. Medicare, though, will only pay for theses procedures when they are performed in a "facility" such as a hospital outpatient department or an ambulatory surgical center. Such a policy does not reflect modern-day medical practice, the interest of patients, or the experience of physicians.

Clinical literature since the early 1990s has confirmed that the physician's office is an appropriate setting for diagnostic arthroscopy. Your staff may be interested in reviewing Wei N., Delauter SK, et. al., "Office-Based Arthroscopic Synovectomy of the Wrist in Rheumatoid Arthritis." *Arthroscopy.* 2001 Oct; 17(8): 884-7 and Small NC, et. al., "Office Operative Arthroscopy of the Knee: Technical Considerations and a Preliminary Analysis of the First 100 Patients." *Arthroscopy.* 1994 Oct; 10(5): 534-9. These are just two articles among many that establish the safety of these procedures.

Additionally, as the proposed 2008 physician fee schedule notes, some physicians – despite reimbursement obstacles – perform arthroscopic procedures in their office today. I am confident that even more physicians would perform this procedure in their office if CMS established payment. Under the current system physicians must send their patients to a second appointment when information from a diagnostic arthroscopy is needed. This needlessly delays medical care, increases costs, and inconveniences the patient.

Accordingly, I urge CMS to recognize the weight o9f the clinical evidence and the practice of the medical community. Establish non-facility practice expense relative value units for arthroscopy procedures.

Sincerely,

G. Blake Chandler, M.D.
GBC/kb

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)

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

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

Dear Ms. Norwalk:

I am writing to express support for the proposed increase to anesthesia payments under the 2008 Physician Fee Schedule. I work in a Community Hospital where access to care for seniors has been limited by providers' ability to care for patients with the low CMS reimbursement. The RUC has recommended that CMS increase the anesthesia conversion factor by 32% (about $4.00 / unit). This would be a major step in correcting a long standing, undervaluation of anesthesia services by CMS.

The current reimbursement does not cover the cost for caring for our seniors and draws anesthesiologists away from hospitals like mine with large Medicare populations. It is imperative that CMS follow through with the proposal in the Federal Registry and immediately implement the increase in the anesthesia conversion factor as recommended by the RUC.

Thank you for your consideration,

David C. Powell M.D.

David C. Powell MD

492

Bradley J. Thomas, M.D.
PO Box 2509
Truckee, CA 96160

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

Dear CMS:

I strongly support the proposed rule to boost the anesthesia conversion factor for Medicare payment. As an anesthesiologist, I have been frustrated for many years over the dramatic undervaluation of my medical services by CMS. Medicare patients are aware of this situation as well. (Please read the enclosed typical letter from one of my patients.)

While I am sensitive to the serious funding challenges faced by the Medicare program, I believe our senior citizens would support this modest and long overdue increase. As a practicing anesthesiologist, I believe it is certainly the right and fair thing to do.

Respectfully,

Bradley J. Thomas MD

Bradley J. Thomas, M.D.

Dr Bradley J. Thomas, MD
P. O. Box 34120
Reno NV, 89533-4120

January 20, 2005

Dear Doctor Thomas,

You may recall that you were the attending anesthesiologist when Doctor Dodd repaired my broken femur bone on February 6, 2004. My injury was sustained from a skiing accident earlier that same day. You and I met prior to the surgery, and you may remember me because I mentioned that I did not want a spinal tap.

I understand the surgery lasted for over three hours and, while routine in nature, it was still a serious surgery because of the specific kind of injury and the fact that I had been under the influence of blood thinners for atrial fibrillation.

Throughout the entire surgery procedure you attended to me and, quite frankly, my life was in your hands.

Subsequent to your medical care for me, you submitted a bill to Medicare for $910. As it turned out, Medicare only approved $245.23 for your services.

I write you this letter because I truly believe your compensation by Medicare was incredulous! The skill you performed on my behalf was worth far more than $245.23.

To put matters into perspective, had you been a plumber and called to the hospital to make a four hour plumbing repair, you would have been paid much more than $245.23.

While I realize nothing can be done at this juncture, I wanted to let you know my feelings about this matter and express my gratitude for a job well done.

Regards,
Dave Stoner

588 Trumbull Court
Sunnyvale, CA 94087

cc: Medicare

Emergency Medical Service of LeFlore County
Post Office Box 1025 – Poteau OK 74953 – 918.647.9270

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Committed to Excellence:
Dedicated to Service

August 27, 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

We understand that you are seeking comments on CMS-1385-P and we would ask that you consider dropping the requirement to obtain signatures altogether for the following reasons.

1) Presently EMS has a very hard time obtaining a beneficiary signature in an emergency situation because the patient is usually in such distress that they cannot understand what we are seeking, or is unable to sign due to their condition. The same can be stated for the beneficiary under non-emergency situations as well.
2) If we are required to obtain a signature after the fact, this will cause an increase in our overhead expense in additional manpower and wasted time as many times, the patient remains incoherent and in some cases, is even less likely to sign after the service has been rendered.
3) Under HIPAA regulation 45 CFR 164.506(c)(3), we understand that the signature is not required. In addition, since we are mandated by statute to provide care to a Medicare beneficiary, it seems redundant to obtain a signature.
4) Finally, most, if not all of our clients are transported to the same local hospitals and back to their extended care facilities, so their signatures are already on file, this adding to the burden placed on EMS providers.

EMS remains one of the most under-reimbursed providers under all healthcare plans, especially Medicare and anything that can be eliminated to help relieve the paperwork burden on us should be considered. Our costs to provide service has continued to explode while reimbursements continue to fall and here in Oklahoma, this has led to the closing of 47 EMS providers since 2001.

CASCADE PHYSICAL THERAPY & SPORTS CLINIC 494
HAROLD VON BERGEN, P.T.
RICK SCHAFER, M.P.T.

August 22, 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: Referral for Profit by Physicians

Dear Mr. Weems:

I am writing to you as a Physical Therapist with 11 years working experience, primarily in the outpatient orthopedic clinic environment. In each location, Medicare patients have made up a 20-40% of clinic clientele. My concern of physicians referring patients for physical therapy to clinics which they have financial interest is based on first hand experience and observation and information gleamed from patients who have eventually presented to me for treatment. It is not uncommon for a patient to describe a scenario where they were given no choice as to the location of preference of physical therapy clinic but were handed a prescription and told to present for scheduling at the clinic that the physician had financial interest in. The reason I would find out regarding these cases would be the patient would protest due to the inconvenience of location and there awareness of our clinic much closer and convenient to their place of residence. Sometimes there have been reports of some raised tension between the physician/physician's assistant and the patient when the patient indicated their desire to receive treatments at a clinic of their choice.

I have never seen this type of reaction or response with people who have DSHS/Medicaid where reimbursement is very low. This is likely more than coincidence as patients with higher paying insurance are of more value if they are able to be retained in-house.

I have also seen people who have presented at physician owned clinics who some weeks or months later will be sent by an alternate doctor to physical therapy at my clinic and will report that they had no idea that they had a choice in the matter regarding the selection of their treating clinic. Presentations like these are cause of great concern to me, not only for the lack of ethics but for the potential of over utilization and potential for fraud.

Thus, I would strongly encourage eliminating physical therapy as a designated health service furnished under the in-office ancillary services exception. I believe that this would both work to provide a better service for Medicare clientele as well as provide an enhanced environment in the community for individuals needing the services of physical therapy.

Thank you for your consideration of the above comments. I trust that they will be combined with all the feedback you are receiving on this issue to help create a better environment in this important area.

Sincerely,

Rick Schafer, M.P.T.

210 FERRY STREET SEDRO WOOLLEY, WA 98284 (P) (360) 856-4216 (F) (360) 856-4217

DESMOND J. REILLY, M.D.
4200 JONATHAN LN.
HARRISBURG, PA 17110
717 - 233-8091

August 26, 2007

CMS-1385-P

Leslie V. Norwalk Esquire
Administrator
Center for MM SVCS
Baltimore

Dear attorney Norwalk:

You will probably never see this letter but as a retired arrestaologist of 30+ years of practice I am delighted that CMS is considering increasing the payment for arrestaea services. For years the $16.19/unit was woefully low. Considering the stress of the practice of arrestaology an increase reflects payment in kind.

I thank you and have a good day.

Sincerily,
Desmond Reilly MD
Harrisburg PA 17110

MAGNOLIA
Physical Therapy

To: Mr. Kerry M. Weens
Administrator – Designate
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services

8/16/2007

From: Beth Winkler-Schmit FAAOPMT and
Lisa K. George, Magnolia Physical Therapy
Subject: Physician Self Referral Issues

Dear Mr. Weems,

We are writing to you as small business owners of a physical therapy private practice in New Orleans to urge CMS to remove physical therapy as a designated health service permissible under the in-office ancillary exception of the federal physician self-referral laws. We have fought hard to resume our business after Hurricane Katrina and have been successful. However, we are very concerned about POPTS (Physician Owned Physical Therapy Practices) and the potential for abuse to refer for profit and how this could affect our clinic and physical therapy as a profession..

We have experienced several incidences where our loyal patients have been encouraged to attend the physician's own physical therapy clinic by the physician or his/her staff members. In one incident a loyal patient of ours replied after being told to go to the physician's own physical therapist that he has been working with us for 4 years after several surgeries and would like to go to a PT he feels comfortable with and that knows his case (this patient has had 10 rotator cuff repairs after an infection from a contaminated needle). The physician stated that he could "look after him" better if he was having therapy in the same building so the patient made appointments there. After the first 2 visits the patient was in so much pain he requested to switch to our facility. At this time the nurse reluctantly gave him the prescription and said "fine, but we better have notes every week from your therapist". The patient reported that every MD visit they tried to encourage him to use their physical therapy services.

Another incident includes a former patient who saw her physician for a new injury. The physician recommended she have PT in his office, however the patient lived 30 miles from the facility. When she mentioned she would like to go to our facility, only 3 miles from her house, he stated that if she went to his facility he could closely monitor her progress. This patient DID attend his PT clinic, stating she was uncomfortable confronting the physician, even though we were closer and she was pleased with us before.

990 N. Corporate Drive • Suite 305 • Harahan, LA 70123
Phone: 504-733-0254 • Fax: 504-734-8869 • www.magnoliatherapyla.com

In another incident, the receptionist went so far as to run after the patient in the parking lot to try to convince her to attend their facility after being reprimanded by her office manager for allowing the patient to attend another facility. She declined.

This is a serious problem and needs to be addressed. As a profession, physical therapists are striving hard to become more autonomous with masters programs advancing to Doctorate programs and incorporating more research and business education in their curriculum. The private practices strive hard for personalized service which patients are noticing AND asking for. The private practices already have to work hard against competing with large hospitals and chiropractors, we shouldn't have to fight for what should be rightfully ours against our own referral sources. Please consider removing physical therapy as a DHS in physician's office.

Sincerely,

Beth Winkler-Schmit FAAOMPT
CEO Magnolia Physical Therapy, LLC

Lisa K George PTA
VP Administration

8/25/07

Mr. Kerry N. Weems
Administrator – Designate
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-13585-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

I am a physical therapist in a supervisory position with a hospital-based outpatient physical therapy clinic. I wish to comment on the July 12 proposed 2998 physician fee schedule rule, specifically the issue surrounding physician self-referral and the "in-office ancillary services" exception. I wish to highlight the abusive nature of physician-owned physical therapy services and support the PT services removal from permitted services under the in-office ancillary exception.

Having leased from a physician-owned orthopedic practice, I witnessed several abusive arrangements. This orthopedic physician-owned practice also owned the x-ray department, the MRI department, and an outpatient surgical center at the same location. The patients spend 2-7 hours at this facility waiting to see the orthopedic surgeon, waiting for expensive test that are ordered before the physician evaluates the patient, waiting for the test results, and waiting to see a physical therapist that may or may not be covered by their insurance company. For example, I was often paged into the patient's room and instructed to "take the patient to physical therapy" so that the physician can "get another patient in". Thus, physical therapy was often requested to get the patient out of the physician's office so that the assembly line could continue. Many times these patients were referred to physical therapy when they were already seeing a physical therapist. When this fact was brought to the physician's attention, he stated that he wanted the patient to receive "one-stop shopping" and insisted the patient be seen by our physical therapy clinic for a one-time home exercise program. In order to prescribe exercises for the patient, an initial evaluation must be performed. However, insurance companies typically only cover one initial evaluation; therefore, if the patient was currently being seen by another physical therapist, the patient would have to pay for this 2nd initial evaluation out-of-pocket. Now that this physician-owned orthopedic practice also owns the physical therapy clinic, they collect the money or reimbursement. Thus, they will not refer out to areas that are closer to the patient's homes or to the physical therapist that the patient may already be working with because it does not fit into their "one-stop shopping" model. I believe this is in direct conflict with the patient's right to choose their own medical care and although I no longer work in this physician's building, I know this practice continues.

When I moved to my new location, some of my patients chose to follow me and continue their physical therapy under my supervision. One these patients returned to her orthopedic surgeon for her follow-up at the same physician-owned practice. While at her appointment, the physician escorted her to their physical therapy department and ordered her to go to their clinic instead of returning to me. Fortunately, my patient's mother is a lawyer and stepped in to inform the physician that he was denying her the patient right to choose her own healthcare service. The physician apologized and she returned to me for the remainder of her physical therapy.

Another patient I had seen while at the previous location had been discharged from physical therapy. She suffered a new injury and went to the Emergency Department where a physician prescribed physical therapy for her back spasms. The patient worked in the building next to our previous location and called the physician-owned physical therapy department to schedule an appointment. The physician's staff informed her that she could not receive physical therapy unless she saw one of the physicians in their practice. The patient informed the staff member that she did not want to pay $30.00 co-pay when she already had a physician's prescription for physical therapy. The staff informed her she could not be seen at their clinic; thus, she contacted my hospital-based physical therapy clinic and received physical therapy from us one week later.

These three examples show the fraud and abuse that occurs when physician-owned practices have an inherent financial incentive to refer their patients to the ancillary services they are invested in. These examples also show how the quality of patient care is replaced with an assembly line production of manufacturing money. The "one-stop shopping" model is a great model when different companies work together to provide patients with the services they need. The model does not work when a physician-owned practice owns all the services and over-utilizes the services for financial gain. This is fraud and abuse of medical power.

Please consider eliminating physical therapy as a designated health service (DHS) furnished under the in-office ancillary services exception.

Thank you for considering my comments and I appreciate your interest in improving the quality of care for all patients.

Sincerely,

Jeanette M De Witt

Jeanette M. De Witt, PT, LAT, ATC

498

Carteret Surgical Associates, PA

General Surgery

Dean R. Marson, M.D.
John T. Johnson, Jr., M.D.
Kevin Martin, P.A.-C.

General and Thoracic Surgery

Bradford D. Drury, M.D.

General and Vascular Surgery

Michael A. Bell, M.D.
Robert J. Brockman, M.D.

Orthopedic Surgery

Jeffrey K. Moore, M.D.
Thomas E. Bates, M.D.
Ashraf F. Guirgues, M.D.
Charles Pfaff, P.A.-C.
Steven J. Huber, P.A.-C.

Orthopedic Surgery & Sports Medicine

Robert E. Coles, M.D.

Urologic Surgery

Robert W. Garrison, M.D.
Arthur G. Klose, M.D.

August 23, 2007

Center for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS – 1385 – P
PO Box 8018
Baltimore, MD 21244-8018

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

Dear Ladies and Gentleman:

I am a urologist in private practice in Morehead City, North Carolina, a rural area, where I have practice urology since 1981, and have been a owner in a joint venture capital LLC that provides lithotripsy services. Physician-owned LLC's in general have been a major cause for the improvement and convenience of health care for the people in our community .The closest major medical center is over 3 hours away, and the type of equipment and facilities that is often required for some of our higher tech procedures, could simply not be accomplished without these physician-owned LLC's. Hospitals generally are unwilling to make major commitments in new technology, and if it weren't for the physicians understanding the significant advances and benefits of these newer procedures, and thus being willing to invest in these technologies, this care would simply be unavailable to the majority of patients. There are many issues regarding the contracting and pro procedure fee prohibition that the CMS is proposing which would simply eliminate many of the physician-owned LLC's, and I think this would be a great detriment to health care in general, particularly health care available to the majority of the country where large medical centers are not available. Thank you for your attention.

Sincerely,

Robert W. Garrison, MD

RWG/rsl

3714 Guardian Avenue Morehead City, NC 28557 (252) 247-2101 Fax: (252) 247-4675

499

MARY L. CLELAND,CRNA
1812 VANDERBILT DR.
LOVELAND, OH 45140

August 26, 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

Dear Ms. Norwalk,

As a member of the American Association of Nurse Anesthetists (AANA) I wish to support the Centers for Medicare & Medicaid Services (CMS) proposal to boost the value of anesthesia work by 32%. Under CMS's proposed rule Medicare would increase the anesthesia conversion factor by 15% in 2008 compared with current levels. (72FR 38122, 7/12'2007) If adopted, CMS's proposal would help to ensure that CRNA's as Medicare Part B providers can continue to provide Medicare beneficiaries with access to anesthesia services.

America's 36,000 CRNA's provide some 27 million anesthetics in the U.S. annually, in every setting requiring anesthesia services, and the predominant anesthesia providers to rural and medically underserved America. For two years of my own career, I and another CRNA provided all the anesthesia care at Meadowview Regional Medical Center in the small town of Maysville, Ky. No anesthesia doctor was interested in that rural setting. It was a busy OR and the patients all received excellent anesthesia care. Who would have done those anesthetics if not for us? 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,

Mary L. Cleland, CRNAFriend,

500

Northern Physical Therapy Services

308 S. Main, Cedar Springs, MI. 49319
Office: (616) 696-6555 ~ Fax: (616) 696-1761

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

SUBJECT: Medicare Program; Proposed Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Rule.
PHYSICIAN SELF REFERRAL ISSUES

Dear Mr. Weems:

As a health care professional, I would like to comment on the July 12th proposed 2008 physician fee schedule rule and the "in-office ancillary services" exception. These ancillary services have led to physician-owned physical therapy services that our abusive to our profession and to the Medicare client.

I have been a Physical Therapist for the past 4 years, serving rural communities in Michigan in outpatient private practice settings. Patients travel to the nearest city for physician and specialist appointments, and initiate physical therapy back in my community which is close to their work and home. From my perspective, physicians who own physical therapy practices abuse and over utilize the practice for financial gains. Patients feel pressured to participate at a PT location that their Doctor recommends, despite long drives, not realizing that it is for the Doctor's financial gains. Also, physician direct supervision is not needed to administer physical therapy services. Physicians are collecting payment on services that they did not oversee, and in certain cases, are not performed by appropriate staff (ie: a physical therapist, or PT assistant) under the "incident-to" policy. I believe that CMS would greatly improve quality patient care and reduce abuse of physical therapy services if you eliminated physical therapy as a designated health service (DHS) furnished under the in-office ancillary services exception.

Thank you for your consideration of my comments and your untiring pursuit improving health care in the United States.

Sincerely,

Ann Fox P.T.

Ann Fox MSPT

8/22/2007

501

REHAB ASSOCIATES
OF CENTRAL VIRGINIA

Clifton Practice
44 Clifton St.
Lynchburg, VA 24501
P:434.528.1848
F:434.845.6748

Thomson Practice
1948 Thomson Dr.
Lynchburg, VA 24501
P:434.845.3499
F:434.845.6820

Timberlake Practice
20311 B Timberlake Rd.
Lynchburg, VA 24502
P:434.237.6812
F:434.237.6814

Forest Practice
P.O. Box 581
Forest, VA 24551
P:434.525.4851
F:434.525.4859

Bedford Practice
3 Cedar Hill Court, Ste. C
Bedford, VA 24523
P:540.586.1138
F:540.587.5903

Monelison Practice
P.O. Box 569
Madison Heights, VA 24572
P:434.845.5641
F:434.847.7715

Appomattox Practice
P.O. Box 999
Appomattox, VA 24522
P:434.352.5799
F:434.352.9559

Brookneal Practice
P.O. Box 209
Brookneal, VA 24528
P:434.376.2008
F:434.376.3773

Hurt Practice
527 Pocket Road
Hurt, VA 24563
P:434.324.9750
F:434.324.9796

August 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

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 Andy Tatom. I am a Physical Therapist who has been living and practicing outpatient orthopedics for the past 25 years in Lynchburg, Virginia. I have remained very much engaged with my profession by passing my orthopedic boards in 1995 and completing my clinical doctorate in Physical Therapy in 2005.

The purpose of my letter is to discuss physician self referral issues. The potential of a person directing the referrals of Medicare patients to a facility that they have a financial interest in is high, because it makes economic sense. I truly believe that no physician in Lynchburg would intentionally abuse the Medicare system, but there have been instances where patients have been guided to a physician owned P.T. practice, when other independent P.T. clinics offer the same service and are more convenient for the patient.

The "in-office ancillary services" has fueled the expansion of physician owned arrangements that provide physical therapy. I can understand why physicians who are constantly facing reduced reimbursement would want to expand into areas that would provide them with a passive source of income.

This puts me at a significant disadvantage in Virginia. I practice with a limited direct access to patients. More than 99% of my patients come to me by physician referral. This gives the physician a captive referral base to draw from to which I have no access.

I believe the designated health service statutes have been misconstrued and have allowed "in office ancillary services" to be provided in space that is only leased by the physician and there is no physician present. I don't believe that a physician needs to be present for the provision of physical therapy, but if they are billing for "in-office ancillary services" they should be present.

I believe the Medicare patient would be best serviced if CMS followed the pharmacy model and prohibited physician ownership or interest in a physical therapy practice. This would remove the potential for abuse and level the playing field when physical therapists compete for patients.

I strongly suggest that CMS remove Physical Therapy as a designated health service permissible under the "in-office ancillary" exception to the federal physician self-referral laws.

Thank you for your consideration.

Andrew J. Tatom, III, PT, DPT, OCS

AJT/lp

REHAB ASSOCIATES
OF CENTRAL VIRGINIA

Rebecca A Britt, PT, DPT
Rehab Associates of Central VA
20311-B Timberlake Rd.
Lynchburg VA, 24502
(434) 237-6812
fax: (434) 237-6814
rebecca.britt@racva.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.

RE: Physician Self-referral Issues

Dear Mr. Weems,

This letter is in regards to the upcoming changes that are to be addressed in the CMS 2008 Medicare physician fee schedule. I have been in practice since 2005 as a doctor of physical therapy and have witnessed the abuse that has resulted from the Stark II in-office ancillary services exception. This exception, which includes physical therapy as a "designated health service," sets the stage for fraud that is completely unethical and goes against the moral agreement of every health care provider to provide an unbiased treatment plan that provides the most benefit to the patient. Patients who were once given a choice where to receive physical therapy services are now being directed towards the clinics which the physician themselves own, operate and profit from. This has set up a situation where the physicians profit simply by referring more patients to their clinics for longer lengths of time, regardless of whether or not it is indicated or in the best interest of the patient. This abuse takes away the patient's right to choose an unbiased treatment from the clinic and physical therapist of their choice.

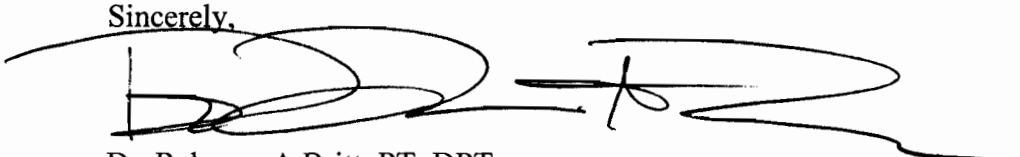
Firsthand, I have had patients start physical therapy in our clinic and, upon returning to the physician, they were switched to a physician owned office to continue their physical therapy. Upon follow-up phone conversations with these patients, I asked if they were unhappy with treatment at our office or if the physician felt they were not making progress or if a specific reason was given for the mid-treatment switch in physical therapy offices. Nine out of ten times, the answer given is that the physician recommended they continue physical therapy and gave the patient an updated referral to their own office. In a somewhat covert way, the physician has not "told" the patient where to receive services but has given them a script that does not allow them to continue receiving treatment at our clinic. The patient, of course, follows the physician recommendation and continues treatment at another office. When in our follow-up phone conversations, I asked these patients if they would like to continue physical therapy at our clinic, making it clear that they have a choice where to receive treatment, some said that they would like to switch but state "I think I will keep going here since my physician referred me here" while others will request a transfer back to our office.

It is also interesting to mention that there are quite a few more patients who will state upon their first visit "the physician referred me to another office but I wanted to go here". When the other office name is requested, it is more frequently the physician owned physical therapy office than any other clinic in our area.

According to the Coalition for Patients' Rights formed by the American Medical Association, the American Physical Therapy Association and 22 other health care groups, the patient has the right to choose where they receive health care. This choice should always be clear and without benefit to the person referring the patient, which is why physician owned physical therapy clinics are not in the best interest to the patient. It sets a president for abuse and fraud, both of which never benefit the patient or the health care system which is designed to provide unbiased treatment. Please, help to protect the patient by putting into place appropriate guidelines and restrictions in the upcoming Stark III regulations.

Thank you for your time and consideration in this matter.

Sincerely,



Dr. Rebecca A Britt, PT, DPT

503-1

1668 Kahatchee Loop
Childersburg, AL 35044
August 25, 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

Physician Self-Referral Provisions
Section II.M.3; In-Office Ancillary Services Exception

Dear Sir or Madam:

I am an Occupational Therapist that has been working for an organization that provides rehab services within a physician practice for over six years now. This is the BEST work situation I have ever worked in during my career as an OT. In the past 13 years my work history has included outpatient private practice settings, hospital based outpatient settings and home health. Of all of these, providing services in this setting has given me the opportunity to deliver the highest level of quality of care to my patients. The reasons for this are as follows:

1. While providing services in the physician's office, I am able to communicate on a daily basis with the doctors I work with, as well as their medical staff. I have access to the patient's records which provides me with up to date notes on the patient's condition, surgical treatments, x-rays, MRI's, etc. With access to this information I am able to better communicate and educate my patients on their treatment plans and outcomes. In the other setting that I worked in, I rarely had this level of communication

2. Based on the interaction with the physicians I work with, I am able to speak directly with them on changes to the plan of care, contraindications, as well as any problems that may arise during the patient's course of treatment. This has been critical in assisting me with the ability to progress my patients further.

3. While treating in a physician's office, I have also experienced a 30 to 40 percent decrease in the number of visits per referral that I see my patients. This has been very effective at keeping insurance and co-pay cost down for my patients. This is directly related to early intervention with patients after surgery or injury, as well as the enhanced level of communication. Also working with physicians has given

me a higher level of education about diagnosis, surgical interventions and treatment options, which enables me to provide a higher level of care.

The ultimate result is lower costs for insurance companies and patients, as compared to privately and publicly owned rehab companies, which are profit driven.

Physical Therapists and Occupational Therapists working within a physician's practice have made a significant impact on decreasing costs, while increasing the level of care. I ask for your continued support of this partnership between physician and therapist. It is one of high accountability and effectiveness. With these traits, the persons that benefit the most are the patients that we serve.

Sincerely,

Doug DeLoach

Doug DeLoach OTR/L

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August 30, 2007

Herb B. Kuhn
Acting Deputy Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
Room 445-G
200 Independence Avenue
Washington, DC 20201

Attention CMS-1385-P

Dear Mr. Kuhn:

The College of American Pathologists (CAP) appreciates the opportunity to comment on the proposed rule CMS-1385-P entitled "*Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2008.*" The CAP is a national medical specialty society representing more than 16,000 physicians who practice anatomic and/or clinical pathology. CAP members practice their specialty in clinical laboratories, academic medical centers, research laboratories, community hospitals and federal and state health facilities.

This letter provides comments on the physician self-referral provisions contained in the CMS-1385-P. Comments on other provisions included in this rule will be addressed in a separate letter.

The CAP applauds CMS for considering substantive changes to the Reassignment Rule and Physician Self-Referral Regulations to stop abuses in the billing and payment for pathology services. The CAP is an advocate for high-quality and cost-effective medical care and has alerted CMS about the proliferation of laboratory schemes that allow physician groups to profit from their self-referrals for anatomic pathology services. These arrangements take advantage of ambiguities in the Medicare rules and represent the type of self-referral enterprises that the Stark Law intended to prohibit.

The CAP supports the establishment of an anti-markup provision on purchased interpretations; however, the CAP wants to ensure that the approach does not hinder legitimate pathology practice arrangements that do not raise the specter of abuse. Consequently the CAP supports an exception for independent laboratories and single specialty pathology physician groups. The CAP also urges CMS to exclude anatomic pathology from the in-office ancillary services exception to the physician self-referral

regulations; this action is the best method of preventing self-referral abuses without risk of inadvertent consequences to pathology groups. These recommendations are discussed below.

Physician Self-Referral Provisions

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

In last year's physician fee schedule proposed rule, CMS stated that previous changes to the rules on reassignment led to confusion as to whether the anti-markup provision on purchased diagnostic tests and conditions for billing for purchased interpretations apply where a reassignment has occurred under a contractual arrangement. Program safeguards, including the anti-markup provision and conditions for purchased interpretations, were built into the purchased diagnostic testing service rule to prevent physician groups from billing for diagnostic testing services furnished by another physician or supplier at a profit to the billing physician group.

Physician groups are circumventing these safeguards by entering into contractual arrangements with physicians and suppliers of diagnostic testing services and then billing for the services at a markup from the charge for the service. CMS has long recognized that allowing physicians who order diagnostic testing services to purchase or otherwise contract for the provision of such services and to then realize a profit when billing Medicare may lead to patient and program abuse and result in higher costs to the Medicare program. Because of ambiguities in the current regulations, physicians are entering into arrangements to bill for and receive a profit from the provision of pathology services they order for their patients but are furnished by pathologists and other suppliers. To stop these abusive billing practices CMS proposes to extend the requirements for purchased diagnostic tests and interpretations to all reassignments, unless the performing physician or supplier is a full-time employee of the billing physician or group.

The CAP supports the establishment of additional program safeguards to prevent physician groups from circumventing the rules for purchased diagnostic tests and interpretations by exploitation of the rules for reassignment. Among CMS' proposals, the CAP supports the extension of the anti-markup provision to both the technical and professional components of pathology services. However, the CAP also cautions CMS that some of its proposals will preclude longstanding and legitimate billing practices by pathology groups. Many pathology groups depend on the reassignment rules to bill for services performed by independent and part-time pathologists; however, these arrangements among pathology groups do not raise the same threat of abuse because the vast majority of pathology services are initiated by a request for a consultation from a referring physician. Because CMS' proposal to incorporate the billing rules for purchased diagnostic testing services to all reassigned services, unless performed by a full-time employee of the group, could adversely affect these longstanding and legitimate

billing practices among pathologists and pathology groups, the CAP recommends an exception for single specialty pathology physician groups and independent laboratories.

The CAP believes that it is necessary to extend restrictions on billing and payment for pathology services to prevent abusive billing arrangements by physicians who seek to profit from the services that they order for their patients but are not capable of personally performing or supervising. However, it is also important to allow pathology groups to retain flexibility in their practice arrangements with other pathologists. Because the pathologist is not in a position to influence the referrals from ordering physicians, these billing arrangements are not susceptible to the same abuses and do not require imposition of the same program safeguards. In fact, the application of the CMS proposal could have devastating results to some pathology practices. For instance, pathology groups that are hospital-based usually bill only the professional component and the hospital bills the technical component. Under the proposal to expand the application of the rules for purchased diagnostic tests and interpretations to all reassignments, these pathology groups would not be able to bill for the interpretations performed by an independent contractor or part-time employee pathologist and reassigned to the group because the group did not perform the technical component, which is proposed as a condition for billing a purchased interpretation. An exception is needed to allow single specialty pathology physician groups and independent laboratories to bill for services performed or supervised by other pathologists, whether independent contractors or full-time or part-time employees, without these additional requirements.

The CAP asks for an exception for single specialty pathology physician groups and independent laboratories from the application of the proposed rules for purchased diagnostic tests and interpretations. CMS already recognizes an exception for independent laboratories that purchase and bill for the technical component of a pathology service. A broader exception for single specialty pathology physician groups and independent labs that covers both the professional and technical components of a pathology service is also supported by the existing rules under the Stark Law. The Stark Law has special rules for referrals made by pathologists for clinical diagnostic laboratory tests and pathological examination services. In developing the restrictions against certain physician self-referrals, Congress recognized that certain physicians, specifically pathologists, diagnostic radiologists and radiation oncologists, who order certain services pursuant to a consultation with another physician do not have the same risk for abuse and; consequently, will not be treated as having made a restricted referral to an entity with which they have a financial interest. For the same policy reasons we ask CMS to recognize an exception for single specialty pathology physician groups and independent laboratories that bill for pathology services performed or supervised by another pathologist, whether an independent contractor or full-time or part-time employee.

CMS is also soliciting comments on how to implement the anti-markup provision for purchased diagnostic tests and interpretations. The CAP concurs with the proposal to limit payment to the net charge for the service by the performing physician or supplier.

The CAP also agrees with the proposal to calculate the net charge exclusive of any amount that takes into account the cost of equipment or space that is leased to the performing physician or supplier by the purchasing physician or group.

The CAP also believes that it is necessary to mandate that the parties to the reassignment arrangement agree to the net charge for each unit of service. Because some physician groups arrange for pathologists to perform services on a per diem or other time basis, it may be difficult to determine the net charge to assess what constitutes a markup of the professional component. Consequently, it is recommended that CMS require as a condition for reassignment of a purchased interpretation that the parties define a net charge for the service, as is required already for purchased diagnostic tests. Under this condition, per diem or other time-based arrangements, which are more susceptible to markups, would not be permitted under the reassignment rule for purchased interpretations. Because the net charge payment limitation has been an effective program safeguard for purchased tests, a similar requirement for purchased interpretations is likely to be the most effective mechanism to prevent markups. Also, by imposing a bright line test based on a net charge, contractors will have a greater ability to monitor and sanction abusive markup practices

B. In-Office Ancillary Services Exception

In comments to last year's physician fee schedule proposed rule, the CAP proposed the exclusion of anatomic pathology services from the in-office ancillary services exception. The CAP is pleased that CMS is soliciting comments on this change. CMS recognizes that Congress created the in-office ancillary services exception to allow for the provision of certain services necessary to the diagnosis or treatment of the medical condition that brought the patient to the physician's office, such as a urine analysis or blood glucose test, which are collected and analyzed by the treating physician while the patient waits. However, anatomic pathology services are very different from the routine clinical lab tests that were originally anticipated under the exception.

First, because of the nature of the services, anatomic pathology cannot be furnished at the time of the office visit while the patient waits. Second, anatomic pathology specimens cannot be interpreted by most of the referring physicians because they lack the professional qualifications to furnish the service. The routine clinical lab tests anticipated under the exception generate positive or negative results that the treating physician can integrate with other clinical information to confirm a diagnostic or treatment plan during the patient's visit. Unlike routine clinical lab tests, anatomic pathology involves high complexity testing that is subject to quality and other standards of the Clinical Laboratory Improvement Amendments. Most physicians, other than pathologists, are not qualified to furnish or supervise the testing services under these standards. For these reasons anatomic pathology services cannot be integrated into the group practice in the same manner as routine clinical lab services and are not the type of services intended to be

protected under the exception; rather, the introduction of anatomic pathology into a group practice is merely to allow for profiting from the self-referral of these services.

Last year CMS proposed changes to the in-office ancillary services exception that focused on certain characteristics of pod labs as a means of restricting abusive self-referral arrangements; however, the narrowly defined changes would not necessarily impact captive laboratories. CMS has now recognized that pod labs and in-house captive laboratories are economically indistinguishable and raise the same concerns for patient and program abuse. Attempting to stop the proliferation of these self-referral enterprises by imposing restrictions in the building, equipment or personnel requirements will only have marginal effect. Moreover, physician groups will continue to create new arrangements structured around any technical requirements to retain the ability to profit from pathology services ordered from their captive referral pool of patients. Because the exception enables physician groups to create a profit center from anatomic pathology services, it is imperative that CMS remove anatomic pathology from the exception.

CMS also recognizes in the proposed rule that the in-office ancillary services exception allows physician groups to potentially mark-up charges for the technical component of diagnostic tests. The CAP alerted CMS to the proliferation of in-house captive laboratories that allow physician groups to bill for the technical component of the pathology services ordered for the group's patients. The physician group engages a technician to furnish the service in a laboratory that is owned or leased by the physician group. The anti-markup provision of the reassignment rule may not apply to these situations, whether the physician group engages the technician as an independent contractor or employee, because the service is considered to be furnished on the group's premises. This loophole allows physician groups to profit from a markup of the technical component. An exclusion of anatomic pathology from the in-office ancillary services exception is the most effective means of preventing program abuses due to the limitations in the reach of the Medicare reassignment rule. Without the exclusion physician groups will continue to structure in-office practice arrangements that allow markups for pathology services under the guise of technical compliance with Medicare billing rules.

Opponents to these proposed changes assert that their captive pathology arrangements enhance patient care. The CAP believes that program safeguards are intended to 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. A categorical exclusion from the in-office ancillary services exception would prevent physicians from having a financial interest in the referrals for the excluded services but would not prevent physicians or group practices from furnishing the services for their patients as a purchased service under the program integrity safeguards or under other available statutory exceptions.

The distinction between the delivery of a health care service and the financial interest in the referral of the service is paramount to the original intent of the Stark Law. CMS previously clarified this distinction as follows:

> "The [Stark Law] only imposes restrictions on a physician who makes a referral for a designated health service (DHS) if he or she has a financial relationship with the ancillary services provider... However, nothing in the law prevents physicians from making available convenient ancillary services when the physician has no financial interest in the provision of the services. For example, a physician may arrange for a diagnostic services provider to perform diagnostic tests in the physician's office for which the diagnostic services provider bills."

66 Fed. Reg. 861-862 (Jan. 4, 2001). CMS also recognized that the imposition of a restriction on who can or cannot have a financial interest in the provision of a service does not act as a restriction on access to such services. CMS noted: "If a physician determines not to provide access to such services in the absence of personal profit, the decision is the physician's... Nothing in [the Stark Law] restricts patient access to those services," *See id.* at 861.

The exclusion of anatomic pathology services from the in-office ancillary services exception will not impact the delivery of pathology services as determined to be in the best interests of the patient; rather, the exclusion will only remove the financial conflict of interest from the referral. The exclusion would ensure that physicians order pathology services based on the best interests of their patients without any influence, even in part, from personal financial interests.

Also, as noted above, financial relationships between physicians and laboratories will continue to be permissible if they satisfy another statutory exception. As CMS noted in the proposed rule, the in-office ancillary services exception has a unique distinction from other compensation exceptions in that it allows a referring physician to receive a share of the profits for his/her referred ancillary services while other compensation exceptions require that the compensation be set in advance, be consistent with fair market value, and not be determined in a manner that takes into account the volume or value of referrals. By requiring physicians to comply with the requirements of the other compensation exceptions, CMS will be imposing additional program safeguards for physicians seeking to retain a financial interest in a laboratory to which they refer.

C. Summary of CAP Comments

The CAP supports CMS' efforts to end abusive markup practices for pathology services by extending the anti-markup provision to both the professional and technical component of the service and applying the conditions purchased diagnostic tests and interpretations to all reassignments, unless the performing physician or supplier is a full-time employee

of the billing physician or group. To protect against inadvertent harm to legitimate pathology practice arrangements, the CAP supports an exception for single specialty pathology physician groups and independent laboratories. The new program safeguards should prevent ordering physicians from profiting from the work of other physicians and suppliers but should not prevent pathology groups from billing for the services of other pathologists, whether engaged on a full-time, part-time or contractual basis.

The CAP also urges CMS to exclude anatomic pathology from the in-office ancillary services exception because it is the best method for removing the taint of financial conflicts of interest from self-referrals without adversely affecting the delivery or quality of pathology services. The exclusion will not interfere with the establishment of alternative delivery models that compete on the basis of quality, reliability, turn-around time, communication, and customer service but will exclude profit motivations from the choice of provider. The exclusion is also is consistent with the original intent of the Stark Law to impose "restrictions on a physician who makes a referral for a designated health service if he or she has a financial relationship with the ancillary services provider...thereby creating a risk that his or her referrals may be motivated, in part, by personal financial considerations" (*See* 66 Fed. Reg. 861-862 (Jan. 4, 2001)). So while the exclusion of anatomic pathology from the in-office ancillary services exception will not prevent the delivery of the services, it will ensure that clinical decisions are determined solely on the basis of quality and in the best interests of the patient.

The College of American Pathologists is pleased to have the opportunity to comment on these regulations and appreciates your consideration of these comments. Any questions regarding proposed changes should be directed to Donna Meyer at 202-354-7112 (dmeyer@cap.org).

Sincerely,

Thomas Sodeman MD FCAP

Thomas M. Sodeman, MD, FCAP
President

Cc: Joanne Sinsheimer, Centers for Medicare and Medicaid Services
Lisa Ohrin, Centers for Medicare and Medicaid Services
Don Romano, Centers for Medicare and Medicaid Services
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August 30, 2007

Herb B. Kuhn
Acting Deputy Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
Room 445-G
200 Independence Avenue
Washington, DC 20201 Attention CMS-1385-P

Dear Mr. Kuhn:

The College of American Pathologists (CAP) appreciates the opportunity to comment on the proposed rule CMS-1385-P entitled "*Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; 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 CAP is a national medical specialty society representing more than 16,000 physicians who practice anatomic and/or clinical pathology. College members practice their specialty in clinical laboratories, academic medical centers, research laboratories, community hospitals and federal and state health facilities.

The CAP comments in this letter focus on the following issues: 1) budget neutrality adjustments to the work relative value units; 2) CMS' indirect practice expense relative value unit methodology; 3) measures for the 2008 Physician Quality Reporting Initiative; 4) physician specialties participation in measure development; 5) independent laboratory billing for the technical component of pathology services; 6) date of service for the technical component of archived specimens; and 7) CMS' proposed reconsideration process for new clinical laboratory diagnostic tests. Comments regarding the physician self-referral provisions contained in this proposed rule will be addressed in a separate letter.

CODING—ADDITIONAL CODES FROM THE 5-YEAR REVIEW

Budget Neutrality Adjuster to Work RVUs

CAP opposes CMS' proposal to revise downward the work RVU adjustor by 1.8 percent to maintain budget neutrality associated with additional RVU changes resulting from the continuation of the third five-year review. CAP believes that the 2008 budget neutrality adjustments should be applied equally across all RVUs (i.e., Work, PE and Malpractice). CAP also urges CMS to revisit their decision to impose the 10.1% budget neutrality adjuster to the work RVUs finalized last year and to also apply that adjustment equally across all RVUs in the 2008 physician fee schedule final rule.

CMS chose not to make the adjustment to the conversion factor as the agency believes that the need to implement the adjustment is largely due to changes proposed as a result of the 5-Year Review of work RVUs. However, changes resulting from the five-year review cannot be considered in isolation as they also impact CMS' practice expense methodology. For example, changes in the RUC surveyed physician intra-service time as a result of the five-year review is used to adjust the direct practice expense inputs associated with clinical staff time for codes where the clinical staff are assisting the physician. Also, changes in the number or level of post-operative visits as a result of the five-year review affects the direct practice expense inputs by changing clinical staff times, and times that equipment and supplies are used. The work RVU is also used in CMS' practice expense methodology to allocate indirect practice expense costs and changes in the physician work RVUs as a result of the five-year review impact this methodology. Given the interdependence of the work RVU and the practice expense formula, we strongly urge CMS to spread the budget neutrality adjustment from the WRVU changes across all RVUs by applying this adjustment to the conversion factor. Furthermore, prior to the implementation of the 2007 fee schedule, CMS historically has adjusted the conversion factor for RVU work changes resulting from the five-year review. We see no reason to continue to deviate from this precedent especially in light of the above and the overwhelming support from the medical community to apply the budget neutrality adjuster to the conversion factor.

In addition, we also oppose CMS' continued use of the adjusted work RVUs in CMS' indirect practice expense formula and we request that unadjusted work RVU be used as the allocator of indirect expenses. In fact, CMS' final 2007 fee schedule stated that as requested by commenters on the 2007 proposed rule, that "we will not use the budget-neutralized work RVUs to calculate indirect PE." However, the adjusted work RVUs were utilized in the practice expense methodology in 2007 and again in this proposed rule.

RESOURCE BASED PE-RVUs

Indirect PE RVU Methodology

The proposed rule continues the implementation of changes to the practice expense methodology for calculating the practice expense (PE) RVUs. The 2008 proposed regulation represents the second year of the four-year transition to the new practice expense methodology and the PE RVUs will be based on 50% of the 2006 PE RVU and 50% of the RVU based on the new methodology. The phase-in continues CMS' method of basing the measurement of indirect costs on the magnitude of direct costs.

The College believes there are some inherent problems in this new practice expense methodology. As indicated in our comments submitted last year on the proposed indirect PE methodology changes, CAP continues to maintain that the methodology for deriving the indirect PE RVU is flawed for professional component (PC) services and we are again requesting modifications to this methodology. Specifically, we are referring to "Step 8" of the methodology, which calculates the service level allocators for the indirect PEs on page 37248 of the June 29, 2006, *Federal Register*. Under CMS' revised practice expense formula the indirect allocator is calculated as follows:

*(indirect percentage * (direct PERVU/direct percentage)) + work RVUs.*

The College has a number of concerns about this approach.

Specifically, for professional component services (those using a –26 modifier), the first part of the equation above is zeroed out, leaving only the Work RVU as the determinant of indirect expenses. (An example of this effect can be seen in Table 1 of the '08 proposed rule for the calculation of CPT code 71020 -26.) This problem is exacerbated by the reduction of the WRVU that was used in 2007 with an additional decrease proposed for 2008 by the overall budget neutrality adjustment.

When the revised practice expense methodology is fully implemented in 2010 and budget neutrality adjustments are applied to the WRVU used, pathologists who are professional component billers (PC-only) will experience significant and inequitable declines in reimbursement rates. Using the latest utilization data our estimates show that pathologists billing the PC-only will experience a payment decrease of over18 percent between 2006 and 2010, over and above any negative adjustments projected for the conversion factor (see Table 1). It is important to note that pathologists who bill PC-only comprise 63 percent of all revenue to the specialty. Global billers comprise approximately one-third of revenues and TC-only billers comprise only 5 percent.

Table 1: Percent Change in Reimbursement Rates Due to Change in WRVU and PE Methodology for Pathologists

	Percent Change		
Type of Biller	**2006-2007**	**2007 -2010**	**Share of Revenues To Pathologists**
Global Billers	0.3%	3.1%	32%
PC-only Billers (-26 modifier)	-8.3%	-10.0%	63%
TC-only billers	4.4%	14.1%	5%
All Pathologists	-1.0%	-4.5%	100%

The College expressed these concerns last year and proposed an alternative indirect allocator formula for PC-only and TC-only billers based on a share of the global indirect allocator. In response, the final 2007 rule stated that the agency "... will retain our current methodology for the allocation of indirect PE for services with TC and PCs, but we welcome further clarification regarding this suggestion." In this proposed calendar year 2008 fee schedule, CMS acknowledges that they will continue to evaluate their new methodology. Therefore, the College requests that CMS carefully consider our rationale and supporting data for changing the formula according to the proposed alternative below.

CMS' revised methodology for calculating indirect PE appears incorrectly to assume that hospital-based pathologists who are PC-only billers are employed by a hospital, and that the majority of their overhead costs are covered by the hospital. In reality, a relatively small minority of pathologists (9%) are actually employed by a hospital. The majority of pathologists (67%) working at hospitals, in fact, are part of a group that contracts with a hospital.[1] Because they are not directly employed by a hospital, many of these pathologists are responsible for directly paying their overhead costs including rent, utilities, billing and administrative support of their practice. The College believes these overhead costs are not adequately accounted for in CMS' current indirect PE calculation.

Data from the AMA's Socioeconomic Monitoring Service shows that indirect practice expenses represent 66% of practice expenses for pathologists. While this data does not explicitly distinguish hospital-based from other pathology practices, we know that a large majority of all pathologists are PC-only billers who work under independent contractual relationships with hospitals, so their expenses must be substantially reflected in this estimate. Explicitly distinguished indirect practice expense data for hospital-based and

[1] Data based on College of American Pathologists 2004 Practice Characteristics Survey.

other pathology practices will be available with the release of data from the 2007 AMA Multi-Specialty Practice Information survey but, unfortunately, that data will not be available until 2008.

To provide data in time for use in this year's proposed regulation, the College conducted a short survey of its members who are PC-only billers to determine the characteristics and magnitude of their indirect practice expenses. The survey was randomly sent to 2,000 pathologists with a response rate of 8% (160 respondents). Of those responding, 58% were PC-only billers, quite consistent with the 2006 Medicare claims file showing approximately 60% of pathologists to be PC-only billers.

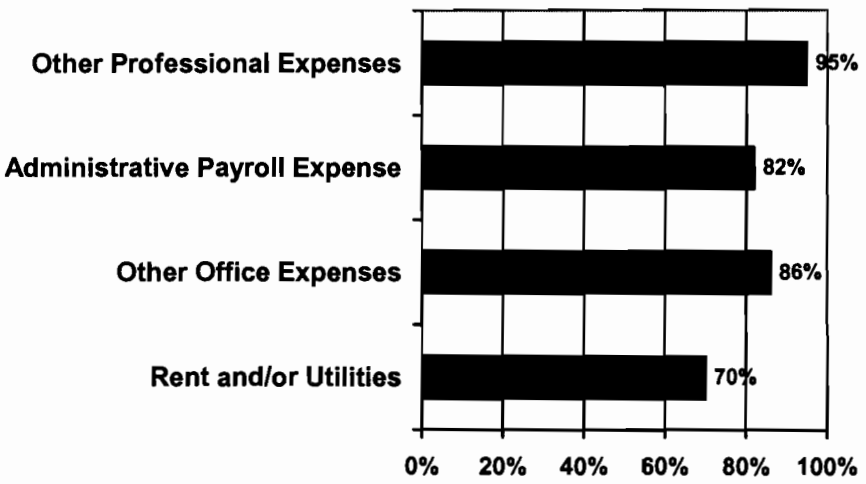
The CAP Survey first asked pathologists who were PC-only billers if they had incurred expenses for specific indirect practice expense categories. The definition of indirect practice expense was consistent with terminology currently in the AMA Multi-Specialty Practice Information Survey.[2] As shown in Figure 1, the CAP Survey found that of those pathologists billing the –26 modifier, 70 percent paid rent and/or utilities, 81 percent paid administrative payroll expenses, and 86 percent paid other office expenses. The CAP Survey also asked respondents to estimate the percent of their total Part B receipts associated with billing the –26 modifier that were necessary to pay for these indirect costs. Both the mean and median expense was 30 percent, suggesting that the data are generally evenly distributed around the mean.

The key question becomes how does the 30 percent relate to CMS's current practice expense (PE) methodology? One way to evaluate how CMS's current practice expense methodology relates to the actual practice costs incurred by pathologists is to take a closer look at two key measures:

- Share of Indirect PE to Total RVUs for Those Who Bill a –26 Modifier
- Share of Indirect PE Relative to Total PE All Types of Billers

[2] Definitions of indirect practice expense included: 1) Rent and Utilities (include telephone, intercom system, heat, light and air conditioning); 2) Other Office Expenses (include non-medical equipment and supplies, including computers, computer maintenance, internet access and provider services, and IT support, postage, shipping, and courier service, maintenance, storage, security, janitorial); 3) Other Professional (include legal fees, insurance other than professional medical liability, worker's compensation, marketing, accounting, billing and office management services, professional association memberships, maintenance of certification and licensure, journal and continuing education, professional care upkeep and depreciation.)

Figure 1: Percent of PC-Only Billers Who Incur a Cost



Source: College of American Pathologists 2007 Survey

Share of Indirect PE to Total RVUs for Those Who Bill a –26 modifier

One way to illustrate how CMS' revised PE methodology compares to pathologists' current practice expenses is to estimate the share of indirect PE to total RVUs for those who bill a –26 modifier. Since 88305 is a very prevalent procedure and represents a large share of billing for pathologists billing the –26 modifier, the following example is based on 88305. As shown in Column 2 of Table 2 below, this ratio (PE RVU/Total RVU) was 30 percent in 2006 prior to any changes to the PE methodology. This is consistent with CAP survey results reported above. Yet, when CMS's current PE methodology is fully implemented, this ratio falls to 22 percent, and thus would underestimate indirect practice costs of PC-only billers.

Share of Indirect PE to Total PE All Types of Billers

Another way to evaluate the adequacy of the new practice expense methodology relative to other available data is to compare the 1999 AMA Socioeconomic Survey data on the share of Indirect Practice Expense to Total Practice Expense weighted by specialty for a given CPT code. For example, for 88305, 61 percent of total practice expenses are attributed to indirect costs. But when the actual PE RVUs are weighted by claims for 88305 across all types of billings this ratio is only 47 percent (see Table 2) suggesting that there is an internal inconsistency in CMS' methodology with available survey data.

Table 2: Alternative Estimates of PE

	Share of Indirect PE Relative to Total RVUs For 88305 –26 For Facilities	Percent of Total PE Attributable to Indirect Costs For 88305 (all types of billers)
2006 Physician Payment	30%	-----
2007 Proposed Rule	22%	48%
AMA Survey	----	61%

As discussed above, we believe that the indirect PE methodology must be sufficiently altered to distribute the indirect costs of global services between the PC and TC services. The College would like to propose to CMS to distribute only the indirect allocator for global billers in Step 8 to the PC and TC based on their share of billings for each service. For example, for 88305, 82 percent of non-global billers are PC-only billers. This would imply that they should reflect a higher share of the indirect expenses between PC and TC. To do this, the PC-only indirect allocator equals 80 percent of the global indirect allocator for 88305.

There is also precedent for dividing the global allocator in this manner. When CMS initially established the resource based practice expense RVUs for calendar year 1999, they divided the administrative costs (i.e. the indirect costs) equally between the PC and the TC services. The final rule published on November 2, 1998 refers to the data tables evidencing this split. In our comments on the 1999 proposed regulation, CAP requested more detailed data supporting these splits. CAP believes the proposed methodology in the current rule represents a drastic departure from this earlier logic, further unbalancing an allocation practice which we felt was, at that time, already unfair to PC-only billers. Table 3 (see attached) shows in greater detail the College's proposed alternative would work for 88305, which has a global, PC and TC component.

Table 4: Percent Change in Reimbursement Rates for 88305 Due to Change in WRVU and PE Methodology for Pathologists

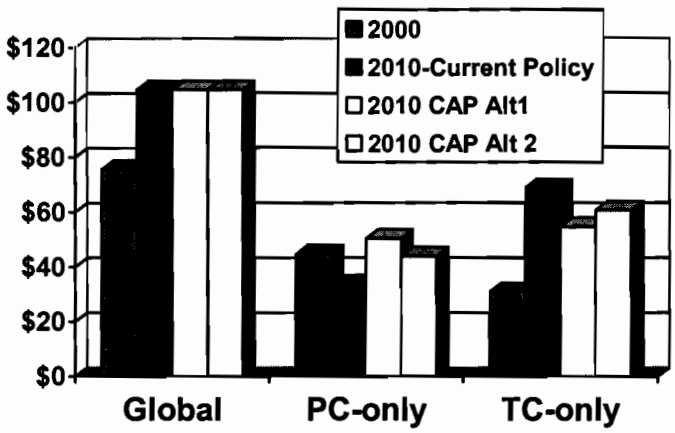
	Current CMS PE Methodology			CAP Alternative Based on Share of Billings (80/20)		CAP Alternative Based on Prior CMS Split (50/50)	
Type of Biller	**2006 Total RVU**	**2010 Total RVU**	**% Change 2006-2010**	**2010 Total RVU**	**% Change 2006-2010**	**2010 Total RVU**	**% Change 2006-2010**
Global Billers	2.73	2.76	1%	2.76	1%	2.76	1%
PC-only Billers (-26 modifier)	1.11	.89	-20%	1.33	19%	1.16	4.5%
TC-only billers	1.62	1.81	12%	1.44	-11%	1.6	-1.2%

To show that our proposed change is more internally consistent with current data, we estimated the ratio of PE RVU for indirect relative to total in our 80/20 and 50/50 split proposals. When this is weighted across all types of billers for 88305, the CAP alternative of splitting the global indirect allocator of 80 percent for PC and 20 percent for TC leads a ratio of 55%, which is much closer to the 60% of indirect costs that the AMA survey found (see Table 5).

Table 5

	Percent of Total PE Attributable to Indirect Costs For 88305 (all)
2007 Proposed Rule	48%
CAP Alt 80/20	55%
CAP Alt 50/50	53%
AMA Survey	61%

Figure 2: Comparison of Reimbursement Rates for 88305 Under Alternative Calculations



We appreciate CMS' openness to review the practice expense methodology during the phase-in, as indicated in both the calendar year 2007 and 2008 physician fee schedule proposed rules. However, we believe that the indirect practice expense methodology needs to be modified prior to the second year of the four-year transition, as it represents the continuation of a major and damaging oversight. Should CMS not accept our proposed change above, at a minimum we would again recommend adherence to the 1998 precedent of splitting the indirect costs evenly between the PC and TC services, pending further review of our recommended approach for modifying the indirect practice expense methodology.

Our proposed redistribution of indirect PE costs for global services represents an equitable proposal to ensure that existing indirect costs continue to be recognized for PC services. CMS described the current methodology used to calculate indirect expenses in the June 29, 2006 proposed Medicare physician fee schedule as follows: "there is not a single, universally accepted approach for allocating indirect practice costs to individual procedure codes. Rather allocation involves judgment in identifying the base or bases that are the best measures of a practice's indirect costs." In our judgment, the proposed methodology uses a flawed basis, and we believe our proposal represents the correct approach to allocating the indirect costs. We would appreciate your serious consideration of our approach.

TRHCA—Section 101(b): PQRI

Measures for the 2008 Physician Quality Reporting Initiative (Table 17)

The CAP worked with the AMA Physician Consortium for Performance Improvement to develop pathology measures for use in the 2008 Physician Quality Reporting Initiative

(PQRI). The descriptions of the two pathology measures included in the list of new PCPI measures (Table 17) are confusing and will make it difficult for the appropriate physicians to identify these measures. The measures should be described as "Pathology reports for breast cancer patients that include pT category, pN category, and histologic grade" and "Pathology reports for colorectal cancer patients that include pT category, pN category, and histologic grade" rather than "Breast cancer patients who have pT category, pN category, and histologic grade for their cancer" and "Colorectal cancer patients who have pT category, pN category, and histologic grade for their cancer".

Physician specialties participation in measure development

While the CAP agrees in concept with the necessity for a consensus-based process for developing quality measures, the CAP believes that including only one physician from a specialty in the measure development process is insufficient to have met the criteria for consensus — defined as general agreement in the regulation. As the CAP has participated in measure development for pathology and for other specialties, it is clear that insights from physicians practicing in different regions, with various patient populations and practice types are essential for the development of measures that improve quality and are applicable and appropriate for the wide range of care settings in the US.

TRHCA—SECTION 104: PHYSICIAN PATHOLOGY SERVICES

The CAP believes that the technical component (TC) grandfather should be made permanent. Under this provision, hospitals would be "grandfathered" and direct payment made to the laboratory if the hospital had been utilizing the services of an independent laboratory as of July 22, 1999. We believe this change is necessary to ensure that hospitals can continue to rely on independent laboratories for critical pathology services without incurring increased costs and administrative burdens.

As CAP has stated in previous comments, there is a concern that TC costs are included in the DRG as CMS has maintained. In 1983, when DRGs were developed, hospitals were instructed NOT to include TC costs in their base cost report if they were utilizing independent laboratories. This applied to all geographical areas — urban, suburban and rural. In 1992 when the Medicare physician fee schedule was begun, the agency reiterated that independent laboratories should bill Medicare directly for both the professional and technical components of physician pathology services furnished to hospital inpatients and outpatients. Again, this applied to urban, suburban and rural areas.

For 16 years after the development of DRGs, the agency maintained its policy of direct payment for pathology TC services. On July 22, 1999, the agency proposed changes that would no longer allow independent laboratories to bill Medicare directly for the TC services provided to hospital inpatients. The agency assumed that the DRG now included TC payments because separate urban and rural DRG rates were eliminated in 1995 and urban hospitals were likely to have included these costs in their base period costs that

formed the DRGs. However, it is not clear that all urban hospitals provided pathology services in-house when DRGs were developed 1983, as the agency itself acknowledged in the proposed rule.

For outpatients, if Medicare continued to allow independent laboratories to bill Medicare directly for hospital ***outpatient*** pathology TC payments, hospitals would simply **NOT** bill the program for these services and would receive no payment. This is because, under outpatient PPS, the hospital bills Medicare a procedure code for each of the services the outpatient receives — e.g. office visit, radiology, surgery, pathology etc. Medicare converts each code to an Ambulatory Procedure Code (APC) that has a determined rate and pays the hospital multiple APCs for each outpatient. In other words, if the laboratory billed for the TC service, the hospital would not. Hence, there is no issue of this resulting in CMS "paying twice."

Without a "grandfather," administrative burdens would be costly, especially for rural hospitals, including critical access hospitals. Under direct billing, laboratories submit a single bill to Medicare for both the TCs and the PCs. Without direct billing, laboratories will have to issue two bills — one to Medicare for the PC and another to the hospitals for the TCs, doubling billing costs. Hospitals would be required to set up systems to receive and account for these bills and pay the laboratories once payment has been received from the hospitals' intermediaries. New billing systems and administrative overhead requirements will have to be created that are costly and unnecessary.

In addition, we believe that language in the proposed rule to terminate this current grandfather is misleading and, if finalized, it is in need of clarification. Specifically, the proposed rule states the following: "For services furnished after December 31, 2007, an independent laboratory may not bill the carrier for physician pathology services furnished to a hospital inpatient or outpatient." We believe that if this provision is implemented, it should read: "For services furnished after December 31, 2007, an independent laboratory may not bill the carrier for the technical component of physician pathology services furnished to a hospital inpatient or outpatient." This modification would clarify CMS' intent should the agency finalize this proposal.

CLINICAL LABORATORY ISSUES

Date of Service for the Technical Component of Physician Pathology Services

In the 2007 final rule physician fee schedule, CMS adopted a policy stating that, for a laboratory test that uses a stored specimen, the date of service is the date the specimen was obtained from the storage if the specimen was stored for more than 30 days before testing. Specimens stored 30 days or less have a date of service of the date the test was performed only if:

- The test is ordered by the patient's physician at least 14 days following the date of the patient's discharge from the hospital;

- The specimen was collected while the patient was undergoing a hospital surgical procedure;

- It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted;

- The results of the test do not guide treatment provided during the hospital stay; and

- The test was reasonable and medically necessary for the treatment of an illness.

In this proposed rule, the agency states that the above provisions apply to clinical diagnostic laboratory tests, and the agency is proposing to apply this provision also to the technical component of physician pathology services, as the collection date for both clinical laboratory services and the TC of physician pathology services is similar. CAP supports CMS' proposal to also apply this provision to the technical component (TC) of physician pathology services and urges the agency to adopt this proposal in the final 2008 Medicare physician fee schedule rule.

New Clinical Diagnostic Laboratory Tests

CMS is proposing a reconsideration process for determining the basis for the amount of payment as well as the actual payment amount for any new test for which a new or substantially revised code is assigned on or after January 1, 2008. We support CMS' proposed reconsideration process, and urge the agency to finalize this proposal in the final 2008 Medicare physician fee schedule regulation. Adoption of the proposed reconsideration process will improve the accuracy of payment determinations for new codes on the clinical laboratory fee schedule and allow for greater review and input from the public in this process.

The rule proposes to create a reconsideration process for determinations of the basis, either crosswalking or gapfilling, for payment of a new clinical diagnostic laboratory test. CMS is also proposing to create a reconsideration process to reevaluate the code or codes and their corresponding fees that were used to determine a new test's fees through the crosswalk process, as well as proposing to provide for a reconsideration process for gapfilled payment amounts. Following the posting of CMS determination for a new test in November, comments would be accepted for 60 days. Those who submit a written comment within the 60-day comment period would have the opportunity to present at the next clinical laboratory public meeting and hear other comments at that meeting. Under CMS' proposed reconsideration process for both the basis for payment and amount of payment, two separate decisions would be made. First, the agency would decide whether to reconsider the prior determination. If CMS elects to reconsider, they would then determine whether CMS should change the prior determination.

* * * * *

The College of American Pathologists is pleased to have the opportunity to comment on these issues and appreciates your consideration of these comments. Questions regarding issues related to the Medicare physician fee schedule and the clinical laboratory fee scheduled should be directed to Pam Johnson at 202-354-7132 (pajohns@cap.org), and question regarding the physician quality reporting initiative should be directed to Fay Shamanski at 202-354-7113 (fshaman@cap.org).

Sincerely,

Thomas Sodeman MD FCAP

Thomas M. Sodeman, MD, FCAP
President

Enclosure

ATTACHMENT

TABLE 3: CALCULATION OF PRACTICE EXPENSE UNDER CMS REVISED METHODOLGY AND CAP ALTERNATIVE

Step	Description	CMS Revised Methodology 88305 Global	88305 PC	88305 TC	CAP Alternative 80/20 88305 Global	88305 PC	88305 TC	CAP Alternative 50/50 88305 Global	88305 PC	88305 TC
DIRECT COSTS										
1	Calculate direct costs from CPEP survey									
	Labor	$30.00	0	$30.00	$30.00	0	$30.00	$30.00	0	$30.00
	Supplies	$29.74	0	$29.74	$29.74	0	$29.74	$29.74	0	$29.74
	Equi+B9pment	$10.07	0	$10.07	$10.07	0	$10.07	$10.07	0	$10.07
	Total Direct Cost	**$69.81**	**0**	**$69.81**	**$69.81**	**0**	**$69.81**	**$69.81**	**0**	**$69.81**
2	Direct Cost Adjustment Compare proposed and current direct PE Costs and adjust so the proposed aggregate direct cost pool does not exceed the current pool (current PE RVUs*CF*Avg Direct PCT) divided by (sum direct inputs) (Note proposed does not use supplemental surveys)	0.584	0.584	0.584	0.584	0.584	0.584	0.584	0.584	0.584
3	Adjust Step 1 by Step 2									
	Labor	$17.52	$0.00	$17.52	$17.52	$0.00	$17.52	$17.52	$0.00	$17.52
	Supplies	$17.37	$0.00	$17.37	$17.37	$0.00	$17.37	$17.37	$0.00	$17.37
	Equipment	$5.88	$0.00	$5.88	$5.88	$0.00	$5.88	$5.88	$0.00	$5.88
4	**Total Adjusted Direct**	**$40.77**	**$0.00**	**$40.77**	**$40.77**	**$0.00**	**$40.77**	**$40.77**	**$0.00**	**$40.77**
5	Convert the Results of Step 4 to an RVU Scale for each service									
	(Labor from Step 3)/CF	0.51	0.00	0.51	0.51	0.00	0.51	0.51	0.00	0.51
	(Supplies from Step 3)/CF	0.51	0.00	0.51	0.51	0.00	0.51	0.51	0.00	0.51
	(Eqp from Step 3)/CF	0.17	0.00	0.17	0.17	0.00	0.17	0.17	0.00	0.17
	Adjusted Direct Costs Converted to RVU	1.19	0.00	1.19	1.19	0.00	1.19	1.19	0.00	1.19
6	Adjusted Work RVU (5-year review) (reduce 10% to account for budget neutrality in work)	0.6612	0.6612	0	0.6612	0.6612	0	0.6612	0.6612	0

Step	Description	CMS Revised Methodology 88305 Global	CMS Revised Methodology 88305 PC	CMS Revised Methodology 88305 TC	CAP Alternative 80/20 88305 Global	CAP Alternative 80/20 88305 PC	CAP Alternative 80/20 88305 TC	CAP Alternative 50/50 88305 Global	CAP Alternative 50/50 88305 PC	CAP Alternative 50/50 88305 TC
INDIRECT COSTS										
7	Use Survey data to estimate weighted average of indirect and direct percentage from supplemental survey data where weights are based on specialties that perform the procedure									
	a) Direct Percentage	0.394	0.394	0.394	0.394	0.394	0.394	0.394	0.394	0.394
	b) Indirect Percentage	0.606	0.606	0.606	0.606	0.606	0.606	0.606	0.606	0.606
8	Indirect Allocator Formula a) (Step 5/Step 7a)*7b =(direct RVU/direct %)*(Indirect %) (this is mathematically the same as (Indirect%/Direct%)*Direct RVU	1.84	0.00	1.84	1.84	1.47	0.37	1.84	0.92	0.92
	b) Add Work RVU except if global service add WRVU and adjusted clinical labor from 5a	1.17	0.66	0.51	1.17	0.66	0.51	1.17	0.66	0.51
	Sum a and b to get total Indirect Allocator	3.02	0.66	2.35	3.02	2.13	0.88	3.02	1.58	1.43
9	Indirect Adjustment Factor Compare current pool of inidirect PE RVUS to the proposed indirect pool and adjust proposed to equal current. (current pe rvus*avg ind pct)/(sum of ind allocators)	0.36	0.36	0.36	0.36	0.36	0.36	0.36	0.36	0.36
10	Adjusted Indirect Factor	1.09	0.24	0.85	1.09	0.77	0.32	1.09	0.57	0.52
11	Indirect PCI (Specialty adj scaler) (the number to the right is specialty specific but in the reg they do service level)	0.87	0.87	0.87	0.87	0.87	0.87	0.87	0.87	0.87
12	**Adjusted Indirect** (Step 10 * 11)	0.95	0.21	0.74	0.95	0.67	0.28	0.95	0.50	0.45
13	PE RVU	2.14	0.21	1.93	2.14	0.67	1.47	2.14	0.50	1.64
	Budget Neutrality Adj (estimate to reach published #)	0.95	0.95	0.95	0.95	0.95	0.95	0.95	0.95	0.95
		2.03	0.20	1.84	2.03	0.64	1.40	2.03	0.47	1.56

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August 30, 2007

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

Attention: CMS-1385-P

Dear Mr. Kuhn:

The American College of Physicians (ACP), representing more than 124,000 physicians specializing in internal medicine and medical students, is pleased to offer comments on the Centers for Medicare and Medicaid Services (CMS) proposed rule *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 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions [CMS-1385-P]* published in the Federal Register on July 12, 2007. As the specialty that provides more care to Medicare beneficiaries than any other, internal medicine is particularly affected by the proposed rule.

RESOURCE-BASED PE RVUS

ACP continues to support the CMS transition to the "bottom up" method of assigning direct practice expense, which is scheduled for the second year of a four year phased implementation in 2008. This methodology is more clear and understandable than the "top down" methodology used in the past and CMS should endeavor to make all elements of the payment for a medical service as transparent as possible.

ACP does not believe that the current 50% assumption of the equipment utilization rate accurately reflects the rate of usage in most cases. ACP is concerned that CMS feels that it must gather more extensive data in order to justify a change in the utilization assumption rate. CMS is aware of data that exists on this subject that shows a higher utilization rate. When the resource-based practice expense methodology was first introduced, CMS proposed to use a utilization rate of 70%, which was based on data from an Abt Associates study. Additionally, a Medicare Payment Advisory Commission

(MedPAC) performed a study of the issue and found that magnetic resonance imagery (MRI) machines have a utilization rate that is higher than 90% and computed tomography (CT) machines have a utilization rate that is higher than 70 % in the representative surveyed markets.[1] CMS acknowledges that the current 50% utilization assumption is an arbitrary figure, so ACP urges CMS to make changes to this assumption immediately based on the data that it does have at its disposal.

ACP supports the creation of mutually exclusive categories of equipment with different utilization rates as suggested as a future option by CMS in the proposed rule as an appropriate next step after an immediate revision to the 50% assumption. ACP urges CMS to address these issues quickly because it has a significant impact on the valuing of these services as well as a significant impact on the payment for all other services. This change would be important step to ensure that payments for service that require high expense equipment are not overpaid. MedPAC and others have expressed concern that overvaluing and, thus, overpaying, services distorts the market and provide the incentive to increase utilization.

ACP is additionally concerned that the current interest rate assumption used for equipment also may be too high. ACP recommends that CMS use an interest rate assumption that accurately reflects what a physician practice would have to pay for capital to acquire this equipment.

CODING - - ADDITIONAL CODES FROM 5-YEAR REVIEW

ACP strongly supports the proposal to accept the Relative Value Scale Update Committee (RUC) recommendation to increase the work value for many of the nursing facility services codes as part of the 5-Year Review of work values. Many nursing home codes received significant revision through the CPT process in 2006, but they were unable to be properly valued because so many of the codes that could have served as reference codes for RUC work surveys were not allowed to be used because they were also under review in the 5-Year Review process. The substantial work and significant effort required of physicians that provide care in the nursing facility settings was evident in the survey data presented to the RUC. The RUC recommendations that CMS proposes to accept will place these codes much closer to where they should be on the relative value scale and will make the payment for these services more appropriate.

ACP is disappointed to see the increase in the work neutrality adjustor that resulted from the extraordinarily significant increase in the work values assigned to anesthesia services.

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[1] Medicare Payment Advisory Commission. Keeping Physicians' Practice Expense Payments Up to Date. Report to the Congress: Increasing the value of Medicare. June 2006. www.medpac.gov/publications/congressional_reports/Jun06_Ch04.pdf

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This 32 percent increase in work values for anesthesia will cause an approximately one percent decrease in work values for every other code in the fee schedule. Each decrease in Medicare fees makes it harder for internists to consider treating Medicare patients to be a financially viable decision.

DRUG COMPENDIA

ACP reviewed with interest the CMS consideration of the issue of drug compendia used as a basis for using chemotherapy agents for off-label uses. The reduction in the number of compendia could cause a reduction in the therapies available to patients. ACP continues to advocate that physicians should have the opportunity to prescribe drugs that are best for their patients as long as there is medical literature to support that decision. Limiting off-label uses to those found in compendia is a significant barrier to physicians being given the opportunity to independently evaluate scientific literature and care for their patients using their clinical judgment.

PHYSICIAN SELF-REFERRAL PROVISIONS

ACP has followed the self-referral issue for many years and has significant concerns regarding some of the proposed and considered changes. Physicians throughout the country continue to struggle with the complex legal issues related to the physician self-referral statute and have often spent far too much on attorneys trying to navigate the confusing and ever-changing regulations. Too many physicians choose not to engage in particular service arrangements for fear of violating the complex strict liability statute despite the fact that the majority of arrangements are for legitimate purposes intended to provide necessary access to care for the physician's patients.

ACP recognizes the challenge in trying to balance the narrow drawing of exceptions to include only those legitimate purposes while excluding those "bad actors" from engaging in illegitimate activity. Unfortunately, ACP strongly believes that CMS has failed to strike that balance in the proposed rule. These proposals, if finalized, would make it even more difficult for physicians to participate in legitimate business ventures and will lead to a decrease in patient access to necessary services. ACP further believes that a far more effective way to balance these two competing interests is for CMS to make an aggressive effort to more accurately pay for the provision of designated health services (DHS). Coupled with the existing exceptions, this approach is a far more effective tool to "weed out" those who would be taking advantage of letter and spirit of the existing statute.

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The College is pleased to offer comment on the following specific areas:

In-Office Ancillary Services Exception

The in-office ancillary services exception is the principle exception most physicians rely upon to protect referrals to provide DHS within their own practices. Although CMS did not offer a proposed change, it did request comments on potential changes to the in-office ancillary services exception to include: (1) whether certain services should not qualify for the exception; (2) whether and, if so, how changes should be made to definitions of "same building" and "centralized building;" (3) whether nonspecialist physicians should be able to use the exception to refer patients for specialized services involving the use of equipment owned by the nonspecialists; and (4) any other restrictions on the ownership and investment in services that would curtail program or patient abuse.

ACP strongly opposes any attempt to further limit services that can be provided by a physician practice under the in-office ancillary services exception. This exception has enabled physicians throughout the country to provide services in their offices where patients are most likely to seek them and benefit from their timely provision. It additionally provides for integration of data systems so that lab values and radiology data are available immediately. This exception allows physicians the greatest amount of flexibility in managing the care of their patients and gives them the opportunity to add services that may be lacking in the community.

More specifically, ACP opposes any significant changes to the "same building" and "centralized building" definition. The use of a "same building" or "centralized building" for services allows both large group practices and coalitions of smaller practices to better provide necessary services for their patients. The in-office ancillary services exception has allowed physician practices to provide what is needed to their patients and the impact of changes to this exception could hurt the practice of medicine. It would be a serious mistake to make the practice of medicine less innovative and reduce the investment in the community of health care services that physicians are making.

Obstetrical Malpractice Insurance Subsidies

ACP is greatly encouraged to see the proposal loosen the restriction on the exception for obstetrical malpractice insurance subsidies. In the proposed rule, CMS states, "We have received accounts, through advisory opinion requests and anecdotally, of patient difficulty obtaining obstetrical care in some communities in States in which obstetrical

malpractice insurance premiums are relatively high." CMS is seeking input on requirements on these subsidies without creating program abuse.

ACP congratulates CMS for seeking to make the exception more flexible and ACP believes the proposed requirements are appropriate for physicians accepting a malpractice subsidy from another entity. ACP urges CMS, however, to expand this exception to include physicians in all medical specialties – not just obstetrics – that are in States where malpractice insurance premiums are relatively high. In doing so, ACP urges CMS to look at the percentage of increase of premiums relative to the average salary of the physician specialty involved. The rising burden of malpractice insurance is a reality for all physicians and this should be recognized. Patients in medically underserved areas will greatly benefit from an expansion of this exception to include all specialties. Finally, ACP urges CMS to work directly with the U.S. Department of Justice to ensure that the Anti-kickback Statute creates a similar safe harbor.

"Set in Advance" and Percentage-based Compensation Arrangements
CMS proposes to limit the type of percentage compensation arrangements that qualify as "set in advance" to personally performed physician services and can only be based on revenues directly resulting from physician services. While this proposed change appears to allow percentage-based compensation arrangements to individual physicians, it would call into question a whole host of other percentage-based arrangements (i.e., lease agreements, practice management agreements, pay-for-performance incentives, etc.) that have little or no risk of abuse. Therefore, ACP believes that CMS should reconsider this proposal to include such arrangements or abandon any proposed change.

Alternative Criteria for Satisfying Certain Exceptions
ACP is also greatly encouraged to see an opportunity for physicians who inadvertently enter into arrangements that are missing a required procedural step to self-report through an alternative compliance method. The College views this attempt by CMS as a positive first-step in recognition that innocent and trivial violations of the statute should not be treated the same as those who knowing and willfully violate the letter of the statute.

ACP believes, however, that the proposed criteria is far too narrowly tailored and it is unlikely that providers would submit – or be counseled to do so – to such an uncertain process that exposes them for innocent mistakes. The physician self-referral statute is confusing and complex; ACP believes that CMS should be focusing only on those who

intentionally or willfully disregard the intent of the statute and should develop a proposal that encourages violators into compliance.

Services Furnished "Under Arrangements"
CMS proposes to significantly limit physician services provided "under arrangements" to hospitals. This proposal would revise the definition of "entity" to include the person or entity that presents claims for DHS (current definition) and the person or entity that either provides the DHS or "causes a claim to be presented" for the DHS. Under this proposal, CMS seeks to expand the scope of the statute to apply to entities that do not even bill the Medicare or Medicaid programs for DHS. ACP believes that this is not within CMS's congressional authority. Nevertheless, this proposal would essentially prohibit all existing under arrangements services contracts with physicians, potentially disrupting access and unnecessarily causing the purchasing of equipment to provide needed services. Therefore, ACP believes that CMS should withdraw this proposal.

The College is greatly concerned over these and other proposed changes to the physician self-referral statute. This section of the proposed rule represents a marked and concerning change in direction to what was once an effort to create bright-line exceptions. As CMS prepares to release Phase III of the physician self-referral regulations, it must seriously consider the impact of significant changes on physician practices, which in turn have a significant impact on the health status of the beneficiary.

While ACP fully understands and shares concerns about inappropriate utilization of certain services, completely restricting the ability of physicians to invest in their own industry is far from the answer. Throughout the proposal, CMS continues to cite "anecdotal evidence" of arrangements that are at risk for fraud and abuse yet provides no actual evidence of program abuse. The College is eager to work with CMS to examine the causes of increased utilization and attack the more important issues of overvalued services that are driving growth in spending rather than making changes to the statute that will significantly deteriorate access to care for beneficiaries.

PROPOSED ELIMINATION OF EXEMPTION FOR COMPUTER-BASED FACSIMILES

ACP opposes the CMS proposal to eliminate the computer-based facsimile exemption to electronic prescribing standards. ACP believes that the concerns that originally led to this exemption being created in 2005 are still concerns today. ACP believes that elimination of this exemption will result in physicians reverting to the use of paper-based prescriptions, which will only make it more difficult to move to electronic prescribing in

the future. CMS must recognize the difficulties that physicians face in implementing electronic prescribing systems and not discourage them for using systems that improve the efficiency of the care that they provide just because the system may not meet the full compliance with electronic prescribing standards. ACP urges CMS to not eliminate this exemption.

TRCHA – SECTION 101(b) (PQRI)
MIEA-TRHCA Requirements for Measures Included in the 2008 PQRI

ACP supports the CMS proposal that the AQA adoption of quality measures meets the statutory requirement that PQRI quality measures be adopted or endorsed by a consensus organization. The College recommends a prominent and expansive role for the AQA so that it can continue to provide valuable contributions in the areas of: measure adoption; establishing criteria for measure implementation prioritization; and developing policies related to measure reporting and data aggregation.

ACP concurs with the CMS expectation that PQRI quality measures be endorsed by the National Quality Forum (NQF) and adopted by AQA. Specifically, ACP agrees with the CMS proposal to:

- Include quality measures in the 2008 PQRI that are endorsed by NQF and adopted by AQA by the November 15, 2007 statutory deadline;
- Include quality measures in PQRI 2008 that are adopted by AQA if NQF has been unable to make an endorsement decision by the November 15 deadline; and
- Decline to include quality measures in PQRI 2008 which AQA has adopted but NQF has specifically declined to endorse.

Proposed 2008 Quality Measures

Structural Measures Currently Under Development

i. Definition of Structural Measures

ACP recommends that CMS work with the College and other stakeholders to develop a definition of a structural measure—that definition should encompass structural capability and use of that capability. A CMS definition of a structural measure, informed by public comment, would help influence further establishment of such measures.

While ACP does not have an official definition of structural measure, ACP does offer language describing how the College has thought of structural capability/measures and includes references to MedPAC's consideration of the issue. The agency can use this information as a starting point for establishing a working definition. In addition, ACP recommends that CMS consult the NQF and the AQA as these consensus organizations will review structural measures to decide whether to endorse and adopt.

ACP has thought of structural capability/measures as:

> Tools and health information technologies that have the capability to support physicians' efforts to improve, measure, and report on the quality of care provided to beneficiaries, improve care coordination of patients with chronic diseases, reduce medical errors, and/or deliver care consistent with evidence-based guidelines of quality and appropriateness.

MedPAC describes structural measures as "measures designed to ensure that the provider is capable of delivering good care" in its March 2005 *Report to Congress.* In its discussion of structural measures specific to physician practices in the context of physician pay-for-performance, MedPAC characterizes structural measures as systematic processes to improve care management and notes that they can involve advanced or more limited health information technology.

ii. Need for Guidance as to what Constitutes Acceptable Structural Measure

ACP recommends that CMS encourage NQF and AQA to develop guidance as to what constitutes an acceptable structural measure based on an accepted definition of what constitutes structural capabilities in a physician practice setting.

iii. Inclusion of Structural Measures in PQRI 2008

CMS Proposed Structural Measures

ACP supports the CMS proposal to include structural measures in the 2008 PQRI. Specifically, the College supports the agency proposal to include the "Adoption/Use of E-prescribing" and the "Adoption/Use of Health Information Technology (Electronic Health Records)" structural measures in the 2008 PQRI. As CMS includes no description of these measures or how they are to be reported in this proposed rule, ACP offers its comments on the version of these structural measures released by Quality Insights of Pennsylvania, the Pennsylvania Quality Improvement Organization (QIO), under contract with CMS, for public comment in May 2007.

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Adoption/Use of E-prescribing
The Quality Insights of Pennsylvania proposal that the physician report a Healthcare Common Procedure Coding System (HCPCS) G code for essentially every encounter with a patient in the ambulatory setting—including encounters for which no medication is prescribed—is excessive and imposes an unnecessary administrative burden on the physician. It also requires the Medicare contractor/CMS to handle a large volume of additional data elements. ACP recommends that CMS establish a more streamlined method that allows a physician to indicate systematic e-prescribing. For example, the physician could sign an attestation to e-prescribing use and a commitment to notify the agency when he or she ceases to e-prescribe. CMS could require all or a subset of physicians who have attested to e-prescribing to provide an electronically generated e-prescription count, a common feature in electronic health records and other prescribing systems. CMS should explore the use of an electronic portal to allow for ease in transmission of attestation and verification related information.

Specific to the Quality Insights of Pennsylvania proposed structural measure, ACP recommends that:

- CMS "grandfather" stand-alone e-prescribing systems implemented prior to August 2006 so that they are exempt from the requirement that they "be fully interoperable with a fully functional Certification Commission for Health Information Technology (CCHIT) electronic medical record (EMR)." This would be consistent with the "Adoption/Use of HIT" proposed structural measure, assuming that CMS intends to retain the Quality Insights of Pennsylvania-proposed component that exempts EMRs implemented prior to August 2006 from the CCHIT certification requirement.
- CMS define the term "advanced patient/disease specific decision support." CMS should reflect the extent to which advanced clinical decision support is common to e-prescribing systems in its definition of the term.

Adoption/Use of Health Information Technology (Electronic Medical Records)
ACP recommends that CMS make clear that this structural measure entails the adoption/use of an EMR.

ACP recommends that establish a process that allows physicians to indicate use of EMR and for the agency to verify that use without requiring physicians to report whether an EMR was used through a G code on each claim for an ambulatory encounter. This process should be electronic to minimize burden.

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The College supports making CCHIT certification a prerequisite for receiving credit for an EMR structural measure for a post-August 2006 EMR. ACP recommends, however, that CMS examine its "entering laboratory tests as discrete searching data elements" requirement to ensure it is presently feasible. It is difficult for many physician practices to import laboratory test results directly into even a CCHIT-certified EMR because of barriers related to interoperability and the cost associated with such implementing these connections – especially for small, lower volume medical practices. ACP notes that Quality Insights of Pennsylvania proposed a structural measure that is to be added on to its "Adoption of Health Information Technology" measure that indicates the physician ability to receive laboratory data electronically directly into his or her EMR. ACP urges CMS to clarify the system capability the agency is requiring pertaining to laboratory data in the HIT/EMR structural measure it proposes. For many small and medium-sized medical practices, the type of interoperability suggested by the draft measure fails to take into account the considerable impediments to implementation and costs associated with these interfaces. Even if the CMS expectation is that the physician practice manually enters laboratory test results into an EMR, this imposes burden on the practice.

Accordingly, it is important that CMS clarify its expectation in this area and to ensure that it is practical.

ACP Recommended Additional Structural Measures

ACP recommends that CMS include physician "Adoption/Use of a Population Management Registry" and "Adoption/Use of Point-of-Care Evidence-Based Clinical Decision Support" as additional structural measures in PQRI 2008. Including these measures—which the literature supports as having high value—enables physicians to demonstrate that they maintain and use structural capability that facilitates quality improvement that is short of a fully functional and operational EMR. Further, installation

of an EMR that includes the capability described in each of the individual structural measures does not ensure physician use of each individual component. The College urges CMS to work with it and other stakeholders to finalize these structural measures and to establish a mechanism that enables physicians to attest to maintaining/using the capability and allows CMS to verify it that imposes minimal burden.

Adoption/Use of a Population Management Registry
ACP recommends that CMS include physician "Adoption/Use of a Population Management Registry" as a stand-alone structural measure in PQRI 2008. ACP's view is that Quality Insights of Pennsylvania proposed use of a population management registry, in part, through its "Ability to Use HIT to Perform Care Management" structural measure

that it offered as an add-on to its "Adoption of Health Information Technology" structural measure. ACP recommends that CMS establish the adoption/use of a population management registry by using the Quality Insights of Pennsylvania-proposed HIT to Perform Care Management measure, without the "real-time decision support within patient encounter" component—which ACP recommends as a separate structural measure, detailed below—and the "patient specific care plan" component. ACP urges CMS to reconsider the patient specific care plan component because, despite the commendable and lofty goals apparent from its definition, it is not yet a common function even in a CCHIT-certified EMR. Further, physicians can use population management registries that are independent of an EMR. These registries can also facilitate the tracking of patients by disease or diagnoses on a longitudinal basis to promote appropriate interventions.

Adoption/Use of Point-of-Care Evidence-Based Clinical Decision Support
Quality Insights of Pennsylvania includes this component/capability in its proposed "Ability to Use HIT to Perform Care Management" structural measure. ACP recommends that CMS recognize the importance of this component by including it as a stand-alone structural measure in PQRI 2008, designated as "Adoption/Use of Point-of-Care Evidence-Based Clinical Decision Support."

ACP's recommendation to include the adoption/use of a population management registry and the adoption/use of point-of-care evidence-based clinical decision support as structural measures for PQRI 2008 is supported by reports and literature:

- The 2007 Center for Information Technology Leadership report "The Value of Information Technology-Enabled Diabetes Management," available at
- http://www.citl.org/_pdf/The_Value_of_IT_Enabled_Diabetes_Management.pdf, cites the ability of diabetes registries and clinical decision support systems to improve patient care. The report determines that the use of a diabetes registry can generate significant net savings over time.
- The California HealthCare Foundation February 2004 report, "Using Computerized Registries in Chronic Disease Care" states that a disease registry is "one type of clinical information system that is effective for supporting new models of chronic care." The background section of the reports cites literature showing how elements of the Chronic Care Model, clinical information systems that include registries and decision support, can improve effectiveness in treating chronic disease. An addendum describes the impact of the use registries by the provider organizations interviewed for the report.
- The October 9, 2002, *Journal of the American Medical Association* article, "Improving Primary Care for Patients with Chronic Illness," by Thomas

Bodenheimer, et al., provides case studies of how implementing elements of the Chronic Care Model can facilitate activated patients interacting with an informed healthcare team.

The California HealthCare Foundation report states that a lack of financial incentives discourages physicians from treating chronic diseases proactively. The CMS inclusion of a registry and decision support structural measure will help incentivize the use of tools that can improve care.

CMS Process for Developing Structural Measures

ACP urges CMS to improve the process by which it initiates/facilitates the development of structural measures in the future. The CMS decision to contract with Quality Insights of Pennsylvania and the QIO process for developing the structural measures missed an opportunity to benefit from the experience of ACP and other entities that have been active in physician-level measure development. The Quality Insights of Pennsylvania-proposed structural measures need significant improvement. CMS use of a more inclusive process would have likely enabled CMS to include structural measures for use in 2008 in this proposed rule that are more fully and adequately defined—the agency fails to even indicate its thinking regarding the Quality Insights of Pennsylvania-proposed structural measures. Further, ACP reiterates its earlier recommendations that CMS work with stakeholders to develop a working definition of structural measures and guidance as to what constitutes an acceptable measure. Collectively, these recommendations will improve the process by which structural measures are developed and selected, increasing the likelihood that they will trigger quality improvement.

ACP would be glad to work with CMS to identify viable processes for physician reporting of the capability defined by structural measures and agency verification of that use. ACP notes that the capability defined by the structural measures discussed in our letter will be used optimally when integrated with an EMR. The College urges CMS to begin thinking about the a longer-term strategy for ensuring that structural measures provide the appropriate incentive to reach the next level of capability based on the current state of technology.

Additional AQA Starter-Set Measures
ACP supports the CMS proposal to include the measures in the AQA "starter set" that the agency did not include in the 2007 PQRI in the 2008 initiative. The CMS condition that these measures retain NQF endorsement and AQA adoption is appropriate.

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Addressing a Mechanism for Submission of Data on Quality Measures Via a Medical Registry or Electronic Health Record

Registry-Based Reporting
ACP recommends that CMS work with the College and other stakeholders to determine the information—clinical and non clinical—necessary for optimal physician quality improvement/performance assessment, as opposed to confining quality reporting/performance assessment options to the parameters of the 2007 PQRI. Each of the five CMS registry data submission options involve the same information elements used in PQRI 2007—information to: determine if a physician successfully reported (80% of eligible cases threshold) using CPT II codes and modifiers; provide the physician a reporting and performance score; and to determine the amount of the bonus payment earned by a physician who reports successfully. While ACP understands that the Tax Relief and Health Care Act provisions that establish the PQRI constrain the agency's options for 2008, ACP urges CMS to begin exploring a wide range of future quality data options.

ACP agrees that registries should comply with privacy and confidentiality rules.

ACP believes that registries should contain enough information to adequately assess a physician's performance, e.g. not limiting registry information to Medicare beneficiaries.

Stakeholders should establish uniform rules pertaining to data collection through a registry. The AQA maintains, multi-stakeholder vetted policy pertaining to this and related topics. The AQA "Principles in the Use of Registries for Enhancing Quality of Care through Performance Measurement" document is at http://www.aqaalliance.org/files/RegistryPrinciplesDocumentV1Approved.doc. Additional AQA policies, including principles on data sharing and aggregation, are available at http://www.aqaalliance.org/default.htm.

The process by which physicians report data to a registry should impose minimal burden and cost.

Physician Submission of Quality Data from an Electronic Medical Record
ACP believes that the long-term goal is physician direct reporting of quality data—using defined standard elements and a standard format—to the entity that will use the information, which could include a variety of stakeholders. The extensive time likely required to define standard data elements and formats provides an opportunity for CMS and other stakeholders to determine the best use of data for quality improvement and other purposes, such as to measure physician/practice performance and, potentially, to

measure efficient use of resources. These issues could include identifying quality indicators that have the highest impact.

In the meantime, testing physician direct EMR reporting through use of Doctors' Office Quality—Information Technology (DOQ-IT) ambulatory quality measures is an appropriate early step in the transition. ACP urges CMS to test physician direct reporting of the DOQ-IT measures as a voluntary alternative to claims based quality reporting in PQRI 2008.

ACP recommends that CMS consider measures/actions/initiatives to facilitate the transition to the time when physician direct EMR reporting is technically and operationally feasible on a widespread basis:

- Limited physician direct EMR reporting of DOQ-IT measures in 2008;
- Facilitate (public, private, and/or joint public-private) data element and format standardization efforts;
- Develop rules pertaining to CMS or its designee receiving data from quality registries; and
- Include the notion that physicians maintain multiple pathways to report quality data through an intermediary to ensure that physicians can provide data using a mechanism that works best for their practice, allowing them to take in consideration of practice redesign, administrative effort, and cost.

The research paper, "Comparison of Methodologies for Calculating Quality Measures Based on Administrative Data versus Clinical Data from an Electronic Health Record: Implications for Performance Measures," by Paul Tang, et al., published in the January/February 2007 *Journal of the American Medical Informatics Association* finds that using coded fields in an electronic medical record is superior to using administrative claims data to identify a target patient population for which quality is measured. The paper, which describes a study that focused on identifying diabetics that was funded by Lumetra (the California QIO) under contract with CMS, states that more precise identification of the target population can facilitate more accurate performance measurement. Further, the NQF HIT Expert Panel, in which CMS has participated in a liaison role, is recommending that a coded problem list in the electronic health record be used to identify patients for quality measurement as opposed to billing codes reported through claims.

TRCHA – SECTION 101(d) (PAQI)

ACP strongly disagrees with the CMS proposal to use the $1.35 billion allocated as part of the Physician Assistance and Quality Initiative (PAQI) fund entirely to fund the Physician Quality Reporting Initiative (PQRI) in 2008. ACP has supported positive

financial rewards to fund quality reporting/improvement initiatives, but is very concerned about the impending 9.9% cut in the conversion factor that will cause physician payments from Medicare to plummet. CMS was given the opportunity to use some of that money to reduce the scheduled payment cuts, but choose to instead use it for this quality reporting initiative. ACP does not agree with the argument that CMS is unable to apply this payment towards a conversion factor adjustment. While ACP understands the difficulties that are associated with assigning a fixed pool of money to an entitlement program, it believes that CMS has the technical capability to apply the money in the fund to offset some of the scheduled conversion factor decrease. ACP encourages CMS to use the PAQI to offset the scheduled decreases to the conversion factor for 2008.

OTHER ISSUES

Anticoagulation Management Codes

ACP strongly disagrees with the CMS decision to continue to consider anticoagulation management codes (99363 and 99364) to be bundled into the work of evaluation and management codes. The initial impetus for the creation of these codes was the statement by CMS that these services were not managed as well as they should be and that the existing coding structure failed to provide incentives to optimize care. In reaction to this, ACP, in cooperation with other medical societies, considered for some time the best way to define the services performed by physicians managing this very serious medication regimen. The complete range of this work is not paid under the current system. During the creation of the code, the Current Procedural Terminology (CPT) editorial panel and the Relative Value Scale Update Committee (RUC) were very careful to create protections in the code that would prevent work from anticoagulation management being included in selecting the level of evaluation and management codes. CMS did not offer any explanation for its decision to bundle payment for these codes into evaluation and management services when it published this action in its final rule for the physician fee schedule for 2007. There is still no explanation offered in the 2008 proposed rule.

These CPT codes are recognition of the important work of managing serious disease and the CMS decision to not pay for this service could have a devastating impact. ACP was given the opportunity to review a proposed Correct Coding Initiative (CCI) edit to be used to prevent the billing of a 99211 on the same day of these codes, according to its common practice of reviewing all CCI edits. ACP opposed this edit based on the possibility that such an event could take place on very rare occasions. However, ACP supports the edit now that the College understands that CMS feels strongly that it will help prevent potential abuse and fraud. ACP believes that physicians should be paid fairly for the services that they provide and will do everything possible to avoid any potential fraud. ACP strongly encourages CMS to not finalize its proposal to consider

these services bundled but instead change their status to active covered services in the 2008 fee schedule.

Researchers are increasingly recognizing the importance of chronic disease management in preventing more costly interventions and improving the quality of lives of patients. The patients who are receiving anticoagulation therapy require extensive medical work and attention from physicians, and in many cases they are forced to give this care away or refuse to accept patients who require this therapy into their practice. Reviewing the research on this issue shows the striking impact of the management of this drug on the healthcare system. It is estimated that there are more than 43,000 adverse drug events treated in the emergency room each year related to anticoagulation therapy.[2] Many of those treated in the emergency room will also end up admitted to the hospital, further degrading the health of the patient and adding to unnecessary spending.

Anticoagulation management services are an important responsibility and CMS should recognize the extensive work involved by paying for this service.

Work Neutrality Adjustor
ACP continues to disagree with the CMS decision to use a separate budget neutrality adjustor for the work portion of the RVUs and recommends that CMS apply the legislatively-mandated adjustment to the conversion factor in the 2008 fee schedule.

ACP disagrees with this approach for a number of reasons. Notably, CMS used this approach in the past and found it to be problematic, noting when it was eliminated in 1999 that

> "[W]e did not find the work adjustor to be desirable. It added an extra element to the physician fee schedule payment calculation and created confusion and questions among the public who had difficulty using the RVUs to determine a payment amount that matched the amount actually paid by Medicare" (*Federal Register*, Vol. 68, No. 216, Pg. 63246). We believe an adjustment to the conversion factor is preferable because it recognizes that budget neutrality is a fiscal issue, not an issue of relativity. Budget neutrality is mandated for monetary reasons. Thus, the conversion factor, as the monetary multiplier in the Medicare payment formula, is the most appropriate place to adjust for budget neutrality.

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[2] Budnitz. National Surveillance of Emergency Departments for Adverse Drug Events. *JAMA. 2006;296:1858-1866*

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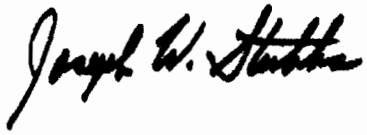
Finally, ACP believes that CMS must recognize that many insurers in the private market use the RVUs to determine payments. While the confidential nature of many private insurer payments has made it difficult to gauge the impact in 2007, ACP believes that a number of insurers are using the budget-neutrality adjusted numbers in order to calculate their own payments to physicians, because they base their payments on RVUs.

ACP appreciates the opportunity to communicate to CMS its perspective on the numerous proposals contained in this rule. If you have further questions, please contact Brian Whitman, Senior Analyst for Regulatory and Insurer Affairs at (202) 261-4544 or bwhitman@acponline.org

Sincerely,



Joseph W. Stubbs, MD, FACP
Chairman, Medical Service Committee

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August 29, 2007

Herb Kuhn, 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: CMS-1385-P – Drug Compendia

Dear Mr. Kuhn:

MGI PHARMA, Inc. ("MGI") appreciates the opportunity to comment on the Centers for Medicare & Medicaid Service ("CMS") proposed rule on Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2008 and Other Part B Payment Policies (the "Proposed Rule"). MGI is an oncology and acute care-focused biopharmaceutical company that acquires, develops and commercializes proprietary products that address the unmet needs of patients in the United States. Aloxi® (palonosetron hydrochloride) injection and Dacogen™ (decitabine) are among the products covered by Medicare Part B that MGI makes available to beneficiaries.

Our comments concern the drug compendia provisions of the Proposed Rule. CMS proposes to create a public notice and comment process related to requests for changes to the list of compendia used to determine medically-accepted indications for drugs and biologicals used in anti-cancer treatments.[1] The Proposed Rule sets forth a process for posting proposed changes on the CMS web site, the requirements for a complete request, the framework for public comments, standards for inclusion of compendia, the timeline for CMS decisions, and requirements pertaining to updated editions of approved compendia.

We commend CMS for addressing this important issue in the Proposed Rule. Cancer care is an area of intense clinical research, and there is a rapidly developing body of knowledge regarding effective oncology treatment options. Congress and CMS have recognized that many emerging cancer treatment options involve compendia-listed uses of FDA-approved drugs and biologicals. It is imperative for Medicare coverage policy to continue to be responsive to these clinical developments in order to ensure that Medicare beneficiaries with cancer have access to the safest and most effective treatment options. We therefore recommend that CMS finalize the compendia process in the Final Rule. We support the process outlined in the Proposed Rule, including, in particular, CMS's proposal to permit public comments on compendia recommendations.

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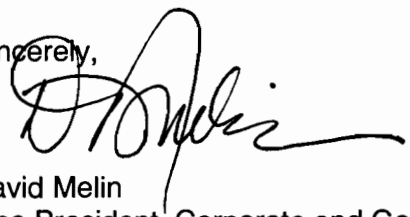
1 Proposed 42 C.F.R. § 414.930.

We also urge CMS to adopt a mechanism to expedite review of a compendium's status when there is a name change or ownership change to promote seamless coverage to the extent possible.

Timely inclusion of qualified compendia through a transparent public process will help enable physicians to prescribe clinically-appropriate cancer treatments for their Medicare patients. We appreciate CMS's commitment to ensuring continued Medicare beneficiary access to appropriate compendia-listed cancer treatments in an expedited manner.

We appreciate your consideration of our comments and would be pleased to answer any questions you may have.

Sincerely,



David Melin
Vice President, Corporate and Government Affairs

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August 30, 2007

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

RE: Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions (CMS 1385-P).

Dear Deputy Administrator Kuhn:

The Cardiology Advocacy Alliance (CAA) represents more than 4,500 independent private practice cardiologists nationwide who provide care to our nation's Medicare population. Our mission is to provide national leadership on legislation, policies and reimbursement methodologies that affect the quality of patient care and access to services as well as the stability of cardiovascular group practices.

CAA appreciates the opportunity to comment on the proposed rule referenced above. While we have outlined our comments on specific portions of the proposed rule in this letter, CAA wants to communicate to CMS our concern with what seems to be CMS' overall approach to many of the issues contained within the proposal. CMS discusses and proposes changes for areas (physician self-referral, per-click and under arrangements, percentage-based compensation, IDTFs, etc) and in doing so, runs the danger of creating anti-competitive situations, setting restrictions that are not universally applied and increasing administrative burdens with no change in outcomes or efficiency. Some proposals ultimately would increase costs to Medicare and its beneficiaries and reduce access to care.

This overall approach is not indicative of an open, objective dialogue between Medicare and its providers. **While CAA acknowledges there may be a concern about fraud within the Medicare system, as may be the case in any large public or private endeavor, the appropriate solution is not to burden all providers with excessive regulation. CAA instead supports the development and use of appropriateness criteria, credentialing and accreditation as reliable methods to ensure appropriate utilization and quality of care.** CAA is eager to share information with CMS about the challenges that independent cardiologists face in providing care to the Medicare population in a positive, open and mutually beneficial process.

RESOURCE-BASED PE RVUs

Discussion of Equipment Usage Percentage - *pp 58-59.*

CMS requested information in relation to alternative percentages and approaches that differentially classify equipment in mutually exclusive categories with category-specific usage rate assumptions. **CAA supports CMS' decision to keep the equipment utilization rate at the current rate of 50 percent. CAA provides the following information to demonstrate that the utilization rate of nuclear and ultrasound imaging equipment for Cardiology is below the current 50 percent rate used in determining the practice expense component of the total RVU for the nuclear and echo imaging procedures.**

CAA enlisted the services of MedAxiom, Inc. to determine the utilization rate of nuclear and ultrasound equipment used extensively in the practice of Cardiology. MedAxiom is a network of more than 250 cardiology practices representing more than 5,000 cardiologists in the United States. MedAxiom conducts an annual survey of its members and compiles the data for use by its members. The data also are important objective measures for issues such as equipment utilization. *The objective of the data collection is group performance and is not in response to a request regarding practice expense calculation.*

For purposes of this study, we used the median and mean number of studies per machine per day as reported in the MedAxiom Nuclear and Echo surveys for CY 2006. There were 70 practice respondents for the Nuclear Survey (representing approximately 1,470 physicians) and 71 practice respondents for the Echo Survey (approximately 1,490 physicians). The mean number of cardiologists per group in the 2006 survey was 20 (std. deviation = 12) and the median was 18.

The tables below demonstrate the utilization percentage for each imaging modality using the median and the mean number of studies per day. The minutes per patient reflect the amount of time the equipment is in use for each patient, plus we added the amount of time for quality control by dividing the total time by the number of studies per machine per day.

Nuclear

	Studies per Machine per Day	Minutes per Patient	Minutes per Machine per Day	Days per Year	Minutes per Machine per Year	Maximum Minutes per Year	Percent Utilization
Median	**5.3**	**50**	**265**	**250**	**66,250**	**150,000**	**44%**
Mean[1]	**5.6**	**50**	**280**	**251**	**70,280**	**150,001**	**47%**

[1] Standard Deviation = 1.7

Echo

	Studies per Machine per Day	Minutes per Patient	Minutes per Machine per Day	Days per Year	Minutes per Machine per Year	Maximum Minutes per Year	Percent Utilization
Median	**4.5**	**60**	**270**	**250**	**67,500**	**150,000**	**45%**
Mean[2]	**4.6**	**60**	**276**	**250**	**69,000**	**150,001**	**46%**

[2] Standard Deviation = 1.3

It is clear that the utilization rate of nuclear and ultrasound imaging equipment for cardiology is below the current 50 percent rate used in determining the practice expense component of the total RVU for the nuclear and echo imaging procedures. Increasing the rate to 70 percent, therefore, is not substantiated. CAA is opposed to raising the equipment utilization rate and supports CMS' decision to keep the rate at 50 percent.

CODING--ADDITIONAL CODES FROM 5-YEAR REVIEW

Bundling of CPT Code 93325 into Doppler Echo Codes 76825, 76826, 76827, 76828, 93303, 93304, 93307, 93308, 93312, 93314, 93315, 93317, 93320, 93321, 93350 and assign CPT code 93325 a status indicator of "B" (Bundled) - *pp. 128-129.*

CMS states that color flow Doppler is "intrinsic" to all echocardiography procedures. CAA disputes CMS' assertion and believes the CPT Code bundling of 93325 into the Doppler Echo Codes is not appropriate for a number of reasons. The American College of Cardiology has submitted data to CMS showing significant variation in the use of color flow Doppler in conjunction with echocardiography codes. CAA members demonstrate similar use patterns in their practices as well.

In reviewing Medicare claims data submitted to the RUC, it is clear that the employment of 93325 with another base echocardiography code is only typical for 99307. Since a code bundling 93307 with 93325 and 93320 has already been approved by CPT and will be valued by the RUC in September 2007, we recommend that CMS consider the RUC recommendations from that meeting in the Final Rule. Since 93325 clearly results in additional physician work, and is not typically performed with the other echocardiography base codes, we recommend that CMS permit the concomitant use of 93325 with the remaining echocardiography base codes.

CAA is opposed to the bundling of these codes and urges CMS to keep CPT Code 93325 separate from all other echocardiography codes as 1) color flow Doppler is NOT intrinsic to all other echocardiography procedures 2) the non-93325 codes do not include RVU reimbursement for color flow Doppler and 3) a code bundling 93307 with 93325 and 93320 has already been approved by CPT and will be valued by the RUC in September 2007.

PHYSICIAN SELF-REFERRAL PROVISIONS

1. Changes to Reassignment and Physician Self-Referral Rules Relating to Diagnostic Tests (Anti-Markup Provision) - *pp. 305-314*

CMS proposes to subject the Professional Component (PC) to an anti-markup provision applied to all arrangements not involving a reassignment from a full-time employee of the billing practice. Although this may require some of our members to review existing contractual arrangements to comply with CMS' proposed anti-markup provision, ***CAA supports subjecting both the TC and the PC to anti-markup provisions.*** On a related note, CAA believes imaging technology should be provided by physicians trained in modality-specific interpretation of imaging procedures who follow appropriateness guidelines set forth by specialty organizations such as the American College of Cardiology and the American Society of Echocardiography. In addition, CAA supports the accreditation of facilities that provide such imaging services as long as CMS provides practices with adequate time to become accredited by relevant organizations such as, but not limited to, the Intersocietal Commission for the Accreditation of Nuclear Medicine Laboratories, Intersocietal Commission for the Accreditation of Echocardiography Laboratories and other organizations dedicated to improving the quality of imaging services.

2. Unit-of-service (Per-Click) Payments in Space and Equipment Leases - *pp. 324-327*, Services Furnished "Under Arrangements" - *pp. 345-352*

CMS currently allows hospitals and physician practices to collaborate on the provision of certain services. A common collaboration between hospitals and physicians/ physician groups is in the provision of testing services. Such arrangements are based on sound business rationale to eliminate duplication of services and costs. These unit-of-service and under-arrangement collaborations enable geographically connected entities to make the most efficient use of limited technologist staff resources and capital equipment investments while providing physician oversight, monitoring and quality control of testing services.

CMS' proposed changes would prohibit common models of hospital/physician practice collaboration, such as 1) services provided to the hospital by a physician practice "under arrangements", or as a vendor to the hospital and 2) services provided from one party to another on a per-unit used basis via leasing of space and equipment. CMS cites concerns that such collaborations could lead to overutilization. However, CMS has not substantiated these concerns with comprehensive analyses or objective data, and our members can demonstrate that such collaborations reduce duplication of services and competition for technical staff within local service areas, thus reducing practice expense and equipment costs for Medicare providers and the Medicare program.

CAA opposes the proposed changes to per-click payments in space and equipment leases and under arrangement services, as elimination of such arrangements will increase Medicare expenditures by increasing facility, equipment and staffing expenses. CAA urges CMS to reconsider the unintended consequence of raising healthcare costs and eliminating physicians' and hospitals' ability to make sound business decisions in the rational distribution of health care assets via these collaborative efforts.

RECALLS AND REPLACEMENT DEVICES - *pp. 373-375*
CAA appreciates CMS initiatives to assess ways to identify the additional health care costs and Medicare expenditures associated with device recall actions. As cardiologists, our members unfortunately have had several experiences of device recalls and the subsequent patient concerns and evaluations.

CAA suggests that Medicare create a recall-specific code when such device recalls occur that physicians can bill under and track the additional time and work associated with such recalls.

REGULATORY IMPACT ANALYSIS - *pp. 479--*
1. Physician Fee Schedule Reduction
Although CMS is bound by the regulatory requirements of the Sustainable Growth Formula and CAA acknowledges that any revision to the annual update must be accomplished through legislative means, our members want to emphasize that the estimated 9.9-percent cut scheduled for 2008 would prove extremely onerous for private practice Cardiology. As the population of older Americans increases and lifespan lengthens, Cardiology as a specialty has seen significant growth. Caring for our elderly population comes at a price, and there will come a point where cardiologists will not be able to sustain services to their Medicare populations should reimbursement for these beneficiaries continue to decrease. Physicians have not received cost-of-living increases for several years although the cost of providing care (nursing and technical staff salaries, physician training, new technology, etc.) has

risen each of those years. We encourage CMS to continue to work with Congress to find a permanent solution to the flawed Sustainable Growth Rate factor.

2. Reduction of Left Heart Catheterization Codes

CAA, in conjunction with the Cardiovascular Outpatient Center Alliance (COCA), is alarmed by the draconian cuts to IDTF/in-practice Left Heart Catheterization (93510TC, 93555TC, and 93556TC) included CMS' proposed 2008 fee structure. CMS accepted the 2007 PERC/RUC direct cost recommendations without considering the more accurate direct cost information that COCA provided to CMS in May 2007. While these values are a slight improvement from the 64-percent cut in reimbursement proposed in the 2006 Physician Fee Schedule for 2007-2010, the PE RVU values set out in the current Proposed Rule still would result in severe cuts in reimbursement for cardiac catheterizations performed in practice or IDTF locations.

If the 2007 conversion factor is applied to the technical components of the primary three CPT codes for a Left Heart Catheterization, the reimbursement in 2008 would be reduced from the current rate by 32 percent, and when fully implemented in 2010 the total reimbursement reduction would be 49 percent. These severe cuts would undoubtedly result in the closing of the majority of non-facility outpatient cardiac catheterization labs in the country forcing Medicare patients who now benefit from improved access and lower costs into more acute and expensive hospital settings. **CAA requests that CMS review the additional cost data provided by COCA and revise the current proposed PE RVUs for outpatient cardiac catheterization procedures to values that more reasonably reflect the direct and indirect costs of providing these services.**

An additional solution would be to recognize the difficulty in determining direct and indirect costs for non-facility outpatient cardiac catheterization centers utilizing RUC criteria and tie reimbursement for these procedures to a reasonable percentage of the APC rate for the same family of procedure codes. The costs of performing these services in facility and non-facility locations are remarkably similar based on actual experience from our members who administer both facility and non-facility cardiac catheterization centers.

This inconsistency of the current rate setting process becomes evident when the proposed negative changes for outpatient diagnostic cardiac catheterization codes listed in the 2008 Physician Fee Schedule are compared with the proposed 2008 APC rate increase of 11.18 percent for APC 0080 "Diagnostic Cardiac Catheterization" published in the August 2, 2007 Federal Register (CMS-1392-P). It is clear that the RUC recommendations regarding the cost of performing these procedures are dramatically at odds with those that CMS determined for the same procedures performed in facility-based outpatient cardiac catheterization centers. This comparison is set out in the following chart:

Comparison of Payment Rates by Site of Service for Family of Diagnostic Catheterization Codes (PFS 93510 TC, 93555 TC, 93556 TC and APC 0080)

	Actual 2007	Proposed 2008	Proposed 2010	% Change	2008 PFS as % of 2008 APC	2010 PFS as % of 2008 APC
APC Rate	$2,283.55	$2,539.00		11.19%		
PFS Rate	$2,138.56	$1,450.34		-32.18%	57.12%	
PFS Rate	$2,138.56		$1,090.69	-49.00%		42.96%

CAA and COCA view APC payment levels as a reasonable benchmark when accurately evaluating the Medicare Physician Fee Schedule payment methodology for outpatient cardiac catheterization procedures where the technical component can be billed separately, and urges CMS to tie reimbursement for these procedures to a reasonable percentage of the APC rate for the same family of procedure codes.

In conclusion, CAA again appreciates this opportunity to comment on the proposed revisions to Medicare, Physician Fee Schedule and other Part B payment policies for CY 2008. Please contact CAA's executive director, Margo Burrage, at 734.878.2108 or via email at *mburrage@cardiologycaa.com* if you have any questions or would like to schedule a meeting to review our comments.

Sincerely,

Ann E. Honeycutt, President
Cardiology Advocacy Alliance

Mark Victor, MD, FACC
Board Member
Cardiology Advocacy Alliance

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SOCIETY OF INTERVENTIONAL RADIOLOGY
Enhanced care through advanced technology™

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August 30, 2007

Herb Kuhn
Acting Director
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
7500 Security Boulevard
Baltimore, MD 21244-1850

Submitted electronically via CMS Web site, http://www.cms.hhs.gov/eRulemaking, with hardcopy sent via FedEx

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:

The Society of Interventional Radiology (SIR) is a physician association with over 4,000 members that represents the majority of practicing vascular and interventional radiologists in the United States. SIR having reviewed the "Medicare Program: Proposed Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008 [CMS-1385-P]" offers the following general and specific comments:

CMS Support for RUC-PERC Process
SIR commends the Centers for Medicare & Medicaid Services (CMS) for the sincere and extraordinary effort of your staff in supporting the RUC process and in particular the RUC-PERC process, which requires diligence, impeccable attention to detail, and an intense level of scrutiny. CMS staff does an exceptional job in ensuring that the data pertaining to practice expense inputs is as accurate and up-to-date as reasonably possible.

Creation of Non-Facility RVU Rates for Peripheral Stent Services
SIR commends CMS for supporting the creation of non-facility RVU rates for codes 37205, 37206 and 75960. However, it appears that the update to the non-facility RVU rate for code 75960 was inadvertently not included in the proposed rule. Per correspondence with CMS staff, this was a result of failing to update the 2007 "C"- carrier price status for this code to an active code. SIR eagerly awaits confirmation of the correction of this minor oversight.

The creation of non-facility RVU rates for peripheral stent services is timely and appropriate. Per Medicare 2005 utilization data, these services are most typically being provided in the outpatient setting (50.21%, including 48.15% hospital outpatient and 2.06% office setting - Source: 2005 Medicare utilization data, American Medical Association/Specialty Society RUC Database 2007)

and SIR asserts that since 2005, undoubtedly the outpatient/office utilization rate has even further increased above the available statistics rate.

There are several studies that clearly establish that peripheral stent services are safely performed with short observation stays as is typical in the non-facility environment. Kruse and Cragg (JVIR 2000) concluded, "many interventional vascular procedures [including stent placement] can be performed safely on an outpatient basis with relatively short observation times [four hours or less]. Early discharge from the SSU did not result in an increased readmission rate to the hospital because of delayed complications." Additionally, Akopian and Katz (J Vasc Surg 2006) found significant cost savings associated with interventional vascular procedures with short observation times with no compromise in safety. Copies of both these articles have been attached for your reference.

CMS' Request for Additional Information Regarding Practice Expense Data
CMS has requested specific information regarding practice expense data for codes 37205/37206 and 36481. Please find SIR's compliance with this request, as follows:

Codes 37205 and 37206
CMS has requested confirmation of the price of the "vascular stent deployment system, a description of the kits contents and the typical quantity needed". A copy of the price listing supporting the $1645 price and a brochure describing the device as supplied by the manufacturer, Cordis (both, of which, have already been submitted to CMS staff) have been attached for your reference.

SIR members currently performing these services in the freestanding/non-facility setting do find that typically 1-2 stents are used in these procedures, supporting SIR's initial recommendation to the RUC-PERC of 1.5 stents. However, RUC-PERC advisors found that non-facility practice expense costs should cover all typical scenarios, hence the RUC-PERC recommendation of 2 stents. Regretfully, as these devices are quite expensive and there is not currently sufficient reimbursement to cover the costs of providing these services in the non-facility setting, the utilization rate of these services in the non-facility is currently relatively low; limiting the availability of published data to challenge CMS' decision to only include 1 stent. It is hoped that CMS is cognizant that this decision is being made based on the information contained in "a published clinical research study". Akopian and Katz (J Vasc Surg 2006) findings regarding the typical number of peripheral stents placed, supports the experience of SIR members with 46 single stent (53%) and 40 multiple stents (47%) placed during 86 stent procedures. SIR asserts that the findings of one study examined by CMS, that can be contradicted by the Akopian and Katz study, should not override the recommendation of the RUC-PERC, which brings the experience of many providers, and strongly urges CMS to reconsider including the practice expense (PE) cost of 2 stents, or at minimum the believed to be "average" of 1.5 stents, in the non-facility PE value for code 37205.

Code 36481
SIR, having reviewed the entire listing of the current three different types of practice inputs (equipment, clinical staff, and medical supplies) for code 36481 (*Percutaneous portal vein catheterization by any method*), as detailed in the "2008 PFS Proposed Rule (CMS 1385-P): Direct Practice Expense Values Used To Create Resource-Based Practice Expense Relative

Value Units" data files, finds that the list of practice expense (PE) inputs for this code appears to be that for a plasma pheresis procedure and does not reflect the PE inputs that would be typical for percutaneous portal vein catheterization. For percutaneous portal vein catheterization, one would anticipate the inclusion of angiographic equipment, catheters to access the portal vein and the inclusion of Radiologic Technologist/Angio Technician staff time. SIR recommends that CMS refer code 36481 to the RUC-PERC process for the development of accurate and appropriate PE inputs for the facility and non-facility settings.

In the interim, SIR recommends that CMS consider cross-walking the PE inputs for code 36481 to a code with similar established non-facility PE inputs. Regretfully, what is believed to be the most similar service to portal vein catheterization, TIPS revision (code 37183 - *Revision of transvenous intrahepatic portosystemic shunt(s) (TIPS) (includes venous access, hepatic and portal vein catheterization, portography with hemodynamic evaluation, intrahepatic tract recanulization/dilatation, stent placement and all associated imaging guidance and documentation*) does not currently have non-facility PE inputs developed. Therefore, until such time as PE inputs for code 36481 can be addressed through the RUC-PERC process, SIR recommends using the non-facility PE inputs for the closest existing code with non-facility PE inputs developed, which is code 36012, (*Selective catheter placement, venous system; second order, or more selective, branch*). While code 36481 is believed to be more resource intensive than code 36012, this code does offer the closet estimate of PE inputs at this time. In addition to referring code 36481 to the RUC-PERC process for the development of PE inputs, SIR recommends that CMS also consider referring the related TIPS revision code 37183 for PE input development.

Proposed Annual Pricing of High Cost Disposable Medical Supplies

SIR is aware that the RUC has recommended that "High cost disposable medical supplies (priced at or above $200) should either be reported separately with J codes or individually identified within the payment bundle and then re-priced on an annual basis." Regretfully, obtaining pricing information from device manufacturers can be time consuming and administratively burdensome. It is believed that this recommendation would result in an undue administration burden on specialties such as interventional radiology that provide device-intensive services. Therefore, SIR recommends that CMS consider instituting a minimum utilization level in conjunction with device price, as the trigger for annual re-pricing of disposables.

Equipment Utilization Assumptions

SIR supports CMS' proposal to retain the current 50% equipment utilization assumption and concurs with CMS' statement, "*We do not believe we have sufficient empirical evidence to justify an alternative proposal [to the 50% utilization assumption].*" Additionally, an increase in the utilization rate assumption is not supported by MedPAC survey data. In fact, MedPAC issued the following warning regarding any attempts to rely on the methodologically flawed survey data they recently commissioned:

"This survey is a first step…It was not nationally representative and it was not designed to determine equipment use rates. Its intent was to assess the feasibility of getting use rate data from the survey….. *I do want to caution that this survey is not representative [of] anything."* (p. 237 and 242 of April 19, 2006 MedPAC meeting transcript).

SIR appreciates the opportunity to provide comment to CMS regarding the valuation of interventional radiology services under the Medicare Physician Fee Schedule. If SIR can be of any assistance as CMS continues to consider and review the 2008 Medicare Physician Fee Schedule, please do not hesitate to contact Dawn Hopkins, Director of Reimbursement & Health Policy at (800) 488-7284, ext. 588, Hopkins@SIRweb.org,

Sincerely,

Gary P. Siskin, MD
Co-chair, Economics Committee

Sean M. Tutton, MD
Co-chair, Economics Committee

CC: Ken Simon, MD, CMS
Edith Hambrick, MD, JD, CMS
Pamela West, CMS
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Dawn R. Hopkins, SIR

Safety of Short Stay Observation after Peripheral Vascular Intervention[1]

Janice R. Kruse, RD
Andrew H. Cragg, MD

Index terms: Angiography, complications • Angioplasty, complications

JVIR 2000; 11:45–49

Abbreviation: SSU = short stay unit

PURPOSE: To determine whether short observation periods (less than or equal to 4 hours) are safe in outpatients undergoing arterial peripheral vascular interventions.

MATERIALS AND METHODS: A retrospective review of 203 patient medical records from the Interventional Vascular Department for 239 lower extremity or abdominal procedures (161 men and 78 women) during a 5-year period was completed. The average patient age was 62.2 years (range, 32–83 years). Thirty-six patients had more than one procedure. Indication, intervention, coagulation status, complication rate, and hospitalizations within 7 days after discharge from the short stay unit (SSU) were reviewed and the outcome was measured. Patients were grouped according to the length of their observation period (≤4 hours or >4 hours) for statistical analysis.

RESULTS: In 85% of the procedures (204 procedures), claudication was the primary indication for intervention. Angioplasty (203 procedures) was also commonly performed. Ninety procedures (38%) required stent placement, and other interventional procedures performed were pulse-spray thrombolysis (eight procedures), atherectomy (two procedures), and stent-graft placement (one procedure). None of the patients required hospitalization as a result of their radiologic intervention within 7 days after discharge from the SSU. Specifically, there were no major "at home" complications in patients discharged after an observation period of ≤4 hours. Two patients were admitted for outpatient procedures and were subsequently hospitalized as a result of a complication from the procedure. The complication rate (including minor complications) was 8% (seven of 87) in the ≤4 hour observation period group compared with 24.3% (37 of 152) in the >4 hour group ($P < .01$). This difference was due to a greater number of minor hematomas in the >4 hour group.

CONCLUSION: Based on the authors' findings, many interventional vascular procedures can be performed safely on an outpatient basis with relatively short observation times. Early discharge from the SSU did not result in an increased readmission rate to the hospital because of delayed complications.

COMPLICATIONS related to vascular interventional procedures have been well documented for the hospitalized patient (1,2). However, partially because of changes in the healthcare market, outpatient angiography and intervention have become more common in the last 5 years. As a result, short stay units (SSU) have been created as cost-effective patient care units for monitoring outpatient's vital signs (and other variables) prior to discharge. Traditionally, patients have been monitored in the SSU for a minimum of 4 hours and up to 23 hours after the procedure (1,3–5).

For the past 5 years, our facility

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has performed angiography and other interventional procedures, such as angioplasty, stent placement, thrombolysis, and atherectomy, as outpatient procedures. In the past several years, a trend toward shorter observation periods has developed. Observation periods of 2–4 hours are now common. The actual length of stay is individually determined by the treating physician, taking into account the patient's overall medical status. Patients are discharged to their home under the supervision of an adult companion for the next 24 hours.

We were interested in assessing the safety of discharging patients in less than 4 hours after their interventional procedure. We were also interested in determining if we provided the appropriate level of monitoring and care (and, if necessary, hospitalization) required by the patient.

MATERIALS AND METHODS

We retrospectively reviewed the medical records of 203 consecutive patients who were admitted on an outpatient basis to our SSU for observation after peripheral lower extremity or abdominal vascular intervention from February 1992 to February 1997. Inpatients or patients admitted directly to the hospital from the interventional suite were not included in the study. Patients who underwent procedures not performed in the lower extremity or abdomen were also excluded.

Prior to the procedure, all patients and their medical histories were evaluated by a physician for the appropriateness of undergoing angiography and an interventional procedure performed on an outpatient basis. Another factor leading to outpatient rather than inpatient observation was physician practice. Some physicians had a preference for longer observation periods and inpatient observations. Diagnostic angiography and the associated intervention were performed in the same procedure. Interventions performed included angioplasty, stent placement, thrombolysis, stent-graft placement, and atherectomy of the aortoiliac or infrainguinal arteries. No arterial closure devices were used in this population and puncture site bleeding was controlled with use of manual compression. Patients were not treated as outpatients if they had any of the following: poorly controlled insulin-dependent diabetes, uncontrolled hypertension, electrolyte imbalances, severe renal insufficiency, symptomatic cardiopulmonary failure, or coagulopathies. The decision to treat a patient as an outpatient was based on general criteria for a group of clinical patients rather than precise laboratory or clinical parameters.

Data collection included (i) indication for the procedure, (ii) comorbidity of the patient, (iii) intervention performed, (iv) sheath size, (v) length of procedure, (vi) length of recovery time, (vii) complications, and (viii) the location where the complications were discovered (in the hospital or outside of the hospital). Major complications were defined as those that required the patient to be hospitalized. Minor complications were defined as those noted in the medical record not requiring hospitalization. In the case of minor hematomas, no distinction was made between the size of the hematoma. A hematoma that required a transfusion or admission as part of the treatment was classified as a major complication.

The patients were admitted to the SSU of the hospital as outpatients 1 hour prior to angiography to obtain laboratory blood analysis and undergo clinical examination performed by an interventional radiologist. After the interventional procedure, the patient was returned to the SSU. The patient's vital signs and puncture site(s) were monitored every 15 minutes for 1 hour, and then hourly while the patient was in the SSU. Patients were positioned with the upper torso at a 45° angle in a patient recliner and were allowed to move from side to side. The routine length of stay in the SSU was 2–6 hours. Prior to discharge, a SSU nurse examined the patient's puncture site(s), checked the vital signs, and made sure the patient was alert, oriented, able to ambulate, and tolerated oral fluids. If these criteria were judged by the nurse to be abnormal or not met, the physician was consulted and the patient was required to stay in the SSU for further observation. Patients also received instructions on activity restrictions, fluid intake, and emergency care should bleeding or other complications arise. Normal activity was restricted until the following day and strenuous physical activity was restricted for 72 hours. Pressure over the puncture site was also recommended during coughing, laughing, or sneezing. Fluids were also encouraged during the 24-hour period after the procedure. Preprocedure medications were resumed after the discharge. The patients were required to have someone transport them home and to be under the supervision of an adult for 24 hours.

A nurse telephoned the patients the next morning from the SSU. The nurse assessed the status of each patient with a short telephone interview and answered additional questions for the patients. Patients were reminded to call the SSU should future complications develop. Information on rehospitalization was obtained by reviewing the medical record. Most of the patients had health insurance and, as a result, would be required to seek emergency care at the same facility that provided treatment.

During the approximate 5-year period, 203 patients underwent 239 procedures (161 men, 78 women). The average patient age was 62.2 years (range, 32–83 years). In the study group, 36% of patients spent 4 hours or less in the SSU. Sixty-four percent spent more than 4 hours **(Fig 1)**. Thirty-six patients underwent more than one procedure during this 5-year period.

Subanalysis of the data was performed by grouping the patients according to the recovery time (≤4 hours or >4 hours) spent by the patient in the SSU, as documented in the patient's medical record. The use of heparin during the procedure was not used as criteria for a longer

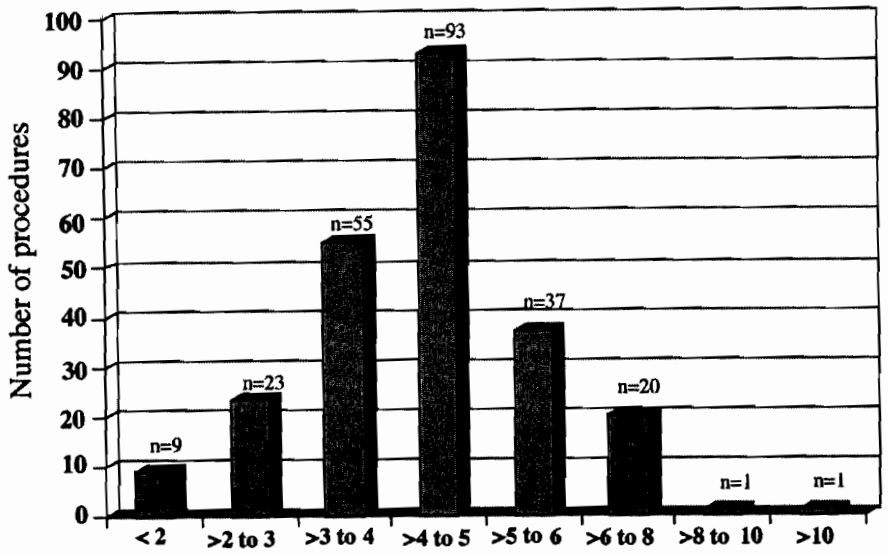

Figure 1. Length of recovery, in hours.

observation period. The complication rate was calculated and the chi-squared test was performed on related variables. Statistical significance was specified as $P \leq .05$.

RESULTS

The primary indication for the intervention was claudication in 204 (85%) of the procedures. Angioplasty was performed in 203 (85%) of the procedures.

Stents were placed in 90 (38%) of the procedures. Other interventional procedures performed were atherectomy ($n = 2$), stent-graft ($n = 1$), and pulse-spray thrombolysis ($n = 8$). The interventions were almost equally performed in the iliac and femoralpopliteal region, 42% and 55%, respectively. Eleven percent of the procedures were performed while the patient was taking an anticoagulant, such as warfarin. The use of heparin during the procedure was also equally split, with 48% of the patients receiving heparin while 52% did not receive heparin.

The majority of sheaths used in all procedures were 6-F (68%), whereas some procedures required a 7-F sheath (8%). In 20% of the procedures, the sheath size was not able to be determined. A 6-F sheath was used in approximately 70% in both observation period groups. The femoral puncture site was used almost exclusively (89%) in all procedures. Femoral access was used in 84% of the procedures in the short observation period group versus 93% in the long observation period group. However, bilateral access was more common in the >4 hour group versus the ≤4 hour group (27% vs. 14%). Many of the procedures lasted approximately 1–2 hours (70%), although in some cases the procedure lasted less than 1 hour (23%). Both observation groups had equal (79%) distribution of the procedure length at 1–2 hours. Claudication as the indication for intervention was also equally distributed (approximately 85%) in each group. Lastly, the presence of heart disease was twice as likely in the >4 hour observation group (28%) versus the ≤4 hour group (13%).

However, there was not a statistically significant relationship between groups for certain variables, such as indication for the procedure, type or location of the intervention, or the patient age greater than 75 years.

In our analysis, there appeared to be two principal reasons for observation periods that were longer than 4 hours. These were physician preference and the need for additional monitoring because of a minor complication or medical condition.

None of the patients who had outpatient procedures required hospitalization as a result of their radiologic intervention within 7 days after discharge. Specifically, no patients who were discharged after the short observation period required readmission for a complication.

The overall major complication rate was the same for both recovery period groups (0%). Minor complications (primarily minor hematomas) were more common in the ≤4 hour group ($P < .003$). **(Table 1)**.

Five patients (six procedures) were admitted to the hospital for other reasons within 7 days after their interventional radiology procedure. The admissions were for nonemergent surgeries, such as bypass surgery ($n = 3$), endartarectomy ($n = 2$), and an amputation of a toe ($n = 1$).

• Complications

There were two patients who were not discharged but admitted directly from the SSU to the hospi-

Table 1
Complication Rates for Length of Recovery Times

Variable	≤4 hrs	>4 hrs	*P* value
Major complications (required readmission to hospital)	0%	0%	NS
Minor complications	8.0% (7/87)	24.3% (37/152)	.003

Note.—NS = not statistically significant.

tal as a result of major complications due to the interventional procedure. The complications were diagnosed in the SSU. One patient who had a stent placed in the common and external iliac arteries developed a moderate hematoma with a small amount of external bleeding and pain in the groin area. The patient was hospitalized as a precautionary measure for overnight observation and did not receive a blood transfusion. The remaining patient, who had an angioplasty in the superficial femoral artery, was hospitalized for 48 hours for medical management of hypertension after symptoms of nausea, vomiting, and vertigo worsened in the SSU. Both patients were discharged from the hospital without any further complications. There were no deaths in this study within 30 days after discharge.

Puncture site hematomas were the most prevalent minor complication and were seen in 15% (n = 37) of the cases, accounting for 84% of the complications. Any evidence of extravascular bleeding was recorded as a hematoma. This included skin induration 1 cm or greater. In all but one case, patients were discharged without further complications. None of these patients received transfusions as part of their treatment.

Heparinization was also more common in the >4 hour group ($P <$ .001) **(Table 2)**. Among those patients who received heparin, the rate of minor complications was not different between shorter and longer observation periods (χ^2 = 3.16). However, among the patients who did not receive heparin, there were fewer complications for those in the short observation period group than those in the long observation period group ($P < .01$) **(Table 3)**.

Table 2
Variables for Length of Recovery Times

Variable	≤4 hours	>4 hours	P value
Indication for procedure			
Claudication	82.8% (72/87)	86.8% (132/152)	NS
All other indications	17.2% (15/87)	13.2% (20/152)	
Intervention			
Angioplasty	84.0% (73/87)	85.5% (130/152)	NS
Stents	32.2% (28/87)	40.8% (62/152)	NS
Procedure location			
Iliac	34.5% (30/87)	46.7% (71/152)	NS
Femoral-popliteal	54.0% (47/87)	55.9% (85/152)	
Heparin use during the procedure			
Received heparin	32.2% (28/87)	57.2% (87/152)	.001
Age of patient			
≤75 y	92.0% (80/87)	85.6% (130/152)	NS
>75 y	8.0% (7/87)	14.5% (22/152)	

Note.—NS = Not statistically significant.

• DISCUSSION

The complication rate associated with angiography has been defined for the hospitalized patient (3). In the past few years, a small number of articles have been published on the complication rates of outpatient angiography and angioplasty.

Recently, Payne et al (3) documented a 4% complication rate for 168 outpatient angioplasties after a minimum observation period of 4 hours. The complication rate included patients requiring hospitalization as a result of the angioplasty. Struk et al (4) showed there was no greater risk of complication in outpatients who received angioplasty and a 6-hour recovery period as compared to hospitalized patients. They documented a complication rate of 5% for 141 outpatient procedures. Hematomas comprised most of the complications requiring hospitalization. Rogers et al (5) also described outpatient angioplasty with a recovery period of 4–6 hours. In this series of 149 angioplasties, one patient required hospitalization as a result of the angioplasty procedure.

Heparin was more common in the longer observation period group. The reasons for differences in the heparinization during the procedure were not readily identifiable in our study, but were likely due to physician practice and individual patient requirements. The fact that heparinized patients tended to stay longer after the procedure likely reflected physician judgment that longer observation was needed.

In our experience, the hospitalization rate of 0% within 7 days after discharge from the outpatient radiology procedure substantiates the safety of performing interventional vascular procedures on an outpatient basis, and discharging these patients with a recovery time of ≤4 hours. Our minor complication rate of 8% for the group that had a recovery time of ≤4 hours is similar to published reports for less complicated vascular intervention (1,4,5). It is important to note that our analysis group included many patients with complex intervention, such as stent placement and thrombolysis.

The rate of minor hematomas was relatively high in both groups in this analysis. This was, in part, a

Table 3
Heparin Use

Variable	≤4 hours	>4 hours	P value
Heparin Use–Minor complications	17.8% (5/28)	25.3% (22/87)	NS
No Heparin Use–Minor complications	3.4% (2/59)	23.1% (15/65)	.01

reflection of the close monitoring of patients by the SSU nurses. Any area of induration >1 cm was recorded as a hematoma. Importantly, none of the patients with minor hematomas required further care or resulted in postdischarge sequelae. Our analysis also found a significant relationship between the occurrence of a minor complication and prolonged observation. We believe this reflected appropriate judgment on the part of the SSU nurses and physicians.

The limitations to our analysis include its retrospective design and the fact that patients were selected for early discharge, in part on the basis of clinical judgment. Nonetheless, the patient populations appeared similar with respect to age, comorbidity, indication for intervention, and procedure length.

Our data suggest that selected patients can be safely sent home soon after extensive percutaneous revascularization procedures. Our principal concern about "at home" recovery from endovascular interventions, such as iliac stent placement, was the possibility of a catastrophic hemorrhagic complication at the treatment site. Our analysis does not exclude this possibility, but it does suggest that in properly selected patients, it should be rare.

There are many advantages to shorter recovery times for patients undergoing interventional procedures. Shorter stays may decrease the shortage of beds in the SSU caused by the increasing popularity of outpatient procedures. The shorter stay would also be cost-effective because these patients are charged an hourly fee for the monitoring. In addition, shorter recovery times may also allow later scheduling of cases, thus increasing interventional laboratory efficiency. Puncture closure devices may further shorten recovery times by potentially lowering the minor complication rate observed in our analysis.

In conclusion, the increased number of interventions performed on an outpatient basis, and shorter observation periods will require proper identification of patients requiring a higher level of care after interventional procedures.

Acknowledgments: The authors thank Jodi Wilking for her assistance in this analysis.

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Peripheral angioplasty with same-day discharge in patients with intermittent claudication

Gabriel Akopian, MD, and Steven G. Katz, MD, *Pasadena, Calif*

Background: **As the number of endovascular interventions increase and resources become scarce, surgeons need to be aware of cost-effective and efficient practice options. Many surgeons routinely admit their patients for overnight observation after uneventful endovascular interventions. Although this may be appropriate for patients with tissue loss and rest pain, we believe that peripheral angioplasty in patients with claudication can be safely performed as an outpatient procedure with significant cost savings.**

Methods: **All patients with intermittent claudication undergoing peripheral angioplasty by a single vascular surgeon were enrolled prospectively in a same-day discharge protocol. Involved arteries and use of stent and closure device were recorded. Time to mobilization and time to discharge were determined. Patients were observed in an observation unit by a registered nurse, and were examined by the surgeon at the time of ambulation and before discharge. Patients were admitted to the hospital if complications arose during the predetermined observation period. Periprocedural complications and reasons for admission were noted. Patients were evaluated at 1 week, 6 weeks, and 3 to 6 months after the intervention.**

Results: **During 27 months, 112 interventions were performed in 97 patients. The superficial femoral artery was the most frequent site of intervention (47%). Multiple sites had angioplasty in 27 (24%) procedures. Nine (8%) procedures resulted in admission. One patient was admitted for a major puncture site hematoma requiring blood transfusion, two patients for observation of a minor hematoma at the puncture site, one for chest pain, and one for observation of transient bradycardia. The mean time to mobilization was 1.4 ± 1.3 hours, and the mean time to discharge was 2.8 ± 1.2 hours. The average postprocedural cost for patients undergoing same-day discharge was $320 per patient, which contrasts with $1800 for routine overnight observation. No deaths or unplanned admissions to the hospital occurred ≤30 days of intervention.**

Conclusions: **Same-day discharge after peripheral angioplasty is safe and cost-effective. Need for admission is evident within 2 hours. Routine admission after peripheral angioplasty for patients with claudication is unnecessary and should no longer be the standard of care. (J Vasc Surg 2006;44:115-8.)**

After the introduction of the coaxial catheter[1] in the 1960s and the subsequent creation of the balloon angioplasty catheter[2] a decade later, percutaneous transluminal angioplasty (PTA) became an acceptable form of treatment for patients with occlusive arterial disease. Over the last two decades, PTA has seen tremendous growth as a treatment option for peripheral vascular disease. With an ever-increasing population of elderly,[3] the prevalence of peripheral vascular disease and vascular interventions is expected to rise. Because catheter based procedures are now being performed with minimal complications, the appropriateness of routine hospitalization after these procedures should be brought into question.

The Society of Interventional Radiology Standards of Practice Committee guidelines[4] in 2003 called for overnight observation after PTA on the basis of the limited number of studies that addressed this issue. Although diagnostic angiography is routinely performed as a same-day procedure, outpatient PTA has been limited to a few centers. Our preliminary observation suggested that many patients having percutaneous interventions for intermittent claudication did not require hospital admission. In an attempt to determine the safety, efficacy, and cost benefits of outpatient PTA, we prospectively enrolled 112 patients in a study protocol of same-day discharge to test this hypothesis. This report focuses on the feasibility of same-day discharge from the short-term complication rates and cost analysis in this series of patients.

From the Department of Surgery, Division of Vascular Surgery, Keck School of Medicine, Huntington Hospital.

Competition of interest: none.

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MATERIAL AND METHODS

Between January 1, 2003, and March 31, 2005, all patients admitted for elective percutaneous interventions were prospectively enrolled in a same-day discharge protocol. Interventions were performed by or under the supervision of one vascular surgeon (S. G. K.). Data were collected according to the guidelines set forth by the Society for Vascular Surgery and the International Society for Cardiovascular Surgery,[5] stratified by Transatlantic Intersocietal Consensus (TASC) classification,[6] and analyzed on an intent-to-treat basis. When multiple segments underwent intervention at one setting, the highest TASC classification lesion was recorded. Patient demographics, presence of comorbidities, history of smoking, use of anticoagulants, stent placement, location of disease, use of closure device, and prior vascular interventions were recorded. The protocol was approved by the institutional review board, and patients gave written informed consent.

All patients were ambulating without assistance before the intervention and had adequate home support. None were from nursing homes, although16 were from assisted living facilities. The payer mix for this population of patients was 43% Medicare, 37% managed care, and 20% private pay. None of the payers require admission or discharge after endovascular interventions.

Patients did not undergo prescreening, and all interventions were planned within the same-day protocol. No patients were admitted the night before the intervention. Before the procedure, patients routinely underwent duplex evaluation of their lower extremities for planning purposes only. The preoperative duplex result did not change the decision to enroll the patients in the same-day protocol.

All patients were begun on clopidogrel (75 mg daily) beginning 4 days before the intervention. Patients able to tolerate aspirin were also given 325 mg daily. Warfarin was discontinued 72 hours before the procedure, and procedures were postponed if the international normalized ratio was >2.0.

Vascular access was obtained through a transfemoral approach using the micropuncture technique. Diagnostic arteriography was performed immediately before the intervention. All patients were systemically anticoagulated with heparin (5000 U). Stents were routinely placed after iliac angioplasty per surgeon preference and initially in infrainguinal vessels if flow-limiting dissection or incomplete angioplasty (residual stenosis >30%) was noted. Beginning in January 2004, stents were routinely placed after superficial femoral artery and popliteal artery angioplasty as part of an ongoing protocol studying the results of primary stenting of the infrainguinal vessels. For occlusions >5 cm, subintimal angioplasty techniques were used in almost all of the patients. For occlusions <5 cm, both transluminal and subintimal techniques were used.

Placement of the Angio-Seal Vascular Closure Device (St. Jude Medical, Inc., St. Paul, Minn) was attempted after all procedures if the puncture site was in the common femoral artery and if there was <40% stenosis ≤1 cm of the puncture site.[7,8] Feasibility of closure device deployment was angiographically determined. When a closure device was not successfully deployed, the physician performed manual groin compression at the groin access site for 10 minutes, re-evaluated for bleeding or hematoma, and pressure was reapplied if there was bleeding or an expanding hematoma. Heparin was not reversed at the conclusion of the procedure.

Patients were ambulated in 1 hour after having successful placement of a closure device and considered for discharge in 2 hours if their post-procedure course was uncomplicated. If manual compression was used, patients were ambulated after 4 hours and considered for discharge shortly thereafter.

Patients were observed in a four-bed observation unit staffed by one registered nurse. Time to ambulation and time to discharge were determined at the end of the procedure and adhered to if there were no complications. All procedures were started between 8 AM and 3 PM and completed between 9 AM and 5 PM. There were no payer requirements that would alter the decision to admit or discharge.

Table I. Comorbidities of study patients

Comorbidity	*N (%)*
Hypertension	88 (78.6)
Tobacco use	61 (54.5)
Hypercholesterolemia	57 (50.9)
Coronary disease	50 (44.6)
Diabetes mellitus	31 (27.7)
Arrhythmias	9 (8.0)
Renal disease*	5 (4.5)

*Defined as serum creatinine >2.0 mg/dL.

Patients underwent duplex evaluation at 6 weeks and every 3 months for the first year, and every 6 months thereafter. Patients were seen in the office at 1 week, 6 weeks, and every 3 months for the first year, and every 6 months thereafter. Additional phone calls were not routinely made, and patients were only seen outside of this follow-up schedule if problems arose.

Cost analysis data were collected from the hospital's business office. Cost analysis was performed on actual costs rather than patient charges. Hospital cost for a 1-hour stay in the observation unit is $115, and an overnight stay in an inpatient surgical bed is $1800. The average cost for patients being discharged was calculated by multiplying the average length of stay by $115. Data are provided as counts or means ± standard deviation. Analysis was performed using SAS (SAS Inc, Cary, NC).

RESULTS

During the 27-month study period, 112 consecutive procedures were performed in 97 patients. Twenty-eight additional interventions, which are not included in this analysis, were performed in other patients for tissue loss or rest pain. The mean age for the group was 74 ± 9 years. There were 49 men and 48 women. In 45 procedures (40%), the patient had undergone a prior vascular intervention.

The most common comorbidity was hypertension (79%), followed by tobacco use (55%) (Table I). In 70 procedures (63%) the patients had Rutherford category 3 (severe) claudication. In 42 procedures (38%) the patients had Rutherford category 2 (moderate) claudication. Interventions were not performed on patients with category 1 (mild) claudication. There were 87 interventions performed on TASC category A and B lesions, and 25 were performed on TASC C and D lesions.

The most common site of intervention was the superficial femoral artery (SFA) in 53 procedures (Table II). Angioplasty was performed on a single segment during 80 procedures (71%) and on multiple segments during 27 procedures (24%). Five patients (5%) failed treatment because the lesion could not be traversed. These patients are included in the analysis on an intent-to-treat basis.

Table II. Location of intervention

Location	*N (%)*
Common Iliac	20 (17.9)
External Iliac	18 (16.1)
Common femoral	4 (3.6)
Superficial femoral	53 (47.3)
Popliteal	41 (36.6)

Stents were deployed in 86 procedures (77%). A single stent was used in 46 procedures (41%), and multiple stents were placed in 40 procedures (36%). Of these, 75 stents were self-expanding, and the rest were balloon-expandable. A 6F sheath was used to perform 104 procedures (93%), seven procedures were performed through a 7F sheath, and one through an 8F sheath.

A closure device was attempted after 99 procedures (88%) and was successful in 92 attempts (93% success rate). Overall, a closure device was successfully placed at the conclusion of 82% of procedures; in the rest, hemostasis was obtained by manual groin compression.

The average length of the procedure was 72 ± 31 minutes (range, 17 to 175 minutes), with an average time to mobilization of 1.4 ± 1.3 hours and average time to discharge of 2.8 ± 1.2 hours. Same-day discharge was achieved after 103 procedures. Nine patients (8%) were admitted for overnight observation. Four patients were admitted for lack of support mechanisms at home. One patient was admitted for chest pain but was found not to have had a myocardial infarction, and one patient was admitted for observation of transient bradycardia, which spontaneously resolved. One patient had a major puncture site hematoma requiring blood transfusion, and two patients had minor hematomas. Of the three patients with hematomas, two had what was assumed to be successful deployment of a closure device, whereas in one patient, deployment of a closure device was not attempted. After procedures in which a closure device was successfully deployed, patients were discharged to home on the same day 95% of the time, while 80% of patients undergoing manual groin compression underwent same day discharge.

Eight of the admissions had TASC A or B lesions, and one patient had a TASC C lesion. Eight of the nine admissions had a length of stay of 1 day, and the patient with chest pain stayed 4 days. In patients discharged the same day, there were no deaths or unplanned readmissions ≤30 days of the procedure. The average postprocedural cost for patients discharged the same day was $320 per patient, which contrasts with $1800 for routine overnight observation.

There were three treatment failures, at 13 days, 17 days, and 27 days. These patients were successfully treated with open elective surgical intervention.

DISCUSSION

The last decade has witnessed striking technologic advances that have radically altered the manner in which care has been delivered to patients with arterial occlusive disease. With the development of catheter-based techniques to treat patients with intermittent claudication, it becomes the responsibility of the operator to perform these procedures in a safe, fiscally responsible, and cost-effective manner. In the past, it has been considered the standard of care to admit these patients to the hospital postprocedure for overnight observation in hopes of recognizing complications in a timely fashion. In our experience, complications have been infrequent and occurred in the early postprocedure period. This led us to attempt to modify our practice guidelines by routinely discharging patients on the day of their procedure. The results of this study confirm that peripheral angioplasty in patients with intermittent claudication can be performed in a cost-effective manner without compromising clinical outcomes.

Several studies[9-14] have addressed the topic of outpatient angioplasty. Although successful, most of their patients were prescreened or preselected for inclusion in the study. In addition, most of these procedures were performed on single arterial segments, and stents were rarely used. In contrast, we assumed that all patients with claudication undergoing PTA had an equal probability of being discharged, and thereby avoided selection bias by including patients having extensive procedures on multiple arterial segments in our study protocol. Still, we were able to discharge 92% of our patients on the day of their intervention. The safety of this approach is evidenced by the fact no patients died or had unplanned readmissions to the hospital ≤30 days of their procedure.

Although all of the patients in our series had claudication, we and others[15-18] have extended percutaneous interventions to those patients with limb threat, with gratifying results. We have found that selected patients with limb threat as their indication for intervention can be discharged on the day of the procedure. The site of intervention, length of the arterial segment treated, or the number of stents placed did not affect the chance of admission. Many complications of peripheral angioplasty are related to puncture site complications.[19,20] Interestingly, almost half of our admissions were unrelated to medical problems and were due to a lack of adequate social support at home. Perhaps with better planning and foresight on our part, some of these admissions could have been prevented.

Traditionally, patients undergoing peripheral angioplasty have been admitted to the hospital for overnight observation. However, preservation of health care resources has become increasingly important. In our area and in many parts of the country, hospitals are running at their maximum capacity, and bed space is at a premium. Limiting unnecessary admissions and optimal utilization of available resources would help to alleviate this problem. In addition, same-day discharge after PTA can result in significant cost savings. In our institution, our patients are observed in an observation unit rather than a recovery room, allowing for a substantial reduction in hospital cost. Our average postprocedural cost for patients undergoing same day discharge was $320 compared with the $1800 institu-

tional cost incurred for overnight admission to an unmonitored medical-surgical bed.

CONCLUSION

Same day discharge after peripheral angioplasty in patients with intermittent claudication is safe, cost-effective, and does not adversely affect patient outcomes. Determination of the need for admission can usually be made ≤2 hours after the procedure. Attention to the social needs of the patient and avoidance of puncture site complications should minimize hospital admission. Although we preferentially use closure devices, we were able to successfully discharge to home on the same day 80% of patients undergoing manual compression. Those who do not use closure devices should not be dissuaded from attempting same-day discharge. We conclude that routine admission after peripheral percutaneous intervention in patients with claudication is unnecessary and should no longer be considered the standard of care.

AUTHOR CONTRIBUTIONS

Analysis and interpretation: SGK, GA
Data collection: GA
Writing the article: SGK, GA
Critical revision of the article: SGK, GA
Final approval of the article: SGK, GA
Statistical analysis: GA
Obtained funding: Not applicable
Overall responsibility: SGK

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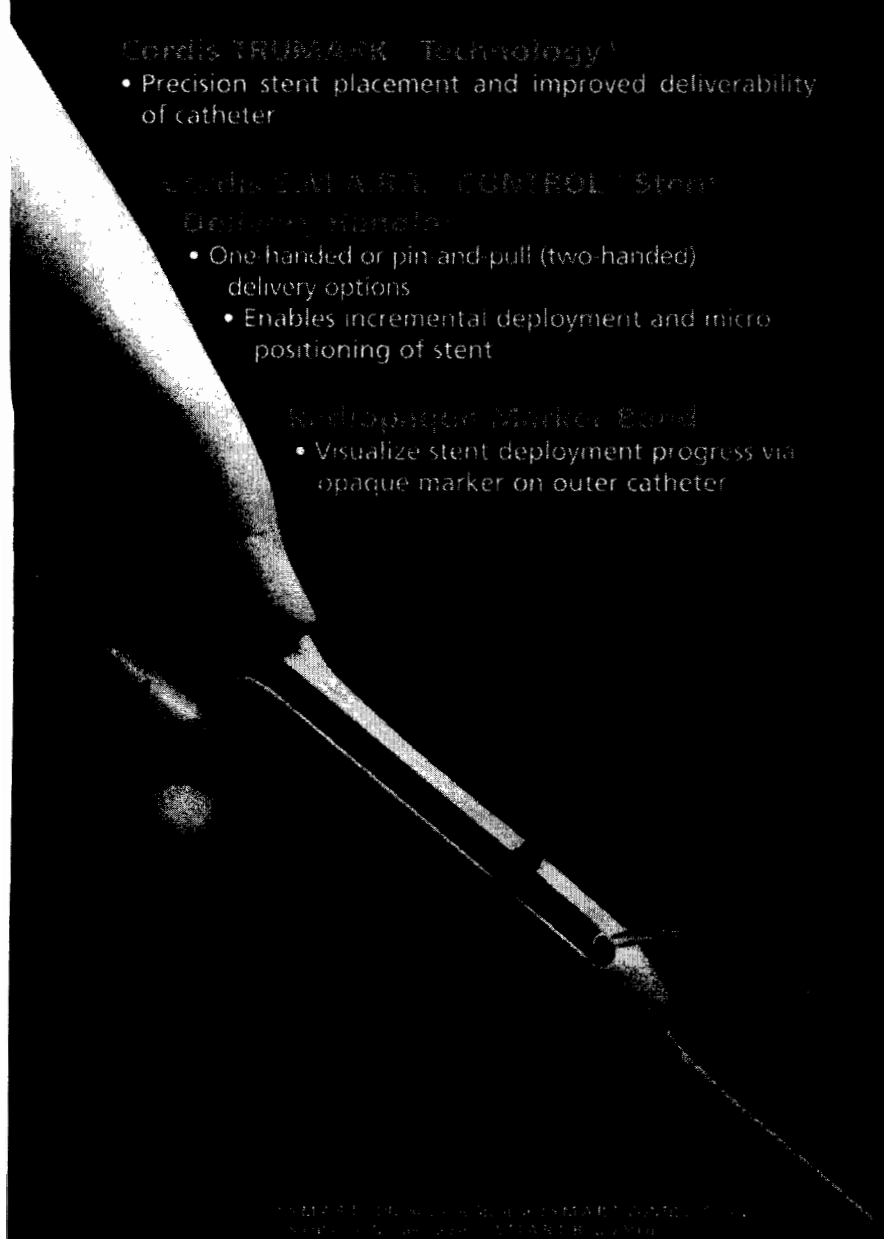

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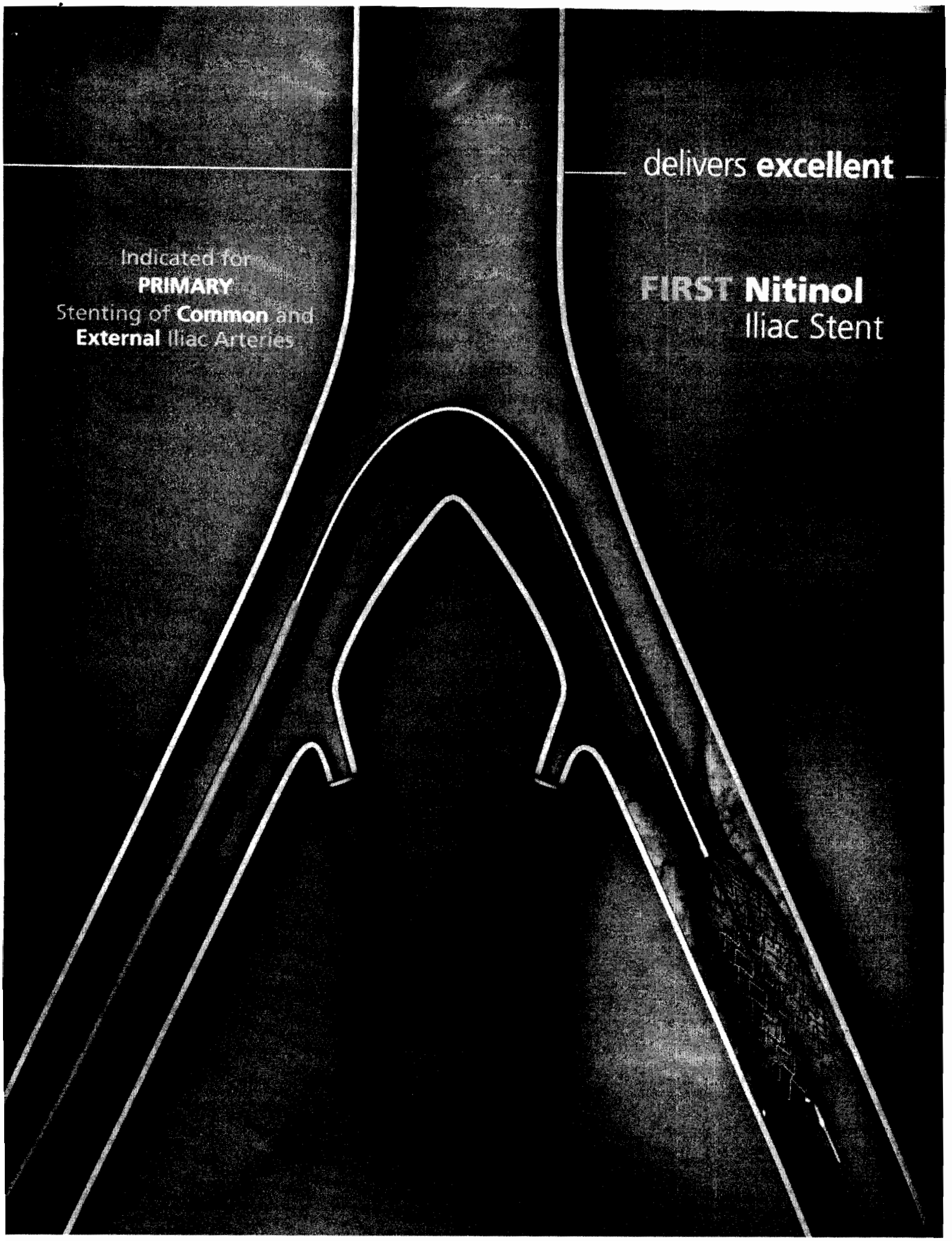
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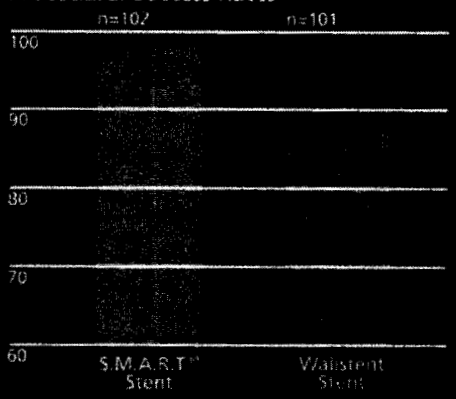

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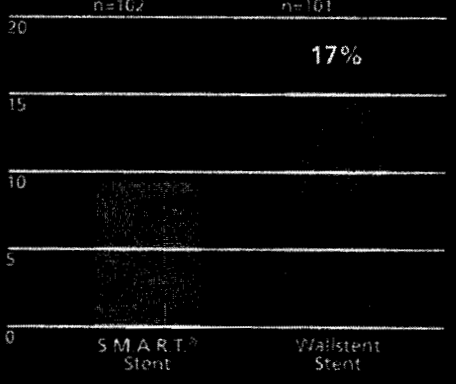

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C06080SL	C06080ML	6	80	6/8
C07020SL	C07020ML	7	20	6/8
C07040SL	C07040ML	7	40	6/8
C07080SL	C07080ML	7	80	6/8
C08020SL	C08020ML	8	20	6/8
C08040SL	C08040ML	8	40	6/8
C08080SL	C08080ML	8	80	6/8
C09020SL	C09020ML	9	20	6/8
C09040SL	C09040ML	9	40	6/8
C10020SL	C10020ML	10	20	6/8
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C14030SB	C14030MB	14	30	7/9
C14060SB	C14060MB	14	60	7/9

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Cordis S.M.A.R.T.® Transhepatic Biliary Stent Indications for Use: • Palliation of malignant neoplasms in the biliary tree. **Contraindications** • Stenting perforated duct where leakage could be exacerbated by prosthesis. • Patients with bleeding disorders. • Severe ascites. **Warnings/Precautions**: • The safety and effectiveness in the vascular system have not been established.• Persons with allergic response to nickel titanium may suffer an allergic response. • Single use only. Do Not resterilize and/or reuse. • Do not use with Ethiodol or Lipiodol contrast media. • Do not expose the delivery system to organic solvents (e.g. alcohol). • The stent is not designed for repositioning or recapturing. • Stenting across a major bile duct branch could lead to compromised future diagnostic or therapeutic procedures. • Device intended for use by appropriately trained physicians • Delivery system not designed for use with power injection systems. • Recrossing a partially or fully deployed stent with adjunct devices. **Important Information:** Prior to use, refer to the "Instructions for Use" supplied with this device for indications, contraindications, side effects, suggested procedure, warnings and precautions. **Caution:** Federal (USA) law restricts these devices to sale by or on the order of a physician. See package insert for full product information.

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C10020ML	SMART CONTROL, ILIAC 10X20ML	1	EA	1485	Stents Sx
C10030SL	SMART CONTROL, ILIAC 10X30	1	EA	1645	Stents Sx
C10030ML	SMART CONTROL, ILIAC 10X30ML	1	EA	1645	Stents Sx
C10040SL	SMART CONTROL, ILIAC 10X40	1	EA	1645	Stents Sx
C10040ML	SMART CONTROL, ILIAC 10X40ML	1	EA	1645	Stents Sx
C10060SL	SMART CONTROL, ILIAC 10X60	1	EA	1645	Stents Sx
C10060ML	SMART CONTROL, ILIAC 10X60ML	1	EA	1645	Stents Sx
C06100SL	SMART CONTROL, ILIAC 6X100	1	EA	2075	Stents Sx
C06100ML	SMART CONTROL, ILIAC 6X100ML	1	EA	2075	Stents Sx
C06020SL	SMART CONTROL, ILIAC 6X20	1	EA	1485	Stents Sx
C06020ML	SMART CONTROL, ILIAC 6X20ML	1	EA	1485	Stents Sx
C06030SL	SMART CONTROL, ILIAC 6X30	1	EA	1645	Stents Sx
C06030ML	SMART CONTROL, ILIAC 6X30	1	EA	1645	Stents Sx
C06040SL	SMART CONTROL, ILIAC 6X40	1	EA	1645	Stents Sx
C06040ML	SMART CONTROL, ILIAC 6X40ML	1	EA	1645	Stents Sx
C06060SL	SMART CONTROL, ILIAC 6X60	1	EA	1645	Stents Sx
C06060ML	SMART CONTROL, ILIAC 6X60ML	1	EA	1645	Stents Sx
C06080SL	SMART CONTROL, ILIAC 6X80	1	EA	1975	Stents Sx
C06080ML	SMART CONTROL, ILIAC 6X80ML	1	EA	1975	Stents Sx
C07100SL	SMART CONTROL, ILIAC 7X100	1	EA	2075	Stents Sx
C07100ML	SMART CONTROL, ILIAC 7X100ML	1	EA	2075	Stents Sx
C07020SL	SMART CONTROL, ILIAC 7X20	1	EA	1485	Stents Sx
C07020ML	SMART CONTROL, ILIAC 7X20ML	1	EA	1485	Stents Sx
C07030SL	SMART CONTROL, ILIAC 7X30	1	EA	1645	Stents Sx
C07030ML	SMART CONTROL, ILIAC 7X30ML	1	EA	1645	Stents Sx
C07040SL	SMART CONTROL, ILIAC 7X40	1	EA	1645	Stents Sx
C07040ML	SMART CONTROL, ILIAC 7X40ML	1	EA	1645	Stents Sx
C07060SL	SMART CONTROL, ILIAC 7X60	1	EA	1645	Stents Sx
C07060ML	SMART CONTROL, ILIAC 7X60ML	1	EA	1645	Stents Sx
C07080SL	SMART CONTROL, ILIAC 7X80	1	EA	1975	Stents Sx
C07080ML	SMART CONTROL, ILIAC 7X80ML	1	EA	1975	Stents Sx
C08100SL	SMART CONTROL, ILIAC 8X100	1	EA	2075	Stents Sx
C08100ML	SMART CONTROL, ILIAC 8X100ML	1	EA	2075	Stents Sx
C08020SL	SMART CONTROL, ILIAC 8X20	1	EA	1485	Stents Sx
C08020ML	SMART CONTROL, ILIAC 8X20ML	1	EA	1485	Stents Sx
C08030SL	SMART CONTROL, ILIAC 8X30	1	EA	1645	Stents Sx
C08030ML	SMART CONTROL, ILIAC 8X30ML	1	EA	1645	Stents Sx
C08040SL	SMART CONTROL, ILIAC 8X40	1	EA	1645	Stents Sx
C08040ML	SMART CONTROL, ILIAC 8X40ML	1	EA	1645	Stents Sx
C08060SL	SMART CONTROL, ILIAC 8X60	1	EA	1645	Stents Sx
C08060ML	SMART CONTROL, ILIAC 8X60ML	1	EA	1645	Stents Sx
C08080SL	SMART CONTROL, ILIAC 8X80	1	EA	1975	Stents Sx
C08080ML	SMART CONTROL, ILIAC 8X80ML	1	EA	1975	Stents Sx
C09020SL	SMART CONTROL, ILIAC 9X20	1	EA	1485	Stents Sx

C09020ML	SMART CONTROL, ILIAC 9X20ML	1 EA	1485 Stents Sx
C09030SL	SMART CONTROL, ILIAC 9X30	1 EA	1645 Stents Sx
C09030ML	SMART CONTROL, ILIAC 9X30ML	1 EA	1645 Stents Sx
C09040SL	SMART CONTROL, ILIAC 9X40	1 EA	1645 Stents Sx
C09040ML	SMART CONTROL, ILIAC 9X40ML	1 EA	1645 Stents Sx
C09060SL	SMART CONTROL, ILIAC 9X60	1 EA	1645 Stents Sx
C09060ML	SMART CONTROL, ILIAC 9X60ML	1 EA	1645 Stents Sx

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August 31, 2007

Herb A. 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

Subject: CMS-1385-P Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2008

Dear Mr. Kuhn:

The Radiology Business Management Association (RBMA) appreciates the opportunity to comment on the proposed rule for the 2008 Medicare physician fee schedule as published in the July 12, 2007 *Federal Register*.

Founded in 1968, the RBMA represents nearly 2,200 radiology practice managers and other radiology business professionals. In the aggregate, RBMA's reach extends to over 24,000 radiologic technologists and 26,000 administrative staff. RBMA is the leading professional organization for radiology business management, offering quality education, resources and solutions for its members and the healthcare community, and helping shape the profession's future.

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Resource-Based Practice Expense (PE) Relative Value Units (RVUs)

Discussion of Equipment Usage Percentage (Page 38132)

RBMA supports CMS' proposal to maintain the 50 percent utilization rate for medical equipment in the PERVU methodology until such time that it can be replaced by a comprehensive, multispecialty, modality-specific, and data-based estimate. Moreover, RBMA recommends that any new utilization rate be phased-in incrementally over a period of several years.

RBMA is concerned about potential future changes to the utilization rate for medical equipment in CMS' PE methodology. The utilization rate is a key variable in CMS' equipment cost per minute calculation. However, the utilization rate is difficult to estimate because of the following:

- Part-time vs. full-time centers – CMS' 150,000 minute/year figure assumes full-time operation (i.e., 50 hours/week * 50 weeks/year). This would be a significant overstatement for the vast majority of centers, particularly those in rural areas which are open only limited days during the week due to staffing limitations, physician availability, and patient volume.

- Missed appointments – missed patient appointments result in available machines being unutilized
- Modality – utilization rates typically vary by equipment type
- Site-of-service – utilization rates may vary by site-of-service (freestanding center, IDTF, mobile)
- Down-time for equipment maintenance – imaging equipment, particularly the high-technology CT, MR, and PET scanners, are routinely taken "off-line" for maintenance
- Down-time for equipment quality control/quality assurance – imaging equipment is routinely tested to ensure image quality while minimizing radiation (if applicable) exposure. Many radiology practices have their equipment accredited by the American College of Radiology (ACR) and other bodies who require this type of testing.
- Staffing issues – in light of today's shortage of radiologic technologists, absenteeism brought about by sickness, tardiness, etc. results in available machines being unutilized
- Specialty – utilization rates could vary by provider specialty
- Other – weather and power outages are examples of uncontrolled influences that reduce equipment productivity

RBMA also cautions CMS that the utilization rate could affect patient access to medical services in underserved areas. For example, rural settings are more likely to have their imaging needs met by part-time centers. A utilization rate based on high-volume centers could have unanticipated negative consequences on quality and access in these areas.

A change in utilization patterns is another potential consequence of adjusting the utilization rate. An increase in the utilization rate will likely result in a decrease in Medicare's technical component (TC) payments. State-of-the-art imaging equipment is a long-term investment and imaging centers, particularly those that are highly leveraged, may not be able to survive at the lower TC payment rates or may engage in activities aimed at increasing volume. Finally, lower TC payments may discourage investment in equipment.

For the abovementioned reasons, **RBMA recommends any significant change in the utilization rate be supported by empirical data and be phased-in incrementally over a period of several years**. For example, a shift to a 70 percent utilization rate would be implemented over four years -- 5 percent per year. This would cushion the financial impact on physician practices and freestanding facilities and could help mitigate potential operational and/or clinical disruptions caused by the change.

***

Equipment Interest Rate Discussion (Page 38132)

RBMA agrees with CMS' decision in the proposed rule to retain the 11 percent interest rate used for PERVU determination.

Tying the PERVU interest rate to a moving estimate like the prime rate (alone or with an adjuster of 2 to 4 percent) adds unnecessary volatility to the Medicare fee schedule. This is an important factor, particularly for the purchase of imaging equipment, as these are typically long-term purchases. The prime rate is influenced by exogenous factors such as inflation, the availability of money, and the health of the economy – along with real and/or perceived perspectives of these factors by the financial markets. While the prime rate has been as low as 4 percent briefly in 2003, primes in the 8 percent to 9 percent range have been more common over time and since the inception of RBRVS in 1992. Further, the recent cuts to the TC payable under the MPFS have decreased the financial health of most non-hospital facilities, making them a greater credit risk and increasing the interest rates

they must pay. Thus, the prime rate plus an adjustor of 2 to 4 percent, results in an approximate rate at the current level of 11 percent. Additionally, with a prime-based methodology, CMS would have to determine when, in terms of timing, to base the prime rate – retroactively (i.e. a look-back) or prospectively (i.e. a forecast).

***

PE Proposals for Calendar Year (CY) 2008 – Radiology Practice Expense Per Hour (Page 38132)

RBMA supports CMS' plans to use the revised practice expense per hour estimate for radiology ($204.86) rather than the current figure ($174.18).

RBMA commends CMS for its ongoing efforts in tailoring its methodology so that it better approximates radiology's practice expenses. Weighting radiology's practice expense data by practice size is an appropriate step in that direction.

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Geographic Practice Cost Indices (GPCI)

Physician Work (Page 38138)

RBMA favors retention of the work GPCI "floor" of 1.0.

The RBMA believes that retaining the work GPCI floor of 1.0 helps providers in rural areas. RBMA encourages CMS to use its authority to extend the GPCI floor into 2008 or to ask Congress for such authority.

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Malpractice

Malpractice (MP) RVUs (TC/PC Issue) (Page 38142)

The total technical component (TC) RVU should include malpractice values in addition to those for practice expense. The TC malpractice RVUs should be subjected to a resource-based evaluation.

In the proposed rule, CMS solicited information on the liability insurance carried by facilities. Radiology TC-providers (e.g., imaging centers) purchase umbrella malpractice liability policies that cover both the facility and its non-physician clinical personnel (e.g., radiologic technologists, nurses, physician assistants). Facilities also carry other (non-malpractice) forms of insurance (presumably falling under the practice expense RVUs). A facility's malpractice coverage is separate and distinct from a radiologist's professional liability insurance which is represented by the professional component (PC) malpractice RVUs.

The agency and the medical community continue to work on the "resource-based" nature of the RBRVS. The work relative values are based on physician time and intensity estimates and undergo a review every five years. Methodologies are in place and data collected for resource-based practice expense values. The physician's malpractice values are based on professional liability premiums. RBMA believes the TC's malpractice values should be resource-based as well and stands ready to assist CMS in this regard.

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Coding – Additional Codes from the Five-Year Review

Anesthesia (Page 38148)

RBMA encourages CMS to apply the budget neutrality adjustment from changes in anesthesiology's work values and other services in the Five-Year Review to the conversion factor rather than the work values.

Budget neutrality adjustments to the conversion factor rather than the relative values maintain the inter-procedural relativity of the RBRVS. It is also more readily apparent and understood by providers and their staff.

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Independent Diagnostic Testing Facility (IDTF) Issues

RBMA commends CMS' efforts to clarify the regulations governing IDTFs and improving the quality of care provided in these facilities.

Proposed Revisions to Existing IDTF Performance Standards – Comprehensive Liability Insurance (Page 38169)

RBMA is concerned that the proposed requirement wherein "the IDTF must list our [Medicare/CMS] designated contractor as a Certificate Holder on the [comprehensive liability insurance] policy" may prevent IDTFs from obtaining such insurance.

The proposed regulation may make it more difficult for IDTFs to obtain comprehensive liability insurance from underwriters due to concerns about indemnifying contractors of the federal government.

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Section 410.33(g) (8) -- Answer, document, and maintain documentation of beneficiaries' questions... (Page 38170)

RBMA believes the proposed requirements are overly burdensome and in excess of that required by other providers in the physician office or hospital facility settings.

Being responsive and empathetic to patient complaints, questions, and inquiries is part of delivering excellent customer service and patient care. All providers should have some mechanism in place for handling such situations and be required to produce such a policy/procedure upon request. CMS would only need to verify that such processes are in place. Therefore, the proposed regulations are unnecessary, not to mention ambiguous (e.g., what constitutes a complaint?) and labor intensive to implement.

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Section 410.33(i) – Enrollment date (Page 38170)

RBMA recommends that retroactive billing (once approval has been determined) be allowed back to the time of the original application (even if the first submission is rejected).

RBMA is supportive of the proposed change establishing the date the initial application is received as the date for which IDTFs may bill Medicare retroactively for services rendered. It is a concern of RBMA's that IDTF applications are experiencing significant contractor processing delays in many cases.

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Section 410.33(g) (15) – Shared space, equipment... (Page 38171)

RBMA supports the proposed prohibition on shared equipment but urges that this regulation be applied to all entities (including physician practices, mobile units, and hospitals) that provide imaging services.

RBMA believes that CMS is correct in being concerned about the potential for circumventing IDTF enrollment and Medicare billing requirements and the potential for abuse that may be caused by these sharing arrangements. Moreover, we suggest that this prohibition be extended to other sites of service given that the potential for abuse exists there as well.

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Physician Self-Referral Provisions

Anti-Markup Provision (Page 38179)

RBMA supports CMS' efforts to remove the "profit" from the reassignment of the professional or technical components from radiology services.

The potential for abuse and over-utilization exists if the billing (purchasing) physician or medical group is able to mark-up the interpretation or test when billing Medicare. RBMA, therefore, supports the proposed anti-markup provision and the expansion of the Purchased Diagnostic Test Rule to the professional component of imaging services. We also strongly support the elimination of the Stark "On the Premise" Interpretation requirement.

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Full-Time Employee Exemption (Page 38180)

RBMA views the full-time employee exemption as generally a step in the right direction, but recognizes that definitional and operational issues exist.

CMS is proposing to change section 414.50 so that, "the anti-markup provision for the technical component (TC) and professional component (PC) apply to all arrangements not involving a reassignment from a full-time employee of the billing entity." In other words, the anti-markup provision would apply to TC and PC reassignments from contractors and part-time employees. RBMA sees this provision as another safeguard against entities profiting from the TC or PC providers and, thus, is supportive of the concept. However, RBMA recognizes the need for CMS to work through some definitional and operational issues. Specifically, the proposed rule defines neither "part-time" nor "full-time" employee.

Secondly, there is no distinction between a part-time employee versus a contract employee of the practice. Without such definitions, confusion and the potential for abuse may result. One potential solution would be to modify the 855-R to state whether the physician is a full-time, part-time, or contract employee of the group. Another solution would be to exempt billing entities which are a radiologist or a radiology group from this requirement.

An alternative to an anti-markup approach would be to set a floor for the professional component. Such a floor (e.g., based on a percentage of the PC) and adjusted for bona fide collection costs, bad debt, etc. would have the same effect of prohibiting the profiting from the professional component.

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Unit-of-Service (Per-Click) Payments in Space and Equipment Leases (Page 38182)

RBMA strongly encourages CMS to move forward with its proposal to tighten the restrictions on per click imaging equipment lease payments as these types of arrangements encourage over-utilization of services and unnecessary self-referral.

Per-click arrangements of imaging equipment have been shown to lead to over-utilization and other forms of abuse. Percentage-based arrangements for space and imaging equipment leases also are prone to abuse and should also be eliminated. Lease arrangements featuring flat-rate payments which are not tied to volume are less susceptible to abuse.

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Ownership or Investment Interest in Retirement Plans (Page 38183)

RBMA agrees with the proposed elimination of the Stark Law exception that allows retirement plans owned by referring physicians to invest in Designated Health Services (DHS).

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"Set in Advance" and Percentage-Based Compensation Arrangements (Page 38184)

RBMA supports the elimination of percentage-based arrangements for space and imaging equipment. Percentage-based arrangements for billing and collections should be permitted.

Percentage-based arrangements for space and imaging equipment leases are prone to abuse and should be eliminated. Lease arrangements featuring flat-rate payments which are not tied to volume are less susceptible to abuse. However, RBMA recommends that percentage based fee arrangements continue to be allowed for billing and collection services even if it causes some variability in physician compensation. Percentage based fee arrangements are the most common method of compensation for billing and collections services, and provide appropriate incentives for quality and accuracy. We believe that percentage based fees for billing and collections services should be set at fair market value.

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Services Furnished "Under Arrangements" (Page 38186)

RBMA agrees with CMS' proposal to change the definition of "entity" in 411.351 to include not only the entity that submits claims to Medicare for DHS but also any person or entity that "performs" the DHS.

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Diagnostic X-ray Tests, Diagnostic Laboratory Tests, and Other Diagnostic Tests: Conditions (Page 38190)

RBMA opposes the proposed denial of payment for an x-ray ordered by a non-treating physician for chiropractic patients.

RBMA believes that if chiropractic patients are referred to radiologists for imaging studies, then Medicare should pay for these imaging studies as they would for any other referred patient.

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TRHCA-Section 101(b): PQRI

General Comment

RBMA suggests that CMS expand the PQRI stakeholders to include hospitals and health information system (including radiology information system) vendors.

A physician's decision to participate in PQRI is somewhat dependent on the access to and ease of retrieving the required information. For hospital-based physicians to participate in PQRI, the hospital needs to be made aware of the information that is required and ensure that it is captured and communicated to the physician. Otherwise, potentially interested physicians will elect not to contribute to the program. Similarly, health information vendors can play an important role in easing the access and transmission of PQRI required information. PQRI information that is collected and stored electronically can be accessed and reported more easily than that in paper form. Many radiologists have elected to not participate in PQRI in 2007 because of their inability to retrieve or the difficulty of retrieving the required data. For example, the requirement in Measure 10 to report whether the patient had an imaging study within 24 hours of arrival to the hospital is difficult to obtain absent the cooperation of the hospital and of the vendors of hospital information systems.

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TRHCA-Section 101(d): PAQI

RBMA favors funding of the Physician Quality Reporting Initiative (PQRI) through the introduction of new money and not through the 2008 Medicare fee schedule update or by redistributing existing monies within the fee schedule.

RBMA commends the agency for policies that promote and/or incentivize the provision of quality health care. Many radiology practices are participating in the Physician Quality Reporting Initiative (PQRI). However, we believe that many more practices would enroll in PQRI if the bonus payments were sizeable enough to entice providers and to compensate them for the additional expenses incurred by participation. If additional funding is not available for PQRI bonus payments, we recommend that the PAQI fund be used to mitigate the cut in the 2008 conversion factor.

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RVU Impacts

Combined Impacts (Page 38214)

RBMA opposes the estimated 9.9 percent reduction planned for the 2008 Medicare fee schedule conversion factor.

Medicare payments comprise a significant portion (approximately 30 to 40 percent) of a typical radiology practice's revenue. Moreover, many radiology contracts with private payors are tied to Medicare's rates. Lastly, Congress through the Deficit Reduction Act (DRA) of 2005 enacted Medicare payment cuts targeting imaging and radiology. Therefore, mounting cuts in Medicare payments are beginning to have serious ramifications for radiology practices, forcing practices to make difficult choices which potentially impact patient care. For example, in a recent RBMA survey of its members, over 60 percent of the respondents planned to forgo imaging technology upgrades and reduce staff in response to the DRA. Additional Medicare payment reductions, like those proposed for 2008, would accelerate this process, forcing practices to consider even more drastic measures such as restricting office hours and eliminating non-viable modalities. This could have a significant impact on Medicare patients' access to quality diagnostic imaging facilities.

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The RBMA appreciates the opportunity to comment on CMS' proposed rule for the 2008 Medicare physician fee schedule. If questions arise or additional information is needed, please feel free to contact RBMA's Executive Director, Michael R. Mabry at 703.621.3363 or mike.mabry@rbma.org.

Sincerely,

Gregory M. Kusiak

Gregory M. Kusiak, MBA
President, Board of Directors

cc: Ken Simon, MD, CMS
Stephanie Monroe, CMS
Rick Ensor, CMS
August Nemec, CMS
David Walczak, CMS
Lisa Ohrin, CMS
Michael R. Mabry, RBMA

August 30, 2007 www.cms.hhs.gov/erulemaking

Herb Kuhn
Acting Deputy Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1385-P
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2008; Proposed Rule

Dear Mr. Kuhn:

The American College of Radiology (ACR), representing over 32,000 diagnostic radiologists, interventional radiologists, radiation oncologists, nuclear medicine physicians and medical physicists, is pleased to submit comments on the proposed notice "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2008" published in the Federal Register on July 12, 2007. We will address malpractice; budget neutrality; resource-based practice expense (PE) relative value units (RVUs); practice expense per hour; Relative Value Update Committee (RUC) recommendations; additional codes from the five year review; the independent diagnostic testing facility requirements; physician quality reporting initiative; and changes to reassignment and physician self-referral rules relating to diagnostic tests [Anti-Markup Provisions].

Malpractice

The ACR has suggested in the past that there is disproportionate allocation of the malpractice values between the professional component (PC) and the technical component (TC). The ACR's recommendation was to flip the malpractice values associated with each of the component parts so the technical component malpractice values are assigned to the professional component and the professional component malpractice values are assigned to the technical component. This is because physicians incur the higher costs for malpractice insurance.

In the past, the RUC also provided comments to Centers for Medicare and Medicaid Services (CMS) and they recommended that the CMS: 1) Flip the malpractice values associated with each of the component parts so the technical component malpractice values are assigned to the professional component and the professional component malpractice values are assigned to the technical component or 2) Make the malpractice values of the technical component equal to the malpractice values of the professional component. The ACR is aware that the AMA RUC comments being submitted in response to this proposed rule may reference a RUC Professional Liability Insurance (PLI) workgroup recommendation that the malpractice values in the technical component should be zero as there are no identifiable professional liability costs associated with providing the TC. CMS should be aware that this position has not been vetted and approved by the full RUC, and that the ACR disagrees with the conclusions of the PLI workgroup. Although the ACR believes that the PC malpractice values should be higher, **the ACR does not believe that the malpractice values in the technical component should be zero.**

The ACR is aware that CMS is requiring independent diagnostic testing facilities to purchase a certain level of liability insurance. CMS is, therefore, acknowledging that some liability costs do exist in the TC and the ACR supports CMS'comments on this issue in past final rules. Also, other clinical staff such as radiology technologists and medical physicists purchase professional liability insurance and are represented in the TC. According to the American Association of Medical Physicists, "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."

Budget Neutrality

The ACR is again disappointed that the CMS decided to apply the budget neutrality adjustment by way of a physician work adjustment factor as a result of the increase in anesthesia physician work under the third five year review. The CMS decision is contrary to the views of almost the entire medical community that are expressed in numerous comments. The vast majority of professional societies whose members treat Medicare beneficiaries recommended that the budget neutrality adjustment be made to the conversion factor and not to the physician work values.

The ACR believes that being consistent with previous adjustments to the conversion factor is a more fair and equitable application of budget neutrality adjustments. In addition to its objection on a methodological basis, the ACR is opposed to the CMS decision because it places a disproportionate burden on hospital-based physicians whose compensation for medical services is derived only from the PC and is thus heavily dependent on the work RVU.

The ACR again strongly recommends that CMS reconsider applying the budget neutrality adjustment to the conversion factor and not to the physician work RVU.

Also, it appears that CMS has used the adjusted work RVUs as the allocator of indirect practice expense in its calculations for the proposed 2008 Medicare Physician Fee Schedule (MPFS). The work RVUs were adjusted solely to meet Medicare's statutory requirement to maintain budget neutrality. In fact, CMS does not even publish the adjusted work RVUs in the *Federal Register*. We believe the use of reduced work RVUs to calculate indirect practice expense costs results in incorrectly reduced PE RVUs and distorts the relativity of the fee schedule. **The ACR strongly recommends that CMS use unadjusted work relative values as the allocator of indirect practice expenses.**

Resource-based PE RVUs

Interest Rate

The ACR supports CMS' decision not to change the interest rate in the practice expense equipment cost calculation of 11 percent. Analysis of the 2007 Small Business Administration (SBA) data on loans and applicable interest rates seems appropriate.

Equipment Usage Percentage

The ACR supports the CMS decision not to change the equipment utilization rate of 50 percent until there is better data to show the correct percentage. Arbitrarily setting high utilization rates on higher priced equipment may not always be accurate. It should not simply be concluded that higher priced equipment is utilized at a higher rate. There are higher priced technologies such as proton beam radiation therapy or magnetoencephalography (MEG) that are highly beneficial to a

select population but are not necessarily utilized at the same rate as other higher cost technologies. In addition, there is no standard definition of a work day among medical practices. Some medical practices are open 8 hours a day, but many others may be open longer or shorter hours. Those that are open longer hours may only be operating certain pieces of equipment on select days such as Mondays, Wednesdays and Fridays.

The ACR agrees that there is not sufficient evidence to justify an alternative proposal on this issue. We support the concept of data collection through extensive survey to accurately determine the utilization rate for **all** medical equipment, using a prospective evidence-based methodology. **The ACR disagrees with others who might propose that CMS arbitrarily choose a rate higher than 50 percent and then allow exceptions based on individual petition.** The ACR is willing and ready to work with CMS to ensure the appropriate equipment utilization rates are captured for the great variety of equipment used in our field.

Practice Expense Per Hour

The ACR appreciates CMS' and the Lewin Group's conclusion that weighing the ACR's supplemental survey data by practice size more appropriately accounts for the small, high-cost entities in the final PE/HR for radiology. The ACR has discussed extensively with the Lewin Group from the beginning of the survey process about how to weight the practice level survey data to be representative of all radiology practices, large and small, in the U.S., and is pleased that CMS agrees that ACR's approach more appropriately identifies the PE/HR for radiology.

RUC Recommendations for Direct PE Inputs and Other PE Input Issues

RUC Recommendations for DXA, CAD and Nuclear Medicine

The ACR appreciates CMS' decision with respect to the direct practice expense inputs for dual energy x-ray absorptiometry (DXA), computer-aided detection (CAD) and nuclear medicine services.

Table 5: Supply Items Needing Specialty Input for Pricing

The ACR supports the cost documentation being submitted by the Society of Interventional Radiology (SIR) for the vascular stent deployment system.

Table 6: Equipment Items Needing Specialty Input for Pricing and Proposed Deletions

The ACR supports information being submitted by the SIR on the plasma pheresis machine with an ultraviolet light source.

Coding – Additional Codes From Five -Year Review

CMS proposes to bundle code 93325 (Doppler echocardiography color flow velocity mapping (List separately in addition to codes for echocardiography) into codes 76825, 76826, 76827, 76828, 93303, 93304, 93307, 93308, 93312, 93314, 93315, 93317, 93320, 93321, and 93350, apparently without adjusting the work values for these codes. The ACR opposes bundling when reporting of multiple codes is required to accurately describe the services performed. The ACR also believes that CMS should rely on the CPT® Editorial Panel and RUC processes to address issues relating to CPT code 93325 and should not rebundle any CPT codes independent of those processes. **The ACR requests that CMS withdraw its proposal to reject the RUC recommendation and to refer CPT code 93325 to the CPT Editorial Panel.**

Independent Diagnostic Testing Facility (IDTF) Issues

Revised Standard Number 6

CMS proposes to change standard 6 to read "Has a comprehensive liability insurance policy in the amount of at least $300,000 per incident that covers both the supplier's place of business and all customers and employees of the supplier and ensures that this insurance policy must remain in force at all times. The policy must be carried by a nonrelative-owned company. The IDTF must list the Medicare contractor as a Certificate Holder on the policy and promptly notify the Medicare contractor in writing of any policy changes or cancellations."

The ACR supports the requirement for an IDTF to have comprehensive liability insurance but is concerned that requiring a Medicare contractor to be listed as a Certificate Holder will create reluctance of insurance underwriters to issue such policies, since listing a Medicare carrier as a Certificate Holder could, theoretically, provide the government with contractual rights to indemnification or payment that it would not otherwise have.

New Performance Standard

CMS proposes to prohibit IDTFs from sharing space, equipment or staff with, or subleasing its operations to, another individual or organization. CMS would have prohibited IDTFs from entering into part-time leases, even if those complied with the anti-kickback and Stark exceptions. Many IDTFs lease space and technologists part-time to radiology groups. Alternatively, many radiology groups have limited liability corporations that own and operate IDTFs, employing the same technologists that work for the IDTF. As the government has recognized historically, radiologists are not in a position to create abusive self-referral arrangements with IDTFs or other entities.[1]

The ACR, therefore, recommends that in its final rule, CMS amend the language of its proposal to read: "a new performance standard at § 410.33(g)(15), which states, 'Does not share space, equipment or staff or sublease its operations to another individual, organization, employee or contractor of such organization, that refers Medicare patients to the IDTF for designated health services (DHS)."

Supervision

The ACR agrees with the CMS proposal to delete the requirement that the supervising physician is responsible for the overall operation and administration of an IDTF. CMS proposes to clarify the standard that a physician providing general supervision can oversee a maximum of three IDTF sites by noting that the term "sites" includes fixed as well as mobile sites. The ACR is concerned that the supervising physician list for each IDTF site may not be kept updated. Failure to keep these records up to date may result in the appearance that a particular physician is supervising more than the allowed number of sites when, in fact, this is not the case. **At this time, the ACR requests that CMS delay the implementation of limiting a physician to supervise more than 3 IDTF sites.** The ACR would like to work with CMS to provide information on various practice patterns and to determine ones that are problematic.

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[1] OIG Advisory Opinions 29 May, 2003 (03-12) and (97-5) 15 Oct, 1997<http://www.oig.hhs.gov/fraud/advisoryopinions/opinions.html>

TRHCA-SECTION 101(b): Physician Quality Reporting Initiative (PQRI)

Proposed Quality Measures for the 2008

In general, the ACR supports the PQRI as an important first step in moving towards a value-based reporting system for physicians. We also appreciate CMS' support for allowing measures to be developed through the AMA Physicians Consortium for Performance Improvement (PCPI) process, and the consensus development and endorsement roles played, respectively, by the Ambulatory Care Quality Alliance (AQA) and the National Quality Forum (NQF).

The ACR's membership has shown a good deal of interest in participating in the PQRI, based on feedback and questions received through our website. While the 2007 PQRI does contain measures which would allow diagnostic and interventional radiologists to report, as well as radiation oncologists, it is the ACR's goal to expand the number of measures applicable to a wider range of radiologists in 2008. This includes measures now under development by the AMA Consortium's Radiology workgroup relating to CT radiation dose reduction, mammography, exposure time reported for fluoroscopy, and expansion of reporting eligibility for two existing 2007 PQRI measures related to stroke/stroke rehabilitation imaging. While these proposed measures are not listed in Table 17 of the proposed rule as under AMA/PCPI development, it is the ACR's expectation that these measures will likely advance and achieve AQA approval prior to the final rule deadline of November 15, 2007 for inclusion in the 2008 PQRI.

The ACR supports CMS' proposal, Table 20, to include in the 2008 PQRI, those AQA starter set primary care prevention and screening clinical measures that were not included in the 2007 PQRI quality measures. The ACR also supports the two structural measures under Table 19, relating to adoption/use of e-prescribing and electronic health records, but would urge CMS to also consider expanding this list to include adoption/use of electronic Radiology Information Systems (RIS) and Picture Archiving and Communication Systems (PACS) which are vital ingredients of radiology patient safety and quality.

Addressing a Mechanism for Submission of Quality Measures via a Medical Registry or Electronic Health Record

The ACR supports the concept of allowing individual physician quality measures to be submitted directly through the vehicle of a medical registry, avoiding duplicate submission of the same data to CMS. We have reviewed the five options for registry-based reporting presented by CMS, and believe Option 3 to be the most feasible in terms of minimized burden on reporting physicians, and the fact that only aggregate individual physician reporting and performance rates must be reported out of the registry. Our major concern is the potential discoverability, under the Freedom of Information Act, of individual physician reporting and performance rates, and the counterproductive chilling effect this might have on physician registry participation. The ACR supports the pilot testing of registry-based reporting in 2008, but is unable to participate at this time as our registries are not collecting any PQRI data.

TRHCA—Section 101(d): PAQI

The following comments concern how CMS will use the $1.35 billion Physician Assistance and Quality Initiative (PAQI) Fund. Under the Tax Relief and Health Care Act of 2006 (TRHCA), CMS has the option of using all of this money for continuing PQRI bonuses in calendar 2008, or applying these funds to buy down the negative update to the Medicare Physician Fee Schedule for calendar year 2008. CMS has stated its preference to use the PAQI funds to support PQRI bonuses in 2008. ACR believes it is vital that the momentum built under the 2007 PQRI be

maintained by assuring the program continues to pay bonuses in 2008. However, the payment of bonuses should be funded as a supplement to Medicare physician reimbursement, and not at the expense of lowering overall physician payments under the 2008 Medicare Physician Fee Schedule.

Speakers at a major pay for performance conference held in Boston in August frequently pointed to a performance bonus in the 5 to 10 percent range as the minimum necessary to effectively gain the attention of providers; a PQRI devoid of a bonus payment would all but end interest in this valuable Federal effort to raise the bar on quality for Medicare beneficiaries. As such, **the ACR recommends that PQRI bonus funding be independent, and not at the expense of, the 2008 Medicare Physician Fee Schedule update.**

Physician Self-Referral Provisions

General

CMS acknowledges that the medical landscape has evolved since Congress extended the Stark law in 1993 to reach radiology and radiation oncology services. There has been unanticipated and significant growth in the use of medical imaging services, particularly MRI, CT and PET. The ACR believes that much of the growth of medical imaging can be explained by the shift from the use of invasive surgical and diagnostic procedures to the use of non-invasive medical imaging studies; the maturation of technologies and the dissemination of their capabilities to practicing physicians; and the overall benefit to patients to establish a timely and accurate diagnosis for the clinical problems.

However, because medical imaging is safe, non-invasive and well tolerated by patients, there is a high potential for inappropriate utilization of these services. At the same time, because these high end procedures are necessary to the care of many patients with both medical and surgical disease, many non-radiologist physicians and physician groups have purchased high-end imaging equipment not only to provide these services for their patients but to also increase the ancillary income for their practices. As this trend has evolved, CMS' recognition that more imaging services occur today under the protective umbrella of the in-office exception that "are often not as closely connected to the physician practice" is truly an understatement of the problem.

In addition to outright purchase of high-end imaging equipment, self-referring physicians have entered into leasing arrangements, purchasing of diagnostic tests and reassignment arrangements that circumvent and subvert the original intent of the Stark legislation's ban on inappropriate self-referral. In its comments to CMS on the CY 2007 MPFS proposed rule, the ACR strongly supported the CMS proposals to restrict abuse through tightening the rules on purchased diagnostic tests and reassigned claims. **We are pleased that CMS, in its CY 2008 MPFS proposed rule, has decided to augment its 2007 proposed restrictions and extend those restrictions to include potentially abusive leasing arrangements, percentage-based compensation arrangements, services furnished "under arrangements," as well as to invite comments on amending the in-office ancillary services exception.**

In general, the ACR does not believe these proposals to be confusing or unfair, nor dos the ACR consider them to create uncertainty, ambiguity or create barriers to the delivery of care. **To the contrary, the ACR believes that barriers to the delivery of high quality care are inherent in the perverse effect on medical decision making that is engendered by the conflict of interest in self-referral of imaging.**

In-Office Ancillary Services Exception

The ACR strongly supports CMS revisiting and changing the in-office ancillary exception. As explained below, the ACR believes that, due to their complex specialized nature, "advanced imaging studies" that involve CT, MR and PET, as well as radiation therapy, should never be defined as "ancillary" services and, therefore, should not qualify for the in-office ancillary services exception. **Additionally, the ACR recommends that CMS require that physicians provide in-office ancillary services within one hour after a patient's scheduled office visit. We also recommend that CMS modify the definition of a "centralized building" to a location within five miles of the building where a physician or medical group furnishes designated health services.** We would support CMS implementing this definition only if it adopts the ACR's recommendations to restrict the time and eliminate certain imaging services from those qualifying for the in-office medical exemption. **Finally, the ACR recommends that non-specialist physicians should not be able to use the in-office ancillary exemption to refer patients for specialized services involving the use of equipment owned, leased, or controlled through a joint venture by the referring physician unless the equipment provides the simple and truly "ancillary" services that Congress originally intended in this exception.**

The ACR believes that the in-office ancillary exception, as it is currently structured, has been counterproductive to what was originally proposed by Congress under the Stark laws. Congress intended to eliminate conflicts of interest for physicians in ordering imaging tests. Thus, while the laws preclude physicians from referring to an imaging center in which they have a financial interest under the in-office exemption, they do not preclude physicians from purchasing and owning the imaging equipment themselves. It was initially believed that the high cost of this equipment would deter most if not all physician practices from entering this market, but as the technology has matured and used imaging equipment became available, more and more self-referring physician practices have entered the market because they view imaging as a major ancillary revenue source. Unfortunately, these self-referring physicians now have significant financial incentives to order high-end imaging studies in order to get a return on their investment.[2] CMS has long recognized an inherent conflict of interest when physicians are allowed to provide pharmacy services to their patients by prescribing medications and then selling the prescribed medication to their patients. We believe it is time to recognize that the same type of conflict arises when physicians are permitted to order medical imaging and then sell that imaging to their patients.

The ACR agrees with CMS that the original intent of the Congress in establishing the in-office ancillary services exemption was to allow patients to receive a test or procedure at the time of the office visit that was truly ancillary to the office visit and necessary to the diagnosis and treatment of the condition that brought the patient to the physician's office. Congress assumed that such testing would involve simple examinations such as laboratory tests and simple x-rays to visualize a fracture or a pneumonia. Congress simply could not have anticipated the expansion of this regulation beyond its original intended purpose and the subsequent abuse this expansion has permitted. Advanced imaging tests involving CT, MRI and PET clearly do not represent "ancillary" services. These tests are sophisticated imaging examinations, requiring the expertise of specialty physicians and technologists with advanced training in radiation safety, examination design and protocol and interpretation of complex image datasets sometimes involving thousands of images for a single patient. The argument that these tests are necessary to assist the physician at the time of the visit is spurious at best and deceitful at worst.

Likewise, radiation therapy services have no place in the referring physician's office and should never be considered as "ancillary" services. Radiation therapy represents a clearly

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[2] Oran Technologies. Association of Otolaryngology Administrators. *An Introduction to In-Office CT.*

distinguishable consultative medical service that is provided only after thorough evaluation of the patient's medical condition by many consultants. It is never provided as an ancillary service for the "convenience" of the patient, and to allow self-referring physicians to provide it under the in-office ancillary services exemption is indefensible.

In-office imaging and radiation therapy may also deprive patients of the significant peer-review benefit of independent interpretation of the diagnostic studies and independent evaluation of the appropriate method of radiation treatment for cancer patients, which in turn may lead to unnecessary surgery or other treatment. When a physician with a clear financial interest is permitted to refer, perform, interpret and act on the findings of a diagnostic examination or make a financially-motivated decision on a course of radiation treatment, the patient is deprived of an objective outside review of the process under medical practice standards, peer-review and case-by-case oversight.

Despite claims that patients receive more convenient service from undergoing a study in an MR or CT scanner in their office suite, physicians have taken advantage of the in-office ancillary services exception, using financial incentives to more frequently order medically questionable studies and then fail to have a trained imaging specialist interpret them. In the physician office setting, studies such as CT, MRI and PET seldom, if ever, occur within the hour for patients for their patient's convenience. In fact, research shows that fewer than three percent of myocardial perfusion and PET nuclear medicine studies, along with MR and CT studies, even take place on the same day a patient visits a physician's office. Such sophisticated imaging studies require separate scheduling and patient preparation (e.g., fasting before study, pre-ingestion of drugs and/or contrast media).

These separately scheduled studies can be provided at a location where there is no financial interest to the referring physician, just as easily as they can be provided in the referring physician's office. Allowing these services to be performed in a "centralized building" is completely contradictory to the intent of Congress in creating this exception.

Congress and CMS have imposed laws and regulations that attempt to mitigate this problem by reducing the reimbursement for these high end examinations. Unfortunately, this only incentivizes those physicians who own or lease imaging equipment to order more studies in order to maintain the profitability of their equipment and inappropriately penalizes hospitals and independent imaging centers.

The ACR, historically, has opposed self-referral arrangements because they may improperly affect medical decision-making and may compromise quality patient care. There can be no question that self-referral in the United States, particularly in diagnostic imaging, has contributed to skyrocketing health care costs and frequently impeded quality of care. The BlueCross BlueShield Association in 2003 and the Medicare Payment Advisory Commission (MedPAC) in 2005 each reported that diagnostic imaging was the fastest growing type of medical expenditure in the United States, with an annual growth rate of nine percent that more than doubles general medical procedures.[3] Technology developments in magnetic resonance imaging (MRI), computed tomography (CT) and ultrasound, coupled with a regulatory vacuum, have created incentives for entrepreneurs and clinicians to increase imaging volume.[4]

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[3] Miller, Mark E., Ph.D. MedPAC recommendations on imaging services. Testimony to Subcommittee on Health Committee on Ways and Means. March 2005.

[4] BlueCross BlueShield Association. (2003). *Medical Technology as a Driver of Healthcare Costs: Diagnostic Imaging.*

Such accelerated volume has certainly led to many unnecessary imaging procedures performed by self-referring physicians.[5] As the MedPAC and BlueCross BlueShield data illustrate, more physicians are responding to financial and regulatory incentives to send their patients "where the money is."[6] Even more importantly, inappropriate and unnecessary medical imaging may compromise patient safety by exposing those patients to excess radiation. The ACR maintains that appropriate use of imaging services, competently performed and interpreted, will maintain quality of care and decrease health care costs.

Fundamentally, in-office medical imaging has proliferated because of the acquisition of high-tech imaging equipment by physicians who were not trained as radiologists, or even to supervise the operation of equipment or oversee these specialized procedures. Radiologists are trained for at least 4 years and usually as many as 5 or 6 years to perform and interpret imaging studies. In their practices, they do not have the opportunity to self-refer. All their patients are referred to them by other physicians, for no other reason than that they desire information about their patients. Conversely, nonradiologist physicians who operate their own imaging equipment (or, through various indirect arrangements own equipment to which they refer) are almost always in a position to self-refer or to refer within their group (which is essentially the same thing as self-referral).

Recent data illustrate how self-referral has spurred imaging utilization. The Department of Radiology at Thomas Jefferson University Hospital years ago formed the Center for Research on Utilization of Imaging Services (CRUISE). David Levin, M.D., and his colleagues have studied utilization trends and practice patterns in imaging, primarily using the CMS Physician/Supplier Procedure Summary Master Files. Their data have corroborated other studies and that have shown quite clearly that self-referring physicians are a major contributor to the rapid growth the Medicare program is experiencing in imaging.

Notably, a recently completed CRUISE study by Dr. Levin, et al. compared utilization trends in MRI, CT, and nuclear scans done on units owned by radiologists or nonradiologist physicians in their private offices. Between 2000 and 2005, the MRI utilization rate per 1000 Medicare beneficiaries increased by 83 percent in radiologist offices, compared with 254 percent in nonradiologist offices. The CT utilization rate increased by 109 percent in radiologist offices, compared with 253 percent in nonradiologist offices. The nuclear scan rate increased 40 percent in radiologist offices, compared with 192 percent in cardiologist offices (cardiologists are the only other specialty having major activity in nuclear scanning). These data substantiate the concerns that CMS has raised and further solidify the evidence against continuation of the in-office ancillary services exemption as it is currently structured.

The ACR understands that there are situations where the in-office ancillary services exception continues to be appropriate and include ultrasound in an obstetrician-gynecologist's office; echocardiography that cardiologists perform and interpret; and simple imaging examinations that need to take place for acute conditions and can be provided immediately (i.e., x-rays for possible fracture or pneumonia). In these situations, patients should be advised that their physicians own this equipment and are performing the studies to provide immediate patient care.

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[5] Moskowitz H, Sunshine J, Grossman D, Adams L, Gelinas L. "The effect of imaging guidelines on the number and quality of outpatient radiographic examinations." *American Journal of Radiology.* 2000 : 175:9-15.

[6] Hoangmai H. Pham, Kelly J. Devers, Jessica H. May, and Robert Berenson
"Financial Pressures Spur Physician Entrepreneurialism." *Health Affairs*, March/April 2004; 23(2): 70-81.

In response to the questions raised by CMS, the ACR firmly believes that changes to the in-office ancillary exemption are necessary.

The ACR recommends that certain medical services should not qualify for the in-office ancillary services exemption. Services that should not qualify, and should never be defined as "ancillary", are CT, CTA, MRI, MRA, PET, PET/CT and radiation therapy.

The ACR also recommends that restrictions should be placed on any service provided under the in-office ancillary services exemption to require that the exempted ancillary service must be provided within one hour of the time of the office visit.

In response to the questions of whether and how to change the definitions of "same building" and "centralized building" the ACR believes that, if convenience and timeliness of diagnosis are the rationale for the in-office ancillary services exception, CMS should require that a "centralized building" be within five miles of the building where the physician or medical group furnishes medical services. We would support this definition only if CMS adopted the ACR recommendations for time restriction and deletion of certain medical services from those qualifying for the in-office medical exemption.

The ACR recommends that non-specialist physicians should not be able to use the in-office ancillary services exemption to refer patients for specialized services involving the use of equipment owned, leased, or controlled through a joint venture by the referring physician unless the equipment provides the simple and truly "ancillary" services originally intended in this exception.

Changes to Reassignment and Physician Self-Referral Rules Relating to Diagnostic Tests [Anti-Markup Provisions]

CMS again proposes to apply the "anti-markup" provision on the technical and professional component of diagnostic tests. This proposal would prevent imaging providers from marking up the TC or PC of studies, whether or not a billing physician or medical group outright purchases the professional component or the technical component, or whether the TC or PC provider reassigns his or her right to bill to the billing physician or medical group (unless the performing supplier is a full-time employee of the billing entity).

CMS also seeks comments on whether to impose the anti-markup rule to TCs that occur in a "centralized building." The ACR recognizes that CMS wants to close a perceived loophole in which a part-time or leased group employee performs the technical component of imaging in a "centralized building," but the group neither gets a reassignment from the employee technician (one who cannot bill the TC or PC directly), nor buys the TC outright from the technician. **The ACR supports CMS applying the anti-markup provision to TCs that are performed in a "centralized building."**

The ACR continues to share CMS' concern "that allowing physician group practices or other suppliers to purchase or otherwise contract for the provision of diagnostic tests and then to realize a profit when billing Medicare may lead to patient and program abuse."[7] For example, the ACR has learned of arrangements where the technical component (TC) for MRI procedures performed under a lease arrangement is billed to Medicare at a significant markup to the supplier's actual charge to the billing entity. The billing entity (usually the self-referring physician or medical

[7] 2007 Medicare Physician Fee Schedule Proposed Rule. Federal Register. Vol. 71, No. 162. 22 August, 2006.

group) thus is essentially in the role of a "broker" of imaging services. They neither provide the actual service nor interpret the images. Nevertheless, they garner the lion's share of the reimbursement for the simple process of "brokering" the transaction, in which their patient is captive and is not offered a choice of imaging provider.

Generally, the ACR agrees with the language proposed by CMS to amend § 424.50 and § 424.80 of its regulations. The ACR has advocated that Congress and CMS adopt quality standards to reverse this disturbing trend, ensure program integrity and safeguard against patient abuse. Consequently, we believe that the proposed purchased diagnostic test and reassignment changes could advance those critical objectives by influencing many physicians, medical groups and other entities to separately bill the technical and professional components of diagnostic studies.

The ACR supports CMS' proposal to exempt from the anti-markup provision diagnostic tests that independent laboratories have not ordered themselves. **The ACR urges CMS to extend this exemption to radiologists' offices.** However, we are concerned that the proposed anti-markup provisions include services performed by independent contractors and part-time employees of the billing physician or medical group. We believe that excluding only full-time employees of the billing physician or medical group from the anti-markup proposals could impair many legitimate, non-abusive arrangements where radiology practices engage exclusive contractors or employ exclusive part-time radiologists or in which radiologists independently contract with or are part-time employees of multiple radiology groups that do not engage in self-referral. The ACR offers the following alternative proposal. Since radiologists are not in a position to profit from abusive self-referral, CMS should extend the anti-markup exclusion to contractors and part-time employees of radiology physicians or radiology groups.

The ACR recommends that CMS change the language in the first column on page 38180 of the proposed rule to read "(unless the performing supplier is a full-time employee of the billing entity or the billing entity is a radiologist or radiology group)."

Unit-of-Service (Per-Click) Payments in Space and Equipment Leases

CMS proposes that the Stark regulatory exception for space and equipment leases may **not** include per click-based payments to a physician lessor for services rendered by an entity lessee to patients who are referred by the physician to the entity. The agency believes that such arrangements "are inherently susceptible to abuse" because the physician lessor would have a clear incentive to profit by referring more patients to the lessee. Imaging leases have boomed since CMS initially proposed the Stark space/equipment rental exception in 1998. Given the Congress' and state attorneys general interest in lease transactions, ACR welcomes CMS focusing on per-click leases in the Rule. We strongly support banning time-based and unit-of-service based leases, with a one-year grace period to allow physicians who have these leases to unwind them.

The ACR maintains that per-unit or "per click" leases fuel an incentive to order unnecessary examinations that is essentially as potent as if the ordering physician is a partner in a joint venture. Additionally, incentives to order unnecessary examinations are just as strong for non-Medicare patients.[8] This further extends the waste of health care dollars.

Professor Jean Mitchell conducted a recent study, finding that almost half of all imaging done outside of the hospital setting was done in a self-referral situation by non-radiologists for CT, MR

[8] Mitchell, J., "The Prevalence of Physician Self-Referral Arrangements After Stark II: Evidence From Advanced Diagnostic Imaging", Health Affairs, April 16, 2007.

and PET. Among this group that billed for these procedures, 61 percent of MR, 64 percent of CT and 30 percent of PET billings were from groups that did not have equipment in their offices.[9] For MR and PET, the data showed that the share of statewide volume billed by the physicians has grown dramatically since 2000. Many self-referring physicians have made the argument that there is a need to have CTs, MRs and PET machines in their office for patient convenience. Mitchell believes, and the ACR agrees, that the large amount of billings of these leases or "per click" arrangements located outside of their offices undermines the convenience argument.

The ACR encourages CMS to use its authority under section 1877(e)(1) of the Act to prohibit time-based or unit-of-service-based payments to an entity lessor by a physician lessee, to the extent that such payments reflect services rendered to patients sent to the physician lessee by the entity lessor.

Perhaps the most abusive unit-of-service leasing arrangement is the scheme whereby a referring physician leases space on a unit-of-service or per diem basis from a MRI facility and then submits a claim to Medicare for the global fee.[10,11] Other provisions of this CY 2008 MPFS proposed rule would restrict any abusive profit to the lessee physician or medical group under such an arrangement. However, since the marketplace has repeatedly created an "advisory industry" (see attachment) to find loopholes, the ACR believes CMS could firmly close the door on such abuses by prohibiting all such arrangements.

The ACR believes that most leasing arrangements are economically driven, do not contribute to patient convenience or any other attributes that promote better patient care and generally drive up utilization. **The ACR supports a ban on all time-based and unit-of-service-based leasing arrangements.**

The ACR supports a one-year grace period to allow unwinding of such banned leasing arrangements.

"Set in Advance" or Percentage-Based Compensation Arrangements

In a further attempt to curtail certain abusive arrangements, CMS would clarify its original intent that percentage compensation arrangements could be used only for compensating physicians for the services they perform by disallowing arrangements that pay for services and items, e.g., medical equipment and office space, on a percentage of revenues the equipment or space realizes. CMS only would allow percentage-based compensation to pay for physician services that a physician personally performs; and that must be derived directly from service-related revenues.

In 2002, the ACR commented to CMS that it supported the ability of physicians to receive compensation for their professional services on a percentage-basis. The ACR agrees with CMS' decision to continue allowing such arrangements and proposed action to curtail potentially abusive percentage compensation arrangements to physicians for non-professional services.

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[9] Mitchell, J., "The Prevalence of Physician Self-Referral Arrangements After Stark II: Evidence From Advanced Diagnostic Imaging", Health Affairs, April 16, 2007.

[10] David Armstrong. WSJ May 2, 2005: "Own Image: MRI and CT Centers Offer Doctors Ways to Profit on Scans; Physicians Pay a Flat Fee For Procedures, Then Bill Insurers – at Higher Rate; Navigating Legal Landscape." Wall Street Journal 2 May, 2005.

[11] Bruce Jaspen. "Doctors' MRI Deals a "Sham", State Says." Chicago Tribune 10 May, 2007.

Stand in the Shoes

The ACR shares the concern of CMS that inserting entities or contracts into a chain of financial relationships linking a DHS entity and a referring physician is a subterfuge that intends to circumvent Stark self-referral prohibitions. **Therefore, the ACR supports CMS' proposal to amend § 411.354(c) to require a DHS entity to stand in the shoes of another entity it owns, to which physicians refer Medicare patients for DHS.**

Under Arrangements

CMS also proposes to restrict certain services furnished 'under arrangements.' CMS is trying to determine the best approach to prohibit certain arrangements under which physicians supply items and services to DHS entities. For instance, a group of radiologists and cardiologists form a joint venture to purchase a 64-slice CT scanner to establish a cardiac imaging center on an academic medical center's campus. Instead of enrolling the venture as a supplier with Medicare and commercial payers, the venture enters into an "under arrangements" contract with the hospital. The venture would provide imaging services to registered hospital outpatients (some of whom the cardiologists would refer), while the hospital bills for the services rendered to Medicare beneficiaries under the HOPPS. In return, the hospital pays the venture a negotiated contract rate for each study it performs.

Current Stark rules do allow such referrals by the cardiologists to the joint venture for imaging because the cardiologists technically are not referring to the joint venture "entity," but rather to the hospital. Only hospitals submit claims to Medicare in the "under arrangements" context. CMS proposes to curb the risk of imaging overutilization by expanding its definition of "entity," so that a DHS entity includes both the person or entity that performs the DHS, and the person or entity that submits claims or causes claims to be submitted to Medicare for the DHS. CMS recognizes that independent diagnostic testing facilities (IDTFs), ambulatory surgical centers (ASCs) and other non-hospital settings have taken advantage of the "under arrangements" opportunity. Accordingly, CMS solicits comments on whether to adopt its approach; MedPAC's recommendation of broadening the Stark definition of "physician ownership;" or a combination of both approaches. If CMS adopts any of these approaches, the U.S. imaging environment would change dramatically. Referring physicians apparently would not be able to participate in joint ventures that provide services to hospitals and others "under arrangements."

The ACR historically opposes any financial arrangements that could harm patients, or give an economic incentive to perform unnecessary imaging. Therefore, we have supported federal legislative and regulatory action to prohibit self-referral or restrict its influence on patient care decisions.

CMS' fundamental concern that many referring physicians have prospered from joint venturing with hospitals for imaging services via "under arrangements" is shared by the ACR. These arrangements are essentially thinly veiled substitutes for the imaging centers that were the original target of the Stark laws. Many of these deals do not appear to have any clinical value yet they may well increase costs to Medicare beneficiaries and the Medicare program. **Thus, the ACR believes the CMS proposal to tighten "under arrangements" services could benefit patient care and reduce undue financial incentives.**

However, the ACR is concerned that the proposal to change the definition of entity at §416.351 to include both the person or entity that performs the DHS as well as the person or entity that submits claims or causes claims to be submitted to Medicare for DHS may not have its desired effect due to potential ambiguity in the interpretation of the meaning of "performs." **While the**

ACR supports this proposed change, we recommend that, in its Final Rule, CMS more specifically define the meaning of "performs" to avoid creation of future loopholes.

The ACR is also concerned that the implementation of this "under arrangements' proposal, as well as the preceding "stand in the shoes" proposal, if instituted without a comprehensive implementation of all other CMS proposals in this rule, as well as recommendations from ACR on the in-office ancillary services exception, could lead to formation of multi-specialty groups of referring physicians for the sole purpose of providing high-cost imaging under the umbrella of the in-office ancillary services exception. This subterfuge would result in no relief from the current abusive practices and could result in a severe revenue loss for already-besieged hospitals.

The ACR, therefore, recommends that CMS not implement its proposed policies on self-referral on a piece-meal basis, but rather implement them in a comprehensive package that allows no escape for abusive practices.

In an environment where there is no shortage of legal advice to individuals who desire to benefit from regulatory loopholes, the ACR believes that CMS should tighten the noose on potentially abusive self-referral by using all the tools at its disposal. **Therefore, the ACR supports including the MedPAC recommendation to expand the definition of physician ownership in the current CMS proposal on services furnished "under arrangements."**

Additionally, we would recommend changing the language of the MedPAC recommendation to state "....an entity that derives a substantial proportion of its revenue from a provider of designated health services or from the business of providing designated health services." We would also recommend that, for this purpose, a "substantial" portion of revenue should constitute 50 percent or greater.

As CMS noted in an earlier Stark II final rule (Phase I; January 4, 2001), restricting "under arrangements" could disrupt patient care and cause administrative burden to physician practices and hospitals. We are aware that certain physician groups who are party to "under arrangements" have negotiated termination clauses if the arrangements no longer comply with federal law or rules.

However, should CMS adopt its proposal in the final MPFS rule effective January 1, 2008, we acknowledge that many physician-hospital ventures would need to be unwound. The ACR, therefore, recommends that CMS consider affording a one-year grace period to such ventures.

Conclusion

Thank you for the opportunity to comment on this proposed notice. The ACR encourages CMS to continue to work with physicians and their professional societies. The ACR looks forward to a continuing dialogue with CMS officials about these and other issues affecting radiology. If you have any questions or comments on this letter or any other issues on radiology, please contact Angela Choe at 800-227-5463 ext. 4556 or via email at achoe@acr.org.

Respectfully Submitted,

Harvey L. Neiman, MD

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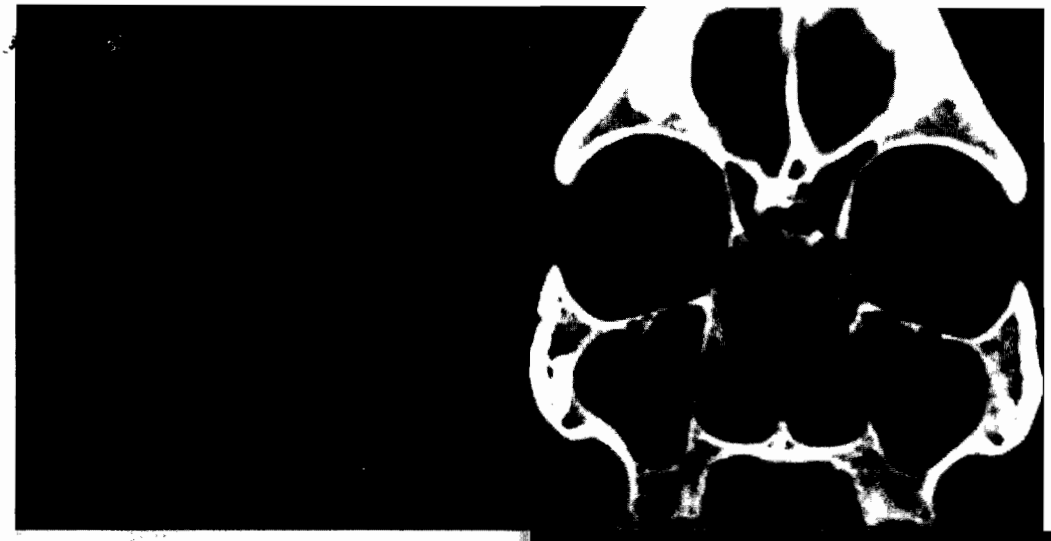
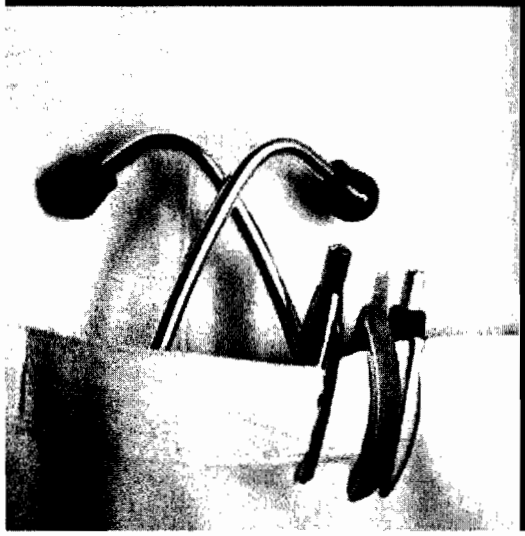
Attachments to be sent under separate cover via U.S. mail.





An Introduction to In-Office CT

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CONTENTS

Xoran Technologies®, Inc., in conjunction with the Association of Otolaryngology Administrators, is pleased to bring you "An Introduction to In-Office CT."

In the following easy to read chapters (many of which were written by your colleagues), you can learn all you need to know about the benefits and steps required for adding a CT diagnostic service to your practice.

The complexity of our healthcare system is creating an ever-growing chasm between the treating physician and patient. Bringing CT scanning to the patient's point-of-care helps to close that chasm by cutting waste and inefficiency out of the process.

In-office CT allows a patient to walk into their physician's office and leave with a diagnosis and course of treatment all within the same visit. Efficiency in terms of dollars and time is clear.

We wish you well on your journey toward streamlining your workflow, helping your doctors diagnose and treat patients more efficiently, and supplementing your practice revenue.

We welcome your questions and comments!

Sincerely,

XORAN TECHNOLOGIES

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FOREWORD

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An Otolaryngologist seeking to improve patient care, reduce patient's costs, and increase office income can do no better than installing a CT scanner in the office.

Over 50% of new patients that go to a typical Otolaryngologist suffer from sinusitis, nasal obstruction and congestion, or recurrent otitis media. In some practices, it is over 75%.

Typically these patients have failed initial therapy by their primary physician and now seek a more specific diagnosis and treatment. A CT scan is one of the most common tests we do to help diagnose the patient's problem.

These diseases often require an initial evaluation by the Otolaryngologist, and appointment with a radiologist, (which can range from one day to two weeks), and a return visit to the Otolaryngologist to complete the diagnosis and treatment plan.

With an in-office CT scanner, the scan is completed in less than 15 minutes. The patient is diagnosed and treated within 15-30 minutes and charged with only one office visit, which is the same CT scan charge. If you were a patient, or an insurance company, which would you prefer?

CT scanners have made leaps and bounds in terms of remarkable accuracy and reduced cost of purchase and emit up to one-tenth the radiation exposure of past machines. ENT specific scanners are easy to use and in many offices can be operated by the physician and a nurse. The space and power requirements are one-third that of a typical full-body scanner. They usually just plug into an office wall socket. The scans are as accurate as any third generation scanner, with t1 mm. cuts, and axial, coronal, with sagital views and can be used with any image-guided surgery system.

The cost of an ENT-specific CT scanner is about one-fifth the cost of a full-body scanner. Offices can charge for the full technical fee and have a radiologist read the film (all the machines have teleradiology software built in), or the office can bill a global fee and provide the interpretations themselves. Head and Neck Specialty Radiologists are also available for teleconferences and consultations.

Just as in-office audiology can expedite care and enhance office revenue, a CT scanner can generate new revenue to a practice.

Many administrators are not familiar with the fact that the American Academy of Otolaryngology Head and Neck Surgery Foundation (AAO-HNSF) has published Clinical Indicators for sinus surgery. A sinus CT is required for surgical planning in all cases following medical therapy. A post-operative CT scan is also often indicated.

If you want to treat your patients better, faster, increase office efficiency, and generate new revenue, in-office CT scanners have now come of age for all Otolaryngologists.

PATIENT BENEFITS
of Point-of-Care CT

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One of the most challenging aspects of being a part-owner of a small private practice is making decisions related to large capital purchases. When making these purchases, our practice has adopted the philosophy: What's good for the patient is good for the practice.

Diagnosis in One Visit
In many practice settings, it is obvious that many of the processes patients experience are designed for the convenience of the facility, not the patient. By incorporating services and technologies that allow the delivery of care in a more patient-centered manner, patients' time is used more efficiently, allowing for faster diagnosis, treatment and relief.

Prior to having a CT scanner in our office, patients who needed scans needed to either go to the hospital or a local imaging center.

Inconveniences Included:
- Making an appointment at the facility for another day, then returning to the doctor's office for another appointment for follow-up
- Office staff spending considerable time on the phone pre-certifying examinations and scheduling these appointments
- Patients going through a lengthy registration process at the imaging center or hospital, duplicating paperwork which they already have filled out at the physician's office

Expedited Patient Treatment and Diagnosis
In-office CT removes barriers to accurate diagnosis in patients that may have questionable but severe symptoms and becomes more convenient for patients traveling long distances.

By scanning patients in the same office visit, particularly while they have symptoms, and in conjunction with a thorough evaluation, an accurate diagnosis is achieved and proper treatment can be initiated.

Offering point-of-care CT is a great example of how practices have been able to incorporate technology that greatly benefits patients.

Patient Benefits:
- Instead of three visits, which may require significant time away from work or arranging child care, patient evaluation is completed in one visit
- Both the patient and the insurance company benefit from not having the cost of an additional office visit for follow-up
- The images are always available and can be reviewed with the patient in the office. In the age of PACS (Picture Archiving and Communications System), it is amazing that we still frequently see patients who bring reports without any opportunity to view their images. We are expected to render a diagnosis based on a report from a radiologist that we may not even know
- Our images are better because we have control of the protocols used
- With the scanner that we purchased, patients requiring image-guidance during their sinus surgery do not need to have a second scan. This can be decided after the imaging is completed and the patient only incurs the cost of one scan and the add-on code if image guidance is going to be used, rather than the cost and inconvenience of two scans
- The patient no longer has to go to the hospital, which may provoke anxiety

OFFICE BENEFITS
of Point-of-Care CT

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Advantages to In-office CT Imaging Include:

- The control of the patient's time and convenience
- Providing correct treatment
- Easier analysis and comparison of previous studies

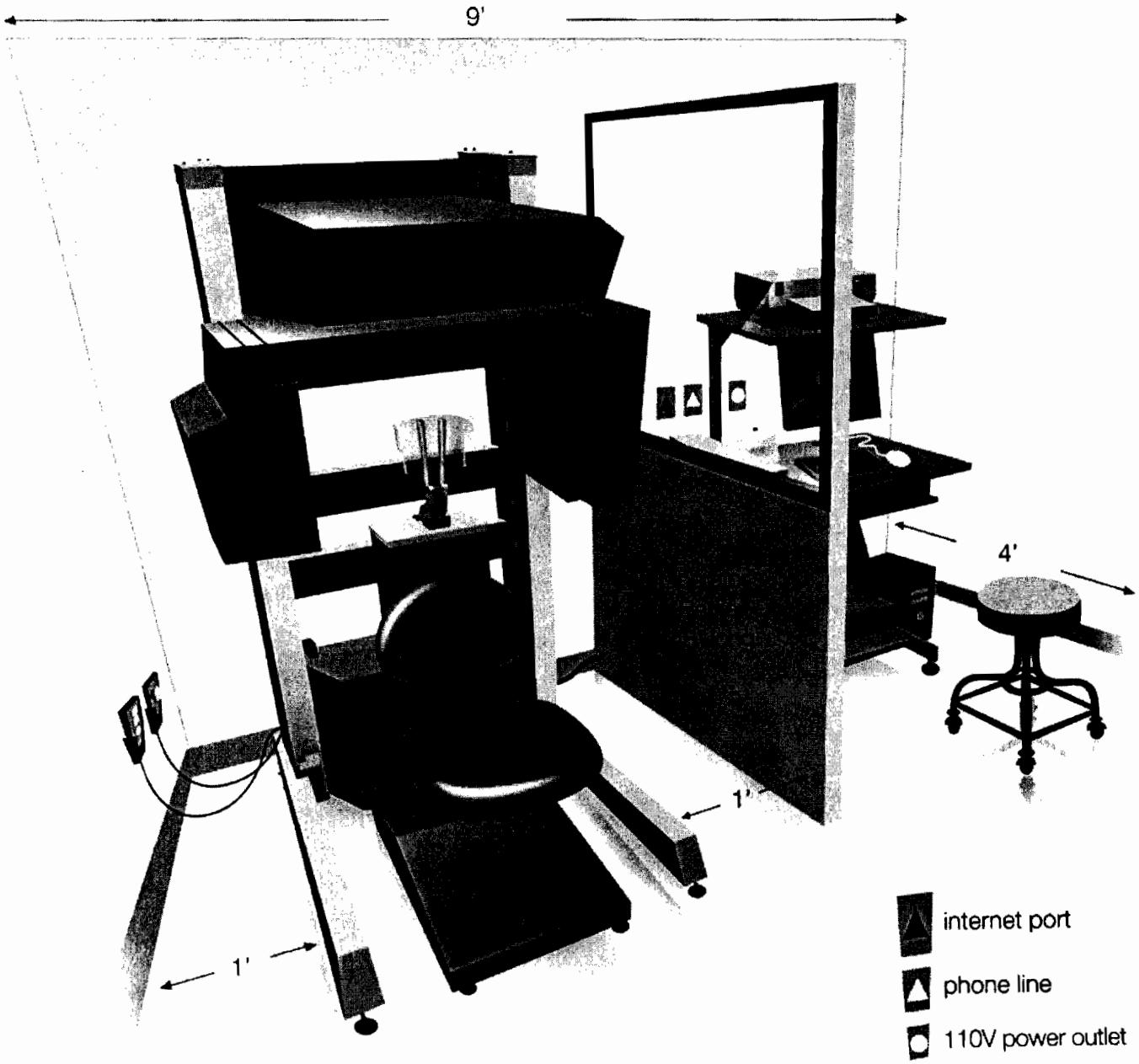
When patients see doctors, most are already suffering with uncomfortable symptoms. The last thing that they want to hear is that they need to go elsewhere for a CT scan in order to determine what is truly wrong.

In some cases, patients have to live with their symptoms for days or weeks until a time can be scheduled to obtain a CT scan followed by an additional appointment for diagnosis and treatment.

In-office Scanning Gives the Ability To:

- Minimize interruption to the daily lives of patients
- Increase patient compliance with having a point-of-care CT scanner. Patients are more willing to obtain a CT scan when it can be done at the same office visit
- Diagnose patients faster and begin treatment right away. This is important to patients because they get relief from their symptoms faster. This also eliminates unnecessary trial medications for treatment of presumed diagnosis
- Control the timing and quality of our CT scans. In-office CT allows for control of slice thickness, choosing pediatric or adult CT scan protocol, and choosing whether it is a full or a limited study
- Compare studies of previous scans and pull scans up right on a computer in the exam room

MiniCAT™
Space Specifications



FINANCIAL FEASIBILITY

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This section is divided into two parts: (1) steps to take in order to make sure a CT scanner is a good fit for your practice (Due Diligence), and, (2) items to think about ahead of time that may affect implementation (Workflow).

Due Diligence

1. Review Records to Check Scan Volume

Owning an office-based CT scanner provides convenience to your patients. Depending on the type of scanner you choose, you may be able to offer a lower dose option for your patients.

Due to insurance companies' over-utilization concerns, however, it's important to keep your scan volume with an in-office CT approximately the same as the number of non-contrast sinus and temporal scans you currently order from radiology. A few ways exist to determine your current scan volume:

- Call your radiologist(s) or local imaging center where you currently have the patients' scans done
- Check internal records (EMR) for the number of scans ordered weekly per physician
- If your major payers require prior authorization, look up the number of CT prior-authorizations your staff called in
- Track the number of scans ordered for 1-3 months. Be sure to track by payer. Knowing the number of scans per payer will help you get a better idea of your projected reimbursement. For example, 20% of your CT patients may come from Medicare at $260 per scan (global bill), but 80% come from Blue Cross at $450 per scan. If you just used Medicare or just Blue Cross reimbursement amounts, your ROI figures would be skewed.

2. Collect Data on CT Scanners

Some scanners will image the whole body while others are specifically tailored for the ENT or allergy physician (they scan only the sinuses and/or ears). As a rule of thumb, multi-specialty clinics will generally have more use for a full-sized CT from such companies as GE, Phillips or Siemens, whereas single specialty ENT or allergy practices are better suited for specialty scanners.

Another question is the type of imaging performed. Full-sized CT scanners are capable of performing soft tissue imaging (good for neck and brain imaging). Soft tissue contrast material will be employed, and doctor supervision will be required.

Due to the complicated nature of these systems, a certified radiologic technologist will need to be hired to perform the scans, process the images, etc. While state regulations differ as to who can perform a CT scan, physicians may perform a scan with their medical license. Specialty scanners are generally easier to use. A nurse or MA can set up the system and the physician can perform the scan himself/herself. Be sure to ask your sales rep what other practices are doing and how easy it is to learn and use the CT scan software.

For physicians who also perform surgery, they often want to use an Image Guided

Surgery system, such as Medtronic (Xomed) Landmarx, the GE Instatrak, or systems by Brainlab, Stryker or other companies. Be sure to ask your CT scanner sales person what navigation systems their scanner is compatible with.

As an added measure, the CT scanner company can often provide you with a CD or disk that you can use to confirm compatibility of the CT scan image with the navigation system.

3. Perform an Affordability Calculation (return-on-investment pro-forma)

Using your scan volume, average the reimbursement rates and expenses to determine if a scanner is financially feasible.

In addition to CT scan revenue, it's important to also consider additional benefits, such as, improved workflow, patient treatment compliance, patient retention, and patient satisfaction. By having a low-dose CT scanner available in your office, you will offer a more turnkey, full-service solution for your practice.

Workflow

1. Determine Who Will Read Scans — Physicians or Teleradiologists

Once physicians have a CT scanner in their offices, many prefer to read their scans themselves. This means they will have to perform a CT interpretation in order to bill for the Professional Component (PC) of the bill. When physicians are reading their own scans, most practices will bill globally — for both the Technical Component (TC) and PC.

Some ENT and allergy physicians have implemented an internal review process. For example, each week a different physician does an over-read of all scans performed that week. Other practices have a weekly or monthly meeting where they review tricky scans.

Still other practices prefer to send a number of scans or even all scans for interpretation by a radiologist. The PC is generally $40-$60 per scan (TC is generally $260-$400). Some practices bill globally and contract with a radiologist for the interpretation. Others bill only for the TC and have the radiologist bill for their portion — the PC.

If you decide to use a teleradiology service, Xoran can help connect you with a prominent neuroradiologist certified in your state.

2. Determine Who Will Perform Scans

Currently, a physician with his/her medical license can perform a CT scan in all 50 states. Only California and Oregon require additional physician training or certification. Depending on the time required and utility of the system you purchase, your physicians can be involved in some part or all of the process.

For full-sized CT scanners, hiring a CT technician is all but required. It will be imperative for this person to understand proper patient positioning, radiation doses and protocols. Full-time RTs or CT techs are generally paid $40,000 - $75,000 per year (plus benefits), depending on location. You may be able to find a tech from your local hospital looking to pick-up a few extra hours and willing to come in for 3-4 hours several times a week. Be sure to check with local employment regulations when deciding whether to hire this person as an employee or independent contractor. Some practices are lucky and already have a nurse who is also a CT tech who is willing to take on additional responsibilities.

The bottom line is that full-sized CTs perform a variety of scans, but you'll need a CT tech. Be sure to calculate these benefits and costs into your return-on-investment calculations. If you go with a specialty scanner, be certain to ask about the time and education needed to operate the scanner effectively. For example, will the physicians be able to review the scan with the patient immediately after the scan?

The most ideal scenario is to have a nurse or medical assistant set up the scanner's computer and position the patient. Then, the physician enters and performs the scan. In some states, such as New York and Arizona, a physician is required to position the patient. Be sure to ask your vendor what the requirements are in your state. And, be sure that your practice adheres to these requirements. You can set up a protocol, for example, in which the physician initials confirming that he or she agreed with patient positioning and performed the scan.

Some practices have found that the physician actually enjoys taking the patient through the entire scan process. With an easy-to-use specialty scanner, the doctor may enjoy the extended patient contact and the ability to explain to the patient immediately after the scan why he or she needs (or does not need) surgery. Such doctor-patient communication increases not only compliance, but the overall patient experience.

3. Billing

You will need to submit charges for either the global bill or the technical component. Here are the CPT codes generally associated with office scanning:

CPT Code	
70486 **Sinus Scan**	Computed tomography, maxillofacial area; without contrast material
70480 **Temporal Bone Scan**	Computed tomography, orbit, sella, or posterior fossa or outer, middle, or inner ear; without contrast material
70376 **Surgical Navigation,** **no independent workstation**	3D rendering with interpretation and reporting of computed tomography; not requiring image postprocessing on an independent workstation
70377 **Surgical Navigation,** **with independent workstation**	3D rendering with interpretation and reporting of computed tomography; requiring image postprocessing on an independent workstation
76380 **Limited CT**	Computed tomography, limited or localized follow-up study

Alternately, you can call a colleague in your area to inquire about reimbursement rates. The CT scanner sales person should also be able to provide you with a list of references in your area.

CT AFFORDABILITY CALCULATION

Example using MiniCAT™ Turnkey Solution and sample calculations.
Calculate your own "Year 1" earnings in the right column.
Provided by Xoran Technologies®, Inc.
Email info@xorantech.com for electronic version

Startup Cost			
MiniCAT™ Turnkey Solution		$230,000	
Shipping		$2,000	
Sales Tax Rate		6%	
Sales Tax		$13,920	
Total Startup Cost		$245,920	
Monthly Loan Payment		**$5,000**	

Operating Costs			
Utility and Supplies	(per scan)	$2	
Technician Salary	(per month)	$0	
Lead Lining		included	
Radiation Safety		included	
Off-site Backup of scan images		included	
Service Agreement	(included in Year 1, price per month)	$1,842	
Total Monthly Operating Costs		**$1,942**	

Revenue			
CT Scans Performed	(per month)	50	
Medicare Average Reimbursement	(per scan)	250	
Total Monthly Revenue		**$12,500**	

Expenses	**Year 1**	**Year 2**	
Monthly Loan Payment	$5,000	$5,000	
Monthly Operating Costs	$100	$1,942	
Total Monthly Expenses	**$5,100**	**$6,942**	

Earnings	**Year 1**	**Year 2**	
Monthly	$7,400	$5,558	
Annual	**$88,800**	**$66,696**	

Please Note:

- Prices are subject to change. Please contact a Xoran Sales Director for current pricing options.
- All purchases are governed by the terms and conditions of Xoran's Purchase Agreement.
- Figures in this pro-forma are intended for illustration purposes only and do not include income tax.
- Xoran does not guarantee that all customers will achieve these returns.
- Service agreement cost starts in year two. Prices assumes a four year contract.
- Reimbursement will vary. Amount shown is based on typical CPT Code 70486.

CT INTERPRETATION
and Teleradiology

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Otologic Imaging[1-4]

CT imaging of the temporal bones has become an important tool in the evaluation of the ear. Current technology allows for detailed depiction of the regional anatomy with submillimetric slices. In most cases, pertinent information can be obtained with a routine noncontrast study. Cases in which postcontrast imaging is helpful include patients in whom complications of otomastoiditis (e.g. sinus thrombosis, abscess formation) or mass lesions are suspected. Any review of the temporal bones requires a survey of the following on axial and coronal imaging:

- Mastoid air cells
  - Degree of pneumatization
  - Presence of opacification or septal erosion

- External ear
  - Auricle
  - External auditory canal

- Middle ear
  - Presence of tympanic cavity opacification
  - Sites of potential erosion: tegmen tympani, cochlear promontory, bone overlying lateral semicircular canal
  - Ossicular chain

- Inner Ear structures
  - Development
  - Presence of abnormal inner ear sclerosis or otic capsule lucency **(Figure 1)**

- Facial Nerve canal
  - Course and caliber
  - Presence of dehiscent tympanic segment

- Major regional vascular structures
  - High-riding jugular bulb
  - Dehiscent jugular plate
  - Aberrant internal carotid artery
  - Persistent stapedial artery

- Internal auditory canal and vestibular aqueduct
  - Presence of abnormal enlargement

- Skull base and paranasal sinuses

Sinonasal Imaging[5-8]

CT imaging of the paranasal sinuses and nasal cavity plays an important role in the evaluation of rhinosinusitis and planning for endoscopic sinus surgery. In addition to imaging evidence of pathology, interpretation of CT studies of the paranasal sinuses requires knowledge of the many sinonasal anatomic variants that can have an impact on procedural planning. A review of the paranasal sinuses requires a survey of the following:

- Nasal septum
  - Deviation
  - Spurring/contact points/perforation

- Anterior skull base symmetry
  - Depression/flattening
  - Dehiscence

- Laminae papyraceae
  - Dehiscence

- Paranasal sinuses and drainage pathways, including ostiomeatal unit (OMU)
  - Mucosal thickening
  - Opacification/air-fluid levels
  - Density of sinus content

  - Variants affecting frontal sinuses and drainage pathways **(Figure 2)**
  - Large agger nasi cell
  - Nasofrontal beak
  - Frontal cells
  - Frontal bullar cells
  - Drainage: meatal vs. infundibular

- Variants affecting sphenoid sinuses and drainage pathways
  - Onodi cells
  - Pneumatization of anterior clinoid process
  - Bone overlying internal carotid arteries and optic nerves
  - Insertion of septations

- Variants affecting maxillary sinuses and infundibula
  - Accessory ostia
  - Haller cells
  - Inferomedial extension of ethmoid bullae
  - Conchae bullosae
  - Paradoxical turbinates
  - Pneumatized/atelectatic uncinate processes

- Nasal cavity
  - Presence of opacification

- Nasopharynx

- Intracranial compartment and orbits

Flat-panel CT
Flat-panel CT technology provides a number of interesting possibilities from an imaging standpoint. From an image acquisition viewpoint, flat-panel CT technology allows examinations to be readily performed in the outpatient clinic with minimal space requirement. Additionally, studies can be tailored to the degree of anatomic detail required while keeping radiation doses to a minimum. With certain protocols, it may be possible to obtain imaging quality that surpasses that of standard multi-slice CT technology **(Figure 3)**.

The Head and Neck Radiologist
The head and neck radiologist can be an important team member to ENT practices. Typically, individuals specializing in head and neck radiology will have undergone a four-year residency followed by a fellowship in neuroradiology for one or two years. Head and neck radiologists can be helpful in answering technical questions related to protocol and examination selection and the need for follow-up imaging or further referral. Image interpretation is the primary role of head and neck radiologists. They excel in the efficient analysis of head and neck imaging studies, allowing the clinician freedom to spend his or her time with patients and procedures, while providing reliable readings from an individual familiar with the clinical context ENT physicians deal with regularly. They can also be helpful consultants in the setting of difficult cases and are specifically trained to identify incidental findings of clinical importance, such as the occasional aneurysm or intracranial mass **(Figure 4)**. Working with a head and neck radiologist can also aid in the implementation of state-of-the-art imaging techniques.

Teleradiology
In the past, receiving interpretations for head and neck radiology studies required affiliation with a radiologist with head and neck expertise as well as that individual being physically available. With the advent of teleradiology, it is now possible for practices of all kinds to receive interpretations any time, from virtually any location in the world. Advantages of teleradiology include faster receipt of imaging reports as well as the ability to have greater control over selecting those individuals responsible for radiologic interpretation. As the increase in demand for imaging services has outpaced the increase in supply of radiologists, teleradiology has been of great value to both clinicians and the imaging community to ensure that studies can be reviewed in a timely and expert fashion.

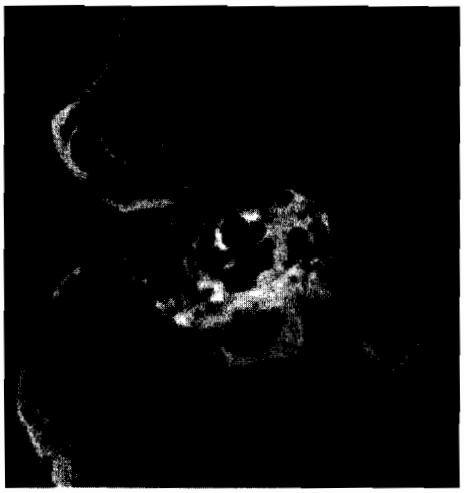

Figure 1
Axial CT image demonstrating extensive abnormal pericochlear lucency with thickening of the cochlear promontory, compatible with retrofenestral otosclerosis

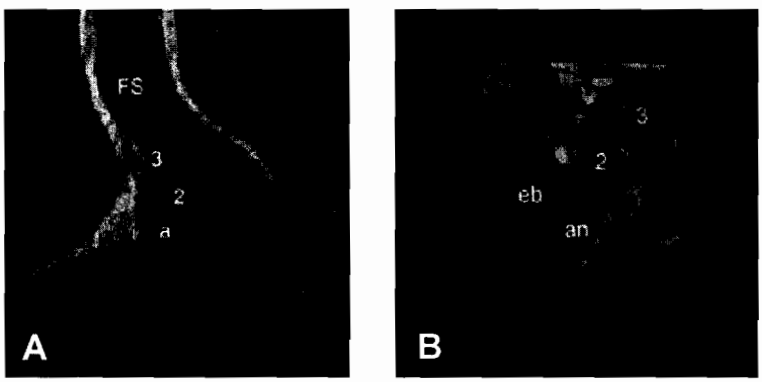

Figure 2
A. Sagittal reformation of sinus CT demonstrating agger nasi cell (a), and frontal cells (2,3), as well as the infundibulum (red arrowhead; FS = frontal sinus)
B. Three-dimensional reformation of sinus CT in same patient demonstrating impingement of frontal cells (2,3), upon frontal recess (light blue), and lower frontal sinus drainage pathway (green)

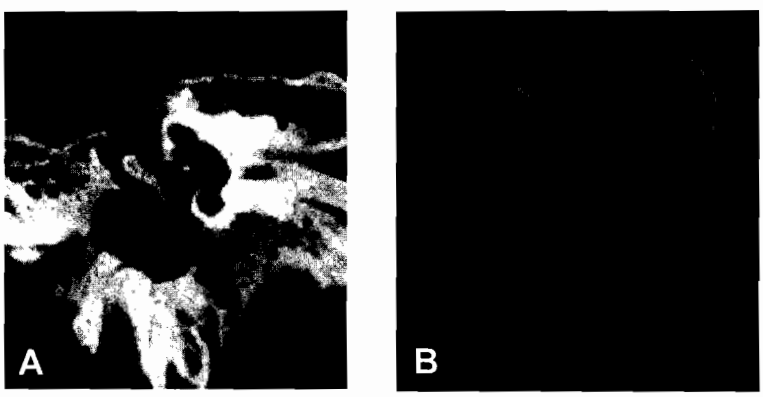

Figure 3
A. Coronal reformation of specimen temporal bone CT performed on Xoran MiniCAT™; notice excellent depiction of inner and middle ear structures, with clear demarcation of bone overlying tympanic segment of facial nerve
B. Three-dimensional reformation of the same data, with detailed depiction of inner ear structures

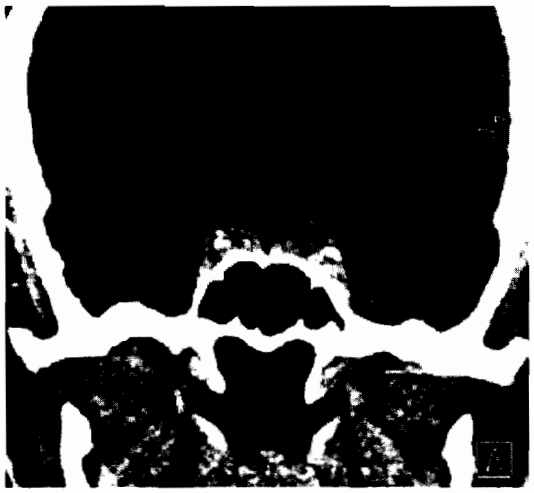

Figure 4
Coronal image from sinus CT demonstrating focus of rounded soft tissue between the frontal lobes (arrow); revealed to be an anterior communicating artery aneurysm on magnetic resonance angiography

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BRIEF HISTORY
and Principles of CT Imaging

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Computed tomography (CT), sometimes referred to as computed axial tomography or computer-assisted tomography (CAT), is a type of medical imaging invented in 1967 by Sir Godfrey Hounsfield. Hounsfield shared the Nobel Prize in Medicine in 1979 for the invention of CT with Alan Cormack, who did earlier work in image reconstruction.

First Generation CT Scanners
- Passed a very thin beam of x rays through the object being imaged to a single detector on the opposite side
- X-ray source and detector collected data while translating across the object at a particular angle and then incremented to the next angular position to translate again
- First generation scanner designs became known as translate-rotate scanners

Second Generation CT Scanners
- Introduced in 1975
- The number of detectors were increased and arranged into a line
- The x-ray beam could be spread out into a fan beam to cover the entire line of detectors. The x-ray source and the detector were still translated and then rotated, but the number of angular positions could be reduced with the additional detectors resulting in much shorter scan times
- Scan time was still long enough to limit these scanners to head imaging

Third Generation CT Scanners
- Introduced in 1976
- Eliminated the translate portion of the acquisition by using a larger array of detectors that rotated opposite of the x-ray source in a fixed orientation
- The speed of the scanning was drastically improved and, therefore, the images were no longer limited to the head. Scanning of the inferior anatomy could be achieved without much interference from respiratory motion
- Third generation CT scanners make up almost all of the conventional CT scanners used clinically today

Fourth Generation CT Scanners
- Introduced shortly after third generation
- Use a ring of detectors that encompassed the patient and required rotation of only the x-ray source
- Eliminated artifacts caused by detector sensitivity instability. However, as detector technology improved, the fourth generation with their inefficient use of detectors was eventually dominated by the third generation

Helical Scanning
After an initial period of rapid development, CT technology quickly became mature, and it was not until the early 1990s that further improvements were made. With the advent of "slip-ring" technology introduced in 1990, the x-ray source and detector (collectively referred to as the "gantry") were able to continuously rotate. Prior to that, the gantry would have to rewind after every revolution and the patient would be incremented in the axial direction. This process would have to be repeated several times to collect contiguous slices. With the slip-ring technology, the patient is moved through the CT scanner while the gantry continuously rotates.

This type of scanning is commonly referred to as helical scanning because data is collected in a spiral pattern. The spiral data is interpolated and reconstructed into axial slices. While scan time is improved, helical scanning has a tendency to broaden slice profiles and increase the prevalence of partial volume artifacts.

Multi-Row Detector CT
Among the most recent advances in conventional CT is the addition of multiple rows of detectors. These multiple rows allow for acquisition of several axial slices in one revolution of the gantry and the data can be reconstructed with finer axial resolution.

Currently, commercially available multi-row detector CT scanners have as many as 64 slices. Multi-row detector CT scanners allow image slices to be stacked together as a representative volume of the imaged object.

Volume CT
The most recent technological advancements in the evolution of CT technology allow CT scanners to go significantly beyond 64 slices. These scanners are referred to as Volume CT scanners because they actually reconstruct the data directly into a volume from the two-dimensional x-ray projections. The flat-panel detector is a very fine array of detector elements, which allows acquisition of a high resolution projection similar to a digital radiograph. Several of these high-resolution, two-dimensional projections are collected in one revolution of the gantry. From the single revolution, the imaged object can be directly reconstructed into a volume representation with exceptionally high, isotropic resolution.

LAWS

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State Certificate of Need Programs
A number of states have Certificate of Need (CON) laws which require prior approval of certain capital projects for the acquisition, addition, expansion or closure of facilities, services or equipment.

CON programs were initiated in many states in the 1960s and 1970s in an effort to contain health care costs by eliminating the proliferation of unnecessary medical facilities, equipment and services. Many CON programs apply to expensive diagnostic imaging equipment, such as CT scanners, MRIs and PET scanners.

CON laws created a permit system centered on the idea that permission to acquire and operate expensive diagnostic equipment would only be granted when there was a demonstrated need within the community for this technology. Although the approval thresholds and types of diagnostic equipment and services vary from state to state, common thresholds for approval include capital expenditures above a specific dollar amount, acquisition of equipment above a specific dollar amount, and adding or expanding a clinical service.

The time required to process a CON application varies from state to state and by type of project within a state. Timeframes in uncontested CON matters typically range from 60 or 90 days to one year. In some states, competing providers have the ability to directly or indirectly challenge the grant of a CON for certain equipment, facilities or services.

Certain third party payers, such as Blue Cross and Blue Shield of Michigan, have their own equivalent standards that apply as a prerequisite to payment for certain services. Some of these third party payer standards are called Evidence of Necessity (EON) standards and may occur in states which lack a CON program, or states in which a CON program is too weak to prevent the proliferation of what the third party payer believes to be unnecessary equipment, facilities and/or services. When considering the acquisition, expansion or replacement of diagnostic equipment, such as CT scanners, it is necessary to check with the state to see if it has a CON program and if the particular technology in question is regulated under the CON program.

Federal and State Stark Laws
Under the Federal Stark law, a physician is prohibited from making referrals for Medicare or Medicaid payable Designated Health Services (DHS) to an entity with which the physician or a member of his or her immediate family has a financial relationship, unless an exception applies.

DHS include:
- Clinical lab
- Physical therapy
- Occupational therapy and speech pathology services
- Radiology, including CT scans, MRI, x-ray and ultrasound services
- Radiation therapy
- DME
- Parenteral and enteral nutrients

- Prosthetics and orthotics
- Home health services
- Outpatient prescription drugs
- Inpatient and outpatient hospital services

Penalties for violating the law can be severe. They include:
- Denial of payment
- Refund of payment
- Imposition of civil monetary penalties

Notably, the Federal Stark law is implicated when physicians provide imaging services within their offices. Once Stark is triggered, the financial relationship(s) must then fall within an applicable exception.

The most practical exception for in-office referrals is the in-office ancillary services exception. This exception is designed to protect the in-office provision of certain DHS.

In order to utilize this exception, a group practice must first qualify as group practice as defined by the Federal Stark law. The in-office ancillary exception exempts services personally provided by the referring physician, a physician who is a member of the same group practice as the referring physician, an individual that is supervised by the referring physician, or if the referring physician is in a group practice, by another physician in the group practice, provided that the supervision complies with all of the Medicare payment and coverage rules for the services.

Under the in-office ancillary services exception, DHS must be furnished to patients in the same building where the referring physicians provide their regular medical services, or in the case of a group practice, in a centralized building. These location rules were designed to give physicians and group practices an important opportunity to provide bona-fide in-office ancillary services to their patients, while at the same time preventing group practices from using the exception to operate self-referred DHS enterprises.

A group practice can satisfy the location requirement by either meeting the "same building" test or the "centralized building" test. The Stark regulations contain three alternative "same building" tests. Under all three tests, referring physicians or group practice members must have offices in the building that are normally open to their patients a requisite number of hours per week. All three tests also require that the physician regularly practices medicine and furnishes physician services for a minimum number of hours per week in that office.

Lastly, the in-office ancillary services exception requires that the services be billed by the physician performing the service (or by the physician's group practice), by an entity wholly-owned by the group practice, or by a third party billing agent.

Many state laws also contain versions of the Federal Stark law. For example, some states have legislation that mirrors the Federal Stark law but apply the law to all sources of payment, not just Medicare or Medicaid. These laws are often referred to as "mini" Stark laws. Physicians and group practices providing diagnostic imaging services through their offices must review their state's mini Stark law to determine whether their practice is in compliance with these laws.

State Radiation Regulations
Each state has laws and agencies which regulate the proper use of radiation, radioactive material and environmental radioactive material. State involvement in radiation regulation has customarily focused on protection programs to ensure the safety of radiation producing machines such as x-ray equipment and CT scanners.

States maintain a registry of radiation emitting equipment in professional offices, diagnostic testing facilities and hospitals. These facilities and equipment are subject to periodic inspection to ensure compliance with state laws and standards.

In most states, the scope of radiation regulation has been expanded to include setting qualifications for technologists, monitoring exposure to radiation doses, evaluating film processing and machine performance, and imposing record keeping and reporting requirements on operators.

Most recently, the scope of radiation protection programs has expanded to include collaborative efforts with equipment manufacturers and users of radiation-producing equipment to reduce radiation doses, improve diagnostic methods, provide increased protection to workers, minimize errors and improve overall radiation safety. In addition, state radiation regulatory agencies work with professional societies and trade associations to develop consensus on emerging issues, such as the legality of preventative full-body CT scans without an order or prescription. States coordinate and cooperate with United States federal agencies.

Two of the most important federal agencies are:
- Federal Drug Administration (FDA), which regulates the testing and use of medical equipment, and,
- National Institute of Standards and Technology (NITS), which establishes physical radiation standards and standards for radiation measurement
  - The Physics Laboratory of NITS establishes physical standards, conducts research on radiation and collaborates with industry on applications of radiation
  - The Occupational Safety and Health Administration of NITS promotes radiation health and safety programs

COMPATIBILITY
with Image Guided Systems

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Patient Care with Image Guided Surgery

The advent of CT scanning offering three-dimensional images of the paranasal sinuses along with the knowledge gained through anatomical research resulting in the adoption of Functional Endoscopic Sinus Surgery (FESS) has brought tremendous improvement in the care of patients with paranasal sinus disease. The persistent problems with this surgery, despite the advancements made, were that the surgeon had to rely on his own experience, encountered visual landmarks, and had crude distance measurements in order to perform FESS.

In theory, surgeons had the correct tools and correct anatomy; however, patients were often incompletely treated. For example, disease that was present in the sinuses could not be eradicated due to difficulty locating the diseased areas. In addition, problems could arise from disorientation during surgery or absence of landmarks resulting in serious and even fatal complications such as orbital injury, CSF leak, carotid artery injury, etc.

Image Guidance Systems (IGS) arose in the 1990s as the next logical extension of CT scanning and FESS. This was made possible by improvements in computer technology and the ability to precisely map a point in three-dimensional space. These two advances have allowed surgeons to integrate a CT scan with a live patient and use a series of probes or instruments to determine the exact location of a point inside a patient's nasal cavity or sinuses. This is demonstrated on their prior CT scan images live on a computer screen in three dimensions during surgery allowing the surgeon to have a great deal of confidence in proper anatomic location. A more complete resection of diseased tissue is allowed, helping to prevent complications by appropriately avoiding problematic or dangerous areas. This technology is not limited to the paranasal sinuses but is also utilized in neurosurgery and orthopedic procedures to accomplish the same goals.

IGS's utilize CT scan data and orient the patient to the CT scan intraoperatively by using a fixed attachment to the patient's head. In some IGS's, this attachment must be present during the CT scan for the CT scan to be valid during surgery. These systems then typically require a pre-operative CT scan. Other IGS's utilize numerous data collection points typically from the contour of the patient's skin of the face. These IGS's then obviously require that all of the facial skin is visible on a CT scan, but if it is, they do not require a second scan pre-operatively.

All IGS's use the data from a CT scanner in order to function. This data is typically downloaded in DICOM format, which is a standard radiological data format, and burned to a CD-ROM. The CD is placed in the IGS just prior to surgery where the data is uploaded and utilized intraoperatively.

In-office CT scanners function very well for this purpose and have many advantages over scans performed at outside facilities (hospitals and outpatient radiology facilities):

- In-office scanners typically have the same or better resolution and image quality (i.e., function equally well in the IGS environment)
- In-office scanning allows the office to have control over how the scans are performed to make certain they are properly done (i.e. no second scan for patient)
- The office has the actual scans circumventing numerous potential perioperative problems
- The office can download the scans to CD whenever needed. Often problems can arise with obtaining the data appropriately formatted onto a CD from outside facilities.

In-office CT scans give surgeons numerous advantages over outpatient radiologic facility or hospital CT scanners when utilized with IGS's. Some in-office scanners may allow for future improvements in IGS technology and resolution.

MEDICAL PHYSICS
and Radiation Safety

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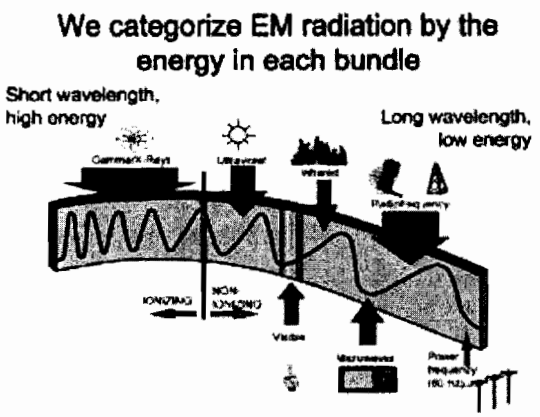
Point-of-care CT allows the ENT practice to provide standard of care CT imaging in a convenient, patient-friendly environment. Because the CT scanner uses x-rays to create the image, it is essential that the ENT practice be knowledgeable about basic radiation safety concepts and regulations that govern the use of x-rays and utilize the expertise of a medical physicist to assure safety and regulatory compliance.

Most jurisdictions require that a radiation safety officer (RSO) be identified. The RSO is the single person who is responsible to assure that the radiation is used safely and within the requirements of state regulations. An ENT physician will usually be identified as the RSO.

A Medical Physicist is a MS or PhD physicist with education and training in the use of radiation in medicine. Medical Physics societies define a qualified medical physicist as one who is board-certified in their specialty: Diagnostic Imaging Physics, Radiation Oncology Physics, Nuclear Medicine Physics or Medical Health Physics.

Some states also require licensing or registration of medical physicists. A medical physicist will help the ENT practice to understand the applicable regulations, perform acceptance testing and periodic QC testing, prepare a Radiation safety/QC Manual, and may help to answer patient's questions in general the medical physicist will assist the RSO with radiation safety and regulatory compliance.

Patients and staff will ask questions about the safety of radiation. The remainder of this chapter will help the ENT practice to answer those questions.



What is Radiation?
The term "radiation" means transfer of energy. X-rays are a form of electromagnetic radiation, such as light and heat. In electromagnetic radiation, energy is carried in bundles called "photons," which have no mass and travel at the "speed of light". The characteristics of electromagnetic radiation are determined by the amount of energy in each photon, and the degree of the effect is determined by the number of photons.

For example, we can see visible light because the rods and cones in the human eye are sensitive to the energy of light photons. With a small number of light photons, we can barely see (as in a dark room). In the presence of a large number of light photons, we reach for sunglasses.

The x-rays used in CT scanners have more energy in the photons than visible light, so they can penetrate the body and be used to create a CT image. We can't see x-rays because the rods and cones are not sensitive to photons in this energy range. The number of photons in

the CT image is determined by the machine design and the x-ray exposure protocol chosen by the physician. CT scanners use the lowest number of photons that will produce the high-quality image needed for diagnosis. Too little radiation will produce a noisy or grainy looking image. For safety reasons, point-of-care CT scanners are limited in the amount of radiation they can produce.

The quantity of radiation is measured in units called the Roentgen, rad, rem, gray, sievert. The term MilliRoentgen (mR) is used to describe 1/1000th of a Roentgen. There are technical distinctions between these units, but they all measure exposure or dose to a person. For our purposes, 1 mR is about equal to 1 mrem or 1 mrad – units you will encounter in this chapter.

Each of us is exposed to natural background radiation every day we are on the earth. We receive about 1 mR per day from natural background radiation caused by the sun, radioactive materials in the earth's crust, including Radon. We receive this radiation to our whole bodies every day, whether or not we receive any medical radiation.

Biologic effects of radiation can be categorized as either Stochastic or Deterministic. Scientists have calculated human radiation risk based on data from animal models and people who have been exposed to radiation through medical procedures, radiation accidents, or the Japanese atomic bomb survivors. Radiation risk is conservatively calculated using the Linear no-threshold model. Many references are available on this subject.

Radiation used in head CT scanning have never been shown to produce any health effects on patients or operators who follow the basic radiation safety rules that will be described below.

ALARA

The public has a general fear of radiation that has been largely formed by the way radiation has been depicted in movies and TV. Patient's fear of their overall health may also be redirected towards fear of radiation.

ENT facilities should be able to answer patients' questions, explaining that the chance of any radiation injury from the CT scan is much lower than the risks we commonly encounter, such as driving in a car.

In general, we assume that lower radiation exposure means lower risk from radiation. The concept of ALARA (As Low As Reasonably Achievable) dictates that the radiation exposure to all persons (patients, operators and others in the office, for example), be as low as reasonably achievable. State radiation regulations also require this concept. For example, ALARA requires that CT operators remain behind the protective lead barrier during x-ray exposure because it is reasonable to do so.

The basic principle of radiation safety is to minimize our exposure to radiation by using the lowest exposure time, the largest distance and using radiation shielding whenever possible.

Those who use radiation in their work, such as physicians and radiologic technologists who operate CT scanners, are called "Occupationally Exposed Personnel". State regulations require that the whole body exposure to occupationally exposed persons be less than 5,000 mrem per year.

Those who have a chance of receiving at least 10% of the maximum are required to wear personnel monitors (commonly called "film badges") while using x-rays. No one who follows the radiation safety rules for point-of-care CT should ever receive this 10% of the maximum permissible exposure. However, it is often a good idea to have some office personnel wear these badges, at least for the first year of operation, to document the low level of exposure.

Pregnancy and Radiation

The developing embryo and fetus has been found to be more sensitive to radiation injury than the late-stage fetus, children or adults. Each patient should be asked if there is a chance that they may be pregnant before the exam. However, the radiation dose to the embryo-fetus from head CT is only slightly above background radiation and is not a contraindication for this procedure.

Office personnel who may be pregnant have the option to declare their pregnancy in writing. Employers are required to assure that the exposure to the fetus of "declared pregnant workers" is less than 500 mrem during the entire gestation period. No one operating the CT scanner or working within the office should ever reach this level of exposure, if proper safety procedures are followed.

In most jurisdictions, x-ray machines (including CT scanners) must be registered with the state department of health or environmental protection. Compliance with radiation regulations requires a number of important steps and vary with jurisdiction. A medical physicist will assist with understanding and complying with the regulations.

UTILIZATION
and Radiology Benefit Managers

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Technological advancements in medical imaging have given physicians the ability to detect and diagnose disease in the earliest stages of development. This level of care has resulted in increased survival rates and fueled the demand for diagnostic imaging, particularly in an aging population. The number of Baby Boomers (those between the ages of 45 and 64) is expected to reach 79 million by 2010, drastically increasing the need for imaging services. As a result, diagnostic imaging is the fastest growing medical expenditure in the United States. The insurance industry is experiencing roughly a 15-35% annual increase in cost and utilization for imaging services.

In an effort to control diagnostic imaging costs, more and more health plans are contracting Radiology Benefit Management (RBM) companies to rein in the usage of high-cost imaging procedures like MRI, CT, PET scans and nuclear cardiology studies. Ultimately, the obstacles insurance companies face in today's world of imaging focus on:

- The need for a reduction in imaging costs
- An assurance of "necessity" for the imaging test
- Concern for quality of equipment and technical competency

The Methods and Motivation of RBM's

Credentialing programs, precertification guidelines, assessing providers' competency to perform diagnostic imaging services and minimizing physician self-referrals are tactics considered by RBM's to control costs of imaging. The extent of the credentialing program and precertification/utilization guidelines will depend on the particular insurance company and the particular RBM, leading to many different guidelines and criteria. While the end results vary, the common theme in all these arrangements is that RBM consulting companies effectively maximize their profit by minimizing the number of scans performed. In other words, they profit by preventing scans from being performed or by denying reimbursement for scans.

Since RBM's have a financial incentive to reduce the costs of imaging, these consultants will typically set up very restrictive credentialing guidelines, which effectively limits imaging to only a small number of select providers in an area.

Precertification can be quite restrictive as well. Requiring physicians to obtain precertification is one of the most common containment methods employed by RBM's to reduce the annual cost and usage of imaging. Doctors who order imaging tests must telephone a call center or write via the Internet to contact reviewers armed with protocols that accept or deny requests. Aggressive first-tier precertification plans have the most reliable effect on bottom lines, as they deny 1 of 5 requests. With second tier, moderate management, 1 in 10 requests are denied and in the third tier, no requests are denied.

In many cases, the administrative cost of attaining precertification can be substantial to a provider. On-site imaging, with precertification, can provide an opportunity to offset this additional administrative cost by providing an added revenue stream, especially at a time when reimbursements are declining.

Though many insurers and their RBM's accept in-office scanning and self-referrals, it is clear that crusaders are against it.

Radiology Benefit Management Players
The leading Radiology Benefit Management companies include:

- American Imaging Management (AIM): http://www.AmericanImaging.net/
- CareCore National: http://www.CareCoreNational.com/
- MedSolutions Inc.: http://www.MedSolutionsInc.com/home.htm
- National Imaging Associates (NIA): http://www.NiaInc.com/index.html
- HealthHelp: http://www.HealthHelp.com

Different RBM's, Different Methods
No doctor as a rule likes the concept of utilization management since it second-guesses the doctor and wedges itself between the doctor and his/her patient. Although the relationship between physician and the RBM can be difficult at times, once precertification for scanning is authorized, reimbursement is assured. Further, the Payor is assured that over-utilization of in-office and off-site scanning is moderated.

The referring doctor is required to obtain precertification whether referring the patient to an off-site scanning facility or performing the scan himself. Some RBM programs have precertification requirements for imaging, which can be very time-consuming and onerous for the referring physician, while other RBM programs rely merely on an educational process to dissuade unnecessary scanning.

An article in Managed Care Week, January 15, 2007, demonstrates these two differing philosophies. The approach of American Imaging Management (AIM) is to dissuade physicians from ordering unnecessary scans, but they won't refuse to authorize or pay for the studies. "We're not going to be in the business of denying scans, even if the best-practice pathway or best-practice recommendation isn't what the provider ultimately decides to do," says Pat Courneya, M.D., the plan's associate medical director. "We're confident an educational process will be nearly as effective as some of the more onerous prior-authorization programs...at least, effective enough for us to achieve substantial improvement." AIM requests "a few pieces of information," Courneya said, including patient demographic data, the test being ordered, clinical indications and some underlying patient medical information. "Most of the studies get approved based solely on that interaction."

National Imaging Associates (NIA) on the other hand is a strong proponent of requiring physicians to obtain preauthorization before ordering imaging services. It is their belief that, left unmanaged, insurers' costs for high-tech imaging services will increase 20% per year, says Bob LaGalia, CFO of National Imaging Associates (NIA). NIA operates RBM programs that can reduce the trend to 2% to 3%, he said.

A New Trend
Some insurance companies are substituting the role of the RBM with the use of accreditation and utilization guidelines for imaging facilities. The guidelines for accreditation are being drafted by independent, third-party organizations so that decisions of necessity and appropriateness remain somewhat objective.

Summary
As imaging technology continues to advance, and the population continues to age, the demand for imaging services will most certainly increase. In the face of these advancements, insurers will seek out new avenues and strategies to reduce their overall costs. With a movement toward accreditation, RBM's will likely shape their strategies to incorporate the trend or be left behind in favor of the independent accreditation system, a potentially less biased and less costly route for the insurer.

ACCREDITATION

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In an attempt to manage costs and adopt uniform standards of quality and safety by providers of CT scanning services, many insurance companies (such as United Healthcare) are taking steps to require accreditation by every facility seeking reimbursement for CT scanning services.

This call for accreditation is a perfect opportunity for you as Administrators to help your doctors position themselves on the forefront of their specialty. By obtaining accreditation for your facility, you will be ensuring that imaging within your practice is performed by only those qualified to do so and that the imaging equipment used meets minimum quality and safety standards.

While the accreditation process may take several months, it will be well worth the investment for your practice. It will minimize or eliminate hassles with getting reimbursed and provide a credible stamp of approval for your imaging services with referring physicians, third party payers, and patients.

A number of Medical Physics consulting groups offer services that help imaging providers obtain accreditation. Xoran will assist our customers in finding and engaging a Medical Physics group that will make this process as easy as possible.

In this chapter, we will first present an overview of the business of medical imaging services, and its rapid growth in the recent years. This will help us understand the context in which the idea of accreditation for all imaging facilities was born. We will then discuss the concerns that this rapid growth has raised for third party payers and the strategies that they may deploy to control the costs and quality of the services. Next we will discuss the benefits you will bring to your doctors and your practice by obtaining accreditation for your facility. Lastly, we will briefly touch upon the steps you need to take to start the accreditation process.

Background: Increased Use of Imaging

Medical imaging is a growing segment of healthcare. It is now an essential diagnostic tool for virtually all major medical conditions and diseases, and is used by a wide range of medical specialists, from cardiologists to oncologists, from internists to ENT physicians, and everyone in between.

More and more physicians are integrating some form of medical imaging into their standard diagnosis and treatment protocols for more medical conditions, in more diverse settings, and to more patient groups. This results in better patient care and outcomes and commensurate cost savings through less-invasive care requirements, quicker recovery, and fewer complications.

The increased utilization of imaging has translated into the increased cost to third party payers and Medicare. The cost of imaging services in the U.S has been growing at 15-35% annually. It increased by 44% between 1999 and 2001 and went from $5.7 billion to $9.3 billion between 1999 and 2003.

Naturally, such a high and rapidly growing component of cost for insurance companies is a source for their concern. Also, with the expansion of imaging into new settings, there is a concern about the safety and quality of the imaging services being performed.

Insurance Companies' Responses to the Increased Cost of Medical Imaging

Insurance companies have responded to this increased cost and potential decrease of quality of imaging by trying to control which facilities can perform imaging ("credentialing") and when it is appropriate to order an imaging exam ("appropriateness criteria" and "pre-certification"). An insurer can set up the credentialing and appropriateness criteria using a "middleman" consultant called "Radiology Benefit Management" (RBM) company or by requiring accreditation from an independent third party credentialing organization or medical society.

Radiology Benefit Management Consultants

Some insurance companies outsource their credentialing guidelines and pre-certification administration to a middleman consulting company, typically referred to as a Radiology Benefit Management (RBM) company.

The flavor of the credentialing program and pre-certification/utilization guidelines will depend on the particular insurance company and the particular RBM, leading to a hodge-podge of different guidelines and criteria. While the end results vary, the common theme in all these arrangements is that the RBM consulting companies effectively maximize their profit by minimizing the number of scans performed. In other words, they profit by preventing scans from being performed or denying reimbursement for scans.

If credentialing or appropriateness criteria and pre-certification are performed by Radiology Benefit Management companies, you as a provider will be at a disadvantage. Because RBMs are financially rewarded for denying imaging-related care, they will be inherently biased against you. You can read more about RBMs in this booklet's chapter titled "Utilization and Radiation Benefit Managers."

Independent, Third-Party Accreditation Organizations and Medical Societies

Some insurance companies, such as United Healthcare, have opted to cut out the middleman by bypassing RBMs (with their attendant fees), and instead chosen to rely on independent, third-party organizations and medical societies to define and administer accreditation and utilization guidelines.

Currently, two recognized organizations provide medical imaging accreditation: the **American College of Radiology (ACR)** and the **Intersocietal Accreditation Commission (IAC)**. As medical imaging continues to expand, the need to ensure quality and safety standards will expand right along with it. Therefore, we may see more independent accreditation organizations develop in the future.

Because these organizations are not paid directly by insurance companies to minimize the cost of imaging like RBMs, they do not have the same inherent financial bias against approving imaging studies. As a result, they are much more appropriate bodies to conduct credentialing (although ACR's guidelines strongly favor Radiologists as proper interpreters of scans). A number of other medical specialties and societies have developed appropriateness criteria for their respective imaging services, such as the American College of Cardiology (http://content.onlinejacc.org/cgi/reprint/48/7/1475). However, no similar guidelines and criteria have been developed by the ENT Academy or other ENT societies.

What Should AAO-HNS and AOA Members Do?

We encourage the AOA, ENT Academy, ARS, and other related medical societies to proactively work on two fronts to ensure that the highest quality of care is provided to their patients in a safe and timely manner:

- Support accreditation through independent, third party organizations whether it is ACR, IAC, or any other organization; and,
- Actively work on establishing proper utilization guidelines for ENT scanning

Accomplishing these two things will put the physician community in the driver's seat so they can continue to deliver high quality patient care and spend less time worrying about random and oftentimes meaningless requirements imposed upon them from various payers and various RBM companies.

ENT physicians are the experts in sinus and ear disease. They should be in the forefront defining and safeguarding the proper standards for head and neck CT.

ACR and IAC in a nutshell

ACR

ACR CT accreditation program has been in place for about 5 years now and to date only a small fraction of imaging facilities in the country has applied for accreditation. You can search for accredited facilities in your area at: http://www.acr.org/accreditation/search.html.

The application will likely take 6-8 months to be processed. ACR application fees are around $2,100 and medical physics consulting fees around $1,000-2,000.

To comply with existing ACR accreditation standards, a typical physician's practice will likely need to outsource interpretation of CT scans to radiologists. This can be done through teleradiology: (http://xorantech.com/contentHTML/teleradiology.php) and outsource the oversight of a quality control program to a medical physicist.

Intersocietal Accreditation Commission (IAC)

Representing a milestone in the evolution of point-of-care CT imaging, IAC has released guidelines for CT accreditation. The program recognizes and will accredit private physicians to perform and read CT scans at the point of care. The Intersocietal Accreditation Commission (IAC) has been in existence since 1990 and has established accreditation programs for PET, MRI, and CT, among other modalities.

The application process begins with the submission of an assessment of daily operation, laboratory operation data, and several case studies. This information is then confidentially peer-reviewed by a group of qualified physicians and technologists who make up the ICACTL Board of Directors. This is a cooperative process aimed at providing guidance for CT facilities to meet the expectations outlined in the Standards.
For more info on IAC accreditation, please visit:
http://www.icactl.org/icactl/index.htm

Now that the IAC CT accreditation program has been announced, Xoran MiniCAT™ customers have a sure pathway to officially demonstrate the quality of their services to patients, staff, and insurance payers. Xoran will help your facility make this happen.
Email accreditinfo@xorantech.com to find out how.

Xoran encourages administrators to urge your doctors to support the Academy's efforts to secure accreditation options both through the ACR and the IAC.

Immediate Next Steps to Get Accredited

The first step is to create a good working relationship with a Medical Physics provider if you have not already done so. You will need his/her services for either ACR or IAC accreditation. If you choose to go with ACR accreditation, you will also need to form a good working relationship with a teleradiology provider if you have not already done so. The Medical Physicist will then guide you through the accreditation process. If you choose to go with IAC accreditation or would like to compare the two programs, you can visit http://www.icactl.org/icactl/index.htm for more information.

For MiniCAT™ users, Xoran will provide a package to help perform necessary tests for accreditation, will assist customers in finding a qualified Medical Physics provider and teleradiologist certified to read scans in your State.

We encourage all Xoran customers that are interested in accreditation to send an email to accreditinfo@xorantech.com to receive updates on accreditation.

Additional Information

The ENT and Allergist community can learn from other medical specialties that have been working on imaging issues for several years now.

The American College of Cardiology (ACC) is working steadily in support of in-office scanning:
http:www.acc.org/advocacy/advoc_issues/rc_imgservicesref.htm

The American Academy of Orthopedic Surgeons is also investing significant efforts in educating payers about the benefits of in-office imaging:
http://www.aaos.org/about/papers/position/1132.asp

The Effect of Imaging Guidelines on the Number and Quality of Outpatient Radiographic Examinations

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Jonathan Sunshine[3]
Donald Grossman[4]
Leslie Adams[1, 2]
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OBJECTIVE. A significant percentage of outpatient diagnostic radiology is performed by nonradiologists. Studies have shown nonradiologists have higher utilization and cost, as well as quality problems. We sought to determine if, in a managed care environment, a set of guidelines limiting imaging privileges of nonradiologist physicians could decrease imaging costs while ensuring that equipment and personnel providing imaging were of the highest quality.

MATERIALS AND METHODS. We determined the number and type of radiographic imaging studies performed the year after these guidelines were set in place (1997) and compared these findings with those of the year before the guidelines were established (1995) and with preguideline trends. We established quality criteria and, based thereon, inspected imaging offices.

RESULTS. The number of radiographic examinations per 1000 enrollees decreased 20–25% from the previous trend. Nonradiologists' share of the total fell from 39% to 15%. No deficiencies were found in the inspection of five radiologists' offices, whereas significant deficiencies of equipment, equipment maintenance, or documentation of the examinations performed were found in 78% of nonradiologists' offices. None of the quality indicators monitored by the health plan showed significant change.

CONCLUSION. Specific guidelines can effect change in the location and number of radiologic examinations performed, with an improvement in the quality of the studies and a decrease in radiation dose and cost. No decline in quality of care appears to result, despite claims by opponents to such changes that widespread serious quality impairment would occur.

The portion of society's resources devoted to health care has been the subject of significant debate in the United States for decades. In 1965, the United States devoted 5.9% of its gross national product to health expenditures. By 1995, this figure had risen to approximately 14%, and this increase had a significant impact on employers and the government. If current projections hold, it is estimated that expenditures will double to $2.3 trillion (United State dollars) or approximately 17% of the gross national product by 2007 [1]. Methods of curbing this significant increase have been sought, and the results have changed the face of American medicine. The rapid emergence of managed care as a majority health insurer for Americans has been heralded as the reason for some of the recent slowdown in the rise of health care costs. Managed care claims credit for eliminating many of the excesses of the system. However, with the increasing age of our population and their health care needs as well as the continued development of new technology, health care costs now seem to be once again increasing at a rate higher than current inflation. Although managed care has helped the system curtail costs, there have been negative effects related to physician choice, accessibility, and the accountability of health plans. Various techniques to decrease health care costs have been developed. One is to decrease the benefits to which a patient is entitled; another, to decrease the payment for each unit of service. Yet another technique is to institute a utilization management program, with the expectation of eliminating unnecessary services.

Diagnostic radiology services constitute a significant portion of both inpatient and outpatient costs. It has been estimated that radiology services use approximately 8% of the health

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care dollar paid to physicians. Many studies have shown that approximately 50% of nonhospital radiology services are performed in a nonradiologist's offices [2–4] and that nonradiologic physicians who have an X-ray machine in their office perform as many as four to five times as many examinations per patient as physicians in the same specialties seeing patients with the same problems but who refer their patients to radiologists for imaging. [5–7]. Other studies have suggested that many radiologic examinations performed in nonradiologists' offices are of poor diagnostic quality and are interpreted incorrectly [8–11].

Materials and Methods

A large health maintenance organization in the northeastern United States decided to establish an effective radiology utilization program based on several objectives. The organization's goals were to reduce utilization of imaging tests that were noncontributory to patient treatment and that thus were inappropriate and, at the same time, to deliver the most cost-effective, high-quality imaging product. The health maintenance organization wanted to address the problems of volume, cost, and quality and to ensure that the equipment and personnel producing and interpreting a radiographic or imaging study were of the highest quality.

The health plan established a radiology advisory committee that consisted of physicians drawn from various academic and community practices throughout the state. The advisory committee is a multispecialty committee consisting of radiologists, a surgeon, an internist, a primary care physician, an orthopedic surgeon, an obstetrician or a gynecologist, and the medical director of the health plan. These physicians were chosen on the basis of board certification in their field, volume of practice, volume of radiographic examinations performed, and, in some cases, individual physician experience. This committee eventually established the guidelines regarding who could perform imaging studies in their office practice. Imaging studies that could be performed by nonradiologists were carefully delineated on the basis of each physician's specialty and demonstrated expertise.

These expertise- and relevance-based guidelines limited the amount of imaging permitted to be performed by nonradiologists. The guidelines removed all imaging privileges from gastroenterologists, general surgeons, nephrologists, neurosurgeons, oncologists, pediatric surgeons, and physiatrists. Cardiologists were limited to performing chest radiography, echocardiography, and nuclear cardiology, and pulmonologists could perform only chest radiography. The only imaging an obstetrician–gynecologist could perform was obstetric and gynecologic sonography; breast sonography was specifically excluded. If an obstetrician's office obtained United States Food and Drug Administration (FDA) approval for mammography, only the technical component of a screening mammogram would be paid by the health maintenance organization. The images had to be sent to a radiologist for interpretation. Orthopedic surgeons were permitted to perform conventional orthopedic radiography but were excluded from performing and interpreting all CT and MR procedures. Otolaryngologists were permitted to obtain conventional radiographs of the sinuses and nasal bones, but soft-tissue radiographs of the neck and cervical spine were excluded. Podiatrists could perform and bill only for radiography of the foot, and rheumatologists could perform only extremity radiography; they were excluded from performing spine radiography.

Primary care physicians, including family practitioners, internists, and pediatricians, were permitted to obtain only chest, rib, and extremity radiographs and were paid only for the technical component. It was required that these images be interpreted by a radiologist who would then bill for the professional component.

The second aspect of the program was to evaluate and ensure the technical quality of the imaging performed. A technology assessment questionnaire (Fig. 1) was sent to all providers who requested imaging privileges. This questionnaire required details of many aspects of the imaging being practiced, including a description of the imaging equipment present in the office, its year of manufacture, its service records, and a physicist's evaluation of the radiology equipment including its output and radiation dose to a patient. The questionnaire inquired about the availability of quality assurance programs (e.g., whether demographic labeling of a radiograph was performed routinely and whether there was a written radiology report for each imaging examination performed). Another requirement was that only licensed technologists could perform radiography. Patient safety programs—for example, whether a patient was questioned regarding pregnancy status—had to be in place. The health plan required that practices performing mammography have FDA approval. Physicians who wished to perform sonographic examinations had to be accredited by the American Institute of Ultrasound in Medicine, the American College of Radiology, or, in the case of vascular sonography, by the Intersocietal Commission for Accreditation of Vascular Laboratories.

Four hundred fifty-two questionnaires were distributed and 411 completed questionnaires were returned to our office for a return rate of 91%. We then inspected a representative group of radiology offices, and we attempted to inspect approximately 25% (100) of the nonradiology offices at which imaging studies were performed. Because of various scheduling problems we could inspect only 92 of

PROVIDER INFORMATION

Please complete this form for each practice location that provides diagnostic imaging services and one Assessment Checklist for each equipment location.

Please type or print information.

Legal Practice Name: _____

Group Practice Tax ID Number: _____

****Please fill out a separate Application/Checklist for each Imaging Site Location****

Imaging Site

Site Name / D.B.A.: _____
Address: _____ Suite: _____
City, State, Zip code: _____
Phone: _____ Fax: _____

____ Equipment Only ____ Billing and Equipment

Billing Site

Site Name / D.B.A.: _____
Address: _____ Suite: _____
City, State, Zip code: _____
Phone: _____ Fax: _____

____ Billing Only ____ Billing and Equipment ____ Billing Service

Imaging Site Demographics

What is your patient volume for diagnostic imaging per month? _____
What is your maximum patient volume for diagnostic imaging per month? _____
Office Manager: _____
Chief Technologist: _____
Document Prepared by: _____

Fig. 1.—Form shows second page of technology assessment questionnaire. This questionnaire requires provider to respond to questions regarding imaging equipment, personnel, and quality assurance programs in each office. D.B.A. = doing business as.

these 100 offices. The 100 offices selected for inspection were those at which the highest number of imaging studies were performed per month. They were inspected by registered radiology technologists who used a checklist to evaluate each specific facet of the inspection and were required to complete a questionnaire about each office. Evaluation of parameters such as quality of the imaging study, storage and handling of films, patient demographic information on the film (patient name, age, date of examination), and the presence of a report on each imaging study was part of the inspection performed by the technologist (Fig. 2).

Only outpatient radiologic examinations were studied in our research. This article addresses only radiography, essentially the only technique aside from sonography that nonradiologists perform in large volume. CT, MR imaging, sonography, and nuclear medicine studies were specifically excluded. We recognize the importance of these studies on radiology expenditures and their place in the changing patterns of imaging examinations used to work up specific disease entities; they are presently being studied and will be the subject of a separate analysis. Outpatient examinations were included in our study regardless of whether they were performed in a private office, imaging center, multispecialty clinic, or hospital. Data were gathered from billing statistics. Each procedure is identified by a specific *Current Procedural Terminology* code [12] and there had to be an appropriate *International Classification of Diseases Indication* [13] for the study. Also, the name of the referring physician as well as that of the physician performing the study and both physicians' specialty were noted. Data were obtained from the HCFA-1500 (Health Care Financing Administration) claim form that was sent to our office for payment of the imaging study.

Our analysis was based on the number of examinations per 1000 enrollees. Because the health plan was growing and the number of enrollees rose during our study years, comparisons of simple counts would not be valid.

The health plan's data for the calendar year before we assumed responsibility for managing radiologic studies (1995) were compared with data for the calendar year after our program had been put into effect (1997). (We assumed responsibility for the health plan in 1996.) This gave us detailed data before our initiation of this program and a complete year's data following, thus avoiding start-up problems. Comparison of the enrollees on the basis of age and sex was undertaken. There was no significant change in the age or sex distribution of the patient population between study years. This was important to study because the number of enrollees rose from 125,000 to 162,000. A change in age or sex distribution of the population could affect radiology utilization. For 1993 and 1994, we had limited access to data that included only the total number of examinations performed and the number of examinations per 1000 enrollees. We used these 1993 and 1994 data to estimate the utilization trends that would have been expected to continue if our program had not been instituted.

RADIOLOGY INSPECTION CHECK LIST

PHYSICIAN NAME: _____ GROUP NAME: _____

ADDRESS: _____ COUNTY: _____

DATE: _____ SURVEYOR: _____

		YES	NO	N/A
1.	Radiology equipment inspected within the past twelve (12) months?			
	A. X-RAY EQUIPMENT:			
	a) Date: _____ By: _____ Physicist _____ Service Engineer _____ Other (please specify)			
	b) Deficiencies corrected within the past twelve (12) months?			
	B. ULTRASOUND EQUIPMENT			
	a) Date: _____ By: _____ Physicist _____ Service Engineer _____ Other (please specify)			
	b) Deficiencies corrected within the past twelve (12) months?			
	C. NUCLEAR IMAGING EQUIPMENT (Dose Calibrator)			
	a) Date: _____ By: _____ Physicist _____ Service Engineer _____ Other (please specify)			
	b) Deficiencies corrected within the past twelve (12) months?			
2.	Program for exposure of women of child-bearing age			
	A. Program/protocol in place to prevent x-ray exposure for women of child-bearing age?			
3.	Patient / Employee Safety			
	A. Office has current OSHA manual?			

Fig. 2.—Form shows page one of three-page inspection document. This document details inspectors' findings regarding equipment service records, patient safety, image quality, and reporting methods. N/A = not applicable, OSHA = Occupational Safety and Health Administration.

Results

Initially, there was considerable unhappiness created by the restriction of physician privileges. Many physician groups insisted that the guidelines would negatively impact their ability to care for patients. After the first several months, it became apparent that these guidelines had not caused significant hardship, and most complaints subsided. All quality-of-care measures charted by the health plan, including those mandated by accreditation from the National Committee for Quality Assurance and those required by the Health Care Financing Administration, were unchanged by the institution of our guidelines. Specifically, there was no significant change in the per enrollee number of hospital days, in emergency department visits, or in quality-of-care complaints by members. In areas such as maternity care management, diabetic care, asthma care management, and all other specific clinical care practices monitored by the health plan, no significant changes occurred.

In 1993, 22,350 radiographic examinations were performed, which is a rate of 226 examinations per 1000 enrollees. In 1994, 30,071 examinations were performed, which is a rate of 257 per 1000. In 1995, of 34,436 radiographic examinations were performed, for a rate of 269 per 1000. In that year, 20,906 examinations, or 163 per 1000, were performed by radiologists and 13,530 (39% of the total), or 105 per 1000, were performed by nonradiologists. In 1997, 38,912 radiographic examinations were performed, for a rate of 253 per 1000. Of the examinations in 1997, 32,970 or 214 per 1000 were performed by radiologists and only 5942 (15%) or 39 per 1000 were performed by nonradiologists. If we directly compare the

1995 data with the 1997 data, a 6% decrease in the number of radiologic examinations per 1000 examinations performed is revealed; a 31% increase in the number of examinations per 1000 enrollees performed by radiologists and a 63% decrease in those performed by nonradiologists are also revealed.

Another comparison reveals that in the years preceding the institution of this plan, radiology services per 1000 enrollees increased approximately 5–10% per year. In 1997, the number of radiographs per 1000 decreased by approximately 20–25% from the number expected if the trend had continued (Fig. 3).

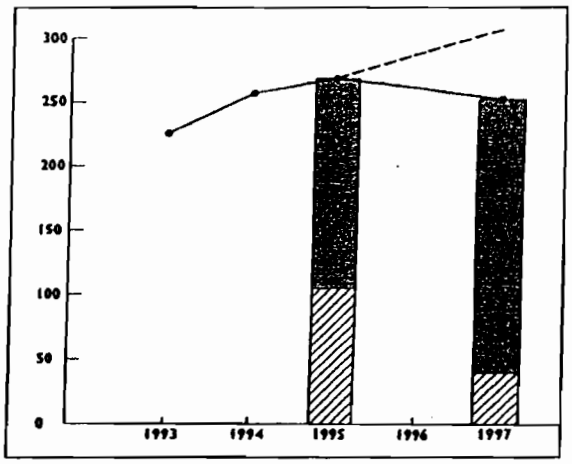

Fig. 3.—Graph shows radiographs per 1000 enrollees. Once plan was instituted, total (*solid line*) decreased 20–25% below previous trend (*dashed line*) and 6% in absolute terms below preplan year. Area with diagonal lines = radiographs obtained by nonradiologists, gray area = radiographs obtained by radiologists.

For each anatomic area, a marked increase in the percentage of imaging examinations performed by radiologists and a marked decrease in that of imaging examinations performed by nonradiologists were also revealed. For example, 96 per 1000 chest radiographs were obtained in 1995, 29% of which were obtained by nonradiologists. In 1997, 104 per 1000 chest radiographs were obtained, with 15% obtained by nonradiologists. These findings indicate a 29% increase in chest radiographs per 1000 obtained by radiologists and a 43% decrease in those obtained by nonradiologists. Even larger changes occurred in examinations of the lumbar spine. In 1995, 10.4 per 1000 examinations were performed, 35% of which were performed by nonradiologists. In 1997, 9.6 per 1000 examinations of the lumbar spine were performed with only 5% performed by nonradiologists. Overall, a decrease in spine examinations of 7% per 1000 was seen; a 35% increase in spine examinations performed by radiologists and an 86% decrease in those performed by nonradiologists occurred. Similarly, of extremity examinations, 11.1 per 1000 wrist examinations were performed in 1995. Of these, 46% were performed by nonradiologists. In 1997, 7.9 per 1000 were performed, only 9% of which were performed by nonradiologists. Overall, a 29% decrease in the number of wrist examinations performed per 1000, with a 20% increase in those performed by a radiologist and an 87% decrease in those performed by nonradiologists (Table 1).

Our technical assessment questionnaire and the follow-up inspection also revealed important findings. Although we examined only five radiology offices, no significant deficiencies were encountered in any of these offices. We then made the assumption that continuing to inspect radiology offices would not be beneficial because they routinely had their equipment inspected, issued a report on each imaging study, and had appropriate patient demographic information on each radiography report and on each image. They also routinely used technologists to perform the radiographic examinations, and all offices had a quality assurance program in place.

Of the 92 nonradiologist offices inspected, 10% had not had their equipment inspected within the previous 12 months. Nine percent of the offices that had deficiencies identified by either a physicist or service personnel had not corrected the deficiencies at the time of the survey. Sixteen percent of the offices did not have the images identified using right-sided or left-sided markers. Sixty-two percent of the offices inspected did not issue a formal radiology report of the imaging procedure performed; a note was made in the chart cryptically stating that a radiograph was either positive or negative, but no formal report was available. This seriously limited audit and quality assurance initiatives.

After tabulation of the deficiencies identified on our inspection, a certified letter was sent to each office requiring that the deficiencies be corrected within 90 days. We required that quality assurance programs be instituted if they were not in place and that all imaging studies have a formal report, either legibly handwritten or typed, and placed in the patient's chart. Of the 92 nonradiologist offices inspected, 72 offices, or 78%, had a significant deficiency identified. If the absence of a report is excluded as a criterion, 32% of the offices had serious deficiencies.

Discussion

There is an extensive literature showing that nonradiologist physicians who have a financial interest in the diagnostic imaging of their patients order more imaging than colleagues in the same specialty who do not have this type of financial interest [3, 5–7, 14–16]. This finding holds regardless of whether the nonradiologist has a financial interest in an outside imaging facility to which he or she refers patients or the financial interest consists of imaging that the nonradiologist performs in his or her own office. The finding also holds regardless of whether data are compared on the basis of the patient's presenting complaint or the data are an aggregate for all patients seen by a physician. Similar findings also hold for other ancillary services, such as physical therapy [17].

Given the ubiquity of this finding and the large differences in imaging frequency typically observed, the usual conclusion has been that financial self-interest is an important cause of the higher imaging utilization of self-referrers. However, because almost all studies are comparisons of two different sets of physicians, rather than comparisons of one set of physicians under two different financial incentives, other explanations are possible. For example, it is possible that physicians whose practice style includes much more imaging (perhaps because they are less inclined to rely on history and physical examination than colleagues) acquire imaging equipment because they naturally use it.

Our study is one of few that directly tests the role of financial incentives. Our plan halted reimbursement to nonradiologists for some forms of imaging but left them entirely free to refer their patients to radiologists if they believed the imaging they had been conducting on their patients was needed.

TABLE 1 Detailed Analysis of Radiographic Procedures: 1995 Compared with 1997

Current Procedural Terminology Codes	Description	1995						1997						Comparison of 1995 and 1997 Values (% per 1000)		
		Total Units	Per 1000	Performed by Radiologists	Per 1000	Performed by All Others	Per 1000	Total Units	Per 1000	Performed by Radiologists	Per 1000	Performed by All Others	Per 1000	Total Units	Performed by Radiologists	Performed by All Others
71010	Chest (one view)	3561	27.8	3209	25.1	352	2.7	4862	31.6	4800	31.2	62	0.4	14	24	−85
71020	Chest (two views)	12,327	96.2	8721	68.1	3606	28.2	16,027	104.1	13,543	88.0	2484	16.1	8	29	−43
73620	Foot (two views)	1712	13.4	74	0.6	1638	12.8	1760	11.4	292	1.9	1468	9.5	−14	228	−25
73630	Foot (complete)	2320	18.1	1128	8.8	1192	9.3	2781	18.1	1924	12.5	857	5.6	0	42	−40
73130	Hand (complete)	1369	10.7	994	7.8	375	2.9	1421	9.2	1285	8.3	136	0.9	−14	8	−70
73610	Ankle (complete)	1877	14.7	1118	8.7	759	5.9	1740	11.3	1641	10.7	99	0.6	−23	22	−89
73600	Ankle (two views)	278	2.2	40	0.3	238	1.9	184	1.2	150	1.0	31	0.2	−45	212	−89
72110	Spine (lumbarsacral)	1326	10.4	867	6.8	459	3.6	1485	9.6	1409	9.2	80	0.5	−7	35	−86
72050	Spine (cervical)	926	7.2	650	5.1	276	2.2	1166	7.6	1087	7.1	79	0.5	5	39	−76
73030	Shoulder	1417	11.1	617	4.8	800	6.2	1145	7.4	1024	6.7	121	0.8	−33	38	−87
73080	Elbow (complete)	471	3.7	294	2.3	177	1.4	571	3.7	538	3.5	33	0.2	1	52	−84
73090	Forearm (two views)	421	3.3	233	1.8	188	1.5	398	2.6	384	2.5	14	0.1	−21	37	−94
73100	Wrist (two views)	591	4.6	87	0.7	504	3.9	206	1.3	179	1.2	27	0.2	−71	71	−96
73110	Wrist (complete)	1417	11.1	767	6.0	650	5.1	1210	7.9	1107	7.2	103	0.7	−29	20	−87
73060	Humerus	188	1.5	104	0.8	84	0.7	203	1.3	198	1.3	5	0.0	−10	58	−95
73510	Hip (complete)	804	6.3	439	3.4	365	2.8	848	5.5	778	5.1	70	0.5	−12	47	−84
72170	Pelvis (anteroposterior only)	665	5.2	396	3.1	269	2.1	850	5.5	804	5.2	46	0.3	6	69	−86
73550	Femur	197	1.5	139	1.1	58	0.5	220	1.4	216	1.4	4	0.0	−7	29	−94
73560	Knee (two views)	1183	9.2	353	2.8	830	6.5	635	4.1	530	3.4	105	0.7	−55	25	−89
73562	Knee (three views)	821	6.4	397	3.1	424	3.3	650	4.2	559	3.6	91	0.6	−34	17	−82
73590	Tibia and fibula	565	4.4	279	2.2	286	2.2	550	3.6	522	3.4	27	0.2	−19	56	−92
Total		34,436	268.9	20,906	163.2	13,530	105.6	38,912	252.7	32,970	214.1	5942	38.6	−6	31	−63

Note.—Codes are from [12].

We found this change produced a decline in imaging of 20–25% from what would have been expected given the previous trend of imaging growth, and an absolute decline of 6%.

Before the institution of our plan, nonradiologists had been performing 39% of outpatient radiographs. The 20–25% decline from the trend that we observed was roughly half this 39% initial share. Thus, our research shows that approximately half the imaging performed by self-referrers disappeared when they lost their financial self-interest in it.

This estimate—that eliminating financial incentives decreases half the imaging self-referrers order—coincides remarkably well with the most relevant data comparing two different groups of physicians. An analysis of Medicare claims data from all nonradiologist physicians in Florida by the United States General Accounting Office reveals that nonradiologists who obtained radiographs of their own patients performed twice as many radiographic examinations per 1000 patient office visits as did physicians who referred their patients to outside offices for radiography [6].

However, results were generally different in the three published studies that, like our research, investigated how physician orders for radiologic studies changed when financial incentives changed. Hemenway et al. [18] reported that when the compensation of primary care physicians at a chain of for-profit ambulatory care clinics was changed from a flat hourly wage to include a bonus related to revenues generated, the number of radiographs per patient visit increased 16% and the number of laboratory tests per visit increased 23%. The authors note that these findings seem like relatively small changes and speculate that the relatively small response may reflect the structure of the bonus system, which provided only a relatively weak financial incentive. Hillman et al. [19] reported that a program somewhat like ours, which generally terminated payment to nonradiologists for the professional component of imaging services but left nonradiologists free to collect payment for the technical component, resulted in a 41% increase in the number of imaging claims payable and a 12% increase in imaging costs in localities in which the insurer instituting the program had a relatively large market share. In contrast, in areas in which the insurer had a small market share, no dramatic changes were seen. It seems possible that if payments from the insurer were a major source of revenues for physicians, physicians noted the new policy and were manipulating the system to maintain their incomes. Kangarloo [20] reported on the effect of a program somewhat like ours that was introduced into the employee health benefit coverage of a large Florida firm that had been experiencing 25% annual increases in total costs for diagnostic imaging. In the first year of the program, the number of radiographs per 1000 covered persons was 419, a 9% decline from the previous year's level. This seems roughly similar to our finding of a 20–25% decrease from the health plan's previous trend, given that there had been a rapid increase in total imaging costs. However, because Kangarloo did not quantify the previous trend in the number of radiographs, only a rough comparison is possible. Obviously, more data than those of the three previous studies plus our study are required to make generalized conclusions about nonradiologists' responses to changes in financial incentives for imaging.

The widely reported finding that self-referrers do more imaging than radiologist referrers casts doubt on the necessity and appropriateness of the large number of radiographs self-referrers obtain. Our finding that many of these radiographs are not obtained, rather than shift to radiologists, when financial incentives change is further evidence of their questionable necessity. To be fair, however, we should note that advocates of in-office self-referral argue that the inconvenience of sending patients outside the office for imaging and then waiting for results causes physicians to omit imaging examinations that would be useful for patient treatment.

However, we could not find any quality-of-care parameters required by accrediting agencies or monitored by the health plan that were altered by our program. There seems to be no measured adverse health effect when self-referral is terminated. The quality parameters monitored may not be particularly sensitive to minor changes in population health, but opponents to programs like ours tend to predict that these programs will produce widespread and severe deterioration in the quality of care. Even somewhat insensitive indicators should detect such changes.

The most dramatic effect of our program was the decline in the number of radiographs obtained by nonradiologists: it fell from 39% of the total before the program was instituted to 15% after it began.

The resulting shift of examinations to a radiologist's office means that more examinations are now performed using modern equipment with low-dose screens, resulting in a reduction in dose per examination and an overall decrease in radiation exposure for the patient. Quality, too, was enhanced; as noted, we found many quality deficiencies in nonradiologists' offices. Although some deficiencies, such as formal reports for each examination, may not have a direct impact on patient care, deficiencies such as failure to have equipment inspected, increased dose per examination, or failure to correct a deficiency that had been identified by a physicist are clinically serious. The lack of adequate labeling of a radiograph could also have serious and tragic consequences.

In addition, we believe our inspection program resulted in improvement in the performance of the imaging that still occurred in a nonradiologist's facility. The program set standards for equipment located in a clinician's office and also ensured that a technologist obtained the radiograph. Quality assurance programs were initiated and deficiencies were corrected. Many offices, faced with increased surveillance and costs, decided to abandon performing radiology examinations. We know that 132 offices have stopped billing the plan for imaging procedures; whether they continue to obtain radiographs and bill other carriers or have ceased imaging is something we do not know.

Like all research, our study has limitations. Data on 1993–1997 trends in the utilization of imaging among health plans not affected by our program would have been useful to show that the trends that were seen in 1993–1995 continued, as we have assumed. The long-term effects of our program can be shown only by data from 1998 and subsequent years, which are not yet available. Quite possibly, utilization may start rising again; historically, the use of health services has grown over time. However, if utilization does start rising, it will start from a level 20–25% below that had we not intervened. Also, effects of our program on other imaging techniques, such as sonography (for which we required accreditation), are presumably important, and there may be spillover effects between radiography and other imaging techniques. As far as we could determine, there was no significant out-of-network utilization of radiology services during the study. Because the health plan is a restrictive health maintenance organization, with a specific panel of providers, there is a small possibility that an occasional patient may have been referred to imaging facilities not associated with the health plan. These studies would not have been paid for by the health maintenance organization, a significant disincentive for this to occur.

In conclusion, our study shows that a program that limits imaging studies to appropriate physicians can decrease cost and improve quality. We reduced the number of radiographic examinations performed by 20–25% from the preceding trend without significantly interfering with the health care of subscribers. Before our study, approximately 40% of radiographs were obtained by nonradiologists; this decreased to 15%, representing a dramatic reduction. One can infer that many of the procedures previously performed in nonradiologists' offices were not necessary. Issues of radiography equipment maintenance, patient safety, and reporting were addressed by inspecting offices that performed imaging. Seventy-eight percent of the nonradiologists' offices had significant deficiencies that we required to be subsequently corrected. Our program decreased cost and radiation burden.

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The Prevalence Of Physician Self-Referral Arrangements After Stark II: Evidence From Advanced Diagnostic Imaging

Data from California suggest that physicians exploit exceptions in the Stark II law to continue to self-refer patients for imaging.

by Jean M. Mitchell

ABSTRACT: Using data from a large insurer in California, we identified the self-referral status of providers who billed for advanced imaging in 2004. Nearly 33 percent of providers who submitted bills for magnetic resonance imaging (MRI) scans, 22 percent of those who submitted bills for computed tomography (CT) scans, and 17 percent of those who submitted bills for positron-emission tomography (PET) scans were classified as "self-referral." Among them, 61 percent of those who billed for MRI and 64 percent of those who billed for CT did not own the imaging equipment. Rather, they were involved in lease or payment-per-scan referral arrangements that might violate federal and state laws. [*Health Affairs* 26, no. 3 (2007): w415–w424 (published online 17 April 2007; 10.1377/hlthaff.26.3.w415)]

UNDER FEDERAL LAW, IT IS GENERALLY ILLEGAL for a physician to refer Medicare or Medicaid patients for designated health services in which the physician has a financial interest. Nearly half of the states have similar prohibitions that apply to the privately insured. These bans on self-referral were enacted during the early 1990s in response to several empirical studies that found that the financial incentives inherent in physician self-referral arrangements resulted in increased use of services and higher payments from third-party payers. Although none of these studies could determine whether any of the higher use associated with self-referral was inappropriate, there is no evidence indicating that it resulted in commensurate improvements in patients' health. On the other hand, proponents contend that self-referral arrangements in which physicians integrate the provision of ancillary services into their practices improve patient care. For example, the justifications for nonradiologist physicians' incorporating imaging into their offices include patient convenience, better continuity of care, and a reduction in the time required to diagnose and treat specific conditions.[1]

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The federal law, also known as Stark II (named for Rep. Pete Stark [D-CA], its sponsor), prohibits many physician self-referral arrangements. It was enacted by Congress in 1993 to address many of the shortcomings of the federal antikickback statute. Under that statute, criminal, civil, or administrative liability can result if one knowingly and willfully offers to pay for, solicit, or receive any remuneration to induce referrals of items or services reimbursable under federal health programs.[2] Remuneration includes the transfer of anything of value, either cash or in kind, and it covers direct, indirect, and covert as well as overt transfers. The statute ascribes liability to parties on both sides of the impermissible "kickback" transaction. Violation of the antikickback statute is a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. Conviction may also result in exclusion from federal health programs.

Although the federal prohibition on self-referral for designated health services has provided clearer guidance on referral arrangements that are illegal, the law contains a number of exceptions that could limit its effectiveness. First, physician group practices are exempt from the prohibition on self-referral for in-office ancillary services if the group practice meets specific criteria. Second, a physician may self-refer if the services are personally performed or supervised by another physician in the same group practice. Third, the federal prohibition does not apply to specific types of facilities—in particular, ambulatory surgical centers and so-called whole hospitals.[3] Yet the law prohibits physicians from making referrals to a hospital department in which they have a financial stake. Some state prohibitions directly parallel the federal statute, while others are much more limited in scope.

Recent newspaper articles provide anecdotal evidence that these exceptions have resulted in new forms of referral arrangements for advanced diagnostic imaging procedures—arrangements specifically designed to take advantage of these exceptions.[4] Such arrangements, which generate additional income for referring physicians, often require them to make minimal or no financial investment. The typical referral arrangement is structured as either a lease agreement or payment per scan performed. Under a so-called lease or time-sharing arrangement, referring physicians rent an imaging center (with equipment and employees) part time, for a specific day of the week or for part of that day. The referring physician sends the patient to the facility on that designated day and then submits a global bill to the insurer for the scan. (The global bill includes a fee for the technical component of the scan as well as the doctor's professional interpretation fee.) To comply with the Stark rules, such part-time arrangements must be with a facility in the same building as the physician's primary practice office. In addition, other Medicare rules require the physician or a member of his or her group practice to supervise the test. The level of supervision required, either direct, general, or personal, depends on the type of test involved.[5]

Alternatively, the referring physician may send his or her patients to a desig-

nated imaging provider and pay this provider a set fee for each scan performed. In this situation, the referring physician submits a global bill to the insurer for each scan referred; the difference between the amount reimbursed by the insurer and the "payment per click" represents pure profit to the referring physician. The legality of both types of arrangements, however, is questionable under both the antikickback statute and the federal self-referral law. Physicians have also avoided the prohibition on self-referral by incorporating advanced imaging machines in their offices, which is permissible under the in-office ancillary exception.[6]

Despite anecdotal evidence on referral arrangements tailored to fit existing exceptions, the extent of such arrangements is unknown. There is no empirical evidence documenting the prevalence and scope of physician self-referral arrangements in this post-Stark era either within particular states or at the national level. Because considerable research documents the fact that physician self-referral arrangements result in increased use of services and third-party payments, both within-office imaging and referral arrangements that involve little financial risk for referring physicians should be of particular concern to insurers, employers, policymakers, and consumers.[7]

Using billing records from a large private insurer in California, I and my colleagues collected information to identify the prevalence and scope of physician self-referral arrangements for three types of advanced imaging technologies: magnetic resonance imaging (MRI), computed tomography (CT), and positron-emission tomography (PET). By directly contacting each provider who billed the insurer for these procedures, we were able to distinguish self-referral situations in which physicians own equipment that is located in their offices from those in which physicians refer and bill for the procedure but do not own the equipment.

California merits examination for at least three reasons. First, California law prohibits self-referral for designated health services, regardless of type of insurance coverage. Second, until 1 January 2007, the California law as it pertains to diagnostic imaging services was more comprehensive than the federal prohibition because it encompassed nuclear medicine and PET scans.[8] Third, as an innovator in the delivery of health care services, California serves as a bellwether for the rest of the United States.

Study Data And Methods

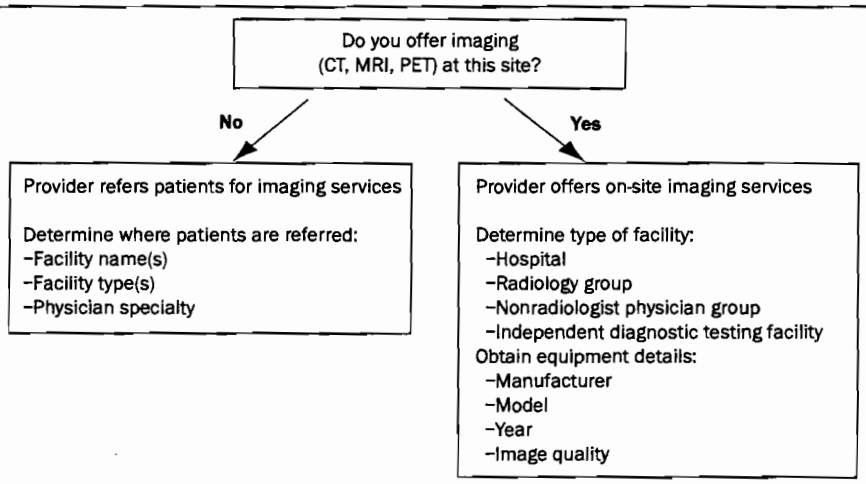
■ **Data source.** Data consist of providers' billing records for ambulatory services rendered to people covered by a large private health insurer in California. In January 2005, the insurer covered more than 5.8 million people, and 2.7 million were enrolled in large employer-group preferred provider organization (PPO) plans. Large-group enrollees represented 67 percent of those who were covered under these types of plans.

■ **Identifying imaging providers.** Providers who bill for advanced diagnostic imaging procedures include hospitals, radiologists, nonradiologist physicians, inde-

pendent diagnostic testing facilities (IDTFs), and radiation oncologists. Physicians (radiologists, nonradiologists, and radiation oncologists) typically submit bills under their group practice's tax identification number. We obtained from the insurer a comprehensive list of providers who during 2004 submitted claims for either the technical component or the global fee (professional and technical components) by procedure type for MRI, CT, and PET scans. By applying this selection criterion, we attempted to screen out radiologists who only billed for the professional fee for the interpretation of the scan. Since these physicians typically work out of hospitals, the technical component billed by the hospital would capture each imaging procedure performed.

The provider lists frequently were missing or had limited contact information and therefore required a considerable amount of editing to incorporate accurate contact information obtained from Internet searches. Once this phase was completed, we contacted each provider by telephone to obtain information on whether the provider offered the imaging procedure of interest, ownership, specialty of physicians if applicable, and details on imaging equipment for providers who owned the equipment. Exhibit 1 depicts graphically the series of questions asked of each provider who billed the insurer for imaging procedures. Between Internet searches, multiple telephone calls, and analysis of claims to ascertain a count of each procedure type performed and amount billed during each given year, we spent an average of two hours per case to obtain complete information on each provider. The final database contains each provider's name, address, and telephone number; Web site if available; ownership/self-referral status; and machine

EXHIBIT 1
Determining Self-Referral Status Of Providers Who Billed One Large Insurer For Advanced Imaging Procedures In California, 2004



SOURCE: Protocol developed by the author.
NOTES: CT is computed tomography. MRI is magnetic resonance imaging. PET is positron-emission tomography.

manufacturer, model, and year.

■ **Classification of self-referral status.** Each provider who billed for either the technical component or a global fee for each advanced imaging procedure was classified as follows: (1) equipment owned or leased by nonradiologist physicians (fewer than 100 physicians in group); (2) equipment owned or leased by large multispecialty group of physicians with 100 or more members; (3) equipment owned or leased by radiologists; (4) equipment owned or leased by hospital; (5) equipment owned as a joint venture between radiologists and hospital providers; (6) equipment owned or leased by radiation oncologists; and (7) equipment owned by an independent diagnostic testing facility. Physicians in group 1 were in a position to refer patients for diagnostic imaging procedures and thus were classified as "self-referral." This group is of particular interest, given concerns about the conflict of interest and financial incentives associated with self-referral arrangements. Group 1 providers were further classified by type of self-referral. Some nonradiologist physician providers who worked in small to medium-size groups submitted global bills for imaging procedures, and the equipment was located within their practices. However, many other nonradiologist physician providers did not own the equipment, nor were the machines located on site. Rather, they either leased time on another provider's machine or paid another provider a set fee per scan and then submitted a global bill to the insurer for each scan ordered.

Large multispecialty physician practices (those with 100 or more members) were also deemed to be "self-referral." The original intent of the group-practice exception was to recognize that physician-members of large group practices routinely make most referrals internally for a wide array of services. The presumption behind this exception was that any financial gain that accrues to an individual physician from making referrals is small. Unlike smaller groups of nonradiologist physician providers, the large multispecialty practices owned the imaging equipment, and it was located on site.

Because radiologists were not in a position to refer patients for diagnostic imaging procedures, this provider group was classified as "not self-referral." For hospital providers, the imaging equipment was either owned or leased by the hospital and was located on the facility grounds. Since physicians, not hospitals, refer patients for imaging procedures, hospitals were categorized as "not self-referral." If however, the hospital was a specialty facility owned by referring physicians, it was classified as "self-referral."

Under Stark II, radiation oncologists are considered to be non-self-referral physicians. Yet radiation oncologists may refer patients for CT scans to be used in planning the course of radiation therapy treatments. For this reason, the self-referral status of radiation oncologists was classified as "indeterminate." IDTFs represent a diverse group of providers; their variable structure and ownership defy simple classification with respect to self-referral status. Although IDTFs submitted global bills to the insurer, anecdotal information indicates that some have estab-

lished personal services contracts (that is, medical directorships, interpretation agreements, or consulting arrangements) with referring physicians to ensure that these physicians refer their patients to the IDTF. Whether or not an IDTF had established such contractual agreements with referring physicians was impossible to ascertain from the claims submitted to the insurer. Rather, one would need to scrutinize the financial records of each IDTF to determine if the entity has established such contractual agreements with nonradiologist physicians. In light of these considerations, IDTFs were classified as having "indeterminate" self-referral status.

The insurer records the names, license numbers, and specialties of physicians affiliated with the each provider tax identification number (billing number). We used these records to cross-check and verify the specialties and self-referral status assigned to each case classified as "self-referral." Despite incomplete information in each of the original provider lists, with significant effort we were able to correctly classify the ownership and self-referral status for 100 percent of the potential provider entries.

■ **MRI providers.** Of the original 1,335 MRI providers, we identified 66 duplicate cases, 125 entries that were deemed "low-volume providers," and 121 radiology practices that worked out of hospitals and therefore only billed for their professional services (interpretation of the MRI scan). Altogether, these exclusions resulted in a list of 1,023 valid providers that billed the insurer for either the technical component or a global fee for MRI procedures.

■ **CT providers.** Of the 1,525 potential providers that billed the insurer either for the technical component or globally for CT procedures, 399 were deemed ineligible because they were either out of state (104); duplicates (39); low-volume providers (204); or obstetricians or dentists (52) who billed for one CT procedure code but did not provide CT or refer patients for CT. We further eliminated 162 radiology groups that work at hospitals and thus only billed for professional services. The final list of providers that billed for CT scans contained 964 providers.

■ **PET providers.** The insurer identified 206 potential providers that billed for either the technical component or global reimbursement for PET scans during 2004. Twenty low-volume cases, two duplicates, and ten radiology groups that only billed for professional services were eliminated. These exclusions yielded a list of 174 providers that billed the insurer for PET scans performed during 2004.

Study Results

Exhibit 2 shows providers who billed either globally or for the technical component for the three types of advanced diagnostic imaging procedures, classified by ownership and self-referral status in 2004. Approximately 33 percent of providers who submitted either global or technical bills for MRIs were nonradiologist physicians practicing in small to medium-size groups and involved in self-referral. Physicians who were members of large multispecialty group practices

EXHIBIT 2
Prevalence Of Diagnostic Imaging Providers Who Billed For The Technical Component Or Globally For Privately Insured People In California In 2004, By Self-Referral Status

Provider type	Self-referral status	Providers who billed for MRI (N = 1,023)		Providers who billed for CT (N = 964)		Providers who billed for PET (N = 174)	
		Number	Percent	Number	Percent	Number	Percent
Nonradiologist physician (small or medium-size group)	Self-referral	340	33.2	210	21.8	30	17.3
Nonradiologist physician (large group)	Self-referral	37	3.6	24	2.5	8	4.6
Radiologist, owned equipment	Not self-referral	291	28.4	280	29.0	40	23.0
Hospital, owned equipment	Not self-referral	276	27.0	402	41.7	62	35.6
Radiology-hospital joint venture	Not self-referral	10	1.0	–[a]	–[a]	–[a]	–[a]
Independent diagnostic testing facility	Indeterminate	69	6.8	24	2.5	34	19.5
Radiation oncologist, owned equipment	Indeterminate	–[a]	–[a]	24	2.5	–[a]	–[a]

SOURCE: Provider records from the insurer, 2004.
NOTES: MRI is magnetic resonance imaging. CT is computed tomography. PET is positron-emission tomography.
[a]Radiation oncologists did not bill for either MRI or PET scans.

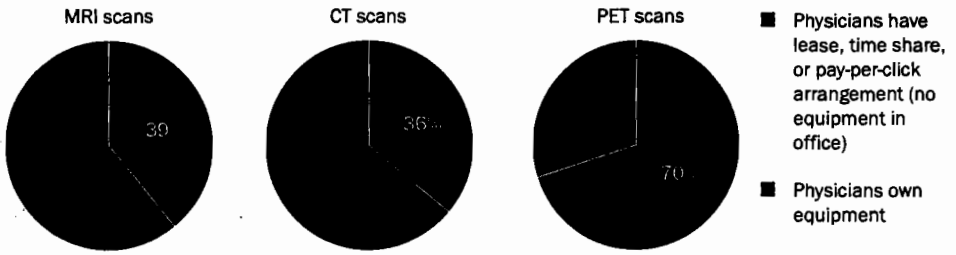
(100-plus physicians) accounted for 3.6 percent; IDTFs accounted for nearly 7 percent. The remaining 56 percent of providers were classified as "not self-referral."

Nonradiologist physician providers who were members of small to medium-size groups and engaged in self-referral accounted for almost 22 percent of the providers who submitted global bills for CT scans during 2004. Large multispecialty groups of physicians, also classified as "self-referral," constituted 2.5 percent. IDTFs and radiation oncologists, viewed as having indeterminate referral status, together accounted for 5 percent of CT providers. The remaining providers did not engage in self-referral.

Slightly more than 17 percent of the 174 providers who billed either globally or for the technical component for PET scans were members of small to medium-size physician groups who engaged in self-referral. Close to 5 percent of PET providers were large multispecialty physician groups. IDTFs represented almost 20 percent; the remaining 58 percent were not involved in self-referral.

■ **Further classification of self-referral cases.** Exhibit 3 depicts self-referral providers who were affiliated with small to medium-size group practices, stratified by type of self-referral arrangement. Almost 61 percent of the 340 nonradiologist physician providers who submitted global bills for MRIs did not own the equipment, nor was the machine located on site. Nearly 64 percent of the self-referral CT providers who worked in small to medium-size groups billed the insurer but had ei-

EXHIBIT 3
Diagnostic Imaging Used By Nonradiologist Physician Providers In Small Or Medium-Size Groups, By Type Of Self-Referral Arrangement, California, 2004



SOURCE: Percentages calculated from data collected from California providers who billed the insurer for these procedures in 2004.
NOTES: MRI is magnetic resonance imaging (N = 340). CT is computed tomography (N = 210). PET is positron-emission tomography (N = 30).

ther a lease or payment-per-click arrangement. Thus, only 39 percent of MRI providers and 36 percent of CT providers who engaged in self-referral had the machines located at their practices. In contrast, nearly 70 percent of PET providers classified as self-referral actually had the machines on site.

Discussion

Laws enacted during the early 1990s to curb physician self-referral were a major step toward addressing the concerns about these arrangements; however, they contain exceptions that could enable self-referral to reappear but in a different form tailored to fit the exemption. This study is the first to document the prevalence and scope of self-referral arrangements in light of these exceptions. The findings presented here, which are based on a comprehensive list of providers who billed a large private insurer in California for advanced imaging procedures in 2004, indicate that prohibition exceptions have enabled self-referral to persist, but in new forms.

In 2004, nonradiologist physicians who were members of small to medium-size groups and engaged in self-referral accounted for 33 percent of the providers that billed the insurer for MRIs but only 11.5 of the statewide volume of this procedure performed. Such physicians represented 17 percent of providers who billed for PET in 2004, yet their share of statewide PET volume exceeded 25 percent. Moreover, for both of these highly reimbursed advanced imaging technologies, the share of statewide volume billed for by such physicians has grown dramatically since 2000. These physicians accounted for 22 percent of providers who billed for CT procedures in 2004, but their share of statewide volume was less than 7 percent. Nonetheless, the share linked to these self-referring providers had greatly increased.

These prevalence rates are probably conservative with respect to the situation in 2007 because they identify arrangements in existence during 2004 and do not reflect developments since then. Additional analyses support this contention. The

research team identified twenty new providers who billed for PET scans for the first time during 2005; half of these were classified as "self-referral."

One aspect of the structure of today's physician self-referral arrangements is particularly noteworthy. The in-office exception in current law was justified under the assumption that when physicians provide imaging to patients within their offices, they do so for patients' convenience and to monitor quality of care. However, the majority of self-referral providers for MRIs and CT scans (61 percent and 64 percent, respectively) did not have the imaging equipment in their offices in 2004. Rather, physicians have figured out how to take advantage of the exemptions in existing law by establishing referral arrangements with other imaging facilities that involve minimal financial risk for the referring physician.[9] The Office of Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS) views these types of arrangements as an opportunity for referring physicians to bill and retain remuneration that is illicit under the antikickback statute, even thought they appear to meet the "safe harbor" guidelines.[10] Moreover, these questionable referral arrangements have come under heightened scrutiny from state and federal prosecutors. In January 2007 the Illinois attorney general's office joined a whistleblower lawsuit and charged twenty MRI centers in Chicago with concocting "sham lease agreements" to pay kickbacks to physicians for referrals.[11] The OIG has filed a federal lawsuit against physicians involved in similar sham lease deals in Florida.[12] Such referral arrangements raise concerns about referring physicians' ability to monitor the quality of care provided because the referring physicians are not on site to directly supervise the provision of imaging services and the site's operation. Finally, arguments regarding patient convenience appear to be tenuous at best, especially if the referral arrangement is structured as a "sham lease agreement."

It is important to recognize that referral arrangements tailored to qualify as permissible under the exceptions in existing self-referral laws are not confined to the three types of advanced imaging procedures examined here. Similar referral arrangements have also been established between referring physicians and medical laboratories for clinical laboratory tests.[13] Moreover, we examined providers who submitted global bills for cardiac nuclear imaging procedures; these analyses, although preliminary, indicate that self-referral arrangements are commonplace.

Although anecdotal evidence suggests that self-referral for diagnostic imaging exists in many states, it is unknown whether such referral arrangements are as prevalent elsewhere as in California. Thus, further research is needed to document the prevalence, scope, and effects of self-referral arrangements for diagnostic imaging that exist in other states. These findings should be of considerable concern to policymakers, employers, insurers, and consumers who recognize the need to control rapidly escalating health care spending. Efforts that address the exemptions in existing federal and state prohibitions on physician self-referral are likely to have major impacts on the increased use that characterizes these arrangements.

This research was supported by the California HealthCare Foundation under a grant awarded to Georgetown University.

NOTES

1. Research documenting the effects of physician self-referral is summarized in J.M. Mitchell, "Physician Joint Ventures and Self-Referral: An Empirical Perspective," in *Conflicts of Interest in Clinical Practice and Research*, ed. R.G. Spece, D.S. Shimm, and A.Buchanan (New York: Oxford University Press, 1996), 299–317.
2. See 42 U.S. Code, sec. 1320a-7b(b).
3. W.J. Lynk and C.S. Longley, "The Effect of Physician-Owned Surgicenters on Hospital Outpatient Surgery," *Health Affairs* 21, no. 4 (2002): 215–221; and U.S. Government Accountability Office, *Specialty Hospitals: Geographic Location, Services Provided, and Financial Performance*, Pub. no. GAO-04-167 (Washington: GAO, October 2003).
4. D. Armstrong, "MRI and CT Centers Offer Doctors Way to Profit on Scans," *Wall Street Journal*, 2 May 2005; and N. Jaquiss, "Money Machine: Is Your Doctor Sending You for an MRI Because You Need One or Because He Needs the Cash?" *Willamette Week*, 7 June 2006.
5. The supervision requirements for diagnostic tests vary from "personal," where the physician must be in the room, to "direct," where the physician must be present in the office suite, to "general," where the physician provides direction but does not need to be present.
6. R. Abelson, "An MRI Machine for Every Doctor? Someone Has to Pay," *New York Times*, 13 March 2004.
7. Mitchell, "Physician Joint Ventures."
8. The California prohibition on self-referral is described in section 650.01–650.02 of the California Business and Professions Code. The Centers for Medicare and Medicaid Services (CMS) recently added nuclear medicine and PET to the list of designated health services covered under the federal self-referral prohibition, effective January 2007. Although the California law is quite similar to the federal law, some differences exist. For example, Stark II clearly defines what constitutes a referral, whereas the state law does not. Under the California law, a loan between a referring physician and the recipient of the referral is not a prohibited financial interest. Stark II contains no exception for loans. More details on differences between the California and federal laws can be obtained from the author; send e-mail to mitchejm@georgetown.edu.
9. Armstrong, "MRI and CT Centers Offer Doctors Way to Profit on Scans"; and Jaquiss, "Money Machine."
10. U.S. Department of Health and Human Services, Office of Inspector General, "OIG Advisory Opinion No. 04-17," 17 November 2004, http://oig.hhs.gov/fraud/docs/advisoryopinions/2004/ao0417.pdf (accessed 19 March 2007).
11. B. Japsen, "Suits Throw Light on MRIs: As Imaging Procedures Soar, Some Providers Come under Scrutiny," *Chicago Tribune*, 11 February 2007.
12. Ibid.
13. D. Armstrong, "Lucrative Operation: How Some Doctors Turn a $79 Profit from a $30 Test," *Wall Street Journal*, 30 September 2005.

THE WALL STREET JOURNAL.

Own Image: MRI and CT Centers Offer Doctors Way to Profit on Scans; Physicians Pay a Flat Fee For Procedures, Then Bill Insurers -- at Higher Rate; Navigating Legal Landscape

David Armstrong. **Wall Street Journal**. (Eastern edition). New York, N.Y.: May 2, 2005. pg. A.1

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Abstract (Document Summary)

Some companies decline to offer referral deals, among them HealthSouth Corp. in Birmingham, Ala. In such deals, the doctor gets a discount and "turns around and bills at a marked-up price," said Karen Davis, head of HealthSouth's diagnostic division. "He takes a quick margin of $300 to $400 for each one. What part of that doesn't feel like a kickback?"

A spokesman for Medquest, of Alpharetta, Ga., said the document didn't go through proper channels and was removed from circulation after senior management learned about it. He called the note "an overzealous attempt" to promote contracts and said that the line about doctors being pleased with their reimbursements was "something that shouldn't have been said and not the kind of thing the company condones." The spokesman added that Medquest's contracts with doctors have been declining in number and make up less than 10% of its business.

Alliance Imaging says its contracts with doctors represent a small slice of its business and are entered into cautiously. "Every single deal like this is reviewed" by outside and internal lawyers, said the company's chief executive, Paul Viviano. "They bless them before we begin dreaming of such a relationship. They view this as in compliance" with referral laws.

Full Text (2401 words)

Medical imaging such as MRI and CT scanning is one of health care's fastest-growing sectors. Last October, an owner of imaging centers told doctors how they could get in on the boom.

At a meeting of cardiologists, neurologists and cancer specialists in Torrance, Calif., Imaging Solutions Inc. proposed that the doctors sign a contract to send patients to one of its centers. According to documents handed out there and physicians who attended, the deal worked this way: The center would charge doctors a flat rate per scan. Then the doctors could bill insurers at the

going reimbursement rate in their area.

For an MRI, the company would charge doctors $375. It pegged the average reimbursement in the region at $706.31.

After deducting the cost of having the scan interpreted, the paperwork said, the doctors would net $234.77 from each MRI. It showed that a group practice could clear $122,078 a year if it referred two patients a day for scans, or $610,390 annually if it referred 10 a day. For a less-common kind of screening known as PET scans, profits would be higher: $525,200 a year to the doctors if they made two daily referrals, or $2.6 million annually for 10 a day.

Arrangements like this are increasingly common, say some doctors, industry officials and health-care lawyers. But few doctors acknowledge taking part in them, and the scanning centers that offer them typically are reluctant to identify referring doctors.

Some lawyers say the referral deals risk running afoul of federal and state laws. Others say the arrangements risk raising usage of expensive procedures at a time when U.S. medical costs already are surging.

It's a federal crime for health-care providers to compensate doctors for referrals, or for doctors to receive such compensation, when Medicare or Medicaid patients are involved. Such a ban, called an anti-kickback law, extends to all other types of patients, too, under 36 state statutes, including one in California. Some lawyers say the doctors' almost assured profits under some imaging-center contracts might be considered illegal inducement for referral.

The arrangements also raise an issue of "self referral," which occurs when doctors refer patients to businesses in which they or relatives have a financial stake. Because this practice, like payment for referral, can encourage overuse of costly medical services, it is barred by a federal statute, in this case a civil one.

But the law against self-referral has exceptions, one of which says the services are all right so long as doctors do them in their own offices. Some imaging companies structure referral deals as leases, under which doctors, each time they send over a patient, are renting the scan center's facilities and employees. Imaging firms appear to be establishing a framework to argue that doctors' offices temporarily include the imaging center, say some health-care lawyers.

Imaging Solutions documents distributed at the gathering in Torrance characterized its contract as a "per use, non-recourse lease agreement." Referral deals labeled leases "have spread like wildfire," Anne Haule, a Chicago health-care lawyer, wrote last June in a newsletter called Diagnostic Imaging Intelligence.

Without citing any specific provider, she said the arrangements posed significant risk of violating laws against payment for referral. She also wrote that there could be fraud if doctors were seen as falsely claiming to have provided a service within their own offices. In an interview, Ms. Haule said she advises clients to avoid such arrangements.

Another health-care attorney, Jeremy Miller of Los Angeles, said that companies offering some of the leasing deals are "pushing the envelope" and that doctors who sign up are "definitely taking a risk." The contracts' legality appears not to have been addressed in court. One case in Georgia, alleging that a deal violated a state self- referral law, was settled without a judicial ruling.

The chief executive of Imaging Solutions, Michael Hofer, said the kind of arrangement his

company offered in Torrance represents about 20% of its business. "We never do it unless we absolutely go to a lawyer and make sure it is OK," said Mr. Hofer, whose company is based in Fargo, N.D.

Asked about the projections for doctors' profits, the CEO said the numbers were provided by Dan Eberhardt, whom he described as "an agent who works for" equipment makers and brings deals for Imaging Solutions to consider. Mr. Eberhardt, however, called himself an executive of Imaging Solutions, in a document on its letterhead that was distributed at the doctors' meeting. Reached by calling Imaging Solutions, Mr. Eberhardt hung up when asked about the documents. Reached again weeks later, he directed calls to Mr. Hofer.

Some companies decline to offer referral deals, among them HealthSouth Corp. in Birmingham, Ala. In such deals, the doctor gets a discount and "turns around and bills at a marked-up price," said Karen Davis, head of HealthSouth's diagnostic division. "He takes a quick margin of $300 to $400 for each one. What part of that doesn't feel like a kickback?"

While the U.S. Health and Human Services Department, which oversees Medicare and Medicaid, hasn't dealt with scanning contracts, it warned recently about a similar laboratory arrangement. A pathology lab had proposed that doctors order services from it -- paying either a per- use fee or a flat monthly charge -- and then directly bill insurers.

This lab "may be offering the Physician Groups impermissible remuneration" by giving them a chance to bill Medicare for more than what they pay the lab, said an advisory that the HHS inspector general published. Without naming the lab, it said that HHS "could potentially impose administrative sanctions . . . under the anti-kickback statute."

Scanning costs are Medicare's fastest-growing item. They rose at three times the rate of other medical services from 1999 to 2002 and popped a further 16% in 2003. The total spent in the U.S. on imaging services and new machines will reach $100 billion this year, up $20 billion in two years, consulting firm Booz Allen Hamilton estimates.

One reason for the boom is medical scans' growing ability to detect health conditions, reducing the need for diagnostic surgery. But another factor, some researchers believe, is the incentive some doctors have to order more scans, either because they've installed a machine in their own offices or because they have one of the lease contracts with imaging centers. Scanning centers are offering these contracts at a time when many doctors see their incomes under pressure from managed care and some are looking for new revenue.

"Utilization goes through the roof" when doctors have a financial stake in providing imaging tests, said Donald Ryan, head of CareCore National Inc. in Wappingers Falls, N.Y., which analyzes imaging claims for insurers to help them control costs.

Contracts between imaging centers and doctors are hard to detect from the claims Mr. Ryan sees. But he said he documented that a neurology practice in Nassau County, N.Y., had a lease deal with an imaging center -- and that its doctors ordered MRI brain scans 47% more frequently than other doctors. Mr. Ryan said the practice, which he declined to name, ordered MRIs for 26 of every 100 patients in 2003. He said that compared with 17.6 per 100 for other Nassau County neurologists dealing with the same insurer.

One imaging company's standard referral agreement with doctors was disclosed in court two years ago. Medquest Associates Inc.'s contract said patients would be scanned at one of its facilities, but the doctors would bill the insurer.

The fee schedule showed Medquest would charge doctors $350 per patient for a CT scan. The suggested sum for doctors to bill insurers was $650 to $850, depending on what body part was scanned. The documents were introduced in Georgia state court in Atlanta, in a civil suit filed by a patient alleging a violation of the state's self-referral law. The case was settled on undisclosed terms.

A Medquest internal note suggested that its salespeople tell doctors to advise insurers that the doctors had begun providing scans on their own. "Experience has shown us that it works best" if doctors are told to remove Medquest's name from the price schedule before submitting it to insurers, said the note, which was also filed in court.

The note, marked "confidential," added: "We have yet to see a group that has not been very pleased when they see the actual numbers from their payors."

A spokesman for Medquest, of Alpharetta, Ga., said the document didn't go through proper channels and was removed from circulation after senior management learned about it. He called the note "an overzealous attempt" to promote contracts and said that the line about doctors being pleased with their reimbursements was "something that shouldn't have been said and not the kind of thing the company condones." The spokesman added that Medquest's contracts with doctors have been declining in number and make up less than 10% of its business.

Still, as many as 25,000 patients in Georgia have been referred to Medquest's facilities under referral contracts, said Medquest co- founder Gene Venesky in a court affidavit June 20, 2003. He said the company was "repeatedly advised by several different attorneys" that the contracts are legal.

(Mr. Venesky and two other officials resigned last week amid an accounting inquiry at the company, which is controlled by an arm of J.P. Morgan Chase & Co. See adjoining article.)

Since insurers pay the same for a scan no matter who files the bill, it might seem that imaging firms giving big discounts to doctors would be leaving a lot of money on the table. Why charge a doctor $350 for a scan when an insurer would reimburse you $700 for it? But locking in usage with a doctor group provides something that imaging centers want: volume.

Insurers, meanwhile, "rarely know anything about" the arrangements, says Cherrill Farnsworth, CEO of HealthHelp Inc., a Houston firm that helps insurers manage radiology benefits.

Helping to keep the practice hidden is the disinclination of all parties to talk about reimbursement levels, for competitive reasons. Insurers, for instance, don't want doctor groups and imaging centers to know that the insurer may be giving a better deal to some than to others -- depending on how badly it needs them in its network. The insurers bargain with providers over reimbursement levels.

The specifics of one imaging center's referral deal with doctors were spelled out in a contract filed with Massachusetts regulators. The agreement was between Alliance Imaging Inc. of Anaheim, Calif., and a 45-doctor group in North Dartmouth, Mass., called Hawthorn Medical Associates. Alliance put one of its MRI machines in one of the doctors' buildings. Alliance pays rent to the doctors for the space, and the doctors agree to send most MRI patients to that machine.

The doctors pay $245 to Alliance Imaging for each MRI they order and then bill insurers for it themselves. Hawthorn says it also has other costs, such as $75 to $100 for a radiologist to interpret each scan, plus scanner supplies, maintenance and the salary of a part-time and full-time

technician. Still, it appears the doctors in the Hawthorn group collect at least a couple of hundred dollars above their costs for each scan they prescribe.

For instance, Harvard Pilgrim Health Care Inc., a health-maintenance organization in the area, reimburses about $610 to $712 for each lower-back MRI, and $1,343 for an MRI brain scan. Hawthorn doctors, who are providers within this HMO's network, are reimbursed in line with the HMO's average, says Hawthorn's medical director, William Caplan.

Dr. Caplan said the medical practice makes money from its deal with Alliance Imaging, but "only a little bit -- no one is getting rich off this." He also said that the lawyers had cleared the arrangement and that it doesn't lead to overuse of scans. He rejected the idea that "doctors run up utilization to make money." Harvard Pilgrim declined to comment.

Alliance Imaging says its contracts with doctors represent a small slice of its business and are entered into cautiously. "Every single deal like this is reviewed" by outside and internal lawyers, said the company's chief executive, Paul Viviano. "They bless them before we begin dreaming of such a relationship. They view this as in compliance" with referral laws.

A company called Integrated Diagnostic Centers Inc. says it has signed more than 1,000 doctors to lease deals for its six scanning centers in Texas, Colorado and Nevada. This firm permits doctors to bill insurers directly only in the case of non-Medicare patients, to avoid running afoul of the federal law barring payment for referrals, said its CEO, John Allen.

In addition, instead of paying a price per scan, the doctors book a set number of hours on a scanner per week, which they must pay for even if they don't send enough patients. This arrangement adds an element of risk that helps make sure there is no violation of anti- kickback laws, Mr. Allen said.

He estimated that doctors who use all of the scanner time they book net about $150 to $200 per patient. He said he doesn't see physicians ordering extra scans after they sign a lease deal.

On IDC's Web site, Las Vegas orthopedist John Thalgott, whose practice has a contract with the imaging center, calls the financial arrangement a "win-win." Dr. Thalgott says in an interview that profits from imaging represent less than 5% of his income.

Matthew J. McMahon, a Las Vegas cardiologist, says his practice also has a contract with IDC. In an interview, Dr. McMahon says the "benefit to the business is plain and simple: it is an economic advantage. Medical imaging is profitable. This is another revenue stream."

Healthy Margin

Some doctor groups have contracts with imaging facilities. Labeled "leases" of the facilities, the deals allow doctors to say an MRI or CT scan was done in their own offices and permit the doctors themselves to bill insurers.

A typical arrangement:

-- Doctors agree to send patients to a scanning center.

-- Center charges flat rate to doctors, say $350 a scan.

-- Doctors bear certain other costs, such as $100 for a scan reading.

-- Doctors bill insurer at going rate, say $700 and ranging up to $1,300.

Bottom line: Doctors profit on each scan they order and imaging center is more likely to have steady volume.

Problem: Deals risk clashing with laws on payment for referral and self-referral, and may encourage overuse.

Doctors' MRI deals a 'sham,' state says

Operators contend that leases are legal

By Bruce Japsen
Tribune staff reporter

May 10, 2007

Chicago-area doctors were told they could earn more than $130,000 a year just for referring patients to some MRI centers, according to new documents filed in probe by the Illinois attorney general's office into radiology business practices.

A civil complaint filed by the attorney general's office was amended recently to include additional details about how some MRI centers allegedly marketed and trained sales people to entice physicians into what the state characterizes as phony lease deals. The state alleges the kickback scheme resulted in health insurers being billed for millions of dollars in fraudulent claims, although the operators of the MRI centers says the lease deals are perfectly legal.

Though MRIs were performed at radiology centers, the lease deals made it appear as though the doctors were in charge of the equipment and billed the services as their own, according to the suit. The attorney general's office alleges that the centers concocted "sham 'lease' agreements" to benefit doctors, who, in return, boosted referrals to the centers, sometimes for unnecessary tests.

The scheme, which dates back to at least 1999, involves "thousands of claims submitted to insurers in Illinois," the suit says, but the attorney general's office has not put a specific price tag on the fraud. Initial details of the alleged kickback scheme were first disclosed in a civil lawsuit unsealed in January.

More than 20 Chicago-area radiology centers are listed as defendants in the case, and the number could grow to include more centers and some individual physicians, according to sources close to the probe.

Most of the centers listed in the complaint operated under the ownership of Virginia-based MIDI LLC or Virginia-based companies with the MIDI name and operated locally under the Open Advanced or Open MRI brands, according to court documents.

"Despite having performed no services for the patient, the referring physician, or MIDI on behalf of the referring physician, bills the patient or the patient's insurer for diagnostic imaging procedures done at MIDI facilities," the amended lawsuit dated April 27 alleges.

Pitches to doctors provided in one MIDI training presentation detailed "scenarios" in which referring physicians could make $177 or $277 per MRI scan. Doctors were told the referrals could result in annual revenue of $84,900 to $132,900, assuming the doctor had a referral rate of 40 scans per month.

Under the larger payment scenario, court documents state, the training presentation laid out that the average reimbursement paid by insurance companies was $800 per MRI. After MIDI fees of $475 and a so-called overage cost of 10 percent was subtracted, potential revenue for the referring physician was $277 per scan.

MIDI's agreements with doctors were shielded from patients and health insurance companies, and they also contained confidentiality clauses "stating that the terms of the agreement shall not be disclosed, and the claim forms

submitted to insurers do not disclose that the physician billing for the imaging services did not personally perform or supervise those services," according to the suit.

But MIDI LLC, through its Chicago legal counsel at Reed Smith Sachnoff & Weaver, said the lease agreements are not only lawful but widespread.

"At least two federal courts have ruled that similar financial relationships as those being challenged by the State of Illinois are legal under federal law," said attorney Steven A. Miller. "MIDI is going to vigorously defend the action."

Miller had no further comment.

While attorneys for MRI operator defendants stand by the legality of the partnerships, one leading Illinois radiologist believes physicians should not participate in them, citing ethical obligations to patients, their insurers and employers who foot the bills for the MRI costs.

"It's treating patients as a commodity, and patients aren't being told," said Dr. Leonard Berlin, chairman of the radiology department at Rush North Shore Medical Center in Skokie and president of the Illinois Radiological Society.

"Is it unprofessional? Absolutely. Is it unethical? Absolutely," Berlin added. "It will be a matter for the courts to decide whether they are legal, but any practicing radiologist or primary-care physician can look at this and see that it is unethical and unprofessional."

Neither Atty. Gen. Lisa Madigan's office nor assistants handling the case would comment on allegations in the amended complaint. The 49-page complaint, however, says MIDI employees continue to "solicit and entice" physicians into joining such "kickback arrangements."

The complaint originally was filed in February 2006 by John Donaldson, the owner of a radiology service in Illinois, who had no comment, according to his lawyer, Anne Haule of Chicago law firm Ungaretti & Harris.

The lawsuit alleges the defendants violated the Consumer Fraud and Deceptive Business Practices Act, Illinois' anti-kickback law and the Insurance Fraud Prevention Act.

It seeks an unspecified restitution, damages and penalties.

Radiological societies say they have concerns about loopholes in current laws and have pushed lawmakers to close them but little has been done. Doctors also say physicians are lured into arrangements by lawyers who entice them into such lease arrangements as a way to make more money.

"The loopholes have to be closed," Berlin said. "It is good that the attorney general has been involved."

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ASCO®
AMERICAN SOCIETY OF CLINICAL ONCOLOGY

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

Re: Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and other Part B Payment Policies for 2008 (CMS-1985-P)

Dear Mr. Kuhn:

These comments are submitted by the American Society of Clinical Oncology (ASCO) in response to the proposed changes to payment policies under the Medicare physician fee schedule and other Part B policies, which were published in the Federal Register on July 12, 2007. ASCO is the national organization representing physicians who specialize in the treatment of cancer, and we are very interested in issues raised by the proposal.

PROPOSED REDUCTION IN THE CONVERSION FACTOR

Unless Congress acts, the sustainable growth rate (SGR) methodology will result in an estimated 9.9% reduction in the fee schedule conversion factor in 2008. Further cuts of almost 40% are projected in the absence of a permanent fix to the Medicare payment formula for physicians. This reduction is entirely unwarranted in light of the increased practice costs faced by physicians and the small increases in recent years that have failed to keep up with inflation. CMS should take administrative steps that would lessen the reduction, such as removing drugs retroactively from the definition of physician services subject to the SGR methodology. We also urge CMS to work with Congress to avert scheduled cuts in 2008 and, in the longer term, repeal the SGR and replace it with a system that keeps pace with increases in medical practice costs.

PHYSICIAN QUALITY REPORTING INITIATIVE

ASCO generally supports the proposed continuation of the PQRI program into 2008. ASCO has actively participated in the AMA Physician Consortium for Performance Improvement process to develop new cancer-related quality measures that could be adopted in 2008 and with the goal of replacing 2007 PQRI measures 71, 72, 73, and 74.

Moving forward, we encourage CMS to continually reassess and evaluate methodologies to assess the quality of care provided to people with cancer.

We have been concerned during this initial year of PQRI that measure specifications and the implementation methodology may have an adverse affect on participation as well as the quality of data collected through the program. One of the challenges for oncology has been reconciling reporting requirements with the realities of clinical practice. For example, it is common for patients to visit the physician office for chemotherapy without having a physician evaluation and management encounter on the same day. However, several current cancer-related measures cannot be reported unless chemotherapy is administered on the same day as an evaluation and management visit.

We also encourage CMS to explore alternative strategies for quality reporting under the value based purchasing program. For example, as part of the 2006 Oncology Demonstration Project, CMS collected data from oncologists on cancer disease status. As we have stated before, if reporting on disease status were continued in lieu of other PQRI reporting requirements, the Medicare program would have a rich repository of claims data that could be analyzed for specific cancer quality measures. ASCO remains interested in working with CMS to discuss the details of alternate methodologies.

CMS has noted separately in the proposed rule that the recent law requiring reporting on anemia quality indicators will be implemented on January 1, 2008. The statute requires that "Each request for payment, or bill submitted, for a drug furnished to an individual for the treatment of anemia in connection with the treatment of cancer shall include...information on the hemoglobin or hematocrit levels for the individual." CMS states in the proposed rule its intent to use the anemia indicators to "facilitate assessment of the quality of care for this condition" and "help determine the prevalence of anemia associated with cancer therapy, the clinical and hematologic responses to the institution of anti-anemia therapy, and the outcomes associated with various doses of anti-anemia therapy." Given CMS' intent to use this requirement to evaluate quality, we would strongly urge that for those physicians who elect to participate in PQRI, reporting on anemia be considered equivalent to reporting on any other PQRI measure, and therefore tied to PQRI data reporting and bonus. While we understand that reporting on anemia is mandatory and participation in PQRI is voluntary, we believe that extending this opportunity is an important signal that CMS views anemia quality indicator reporting to be on par with the other measures. The implementation requirements for both types of measures could remain unchanged; that is, the anemia reporting occurring on every claim including a bill for the treatment of anemia and the PQRI measures reported for a minimum of 80% of applicable cases. ASCO would help educate our members accordingly.

COMPENDIA FOR DETERMINING MEDICALLY ACCEPTED OFF-LABEL USES

Section 1861(t)(2) of the Social Security Act (in conjunction with sections 1832 and 1861(s)(2)) requires Medicare to cover "medically accepted" uses of drugs and biologicals used in cancer chemotherapy regimens if the uses are supported by citations that are

included, or approved for inclusion, in specified compendia. The compendia specified in the statute are AMERICAN HOSPITAL FORMULARY SERVICE – DRUG INFORMATION, AMERICAN MEDICAL ASSOCIATION DRUG EVALUATIONS (which is no longer published), and UNITED STATES PHARMACOPOEIA – DRUG INFORMATION. The statute provides that CMS "may revise the list of compendia . . . as is appropriate for identifying medically accepted indications for drugs."

The Proposed Changes

CMS has proposed to establish a process for adding or deleting compendia from the list of authoritative compendia. Under the proposal, CMS would annually issue a notice inviting requests to revise the list. The notice would establish a 30-day window for accepting requests, which would start 45 days (or later) after publication of the annual notice. Requests would be required to include a copy of the compendium at issue and would need to include detailed, specific documentation showing that the compendium does or does not meet CMS's standards for compendia. CMS would publish a list of the complete requests received, and the public would have 30 days to comment on them. CMS would reach a final decision within 120 days after the close of the comment period. CMS proposes to execute the various steps in the process through notices posted on its website, although other "reasonable means" could also be used. In addition to the annual notice, CMS would reserve the right to act on its own initiative at any time.

The standards that CMS is proposing to apply in evaluating the compendia appear to fall into three categories. First, CMS is defining a compendium as having the following characteristics:

- It is a comprehensive listing of FDA-approved drugs and biologicals or a comprehensive listing of a specific subset of drugs and biologicals in a specialty compendium, such as a compendium of anticancer treatment.
- It includes a summary of the pharmacologic characteristics of each drug or biological and may include information on dosage, as well as recommended or endorsed uses in specific diseases.
- It is indexed by drug or biological (and not by disease).

Second, CMS would "consider a compendium's attainment" of the "desirable characteristics" recommended by the Medicare Evidence Development and Coverage Advisory Committee (MedCAC) at its March 2006 meeting. As listed in the July 12 notice, the Committee identified the following desirable characteristics:

- Extensive breadth of listings.
- Quick throughput from application for inclusion to listing.
- Detailed description of the evidence reviewed for every individual listing.

- Use of pre-specified published criteria for weighing evidence.
- Use of prescribed published process for making recommendations.
- Publicly transparent process for evaluating therapies.
- Explicit "Not recommended" listing when validated evidence is appropriate.
- Explicit listing and recommendations regarding therapies, including sequential use or in combination in relation to other therapies.
- Explicit "Equivocal" listing when validated evidence is equivocal.
- Process for public identification and notification of potential conflicts of interest of the compendia's parent and sibling organizations, reviewers, and committee members, with an established procedure to manage recognized conflicts.

Third, CMS is proposing additional criteria:

- Unspecified "reasonable factors" such as, for example, factors "that are likely to impact the compendium's suitability for this use, such as a change in ownership or affiliation [,] the standards applicable to the evidence considered by the compendium, and any relevant conflicts of interest. We may also consider that broad accessibility by the general public to the information contained in the compendium may assist beneficiaries, their treating physicians or both in choosing among treatment options."
- The compendium's grading of evidence and the process by which the compendium grades the evidence.

Comments on the Proposed Process

We agree with CMS's conclusion that there should be a formal process to consider revisions to the list of authoritative compendia. We do not, however, support the proposed process as outlined in the July 12 Federal Register.

Initially, we question the need for an annual process. The universe of compendia is small – only six compendia were identified for consideration by the MedCAC in 2006, and new compendia are rarely introduced. An annual process to consider and reconsider these same six compendia, and possibly one or two additional compendia in future years, seems highly disproportionate to the scope of the potential work involved.

In addition, the informal process proposed by CMS would be inconsistent with statutory requirements. Section 1871 of the Social Security Act provides that any "rule, requirement, or statement of policy . . . that establishes or changes a substantive legal standard governing the scope of benefits" must be promulgated as a regulation after a 60-day period for public comment. The identity of the compendia deemed authoritative under section 1861(t)(2) directly affects the drug uses covered under the Medicare Part B benefit, and therefore any

changes in the list of authoritative compendia may be adopted only through the issuance of regulations after notice and opportunity for public comment. The proposed process of using notices posted on the CMS website and a 30-day public comment period does not conform to the requirements of section 1871.

ASCO suggests that CMS announce a procedure in which it is continually open to receiving requests to add or delete compendia from the list authorized by section 1861(t)(2). If a request is supported by adequate information, CMS could propose a regulation for public comment in the same manner as for other changes in the regulations.

Comments on the Proposed Criteria

We have serious concerns about the criteria that CMS is proposing to use in deciding which compendia should be deemed authoritative. Our initial concern is that the proposal gives no indication as to how CMS will apply the criteria. The proposed factors do not appear to be definitive standards that must be met but instead are apparently only a list of characteristics that CMS will apply, or not apply, in particular cases in some unspecified manner. Any criteria used to evaluate compendia should be recast as specific standards that must be met or should otherwise provide clear rules defining what qualifies as an authoritative compendium.
Moreover, we question the substance of the proposed criteria. The July 12 notice states that "MedCAC concluded that none of the compendia fully display the desirable characteristics." By proposing to adopt the MedCAC criteria, which the statutorily authorized compendia apparently do not meet, CMS seems to be preparing a case for revoking the authoritative status of the currently designated compendia. ASCO strongly opposes dismantling the coverage requirements set in statute, including invalidation of the originally named compendia. Instead, we believe that it would be more consistent with the statute to identify the characteristics of the compendia that Congress deemed satisfactory, and apply those criteria to other compendia that are not currently recognized.

In addition, the proposed criteria are not closely tied to the statutory standard for revisions to the list. Section 1861(t)(2) permits CMS to revise the list "as is appropriate for identifying medically accepted indications for drugs." Under this statutory language, the test for a satisfactory compendium should be whether the compendium identifies the medically accepted uses of drugs with sufficient accuracy. By contrast, many of the proposed criteria, such as those requiring descriptions of the evidence, use of a published and transparent process, dealing with conflicts of evidence, and grading the evidence, do not directly bear on the statutory standard. ASCO recommends that CMS adopt the standard that a compendium should identify medically accepted uses of drugs with sufficient accuracy as the key determinant for authoritative status.

The proposed criteria should also be consistent with the statutory standard for using the compendia to determine Medicare coverage. Section 1861(t)(2) requires Medicare coverage when the "use is supported by one or more citations" in the compendia. For a compendium to be useful for purposes of section 1861(t)(2), its format should make clear whether its

citation does or does not support the particular use of the drug. In that connection, we note that the proposed criteria would consider whether the compendium grades the evidence used in making its recommendation. Although grades of evidence may be valuable from a medical standpoint, they are a confusing factor in determining whether the compendium citation "supports" a particular drug use. To implement section 1862(t)(2), we believe that it would be desirable for a compendium to make c lear whether it regards each drug use as medically accepted or not, thus avoiding the need for interpretation of its conclusions.

ASCO Recommendation

Section 1861(t)(2) makes the compendia authoritative only with respect to drugs used in cancer chemotherapy regimens. Although Medicare contractors are free to rely on the compendia in determining coverage for other types of drugs, we believe that CMS's focus on evaluating compendia should be on their statutory function, which relates to cancer treatment.

As discussed above, the key determinant under the statute should be whether a compendium identifies the medically accepted uses of drugs used in cancer therapy with sufficient accuracy. We suggest that, as a practical matter, the most efficient way to assess this characteristic is to seek the opinions of oncologists. A group of qualified oncologists could be added to the MedCAC for the purpose of evaluating a compendium and could recommend to CMS whether the compendium is sufficiently accurate in identifying medically accepted uses of drugs used cancer chemotherapy regimens. We encourage CMS to consult with ASCO in forming an expert panel for this purpose.

United States Pharmacopoeia – Drug Information

We understand that the publisher of UNITED STATES PHARMACOPOEIA – DRUG INFORMATION is no longer updating the compendium under that name and that the successor publication is called DRUGPOINTS. We urge CMS to advise its contractors that DRUGPOINTS is an authoritative compendium under section 1861(t)(2) and to provide the contractors with any instructions necessary for the contractors to begin using the successor publication immediately.

INTRAVENOUS IMMUNE GLOBULIN

There is currently a payment amount based on 1.97 relative value units for pre-administration related services for intravenous infusion of IVIG. CMS is proposing to continue this payment amount through 2008.

ASCO supports this proposal. There continue to be significant problems in obtaining IVIG for less than the Medicare payment amount, and this additional payment amount helps to mitigate the adverse financial impact that many physicians experience in obtaining IVIG for their patients.

WAMP AND AMP THRESHOLD

The statute authorizes CMS to establish a payment amount for a drug based on its widely available market price (WAMP) or average manufacturer price (AMP) if the ASP exceeds the WAMP or AMP by a specified threshold percentage. For 2005, the statute set the threshold at 5%, and CMS has administratively continued the threshold at the same percentage in subsequent years. CMS is proposing to maintain the threshold at 5% in 2008 as well.

ASCO supports continuing the threshold at 5%. The ASP-based payment system does not ensure that physicians are able to purchase drugs for less than the Medicare payment amount, and in many cases they are not able to do so. The surveys of WAMP and the calculations of AMP should not be used to reduce the Medicare payment amounts.

COMPETITIVE ACQUISITION PROGRAM

There are serious problems with the competitive acquisition program (CAP) that make it unattractive to most physicians. While we recognize CMS' attempt in this proposal to improve aspects of the CAP, we believe that the CAP has fundamental defects that the proposals do not resolve.

CMS is proposing to broaden the definition of "exigent circumstances" in which a physician can cancel the CAP election agreement before the end of the calendar year. Because of the problems posed by the CAP, which physicians may not recognize when they enroll in the program, ASCO supports these changes.

The notice asks for comment on the current rule requiring drugs to be shipped to the site at which they are administered. As ASCO has previously commented, this restriction is an obstacle to CAP enrollment by oncologists who use satellite offices that are not continually staffed. Physicians who administer drugs are well-qualified to maintain their integrity when transporting them to an alternative site of administration, and there should be no restrictions on their doing so. We do not understand the basis for CMS's concerns that the CAP vendor needs to maintain control over the drugs and that this control is somehow jeopardized if a physician transports drugs from one practice site to another. Once the CAP vendor ships drugs, it is relying on the receiving physician to properly handle and account for them, and we do not see how the CAP vendor's interests are threatened if the physician is permitted to transport the drugs to another practice site.

CMS also asks for comments on the current requirement that the physician enter the CAP's prescription order number on the claim form that the physician submits to Medicare for the related drug administration services. CMS recognizes that this administrative requirement is burdensome and asks for comment on alternative mechanisms. We suggest that the Medicare contractors simply match claims from the CAP vendor to claims from physicians. Generally, it should be possible to match the claims successfully, and if there are substantial discrepancies, the contractor could make inquiries or conduct an audit. This change would

eliminate a significant current administrative burden on physicians who participate in the CAP.

REPORTING OF ANEMIA QUALITY INDICATORS

The proposal implements the recent statutory amendment requiring that claims for drugs administered for the treatment of anemia in connection with the treatment of cancer must be accompanied by information on the patient's hemoglobin or hematocrit level. The proposed regulation provides that the claim must indicate the patient's "most recent" hemoglobin or hematocrit level.

ASCO supports the proposal to require the "most recent" hemoglobin or hematocrit level to be reported. This formulation makes clear that patients are not required to undergo a medically unnecessary blood test solely for the purpose of the Medicare claims process.

* * * * *

Thank you for the opportunity to comment on the proposal.

Sincerely,

Joseph S. Bailes, MD
Chair, Government Relations Council

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Physician Self-Referral Issues

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

I am a physical therapist in an outpatient clinic in Claremore, Oklahoma. I have practiced for about a year and a half seeing all types of patients with orthopedic problems.

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 clinic has already seen and experienced problems with these rules and regulations, where physicians stop referring patients to our clinic and start referring to themselves. I feel that it is morally and legally wrong for physicians to refer patients to their own PT clinics, just so they can get the monetary "kick back". Patients should be sent to the clinic that best suits them and their injuries. These physician self referrals seem abusive and fraudulent to the medical system and most of all the patients. The ability to refer patients to your own physical therapy clinic should be and must be stopped.

Audra George, MPT

Sincerely, Audra George, MPT

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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

Physician Self-Referral Issues

Dear Mr. Weems:

My name is Rodney McCaslin and I am a Physical Therapist and clinic manager at Summit Physical Therapy in Catoosa, OK. I have been practicing physical therapy for eight years.

I am writing today to express my concern regarding the July 12 proposed 2008 physician fee schedule rule. On several occasions, my Medicare/Medicaid patients who live in Catoosa have told me when they received their referral for physical therapy, they were first requested to perform their physical therapy at the "Physician owned clinic." Only when the patient complains that they are on a fixed income and can not afford to drive into Tulsa three times a week, are other options or clinics offered. These patients should be offered to perform their therapy at a reliable physical therapy clinic that is more convenient for them.

My other concern is how many referrals our small clinic loses each year due to the physician's incentive to refer patients to their own therapy clinics. 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 closing I would like to thank you for your time and consideration of my comments.

Sincerely,

Rodney McCaslin, PT

Physician Self-Referral Issues

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

I am a physical therapist and member of the APTA from Claremore, OK.

I am not against physician owned physical therapy clinics. Nevertheless, I have a 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 concerned is that physician-owned physical therapy clinics and self referral; if allowed may discourage patients from choosing where and from whom they receive their treatment. The patients may feel undue pressure from their physician to receive treatment from "his" therapy clinic even if a more convenient or "preferred" therapy clinic would have been the patient's first choice.

As long as patients are educated on their right to choose their physical therapy provider this issue could be avoided even with physician owned clinic and self referral.

Sincerely, **Wendi Schaffitzel, PT**

Physician Self-Referral Issues

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

My name is Brent Foster and I am a clinic coordinator and staff physical therapist at an outpatient in Claremore, OK. I have practiced for a little over two years now and look forward to a long career as a physical therapist.

I am writing today to express my concerns regarding the July 12 proposed 2008 physician fee schedule rule, specifically the issue surrounding physician self-referral and the "in-office ancillary services" exception. Over the past several months I have seen the effects of the loopholes in the previous rules and have witnessed there effect on a number of patients and our clinic. Probably the most irritating case was when a Dr. told one of my patients that he was behind schedule in his rehab and thought it would be best if he were to attend a physical therapy clinic in Tulsa, OK that was part of his group. Not only did the Dr. lie to the patient, who was ahead of schedule according to the Dr. provided protocol, but he also made the patient waste his time and money by making the patient drive an extra 40 minutes and waste his gas. There are many other cases I could elaborate on, but due to time I will not go into all the details.
This is a very important issue and could greatly affect the future of our profession.

Thank you for your time and consideration.

Sincerely, Brent S. Foster MPT

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.

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

My name is Teresa McIlroy and I am a physical therapist practicing in the state of Oklahoma. I have been licensed 21 years and am currently employed by Summit Rehab providing pediatric physical therapy services.

I am writing to state my strong support of the July 12 proposed 2008 physician fee schedule rule and any efforts 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 urge the CMS to remove Physical Therapy as a DHS permissible under the in-office ancillary exception of the federal physician self-referral laws.

The current broadly defined physician referral laws facilitate 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 current referral requirements physicians have a captive referral base of physical therapy patients in their offices thereby creating an atmosphere for abuse and fraud.

Again, I strongly support any efforts to regulate and revise payment policies under the physician fee schedule and other Part B payment policies for CY 2008 and the proposed rule.

Thank you for your consideration in this matter.

Sincerely,
Teresa McIlroy, RPT

Mr. Kerry N. Weems

Administrator- Designate

Centers for Medicare and Medicaid Services

U.S. Department of Health and Human Services

Attention: CMS 1385-d

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

My name is Benta Hicks; I am certified occupational therapist assistant. I presently work for a private pediatric therapy company with 8 years of experience.

Physician Self-referral Issues

I wish to comment on the July 12 proposed 2008 physician fee schedule rule, most importantly the issue of physician self-referral and the in office auxiliary services and exceptions. The abuse would become widespread with physician-owned physical and occupational services and I support physical therapy and occupational therapy's removal from the permitted services under the in office auxiliary exception. The potential for fraud and abuse would be over-whelming to the system and the services to be provided to patient care; by eliminating physical and occupational therapy as a designated health services (DHS) furnished under the in office auxiliary services exception. CMS would reduce a significant amount of programmatic abuse and fraud to the Medicaid program. It would only enhance the quality of patient care which is the priority of the physical and occupational profession

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

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

As a speech pathologist, I have treated with many good and excellent physical therapists. I believe that the only way to find an excellent therapist is to ask someone from a different discipline. Therapists don't usually observe each other, so it is through co-treating that we all gain a knowledge and respect of whom is a good therapist and who is a great therapist. I can recommend many speech pathologists that I think that are great but how do I really know-I haven't seen them in treatment. By contrast, I can recommend many excellent physical and occupational therapists because I have worked closely with them over the past 15 years.

Therefore, when my father needed a physical therapist last year, I had a definite opinion on who he should see and where he should go. However, his physician referred him to a "colleague". I do not believe that my father received substandard care by any means; however, I do believe that his request to see a physical therapist that specialized in his area of need should have been honored instead of being referred to a physical therapist that worked with his doctor.

The fact remains that excluding physical therapy from the "in-office ancillary services" that physicians provide does not allow patients to seek out the best possible care for themselves. There is also a concern that the treatment these patients receive can be dictated by the financial gains of the providers instead of the treatment needs being determined by an unbiased, licensed physical therapist.

Again, I do not believe that my father received substandard care, but I do not believe that he received that best possible care that he could have if he would have been able to choose where he received physical therapy. He continues to have pain but his response to my encouragement to talk to his doctor about it is "Why bother?" Is that really the impression that a physical therapist wants to leave?

Sincerely,
Kym Claborn, M.S., CCC-SLP

SUMMIT
Physical Therapy & Rehab
PHYSICAL, OCCUPATIONAL & SPEECH THERAPY SPECIALISTS

Sean Cox, RPT/owner • Bret McGuire, RPT/owner
Brent Foster, RPT • Scott Hamel, RPT • Rod McCaslin, RPT • Anissa McGuire, RPT
Wendi Schaffitzel, RPT, CHT • Audra Steinbrook, PT • Erin Herrman, ATC
Colleen Caton, OTR • Robyn Foxworth, MA

www.ptsummit.com

Mr. Kerry N. Weems
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
8-28-2007

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

Mr. Kerry N Weems,

I am a outpatient physical therapist in a rural community that serves several surrounding communities. I have been a physical therapist for three years. My experience encompasses in and out patient settings in hospitals as wells as privately owned clinics. I am writing you this letter to comment on the July 12 proposed 2008 physician fee schedule rule. I will be focusing my comments on the physician self-referral and the in-office ancillary services exception.

I would urge action on your part to remove physical therapy services from the designated health service. This current system makes abuse and overuse of physical therapy services to easy in a system that is already strained. It is my belief that there is no overwhelming benefit for the Medicare patient to be treated in a physician owned physical therapy clinic. I do believe that there is an overwhelming benefit for the physician to own a physical therapy clinic due to the current law restricting a physical therapist from direct access to patients without a physician's referral. A patient may be referred to a physician owned clinic to enhance his financial gain not necessarily provide the best treatment possible for that patient. I would comment that the physician practice of referring patients to physical therapy treatment has become more about financial gain than what is best for the patient. For example, my patient had surgery and she was told that only their in-office physician owned facility was capable of getting a successful outcome for that particular surgery, so this patient was forced to travel three times a week for a month or more to a physician owned facility that was one and half hours away from her residence. I believe this is a prime example of abuse of the current rules and by no means does this protect patients from undue hardship and unethical decision making.

I believe that the continued growth of physician owned physical therapy clinics would create an environment for treating physical therapists to become complacent. The physical therapy clinic that is owned by non-physicians work to earn every referral with consistent good outcomes from the patient referred to the clinic by physicians. A non-physician owned clinic is made by its reputation and current good standing in the community and not by the deals for profit sharing and partial ownerships with referring physicians. I personally am driven to provide the best treatment possible with the knowledge available to me today to my patient because my professional and financial future depends on the outcomes I can achieve to foster continued growth and good relations with patients, physicians, and the community. If as a physical therapist you are provided with patients from a referring physician only because that physician will gain financial benefits from that referral then the referral becomes more about financial benefit and less about maximum physical benefit.

In closing, I appreciate the opportunity to state my thoughts about this subject matter. I also thank you for your careful consideration of this topic, Mr. Weems, because this decision could ultimately hurt patients and cause mass abuse of Medicare funds.

Sincerely,

Bryce Conly, M.P.T.

Bryce Conly, M.P.T.
Master of Physical Therapy

August 30, 2007

VIA FEDERAL EXPRESS

Herb Kuhn
Acting Deputy Administrator
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: 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

Dear Acting Deputy Administrator Kuhn:

I am a urologist who practices in the State of Maryland as a member of Chesapeake Urology Associates, P.A. ("Chesapeake Urology"). Chesapeake Urology, which is the largest urology practice in Maryland, is comprised of over 40 physicians with offices in six Maryland counties. Collectively, we care for over 200,000 Maryland patients every year. Physicians in our practice specialize in both general adult and pediatric urologic care. We also provide specialized care in advanced laparoscopy, robotics, incontinence and infertility, which is unique to our practice. I am a general urologist and personally care for over 5000 patients a year. As a physician and a member of Chesapeake Urology we are dedicated to furnishing the highest quality of medical and surgical urologic care, with a full range of services provided in a convenient, comfortable, supportive and patient-friendly setting.

Our mission is to give better patient care! Let us continue that mission.

As a Maryland urologist, I thank you for the opportunity to comment on the Proposed Rule, published by the Centers for Medicare & Medicaid Services ("CMS") on July 12, 2007. See 72 Fed. Reg. 38122 (July 12, 2007). Although I commend CMS on its continuing efforts to develop clear and comprehensive regulations that implement the Stark Law, I write to express my concerns about the changes contained in the Proposed Rule and the nature of the Preamble discussion with respect to the in-office ancillary

services exception (the "Exception"). 42 U.S.C. § 1395nn(b)(2)(A). Let me begin by saying that I do not think that changes to the Exception are necessary to protect against program or patient abuse. In fact, any narrowing of the Exception, or the implementation of the changes to the reassignment and anti-markup provisions of the purchased diagnostic tests rule that are contained in the Proposed Rule, 72 Fed. Reg. at 38225, 38229, would have a deleterious effect on the health care community generally and on the quality and availability of patient care services offered by Chesapeake Urology in particular.

The physicians at Chesapeake Urology take pride in furnishing the very best in quality patient care in a manner that maximizes patient convenience. The care that we provide is enhanced by our current ability to furnish diagnostic services in our offices, namely (1) in-office diagnostic imaging services, including computed tomography ("CT"), and (2) pathology services, which we provide through bona fide employment and independent contractor arrangements with four pathologists who specialize in urological pathology.

The ability of physicians to affiliate with pathologists allows practices such as ours to identify and work with highly qualified and trained specialists with whom we are familiar and whose work product we trust. This, to us, is critical to our ability to furnish the highest quality care to our Maryland patients. Because we at Chesapeake Urology know and personally have selected the pathologists with whom we work based on their outstanding credentials (each is Board Certified and has completed a fellowship at one of Maryland's leading medical centers), our present ability to practice with pathologists of our choosing provides for a considerably and consistently higher quality of care. Moreover, the three pathologists who are part of our practice each reads 5,000 to 6,000 prostate slides every year. They have, in essence, developed a subspecialty in prostate-related diagnoses, have a special interest in prostate pathology and have become experts at reading prostate slides. They are better able, for example, to identify true prostrate cancer from benign tissue and prostate cancer mimickers, thereby reducing "false positives" and saving our patients unnecessary anxiety and cancer treatments. As such, we know and trust the consistency and quality of their reads, which is not something we could do if we are forced by changes in the Exception or the purchased diagnostic tests rule no longer to provide pathology services in the office setting and to send our prostate slides to large hospital-based or commercial labs. Under such circumstances, we would have no idea who is reading the slide; what that person's credentials are; the nature of the person's expertise or training; or whether that person has read one prostate slide or 1,000 prostate slides.

Because we work together with our pathologists on a daily basis, the means by which we communicate and discuss test results and prepare written reports have become standardized, thereby increasing the efficiency of our practice and our ability rapidly to deliver diagnoses to our anxiously waiting patients. In fact, whereas the national average for turning around test results is five to seven days, our pathologists return test results in three to four days. Moreover, better and more proximate communication with our pathologists, particularly in difficult cases, results in improved clinical diagnoses and outcomes for our patients.

Chesapeake Urology physicians always have immediate, often face-to-face access to our pathologists to discuss nuances in results and diagnoses, and to engage the pathologist in the development of an appropriate plan of care for a particular patient. Because our pathologists are part of our practice, they have access to the patient's complete medical record, previous biopsies and clinical history, and they even can review the slides with the treating physician in person. The treating physician and the pathologist then can – and do – track the effectiveness of the treatment plan and are able quickly to compare test results over a period of time, something that cannot easily be done, if at all, if a member of our practice is forced to rely on community or large commercial labs. Finally, our pathologists clearly are exercising their prerogative to affiliate with Chesapeake Urology in an arrangement of their choosing, something that might be prohibited by changes to the purchased diagnostic tests rule or a narrowing of the Exception.

I cannot tell you how many times a patient has come in to the office with severe pain. They are seen immediately and obtain a CT scan in our office. I can read the scan at that moment or our radiologist reads it and calls me in to look at the results. Whichever, the diagnosis is made within 10 minutes and a treatment plan is instituted on the basis of that scan. They can be sent to our ASC for treatment or they are sent to the hospital, taken to the operating room directly and the problem is resolved. If we do not have that ability that patient would have been sent to the hospital emergency room, probably sit in the waiting room for 2-7 hours and then after they have sat in the room for 1-2 hours finally get their CT scan. By then it is 1 am and they cannot get their surgery to remove that stone until the next morning.

The same attention to patient care can be said by having the Pathologist as part of Chesapeake. Our Pathologist are there to look at slides with the doctors and the patients if necessary. Our patients are confident that their doctor is involved and are confident they are receiving the best available care. If it is my prostate slides they are reading I want them read by the Pathologist reading thousands instead of a few. That is what we have at Chesapeake Urology.

With respect to diagnostic imaging, any narrowing of the Exception might impose limits on patient access to the very types of diagnostic imaging services that have become the standard of care in Maryland and throughout the United States by restricting or prohibiting non-radiologists from providing CT services to patients in the office setting. The rapid advance in CT technology, followed by a reduction in acquisition and installation costs, makes it possible for patients to avoid the inconvenience of having to see multiple doctors to have CT services performed outside of their own doctor's offices. This technology, once considered expensive, cumbersome and difficult to use, has advanced into available, affordable and indeed indispensable patient diagnostic tools. As a result, we have incorporated CT technology into our practice to provide more effective and cost efficient diagnosis and treatment to our patients. It is important to note that no matter where a Maryland patient goes for his or her MRI or CT scan, the actual images will be taken by trained technicians who are licensed by the Maryland Board of Physicians using the appropriate imaging technology, and a radiologist will read and interpret the images. There is, therefore, no clinical, quality of care reason to restrict the definition of in-office ancillary services so as to eliminate our ability to furnish state-of-the-art diagnostic imaging services in a setting that is most convenient for our patients and is most efficient with respect to our ability to make a diagnosis.

The changes suggested by the Proposed Rule, and the nature of the comments solicited with respect to the Exception, go far beyond what is necessary to protect the Medicare program from fraud and abuse and to ensure patient care. The Exception as currently interpreted and applied recognizes that certain employment and contractual relationships among physicians are beneficial to patients and strike the appropriate public policy balance between the prophylactic prohibition on self-referrals and the recognition that certain arrangements not only are appropriate, but also are necessary to enhance the efficient provision of quality health care.

Consequently, if the Exception is narrowed in any meaningful way, particularly in a manner that limits the types of ancillary services that can be provided pursuant to the Exception or that restricts the ability of physicians or groups to furnish services in the "same building," 42 U.S.C. § 1395nn(b)(2)(A)(ii)(I), the manner in which the physicians of Chesapeake Urology practice medicine will be severely impacted, and the quality and convenience of care that we provide to our patients will be significantly compromised. The practical effect would be to restrict access for our patients to routine medical procedures that have become the standard of care throughout the country. Implementation of the proposed changes to the purchased diagnostic test rules would have a similar effect by limiting our ability to provide such services with anything but full-time employees. Both potential changes would create an unjustified monopoly for particular physician specialties to the detriment of patient access and care.

Thank you again for the opportunity to submit these comments on the Proposed Rule.

Sincerely,

.KENNETH F. LANGER M.D.

Physician Self Referral Issues

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

My name is Colleen Caton and I am an Occupational Therapist at an outpatient clinic in Claremore, OK. I have practiced 8 of my 28 years in this clinic. I have seen this clinic built by 2 dedicated therapists and have been a part of its growth. The success of this clinic has been because of superior care and positive outcomes for the persons whom have been served.

I am writing today to express my concerns regarding the July 12 proposed 2008 physician fee schedule rule, specifically the issue surrounding physician self-referral and the "in-office ancillary services" exception. People in our community may be asked to be treated many miles away. The clinic has been built on hard work and good reputation and not self referral.

This is a very important issue and could greatly affect the future of our professions.

Thank you for your time and consideration.

Sincerely,

Colleen Caton OTR/L

Colleen Caton, OTR/L

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Brent Foster, RPT • Scott Hamel, RPT • Rod McCaslin, RPT • Anissa McGuire, RPT
Wendi Schaffitzel, RPT, CHT • Audra Steinbrook, PT • Erin Herrman, ATC
Colleen Caton, OTR • Robyn Foxworth, MA

www.ptsummit.com

CMS
RE: Physician Self Referral/ Stark Law Review
Date: August 30, 2007

To Whom it May Concern:

I am writing this letter in regards of the current status of the Physician Self Referral issue related to the previous changes of the Stark Law. As a practicing clinic physical therapist and clinic owner of a private practice serving a developed rural area in NE Oklahoma, I have commonly seen the negative impact imposed on the patient. I typically see the related impact on patients 15-20 times per year since the reduced restrictions of the Stark Law. The typical occurrence is the patient being pressured by the referring physician who has financial ownership in the PT clinic to attend therapy in that clinic, burdening the patient with the additional drive and related cost to go 30 miles, when a quality local provider is available. I've had multiple events when the patient repeatedly stated their desire to stay local, but with continued pressure from the physician to attend their clinic. This is a breach of ethics, and removes the ability of choice of the patient as the consumer. I am obviously affected professionally as a physical therapist, but also a health care consumer, as I am a firm believer that all patients should have the ability to choose their provider in all realms of health care.

This self referral allowance establishes a bad incentive for excessive referral patterns and fraud and abuse for financial gain of the physician. The best method of referral for service for all health care is a needs based system, in which referrals are made based on true medical need, not influenced by financial gain. I have seen the allowance of the physician self referral method diminish this method, causing unnecessary inflated cost to CMS and other insurers, adding to the already inflated cost of healthcare. I have seen the needs based design work very effectively and cost effectively in the process in the years preceding the loss of the Stark restrictions.

In closing, it only makes sense in terms of protecting the choice of the patient and cost controls to eliminate the physician self referral patterns by re-instating the restrictions as set forth in the original Stark Legislation.

Signed,

Sean Cox, PT

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

Mr. Weems,

The purpose of my letter is regarding **Physician Self-Referral Issues.** I am a Physical Therapist currently working in a privately owned outpatient facility.

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. These new rules open the door for the potential of considerable physician abuse of self-referral of physical therapy services. In addition, there is the concern that these physicians will inappropriately mislead their patients into believing that it is necessary for them to be treated at the physician's office and not inform them that they have the choice of which clinic they choose to go to.

The clinic that I work at is located in a small town with limited access to therapy facilities. I grew up in the town that I work in so this subject is very near and dear to my heart. The Physician owned practices are falsely leading patients to believe that the care they receive at their clinics will be closely supervised by a physician, and this therefore sways the patients decision on where they will receive therapy.

A number of our patients appreciate the close proximity of our clinic to their homes. Without access to our clinic they would be required to drive at least 30 minutes to the nearest big city for treatment. Unfortunately, a number of physicians have not made it clear to a number of patients that they are free to go to any clinic they choose. As a result a number of patients have had to drive over 30 minutes to receive the same quality of treatment they could have received 5 minutes from home. I work in the town where my entire family lives and when my Uncle tore his rotator cuff the Dr. had him convinced that he had to go the his physical therapy department. It took me over a week to convince my Uncle that he had the right to go where ever he pleased and that his insurance would cover it. And this was my own family member who had been deceived!

Please consider eliminating Physical Therapy as a designated health service furnished under the in-office ancillary services exception. By eliminating physical therapy as a designated health service furnished under the in-office ancillary services exception, the Centers for Medicare & Medicaid Services 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.

PT

Lisa Otterbein, MSPT

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

Mr. Weems,

The purpose of my letter is regarding **Physician Self-Referral Issues.** I am a Physical Therapist currently working in a privately owned outpatient facility.

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. These new rules open the door for the potential of considerable physician abuse of self-referral of physical therapy services. In addition, there is the concern that these physicians will inappropriately mislead their patients into believing that it is necessary for them to be treated at the physician's office and not inform them that they have the choice of which clinic they choose to go to.

The clinic that I work at is located in a small town with limited access to therapy facilities. A number of our patients appreciate the close proximity of our clinic to their homes. Without access to our clinic they would be required to drive at least 30 minutes to the nearest big city for treatment.

Unfortunately, a number of physicians have not made it clear to a number of patients that they are free to go to any clinic they choose. As a result a number of patients have had to drive over 30 minutes to receive the same quality of treatment they could have received 5 minutes from home. Not only is the long drive to physician owned physical therapy clinics inconvenient, it is often unsafe for a number of our injured and elderly patients.

Please consider eliminating Physical Therapy as a designated health service furnished under the in-office ancillary services exception. By eliminating physical therapy as a designated health service furnished under the in-office ancillary services exception, the Centers for Medicare & Medicaid Services 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.

Sincerely,

Sarah Dowdy, PT

Northern Physical Therapy Services
709 W. Superior **Wayland,** MI 49348 269-792-4440 • fax: 792-4475
From the Desk of Janis Kemper, PT

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 Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Rule

Dear Mr. Weens:

Thank you for the opportunity to express my opinion regarding **Physician Self-Referral Issues**.

I am a physical therapist and have been in practice since 1988. I have been the co-owner of Northern Physical Therapy Services (NPTS) since 2003. NPTS is a rehab agency with 5 rural locations surrounding the Grand Rapids, MI area.

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. It is my opinion, that there is an inherently abusive nature to physician-owned physical therapy services. I strongly recommend the removal of physical therapy and occupational therapy as a permitted service under the in-office ancillary exception.

The potential for fraud and abuse arises whenever physicians are able to refer Medicare beneficiaries to entities in which the physician has a financial interest. A physician's referral to therapy should be based solely on the best interest of the patient. The physician's focus should be who can provide the best quality care and who is in a convenient location for the patient. The unavoidable financial bias that is present with physician owned physical therapy, often results in patients receiving lesser quality care, traveling to inconvenient locations, and overutilizing services. By eliminating physical therapy as a designated health service (DHS) furnished under the in-office ancillary services exception, CMS can reduce a significant amount of programmatic abuse, curb overutlization of physical therapy services under the Medicare program, and enhance the quality of patient care.
The following are examples of personal experiences that I believe clearly demonstrate why physician owned physical and occupational therapy should not exist.

We at NPTS have worked very hard to develop a reputation for excellent quality care within our market. We frequently are told by patients from our communities that when seeking a referral for therapy at NPTS, their physician (or physician's office manager)

Northern Physical Therapy Services
709 W. Superior **Wayland,** MI 49348 269-792-4440 ◆ fax: 792-4475
From the Desk of Janis Kemper, PT

redirects them to a clinic we know to be owned by the physician. In fact, recently, my own sister's doctor recommended physical therapy and she requested to be seen at one of my offices, but instead, her physician strong armed her into a clinic he owns. I'm sure we all understand how intimidated a patient can be by their physician.

Similar stories are all too common and usually include the physician's explanation that "their therapists will work closely under the physician's supervision" or they provide more "expert care". In fact neither of these are the case, the only reason the doctor pushes their own clinic is for financial gain.

Our clinics are located in outlying areas. Frequently, I see physicians forcing their patients to travel long distances to reach urban clinics only because the physician owns the clinic. I am certain that given the option, patients would have preferred to receive therapy at a local clinic. Travel can be especially difficult for the elderly. In an extreme case, I experienced a physician that refused to refer a patient to therapy unless the patient agreed to use the physician's therapy clinic. Coming to our clinic saved the patient a 20 mile one way drive. I doubt this physician was looking out for the patient's best interest.

Physician's "expertly trained therapists" are often new graduates that can be hired at the bottom of the wage scale. I have seen several examples of physicians looking to recruit experienced therapists/practices that they have been happy with. When the therapist/practice agrees to set up shop within the same building, but does not agree to be physician owned, the deal is immediately broken. Another example of how quality care is sacrificed for financial gain.

I am aware of situations that exist within our market that involved physicians employing athletic trainers, personal trainers, massage therapists and other unqualified individuals to provide physical therapy care. These physicians are using these unqualified individuals as physical therapists and billing as such. We in the physical therapy field are not able to use aides or athletic trainers to assist our qualified therapists, yet we are forced to compete with those who seem to be bound by a much lower standard of care.

Again and again a physician's ability to objectively direct his or her patients to therapy is clouded by their own desires for profit. As long as physicians remain the gate keeper for therapy services, I believe both the patient, and the insurance carrier can only be fairly served by removing the distraction that is physician owned practices. If allowed to continue, physician owned practices seriously jeopardize the existence of the independent physical therapy practice. I strongly believe that patients and insurance carriers both benefit from the existence of and the competition between independent therapy sources. For our patient's sake, CMS' sake, and for all private PT owned practioners, I urge you to establish a level playing field.

I would like to thank you for taking the time to review and consider my comments.

Sincerely,

Janis Kemper, PT

MANKATO CLINIC

627

It's all about 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

528

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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

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

August 28, 2007

Dear Mr. Weems,

I am a physical therapist with 22 years of experience. I have seen many changes in the health care environment and delivery of physical therapy services since graduating from college. I currently practice in an outpatient setting with Physiotherapy Associates, formerly, Benchmark Medical, Inc. I have also been a member of the APTA for over 15 years.

I would like to comment on the July 12 2008 physician fee schedule rule, specifically the issue surrounding physician self-referral and the "in office ancillary services" exception. I have worked with physicians in several markets that would refer a small amount of business to physical therapy prior to owning their own therapy. They would state, in conversations with me, that they referred all appropriate patients to therapy. However, upon taking the therapy "in-house", their referrals to therapy significantly increased. There was no significant change in the demographics of their patient load to explain this increase. Also, when a patient asked to return to me or another therapist not part of their practice, they were told that they prefer them to attend their "therapy next door" as they "work together as a team". The fact that the patient has a choice was not mentioned. I am able to communicate with the physician, and hope to, to promote the team atmosphere. They were familiar with my skill level, and felt comfortable with it prior to taking the therapy in house. I do want to clarify that this is not ALL physicians; some

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refer the same amount when they take it in house. However, the potential for fraud and abuse exists whenever physicians are able to refer Medicare beneficiaries to entities in which they have a financial interest.

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 PT patients in their offices. Please help to correct this situation.

Thank you for considering my comments. If you have any questions, please contact me at 484-653-8117.

Sincerely,

Cathy Stahl P.T. M.B.A.

Cathy Stahl P.T. M.B.A.
Physiotherapy Associates

Physician Self Referral

Dear Mr. Weems,

My name is Matt Sheehan and I have been a registered physical therapist for almost six years. I have owned my own PT business for the past nine months. I am writing you today in regards to Physician Self Referral.

The first clinic I worked for had enough office space to have a Physician on the premises. He would not be charged rent if he referred 10 patients a month to the clinic. He could save himself thousands of dollars a month by self referring.

Many surgeons in the area exclusively self refer. Patients don't always live near the MD that performed their surgery, so they have to travel 2-3 days a week for their appointments. Because of Medicare referral requirements, physicians have a captive referral base of physical therapy patients in their offices.

Most physicians offices that specialize in Occupational Health do the same. Because of this, patients have no choice in where to go for PT, and usually have to wait a few weeks to get treatment due to the high number of work injuries that these offices treat. I realize this does not impact Medicare patients, but I hope that workers compensation in California would follow Medicare's lead.

Thank you for considering my comments.

Sincerely,

Matt Sheehan, PT 

August 27, 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, Maryland 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 currently a practicing Licensed Physical Therapist located in the Tricities, Washington area. I am writing this letter to comment on the July 12th proposed 2008 physician fee schedule, specifically the issue surrounding Physician Self Referral and the "in office ancillary services" exception. I am concerned that the "in office ancillary services" exception is defined so broadly that it facilitates the creation of abusive referral arrangements. 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.

Mr. Kerry Weems

Administrator - Designate

Additionally, as patients look to their physicians for direction in their health care and as such they feel obligated to receive services where their physician directs them.

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.

I support PT services removal from the permitted services under the in-office ancillary exception.

Mr. Weems, thank you very much for your consideration of these comments.

Sincerely,

Physical Therapist

99336

531

August 27, 2007

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

Subject: **Physician Self-Referral Issues**

Dear Mr. Kerry Weems,

My name is Denise Porter, and I am the office manager for a physical therapist owned physical therapy practice in Conway, Arkansas. I am writing to encourage you to support the removal of physical therapy as a designated health service permissible under the in-office ancillary exception of the federal physician self-referral. Any situation where a profit can be made from "self-referral" there is huge potential for fraud and abuse.

Thanks for your consideration of this issue.

Denise Porter

Denise Porter

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:

My name is Gwendolyn Gathers and I am a physical therapist assistant practicing in Lynchburg, VA in an outpatient private practice setting for the past 10 years. The intent of this letter is to comment on physician self-referral issues and the potential for abuse by physicians who have a financial interest in physical therapy services under their ownership and/or employment.

In Virginia, physical therapy services are almost exclusively by physician referral only. There are few exceptions. We rely on physician referral for our access to patients. Allowing physical therapy services to remain an exception to the "in-house ancillary services" could impact not only my livelihood but also create the potential for abuse by physicians who face decreased reimbursement as all of us in healthcare delivery do.

I urge you to suggest that CMS remove Physical Therapy as a designated health service under the "in-office ancillary" exception to the federal physician self- referral laws.

Thank you for your time and consideration of this matter.

Sincerely,
Gwendolyn L. Gathers, LPTA
Gwendolyn L. Gathers, LPTA

August 27, 2007

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

Subject: **Tempting Physician Self-Referral Issues**

Dear Mr. Kerry Weems,

I am writing to you to express my **strong support** of the efforts **to remove physical, occupational and speech therapy from the designated health service exception.** As an employee of a physical therapist owned therapy clinic, I urge you to take a closer look at this issue. I believe that removing the exception, the way that many other ancillary services have been, will help potential therapy patients to receive the best care, from the right place, only when it is needed. The current exception makes the likelihood for abuse is too great.

As you know, checks and balances are an essential part of every facet of governmental affairs. When a physician is able to own their office, see a patient, and refer them to a therapy clinic they own, the checks and balances are gone. Regardless of the quality of therapy at the physician-owned therapy clinic, the physician will refer their patients to it. This develops the potential for patients to go to a sub par therapy clinic that does not make them any better. It would be much like a physician profiting from the prescriptions they write- **there is too much of a profit incentive.**

Thank you for your time and consideration in this matter.

Jackie Bracey

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August 27, 2007

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

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:

My name is Angie Smithson, PT. I am a practicing Physical Therapist in the State of Arkansas. I have been a Physical Therapist in Arkansas for 20 years. I graduated from the University of Central Arkansas in December 1987. I have practiced in the Acute Care, Out-patient, and Home Health areas of Physical Therapy. I am currently the Director of Therapy Services for Conway Regional Health System in Conway, AR.

I am writing to voice my concern regarding **Physician Self referral Issues.** I have serious concerns regarding the amount of current abuse and the serious potential for continued abuse that occurs in my profession regarding Physician referrals for Physical Therapy services in Physician owned practices. I would strongly encourage CMS to support the removal of PT services from the in-office ancillary exception to reduce fraud and abuse that is occurring in the PT profession in these settings.

Respectfully submitted,

Angie Smithson, PT

Angie Smithson
Director of Therapy Services
Conway Regional Health System
2302 College Ave
Conway, AR 72034

August 27, 2007

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

Subject: **Physician Self-Referral Issues**/ Stark Law

Dear Mr. Kerry Weems,

My name is Nicole Young and I work in a physical therapist owned physical therapy office in Conway, AR. **Please support** the Centers for Medicare and Medicaid Services **efforts to remove physical therapy as a designated health service** permissible under the in-office ancillary exception of the federal physician self-referral laws.

Thank you for taking the time to read my letter and consider this issue.

Nicole Young

Nicole Young

Cristy Smith, PTA
1004 Paulding Road
New Haven, In 46774
Phone: 260-749-8128
Cell: 260-620-9027
Csmith749@comcast.net

August 28, 2007

Dear Mr. Weems,

This letter is in regards to Physician Self Referral Issues. I am a Physical Therapist Assistant currently working in an out- patient clinic and am worried about the future of my career. I see Physician owed practices as a threat to the physical therapy community. With Doctors referring to themselves there is a major risk of fraud and abuse of the entire system, especially for Medicare patients. By allowing Physicians to monopolize patients in this way many therapy clinics across the nation will be force to let therapists go and may even have to close their doors. In a time when reimbursement continues to decline, this field cannot afford a decline in referrals as well. Please help us in out fight to stop Physicians from putting our jobs in danger. Thank you for reading this and caring about our community.

Sincerely,

Cristy Smith

Physician Self-Referral Issues

I am a physical therapist in North Charleston, South Carolina. I work in a privately owned independent orthopedic clinic. I have been a member of the American Physical Therapy Association since 2002 during physical therapy school. I have served this area since the completion of my academic pursuits in 2004. In the past year I have continued my growth in the health and wellness field by becoming a Certified Strength and Conditioning Specialist

The purpose of this letter is to comment on the July 12th proposal on the 2008 physician fee schedule rule. This is an issue that directly affects the clinic that I serve in and surrounding clinics that are privately owned. The exception for "in-office ancillary services" allows for physicians to control where patients are referred for physical therapy services to the clinic that they own. Physician-owned physical therapy services do not center attention on the patient, but on financial interests. The main strive for these services are to profit and make more money "in-office". The patients and the surrounding privately owned practices suffer from this abusive cycle.

Thank you for your time and the ability to allow for a voice to be heard. I hope that this letter will give some insight on the problem with these physician-owned physical therapy services. Please do not support this abuse to the system. May we strive to keep patients our priority and not financial gain.

Sincerely,

MPT, CSCS

Bryan Warlick MPT, CSCS

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CAPE GIRARDEAU
UROLOGY ASSOCIATES, INC.
ADULT AND PEDIATRIC UROLOGY

3 DOCTORS PARK
CAPE GIRARDEAU, MO 63703

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.

(573) 334-7748
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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,

Donald L. Gentle, M.D., F.A.C.S.

ORTHOPAEDIC &
SPINE REHABILITATION
of CINCINNATI, INC.
BACKINMOTION SPORT FITNESS & WELLNESS

August 27, 2007

Centers for Medicare and Medicaid Services
US Department of Health and Human Services
P.O. Box 8018
Baltimore. MD 21244-8018

Subject: Physician Self-Referral Issues

Dear Mr. Weems,

I have been in the physical therapy field for forty plus years, working in several different areas. I have been an owner of a private practice clinic for the last fourteen years and have seen many changes in the physical therapy industry. I would like to offer the following comments on the issues surrounding physician self-referral and removal of physical therapy services from the "in-office ancillary services exception".

For the last several years the physical therapy industry has quietly suffered while the doctors and hospitals have argued with insurance companies over decreased reimbursement. We have also been vocal in this battle but not to the degree of others. We continue to treat our patients utilizing all our knowledge and skills but continue to see our reimbursements diminish as well as other practitioners being allowed to submit charges for physical therapy services eroding the financial stability of the private practice. We have noticed a significant drop in referral patients over the last few years from physicians or physician groups that have a financial interest in providing physical therapy services. In my clinic I have seen an average of a 28% drop in patients from these groups with only the most time consuming and difficult patients being referred. I have been told by some of the doctors that they have an obligation, financial or otherwise, to send patients to facilities their group owns and even though they feel the quality of care they receive is not the same they are required to do so. Some of the doctors that have left practices with these arrangements have returned to sending our facility patients. When I discuss their reasons for returning to send us patients they respond our patient care and results are significantly better than the physician owned facilities.

We have current patients who have been called repeatedly by their doctor's physical therapist to schedule their appointments with them and cancel at our facility. In a few cases even the doctors have called the patients at home and strongly suggested they return to their facility or it could affect the outcome of their treatment. We have other doctors that refer Medicare patients to us only when they are close to utilizing all their allotted benefits and progress has been minimal. This is a practice that at one time was used only by unethical Chiropractors.

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Physicians or Physician Groups whos practices provide physical therapy services have an inherent financial incentive to refer their patients to practices they have invested in and to over utilize those services for financial gains. The potential for fraud and abuse exists whenever a group is able to refer a particular "captured market" .i.e. ,Medicare beneficiaries, to facilities in which they have a financial interest.

Below I have listed some of the comments that our patients have relayed to us as to why their doctors want them to utilize their physical therapy services.

- Doctor feels they need to have treatment close by in case there is a problem they can be notified. *In some practices the physical therapy services are preformed in different facilities. Doctors are not in every facility every day.*
- Doctor states that he will be in constant contact with therapist since they are in the same group. *Contact with therapist staff is minimal due to time constraints and location.*
- Doctors claiming there is a lot of additional paperwork involved going to an outside facility and their staff can handle all paperwork in-house. *Paperwork required in either facility is the same and no additional signatures required.*
- Assuring patients they will receive better care. *Quality of care and individualized programs have always been at the forefront of private practice physical therapy clinics. In most cases the doctor was a referring physician before he invested in providing physical therapy services.*

In closing, by removing physical therapy services from the in-office ancillary services exception, CMS would significantly reduce the amount of programmatic abuse and overutilization of physical therapy services under the Medicare program as well as enhance the quality of patient care provided.

Sincerely

Barbara J. Dunlavy P.T.

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

Re: Anesthesia Services
Re: CMS-1385-P

Dear Administrator:

As a Nurse Anesthetist (CRNA) and member of the American Association of Nurse Anesthetists, I write to support the CMS proposal to boost the value of anesthesia work by 32%.The CMS proposal to increase the Conversion factor by 15% in 2008 as compared with current levels which have steadily decreased for years. This would help CRNAs to be maintained by hospitals to provide care to those with Medicare and Medicaid.

Anesthesia has been reimburse at 40 % instead of 80% compared to other practitioners.

This rule changes for 2008.

This change in relative value of anesthesia work will correct the value of anesthesia work which has fallen way behind in relation to inflation adjustments (which actually paid less than 2002 rates)

If these changes are not enacted rates will be less than 1992 rates and hospitals will suffer, and our patients will suffer due to lack of cost efficient anesthesia care givers, new state of the art equipment is not purchased by the hospitals to maintain salaries and staffing and thus we use older model equipment which is not safe for you nor our patients.

As CRNAs we provide over 27 million anesthetics yearly. We are the predominant anesthesia care providers in rural America. Medicare and Medicaid patients depend on our services. I support the agency's recognition that anesthesia payments have been undervalued and it's proposal to increase the valuation of anesthesia services in a manner that returns Medicare payments to adequate levels of reimbursement.

Sincerely,

Brendan Wrynn CRNA
3100 Waterloo Rd. #36
Connersville, IN 47331
August 27, 2007

August 25, 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 (BACKROUND, IMPACT)
ANESTHESIA SERVICES

Dear Ms. Norwalk:

As an anesthesia student and member of the American Association of Nurse Anesthetist (AANA), I am writing you in immense support of the Centers for Medicare and Medicaid Services proposal to boost the value of anesthesia work by 32% and to increase the anesthesia conversion factor by up to 25% in 2008. If this proposal is adopted, Certified Registered Nurse Anesthetists (CRNAs) would be guaranteed the accurate value of anesthesia services provided, which in the past have been undervalued. This proposal would help ensure CRNAs as Medicare Part B providers to provide Medicare beneficiaries with access to anesthesia services.

If this proposal is not passed and Congress does not reverse the 10% sustainable growth rate cut to Medicare payment, then 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 CRNAs are vital in the healthcare setting as they provide some 27 million anesthetics in the U.S. annually according to the American Association of Nurse Anesthetist. Medicare patients and health care delivery in the U.S. depends on our services because CRNAs are the primary anesthesia providers in rural America. The availability of anesthesia services is dependent on Medicare paying 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 payment.

Sincerely,

Holly Creighton
7103 Bluewater Drive
Clarkston, MI 48348

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

Ms. Norwalk,

I am a member of an all-CRNA group, providing exclusive anesthesia services to a rural-access hospital in Washington state, 24 hours/day 7 days/ week. Medicare patients and healthcare delivery in this area is dependant upon our ability to recruit and retain competent CRNAs. The availability of anesthesia services in this medically underserved area depends, in part, on ***FAIR*** Medicare payments. I applaud the agency's acknowledgement that anesthesia payments have been undervalued, and wholeheartedly support it's proposal to increase the valuation of anesthesia services that will boost Medicare anesthesia payments.

As one of the 36,000 CRNAs that are represented by the (AANA) American Association of Nurse Anesthetists, I write to you today to support the CMS in its proposal to boost the value of anesthesia services by 32%. The CMS-proposed rule would increase Medicare's anesthesia conversion factor by 15% in 2008. If adopted as proposed, this increase would help to ensure that CRNAs as Medicare Part B providers can continue to provide Medicare patients with access to anesthesia services.

If CMS' proposed change is not enacted and Congress fails to reverse the 10% sustainable growth rate cut to Medicare payments will result in an effective cut of 17% ***BELOW*** 2006 payment levels, and more than 33% ***BELOW*** 1992 payment levels when adjusted for inflation! All of this is happening at a time when the numbers of anesthesia providers are decreasing, making it much more difficult to attract practitioners to rural/underserved areas.

Respectfully Submitted,

Gary L. Wagner, CRNA
19621 S.E. 424th St.
Enumclaw, WA 98022

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

Re: CMS- 1385-P
Anesthesia Services

Dear Administrator:

As an RN, a wife of a CRNA and a rural access healthcare user, I urge you to support the CMS proposal to boost the value of anesthesia work by 32%. This would increase the CMS Medicare anesthesia conversion factor by 15% for 2008. This would ensure that my husband would be able to continue providing anesthesia as a CRNA as Medicare Part B providers in our community.

The increase would replace the under-reimbursements for anesthesia services that have occurred for the past several years, impacting our ability to recruit new CRNAs to our rural setting.
This proposal adjusts services for the 2008 year.
This proposal corrects the value of anesthesia services that have long slipped behind inflationary adjustments that others have received but we have not.

If these changes are not made we will fall back to below 1992 levels. This is not a situation that our CEO has indicated is sustainable.

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 increases Medicare payments.

Sincerely,

Patricia Wrynn, RN

Patricia Wrynn RN
3100 Waterloo Rd. #36
Connersville, IN 47331
August 27, 2007

University of Pittsburgh Medical Center
Physician Services Division
August 31, 2007

Comments on Federal Register / Vol. 72, No.133 / July 12, 2007 / Proposed Rules
File Code: CMS – 1385 – P

Federal Register / Vol. 72, No.133 / Page 38143 / "MEDICARE TELEHEALTH SERVICES"

Issue: Current Telehealth policy restricts its application to non-metropolitan areas. The geographic restriction was intended to save patients and providers the time and expense of travel between rural areas and health care facilities, and to provide access to specialty services that may not exist in rural areas. This restriction does not consider barriers beyond time and distant travel and therefore prevents the use of Telehealth technology within metropolitan areas, putting patient's health at risk.

Recommendation: UPMC recommends that the metropolitan restriction be removed from Telehealth services. The unavailability of Telehealth technology in metropolitan areas creates a patient care issue for urban patients for many services, especially the initial care for stroke patients. Stroke is the third leading cause of death and the number one cause of disability in the United States and any hospital with an Emergency Room anticipates seeing a volume of stroke patients. With an overwhelming majority of the nation's population reaching the age bracket where stroke is most prevalent, there is an immediate need for consistent quality care from stroke specialists such as Stroke Neurologists.

Research trials have demonstrated improved outcomes for stroke patients who receive intravenous tissue plasminogen activator (IV TPA) within 3 hours of symptom onset. IV TPA is only approved for use within the 3 hour window, and it must be given by a Stroke Neurologist. If a Stroke Neurologist is not able to be physically present in a metropolitan area in time for the IV TPA to be effective, Telehealth technology would make the service available. Western Pennsylvania stroke statistics provided by the Pennsylvania Health Care Cost Containment Council indicate that 8,667 patients had principle diagnosis of stroke in Southwestern Pennsylvania in the 9 month period ended March 31, 2006. Only 49 of those patients actually received IV TPA. Many more patients would have benefited from the therapy if they had timely access to a Stroke Neurologist. Based on these statistics, we recommend that all patients have access to IV TPA through Telehealth technology and not be discriminated against based on physical location.

University of Pittsburgh Medical Center
Physician Services Division
August 31, 2007

Comments on Federal Register / Vol. 72, No.133 / July 12, 2007 / Proposed Rules
File Code: CMS – 1385 – P

Federal Register / Vol. 72, No.133 / Page 38146 / "CODING—MULTIPLE PROCEDURE PAYMENT REDUCTION FOR MOHS SURGERY"

Application of Multiple Procedure Payment Reduction for Mohs Micrographic Surgery (CPT Codes 17311 through 17315)

Issue: CMS will apply multiple surgery discounts to all Mohs surgery procedures beginning January 1, 2008, thus causing a reimbursement reduction for these services.

Recommendation: No changes should be made to the billing methodology which is currently being used.

Over a million Americans are diagnosed with skin cancer each and every year. Mohs surgery is a valuable procedure for treating large, aggressive or ill-defined cancers. If the multiple surgery discount is applied, services will be reimbursed at a level which do not cover the basic costs of each procedure. Also, completion of Mohs services within 2-4 hours reduces the delays in treatment, which if not taken care of immediately, could increase the risk for high-risk patients such as organ transplant patients with multiple squamous cell carcinomas, and for patients with syndromes such as basal cell nevus syndrome.

In 1991, CMS agreed that the Mohs excisions were "separate staged procedures; they will be paid separately with no multiple surgery discount." In 2004, Mohs Surgery codes were added to the CPT Appendix E list as codes exempt from the -51 modifier and the multiple surgery discount. In addition, the exemption of Mohs CPT codes from the MSRR has been maintained by CMS since 1992 and was not questioned during the CMS mandated five-year review which occurred last fall or during the presentation of the new Mohs codes to the AMA Relative Value Update Committee as recently as October of 2006. Note that services where the multiple surgery discount is applicable experience a 50% reduction in total work, while the other 50% represents pre- and post-service work. For Mohs surgery, more than 80% of the work is intra-service work and does not overlap when two or more surgeries are performed. Also, while most secondary procedures are made up of 50% pre and post service work, Moh's work values for pre- and post-service are minimal since there is a zero day global period. In addition, the pathology service associated with the Mohs surgery makes up a significant portion of the work and is not reduced with multiple procedures. When these two portions of the procedure are combined, there is not a significant amount of overlap or reduction in work when two or more tumors are treated on the same patient on the same day.

University of Pittsburgh Medical Center
Physician Services Division
August 31, 2007

Comments on Federal Register / Vol. 72, No.133 / July 12, 2007 / Proposed Rules
File Code: CMS – 1385 – P

Federal Register / Vol. 72, No.133 / Page 38196 / "TRHCA – SECTION 101(b): PQRI"

TRHCA - SECTION 101(b): PQRI

Issue: CMS notes that in addition to the testing of registry-based quality data there is consideration of accepting quality data submitted from Electronic Health Record's (EHR's). The current reporting of CPT II codes in support of the existing CMS PQRI initiative has been both labor intensive and required the investment of additional resources by physician providers. These additional investments are being required in parallel with the significant investment in EHR technology and infrastructure.

Recommendation: UPMC strongly recommends that CMS permit providers to leverage EHR technology and submit quality data via electronic mechanisms in 2008. UPMC would be like to explore opportunities to partner with CMS in capitalizing on this opportunity.

University of Pittsburgh Medical Center
Physician Services Division
August 31, 2007

Comments on Federal Register / Vol. 72, No.133 / July 12, 2007 / Proposed Rules
File Code: CMS – 1385 – P

Federal Register / Vol. 72, No.133 / Page 38179 /
"PHYSICIAN SELF-REFERRAL PROVISIONS"

The comments below exclude a review of the Stark III regulations published August 22, 2007.

A. General Comments-- Contractual Arrangements Among Suppliers: While preventing "gaming" is important, the overall impact of the proposal suggests that physician groups must operate practices where only fulltime employees and/or fully-owned equipment are utilized. This ignores several realities of patient care: patient volume may not sustain the expense of a full time employee or purchase of certain equipment. The flexibility to contract with other providers and/or suppliers to provide a wider range of services is pro-patient and encourages coordination of care. Concern about over-utilization of imaging can be addressed without requiring patients to find specialty groups large enough to carry full time employees and equipment, or by limiting physician investment in delivery of ancillary services altogether.

1. Anti-markup provisions. Portions of the proposal to apply anti-markup provision to purchased professional component are overly broad. Physician services may be delivered and reimbursed by independent contractor arrangements and physician services are leased among group practices for a variety of valid reasons, including, disability leave coverage and weekend coverage. In the event that a physician practice leases or independently contracts a physician's services to another group, the expanded provisions could require a set-off of any salary support collected, which may not be allocated to the billable service at all, but rather on a per-shift or weekend rate. Similarly, physician practices that would otherwise recover legitimate overhead costs for employment of part-timers or contractors are penalized if those expenses are considered "mark-up" revenue. We recommend that the anti-markup provisions not be expanded and that the legitimate practice of leasing or independently contracting a physician's services continue to be permitted.

2. Per Click and Percentage-based Compensation. Per-click or unit of service based payments have been protected as long as the payment per unit is at fair market value and is not modified to account for DHS referrals. The proposal would prohibit unit-of-service-based payments to a physician lessor for services to patients referred by the physician. Current fair market value and set in advance requirements, along with existing medical necessity rules, are sufficient to protect program integrity. Eliminating the option of per-click leases and percentage-based rental arrangements unnecessarily restricts the ability of physician groups to contractually generate legitimate revenue which may afford equipment upgrades and replacement on a more timely basis, since some partial expense can be recouped via rental arrangements.

   Likewise limiting percentage-based compensation only for paying for personally performed physician services unreasonably restricts the ability of a physician practice to enter into management and billing services agreements (and perhaps other equipment and space rentals) which are often negotiated as percentage-based compensation to promote positive management and/or administrative practices without any intent to impact referrals. An absolute prohibition on percentage-based compensation is overly broad. It will restrict physician practice's ability to utilize such management and billing services and could discourage physician practices from obtaining expertise in these areas if fixed compensation, regardless of revenue realized, is imposed as an absolute requirement.

B. General Comments -- Indirect Compensation Arrangements—"Stand in the Shoes": The proposal provides that, where a DHS entity owns or controls an entity to which a physician refers Medicare patients, such DHS entity would stand in the shoes of the entity that owns or controls and would be deemed to have same compensation arrangements with the parties on the same terms. The example provided is a Sole Member Hospital of a non-profit corporation employing physicians. The commentary is silent, but if CMS proposes "to collapse" the corporate entities for purposes of Stark analysis, any change should clarify that "collapsed" relationships will also be considered eligible for bona fide employment exception treatment under § 411.357(c) as well as physician groups in such "collapsed" entities for group practice exception under § 411.352.

Our Postal Code is 15213-2582.
Our category is Health Care Provider / Association

Our comments are submitted by: Ann M. McElroy, Chief Financial Officer
Physician Services Division
University of Pittsburgh Medical Center (UPMC)

ADULT PEDIATRIC UROLOGY

545

EUCLID J. DESOUZA, M.D., F.A.C.S.
JOHN D. HORGAN, M.D., F.A.C.S.
BRUCE E. LUNDAK, M.D.
ANDREW F. TRAINER, M.D.
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DAVID H. KUPER, M.D.
LARIS E. GALEJS, M.D.
STEFANIE L. BOLTE, M.D.
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,

ADULT PEDIATRIC UROLOGY

546

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Herb Kuhn
Acting Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
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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.

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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,

LARIS GALETS, MD

THE UROLOGY CENTER

OF SOUTHERN CALIFORNIA, MEDICAL GROUP, INC.

BRUCE HOUMAN, M.D., FACS

Sy Tsi, M.D.

Edward J. Yun, M.D.

Diplomates of the American Board of Urology

Gerald H. Yoon, M.D.

- Adult & Pediatric Urology
- Urological Oncology
- Female Urology and Incontinence
- Male Infertility and Andrology
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- Cryo-Surgery for Cancers
- Microsurgery
- Sexual Dysfunction and Impotence
- Stone Disease and Lithotripsy
- Urology Laser Surgery
- Advanced Laparoscopic Surgery
- Radioactive Seed Implantation

August 24, 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 a board certified urologist who practices in a four-man urology medical group. in Riverside County, in Southern California. We have a large number of Medicare patients with variety of Urological conditions such as prostate problems and variety of urological cancers. They have moved from the expensive areas of Los Angeles and Orange County to have an affordable living in this area although it is getting financially tough for us for us as well as them to make a living here.

I am writing to comment on the proposed changes to the physician fee schedule rules which 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 on the way our group practice, 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 urologists to care for their patients and to have the ability to provide laboratory and 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 or any other necessary services to their patients.**

It is important to allow the urologists to continue to treat their patients with (TUMT) Thermotherapy that has helps many patients in the office and in fact has saved money for the government by reducing other costs associated with old fashion surgeries done in the hospitals.

It is important to allow the urologists to continue to do "RELATED" laboratory tests in their offices to expedite the service for their patients, such as total and free PSA tests related to prostate diseases, and hormonal evaluations for men in regards to their health, and variety of Urine analysis, and Sperm analysis, and microbiological evaluation.

Limiting these tests could further delay the results, and care of the patients, could cause monopoly, and ultimately will increase the costs.

The proposed changes to the reassignment and purchased diagnostic test rules will make it difficult, if not impossible for us to provide, **THERMOTHERAPY, PSA test analysis, and other laboratory tests.** If we are not able to do these or other NEWLY DEVELOPED procedures in our clinics the care of the patients will be interrupted and hindered, delayed, which in turn will cause more damage to the patients, and increase more costs, and complications. SOME OF THESE PROCDURES ARE NOT AVAILABLE IN HOSPITALS, AND TRADITIONALLY DONE IN UROLOGISTS OFFICES.

The proposed "under arrangement" rule will prohibit the provision of **THERMOTHERAPY, PSA test analysis, and other laboratory tests, IMRT, and lasers.**

Although we do not own any IMRT, or LASER joint venture, we believe these arrangements have brought positive outcomes for patients, and without a joint venture, the service would not have been available in the community.

The prohibition of equipment rentals will prohibit use of available technology at the affordable price and loosing the modern technology will be detrimental to patient care.

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. **We believe the rules should be revised to only prohibit those specific arrangements that are not beneficial to Patient care.**

Thank you for your consideration,

Bruce Houman, MD, FACS
CEO, Urology Center of S. Cal.

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MINNEAPOLIS RADIATION ONCOLOGY, P.A.
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August 28, 2007

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

Re: Physician Self-Referral Provisions; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008

Dear Mr. Kuhn:

Minneapolis Radiation Oncology, P.A. (MRO) is the largest provider of radiation therapy in the State of Minnesota. All of the owners and physicians of MRO are radiation oncologists and, therefore, all referrals to MRO are from disinterested physicians. MRO appreciates the opportunity to provide written comments on the "Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008" published in the *Federal Register* as a proposed notice on July 12, 2007 (the "Proposed Revisions"). More specifically, MRO desires to focus its comments on issues it has identified in the Proposed Revisions comments regarding the physician self-referral law (commonly known as "Stark").

MRO's experience and perspective is limited to the designated health service of radiation therapy. While MRO's comments contained herein may well apply to other DHS, MRO does not have the depth of perspective to propose CMS revisions to the Stark law for any DHS other than radiation therapy. Radiation therapy seems to be the textbook case for "ancillary services" to the practice of any referring physician. Because radiation therapy, by its nature, is therapeutic and not diagnostic, any referring physician is able to complete his or her care for the patient in their own field of practice. The referring physician then relies on the radiation oncologist for the radiation therapy. Radiation therapy is a separate modality of treatment managed solely by the radiation oncologist. It is the prospect for high levels of profit from engaging in radiation therapy that, unfortunately, is attracting those referring physicians that control utilization of radiation to seek opportunities and ventures where they can participate in the profits from their referrals. MRO has reviewed the proposed fixes by CMS to the Stark rules and has identified areas where the proposed revisions are

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inadequate to prevent abuses. MRO encourages CMS to continue its efforts to prevent self referral from jeopardizing the health and welfare of patients and driving up costs through over-utilization.

I. Changes to the In-Office Ancillary Services Exception (72 Fed. Reg., 38181)

A. Purchased Services

CMS described a concern where hospitals may enter into arrangements with referring physicians to share profits from designated health services. CMS's proposal to remedy this situation is to expand the definition of "entity" under Section 411.351 to include both the entity that bills for the service as well as the entity that actually performs the service. While this may address situations that relied exclusively on Stark exceptions to compensation arrangements, it still does not stop abusive physician self referral in ownership arrangements that may otherwise qualify for in-office ancillary services exception (IOAS).

For example, a hospital with a radiation therapy department relies on referrals from the local medical oncology group. The medical oncology group threatens to bring all radiation therapy "in-house" and build their own cancer center unless the hospital gives the medical oncologists revenue from radiation therapy. The hospital and the medical oncology group then form a joint venture that acquires the radiation therapy department of the hospital that is a building in which the medical oncology group maintains clinical offices (and, thus, satisfies the same building requirement under IOAS). In order to meet the "billing requirement" under the IOAS, the medical oncology group subcontracts the radiation therapy services from the joint venture such that the medical oncology group is the DHS provider and bills and collects.

Under CMS's proposed tightening of these rules to prevent this abuse, the "entity" to be analyzed with reference to the medical oncologist as referring physician would include both the joint venture, as the entity actually providing the service, and the medical oncology practice entity itself, as the entity billing for the DHS. The expansion of the "entity definition", therefore, has done nothing to prevent the arrangement whereby the medical oncology group can profit from self referral and engage in abusive utilization.

MRO has seen these arrangements and the pressures brought to bear by medical oncologists and urologists that control referrals of radiation therapy services. MRO suggests that CMS revise IOAS such that this exception would not be available if a radiation therapy provider that bills for the service does not itself provide the service. If this revision was adopted, then the arrangement described above would not comply with Stark unless the hospital and medical oncologists were truly integrated into one organization. This seems consistent with the intent of Congress in having this exception available for "ancillary services" to the core practice.

B. Per Click Compensation Arrangements

CMS has proposed to limit the availability of unit-of-service-based payments in the space and equipment lease exception in compensation arrangements. However, the elimination of these "per click" leasing arrangements as qualifying under the space and equipment lease exception still leaves the door open for having these same arrangements qualify under IOAS. Because IOAS is an eligible

exception for ownership and compensation arrangements, the failure of an arrangement to meet the space or equipment lease exception does not preclude that exact arrangement from being permitted under IOAS.

In the fact pattern described above, a joint venture could lease radiation therapy equipment and space to a medical oncology group owned by referring physicians. This lease arrangement could be based on a "per click" rent and the referring physicians' compensation arrangement and ownership would still be exempt from Stark by virtue of IOAS. MRO, therefore, proposes that CMS revise the Stark rules that IOAS will not be an exception to a compensation arrangement of a "per click" leasing arrangement. Therefore, this particular type of compensation arrangement would need to separately satisfy the requirements to meet the compensation arrangement exception for "per click" leases. This would then allow CMS' tightening of these rules to be effective.

C. Blanket Prohibition of Radiation Therapy Use of IOAS

While CMS has requested comments on whether certain services should not qualify for IOAS and MRO believes that radiation therapy should, in fact, be prohibited from using this exception, MRO has two concerns over a blanket prohibition: (i) such prohibition would exceed CMS' authority under the statute and, therefore, not be enforceable; and (ii) such blanket prohibition would not be adopted over concerns about large truly integrated clinics such as the Mayo Clinic.

Congress carved out specific DHS when it enacted IOAS (i.e., durable medical equipment [excluding infusion pumps] and parenteral and enteral nutrients, equipment and supplies) which shows its use of discretion in deciding which DHS to make available this exception. CMS' authority is to impose "such other requirements" as needed to protect patients and abuse. The addition of another category of DHS to be excluded from availability of IOAS may, therefore, require Congress to amend the statute to reliably make this change.

The intent of IOAS is to cover truly "ancillary services". Large integrated clinics, such as the Mayo Clinic, need not be dismantled in CMS' attempt to curb abuse of physician self-referral. Given the common structure of these clinics as tax-exempt nonprofit corporations, the relationship of referring physicians to these DHS entities is commonly limited to compensation arrangements that may be cleansed through other Stark exceptions. Therefore, a blanket prohibition of use of IOAS for radiation therapy would not likely impact these clinics. Alternatively, IOAS for radiation therapy could apply only to those DHS entities where income from radiation therapy does not exceed 1% of their annual income.

II. Changes to the Space and Equipment Lease Exceptions

MRO also agrees with CMS that per-click leasing is another method used by parties to circumvent Stark as to radiation therapy. However, the Proposed Revisions do not achieve their objective of prohibiting the problematic per-click arrangements identified by CMS. The Proposed Revisions identified the relevant factual scenario when it described that:

> "We are also concerned about arrangements where the physician is the lessee and rents space or equipment from a hospital or other DHS entity on a per-click basis. For example, if a physician rents an MRI machine from a hospital only when the physician refers a

> patient for an MRI and then provides the facility portion of the MRI service under arrangements with the hospital, the physician benefits financially and the arrangement could provide an incentive for overutilization or other program abuse."

See Proposed Revisions, Page 325. This fact pattern is analogous to the joint venture fact pattern set forth in Section I of these comments. In order to effectively prohibit these arrangements, CMS would need to: (i) prevent qualification of these arrangements by virtue of IOAS (as described above); (ii) ensure that physician owned entities may not be used to circumvent the prohibition; and (iii) prohibit these arrangements where the physician interest is either as a lessor or lessee.

CMS has proposed that "space and equipment leases may not include unit-of-service based payments to a physician lessor for services rendered by an entity lessee to patients who are referred by a physician lessor or to the entity". *See* Proposed Revisions, Page 327. This language suggests that the physician would personally own the space or equipment being leased rather than an entity that is owned by the referring physician being the lessor. While MRO maybe taking the language in CMS's proposal too literally, CMS was specific when it refers to an "entity" and MRO wanted to clarify that the prohibition on a physician lessor should apply to a referring physician and any entity to which it has a financial relationship. The same notion would apply to any rule governing physician lessees. The rule would apply to entity lessees to which a referring physician had a financial relationship.

CMS is soliciting comments on whether it should prohibit time based or unit-of-service based payments to a lessor by a referring physician lessee to the extent that such payments reflect services rendered to patients sent to the referring physician lessee by the lessor. MRO has seen referring physicians for radiation therapy achieve their objectives of participating in the profits from their referrals of radiation therapy in many business models. A "per click" lease is simply a model to allocate profits between the lessor and lessee. Whether the physician is receiving his or her profits on radiation therapy as a lessor on a "per click" arrangement or is receiving his or her share of profits by retention of fees in excess of the "per click" arrangement paid to a lessor, it results in the same outcome that the referring physician profits from the referral. Therefore, MRO encourages CMS to prohibit the unit-of-service based payments in any leasing arrangement which involves a referring physician, or an entity to which the referring physician has a financial relationship, from participating as a lessor or a lessee.

III. "Set in Advance" Definition and Percentage Compensation Arrangements

Finally, MRO agrees with CMS that percentage compensation lease arrangements are another method used by parties to circumvent Stark. Unfortunately, CMS' attempt to prohibit percentage compensation lease arrangements falls short of its objective. The Proposed Revisions allow percentage compensation lease arrangements through the indirect compensation exception because the indirect compensation exception does not require that compensation be "set in advance." CMS noted that, "We are concerned that percentage compensation arrangements in the context of equipment and office space rentals are potentially abusive." *See* Proposed Revisions, Page 335. CMS made the decision to address these perceived abuses by modifying the definition of "set in advance," which applies to the space and equipment rental exceptions, to preclude percentage compensation unless it is being paid for personally performed physician services.

Again, this proposal leaves a glaring opportunity for parties to structure their equipment leases as an indirect compensation arrangement which qualifies for the indirect compensation exception which does not require compensation to be "set in advance." As stated above, the realty is that physicians do not directly lease equipment. Therefore, most leasing arrangements are indirect compensation arrangements and not reliant on the "set in advance" definition.

A potential solution to this issue would be to amend the indirect compensation exception to require that indirect compensation be "set in advance." With the proposed change to "set in advance", percentage leases would be precluded under the indirect compensation exception. This proposal would meet CMS' objective.

Conclusion

The Proposed Revisions do not adequately prohibit the scenarios identified by CMS as to radiation therapy services. Rather, the Proposed Revisions merely close only some of the avenues available to parties in structuring the abusive relationships. In order to achieve its objectives it will be necessary for CMS as to radiation therapy services (1) amend IOAS to prohibit a DHS entity from purchasing services from a third party, (2) amend IOAS to not apply to per-click or percentage compensation arrangements, (3) amend the space and equipment rental exceptions to cause the rule to apply so referrals of physicians owner get imputed to lessors and lessees to which such physicians have a financial relationship, and (4) amend the indirect compensation exception to require compensation to be "set in advance."

We thank you in advance for your time and consideration of our comments regarding the Proposed Revisions. MRO believes it has a unique perspective on the issues surrounding physician self referral of radiation therapy services and welcomes the opportunity to further discuss its position with CMS officials. Should you have any questions on MRO's position on these matters, please feel free to contact me.

Respectfully,

Robert Haselow, M.D., President
Minneapolis Radiation Oncology, P.A.

1149870.2

August 24, 2007

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

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 Iowa, who has worked for the same hospital for 25 years. As a member of the Iowa Physical Therapy Association, I am very proud of the profession of Physical Therapy. Many times I have witnessed first hand the impact physical therapists have in making a significant difference in the lives of the people we serve. I feel very fortunate to work with highly qualified staff with multiple national certifications in the fields of physical and occupational therapy. We provide services in the hospital and in two outpatient clinics.

My purpose in writing this letter is to bring to your attention several issues in regards to physician self referral. 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. The physicians in our community (a large multi-specialty physician clinic located in central Iowa) made the decision to open their own physical therapy clinic about 10 years ago. When they made this decision, the flow of patient referrals to qualified physical therapists throughout our region took a dramatic turn.

For me, this turn took the form of clients with higher paying commercial insurance being directed away from our clinics, to the one the physicians owned. Complex and challenging cases were no longer referred to us, unless they were in the hospital or they were uninsured or had a low reimbursing insurance carrier. A specific example would be in the area of hand surgery referrals. We have had two occupational therapists hired away by the physician owned practice. In both cases, they weren't seen as good enough to receive the hand surgeon's referrals, until they were employed by his practice. To this day, we don't see referrals unless they are either uninsured or they are a workman's compensation case from our hospital.

Even more disturbing was the impact on physical therapy practices outside of our community. Patients were not being given the option by their physician of going to see their local therapist for care. They were being directed to come back to the physicians therapist (sometimes driving 45 to 60 minutes), when their local therapist could have easily seen them for their condition. Physicians were saying that they should come and see "our knee specialist" or "our shoulder specialist" when those were very common conditions that the local therapists were quite well qualified to see and treat.

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 financials 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 and over utilization of physical therapy services under the Medicare program.

The "in-office ancillary services" exception has created a loophole that has resulted in the expansion of physician-owned arrangements that provide physical therapy services. Because of Medicare referral requirements, physicians have a captive referral base of physical therapy patients in their offices.

Forty-eight states allow physical therapists to evaluate patients without a prior physician's referral, and forty-three states and the District of Columbia approve accessibility further allowing physical therapists to evaluate and treat, under certain conditions, patients without a referral from a physician. Currently Medicare statutes limit beneficiaries' ability to directly access the services of a physical therapist, while other insurances allow access to PT services. As a result, Medicare beneficiaries may experience delays in getting in to see a physical therapist, having to go through their physician to access physical therapy.

A study on the cost-effectiveness of direct access to physical therapists found that there were significant cost savings, appropriate utilization, and a lower number of patient visits when compared with referral physician referral initiated physical therapy.

The Medicare Patient Access to Physical Therapists Act (HR 1552/S 932) would improve access to physical therapist services for beneficiaries by eliminating Medicare's burdensome requirements, such as a physician's referral or certification of the plan of care. This would allow beneficiaries to access care as permitted by current state laws. Changing Medicare law to eliminate unnecessary burdensome requirements will help make Medicare more of what it was intended to be – an effective and efficient way for our nation's senior citizens to get the health care they need and deserve.

Thank you for considering my comments on this subject. I hope you will consider them and contact me if you have questions or desire clarification on anything mentioned.

Sincerely,

Kevin Rippey, PT, MPA
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515-233-5117
rippeys@mchsi.com

Physician Self-Referral Issues

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

My name is Chris Whisenhuunt and I am a Physical Therapy Assistant. I have been a therapist for 7 years in a variety of settings but currently work in an out-patient orthopedic clinic.

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. I support PT services removal from permitted services under the in-office ancillary exception. I believe that the opportunity for fraud and abuse with referring for wrong reasons and overutilization of therapy services for profit is to great. Patients should not be forced or pressured to go to clinics outside of there own towns when a local independent clinic is available and very capable of providing care for them.

Sincerely,

Chris Whisenhunt, PTA

Mr. Kerry N. Weems
Administrator-Designate
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1385-P
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. Terry Weens:

I am corresponding with you regarding the issue of Closing The Stark Referral for Profit Loophole created by the July 12th proposal 2008 physician fee schedule rule to allow physical therapy as an "in office ancillary service". Studies have shown that when physicians own physical therapy services the number of referrals to and over utilization of physical therapy services more than doubles, when compared to the same physician practice patterns prior to owning a physical therapy clinic. This is why we as private practitioners of physical therapy refer to physician owned physical therapy services (POPTS) as referral for profit.

I am a licensed physical therapist since 1983 after graduation from the University of Pittsburg and I have worked in numerous physical therapy settings since then: including large and small hospitals, specialty hospitals, home care therapy, nursing homes, athletic fields, and outpatient sports medicine, industrial medicine, and outpatient physical therapy clinics in the state of Louisiana, Pennsylvania, Indiana, and Kentucky. I presently am the owner of Danville Physical Therapy and have been since 1994. I have been a member of the American Physical Therapy Association since prior to graduation from physical therapy school, and am voluntary faculty for the University of Kentucky and the East Tennessee State University physical therapy programs, and the Somerset Community College physical therapy assistant program.

Physical therapists are a healthcare specialty in movement of the human body including musculoskeletal and neurological conditions. We are professionals with unique training and evaluation in treatment of movement disorders to alleviate pain and restore motion, strength, coordination, and balance activities to improve and restore function in the quality of life of our patients. As you may or may not be aware, most states allow the legal evaluation and treatment of patients by physical therapists without a physician's referral or supervision.

The 'in office services" exception is defined in the regulations in such a manor that it supports the creation of abusive referral arrangements. I have met physical therapists in other states who have owned their own successful clinics for many years, only to be put out of business by referring physicians who have started their own physical therapy clinics.

I have also met physical therapists (PT's) who have been fired from employment at POPTS for not continuing to see patients who were either inappropriate referrals for PT, or have discontinuing treating patients who have achieved maximum benefits from PT.

I have personally had physicians who were referring patients to me and commented on my good results with patients; and they stopped referring patients if I wouldn't pay kick backs for continued referrals.

I have had physicians refer their family to me, but would not refer their routine patients, when they had a financial incentive to refer somewhere else.

I have had physicians in Louisville and Lexington require patients to drive a 75 or 35 miles to their owned facilities even when those patients were getting good results at my facility locally.

I have had physicians who referred patients to me; who stopped referring patients when they hired a PT or opened their own physical therapy clinics.

I have seen physicians in my town and others who never referred patients for PT until they hired a physical therapist to work for them.

I have had one MD in town that has never referred any patients for PT; ask me to provide PT in his office, where he could refer at least two to three patients a day for PT.

I have also had MD's refuse to let patients come to my facility at the patient's request, when there is a financial incentive to have patient come to their facility, even when the same physicians have sent their family members to me.

I have had some patients who were getting results at my clinic, stop attending PT at my office so they can attend PT at the physician's office or owned clinic.

Needless to say anymore, I have seen and heard the abusive and unethical referral for profit relationships which are fostered by the Loophole in the Stark physicians self referral law, which should be closed, to protect physical therapy services as congress originally intended. I implore you to take ethical action by removing physical therapy from the "in office ancillary services" exception to the federal physician self referral laws, for the benefit of the patients, and the public we serve as licensed physical therapists. By acting to remove this exception to the Stark Referral laws, you will truly encourage the greatest good, for the greatest number of the public who could benefit from the unique skills provided by physical therapists, at the same time reducing the cost and over utilization of inappropriate PT referrals.

Thank you for your time and consideration on this issue.

Respectfully submitted,

Glenn J. Decker, P.T.

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MIDWEST
UROLOGY
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Richard G. Harris, M.D.
Steven B. Dritz, M.D.
Robert S. Lai, M.D.

Comprehensive Urologic Care · Infertility · Sexual Dysfunction · Female & Reconstructive Urology and Neurourology · Urodynamics

August 22, 2007

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

Re: Under arrangements and per click services

Dear Sir or Madam:

By introduction, I am Dr. Richard G. Harris a practicing urologist in the metropolitan Chicago area. I have been in practice for over 20 years and I am currently the Chairman of Surgery at one of my hospitals, as well as one of the managing partners of a 40-man urology group that encompasses the whole Chicago metropolitan area. I am writing in regards to CMS proposals that would prohibit under arrangements and per click basis arrangements between physician-owned entities and hospitals. I am quite perplexed why the government and CMS would even go down that road as it really makes no sense whatsoever. In a day when the government is trying to stop physicians from starting specialty hospitals that are totally physician owned and cherry picking insurance patients from hospitals, and in an era when hospitals are struggling all over the country for survival, it would seem to me to make great sense to have hospitals and physicians work together for the common good of their patients.

In fact, that is what under arrangements and per click arrangements have provided for all patients including a plethora of Medicare patients. Indeed the availability and treatment of patients and Medicare patients has been vastly improved in the past decades by these arrangements. A case in point would be lithotripsy which has revolutionized kidney stone treatment and changed an open seven-day hospital stay procedure into an outpatient procedure providing great benefit and cost savings to the patients and the payers.

These arrangements have also been utilized for things such as lasers and cryotherapy of the prostate for prostate cancer in scenarios where hospitals either could not afford to purchase the equipment, did not have the volume to justify purchasing the equipment or were afraid to purchase the equipment because of rapid changes in technology which would make the equipment obsolete in a short period of time. This is a common problem with hospitals and as I

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Rush Medical Office Building · 610 S. Maple Avenue, Suite 2600 · Oak Park, IL 60304 · Phone (708) 383-1810 · Fax (708) 383-1829
Elmhurst Memorial Health Center · 130 S. Main Street, Suite 203 · Lombard, IL 60148 · Phone (630) 261-9225 · Fax (630) 261-9226

spoke to my operating room chief nurse, she told me that the hospital does not want to purchase lasers and/or cryotherapy equipment because they become obsolete so readily and they much prefer these under arrangement and per click arrangements. If these arrangements were prohibited it would greatly harm patients and make it exceedingly difficult for hospitals and physicians to provide the optimal state of the art cutting edge therapy which we have been able to do in this country.

The obvious reasons for preventing these arrangements, is over utilization and monetary issues. I am not aware, and I think the government would be hard pressed to show any documented data or evidence that suggests that there has ever been an over-use issue with the urologists in any of their under arrangement or per click ventures that have been therapeutic in nature. I think a clear distinction must be made between therapeutic options and diagnostic options where the latter may have abuse potential because really you could be sending well patients to get diagnostic tests. Under no circumstances would any ethical, honest physician do a therapeutic service on a patient who did not have a disease entity specific for that treatment.

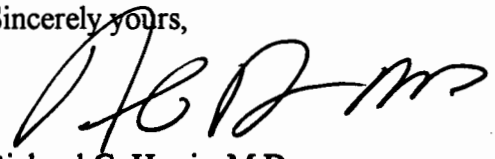
It is quite disturbing that the implication is that physicians are not ethical and would not be treating their patients in an ethical manner, if indeed there was physician ownership. I must tell you that when our urology group meets, we spend hours discussing technologies, treatments and the ethics involved in any new therapy. As you know, physicians are considered the most trust worthy in all public opinion polls and I think that is for good reason. Most people go into medicine for altruistic reasons and certainly in practice uphold those ethical standards. Obviously there are a few bad apples in the medical profession as there are in any other profession but I would suggest that the vast majority of physicians are highly ethical and extremely concerned about their patient's well being and providing the best care and outcomes for their patients. In an environment where the urological community is small and everybody knows each other, one's reputation is of the utmost importance and ethical behavior is maintained to the highest degree amongst most practicing urologists.

With under arrangement and per click arrangements it actually adds an additional layer of scrutiny over patient management as now these procedures are being done in a hospital and there is peer review in a hospital which would supersede any type of abuses in regards to patients being over treated for a particular condition. These types of peer reviews would not happen in the individual office and probably not in most surgery center scenarios.

For the above-stated reasons, I therefore highly recommend that CMS continue to allow under arrangements and per click arrangements between physicians and hospitals as I think that the

future of medicine really benefits from physicians and hospitals working together to enhance the treatment options and provide cost savings for medical treatments. To do otherwise would be both unjust and unAmerican.

Sincerely yours,



Richard G. Harris, M.D.
President, Midwest Urology Associates
Managing Partner, Uropartners
Chief of Surgery, Gottlieb Memorial Hospital

RGH:MTS/o #1490

Advanced Urology, P.C.

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Jon Owen Marks, M.D .• Steven Marc Berman, M.D. • Mark Stein, MD, F.A.C.S .• Daniele Dolin, M.D.

August 15, 2007

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

Dear Mr. Kuhn:

I am a urologist who practices in New York City. We have a fairly large Medicare population. I practice with three other urologists, and we are collectively members of a lithotripsy partnership. This partnership also provides laser machines to a variety of hospitals, which are used to treat prostate hypertrophy.

I am writing to address a specific problem with the proposed rule changes regarding the so-called "per-click" arrangements.

It is my firm conviction that per-click is actually the fairest way for hospitals to contract for devices and services that their own capital budget prevents them from acquiring. Per-click arrangements result in payments by the hospital only for the volume of services used. If a hospital were to contract on a yearly basis for 200 procedures, let's say, it would be paying twice as much as the fair market value if only 100 procedures were performed. Under that scenario, one could consider the hosptial's overpayment for services an inducement for urologists to bring their patients. "Per-click" prevents this sort of abuse.

Insofar as other proposed changes, I agree wholeheartedly that the potential exists for abuses in the current "under-arrangement" and "reassignment" methodology. However, the small number of abuses relative to the overall benefit received by patients suggests that eliminating these existing service arrangements would penalize physicians and hospitals that were not in abusive situations.

It is my conviction that the majority of urologists practice in an ethical fashion and that the arrangements with hospitals are structured to bring capital equipment to hospitals that they would otherwise not be able to provide (especially in view of the significant financial distress faced by most hospitals).

Patient care is improved through these arrangements, as has been demonstrated in our own geographic area over the past 20 years.

Several of the hospitals that I admit my patients to lack facilities to do prostate laser treatment. This represents a terrible inconvenience and an injustice to the patients who either have to undergo antiquated procedures while inpatients at the hospitals or have to be transferred to another hospital

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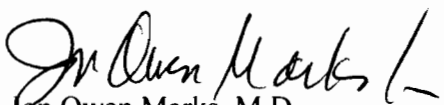
where the service is provided. We are currently in negotiations with two of these hospitals (Beth Israel Medical Center and St. Vincent's Medical Center) in order to bring service to them, which they would otherwise not be able to provide. If CMS blindly eliminates all such service arrangements, patient care will most definitely suffer. If physicians want to assume the risk of acquiring capital equipment and then enter into an arrangement with a hospital to bring that equipment to one or more hospitals, it should be their prerogative to do so. CMS should consider regulating such arrangements, but this is no different than the IRS policing all taxpayers to be sure that they are following the law.

In short, police whatever abuses you may unearth but don't penalize all Medicare beneficiaries by denying them state-of-the-art care that they would otherwise not be able to receive.

Very truly yours,



Jon Owen Marks, M.D.

JOM/dcc

cc: Ms. Robin Hudson
Senior. Manager for Quality Initiatives and Health Policy
American Urological Association
1000 Corporate Boulevard
Linthicum, MD 21090

HANDS-ON PHYSICAL THERAPY
and Sports Medicine

August 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.

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 over utilize services under the in-office ancillary services exception.

This creates an anti-trust/monopoly. Since insurance companies only require a physician referral for payment, then doctors self-referring will present an unfair advantage to the local physical therapist in private practice across the street (APTA has made presentations to the Federal Trade Commission on this issue).

Other professions (attorneys, CPAs, etc.) have legally limited ownership of their profession to "only" members of that particular profession. Precedence has been established and like professional ownership is a viable argument. There is no need for a physician to own a physical therapy practice.

The quality of non-physical therapy owned practices is at a below par standard when compared to that of physical therapy- owned practices. The strong implication is that physician based physical therapists have compromised their ethical standards as well as their clinical knowledge base and commitment to excellence. "No real therapist would ever work for a doctor." Those therapists are putting money before their profession."

2828 N. Clark Street :: Chicago, Illinois 60657
office 773.525.0190 :: fax 773.525.0583

This also creates an ethical dilemma. Since the physical therapists are paid by the doctors, then if the doctor wants more visits for a patient than the physical therapist deems necessary, the treating therapist will compromise their legal obligations of patient discharge, leading to unethical over-utilization due to fear of unemployment.

Physician owned physical therapy clinics create a conflict of interest with over utilization. Journal articles published in 1991 and 1992 show evidence for over utilization. JAMA vol. 258 Oct. 21, 1992 Physician Ownership of Physical Therapy Services and vol. II, September 1991 State of Florida Health Care Cost Containment Board. 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,

V. Wochner, PT, CSCS

Vanessa A. Wochner, PT, CSCS
Clinic Director/Owner
Hands-On Physical Therapy & Sports Medicine\
2828 N. Clark Street
Chicago, IL 60657

Re: CMS-1385-P; Proposed Physician Fee Schedule and other Part B Payment Policies for CY 2008
"IDTF ISSUES"

Dear Mr. Nemec

I am writing to address some of the "Proposed Revisions of Existing IDTF Standards" as described in CMS-1385-P. As president and owner of an IDTF providing non-invasive echocardiographic, peripheral vascular and nuclear cardiology testing in southern Colorado since 1989, I feel qualified to speak. We at Cardiodiagnostics (Cardio) like you, strive to insure that our patients and clients get value for the dollar. It is incumbent upon CMS to work with providers to insure the highest quality service with the least amount of bureaucratic oversight. Toward that regard I would offer the following comments:

1. Documentation of Comprehensive Liability Insurance
The requirement of $300,000 per incident is reasonable (actually quite low). We provide on-call coverage to several Rehabilitation Hospitals in the area as well as general coverage to several small hospitals out on the eastern plains. Most all require $1,000,000 per incident. We designate all such accounts as Certificate Holders on our policy. As such our Broker/Agent automatically mails copies of any policy limit changes to each at the time theses are made. As to contacting the underwriter, the broker informs me that they would not disclose that type of information. To accomplish verification Broker/Agent should be more than adequate.

2. Reporting Changes in Status
The requirement to report changes depending on the type in 30 or 90 days puts an unfair burden on us. Certainly a change in address would need to be reported within 30 days but, as to reporting changes in general supervision or even ownership, annually should be more than sufficient. If you choose to pursue this issue a proposed, I would like to see the ability to make changes on line. The proposal for 30/90 day reporting will mean a substantial administrative commitment (burden) for the Intermediaries as well as the IDTF.

3. Complaint Documentation
In our facility we document billing questions and responses in our billing software, problems that occur in the clinical setting (fall, needle stick) are thoroughly documented in incident reports and maintained in our administrative area. The thought of a single document for all these just adds one more element of administrative work when the information is at hand elsewhere. Secondly, the definition of "complaint" can be very broad. Is a patient call to our billing department to protest our balance billing them for their twenty (20) percent of the allowable a complaint? If so we might be very busy (these are however, documented in our billing software).

4. IDTF Physician Supervision
The prohibition of physician supervision to three (3) sites will only add cost to doing business without changes in quality. Cardio has certification by the Intersocietal

Commission for our echocardiography, peripheral vascular as well as nuclear medicine (ICAVL,ICAEL,ICANL) components. If I understand this proposal correctly, if we provide coverage to two (2) Rehabilitation hospitals, one rural acute care hospital and a fixed site diagnostic center, we would be required to have at least two (2) physician supervisors. This is an unreasonable level of over-site in light of the fact that these are the same technologists, same equipment and often the same interpreting physicians, all of which must meet our Intersocietal Commission requirements to remain credentialed.

5. Does not Share Space Proposal

I find this to be very confusing. What constitutes commingling of office space, staff and equipment? If I pay a Medical Assistant from a client's office to scan Holter Monitor studies after hours, is that staff commingling? If we loan an RN to a client to do a presentation on infection control to there staff, is that commingling? This part of the proposal is difficult to understand and will be equally difficult to enforce. At a minimum, I would like to see all the elements better defined. This holds especially true for mobile sites.

We continue to see increasing bureaucratic over-site in the face of declining reimbursement. I suspect there are organizations out there that are less committed to quality than bottom line. These companies represent a small portion of providers but as always, legislation is done with a broad paint brush affecting all providers. Healthcare providers continue to struggle to find ways to provide services to an ever increasing Medicare population. There is need for <u>some</u> over-site but, it needs to be balanced against the cost of providing these services.

Thank you for allowing me the opportunity to comment on these important issues.

Darrell Griffin

Darrell Griffin, BS, RDCS
President
Cardiodiagnostics of Colorado Springs Inc.

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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;** 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 an out-patient, orthopedic physical therapist who has been in practice in Central Ohio for over 8 years. I am writing you because I feel I have the local professional experience, maturity and social conscious to inform you of the fraud and abuse that is occurring inside of physician-owned physical therapy practices in Central Ohio.

The strong and almost unavoidable potential for fraud exists whenever physicians are able to refer patients to entities in which they have financial interest. A physician can see a patient and bill for his/her services and then refer that patient to his/her physical therapy facility where the billing and profit (for the referring physician) can continue. Most patients will simply rely on the recommendations of their physician on where to go for therapy instead of taking time out of their days to locate a physical therapy clinic. It is this recommendation of the physician to his/her own physical therapy clinic that is fraudulent and is happening every day in Central Ohio in very high volumes.

My first exposure to potential fraud was when a very large group of orthopedic surgeons recently developed their own building in which a privately owned, national provider of physical therapy services was subleasing space. After a few years, in hopes of generating more potential income, the physicians opened their own physical therapy practice across the street and began offering this location to their patients, while still collecting rent from the privately owned, national provider. I can tell you this is absolutely not a case of convenience, as the patients need to walk past the privately owned physical therapy practice to leave the facility.

Another case of fraud involves this same group of orthopedists who hired a business consulting group to assist them in setting up their physical therapy practice and were

paying the consulting group base on a percentage of profit – which goes directly against the Office of the Inspector General's Special Advisory Bulletin on the Practices of Business Consultants dated June 2001. Furthermore, this business consulting group set up the physician owned billing system so that all care provided by their 10+ physical therapists are billed under one particular physical therapist who is credentialed; none of the other physical therapists in the group are credentialed.

Another common occurrence is a physician opening their own physical therapy clinic and entering an agreement with a physical therapist to run the daily operations. This position is a difficult one for the physical therapist who could be paid $10-$20,000+ more per year in salary or easy-to-reach referral based bonuses and may personally have over $100,000 in student loans to re-pay. This just recently happened with a physician who fully supported and openly praised the skills of myself and my staff to his patients. However, since the week he opened his own physical therapy clinic, we have not received a referral from him or his associate. Adding to the irony of this story is the fact that his head physical therapist was hired out of an acute-care/geriatric setting in which he did not see any of the specialized spine and orthopedic conditions he is currently seeing. This is definitely not a case of quality or convenience to the patients.

Finally, I would like to reference the findings in the OIG report (OEI-09-02-00200) released May 1, 2006. This study found that 91% of physical therapy billed by physicians in the first 6 months of 2002 failed to meet program requirements, resulting in improper Medicare payments of over $136 million. The Inspector General found that the total payments for physical therapy claims from physicians skyrocketed from $353 million in 2002 to $509 million in 2004, and that the number of physicians billing the program for more than $1 million in physical therapy more than doubled in that 2-year period.

Mr. Weems, writing this letter has taken some courage on my part, since my job and livelihood are dependent on the referrals of physicians in the Central Ohio region. It is this very fact that may be the most important note in this letter. If CMS does not take action in preventing the actions of physicians billing for physical therapy services, I fear that physician-owned physical therapy practices will become "the norm" and ethically charged independent clinics owned by physical therapists will become extinct. I respectfully ask that you refrain from releasing my name, but use all the factual information I have enclosed in this letter to protect the quality of care that patients receive and to level the playing field by eliminating fraudulent and abusive physician self-referral situations in physical therapy.

Thank-you very much for your time and consideration in bringing this important issue to the attention of CMS. Please feel free to contact me if you would like to further discuss the details within this letter.

Sincerely,

Dayne Conley, MPT, MS, NASM-PES

Daniel M. Silverberg, MD, FACS
Adult and Pediatric Urology
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Allentown, Pennsylvania 18103

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Fax (610) 432-8640

Diplomate of the American Board of Urology

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August 27, 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 urologist in Allentown, Pennsylvania. Since most of my practice is Medicare patients, I am very cognizant of the need to balance clinical effectiveness of treatment and the cost of treatment within the Medicare program. As urologist, I have been providing lithotripsy services to my patients through a joint venture with other urologists. Without the ability to form this joint venture, lithotripsy services would be unavailable in Allentown. The hospitals are too risk-averse to invest in this technology on their own. In many cases, hospital CEO's and boards of directors who are not urologists cannot understand the potential benefits to the patients. In addition, there are very few hospitals which could support a lithotripsy machine by themselves. It is only through large joint ventures with mobile lithotripters and sharing of equipment that this technology becomes accessible to everyone. Before our joint venture in eastern Pennsylvania, lithotripsy patients were forced to travel 60 miles to Philadelphia for treatment. Transportation was always a problem, and the return trip with the hangover affects of anesthesia could be a harrowing experience for these elderly and frail patients.

I fear that the proposed CMS regulations to ban legitimate physician joint ventures will interfere with the availability of advanced care for Medicare beneficiaries. It appears to me that CMS believes that physicians who invest in these ventures cannot have their patients' best interests at heart. In fact, these physicians take part in these ventures **because** they have their patients' best interests at heart. These physician-investors are placing themselves at financial

risk in order to improve patient care. In all circumstances, the professional fee received by the physician dwarfs the potential profit to the physician from the joint venture. The joint venture does have to make financial sense in order to attract any investors at all, of course. Without these physician- investors, easy availability of lithotripsy throughout the country simply would not exist.

It appears to be CMS's goal to push as many procedures as possible into the ambulatory surgical center environment so as to diminish costs and reimbursement. In Allentown, the oldest and largest ambulatory surgery centers are hospital-owned. As a physician, if I'm not permitted to use a hospital-owned ambulatory surgery center for my joint-venture lithotripter, I may need to construct another ambulatory surgery center simply to take care of these patients. This regulation will force the dismantling of functioning system for lithotripsy treatment and the creation of a new, larger and more complex system.

Lastly, CMS proposes that I prove that my payments are at fair market value and not a based upon volume referred to the joint venture under the Stark regulations. In my opinion, if CMS thinks I am violating the law, it should be up to CMS to prove violation. It should not be my burden to prove the absence of violation. In a very real sense, in the eyes of CMS, I am guilty until proven innocent. Certainly, this is contrary to American law and tradition.

In conclusion, I ask that CMS differentiate between beneficial therapeutic joint ventures which are not actually DHS and questionable diagnostic ventures that some physicians and hospitals may have propagated in the past. The urologic community, through its joint ventures, has brought advanced treatment to Medicare patients. In the process, these joint ventures have improved the care of thousands of Medicare beneficiaries and saved CMS millions of dollars. This is a system that has worked well for CMS, for Medicare beneficiaries and for physicians. Please do not regulate this valuable component of the health care delivery system out of existence.

Very truly yours,

Daniel M. Silverberg

Daniel M. Silverberg, MD, FACS

Reid Hospital
& Health Care Services

August 23, 2007

Centers for Medicare & Medicaid Services

Comments on Proposed Regulations of Physician Ownership

Reid Hospital, a 233-bed sole community provider in rural East Central Indiana, has actively developed joint ventures with its medical staff to economically and clinically align our patients' care. Provider-based centers are a significant piece of this overarching strategy. We embarked on this about 10 years ago, starting with consensus building and moving through to completed programs. Preserving community interest by ensuring economic survival of the hospital and the medical community, in a way that meets all federal and state laws was our prime motivation. We felt that it was detrimental, in a community with only one hospital, for the hospital and medical staff to be at odds in any way.

Duplicative facilities and services were not only economically silly, but might also weaken services by siphoning away highly trained workers...a scarce commodity in small towns. Vibrant joint ventures that clinically and economically align hospitals with its medical staff also provides a valuable physician recruitment tool in a time when rural communities struggle to attract and retain physician talent. Endangering the only acute care facility in a wide radius was not the administration's or medical staff's idea of good stewardship.

Reid structured some of its outpatient joint ventures under the CMS provider-based rules and requirements. Through these rules, CMS has provided mechanisms to ensure the service is truly acting as a hospital service and complying with hospital guidelines. By acting under provider-based rules, the joint ventures are required to comply with utilization review, quality improvement initiatives, and regulatory requirements. These requirements do come at a cost to the entity – justifying the admittedly higher reimbursement.

While we understand CMS' concern to protect against abuse of clinical services by physicians for pure financial gain, we believe that both CMS and a rural hospital and medical staff's interests can be achieved through provider-based joint-ventured entities. While free-standing joint ventures with hospitals may also provide some economic alignment, they do duplicate hospital services which must also be provided. Further, these freestanding facilities prevent an integrated medical record across time. However, in our market, provider-based entities:

- Protect against unnecessary duplication of services, equipment, staff, and facilities
- Provide clinical integration for the patient through a single, integrated medical record across hospital services

- Require hospital-based utilization review and quality improvement mechanisms and reporting
- Require compliance with stringent hospital accreditation requirements
- Provide a financial model that sustains a non-profit hospital
- Create a mechanism to attract and retain a quality community-focused medical staff
- Facilitate equitable treatment of all patients, including charity care
- Encourage physician involvement in both business and clinical decisions

We strongly request that CMS allow for provider-based services that are jointly-owned between hospitals and physicians, especially in rural communities, as a mechanism to provide clinically sound and cost effective services to its community.

I am my staff are ready to answer any questions you may have regarding this critical issue. Please feel free to contact me at (765) 983-3000.

Best regards,

Barry MacDowell
President

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CLAUSEN CHIROPRACTIC

Anna M. Clausen, D.C.

217 Gilman St
P.O. Box 520
Sheffield, IA 50475
#641-892-4008

08-27-07

Dear Alene,

I am writing to you because you have benefits under Medicare, Medicaid, or both. I have just received notification from the Iowa Chiropractic Society that the Centers for Medicare and Medicaid Services are attempting to adopt a new ruling that will exclude some x-ray benefits. Currently, Medicare and Medicaid will pay for x-rays taken at a hospital or clinic when ordered by a Doctor of Chiropractic. The new ruling states that they will no longer pay for these services. If you need x-rays, you would need to be referred to another provider (orthopedist, rheumatologist, etc) for another or duplicate examination before being referred to a radiologist for x-rays or you would pay for them out of your own pocket.

In an attempt to override this new ruling that will eliminate current x-ray benefits, I urge you to read, sign, and mail the enclosed letter in the stamped, addressed envelope I have included. **The letter must reach Medicare and Medicaid no later than Friday Aug. 31st.**

If you have any questions, please call us at the office at #641-892-4008. Thank you for your time.

Sincerely,

Alene L Fair

Anna M. Clausen, DC

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County of Santa Cruz

HEALTH SERVICES AGENCY
ADMINISTRATION

HEALTH SERVICES AGENCY
P.O. BOX 962, 1080 EMELINE AVENUE
SANTA CRUZ, CA 95061
(831) 454-4000 FAX: (831) 454-4770

August 24, 2007

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

Re: Proposed reconfiguration of CA physician payment localities

I am writing to represent the health of the citizens of Santa Cruz County whose access to healthcare has been curtailed due to unfair reimbursement strategies promulgated by CMS. I am of course referring to the reimbursement formulas as set forth in Locality 99. Many of our physicians and citizens have joined our legislators and in advocating for a change in Santa Cruz County's "Rest of State" designation under Locality 99; we have done so strongly since 2002. The failure of CMS to make any adjustment, despite clear evidence that significant economic and demographic changes have occurred since the last reconfiguration of physician payment localities in 1996, has significantly harmed our medical community and has reduced access for Medicare patients to needed medical services in our County.

I would like to take this opportunity to comment on the three options outlined in the proposed physician payment rule for 2008 with respect to reconfiguration of physician payment localities in California.

Santa Cruz County has been uniquely disadvantaged since the last reconfiguration in 1996 with respect to CMS physician payment localities. Not only has Santa Cruz County had the largest underpayment within Locality 99 in California each year since 1996, we have also had the largest boundary payment difference between our county and San Mateo/Santa Clara Counties, the largest of any adjoining counties in the nation. We note that the hospitals in this county (which is a one-county Metropolitan Statistical Area) now have the highest wage index/Geographic Adjustment Factor of any MSA in the nation. The status quo has Santa Cruz County's physicians paid at the lowest level in California and the

hospitals of this county paid at the highest level in the nation. As a result we continue to lose local physicians who are drawn to practice in neighboring localities, and our Medicare beneficiaries are facing critical access issues.

The GAO has recently called for a national reform of the payment localities. They interviewed many providers in this county, including several in this organization, during the development of their report. I am concerned that only one of the three proposed options in the rule reflects the recommendations of the GAO. Neither Option 1 nor 2 includes an iterative reconfiguration of California's localities, which was the approach used by CMS in 1996 and by the GAO.

I support Option 3 which constructs six payment localities for California. CMS describes the application of a 5% floor for a given locality based upon the highest GAF of a county within that locality. CMS presented this option in past Federal Register proposals. However, I believe CMS miscalculated the designation of the new payment localities in California. I recommend that the text described in the proposed rule be accepted but that I request that CMS recalculate the county groupings accurately.

Further, I am confused as to the actual GAF for Santa Cruz County. The proposed rule's Option 1 and Option 2 list Santa Cruz's GAF at 1.100 but lists its GAF in Option 3 at 1.098. This is not due to rounding errors as similar inconsistencies are noted for other counties. This is important in that the proposed Option 3 reconfigures counties based on these values. CMS should share not only the source GPCIs used to calculate the GAFs but also should share the cost input data used in the calculation of the county GPCIs, such as rent and wage index data.

I am also concerned about the proposed decrease in GAF values for several other SF Bay Area counties, most notably Santa Clara County. It doesn't make sense to me that Santa Clara County, in a non-census year for GPCI recalculation, could have a 9.2% decrease in its GAF. I request that CMS publish in the final rule the detailed source data that led to this abrupt, disruptive, and unanticipated decrease.

If CMS were to select Option 1, I recommend that each county that is removed from Locality 99 (and Locality 03) be assigned into its own fee schedule areas. This is especially true given that the most likely eligible counties (Santa Cruz, Monterey, Santa Barbara, and San Diego) all currently exist as one county Metropolitan Statistical Areas in the Hospital GAF. Further, I recommend that an iterative 5% threshold be applied if you choose this option.

CMS must not defer the implementation of this long-awaited reform to a state medical society. I understand that the California Medical Association will provide CMS a copy of its current policy with respect to locality reform. I am aware that this policy recommends that CMS institute those changes necessary to improve

payment accuracy and to mitigate decreases in payments to rural counties. I believe that all three options are consistent with that policy. I believe that the past delegation by CMS to state medical societies to initiate and to approve proposed locality revisions is inappropriate: they are charged with representing ALL Counties and should not be asked to choose between the benefit to the detriment of another. Further, there are many provider types (i.e. Podiatrists, Nurse Practitioners, Audiologists, Occupational Therapists, Physical Therapists, and Optometrists, among others) that are disadvantaged by the Locality 99 structure established in 1996 and the state medical society does not represent those providers of service. My colleagues and I believe it is CMS, as it acknowledged in the 2005 final rule, that bears the responsibility to update the physician payment localities.

Thank you for your attention to my comments and recommendations. Please consider the fairest approach for **all** the MediCare beneficiaries of the State of California in your final ruling. Thank you.

Sincerely,

Rama Khalsa, Ph.D.
Director, Health Services Agency

Cc. Sam Farr, Anna Eshoo Members of Congress
Diane Feinstein, Barbara Boxer US Senate

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ANNE ARUNDEL UROLOGY, P.A.
Anne Arundel Urological Surgery Center, L.L.C.

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August 30, 2007

VIA FEDERAL EXPRESS

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Mail Stop C4-26-05
7500 Security Blvd.
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

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services exception (the "Exception"). 42 U.S.C. § 1395nn(b)(2)(A). Let me begin by saying that I do not think that changes to the Exception are necessary to protect against - program or patient abuse. In fact, any narrowing of the Exception, or the implementation of the changes to the reassignment and anti-markup provisions of the purchased diagnostic tests rule that are contained in the Proposed Rule, 72 Fed. Reg. at 38225, 38229, would have a deleterious effect on the health care community generally and on the quality and availability of patient care services offered by Anne Arundel Urology in particular.

The ability of physicians to affiliate with pathologists allows practices such as ours to identify and work with highly qualified and trained specialists with whom we are familiar and whose work product we trust. This, to us, is critical to our ability to furnish the highest quality care to our Maryland patients. Because we at Anne Arundel Urology know and personally have selected a pathologist with whom we work based on his outstanding credentials (Board Certified and has completed a fellowship at one of Maryland's leading medical centers), our present ability to practice with pathologists of our choosing provides for a considerably and consistently higher quality of care. He has, in essence, developed a subspecialty in prostate-related diagnoses, have a special interest in prostate pathology and have become experts at reading prostate slides. They are better able, for example, to identify true prostrate cancer from benign tissue and prostate cancer mimickers, thereby reducing "false positives" and saving our patients unnecessary anxiety and cancer treatments. As such, we know and trust the consistency and quality of his reads, which is not something we could do if we are forced by changes in the Exception or the purchased diagnostic tests rule no longer to provide pathology services in the office setting and to send our prostate slides to large hospital-based or commercial labs. Under such circumstances, we would have no idea who is reading the slide; what that person's credentials are; the nature of the person's expertise or training; or whether that person has read one prostate slide or 1,000 prostate slides.

Because we work together with our pathologist on a daily basis, the means by which we communicate and discuss test results and prepare written reports have become standardized, thereby increasing the efficiency of our practice and our ability rapidly to deliver diagnoses to our anxiously waiting patients. In fact, whereas the national average for turning around test results is five to seven days, our pathologist returns test results in three to four days. Moreover, better and more proximate communication with our pathologists, particularly in difficult cases, results in improved clinical diagnoses and outcomes for our patients.

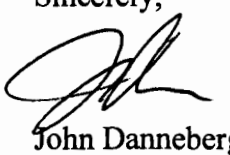
With respect to diagnostic imaging, any narrowing of the Exception might impose limits on patient access to the very types of diagnostic imaging services that have become the standard of care in Maryland and throughout the United States by restricting or prohibiting non-radiologists from providing CT services to patients in the office setting. At the present time, Anne Arundel Urology does not provide radiologic services in our offices. We realize that the rapid advance in CT technology, followed by a reduction in acquisition and installation costs, makes it possible for patients to avoid the inconvenience of having to see multiple doctors to have CT services performed outside of their own doctor's offices. This technology, once considered expensive, cumbersome and difficult to use, has advanced into available, affordable and indeed indispensable patient diagnostic tools. We would like to be able to provide these services to our patients in the future. There is, therefore, no clinical, quality of care reason to restrict the definition of in-office ancillary services so as to eliminate our ability to furnish state-of-the-art diagnostic imaging services in a setting that is most convenient for our patients and is most efficient with respect to our ability to make a diagnosis.

The changes suggested by the Proposed Rule, and the nature of the comments solicited with respect to the Exception, go far beyond what is necessary to protect the Medicare program from fraud and abuse and to ensure patient care. The Exception as currently interpreted and applied recognizes that certain employment and contractual relationships among physicians are beneficial to patients and strike the appropriate public policy balance between the prophylactic prohibition on self-referrals and the recognition that certain arrangements not only are appropriate, but also are necessary to enhance the efficient provision of quality health care.

Consequently, if the Exception is narrowed in any meaningful way, particularly in a manner that limits the types of ancillary services that can be provided pursuant to the Exception or that restricts the ability of physicians or groups to furnish services in the "same building," 42 U.S.C. § 1395nn(b)(2)(A)(ii)(I), the manner in which the physicians of Anne Arundel Urology practice medicine will be severely impacted, and the quality and convenience of care that we provide to our patients will be significantly compromised. The practical effect would be to restrict access for our patients to routine medical procedures that have become the standard of care throughout the country. Implementation of the proposed changes to the purchased diagnostic test rules would have a similar effect by limiting our ability to provide such services with anything but full-time employees. Both potential changes would create an unjustified monopoly for particular physician specialties to the detriment of patient access and care.

Thank you again for the opportunity to submit these comments on the Proposed Rule.

Sincerely,



John Danneberger, M.D.

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August 30, 2007

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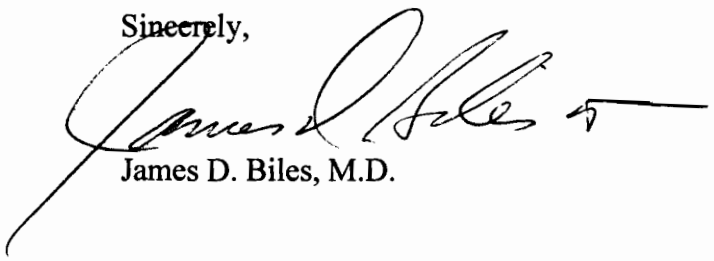

James D. Biles, M.D.

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FAX 410-768-0067

services exception (the "Exception"). 42 U.S.C. § 1395nn(b)(2)(A). Let me begin by saying that I do not think that changes to the Exception are necessary to protect against - program or patient abuse. In fact, any narrowing of the Exception, or the implementation of the changes to the reassignment and anti-markup provisions of the purchased diagnostic tests rule that are contained in the Proposed Rule, 72 Fed. Reg. at 38225, 38229, would have a deleterious effect on the health care community generally and on the quality and availability of patient care services offered by Anne Arundel Urology in particular.

The ability of physicians to affiliate with pathologists allows practices such as ours to identify and work with highly qualified and trained specialists with whom we are familiar and whose work product we trust. This, to us, is critical to our ability to furnish the highest quality care to our Maryland patients. Because we at Anne Arundel Urology know and personally have selected a pathologist with whom we work based on his outstanding credentials (Board Certified and has completed a fellowship at one of Maryland's leading medical centers), our present ability to practice with pathologists of our choosing provides for a considerably and consistently higher quality of care. He has, in essence, developed a subspecialty in prostate-related diagnoses, have a special interest in prostate pathology and have become experts at reading prostate slides. They are better able, for example, to identify true prostrate cancer from benign tissue and prostate cancer mimickers, thereby reducing "false positives" and saving our patients unnecessary anxiety and cancer treatments. As such, we know and trust the consistency and quality of his reads, which is not something we could do if we are forced by changes in the Exception or the purchased diagnostic tests rule no longer to provide pathology services in the office setting and to send our prostate slides to large hospital-based or commercial labs. Under such circumstances, we would have no idea who is reading the slide; what that person's credentials are; the nature of the person's expertise or training; or whether that person has read one prostate slide or 1,000 prostate slides.

Because we work together with our pathologist on a daily basis, the means by which we communicate and discuss test results and prepare written reports have become standardized, thereby increasing the efficiency of our practice and our ability rapidly to deliver diagnoses to our anxiously waiting patients. In fact, whereas the national average for turning around test results is five to seven days, our pathologist returns test results in three to four days. Moreover, better and more proximate communication with our pathologists, particularly in difficult cases, results in improved clinical diagnoses and outcomes for our patients.

With respect to diagnostic imaging, any narrowing of the Exception might impose limits on patient access to the very types of diagnostic imaging services that have become the standard of care in Maryland and throughout the United States by restricting or prohibiting non-radiologists from providing CT services to patients in the office setting. At the present time, Anne Arundel Urology does not provide radiologic services in our offices. We realize that the rapid advance in CT technology, followed by a reduction in acquisition and installation costs, makes it possible for patients to avoid the inconvenience of having to see multiple doctors to have CT services performed outside of their own doctor's offices. This technology, once considered expensive, cumbersome and difficult to use, has advanced into available, affordable and indeed indispensable patient diagnostic tools. We would like to be able to provide these services to our patients in the future. There is, therefore, no clinical, quality of care reason to restrict the definition of in-office ancillary services so as to eliminate our ability to furnish state-of-the-art diagnostic imaging services in a setting that is most convenient for our patients and is most efficient with respect to our ability to make a diagnosis.

The changes suggested by the Proposed Rule, and the nature of the comments solicited with respect to the Exception, go far beyond what is necessary to protect the Medicare program from fraud and abuse and to ensure patient care. The Exception as currently interpreted and applied recognizes that certain employment and contractual relationships among physicians are beneficial to patients and strike the appropriate public policy balance between the prophylactic prohibition on self-referrals and the recognition that certain arrangements not only are appropriate, but also are necessary to enhance the efficient provision of quality health care.

Consequently, if the Exception is narrowed in any meaningful way, particularly in a manner that limits the types of ancillary services that can be provided pursuant to the Exception or that restricts the ability of physicians or groups to furnish services in the "same building," 42 U.S.C. § 1395nn(b)(2)(A)(ii)(I), the manner in which the physicians of Anne Arundel Urology practice medicine will be severely impacted, and the quality and convenience of care that we provide to our patients will be significantly compromised. The practical effect would be to restrict access for our patients to routine medical procedures that have become the standard of care throughout the country. Implementation of the proposed changes to the purchased diagnostic test rules would have a similar effect by limiting our ability to provide such services with anything but full-time employees. Both potential changes would create an unjustified monopoly for particular physician specialties to the detriment of patient access and care.

Thank you again for the opportunity to submit these comments on the Proposed Rule.

Sincerely,

Edward M. Zagula, M.D.

564

WINTHROP
University Hospital

Care without compromise.

Virginia Donovan, M.D.
Chair, Department of Pathology
Residency Program Director

Tel: 516-663-2450
Fax: 516-663-4581
E-mail: vdonovan@pathology.winthrop.org

August 27, 2007

RE: Self-Referral Provisions

Thank you for the opportunity to submit comments on the Physician Self Referral Provisions of CMS-1385-P entitled "Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2008". I am a board-certified pathologist and a member of the College of American Pathologists. I practice in Mineola, New York as a attending pathologist at Winthrop University Hospital as part of an 11 member pathology group.

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

Specifically, I support the expansion of the anti-markup rule to purchase 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 service unless the physician is capable of personally performing or supervising service.

Opponents to these proposed changes assert that their captive pathology arrangements enhance patient care. I agree that the Medicare program should ensure that providers furnish care in the best interest of their patients and restrictions on 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 compromised the integrity of the Medicare program.

Sincerely,

Virginia M. Donovan, M.D.
Chair, Department of Pathology
Winthrop University Hospital

From: drjscotthassell@aol.com
Subject: **Fwd: cms**
Date: August 30, 2007 6:34:51 PM CDT
To: drjscotthassell@mac.com

-----Original Message-----
From: drjscotthassell@aol.com
To: bjeankelly@aol.com
Sent: Thu, 30 Aug 2007 6:32 pm
Subject: cms

August 30, 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

Ladies and Gentlemen:

I practice within a group of four Urologists in Plano, Texas. The four of us have long participated in a joint venture to provide lithotripsy to our patients. The financial risk taken by ourselves and Urologists like us in such joint ventures provided a needed service that patients in our community would otherwise have been without, while saving Medicare millions in revenue. Despite this mutually beneficial relationship, the 2008 Physician Professional Fee Schedule proposed in July appears to threaten the very existence of such ventures, and in turn threatens patient access to needed care. This is of grave concern to each Urologist providing such care. I believe the following illustrates why the proposal is misguided:

1. Under Arrangements
This component assumes that lithotripsy is a designated health service to be listed in the same category as imaging services with an accompanying high risk of physician inappropriate referral and overuse for financial benefit. Urologists who bring lithotripsy as well as cryotherapy and laser therapies to hospitals through joint ventures know that these modalities are used appropriately by the physician owners to the benefit of all involved, and most importantly the patient. As detailed in American Lithotripsy Society v. Thompson, Extracorporeal Shock Wave Lithotripsy is not a DHS; in this light, the CMS is choosing to rewrite history. The new CMS proposal flies in the face of the known history of Urologist utilization of this modality, which has been ethical and appropriate. To lump ESWL together with Imaging ventures and their separate history is patently unfair.
2.Per Click Fee
The CMS proposal to ban per click fees is contradictory to Congressional Intent, as stated in your commentary. Furthermore, such arrangements allow improved patient access to care in areas that otherwise would not or could not provide such care, while the physician in a joint venture bears the risk. Per click arrangements should continue to be permitted on this basis.
3. Percentage Fee Reimbursement
Again, as in the case of per click fees, such arrangements allow services that would otherwise be unavailable to patients to become available, with the burden of risk falling to the physician in a joint venture. Disallowing such arrangements in turn disallows provision of needed care to the Medicare patient in the instance of new, innovative and expensive therapies.
4. Stand In the Shoes
Ambulatory Surgical Centers provide care at a lower cost. If referral to an ASC owned or controlled by a hospital is considered a referral to the hospital, legitimate physician joint ventures may no longer provide services at such ASC's. This would likely end in the marked reduction in the current efficiency of ASC's due to the proliferation of centers that would otherwise not be needed.
5. Burden of Proof
Under this segment of the CMS proposal, the provider must prove innocence on his/her part in regard to Stark violations. Stark penalties extend to anyone who causes a claim to be submitted in violation of the regulations, leaving CMS as omnipotent

judge and jury. Not only is this segment of the proposal in direct conflict with a tenet of American justice, it is a blatant abuse of power by a governing body. Should this segment stand, I think a large element of trust is lost for the CMS.

In all, therapeutic joint ventures benefit the Medicare beneficiary in providing needed and otherwise unavailable new medical technologies, bring efficiency to healthcare and save hundreds of millions of dollars for CMS to utilize for more worthy causes. Diagnostic joint ventures may invite unethical practice, inappropriate referral and overuse, and likely need better regulation. History has proven each, and CMS should pay attention to history before finalizing this proposal.

Signed,

Jeffrey Scott Hassell, M.D.

MAYO CLINIC

200 First Street SW
Rochester, Minnesota 55905
507-284-2511

August 17, 2007

Mr. 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

Re: File Code CMS-1385-P

Comments to Proposed Rule 72 FR 38122, 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 appreciate the opportunity to provide comments on the proposed changes to the Physician Fee Schedule (PFS) published in the July 12, 2007 Federal Register.

"Impact – Conversion Factor Update"

The proposed reduction for the 2008 Medicare physician fee schedule payments of 9.9 percent is excessive and may lead to limiting access to physician care for many Medicare beneficiaries. We recognize CMS is required to follow current payment policy requirements; however, we encourage CMS to work with Congress to alleviate the proposed reduction. Additionally, the current sustainable growth rate methodology is seriously flawed and unjustly penalizes many physicians and group practices who strive to control costs and practice effective quality-based medicine. Until an update formula is developed that realistically identifies an update to the conversion factor and subsequent physician payment, CMS and physicians will continue to be presented with unwarranted negative updates for the Medicare physician fee schedule. CMS should encourage Congress to develop a payment system based on value-measurable outcomes, safety and service compared to the cost over time.

Anesthesia Coding Five-Year Review

We support the RUC recommendation to recognize the 32 percent undervaluation of the physician work identified in the anesthesia relative values. We are also grateful that CMS is proposing to recognize this by increasing the anesthesia conversion factor by 25 percent. This will help to ensure that Medicare patients have access to expert anesthesiology medical care.

"Coding - Multiple Procedure Payment Reduction for Mohs Surgery"

We request CMS continue the long-standing exemption of Mohs procedures, codes 17311 through 17315, from the multiple procedure reduction rule. The major portion of the physician work in these procedures is in the intra-service work component, which is the reason this exception is appropriate. To reduce payment for these services by fifty-percent would not provide payment commensurate to the services actually provided. If there are reasons to remove the exemption, we would like the reason published in a proposed rule to permit comment and discussion from the health care community.

"Resource Based PE RVUs - Mohs Procedure Relative Values"

We request CMS reconsider setting RVUs for facility services in the same manner as non-facilities for the first tier CPT codes for Mohs procedures In the 2007 Final Rule, the relative value units (RVUs) were issued for new CPT codes which included Mohs procedures. As we commented last year, we are concerned that the RVUs for the first tier procedures (CPT 17311 and 17313) provided in a facility are disproportionately reduced when compared with the RVUs for services provided in a non-facility. The physician work required to perform these procedures in the facility is at least the same as the non facility setting and often greater due to case complexity. Without consistent payment for the physician services in both settings, we believe there will be a disincentive for patients to receive these services in a facility setting. This may have a negative impact for outreach services to rural communities where the hospital may become the only venue for the services and for tertiary care providers that care for complex patients who often have large or multiple skin cancers due to immunosuppression secondary to transplantation or a host of other comorbid conditions.

"Coding – Additional Codes from 5-Year Review – Code 93325"

We disagree with CMS' proposal to bundle payment for CPT code 93325 *doppler echocardiography color flow velocity mapping,* into payment for several other echocardiography services as an "intrinsic" component of the service. We consider this service an integral and separate service from other echocardiography services. While color flow doppler can be performed concurrently or in concert with the imaging component of echocardiographic studies, the performance of color flow doppler increases the sonographer time and equipment time that are required for a study. In fact, the physician and sonographer time and resources involved have increased as color flow doppler's role in the evaluation of valve disease and other conditions has become more complex. The sonographer and equipment time and the associated overhead required for the performance of color flow doppler are not included in the relative value units for any other echocardiography "base" procedure. Moreover, CMS is incorrect in assuming that color flow doppler is "intrinsic" to the provision of all echocardiography procedures. We understand that data gathered by an independent consultant and submitted by the American College of Cardiology and the American Society of Echocardiography (ASE) confirms that color flow doppler is routinely performed in conjunction with CPT code 93307. However, this data, which was previously submitted to CMS, also indicates that

an estimated 400,000 color flow doppler claims each year are provided in conjunction with 10 echocardiography imaging codes other than CPT Code 93307, including fetal echo, transesophageal echo, congenital echo and stress echo. For many of these echocardiography "base" codes, the proportion of claims that include color flow doppler approximates or is less than 50 percent. More recent data submitted by the ASE in response to the Proposed Rule confirms that this practice pattern has not changed over the past several years. Expanding the bundling proposal to services other than 99307 would result in an inappropriate identification of resources for those services. We request that CMS does not bundle CPT code 99325 for 2008 and that CMS retain the relative value units and payment status from the 2007 fee schedule for 2008.

"Coding – Cardiac Rehabilitation"

We support CMS' initiative to reimburse cardiac rehabilitation on a per hour basis. We encourage CMS to work with the AMA to expand the existing CPT definition for these codes (93797, 93798) to allow for time-based reporting. This will allow providers and suppliers to use existing codes for all payers and decrease the administrative burden associated with different codes and billing processes based on payer type. We encourage CMS to retain the existing CPT definitions of these codes, with the exception of adding the time element.

"Physician Self-Referral Provisions"

In relation to the anti-markup provision, we believe that purchased diagnostic tests and purchased interpretations involving part-time employees should be acceptable in cases where the part-time employee does not have any other health care employment and is truly a "part-time" employee at a single healthcare organization. We would like CMS to clarify the definition of a "full-time and part-time employee of the billing entity" in the Final Rule. Otherwise, we believe that prohibiting physicians from marking up tests which they did not perform is a positive development.

"Therapy Standards and Requirements"

We support CMS' proposal to expand recertification for the plan of treatment from 30 days to 90 days. We believe this will decrease the administrative burden of obtaining signatures on the plan of treatment.

We disagree with CMS' proposal to apply outpatient therapy standards in the inpatient setting. There are considerable differences between an inpatient and outpatient therapy plan of treatment. The type, duration, and frequency of treatment, and goals for inpatient therapy may be significantly different than outpatient therapy. An inpatient plan of treatment will be more frequent, very short term, and discharge oriented. Thus, the documentation and criteria for an inpatient plan of treatment and goals will generally not align with the same documentation and criteria for the plan of treatment in the outpatient setting.

"TRHCA – Section 101(b): PQRI"

We concur with CMS' initiative to improve health care quality and believe that an incentive program may be useful toward that goal. However, to be useful, the incentive program should link a specific objective of improving the value of health care to a payment that is substantial enough to influence behaviors. The measures chosen for reporting should be tightly related to a desired outcome with good scientific studies to demonstrate this relationship. A program that simply institutes process measures as a basis of reporting for some form of incentive payment does not necessarily advance the goal of enhanced value and may do nothing more than increase administrative costs for both physician practices and the Medicare program.

The proposed rule increases the number of quality measures to more than double the current number and does not include supporting credible evidence that the proposed measures are related to improved outcomes. Adding measures for every specialty or subspecialty only creates more metrics and does nothing to encourage improved quality. At the same time, the additional measures add cost for development and review of the measures, costs for inclusion in the Medicare payment program, and costs for practices to incorporate such measures. Without at least an equal improvement in performance of the health care system, it is impossible to say that there is any benefit in this approach. We understand CMS' desire to provide all physicians with the option to report quality measures; however, we believe focusing on specific areas such as chronic disease health care improvements, where most healthcare dollars are spent, aligns with improving health care quality. Simply reporting of process measures alone is unlikely to improve health care quality.

We appreciate CMS' interest in comments regarding the proposed registry reporting mechanism. The proposed rule outlines five registry-based reporting options. Each registry option continues to require claims data or ties to claims data. The registry-based reporting options do not allow physicians to reconcile the quality data which Medicare uses to determine successful reporting. Any option, including registry-based options, should allow physicians to reconcile the quality measures and reimbursement, regardless of the method used to record and/or submit quality data. There are multiple existing specialty, State, and other type of registries currently used to report quality data. We encourage CMS to evaluate and use these existing registries for the PQRI rather than to create additional administrative burden on physicians. Specifically, in the state of Minnesota, the Minnesota Community Measurement Project measures performance for several chronic diseases based on guidelines for care. This information is used to determine how practices fare in care of important conditions, and is the basis of determining which practices might receive bonus payments for best care. This information should be adequate for PQRI and practices that report using the Minnesota Community Measurement Project, or a similar system, should be considered to be reporting. The existing claims-based reporting mechanisms and proposed registries are resource intensive and require significant administrative and information technology resources to manage, far outweighing any modest payment incentive. For an incentive program to be successful, the incentive must offset the administrative burden.

If CMS does desire to continue the current PQRI process, we suggest that at a minimum, CMS should allow multi-specialty group practices to report using sampling techniques or to focus on chronic conditions similar to the Physician Group Practice Demonstration projects.

We also suggest that CMS consider ways to utilize existing cost and outcome data, such as the Dartmouth Atlas, to help adjust payments to regions that have demonstrated better outcomes at lower costs than other regions. This would allow for an outcome based payment methodology immediately without the need to devise and pilot new performance based payment systems. We would be glad to discuss a proposal at any time.

We also note, with interest, the desire of CMS to explore methods of extracting information from the electronic health record for use in reporting. We have implemented a new software application that performs this extraction work and would be interested in exploring options for its use with appropriate CMS staff.

Finally, we urge CMS to craft and implement a solid incentive-based program for reporting physician quality measures for chronic diseases using existing quality reporting registries. Existing mechanisms and/or slight modifications to existing reporting mechanisms (i.e., existing registries) will allow health care resources to focus on improving health care quality rather than reporting quality.

*****

Thank you for your consideration of our comments. If you have any questions, please contact either Brenda Mickow at (507) 284-1871 or me at (507) 284-4627.

Very truly yours,

Ronald W. Grousky
Director, Medicare Strategy

28 Aug 07

Center for Medicare + Medicaid Services
Dept of Health + Human Services
attn: CMS-1385-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore MD 21244-1850

Dear Sir or Madam;

I am a retired physician (as of 1 Jan 02), formerly having practiced urology. In 2006 I developed almost complete urinary obstruction because of prostatic hypertrophy. Because of Coumadin therapy required for my auricular fibrillation, I was not a candidate for TUR prostate and I had failed medical therapy (Avodart and Flomax), I underwent PVP-photo vaporization of prostate - which completely resolved the obstruction and required only overnight inpatient observation. The hospital does not have PVP equipment which fortunately was provided by others.

I am writing to you regarding proposed CMS changes in physician self-referral provisions. Any changes which will inhibit joint ventures by urologists to provide new technology will only be a great detriment to patient care. Hospitals are reluctant to provide the newest technology because of expense and because it makes present equipment obsolete. Urologists who are willing to risk investment in new technology thru joint ventures can make this new technology available to many patients +/or many hospitals. It should be a win-win situation with patients receiving better care and medicare saving on costs.

I realize CMS is trying to prevent abusive arrangements such as existed with diagnostics. However CMS should not interfere with a patient's ability to have access to the best therapeutics which are available. Thank you for having considered my comments.

Thanks you again,

Lorris M Bowers MD,
LORRIS M. BOWERS MD
12201 W. US HWY 150
BRIMFIELD, IL 61517-9560

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Urology Associates of Dayton, Inc.

(937) 208-2540
(937) 208-2551 (Fax)

Lawrence J. Litscher, M.D. **David W. Key, M.D.** **Mark A. Monsour, M.D.** **Michael K. Yu, M.D.**

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August 24, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Mail Stop C4-26-05
7400 Security Blvd.
Baltimore, Ohio 21244-1850

Ladies and Gentlemen,

I appreciate the opportunity to give my input regarding the recent published proposed changes regarding physician joint ventures. I believe I am in the minority in that I agree with the basic foundation. Although some joint ventures certainly improve access to care and new technology, it has become an abused situation. One only needs to look at the intensity modulated radiation therapy for cancer patients, in my speciality prostate cancer, to understand how this is being abused. By report, the profit margin is $15,000 per patient. Therefore, multiple joint ventures have sprung up purely to capture this passive income.

I feel strongly that this money would be better served raising payment to physicians for the direct patient care services and not for purposes such as these. As it was appropriate to drastically cut the "golden ghost" from chemotherapy passive income, it is also appropriate to cut this essentially obscene profit margin for IMRT.

Sincerely,

Lawrence J. Litscher, M.D., F.A.C.S.

LJL/mls

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

To Whom It May Concern:

I am a physical therapist employed by an organization that provides rehab services within physician practices. My previous work experiences include acute hospital care, inpatient rehab, hospital outpatient, and private practice outpatient therapy. Of all these, my current setting within a multi-physicians' practice has been the most rewarding in terms of quality of patient care, cost containment, and efficiency in the utilization of therapy services.

Practicing within the same physical space as physicians has proven to be entirely patient-oriented. The relationship I have developed with our physicians has enabled me to be in constant communication with them regarding individualized treatment plans and better development of diagnosis-specific clinical protocols. The doctors are very involved in their patients' progress in therapy and are eager for feedback from each therapist. I have more streamlined access to physician dictations, diagnostic and surgical reports, and financial records that afford me the opportunity to make timely and appropriate care decisions in the best interest of my patients. Because of this enhanced physician-to-therapist communication, I am also able to make immediate revisions to a patient's physical therapy plan of care when changes occur in the patient's condition, which increases my ability to reach appropriate functional outcomes for each patient.

Our patient satisfaction survey scores are consistently very high. We take pride in the fact that our patients can choose any local provider for therapy, yet they choose to come to our clinic because of convenience, because of past experiences with us, or because they were referred by a friend, family member, or neighbor. Our patients have input into their treatment and plan of care, and they receive therapy in an enjoyable, encouraging environment that is focused on attaining their goals and returning them to a normal lifestyle.

Compared to my previous work experiences, the in-house rehab model represents the greatest stewardship of resources. Our company consistently falls below national averages in visits per referral as well as referral rates per physician. This allows us to save our patients valuable healthcare dollars in a world where such resources are continually diminishing. We view therapy as an invaluable ancillary service that physicians' offices can provide in order to offer a convenient, comprehensive approach to health care for their patients. Our physician partners are unremittingly concerned with how well their patients are cared for, not how many of their patients are being cared for in therapy. Fully meeting our patients needs while being fiscally and ethically responsible is our number one priority.

In closing, I ask for your continued support of this model. The partnership between therapy providers and physicians is an appropriate and beneficial means for patients to receive rehab services in a convenient, ethical, and efficient manner, and such an institution is beneficial to the entire healthcare system at large.

Sincerely,

Brett Rivers, PT

571

KENDALL L. WISE, M.D.
BOARD CERTIFIED UROLOGY
COLONIAL SQUARE
1044 GOODLETTE ROAD N.
NAPLES, FLORIDA 34102

TEL. (239) 261-5400

FAX (239) 261-4387

August 29, 2007

Centers for Medicare and Medicaid Services
Dept. of Health and Human Services
Attn: CMS-1385-P

Dear Sir:

I am writing to express my concern with the 2008 Proposed Physician Fee Schedule. Provisions against physician owned lithotripsy services are counterproductive to your stated objectives. Patients referred to a lithotripsy service undergo a surgical procedure and the referring doctor is generally the same doctor who performs the procedure. In performing the procedure he charges and is paid a professional fee far in excess of the profit from his ownership in the device. Furthermore, these devices are used on patients with kidney stones. Such patients are often in severe pain and would greatly resent any intervention form CMS that makes lithotripsy units less plentiful or less accessible in our community.

These arguments apply to joint ventures seeking to provide other cutting edge therapeutic technologies and should be subject to different guidelines than diagnostic services.

Sincerely,

Kendall L. Wise, M.D.

572

Vantage Oncology

August 29, 2007

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

Re: Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008 (CMS-1385-P)

Dear Mr. Kuhn:

Vantage Oncology welcomes the opportunity to provide written comments on the "Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008" published in the *Federal Register* as a proposed rule on July 12, 2007. Our comments will focus exclusively on the Physician Self-Referral Provisions, specifically the In-Office Ancillary Services Exception.

PHYSICIAN SELF-REFERRAL PROVISIONS
In-Office Ancillary Services Exception

Vantage Oncology is a private company founded about five years ago by several well-recognized radiation oncologists and healthcare executives experienced in the treatment of cancer. Our mission is to partner with radiation oncologists and hospitals to develop and operate state-of-the-art radiation treatment facilities. By having access to our management expertise and financial resources, our partner radiation oncologists and hospitals can offer more efficient facilities with the latest technology. There are currently 22 facilities located throughout the United States that Vantage, in conjunction with its partners, has either developed new, or acquired and upgraded. Vantage has also invested considerable resources in the development of an oncology-specific Electronic Medical Record (EMR) in conjunction with one of our vendors. Our plan is to use the data collected using the EMR to report clinical outcomes and improve the process of care.

We have watched with considerable concern over the last few years and in particular this past year as the aggressive use of the in-office ancillary services exception with respect to radiation oncology services has increased. We do not believe that radiation therapy services meet the definition of "ancillary" services for which the in-office ancillary services exception should apply, nor do we believe it was the intent of Congress or CMS for radiation therapy services to be included among such ancillary services. We agree with the position of the American Society

for Therapeutic Radiation and Oncology (ASTRO) on this matter as set forth in its August 20, 2007 letter to you -- that radiation therapy services should be carved out of the designated health services that qualify for the in-office ancillary services exception.

We are particularly concerned with the growth in business models in which companies or a group of specialist physicians, who are traditionally referrers to radiation oncologists, engineer the combination of physician specialists (for example, urologists and radiation oncologists) who have very rarely combined in the past. The main objective of these models appears to be to legitimize under the in-office ancillary services exception a payment to the referring physicians (in this case the urologists) that the Stark law would otherwise prohibit.

The proponents of these business models typically argue that such combinations are essential for "comprehensive treatment" or "continuity of care". But neither in theory, nor in practice as they are implemented, do such models accomplish these goals. Historically, these specialist physicians have always operated in the traditional referral relationship with radiation oncologists, without the need for combining into one group. Further, it is rare in these structures that there is any significant change in the actual interaction among the physicians in the groups. A typical radiation therapy center that is owned by urologists or other specialists is in a "centralized building" that is a distinctly separate location from the referring physician's (and now radiation therapy office owner's) primary practice office. Further, the referring physician specialists rarely come to the centralized building and are not involved in the care of the cancer patients in any manner different from the past.

In other words, based on our observations of these specific types of arrangements, there typically is not greater continuity of care or improved day-to-day oversight of the radiation therapy process. To the contrary, the primary objective achieved by the specialist physicians is to achieve ownership in a "downstream" provider's practice income, in this case that of the radiation oncologists. Moreover, these types of arrangements create a strong financial incentive for the specialists to change their practice patterns, resulting in the referral of patients to the more lucrative downstream "ancillary" service in which the specialists have an investment. Not only do the resulting practice patterns limit patient choice, they also increase the overall costs of the healthcare system.

We are often asked to assist groups of radiation oncologists who are facing such threats from groups of urologists and other specialists or from companies organizing them in such business structures. As described in the ASTRO letter, the radiation oncologists are faced with bowing to such pressures or jeopardizing the financial well-being of their practices. Further, we also see the negative impact on quality of care, patient choice and access in communities where these structures have been implemented.

In conclusion, we strongly agree with ASTRO's position that radiation therapy services should be excluded from the list of designated health services for which the in-office ancillary services exception would apply.

* * *

Thank you for the opportunity to comment on this proposed rule. Should you have any questions on our comments, please call Steven Udicious, our General Counsel, at (610) 519-0550.

Respectfully,

Michael Fiore
Chief Executive Officer

Leslie Botnick, M.D.
Chief Medical Officer

Christopher Rose, M.D.
Chief Technology Officer

ADULT PEDIATRIC UROLOGY

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JOHN D. HORGAN, M.D., F.A.C.S.
BRUCE E. LUNDAK, M.D.
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STEFANIE L. BOLTE, M.D.
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.

7710 MERCY ROAD, SUITE 406 • OMAHA, NEBRASKA 68124 • (402) 397-7989
2206 LONGO DRIVE, SUITE 105 • BELLEVUE, NEBRASKA 68005 • (402) 293-7980
3434 WEST BROADWAY, SUITE 102 • COUNCIL BLUFFS, IOWA 51501 • (712) 325-0014
17055 FRANCES STREET, SUITE 102 • OMAHA, NEBRASKA 68130 • (402) 397-7989

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,

BE [illegible] MD

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Thank you for your consideration,

Andrew Trainer MD

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PRACTICE LIMITED TO UROLOGY
OFFICE HOURS BY APPOINTMENT

August 30, 2007

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

Dear Sirs or Mesdames:

I am a Urologist practicing in Petersburg, Virginia for the last 31 years. Down through the years and early in my practice, we were required to make large incisions to remove kidney stones. Since that time, the development of technology has allowed for noninvasive therapy of these kidney stones, which are among the most painful things that individuals can have. Because of the foresight of certain urologists, partnerships were established to take the financial risk to bring the technology of extracorporeal shock wave lithotripsy to localities such as mine, so that patients can be treated effectively for their stones without painful incisions. To bring this technology to areas, many of us have had to make substantial financial investments with unclear outcomes as to whether these technologies would be lasting. We have always done so on behalf of the patients.

It has come to my attention that there are certain proposals in the recently released 2008 Medicare Physician Fee Schedules (MPFS) that cause me great concern that the patients that are Medicare beneficiaries will be robbed of the willingness of practicing physicians to take chances to help them with the technology that I just enumerated, as well as other technologies for treatment of urological problems. During times of change, we physicians have accepted the risk of the technology developments on behalf of the patients and yet the proposals in your 2008 physician professional fee schedule attack the very substance of joint ventures that have saved Medicare millions of dollars and have also saved patients from painful incisions because of our willingness to take changes on these investments. Joint ventures that are involved take care of careful quality assurance. The lithotripsy partnerships in particular are only used on people who

require interventions for their kidney stones and this is carefully monitored in the quality assurance aspects of the partnerships.

Among the more bothersome proposed changes that are being entertained at this time is a change for classification of an entity billing for the service of medical care being rendered. Historically, CMS interpreted "entity" under the Stark statute to only mean the entity building for the service in an under arrangement contract, which will be the hospital. New MPFS rule proposes to change the Stark definition of "entity" to mean not only the hospital that bills for services, but also the personal entity that provides the designated health service or "causes a claim to be presented" for the DHS. Change essentially would require urologist owned entities providing these services to be disallowed from continuing to perform these services under these arrangements. A rather complicated interpretation of what designated health services is involved in this rule change, but in essence, this threatens to make it difficult, if not impossible for well needed urological services to be provided by partnerships that involve urologists to no longer be available to these patients. Changing technicalities, such as in these proposed rule change is a detriment to the patients that we who practice urology, as well as the patients who will receive this care there. In essence, this system has worked well to provide patient's with the kind of care that CMS wishes and the arbitrary change to eliminate those of who take the risk of providing technology to not be a part of the beneficial ownerships of the successes is most unnecessary. The result will be that the patients will be denied the services.

It is my understanding that one additional plan change to arrangements for leased equipment and space for medical procedures by CMS is to reverse the allowance of time based or unit of service based payments for space and equipment leases. As I understand it, it was the intent of Congress to permit these situations, and therefore, the plan by CMS to prohibit these is against the wishes of congress. It is particularly true that in the case of lithotripsy and other urological procedures that are done, not as diagnostic, but therapeutic procedures with identified pathology that the concerning "abuse" arrangements do not really apply in this case. These, therefore, are not in the same vein as designated health services. At times, patients who have lithotripsy services will require unexpected additional or suspected additional or separate services such as insertion or removal of a stent, ureteroscopic manipulations or cystoscopy. The hospital and the company that provide the service cannot determine in advance when these procedures are necessary, and therefore, charges that are based on the so called per click fees are the only scale way to determine conversation. The next concern I have is that the assertion that percentage based compensation arrangements are inherently abusive. Percentage based arrangements allow the apportionment of the risk of low or no volume for new or costly therapeutic modalities. A company, regardless of its ownership, which provides technology and a valuable service to patients, should be compensated in proportion for these services. Fee arrangements, which are apparently advocated by MCS, do not reflect the value of the efforts provided by the entities to the hospital. A blanket prohibition of percentage based fee arrangements would result in the loss of services to Medicare patients and should not be the part of any revisions.

In conclusion, I would like to point out that many of the planned revisions of rules have to do with possible abuses of underlying diagnostic procedure ventures. In the urological community, we are concerned with therapeutic joint ventures in which only patients that have the documented need for the treatment such as lithotripsy for kidney stones or new treatments for

obstructing benign prostatic hyperplasia or other therapeutic needs. I believe that there is a marked difference in this venue from diagnostic procedures, which could be done in search of possible pathology. At this particular point, many urologists who have joined together to bring technology, largely at their own financial risk to their patients, should not be prohibited by rules that are totally unfair for compensation should these technologies prove beneficial I would urge you to differentiate between diagnostic ventures and therapeutic ventures, the latter of which are what we in the urological community have provided and should be able to continue to provide to our patients and to your Medicare beneficiaries, of which I am about to become one.

Respectfully yours,

H. Alan Bigley, Jr., M.D., F.A.C.S.

HAB/smc

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FILE NO.: 52767.00001

August 30, 2007

Via UPS 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: Proposed CMS Full-Time Physician Employee Requirement

Dear Sir or Madam:

On behalf of our clients, we are writing to respectfully request that the Centers for Medicare and Medicaid Services ("CMS") reconsider its proposed full-time physician employee regulatory requirement in order for a urology or gastroenterology physician practice (the "Practice") to bill and collect full physician reimbursement from the Medicare program for the professional pathology services rendered by a pathologist (the "Pathologist") to its patients relating to anatomic pathology specimens. As described in more detail below, we believe that it should not matter to CMS if the Pathologist is an employee or independent contractor, nor should it make a difference whether the Pathologist works full-time hours or not. From our vantage point, CMS should always reimburse in accordance with the Medicare physician fee schedule in order to encourage physician practices to hire or engage pathologists, part-time or full-time, because we believe: (a) the overall quality of the professional services provided to Medicare beneficiaries improves; (b) the provision of professional pathology services by physician practices is revenue neutral to the Medicare program; (c) Medicare beneficiaries would not be subjected to any unnecessary testing simply because physician practices have hired or engaged part-time pathologists; (d) CMS already has sufficient safeguards in place to protect the program from financial abuse; and (e) to do otherwise would interfere with the practice of medicine.

1. Background. In order to provide professional pathology services to their patients, many Practices throughout the country are either hiring a Pathologist as an employee or engaging one as an independent contractor to be an integral part of the physician practice on a part-time basis. In some instances, Practices are also engaging pathology practices as independent contactors in order to arrange for the provision of professional services by part-time pathologists to their patients.

There are two common approaches for a Practice to provide professional pathology services to its patients. These are: (a) the TC-PC model; and (b) the In-Office Laboratory model (collectively, the "Models"). Whether the Practice uses the TC-PC model or the In-Office Laboratory model often depends on the number of physicians in the Practice. In each of the Models, however, a Practice needs to employ or engage a Pathologist, typically on a part-time basis, to provide the professional pathology services to its patients.

In the TC-PC model, the physicians in the Practice will send the anatomic pathology specimens taken from their patients during ambulatory surgery procedures to a laboratory (the "Laboratory"). The Laboratory will prepare slides from each anatomic pathology specimen and send them to the offices of the Physician Practice. Physically present in the Physician Practice's offices, the Pathologist will interpret the slides and prepare reports for each patient's referring physician who is in the Practice. The Practice provides the Pathologist with an office, microscope and dictation equipment. In the TC-PC model, the Laboratory prepares the slide and bills the Medicare program for the technical services it renders for the patients of the Physician Practice while the Practice bills the Medicare program for the professional services rendered by its Pathologist to Medicare patients on a part-time employee or independent contractor basis.

In the In-Office Laboratory model, the Practice has its own laboratory, including equipment, technicians and reagents. The Practice's in-office laboratory prepares slides from anatomic pathology specimens taken from the Practice's patients by its physicians during ambulatory surgery procedures. Like the TC-PC model, this approach requires the Practice to have a Pathologist who is physically present in its offices to interpret the slide and prepare a report for the ordering physician. The Practice has an office, microscope and dictation equipment for the Pathologist. Unlike the TC-PC model, this approach does not involve an outside laboratory because the Practice has its own in-office laboratory to prepare the slides for its Pathologist who is either a part-time independent contractor or employee. In the In-Office model, the Practice bills the Medicare program globally for the technical and professional pathology services it renders to Medicare patients.

CMS's proposed requirement that a pathologist must be a full-time employee in order for a Practice to bill and collect from the Medicare program for professional pathology services would eliminate the TC-PC model and almost entirely destroy the In-Office Laboratory model. Almost all Practices that use the TC-PC model only have a sufficient volume of anatomic pathology specimens to engage or hire a part-time Pathologist. Virtually all Practices that use the In-Office model do not have a sufficient volume of anatomic pathology specimens to employ a full-time Pathologist. Even those

Practices that could support a full-time and employed Pathologist need to be able to arrange for vacation, personal holiday and sick time relief as well as coverage while its Pathologist is taking continuing medical education courses. For the following reasons, we believe that CMS should reconsider its proposal to require a Pathologist to be a full-time employee in order for the Practice to bill and collect from the Medicare program the entire reimbursement identified on the physician fee schedule for the professional services rendered.

2. Improved Quality of Professional Pathology Services. In both the TC-PC and In-Office models, we believe that the quality of the professional services provided to Medicare patients improves significantly. Among other reasons, virtually all of the Practices who use either of the Models do so because of general dissatisfaction with the professional pathology services provided by commercial laboratory companies. Whether it is slow turnaround time on pathology reports or difficulty in asking follow-up questions of generally unavailable pathologists who are located at remote laboratories, a Practice that has its own Pathologist provides better quality professional pathology services to its patients in a timelier manner. With a Pathologist physically present in its offices, a Practice is able to enhance the quality of patient care rendered to Medicare beneficiaries through improved pathology consultations. In addition and perhaps most importantly, the Practice's Pathologist typically specializes in the Practice's area of medicine (e.g. urology or gastroenterology) which further improves the reliability and quality of the professional interpretations and the associated face-to-face pathology consultations. In contrast, physician practices that send anatomic pathology specimens to commercial laboratories do not: (a) choose the pathologists who interpret the slides and send them reports; or (b) know the qualifications of the pathologist to whom important patient care decisions are ultimately entrusted.

3. Revenue Neutral to the Medicare Program. CMS's proposed anti-markup of the professional fee billed by a Practice for the professional services rendered by its part-time employee or independent contractor Pathologist is not needed to protect the financial integrity of the Medicare program. In the Models, the Medicare program does not spend an additional penny on professional pathology services than it otherwise would spend in the traditional model by which anatomic pathology specimens are referred to an independent laboratory and the ordering physician simply receives a pathologist's report. Regardless of its use of the TC-PC model or the In-Office Laboratory model, a Practice bills and collects from the Medicare program based on the then current Medicare physician fee schedule. Because the Practice incurs the costs associated with providing its Pathologist with an office, microscope, dictation equipment and/or benefits (benefits oftentimes depend on number of hours employed), the payment by Medicare of the practice expense component of the physician fee to the Practice is fully justified. In the event a Practice profits financially from the employment or engagement of its part-time Pathologist, it is no different than a commercial or hospital based laboratory profiting from their respective part-time pathologists. In fact, it is also no different than a physician practice profiting from its full-time Pathologist if the proposed regulation is adopted by CMS. Addressed in Section 4 below, we also believe the Models are revenue neutral to the Medicare

program because neither TC-PC or the In-Office Laboratory models lead to unnecessary tests ordered for Medicare patients.

4. No Unnecessary Testing. In both the TC-PC and In-Office Laboratory models, the Practice will benefit from providing higher quality professional pathology services to their Medicare beneficiaries. We do not believe, however, that a Practice which provides professional pathology services to its patients would lead to unnecessary testing of Medicare beneficiaries for the simple reason that the Models are based on anatomic pathology specimens taken from patients during ambulatory surgery procedures.

It is longstanding CMS policy that physicians who perform ambulatory surgery cases can own ambulatory surgery facilities. While there are very rare exceptions, physicians who perform ambulatory surgery do not perform invasive procedures for financial reasons. Similarly, the Pathologist in a Practice interprets slides prepared from specimens taken from patients who have had ambulatory surgery. Like virtually all physicians who are not likely to perform unnecessary ambulatory surgery due to the invasive nature of the procedure, we do not believe the same physicians would take extra specimens from a Medicare beneficiary for financial benefit.

To the contrary, we believe that testing of anatomic pathology specimens taken from Medicare patients will likely be reduced by the TC-PC and In-Office Laboratory models. In the Models, a Practice is likely to have a Pathologist who specializes in the Practice's area of medicine. For example, a Practice that specializes in gastroenterology would employ or engage a pathologist who specializes in gastroenterology. Unlike the commercial laboratories where a gastroenterology patient's specimen slide could be read by a pathologist who specializes in dermatology, we believe that the Pathologist who specializes in the same area of medicine as the Practice will, as a result of his or her expertise, not need to practice defensive medicine by ordering additional tests which we understand is oftentimes the case in commercial laboratory companies because slides are randomly assigned to pathologists, regardless of his or her specialty.

Finally, it is our understanding that the General Accounting Office ("GAO") studies undertaken in the early 1990s that lead to the Stark Law prohibition on referring physician ownership of laboratories did not analyze utilization of anatomic pathology services. In fact, we know of no study that would demonstrate that a referring physician who benefits financially from the provision of anatomic pathology services takes more specimens from a Medicare patient and/or orders unnecessary tests. Why is there no such study results showing over utilization of anatomic pathology services? The simply answer is that a colon or prostate biopsy is much more invasive to a patient than clinical laboratory tests like the dip stick urine, finger stick for hematocrit or even a venipuncture for blood analysis. In the absence of studies to the contrary, we do not believe CMS should be concerned about the potential for over utilization of anatomic pathology tests ordered on Medicare patients by a Practice that has engaged or employed a Pathologist on a part-time basis to provide professional pathology services to its patients. In other words, the adoption of the full-time employee requirement would be

an arbitrary, capricious and unfair action by CMS, unless such an action is supported by objective studies like the ones undertaken by the GAO in the early 1990s.

5. Medicare Already Has Sufficient Safeguards In Place. Any potential concerns that CMS has relating to a Practice hiring or engaging a part-time Pathologist to provide professional pathology services to its patients is already sufficiently addressed by the current: (a) Medicare reassignment rules; (b) Stark Law; and (c) Anti-Kickback Law. The Medicare reassignment rules permit independent contractors to assign the right to bill and collect for professional services with no prohibition on part-time status. Similarly, each of the Stark Law and the Anti-Kickback Law as well as their respective implementing regulations do not prohibit part-time employment or independent contractor relationships. Each such law and its applicable regulations, however, have independent contractor restrictions that would need to be satisfied by a Physician Practice that: (a) engaged a Pathologist or a pathology physician practice as a part-time independent contractor; or (b) hired a Pathologist as a part-time employee. From our vantage point, the foregoing regulatory restrictions are more than adequate to protect the Medicare program from financial abuse and Medicare beneficiaries from unnecessary testing.

6. Interference with the Practice of Medicine. The adoption of the full-time employee requirement by CMS would, in our view, unfairly interfere with the practice of medicine. While we do not believe that it is CMS's intention to do so, the effect of a CMS decision to adopt the full-time employee requirement would severely limit a Practice's right to organize itself as it sees fit to deliver quality care to its patients. Such a CMS decision would have implications nationwide with respect to the practice of medicine. While some might argue that the full-time employee requirement does not interfere with the practice of medicine because it only prohibits Medicare reimbursement in certain circumstances, the reality is that CMS would prohibit a Practice from having sufficient revenue to hire or engage a part-time pathologist which is the common mode of operation whether the Practice uses the TC-PC model or In-Office Laboratory model. For any Practice with a significant number of Medicare patients, the elimination by CMS of reimbursement for professional pathology services provided by a part-time pathologist employee or a part-time independent contractor would interfere with the multi-disciplinary approach that it has decided best serves its patients.

7. Summary. In the absence of compelling reasons to the contrary, CMS's proposal to require a Practice to have a full-time Pathologist as an employee in order to bill and collect the entire reimbursement identified on the physician fee schedule for professional pathology services rendered to Medicare patients should not be adopted because this requirement would effective eliminate the TC-PC model and almost completely destroy the In Office Laboratory model. Both the TC-PC and the In-Office models rely on the use of part-time employees and independent contractors. A Practice that can provide professional pathology services to its patients by hiring or engaging a Pathologist improves the timeliness and quality of medical services provided to Medicare beneficiaries. In addition, the provision of professional pathology services to its patients by a Practice would be revenue neutral to the Medicare program. In light of the revenue neutrality, CMS should not be concerned about a

Practice's potential profits because commercial laboratories and hospital based laboratories also may profit from their part-time pathologist employees and independent contractors. Moreover, Medicare patients would not be subjected to unnecessary testing due to the invasive nature of ambulatory surgery procedures that generate anatomic pathology specimens. Toward this end, neither the GAO's studies of physician owned laboratories or any other study that we are aware of has shown that a physician's financial interest relating to the provision of anatomic pathology services leads to over utilization of laboratory tests ordered.

It is also important to note that CMS already has adequate safeguards in place to protect against financial abuse of the program through the existing Medicare reassignment rules as well as the Stark Law and Anti-Kickback Law. None of the foregoing prohibits part-time employees or independent contractor relationships. In addition, a CMS decision not to permit Medicare reimbursement for part-time pathologist employees or independent contractors, in effect, interferes with the practice of medicine by effectively eliminating this specific multi-specialty approach to providing patient care to Medicare patients because virtually all Practices do not have a sufficient number of patients to support a full-time and employed Pathologist.

Finally, physician practice-based anatomic pathology services are the wave of the future. Do not throw the baby out with the bath water by making it virtually impossible for a physician practice to provide professional pathology services to it patients by adopting the full-time employee requirement as a pre-requisite for billing and collecting from the Medicare program.

Sincerely yours,

James L. Petsche

JLP/

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1957 — 50 Years — 2007

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FILE NO.: 52767.00001

August 30, 2007

Via UPS Overnight Mail
Centers for Medicare & 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: Proposed CMS Full-Time Physician Employee Requirement

Dear Sir or Madam:

This Firm represents physician practices that each provide professional anatomic pathology services to their respective Medicare patients. On behalf of these physician practices, we are writing to ask that CMS not adopt the proposed "anti-mark-up" requirement relating to a physician practice seeking Medicare reimbursement for the professional services rendered in connection with diagnostic tests. As described below, CMS's efforts, in our view, should instead be focused on eliminating existing pathology arrangements that have harmed the financial integrity of the Medicare program as well as led to unnecessary testing of Medicare patients.

The following examples are provided to illustrate some of the abuses of the Medicare program that should be addressed before adopting new regulations that limit the provision of physician based anatomic pathology services. These are:

1. Uniform Enforcement of the Purchased Diagnostic Test "No Mark-Up" Prohibition. Hospital based pathology practices oftentimes purchase technical services from their hospital based laboratories at discounted prices. The technical services relate to anatomic pathology services obtained from local physician practices. The Medicare program is billed globally by the pathology practice which reaps the hugh financial benefit from the discounted technical fee by not complying with the anti-mark-up prohibition. A similar scenario takes place when a pathology practice or laboratory purchases, at a discount, technical services from a specialized laboratory. We suggest that

CMS should enforce this no-mark-up requirement on purchased diagnostic tests by auditing pathology practices and laboratories.

2. Unnecessary Testing By Pathologists. There is widespread ordering of unnecessary tests by pathologists with no regulatory oversight by CMS. For example, pathologists determine the criteria for review of abnormal pap smears. There is, however, no published protocols for such reviews: it is left to the judgment of the individual pathologist who also bills the Medicare program. This same concept would apply to pathologists ordering special stains for which there are no recognized standards. We suggest that CMS adopt reasonable protocols and standards for the review of pap smears, among other tests, as well as special stains, which would significantly reduce unnecessary testing by pathologists and result in tremendous cost savings to the Medicare program. If fair and reasonable national standards were adopted, it should not matter whether the pathologist is employed or engaged full-time or part-time nor whether he or she was providing professional services at a commercial laboratory, hospital laboratory or in a physician practice.

Thank you, in advance, for consideration of the foregoing concerns. Effective enforcement and application of current regulations by CMS to the pathology community would obviate the need to add new regulations that would limit physician practices from providing quality pathology services to their Medicare patients.

Very truly yours,

Christopher Wisniewski

CW

CLAC: 142001.1

Mid-County Urology, Inc.
621 S. New Ballas Rd.
Suite 6011B
St. Louis, MO 63141
314-569-1750

August 29, 2007

Dear Sir or Madam:

I am an Urologist practicing in the St. Louis metropolitan area and I am deeply concerned about legislation sponsored by the CMS attacking physician joint ventures. Having practiced for over twenty-five years in the area, I can tell you from a historical perspective that most physician joint ventures were precipitated by the hospitals refusal to purchase new technology or unwillingness to allow community physicians access to such technology.

The proposals entitled-under arrangements, per click fee, percentage for arrangements, stand in the shoes, and burden of proof-are worrisome.

In under arrangements, I understand CMS would prohibit a hospital from billing Medicare for a service if the service was provided to the hospital "under arrangements" by the physician or a physician investor group. It seems more prudent for the CMS to limit the Stark provisions to those situations that are known to be abusive and for which the Stark provisions were initially intended.

In therapeutic urological procedures, the professional fee is greater then the portion of the technical fee the physician would earn from investing in a joint venture. This therefore does not constitute a sentient inducement to make referrals and thus prohibition on service furnished under arrangements should not apply to services where the investor physician performs the professional portion of the procedure.

As indicated initially many physician joint ventures were precipitated by hospital refusing to make large capital investments in technology which would replace procedures and equipment already in use in their OR theatre and cut off revenue form the services already provided. Physicians in joint ventures have been able to provide state of the art equipment and state of the art care to their patients. This has allowed physicians practicing at rural hospitals access to this equipment on a rotating basis whether a hospital has enough volume to justify the purchase of expensive technology.

To accommodate hospitals' fear of not succeeding, urology joint ventures have accepted per click fee contracts. The urology joint venture accepts the risk and so the hospitals are able to avoid their concerns that the volume will be lower than projected and not justify providing these therapeutic options to their patients.

The percentage fee arrangement is another way hospitals avoid risk by permitting the physician joint venture to shoulder some of the risk caused by variation in reimbursement to hospitals but at the same time allow the physicians to receive a few payments for service.

Stand in the shoes proposal would further impact the delivery of quality health care by not allowing an ASC with hospital ownership to contract on a per click basis or on a percentage basis. Physicians would likely withdraw from ownership in ASC where hospitals are investors. Legitimate joint ventures should not be forced to abandon all ASC with any hospital involvement.

In today's democratic society it is insulting to physicians that the CMS would want the provider to prove non-violation of laws drafted by the CMS for doctors to follow. Historically burden of proof has always been placed on the body creating the rules.

Overall urology joint ventures have provided state of the art technology to all hospitals in all areas through a shared service concept; have saved millions of dollars through the efficiency of the shared service model and non-duplication of services. The CMS on the other hand should limit the reach of Stark laws to arrangements that are known to be abusive and that Congress intended to reach.

Thank you for your consideration,

Leonard D. Gaum M.D., F.A.C.S., F.R.C.S. (C)

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August 30, 2007

Via Federal Express

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Mail Stop C4-2605
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Provisions in 2008 proposed Physician Fee Schedule

Ladies and Gentlemen:

I am a health care law attorney with over thirty years of practice experience. I am writing this letter on behalf of a client that operates several mobile lithotripters and has significant concerns that some of the recent proposals made by CMS in the 2008 proposed Physician Fee Schedule will adversely affect the delivery of health care to urological patients in this country for reasons outlined herein. In particular, I believe that some of the proposals, if adopted, would result in substantial delays in the introduction of new treatment technologies that are more cost-effective and safer than traditional treatment options.

Physicians are on the front lines of the delivery of health care in our country. In most cases they are the first to realize the potential benefits to the patient of new technologies and the advantages that those technologies would have over traditional forms of treatment. They see firsthand problems and complications that arise out of traditional forms of treatment, and are quick to appreciate, and want for their patients, the prospect of improved results and lower complications that can often come from adoption of new technologies.

Hospitals are wonderful institutions, but they are much slower than the physician-community in embracing new technology, particularly technology that will require a large outlay of capital and at the same time reduce hospital revenues from traditional surgical procedures. Often, it appears that hospitals rationalize the delay in the introduction of new technology on the premise that it is new and has not been sufficiently tested, even if it is in use in other parts of the country. However, with the proliferation of professional liability suits, physicians are

extremely risk adverse, and are in the best position to evaluate the medical benefits and risks of the new technologies. I have seen situations in which the purchase of equipment for medical procedures that are quite common place today were initially resisted by hospitals on the ground that they were "untested", even though physicians were being trained to do those procedures at our best medical schools.

For example, many years ago ophthalmologists trained in laser surgery were required to transport their patients to hospitals in different counties because a local hospital would not purchase the laser equipment to do a procedure that is quite common place today. Of course, the local hospital eventually acquired that equipment, but for quite some time ophthalmologists or its medical staff were required to perform surgeries in the traditional way, or to obtain medical staff privileges at a hospital in a different county and transport the patients there.

When new technologies first become available, they often are too expensive for a single physician to purchase. However, the equipment used in many new technologies is mobile and can be transferred on a rotating basis to different locations. Physicians quickly learned that they could form joint ventures to purchase the equipment and make it available, and often times that was the only way the new technologies could be introduced in the community at an early stage.

In the 1980's lithotripsy became commonly available, and permitted kidney stones to be treated by extracorporeal shockwave therapy in lieu of more invasive surgeries. At that time, many hospitals in the state did not purchase lithotripters. Our client, a physician owned group of urologists, raised the capital to purchase lithotripters. A Certificate of Need is required in this state for Lithotripters, and our client's attempt to do so was initially opposed by hospitals. Our client was eventually able to purchase several mobile lithotripters which it now transports to various geographic locations, many of which are non-metropolitan areas. As a result, this technology has been made available in areas where it would otherwise not have been introduced, at least for many years. This has resulted in significant cost savings and improved health care to a large population of patients.

This is why the proposed changes to the Stark regulations regarding services furnished under arrangements with hospitals is of such concern. It is demonstrable that many physician joint ventures that have brought new technologies to their communities have significantly improved patient care and access to services. In many cases, a single hospital, particularly in a rural area, does not have sufficient volume to justify purchasing new technology. However, the new technologies can be transported on a mobile basis from site to site, and in our experience, physicians are more familiar with the new technologies and are more willing to form joint ventures to make the new technologies available. The joint ventures have transported these technologies to hospitals in different communities, giving them the ability to provide treatment there and to utilize the hospitals' recovery rooms and other facilities if needed.

I understand CMS's long-standing concern about physician ownership of questionable diagnostic imaging arrangements. However, we believe that its concerns should not apply to treatment procedures as opposed to diagnostic procedures. If a patient has a diagnosed medical condition, he or she clearly should, if possible, have access to new technologies that are safer and hold the prospect for a more successful result. Unfortunately, CMS's proposal with respect to services under arrangement is so broad that it would ban contractual arrangements for therapeutic services that would not even be Stark designated health services except for the fact that they are performed in a hospital setting. The proposed regulations would not only affect lithotripsy services that are provided under arrangements with hospitals, but a number of other laser procedures for prostate disease and some treatment modalities that are now available for certain types of cancer.

It is ironic that in most economic settings, entrepreneurism and competition is considered healthy and vital to the introduction of goods and services that enhance our lives. The same is true in health care. We believe the CMS should not take steps to prohibit entrepreneurial joint ventures that demonstrably have assisted in the delivery of quite beneficial new technologies to our patients.

Our client is also concerned about the CMS's concern over per click arrangements for designated health services when physicians have ownership in the service delivered. As noted above, in many cases, new technologies would not be brought to market nearly as quickly without physician joint ventures delivering them on a mobile basis. Many hospitals do not have sufficient volume to justify the expense of new technologies. Additionally, hospitals that contract with physician joint ventures for new technologies often prefer not to take financial risks. Accordingly, many hospitals do not wish to sign flat fee contracts, and prefer a per procedure price so they have downside protection if there is insufficient volume. In our client's experience, a per procedure, or "per click" fee arrangement is beneficial to bring new and improved technologies to hospitals that are often unwilling to purchase the equipment themselves.

We understand that the legislative history of Stark indicates that per click procedures should be permitted. Because of that, and for the economic reasons stated above, we believe the CMS should not prohibit per click fees. If it does, at a minimum, we believe that per click fees should not be restricted with respect to therapeutic treatments that would not even be considered designated health service, except for the fact that they are being provided "under arrangements" with a hospital and billed by the hospital as a hospital in-patient or out-patient service.

In summary, we believe that physician joint ventures that contract with hospitals have facilitated and hastened the delivery of new technologies to patients, have broadened the access of new procedures to significant segments of our population, and, in the process, have saved CMS significant money. We believe that it would be a mistake to discourage physician joint

ventures for the delivery of treatment modalities that would not even be considered designated health services except for the fact that they are provided in a hospital setting.

Thank you for your attention to this.

Very truly yours,
NELSON MULLINS RILEY & SCARBOROUGH LLP

Richard B. Howington

RBH:rbe

~ Doc# 31988.1 ~

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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

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 the 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 urologist, who understand the technology and its value to our patients, including many Medicare and Medicaid recipients. In our partnership arrangement, these services would not be available through providers not affiliated with the physicians. While this is partially true, no other provider will meet our needs.

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 the " under arrangement"scenario, these patients would be subjected to more invasive treatment, necessitating longer hospital stays and more compication. 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 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 business for good reasons; they make good sense and benefit all involved. Prohibiting such arrangements would make new technology and equipment beyond the reach of 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. I believe that a person should be innocent until proven guilty. In any court cases in which I been an expert, 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 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.

Thank you,

Jack Paulk, M.D.

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CSL Behring

Via Federal Express
August 30, 2007

The Honorable Herb Kuhn, Acting Deputy Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Avenue
Baltimore, MD 21244-1850

ATTN: (CMS-1385-P) Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule and Other Part B Payment Policies for CY 2008

Dear Deputy Administrator Kuhn:

CSL Behring is a leading researcher and manufacturer of life-saving biotherapeutics including intravenous immune globulin (IVIG), which is used in treating conditions such as immune deficiencies; blood clotting factors to treat bleeding disorders, including hemophilia and von Willebrand disease; and alpha$_1$-proteinase inhibitor, used to treat alpha$_1$-antitrypsin deficiency, which is commonly referred to as genetic emphysema. These therapies are created by pooling and manufacturing donated human blood plasma into lifesaving therapies or through the development of recombinant DNA technology.

Thank you for allowing CSL Behring the opportunity to comment on the proposed rule regarding the 2008 changes to Medicare Part B and the Physician Fee Schedule. As you know CSL Behring has been concerned about the adverse impact Medicare reimbursement for IVIG has had on patient access. In the proposed rule, CMS takes two important and necessary steps to improve patient access: the creation of individual Healthcare Common Procedure Codes (HCPCS) for each liquid brand of IVIG; and maintaining the existing temporary code and payment rate for IVIG pre-administration (G0332). We commend CMS for taking these actions because they are positive and necessary steps in assuring patient access. To fully address patient access problems, CSL Behring continues to believe that in addition to the two steps CMS is proposing, an additional add-on payment is necessary, as was done with blood clotting factor.

Lastly, CSL Behring supports the agency's proposal to increase the blood clotting furnishing fee according to the Consumer Price Index for CY 2008. We further support the agency's proposal that, beginning in CY 2009, CMS will announce the blood clotting furnishing fee update using the applicable program instructions and posting on the CMS Web site.

Coding - Payment for IVIG Add-On Code

CSL Behring strongly supports the proposed rule by CMS maintaining the temporary pre-administration code (G0332) and payment rate ($71 per day) associated with IVIG. This continuation at the existing rate will allow physicians to bill for pre-administration of IVIG while assisting with the shortfalls associated with the reimbursement for administration services surrounding IVIG. CSL Behring commends CMS for recognizing the importance of patient access in this situation.

The maintenance of this furnishing fee is especially important for CY 2008 as the conversion factor for the Medicare Physician Fee Schedule is slated for a mandated 9.9% reduction unless Congress intervenes. The ability for physicians to be properly reimbursed for costs associated with administering IVIG is vital, so it is greatly appreciated that CMS will maintain the temporary pre-administration code for CY 2008.

CSL Behring also supports the measures that CMS has implemented surrounding the creation of individual HCPCS codes for each brand of liquid IVIG. This measure will expand access to IVIG by removing artificial barriers that accompany reimbursement under a single bundled code. Under a bundled methodology, those brands that were above the volume weighted average sales price were more difficult for a provider to purchase, without doing so at a financial loss. Automatically, certain brands of IVIG were less accessible as a result. The creation of individual HCPCS codes for the liquid IVIG brands will ensure that each brand is equally accessible in terms of product reimbursement. This is of vital importance since each brand is unique and not interchangeable in treating the conditions where IVIG use is medically indicated. CSL Behring compliments CMS for recognizing the need for individual HCPCS codes for IVIG and believes this is a substantial step in the right direction.

While CMS has taken some significant steps to address IVIG reimbursement, CSL Behring would still like to put forward the idea of an additional payment for the product, as is currently occurring for blood clotting factors. Three major reports were issued in 2007[1] regarding IVIG and each one highlights IVIG reimbursement as a significant and ongoing problem. One

[1] Department of Health and Human Services Office of the Inspector General – Intravenous Immune Globulin: Medicare Payment and Availability – April 2007, OEI 03-05-00404;
Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation – Analysis of Supply, Distribution, Demand and Access Issues Associated with Immune Globulin Intravenous – February 2007;
Philipson, Tomas and Anupam B. Jena, The Impact of Medicare Modernization Act Reimbursement Changes on the Utilization of Intravenous Immune Globulin, The University of Chicago Irving B. Harris Graduate School of Public Policy Studies

report, the Office of Inspector General's study[2], found that for the third quarter of 2006, only 59% of IVIG sales to physicians by the three largest distributors occurred at prices below the Medicare payment amounts. It might be assumed this percentage would further decrease for the market as a whole as smaller distributors are taken into account. That over 40% of providers reportedly cannot purchase IVIG without doing so at a loss is alarming in terms of patient access. As the reimbursement of the product itself remains the centerpiece in the ability to provide IVIG to patients, CSL Behring believes that an additional payment to be determined by the Secretary is warranted. Further, the data illustrating the shortfall in product reimbursement as outlined in the recent reports is consistent with previous data submitted to CMS over the past few years, most notably from The Lewin Group[3].

CMS has the legal authority[4] to create an additional payment and also a precedent, thus we ask the agency to take this last step to remedy the ongoing IVIG patient access dilemma once and for all.

ASP Issues: Blood Clotting Furnishing Fees

CMS has proposed, consistent with the Social Security Act[5] to increase the clotting factor furnishing fee by the percentage increase in the Consumer Price Index (CPI) for medical care for the 12-month period ending in June 2007[6]. CSL Behring supports this proposal and requests that CMS publish the updated furnishing fee in the final rule once the CPI data becomes available.

CSL Behring also agrees with the proposal to remove the annual blood clotting factor additional payment update from the rulemaking process and instead issue future updates through program instructions. Because the annual June CPI information is not available at the

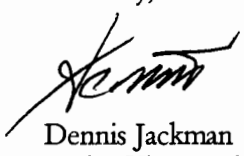
[2] Department of Health and Human Services Office of the Inspector General – Intravenous Immune Globulin: Medicare Payment and Availability – April 2007, OEI 03-05-00404, p.9
[3] The Lewin Group - Accessing the Cost of IVIG Infusion in Physician Offices and Hospital Pharmacy Departments, December 27, 2005
[4] Legal opinion from Hogan and Hartson previously provided to CMS
[5] SSA § 1842(o)(5)(C).
[6] 72 Fed. Reg. at 38,152

time the proposed physician fee schedule is published, CSL Behring would support the CMS proposal. Should methodological changes be made in the future, however, we would ask that CMS go through the formal rulemaking process.

Thank you for the opportunity to comment on this proposed rule. We recognize the great steps that CMS has taken to date regarding IVIG patient access and believe that one final step will rectify the situation for good.

Should there be any questions or if we may be of assistance, please feel free to contact either myself or Patrick Collins (610-878-4311). Your consideration of these comments in the formulation of the final rule is greatly appreciated.

Sincerely,



Dennis Jackman
Senior Vice President, Public Affairs

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 CMC-1385-P
Physician Self-Referral Provisions
Section II.M3: In Office Ancillary Services Exception

Dr. Sir or Madam,

I am a physical therapist, working for a rehabilitation company that provides physical therapy within a physician's office. The model that I work within is one that provides high quality patient-centered therapy in the most time efficient and cost effective manner. Overall, patients are seen more promptly resulting in a quicker recovery period. Thus, managing the overall cost containment if treatment with fewer visits.

Collaborating with the doctors under the same roof allows for the most effective communication regarding the patient's status and the progression of their treatment. As often is the case, the physicians will stop into the therapy office to discuss a patient's current plan of care and/or make any revisions necessary due to any changes in their status. In addition, our proximity enables me to speak directly with the doctor regarding any testing that the patient may have had in the past or recently such as radiographic imaging, MRI, EMG, and etc. and how this may effect their treatment. This additional information allows me to provide the most up to date comprehensive treatment possible for each patient.

The patient satisfaction surveys at my clinic I believe speaks volumes in it's self for having physical therapy inside a doctors office. Most often is the case, the patient's feel much more confident and comforted in the whole rehabilitative process. The patient has the comfort of knowing that their doctor is just down the hall should there be any questions or complications. Secondly, they have a greater confidence in the system because they are able to see our communication with each other knowing that each provider is on the same page with their treatment protocol.

Of all the places that I have worked, I would have to say that the in-house physical therapy model, of which I work in, is the best for both patient care and cost containment. Patients are seen earlier, resulting in faster recovery rates and thus minimizing costs with that of continued care. This benefits the patients, insurances, and all parties involved.

Sincerely,
Concerned
Physical Therapist

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ANNE ARUNDEL UROLOGY, P.A.
Anne Arundel Urological Surgery Center, L.L.C.

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August 30, 2007

VIA FEDERAL EXPRESS

Herb Kuhn
Acting Deputy Administrator
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: 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

Dear Acting Deputy Administrator Kuhn:

I am a urologist who practices in the State of Maryland as a member of Anne Arundel Urology, P.A. Anne Arundel Urology, which is the largest urology practice in Anne Arundel County, is comprised of 9 physicians with offices in Annapolis, Glen Burnie, and Bowie. Physicians in our practice specialize in both general adult and pediatric urologic care. We also provide specialized care in advanced laparoscopy, robotics, incontinence and infertility. The physicians of Anne Arundel Urology are dedicated to furnishing the highest quality of medical and surgical urologic care in the State of Maryland, with a full range of services provided in a convenient, comfortable, supportive and patient-friendly setting.

As a Maryland urologist, I thank you for the opportunity to comment on the Proposed Rule, published by the Centers for Medicare & Medicaid Services ("CMS") on July 12, 2007. See 72 Fed. Reg. 38122 (July 12, 2007). Although I commend CMS on its continuing efforts to develop clear and comprehensive regulations that implement the Stark Law, I write to express my concerns about the changes contained in the Proposed Rule and the nature of the Preamble discussion with respect to the in-office ancillary

services exception (the "Exception"). 42 U.S.C. § 1395nn(b)(2)(A). Let me begin by saying that I do not think that changes to the Exception are necessary to protect against - program or patient abuse. In fact, any narrowing of the Exception, or the implementation of the changes to the reassignment and anti-markup provisions of the purchased diagnostic tests rule that are contained in the Proposed Rule, 72 Fed. Reg. at 38225, 38229, would have a deleterious effect on the health care community generally and on the quality and availability of patient care services offered by Anne Arundel Urology in particular.

The ability of physicians to affiliate with pathologists allows practices such as ours to identify and work with highly qualified and trained specialists with whom we are familiar and whose work product we trust. This, to us, is critical to our ability to furnish the highest quality care to our Maryland patients. Because we at Anne Arundel Urology know and personally have selected a pathologist with whom we work based on his outstanding credentials (Board Certified and has completed a fellowship at one of Maryland's leading medical centers), our present ability to practice with pathologists of our choosing provides for a considerably and consistently higher quality of care. He has, in essence, developed a subspecialty in prostate-related diagnoses, have a special interest in prostate pathology and have become experts at reading prostate slides. They are better able, for example, to identify true prostrate cancer from benign tissue and prostate cancer mimickers, thereby reducing "false positives" and saving our patients unnecessary anxiety and cancer treatments. As such, we know and trust the consistency and quality of his reads, which is not something we could do if we are forced by changes in the Exception or the purchased diagnostic tests rule no longer to provide pathology services in the office setting and to send our prostate slides to large hospital-based or commercial labs. Under such circumstances, we would have no idea who is reading the slide; what that person's credentials are; the nature of the person's expertise or training; or whether that person has read one prostate slide or 1,000 prostate slides.

Because we work together with our pathologist on a daily basis, the means by which we communicate and discuss test results and prepare written reports have become standardized, thereby increasing the efficiency of our practice and our ability rapidly to deliver diagnoses to our anxiously waiting patients. In fact, whereas the national average for turning around test results is five to seven days, our pathologist returns test results in three to four days. Moreover, better and more proximate communication with our pathologists, particularly in difficult cases, results in improved clinical diagnoses and outcomes for our patients.

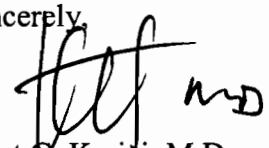
With respect to diagnostic imaging, any narrowing of the Exception might impose limits on patient access to the very types of diagnostic imaging services that have become the standard of care in Maryland and throughout the United States by restricting or prohibiting non-radiologists from providing CT services to patients in the office setting. At the present time, Anne Arundel Urology does not provide radiologic services in our offices. We realize that the rapid advance in CT technology, followed by a reduction in acquisition and installation costs, makes it possible for patients to avoid the inconvenience of having to see multiple doctors to have CT services performed outside of their own doctor's offices. This technology, once considered expensive, cumbersome and difficult to use, has advanced into available, affordable and indeed indispensable patient diagnostic tools. We would like to be able to provide these services to our patients in the future. There is, therefore, no clinical, quality of care reason to restrict the definition of in-office ancillary services so as to eliminate our ability to furnish state-of-the-art diagnostic imaging services in a setting that is most convenient for our patients and is most efficient with respect to our ability to make a diagnosis.

The changes suggested by the Proposed Rule, and the nature of the comments solicited with respect to the Exception, go far beyond what is necessary to protect the Medicare program from fraud and abuse and to ensure patient care. The Exception as currently interpreted and applied recognizes that certain employment and contractual relationships among physicians are beneficial to patients and strike the appropriate public policy balance between the prophylactic prohibition on self-referrals and the recognition that certain arrangements not only are appropriate, but also are necessary to enhance the efficient provision of quality health care.

Consequently, if the Exception is narrowed in any meaningful way, particularly in a manner that limits the types of ancillary services that can be provided pursuant to the Exception or that restricts the ability of physicians or groups to furnish services in the "same building," 42 U.S.C. § 1395nn(b)(2)(A)(ii)(I), the manner in which the physicians of Anne Arundel Urology practice medicine will be severely impacted, and the quality and convenience of care that we provide to our patients will be significantly compromised. The practical effect would be to restrict access for our patients to routine medical procedures that have become the standard of care throughout the country. Implementation of the proposed changes to the purchased diagnostic test rules would have a similar effect by limiting our ability to provide such services with anything but full-time employees. Both potential changes would create an unjustified monopoly for particular physician specialties to the detriment of patient access and care.

Thank you again for the opportunity to submit these comments on the Proposed Rule.

Sincerely,



Kent G. Krejci, M.D.

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ANNE ARUNDEL UROLOGY, P.A.
Anne Arundel Urological Surgery Center, L.L.C.

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August 30, 2007

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Acting Deputy Administrator
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: 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

Dear Acting Deputy Administrator Kuhn:

I am a urologist who practices in the State of Maryland as a member of Anne Arundel Urology, P.A. Anne Arundel Urology, which is the largest urology practice in Anne Arundel County, is comprised of 9 physicians with offices in Annapolis, Glen Burnie, and Bowie. Physicians in our practice specialize in both general adult and pediatric urologic care. We also provide specialized care in advanced laparoscopy, robotics, incontinence and infertility. The physicians of Anne Arundel Urology are dedicated to furnishing the highest quality of medical and surgical urologic care in the State of Maryland, with a full range of services provided in a convenient, comfortable, supportive and patient-friendly setting.

As a Maryland urologist, I thank you for the opportunity to comment on the Proposed Rule, published by the Centers for Medicare & Medicaid Services ("CMS") on July 12, 2007. See 72 Fed. Reg. 38122 (July 12, 2007). Although I commend CMS on its continuing efforts to develop clear and comprehensive regulations that implement the Stark Law, I write to express my concerns about the changes contained in the Proposed Rule and the nature of the Preamble discussion with respect to the in-office ancillary

services exception (the "Exception"). 42 U.S.C. § 1395nn(b)(2)(A). Let me begin by saying that I do not think that changes to the Exception are necessary to protect against - program or patient abuse. In fact, any narrowing of the Exception, or the implementation of the changes to the reassignment and anti-markup provisions of the purchased diagnostic tests rule that are contained in the Proposed Rule, 72 Fed. Reg. at 38225, 38229, would have a deleterious effect on the health care community generally and on the quality and availability of patient care services offered by Anne Arundel Urology in particular.

The ability of physicians to affiliate with pathologists allows practices such as ours to identify and work with highly qualified and trained specialists with whom we are familiar and whose work product we trust. This, to us, is critical to our ability to furnish the highest quality care to our Maryland patients. Because we at Anne Arundel Urology know and personally have selected a pathologist with whom we work based on his outstanding credentials (Board Certified and has completed a fellowship at one of Maryland's leading medical centers), our present ability to practice with pathologists of our choosing provides for a considerably and consistently higher quality of care. He has, in essence, developed a subspecialty in prostate-related diagnoses, have a special interest in prostate pathology and have become experts at reading prostate slides. They are better able, for example, to identify true prostrate cancer from benign tissue and prostate cancer mimickers, thereby reducing "false positives" and saving our patients unnecessary anxiety and cancer treatments. As such, we know and trust the consistency and quality of his reads, which is not something we could do if we are forced by changes in the Exception or the purchased diagnostic tests rule no longer to provide pathology services in the office setting and to send our prostate slides to large hospital-based or commercial labs. Under such circumstances, we would have no idea who is reading the slide; what that person's credentials are; the nature of the person's expertise or training; or whether that person has read one prostate slide or 1,000 prostate slides.

Because we work together with our pathologist on a daily basis, the means by which we communicate and discuss test results and prepare written reports have become standardized, thereby increasing the efficiency of our practice and our ability rapidly to deliver diagnoses to our anxiously waiting patients. In fact, whereas the national average for turning around test results is five to seven days, our pathologist returns test results in three to four days. Moreover, better and more proximate communication with our pathologists, particularly in difficult cases, results in improved clinical diagnoses and outcomes for our patients.

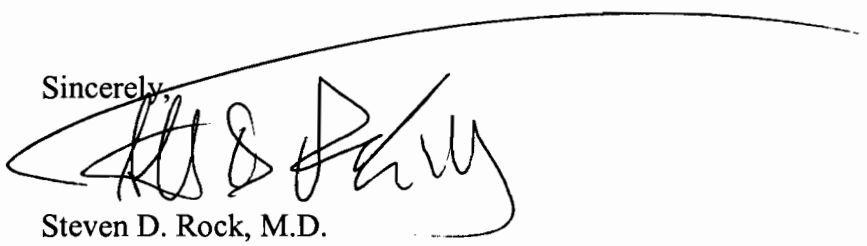
With respect to diagnostic imaging, any narrowing of the Exception might impose limits on patient access to the very types of diagnostic imaging services that have become the standard of care in Maryland and throughout the United States by restricting or prohibiting non-radiologists from providing CT services to patients in the office setting. At the present time, Anne Arundel Urology does not provide radiologic services in our offices. We realize that the rapid advance in CT technology, followed by a reduction in acquisition and installation costs, makes it possible for patients to avoid the inconvenience of having to see multiple doctors to have CT services performed outside of their own doctor's offices. This technology, once considered expensive, cumbersome and difficult to use, has advanced into available, affordable and indeed indispensable patient diagnostic tools. We would like to be able to provide these services to our patients in the future. There is, therefore, no clinical, quality of care reason to restrict the definition of in-office ancillary services so as to eliminate our ability to furnish state-of-the-art diagnostic imaging services in a setting that is most convenient for our patients and is most efficient with respect to our ability to make a diagnosis.

The changes suggested by the Proposed Rule, and the nature of the comments solicited with respect to the Exception, go far beyond what is necessary to protect the Medicare program from fraud and abuse and to ensure patient care. The Exception as currently interpreted and applied recognizes that certain employment and contractual relationships among physicians are beneficial to patients and strike the appropriate public policy balance between the prophylactic prohibition on self-referrals and the recognition that certain arrangements not only are appropriate, but also are necessary to enhance the efficient provision of quality health care.

Consequently, if the Exception is narrowed in any meaningful way, particularly in a manner that limits the types of ancillary services that can be provided pursuant to the Exception or that restricts the ability of physicians or groups to furnish services in the "same building," 42 U.S.C. § 1395nn(b)(2)(A)(ii)(I), the manner in which the physicians of Anne Arundel Urology practice medicine will be severely impacted, and the quality and convenience of care that we provide to our patients will be significantly compromised. The practical effect would be to restrict access for our patients to routine medical procedures that have become the standard of care throughout the country. Implementation of the proposed changes to the purchased diagnostic test rules would have a similar effect by limiting our ability to provide such services with anything but full-time employees. Both potential changes would create an unjustified monopoly for particular physician specialties to the detriment of patient access and care.

Thank you again for the opportunity to submit these comments on the Proposed Rule.

Sincerely,



Steven D. Rock, M.D.

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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 28, 2007

VIA FEDERAL EXPRESS OVERNIGHT

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 PHYSICIANS FEE SCHEDULE AND PROPOSED REGULATIONS

Dear Sir or Madam:

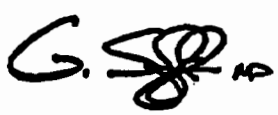
There are certain proposals in the recently released 2008 Proposed Physician Fee Schedule, which are concerning to me and my patients. As a practicing urologist in Fredericksburg, Virginia, I am concerned that these changes will cause unjustifiable harm to Medicare patient and providers. I understand the support efforts by CMS to prevent abusive practices, but I am concerned that current proposals will ultimately harm patient care and are not in the patients' best interests.

I am concerned that various anti-physician ownership proposals will have an overall negative effect on the healthcare system and delivery of patient care. Specifically, certain proposed amendments to stock violation clauses will place significant burden upon hospitals to provide services currently rendered through physician-owned ventures using hospital funds or supplies. The hospitals are currently hard pressed to provide patients with updated and current advances in medical technology as they are generally expensive and in certain cases specialized with limited applications to some services. As a result, hospitals are reluctant and hard pressed to justify the purchase of expensive equipment such as lithotriptors for general use and rely on agreements with outside agencies to provide services to Medicare patients using these expensive pieces of equipment frequently, which are located out on mobile units traveling between hospitals. These units tuck down on the cost incurred by hospitals and the system by sharing resources over large geographic areas, thus, improving access and patient care. The proposed changes to the stock regulations would prohibit these legitimate arrangements and limit access to Medicare patients who are currently benefiting from these important services.

It is important to note also that these services in question are not diagnostic, but rather therapeutic options, which are shown to have low risk of abuse and have clear established guidelines of usage and benefit to patients. Other services such as laser partnerships or use of operating room equipment in similar mobile or multispecialty group arrangements would also be affected by the proposed stock regulations and, again, these treatments would not be available to patients unless hospitals purchased the equipment directly. These concerning oversights to the proposed stock regulation changes will, undoubtedly, adversely affect the patient care immediately effectively limiting access to these life saving vital treatments to Medicare patients.

In conclusion, I would ask CMS to separate beneficial and therapeutic joint ventures from the abusive and questionable diagnostic ventures, which are currently under scrutiny for stock violations. It should be clear that if these proposed revisions were to pass that they would immediately and adversely affect the care, which patients receive, and jeopardize the health of millions of Americans and at the same time cause increased financial burden upon small communities who are already hard pressed to provide adequate services under current arrangements, essentially negating the beneficial effects of these valuable and life saving therapeutic treatments.

Sincerely,



Gregory R. Szlyk, M.D., F.A.C.S.
Urology Associates of Fredericksburg
1101 Sam Perry Boulevard, Suite 219
Fredericksburg, VA 22401

GRS:ak

D: 08/28/07
T: 08/29/07
J: 0829-039

August 29, 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 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 inpatient rehab, out-patient rehab within a hospital, and private practice out-patient rehab. Of all these, my current setting within a multi-physicians' practice has been the most rewarding in terms of quality of patient care, cost containment, and efficiency in the utilization of therapy services.

Located within the same physical space as the physicians enables me to have frequent contact with them concerning individualized treatment plans, 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 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, 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 co-lateral scrutiny between partners, to execute best practices, benefits the patients and the health care system at large.

Sincerely,

Joy Wilkerson OTR/L

SALINA UROLOGY ASSOCIATES, P.A.
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RANDY D. HASSLER, M.D.
WILLIAM D. MAUCH, M.D., F.A.C.S.
BRIAN G. SMITH, M.D.
D. ALLEN SHRADER, M.D., F.A.C.S.

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August 29, 2007

Center for Medicare/Medicaid Services
Department of Health & Human Services
Attn: CMS-1385-P Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

Dear Sir or Madam:

I am a practicing full-time urologist in Salina, Kansas, now for almost 30 years. During that time frame, I have had the opportunity to observe the ebb and flow of health care reimbursement and CMS's attempt to address issues of over-utilization, fraud and abuse and cost containment issues over the years. I am writing at this time to express my concerns regarding certain proposals in the recently released 2008 Proposed Physician Fee Schedule. Although I understand and support the efforts by CMS to prevent abusive practices, I believe the current proposals will extend beyond this worthy goal to hamper valuable and legitimate joint venture arrangements.

As a urologist, it has been very obvious the positive impact joint venture partnerships have brought to our local community. Our ambulatory surgery center is jointly owned by physicians and the hospital, and provides cutting edge technology, the latest and greatest equipment, and more efficient cost effective treatment than can be provided by the hospital. The alternative to this joint venture, would have been two ambulatory surgery hospitals, one owned by the physicians and the other by the hospital. This arrangement was totally rejected by the local community as over-expensive, redundancy in care and yet your proposals attacked the very mechanism that has created a more cost effective higher quality medical care solution. Without my involvement with providing my patients with lithotripsy and other cutting edge technologies for urological disease, these joint ventures would not have succeeded in providing these patient services. By accepting the risk of providing these costly services, which the hospitals either refuse or are financially unable to provide, urology joint ventures have greatly expanded patient access through very worthwhile and effective treatments in our area. Yet it appears your proposals for the 2008 Physician Professional Fee Schedule, attack the very notion of joint ventures that by all accounts have saved Medicare millions of dollars and increased beneficiary access to effective treatments in our own community.

In rural Kansas, unlike legislators in the beltway, medical accessibility for the latest medical technologies are not frequently available. The hospitals are strapped for cash for these expensive technologies and cannot justify the cost based on our small volumes locally. Therefore the ability through joint venturing to be able to contract with hospitals, allows everyone to spread the

cost by sharing this expensive equipment among many hospitals and providers. It is my understanding that the American Lithotripsy Society vs. Thompson case established that lithotripsy is not a designated health service (DHS) under Stark law. Therefore, our joint venture partnerships should not be deemed as providing a DHS claim.

I understand CMS's concern that physicians under arrangement contracting, results in over utilization and higher costs to the Medicare program. I must point out, however, that lithotripsy along with BPH, laser services and microwave services and many other urological procedures are therapeutic and not diagnostic. It is very easy to validate a kidney stone or an enlarged prostate, so the risks of over utilization or fraud and abuse, are non-issues. It has also been my understanding that historically Stark legislation indicates Congress clearly intended under arrangement contracting, to only require compensation exception and not an ownership exception.

I will point out one more clear example in our local community of the importance of joint venture arrangements for providing up-to-date medical technology services. The latest and greatest treatment for prostate cancer is a radical prostatectomy with the da Vinci robot. Unfortunately, robotic surgery is terribly expensive at this point and our local hospital has refused to place this expensive item in their budget for the foreseeable future. Because of this, I and my partners are in the process of trying to put together a joint venture purchase with other urologists in Kansas and contract with hospitals in North Central and East Kansas to provide this newest technology. If your proposals, as I understand them, become law, this type of arrangement will be prohibited and will materially diminish our patients' access to quality care.

In summary, I believe the ability to joint venture and provide contract services with hospitals in rural Kansas is a very necessary service to provide Medicare beneficiaries with the best possible treatments in technology. I understand CMS is in a difficult position of trying to hold down costs and provide the highest quality medical care for their beneficiaries. I support your efforts in trying to reach an equitable solution and I hope that you can do what is right for everyone involved including providers, beneficiaries and CMS.

I want to thank you for your attention and wish you good luck in your deliberations.

Sincerely,

Randy D. Hassler, M.D.

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BRIAN G. SMITH, M.D.
D. ALLEN SHRADER, M.D., F.A.C.S.

August 29, 2007

TO BE SENT OVERNIGHT MAIL

Center for Medicare/Medicaid Services
Department of Health & Human Services
Attn: CMS-1385-P Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

Dear Ladies and Gentleman:

I am a urologist in Kansas. I recently became aware of the 2008 proposed physician fee schedule changes to Stark Physical Self-Referral Rules.

I believe that physician ownership of partnerships that provide technology for use in health care, has improved access for Medicare beneficiaries. Hospitals are unwilling, or unable, to invest money in new treatments when they cannot determine the volume or the profitability. I previously practiced in Idaho when these technologies were not available and everything had to be referred a substantial distance away, causing increased difficulties and inconvenience. In Salina the availability of mobile lithotripsy, have afforded access or substantial improvement to treatments that were not available previously. I believe this also actually saves CMS money by allowing out-patient therapies and less invasive costly treatments than would be required if they were not available. There are well established criteria for these therapeutic modalities and so overuse or inappropriate use could easily be determined. Therefore I do not believe that these treatments are likely to be used in an abusive manner.

I do not believe that the proposed rules relating to under arrangement services and per procedure fee arrangements would be beneficial to Medicare beneficiaries, nor do I believe they are in line with CMS's own best interest or with regard to controlling the cost of health care.

Thank you for your attention to this matter.

D. Allen Shrader, M.D., F.A.C.S.

MaCMS ecr
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August 29, 2007

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Center for Medicare/Medicaid Services
Department of Health & Human Services
Attn: CMS-1385-P Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

Dear Ladies and Gentleman:

I am a urologist in Kansas. I recently became aware of the 2008 proposed physician fee schedule changes to Stark Physical Self-Referral Rules.

I believe that physician ownership of partnerships that provide technology for use in health care, has improved access for Medicare beneficiaries to up-to-date medical treatments. I believe this typically occurs because hospitals are unwilling, or unable, to invest money in new treatments when they cannot determine the volume of treatments they will perform or the profitability of those treatments. Certainly, in our town, the availability of mobile lithotripsy, cryotherapy and BPH units have afforded access or substantial improvement to treatments that were not available previously or were available previously, but only with out-dated equipment and procedures. I believe this also actually saves CMS money by allowing out-patient therapies and less risky, less costly therapies than would be required if these treatments were not available. Typically these treatments are therapeutic and not diagnostic. It can be relatively objectively determined whether these treatments are necessary or not. For example, it is quite clear that if a person does not have a urinary stone that has been demonstrated, lithotripsy would not be appropriate. Therefore I do not believe that these treatments are likely to be used in an abusive manner.

In short, I do not believe that the proposed rules relating to under arrangement services and per procedure fee arrangements either are consistent with Congress's intent nor do they serve to provide Medicare beneficiaries with the best possible treatments, nor do I believe they are in line with CMS's own best interest with regard to controlling the cost of health care and to providing treatment for Medicare beneficiaries.

Thank you for your attention to this matter.

William D. Mauch, M.D., F.A.C.S.

ATLANTIC UROLOGY CLINICS, LLC

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Grand Strand Urology
Kenneth Krzyzaniak, MD
William Bogache, MD
Neal Shore, MD
Richard Young, MD
Brian Roberts, MD
Attila Barabas, MD

Adult & Pediatric Urology Center of the Carolinas
Glenn Gangi, MD
Andrew Grudzinski, MD

Coastal Urology Centers
Marshall Sasser, MD
Timothy Quillen, MD
Keith Gawith, MD
Joseph Wood, MD
James Fogarty, DO
Colleen Farley, APRN

Waccamaw Urology Associates
Thomas Cerasaro, MD
Walter Frank, MD

Atlantic Urology Clinics Pathology
Brian Schnell, MD

August 30, 2007

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

Dear Mr. Kuhn:

I am an urologist in Myrtle Beach, SC. I am one of 15 urologists that practice in Atlantic Urology Clinics. This is a rapidly growing area, with a large retirement population. Since I started practice here in 1993 we have seen tremendous change in the practice of medicine. The hospital medical staff and particularly the urologists I work with continuously improve the quality of care delivered to our patients. We take great pride in providing up to date and cutting-edge training, technology, and systems of care.

Unfortunately, Medicare has expressed no interest in helping us improve the quality of care we provide to our patients. In fact, it usually feels we are battling Medicare. It is as if Medicare was trying to thwart our every step. It certainly is not a cooperative effort.

My concern now is one with which you are no doubt familiar. On July 12, 2007 Medicare proposed changes to the Stark self –referral rule and the reassignment and purchased diagnostic test rules. No mention is made as to why these rule changes have been proposed. However, there are many reasons why the proposed changes should be withdrawn.

My practice has joined with several other urology practices around the country to provide top-notch, specialized, high volume genito-urinary pathologic services to thousands of urology patients. I cannot describe the tremendous effort our practice and many others put forth to get Uropath, LLC running. It has been hugely rewarding to see it function as we knew it could. Most importantly, our pathologists now see the most prostate biopsies of just about any pathologists in the world. They are leaders in the field of genitor-urinary pathology. And every one of our patients now gets their pathology reviewed by a true world-class expert.

We did it without charging one cent more to any patient (or to Medicare).

ATLANTIC UROLOGY CLINICS, LLC

Grand Strand Urology
Kenneth Krzyzaniak, MD
William Bogache, MD
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Brian Schnell, MD

The proposed changes to the reassignment and purchased test rule appear to be designed to purposely dismantle the high quality pathology services company we built. That would be a huge loss to every patient that needs a prostate biopsy, a huge loss to every patient we manage with bladder cancer, and a dagger in the heart of every physician that has struggled to deliver top quality care in the face of constant annual budget cuts for the past 20 years.

We are currently trying to build a multi-specialty cancer treatment center – a single facility where a patient can see their medical oncologist, radiation oncologist, and surgical oncologist – a place where all the specialists involved in a patient's complex cancer care can meet and work together to ensure top quality care for every patient with cancer. We can do it by joint-venturing several different groups and one or two area hospitals. Unfortunately, the proposed "under arrangement" rule would prohibit our economic model. Already, after seeing the proposed rule one of our local hospitals has withdrawn from our state Certificate-of-Need application for a multi-specialty cancer treatment center. If the rule passes, it may be years if not decades before a true cancer center is built in Myrtle Beach. Virtually all cancers should be treated at such a center. The real losers are not the hospitals or physicians but the taxpayers and patients. And it is not the hospitals and physicians who are denying them the care they need. It's CMS and these mindless beaurocratic rules.

Did I mention the cost to Medicare to treat patients at our planned multi-specialty cancer center? Not one cent more than Medicare is paying now.

In brief, it appears that the proposed changes would seriously impair the quality of care I can deliver to my patients. CMS has no explanation as to how these changes might increase quality of care or even decrease cost of care.

We would be happy to engage in a dialogue with CMS over any concerns regarding the quality or cost of care we provide. Perhaps a cooperative effort could lead to better care for the cost. The current proposed changes certainly appear without merit. And for the changes to be made without a stated reason for the change is baffling.

I would urge CMS to withdraw the proposed changes and to work with physicians to improve quality of care.

Sincerely,

Richard W. Young, MD, FACS

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ATLANTIC UROLOGY CLINICS, LLC

Grand Strand Urology
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Brian Schnell, MD

August 28, 2007

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

Dear Mr. Kuhn:

I am a practicing urologist in a group practice in Myrtle Beach, South Carolina, and 60% of my patients are insured by Medicare. I see a large number of patients with cancer of the kidney, bladder, and prostate as well as BPH, kidney stones, urinary infections, and incontinence. I am writing to comment on the proposed fee schedule rules that were published on 07/17/07 that concern the self-referral rule and the reassignment and purchased diagnostic test rules, because implementation of these rule changes will have a significant impact on access and quality of health care for my patients.

As you are aware, Medicare reimbursement to physicians for procedures is now less than half of what it was 15 years ago, and overhead continues to rise for physician practices at a rate of 5-10% a year. Surgeons are being reimbursed for complex surgical procedures, with extended hospital stays, and 90-day global coverage at a skilled trade wage rate similar to an hourly rate for a plumber. This is an unsustainable business model, particularly under the flawed SGR formula which mandates a 10% cut in reimbursement for 2008.

The part D Prescription Drug Act also hurt Urology practices significantly by eliminating the margin in our office administered drug inventory. This margin helped to offset rising overhead expenses, but now we are actually reimbursed less than the cost for some drugs.

Urology practices across the country are trying to find the means to stay in business without dropping our Medicare patients and my practice it is no exception. The changes proposed in these rules will have a serious impact on the way I practice medicine and will be detrimental to quality of care for my patients. With respect to the in-office ancillary services exception, the definition should not be limited in any way. By having our own dedicated GU pathologist, we have been able to significantly improve the diagnostic accuracy and the quality of pathology for our patients at no additional cost to Medicare.

ATLANTIC UROLOGY CLINICS, LLC

Grand Strand Urology
Kenneth Krzyzaniak, MD
William Bogache, MD
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Walter Frank, MD

Atlantic Urology Clinics Pathology
Brian Schnell, MD

For many years, I was dissatisfied with the quality of interpretations from our local hospital pathologists and for several years even tried outside pathology labs which also gave poor service. Having control of our own quality of pathology allows us to provide better service without sending out slides for second and third opinions. By providing in-office pathology, we are not only able to provide better diagnostic reads, but also save the Medicare system additional cost of second and third opinions. The OIG has inspected our pathology model and found it to be complaint with Stark laws with no evidence of over utilization. The proposed rule changes would be detrimental to our ability to provide quality service to our patients, in addition to being punitive by attempting to bypass the current Stark legislation.

Decreases in Medicare reimbursement for surgical procedures such as transurethral resection of the prostate (52601) has caused urologists to shift treatment of BPH to medical therapy and outpatient procedures such as laser resection of the prostate or transurethral microwave therapy. Some of this equipment is expensive and must be leased on a per click basis. The proposed changes to the reassignment and purchased diagnostic test rules, will make it difficult if not impossible for us to provide this service to our patients and soon we will be limited to simply managing urinary retention with long-term indwelling Foley catheters with resulting chronic urinary infection.

Forty percent of the urologists in this country are over age 50 which could severely limit access to health care if you are successful in driving urologists out of business or into early retirement. Physician shortages would make Medicare insurance essentially worthless.

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. These rules should be revised and only prohibit those specific arrangements that are not beneficial to patient care, and changes to our laws should only be made by the legislative branch of our government.

Sincerely,

Kenneth E. Krzyzaniak MD

Kenneth E. Krzyzaniak, M.D.
KEK/br/RPI/KEK14497

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ATLANTIC UROLOGY CLINICS, LLC

Grand Strand Urology
Kenneth Krzyzaniak, MD
William Bogache, MD
Neal Shore, MD
Richard Young, MD
Brian Roberts, MD
Attila Barabas, MD

Adult & Pediatric Urology Center of the Carolinas
Glenn Gangi, MD
Andrew Grudzinski, MD

Coastal Urology Centers
Marshall Sasser, MD
Timothy Quillen, MD
Keith Gawith, MD
Joseph Wood, MD
James Fogarty, DO
Colleen Farley, APRN

Waccamaw Urology Associates
Thomas Cerasaro, MD
Walter Frank, MD

Atlantic Urology Clinics Pathology
Brian Schnell, MD

August 28, 2007

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

Dear Mr. Kuhn:

I am a practicing urologist in a group practice in Myrtle Beach, South Carolina, and 60% of my patients are insured by Medicare. I see a large number of patients with cancer of the kidney, bladder, and prostate as well as BPH, kidney stones, urinary infections, and incontinence. I am writing to comment on the proposed fee schedule rules that were published on 07/17/07 that concern the self-referral rule and the reassignment and purchased diagnostic test rules, because implementation of these rule changes will have a significant impact on access and quality of health care for my patients.

As you are aware, Medicare reimbursement to physicians for procedures is now less than half of what it was 15 years ago, and overhead continues to rise for physician practices at a rate of 5-10% a year. Surgeons are being reimbursed for complex surgical procedures, with extended hospital stays, and 90-day global coverage at a skilled trade wage rate similar to an hourly rate for a plumber. This is an unsustainable business model, particularly under the flawed SGR formula which mandates a 10% cut in reimbursement for 2008.

The part D Prescription Drug Act also hurt Urology practices significantly by eliminating the margin in our office administered drug inventory. This margin helped to offset rising overhead expenses, but now we are actually reimbursed less than the cost for some drugs.

Urology practices across the country are trying to find the means to stay in business without dropping our Medicare patients and my practice it is no exception. The changes proposed in these rules will have a serious impact on the way I practice medicine and will be detrimental to quality of care for my patients. With respect to the in-office ancillary services exception, the definition should not be limited in anyway. By having our own dedicated GU pathologist, we have been able to significantly improve the diagnostic accuracy and the quality of pathology for our patients at no additional cost to Medicare.

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Having control of our own quality of pathology allows us to provide better service without sending all slides for second and third opinions. By providing in-office pathology, we are not only able to provide better diagnostic reads, but also save the Medicare system additional cost of second and third opinions. The OIG has inspected our pathology model and found it to be complaint with Stark laws with no evidence of over utilization. The proposed rule changes would be detrimental to our ability to provide quality service to our patients, in addition to being punitive as well as an attempt to bypass the current Stark legislation.

Decrease in Medicare reimbursement for surgical procedures such as transurethral resection of the prostate (52601) has caused urologists to shift treatment of BPH to medical therapy and outpatient procedures such as laser resection of the prostate or transurethral microwave therapy. Some of this equipment is expensive and must be leased on a per click basis. The proposed changes to the reassignment and purchase diagnostic test rules, will make it difficult if not impossible for us to provide this service to our patients and soon we will be limited to simply managing urinary retention with long-term indwelling Foley catheters with resulting chronic urinary infection.

One-third of the American physician work force is now over 50 and 40% of the urologist in this country are over 50 which could severely limit access to health care if you are successful in driving urologists out of business or into early retirement. Physician shortages would make Medicare insurance essentially worthless.

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. These rules should be revised and only prohibit those specific arrangements that are not beneficial to patient care.

Sincerely,

William K. Bogache, MD
WKBbr

BERKELEY UROLOGICAL ASSOCIATES
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DIPLOMATES AMERICAN BOARD OF UROLOGY
FELLOWS AMERICAN COLLEGE OF SURGEONS
ADULT & PEDIATRIC UROLOGY

August 29, 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

Dear Ladies and Gentlemen:

I am writing to express my sincere concerns regarding certain proposals in the recently released 2008 Proposed Physician Fee Schedule. As a physician practicing in Berkeley, California, I feel that several of the proposed changes to the physician self-referral rules would needlessly and unnecessarily harm Medicare patients and providers. I understand efforts by CMS to prevent abusive practices but I believe that certain proposals extend beyond this scope and will actually have detrimental effects on the health care system and physicians ability to deliver what have become standard of care type medicine to Medicare beneficiaries.

As a urologist I have seen first hand the beneficial effects that joint ventures have had on the health care system in terms of delivery of health care and also saving dollars. As you are aware, there has been a shift in the health care system towards efficiency, quality, and the cost effective delivery of health care. Much of the technology that has been developed recently including lithotripsy, green light photo vaporization of the prostate, cryotherapeutic ablation of the prostate, and various laparoscopic techniques are in accordance with those goals and concerns. However, If it were not for the joint ventures of urologists many Medicare beneficiaries would not be able to take advantage of these new and innovative techniques. Personally, I have been involved with providing lithotripsy as well as green light photo vaporization of the prostate in addition to cryotherapeutic ablation of the prostate to Medicare patients. These services would not have been possible if it had not

been for physician joint ventures. Hospitals typically refuse to accept the risk involved with providing services that are new and innovative especially with the fear of obsolescence. Urologists and many other physician specialties have been willing to accept that risk in an effort to bring these valuable services to their patients. Yet your proposals in the 2008 Physician Professional Fee Schedule attack the substance of the very joint ventures that have benefitted my patients to save Medicare millions of dollars in terms of treatment costs.

I would like to address several of the anti-physician ownership proposals that I believe will have a negative effect on the health care system in terms of delivery of health care and also in terms of resulting in higher costs to the Medicare system if they are adopted. My main concern is the services furnished under arrangements. The goal of the proposed changes to the Stark regulations regarding services furnished under arrangements is it appears to prohibit physician joint ventures from contracting with hospitals to provide diagnostic DHS. Unfortunately, the proposals as written are so broad they would ban legitimate and non-abusive arrangements for therapeutic services that are not otherwise DHS except for the fact that they are performed in a hospital setting. Therapeutic services that are affected from the urologic prospective include a variety of laser procedures for benign disease and cryotherapeutic ablation of the prostate for prostate cancer. The commentary in the proposed rule is somewhat insulting in that it suggests that physicians who invest in joint ventures do so at the good of patient care. Nothing could be further from the truth. Most physicians invest in joint ventures where they understand the technology and believe in the technology and believe that they are delivering the best possible alternatives for treatment to their patients.

A prime example would be extracorporeal shock wave lithotripsy. Prior to lithotripsy most stones were removed either transureteroscopically or through open stone surgery which require significant hospital stays and extended recovery time on the part of the patient. Lithotripsy provided a non-invasive way to treat most stones that were too large to pass spontaneously. Physicians wanting better treatment for their patients form joint ventures to buy lithotriptors and work for it at every turn by the hospital. These same hospitals were at the same time unwilling to take on the risk of purchasing lithotriptors to provide these services. Part of this is understandable because a single hospital often times does not have enough volume to justify the expense of purchasing certain technology. However, physicians want to have up-to-date treatment for their patients and are willing to invest in joint venture with other physicians at other practicing hospitals in order to purchase the technology for use on their patients. This way, uses can be spread among several hospitals on a rotating basis. The entire health care system benefits because without these arrangements this more efficient technology could be brought to both urban and rural settings with the cost spread out among several providers reducing overall capital costs. In addition, the cost savings by these more

efficient procedures spread throughout the entire health care system not in just some privileged areas where the hospitals are able to afford to purchase the capital equipment. By eliminating physician ventures especially in urology you are encouraging a two-tier health care system for patients in rural and poor areas who do not have access to treatment that has now become standard of care in most communities.

As an aside, several urologic procedures such as green light photo vaporization of the prostate as well as cryotherapeutic ablation of the prostate and lithotripsy can easily, safely, and more cost effectively be performed on an outpatient basis in an ambulatory surgery center. However, Medicare continues to embrace policies that prohibit such services being done in ambulatory care centers. As you know, procedures can be done more efficiently and more inexpensively in an ambulatory care center. It is somewhat frustrating to not be able to take advantage of cost savings and continue to do lithotripsy in a hospital setting. In addition, green light photo vaporization of the prostate was designed to be done as an outpatient procedure in an ambulatory care center. Yet the rules of reimbursement are such that these procedures have to be done in the hospital setting because reimbursement to ambulatory care centers presently are cost prohibitive. Likewise, cryotherapeutive ablation of the prostate can be done as an outpatient procedure but because of reimbursement guidelines must be done in a hospital setting. In addition, hospitals encourage a one day stay for cryotherapeutic ablation of the prostate patients because reimbursement to the hospitals if the procedure was done as an outpatient do not generally cover the cost. These inequities within the Medicare reimbursement system are both frustrating for the physician and inefficient for the system. These reimbursement issues are again an aside and I will return to the main focus of this letter.

In terms of physician joint ventures as they relate to health care delivery in the year 2008 I would ask CMS to separate those beneficial joint ventures which are not of themselves DHS and include lithotripsy, various laser ventures, and cryotherapeutic joint ventures, from the abusive and questionable diagnostic radiologic ventures requisitions and hospitals may have propagated. As you are aware in the court case ALS vs. Thompson noted extracorporeal lithotripsy is not a DHS even though it is provided under an arrangement with the hospital. Green light photo vaporization, holmium laser, and cryotherapy for prostate cancer are very similar in nature and, hopefully, will be judged accordingly. Undoubtedly, the urologic communities joint ventures have broadened access to new technology for Medicare patients, brought needed efficiency to the market and if utilized properly has the potential to save CMS hundreds of millions of dollars if these procedures are allowed to move to the ambulatory care centers.

There are other aspects of the new provisions for 2008 which are troubling but I'm sure have

been elucidated perhaps more clearly by many of my colleagues. These include the burden of proof provision as well as per click payments, stand in the shoes, and "set in advance" percentage based fee arrangements. I trust that you will analyze each of these provisions carefully and apply them narrowly to those potentially abusive and questionable diagnostic ventures and not to the beneficial therapeutic joint ventures such as lithotripsy, various laser technologies, and cryotherapeutic ablation of the prostate, which are helping to drive the health care system forward in a positive and cost effective way.

Yours Sincerely,

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JWF/la

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SOUTHEASTERN IDAHO UROLOGY CONSULTANT
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ROBERT W. BOHUS, M.D., F.A.C.S.
DIPLOMAT AMERICAN BOARD OF UROLOGY

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 have been practicing urology in Wyoming and Idaho for 20 years. I started my practice in Sheridan, Wyoming when lithotripsy became available. At that time the units were cumbersome, very expensive and I had to transfer my patients to Denver, Colorado for a minimally invasive procedure for a kidney stone.

With the advent of mobile units and physician group partnerships to make this technology more available, this has greatly improved the ability to treat patients in a timely fashion. For example, at our hospital in the past couple of months we have only treated 4 or 5 kidney stones. These technologies are quite expensive and our mobile unit travels throughout southeastern Idaho from Boise to Pocatello.

I think it is very important to keep in mind that we have ownership in technologies that are therapeutic, not diagnostic. Kidney stones come to us and we would like to treat them in the most expedient and least invasive way.

I can tell you that our hospital has balked on buying me a laser for treating distal stones simply because of the tremendous cost of the equipment, the fibers, and the poor reimbursements. I believe mobile lithotripsy will become less available because many hospitals will find it difficult to justify the cost of these technologies that change rapidly.

Thank you for your attention and consideration in this matter. Best personal regards.

Sincerely,

R Bohus

Robert W. Bohus, M.D., F.A.C.S.

RWB/lg

500 S. 11TH AVE., SUITE 301 • POCATELLO, ID 83201 • (208) 233-3355 • (208) 232-6118 FAX

August 29, 2007

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

Re: Changes to Reassignment and Physician Self-referral Rules Relating to Diagnostic Tests (Anti-Markup Provision)

Dear Mr. Kuhn:

We are leaders of two of the largest radiology group practices in Connecticut, Jefferson Radiology Associates and Advanced Radiology Consultants. We respectfully submit the following comments in response to CMS' proposed rules for the 2008 Medicare Physicians' Fee Schedule. We are certain that CMS will receive comments from a broad spectrum of interested parties. We will focus here on providing information that is specific to our situation.

CMS has made strong statements in its proposed rules that point to one very important factor in the growth of imaging – the conflict of interest that arises when a physician who orders a test also profits from its performance. Imaging has transformed healthcare and has improved both diagnosis and therapy. Indeed, imaging has been cited by the prestigious New England Journal of Medicine as one of the ten most important developments in medicine in the twentieth century. Thus, it is incumbent upon us to make sure that we preserve the positive aspects of imaging, without undue cost to the system. While this will certainly be a complex process, the first thing to be done is to remove artificial and counterproductive incentives for the use of imaging. Thus, we strongly support CMS' resolve to deal with in-office imaging and the many permutations thereof that, according to CMS, "corrupt(ing) medical decision making."

Thanks to forward thinking legislators and resolute private payers, Connecticut provides what is perhaps a unique perspective on the issue and a model for potential actions that might remedy any future inappropriate growth in imaging. Connecticut has Certificate of Need laws. Unlike many states, Connecticut has not only retained its law, but strengthened it over the years. Most recently, in recognition of the technological advances that have made prior-generation, advanced imaging less costly and available to a broader array of providers through in-office imaging, the legislature removed previous threshold for acquisition and made **all CT, MRI, PET scanners subject to CON requirement**. To this date, only one non-radiologist physician has obtained a CON for advanced imaging, and that was to replace a scanner that was acquired at a cost below the prior threshold.

Also, in 2001, the Connecticut legislature became the first in the country to pass a law that requires ACR accreditation to operate an MRI scanner here. Rhode Island has since become the second state.
The private insurance companies recognized the increased utilization of imaging that was engendered by self-referral. In response, all major private payers have instituted specialty-specific privileging programs that preclude almost all advanced imaging from being reimbursed to facilities that are not owned by radiologists or hospitals. Anthem Blue Cross Blue Shield, HealthNet, Oxford, Cigna, Aetna, and Connecticare have all done so. The first of these was documented in an article in a peer-reviewed journal. (Sample programs and article attached.) Link to article:
http://www.ajronline.org/cgi/content/abstract/175/1/9

The confluence of situations described above has led to relatively lower utilization of imaging among Medicare beneficiaries when compared with Connecticut's neighboring states (see attached annotated map) Connecticut residents have no problems with access to medical imaging. More importantly, there is no adverse effect on the health of Connecticut's Medicare beneficiaries. Notable is the publication by HCFA in the Journal of the American Medical Association in 2000 of the relative overall quality of care in the

states, wherein Connecticut, was ranked number 6 in the country for quality of care to Medicare beneficiaries. This matches up well (especially when one considers the cost of care) in comparison with adjacent states.
Perhaps because of the overall paucity of self-referred imaging in Connecticut, the few situations where self-referral has found a foothold can be analyzed more easily and can provide to CMS a stark contrast between the utilization of services with and without the overhanging conflict of interest.

The first situation is that of an IDTF that received a CON to provide cardiac CT/PET. Immediately, the IDTF embarked upon a dual business model: leasing part of the time to cardiology groups who would provide services as if the machine belonged to them; and the rest of the time as an independent provider of the service. We have obtained information from three large private payers in Connecticut showing the following over the 18-month period through June, 2007:

a. 218 cardiac PET examinations were done in the entire state by these 3 payers.
b. the other sites are the two largest hospitals in the state, where the hospitals own and bill for the examinations done on the scanners.
c. 134 of the 218 (63%) were done at the site where the two cardiology practices provide services on leased time. These are the only two cardiology practices who have the ability to bill for PET. These two practices comprise less than 20% of the cardiologists in the stated service area of the IDTF, yet virtually all the examinations in the service area are referred by them, and none was referred anywhere by any of the other cardiologists. Similarly, they comprise a very small percentage of the cardiologists in the state, but perform (63%) of the total studies in Connecticut.
c.100% of all patients done at that address were authorized to be done by the physicians in those two practices as the providers.
d. Zero were done by the IDTF on patients referred by general medical community. This raises serious questions as to the need for this examination if the other cardiologists never order the examination from the IDTF.
e. 128 of the 134 (96%) were referred by physicians with same tax ID or practice address. Thus, only 6/134 might have been in non-self-referred situation. Even those might have been referred at the suggestion of the cardiologists.

Thus, we see an examination where **the only demand comes from self-referring practices. NO other cardiology practices in the area ever order the test,** which is available at an independent facility.
Other practice in building not really there – "affiliated."

The second situation relates to PET scanning in the hands of a medical oncology group. Here, the oncologists purchased a PET scanner before the CON threshold was eliminated. The oncologists had previously referred their patients to the local hospital, which was leasing a mobile scanner once a week and was planning to upgrade the service to PET/CT, at some additional cost. Prior to the oncologists obtaining their own PET scanner, the hospital in question was performing between 200 and 250 scans per year approximately 20 studies per month with the most during any single month possibly 30. This remained relatively constant over at least 4 years. The oncologist's scanner became operational in July, 2006. Their average monthly volume has been approximately 45 scans per month for a yearly total of approximately 540. The hospital's volume now averages 10 or less per month, just less than half of what they were previously performing. This has put the hospital on uncertain footing as far as the ability to provide ANY PET services in the future, let alone upgrade to PET/CT. The hospital's commitment to the leasing company provides PET scanning one day a week with a minimum guaranteed charge to the hospital of 3 patients per day. Most weeks they are fortunate to make their minimum and, at best, break even providing the service. The hospital is one of the few still providing PET-only scanners (as opposed to the more up-to-date PET/CT). The leasing company would like to phase out its PET-only scanners. Thus, it may not provide PET-only beyond the current calendar year, leaving the hospital with no scanner at all. The leasing wants a 5 patient minimum to provide PET/CT. This would mean the hospital would definitely lose money to provide the service and cannot be afford to do that. It would now certainly be irresponsible and out of the question for the hospital to consider purchasing a PET/CT unit of its own. Thus, the hospital may be forced to give up the service altogether and send area patients to an out of town facility.

Recently, a group of urologists acquired a CT scanner before the CON law changed. (Incidentally, they obtained a 2-slice scanner, probably the only scanner in the state that is not four or more detectors.) As reported above, private payers in Connecticut have resisted paying non-radiologists for advanced imaging. Bowing to political pressure, last April one payer relented and gave them privileges. That payer reports an immediate increase of referrals for CT by that practice of 20% - in the first month of the more liberal policy. The payer says it will continue to monitor their utilization.

Historically, insurance companies and the business community have been opposed to CON laws, believing that they restrict competition. Competition, they advocated, would lead to price declines. A significant change in their attitudes was signaled by the recent testimony before the Public Health Committee of the Connecticut legislature by the Connecticut Association of Health Plans and Anthem Blue Cross. The texts of their testimonies are attached. See the highlighted sections which indicate that the in-office imaging is increasing, is becoming onerous, and is not linked to need or quality of care. They make the point that there are more machines in offices of physicians who "drive their patients to these units."

Their testimony reflects their realization of the demand that is CREATED by the opportunity for increased revenues on the parts of the referrers, and that these situations are, in fact, ANTI-competitive. Much as Microsoft controlled the operating systems of computers and made it difficult to use third party software; much as the oil trusts of the nineteenth century controlled both the supply and the demand for their product; so do self-referring physicians control the "demand" for the product that they are "selling." Advocates of in-office imaging have likewise contended that radiologists want to restrict patient choice. Given the unique aspects of the physician-patient relationship and the pressures it brings to bear on the vulnerable patient, it is actually the self-referrers who are restricting the choices of the consumers.

So, what have we reported to you here and what relevance does it have for the proposed rules? We have shown you that you are correct in your assessment of the distortions produced by self-referral of imaging. We have given you some perspective on conditions in our state and among private payers that can limit the opportunities to practice self-referral. **We urge stringent restrictions on all the abuses of the loopholes in the Stark laws that you have recognized and are increasingly being recognized around the country (Illinois, Maryland, Louisiana, Florida, Texas, California, etc).**

There seem to be developing in Washington two distinct approaches to dealing with the cost of imaging. With the DRA, and now with proposals in the House CHAMP bill, Congress has embarked upon a program that would drastically reduce the reimbursement for providing the technical component to levels that may be unworkable for many practices, especially those in rural Connecticut. If this legislation stands, it will cripple an industry and stifle development in a branch of health care that has been a major contributor to the well-being of Americans. As evidenced by the text of its proposed rules, the CMS approach prioritizes the regulation of anti-competitive and abusive practices that artificially increase the cost of imaging. CMS wrote:

At this time, we decline to issue a specific proposal for amending the in-office ancillary services exception. Rather, we are soliciting comments as to whether changes are necessary and, if so, what changes should be made. We are interested in receiving comments on: (1) Whether certain services should not qualify for the exception (for example, any therapy services that are not provided on an incident to basis, and services that are not needed at the time of the office visit in order to assist the physician in his or her diagnosis or plan of treatment, or complex laboratory services); (2) whether and, if so, how we should make changes to our definitions of same building and centralized building; (3) whether nonspecialist physicians should be able to use the exception to refer patients for specialized services involving the use of equipment owned by the nonspecialists; [[Page 38182]] and (4) any other restrictions on the ownership or investment in services that would curtail program or patient abuse.

We applaud CMS for its insight and also prospectively in anticipation of decisive action, and **recommend the following** (in descending order of preference):

1. **That CMS reconsider and issue a specific proposal for amending the in-office ancillary services exception.** As the counterproductive aspects of self-referral have been recognized, measures taken to

curb it have been mostly indirect – i.e., dealing with privileging, curtailing the leasing relationships, medical directorships, etc. While CMS did not propose that the exception for in-office imaging be repealed, we believe what is really needed is, indeed, **the removal of the exception for in-office imaging, thereby obviating the need for the many indirect measures.**

2. Recognizing that the complete removal of the in-office ancillary services exception may not be what CMS wants to do now, we suggest **that CMS remove the exception for certain advanced imaging tests** that were not prevalent in non-radiologist office settings at the time of passage of the Stark laws and are rarely used for immediate evaluation of patients at the times of their initial evaluations. These would include **Computed Tomography, Magnetic Resonance Imaging, and Positron Emission Tomography.** These are not yet overly prevalent in non-radiologists' offices, but have been shown to be the fastest growing procedures in the office setting and the office growth has accounted for the overwhelming preponderance of the growth of imaging. In addition, we are seeing interest by certain specialist groups in purchasing **radiation therapy units for their offices. These should be excluded from any in-office ancillary services exception, as well.**

3. **That non-radiologist physicians not be able to refer patients for imaging services involving the use of the above advanced imaging equipment from which they (or their relatives) might profit in <u>any</u> fashion** - including, but not limited to arrangements involving ownership, as leasors or leasees, or through professional services arrangements, such as medical directorships, etc.

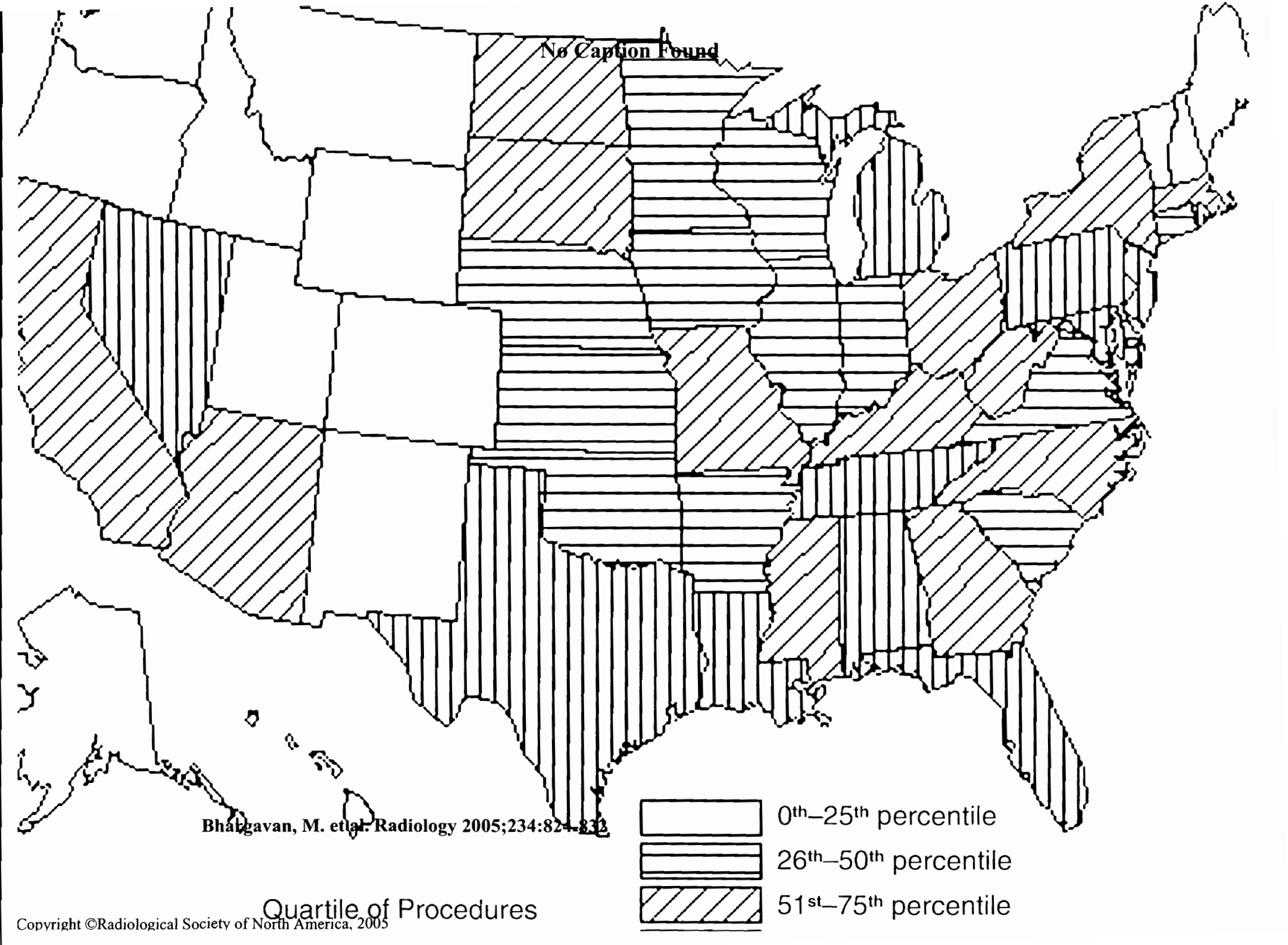
4. **That CMS ban sharing of equipment among different practices, ban markups of the technical and professional components, and ban "under arrangements" relationships.** Likewise, "under arrangements" relationships are being discussed by non-radiologists as ways of profiting from imaging without actually even having the units in their offices. These specialists use their power to bring patients to hospitals and the threat of loss of referrals for imaging as leverage to induce the hospitals to enter into these arrangements.

We thank CMS for the opportunity to present this information and for your consideration thereof.

Respectfully submitted,

Darlene Zase, MS, CMPE
Executive Director
Advanced Radiology Consultants, LLC

William Glucksman, MD
President,
Jefferson Radiology, P.C.



Cigna /AIM AJR 2000; 175; 9-15

- Multi-specialty radiology panel
- Strict privileging by specialty
- Court challenge
- Did not even address major SR: cardiac
- Limited addressing of ortho plain films
- Reduction of utilization
  - total # exams decreased 20-25% from trend
  - SR exams 40% -> 15% of total = 63% dec.
  - 50% of likely SR exams disappeared

CARECORE NATIONAL
PRIVILEGING BY SPECIALTY
JANUARY 2004

The privileging program is designed to improve quality by limiting coverage of imaging services to those services provided in the most appropriate setting. The list below details the imaging CPT codes that physicians other than radiologists can perform in their office.

Note: The privileging program applies to all settings, including inpatient.
*These procedures require pre-certification.
***Any studies beyond three require pre-certification.

PHYSICIAN TYPE	CPT CODES	DESCRIPTION
Primary Care Physicians: Internal Med., Family Practice	71010-71030 76075,76076	Chest imaging DEXA studies, bone densitometry
Cardiologists	71010-71030 78464*, 78465*, 78469* 78472*, 78473* 78478*	Chest imaging Tomographic SPECT studies Cardiac blood pool imaging Wall motion study
Cardiologists – Pediatric only	76825***, 76826 ***, 76827***, 76828***	Echocardiography, fetal
Chiropractors	72010, 72040, 72069, 72070, 72080, 72100	Spine imaging
Endocrinologists	76075, 76076 76942 76536 (AACE Accredited Endocrinologists only)	DEXA studies, bone densitometry Ultrasonic guidance for needle biopsy Thyroid ultrasound
Gastroenterologists	76975*	Endoscopic ultrasound
General Surgeons: AIUM-accredited	76942	Ultrasonic guidance for needle biopsy
General Surgeons, Vascular Surgeons, Cardio-Vascular Surgeons	75940 75952 75953	Percutaneous placement of IVC filter, radiological supervision & interpretation Endovascular repair of infrarenal abdominal aortic aneurysm Placement of proximal or distal extension prosthesis for endovascular repair
Hand Surgeons	76000 73100-73140	Fluoroscopy Upper extremity imaging

*Maternal and Fetal Medicine Neonatal Perinatal Medicine [redacted]	76075, 76076 76083 76092 76801***-76828*** 76830, 76856, 76857 76930, 76941, 76942, 76945, 76946, 76948	DEXA studies, bone densitometry Digitization of radiographic images Screening mammography Ultrasounds-pelvis Ultrasounds-pelvis Ultrasonic guidance Ultrasonic guidance
Ob/Gyns	76075, 76076 76083 76092 76815***, 76816***, 76817***, 76830, 76831, 76856, 76857 76930, 76941, 76945, 76946	DEXA studies, bone densitometry Digitization of radiographic images Screening Mammography Ultrasounds-pelvis Ultrasounds-pelvis Ultrasonic guidance
Ob/Gyns AIUM/ACR Accredited	76801***, 76802***, 76805***, 76810***, 76811***, 76812***, 76818***, 76819***, 76825***, 76826***, 76827***, 76828***	Ultrasounds-pelvis
Oral Surgeons	70100, 70110, 70140, 70150 70300, 70310, 70320 70328, 70330 70350 70355	Mandible and facial bone imaging Teeth imaging TMJ imaging Cephalogram, orthodontic Orthopantogram
Orthopedists	71100-71111 71120-71130 72010-72120,72170, 72190, 72200-72220 73000-73140, 73500-73660 76000, 76003, 76005 76006 76040 76066	Radiologic examination, ribs Radiologic examination, sternum Spine and Pelvis imaging Imaging- Upper and lower extremities Fluoroscopies Radiologic examination, any joint Bone length studies Joint survey
Pain Specialists (physiatrists, anesthesiologists, neurologists, and neurosurgeons)	76000 76005	Fluoroscopy (separate procedure), up to one hour physician time, other than 71023 or 71024 (eg, cardiac fluoroscopy) Fluoroscopic guidance and localization of needle or catheter tip for spine paraspinous diagnostic or therapeutic injection procedures including neurolytic agent destruction
Pediatricians	71010-71030	Chest imaging
Podiatrists	73620, 73630, 73650, 73660	Lower extremity imaging
Pulmonologists	71010-71030	Chest Imaging
Radiation Oncologists	76370	Computerized tomography

		guidance
	76873	Prostate volume study for brachytherapy treatment planning
	76950	Ultrasonic guidance for placement of radiation therapy fields
	76965	Ultrasonic guidance for interstitial radioelement application
Reproductive Endocrinologists [redacted]	76075, 76076	DEXA studies, bone densitometry
	76083	Digitization of radiographic images
	76092	Screening Mammography
	76801***-76828***	Ultrasounds-pelvis
	76830-76857	Ultrasounds-pelvis
	76930, 76941, 76945,76946	Ultrasonic guidance
	76948	Ultrasonic guidance for aspiration of ova, imaging supervision and interpretation
Rheumatologists	72010-72120,72170, 72190,	Spine and pelvis imaging
	72200-72220	Imaging- Upper and lower extremities
	73000-73140, 73500-73660	Fluoroscopies
	76000, 76003	Bone length studies, joint survey
	76040, 76066	DEXA studies, bone densitometry
	76075,76076	
Urologists	76870, 76872	Ultrasounds – echography, genitalia, bladder
	76942	Ultrasonic guidance for needle biopsy

The Effect of Imaging Guidelines on the Number and Quality of Outpatient Radiographic Examinations

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Lynn Gelinas[4]

OBJECTIVE. A significant percentage of outpatient diagnostic radiology is performed by nonradiologists. Studies have shown nonradiologists have higher utilization and cost, as well as quality problems. We sought to determine if, in a managed care environment, a set of guidelines limiting imaging privileges of nonradiologist physicians could decrease imaging costs while ensuring that equipment and personnel providing imaging were of the highest quality.

MATERIALS AND METHODS. We determined the number and type of radiographic imaging studies performed the year after these guidelines were set in place (1997) and compared these findings with those of the year before the guidelines were established (1995) and with preguideline trends. We established quality criteria and, based thereon, inspected imaging offices.

RESULTS. The number of radiographic examinations per 1000 enrollees decreased 20–25% from the previous trend. Nonradiologists' share of the total fell from 39% to 15%. No deficiencies were found in the inspection of five radiologists' offices, whereas significant deficiencies of equipment, equipment maintenance, or documentation of the examinations performed were found in 78% of nonradiologists' offices. None of the quality indicators monitored by the health plan showed significant change.

CONCLUSION. Specific guidelines can effect change in the location and number of radiologic examinations performed, with an improvement in the quality of the studies and a decrease in radiation dose and cost. No decline in quality of care appears to result, despite claims by opponents to such changes that widespread serious quality impairment would occur.

The portion of society's resources devoted to health care has been the subject of significant debate in the United States for decades. In 1965, the United States devoted 5.9% of its gross national product to health expenditures. By 1995, this figure had risen to approximately 14%, and this increase had a significant impact on employers and the government. If current projections hold, it is estimated that expenditures will double to $2.3 trillion (United State dollars) or approximately 17% of the gross national product by 2007 [1]. Methods of curbing this significant increase have been sought, and the results have changed the face of American medicine. The rapid emergence of managed care as a majority health insurer for Americans has been heralded as the reason for some of the recent slowdown in the rise of health care costs. Managed care claims credit for eliminating many of the excesses of the system. However, with the increasing age of our population and their health care needs as well as the continued development of new technology, health care costs now seem to be once again increasing at a rate higher than current inflation. Although managed care has helped the system curtail costs, there have been negative effects related to physician choice, accessibility, and the accountability of health plans. Various techniques to decrease health care costs have been developed. One is to decrease the benefits to which a patient is entitled; another, to decrease the payment for each unit of service. Yet another technique is to institute a utilization management program, with the expectation of eliminating unnecessary services.

Diagnostic radiology services constitute a significant portion of both inpatient and outpatient costs. It has been estimated that radiology services use approximately 8% of the health

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care dollar paid to physicians. Many studies have shown that approximately 50% of nonhospital radiology services are performed in a nonradiologist's offices [2–4] and that nonradiologic physicians who have an X-ray machine in their office perform as many as four to five times as many examinations per patient as physicians in the same specialties seeing patients with the same problems but who refer their patients to radiologists for imaging. [5–7]. Other studies have suggested that many radiologic examinations performed in nonradiologists' offices are of poor diagnostic quality and are interpreted incorrectly [8–11].

Materials and Methods

A large health maintenance organization in the northeastern United States decided to establish an effective radiology utilization program based on several objectives. The organization's goals were to reduce utilization of imaging tests that were noncontributory to patient treatment and that thus were inappropriate and, at the same time, to deliver the most cost-effective, high-quality imaging product. The health maintenance organization wanted to address the problems of volume, cost, and quality and to ensure that the equipment and personnel producing and interpreting a radiographic or imaging study were of the highest quality.

The health plan established a radiology advisory committee that consisted of physicians drawn from various academic and community practices throughout the state. The advisory committee is a multispecialty committee consisting of radiologists, a surgeon, an internist, a primary care physician, an orthopedic surgeon, an obstetrician or a gynecologist, and the medical director of the health plan. These physicians were chosen on the basis of board certification in their field, volume of practice, volume of radiographic examinations performed, and, in some cases, individual physician experience. This committee eventually established the guidelines regarding who could perform imaging studies in their office practice. Imaging studies that could be performed by nonradiologists were carefully delineated on the basis of each physician's specialty and demonstrated expertise.

These expertise- and relevance-based guidelines limited the amount of imaging permitted to be performed by nonradiologists. The guidelines removed all imaging privileges from gastroenterologists, general surgeons, nephrologists, neurosurgeons, oncologists, pediatric surgeons, and physiatrists. Cardiologists were limited to performing chest radiography, echocardiography, and nuclear cardiology, and pulmonologists could perform only chest radiography. The only imaging an obstetrician–gynecologist could perform was obstetric and gynecologic sonography; breast sonography was specifically excluded. If an obstetrician's office obtained United States Food and Drug Administration (FDA) approval for mammography, only the technical component of a screening mammogram would be paid by the health maintenance organization. The images had to be sent to a radiologist for interpretation. Orthopedic surgeons were permitted to perform conventional orthopedic radiography but were excluded from performing and interpreting all CT and MR procedures. Otolaryngologists were permitted to obtain conventional radiographs of the sinuses and nasal bones, but soft-tissue radiographs of the neck and cervical spine were excluded. Podiatrists could perform and bill only for radiography of the foot, and rheumatologists could perform only extremity radiography; they were excluded from performing spine radiography.

Primary care physicians, including family practitioners, internists, and pediatricians, were permitted to obtain only chest, rib, and extremity radiographs and were paid only for the technical component. It was required that these images be interpreted by a radiologist who would then bill for the professional component.

The second aspect of the program was to evaluate and ensure the technical quality of the imaging performed. A technology assessment questionnaire (Fig. 1) was sent to all providers who requested imaging privileges. This questionnaire required details of many aspects of the imaging being practiced, including a description of the imaging equipment present in the office, its year of manufacture, its service records, and a physicist's evaluation of the radiology equipment including its output and radiation dose to a patient. The questionnaire inquired about the availability of quality assurance programs (e.g., whether demographic labeling of a radiograph was performed routinely and whether there was a written radiology report for each imaging examination performed). Another requirement was that only licensed technologists could perform radiography. Patient safety programs—for example, whether a patient was questioned regarding pregnancy status—had to be in place. The health plan required that practices performing mammography have FDA approval. Physicians who wished to perform sonographic examinations had to be accredited by the American Institute of Ultrasound in Medicine, the American College of Radiology, or, in the case of vascular sonography, by the Intersocietal Commission for Accreditation of Vascular Laboratories.

Four hundred fifty-two questionnaires were distributed and 411 completed questionnaires were returned to our office for a return rate of 91%. We then inspected a representative group of radiology offices, and we attempted to inspect approximately 25% (100) of the nonradiology offices at which imaging studies were performed. Because of various scheduling problems we could inspect only 92 of

PROVIDER INFORMATION

Please complete this form for each practice location that provides diagnostic imaging services and one Assessment Checklist for each equipment location.

Please type or print information.

Legal Practice Name: _____

Group Practice Tax ID Number: _____

****Please fill out a separate Application/Checklist for each Imaging Site Location****

Imaging Site

Site Name / D.B.A.: _____
Address: _____ Suite: _____
City, State, Zip code: _____
Phone: _____ Fax: _____

____ Equipment Only ____ Billing and Equipment

Billing Site

Site Name / D.B.A.: _____
Address: _____ Suite: _____
City, State, Zip code: _____
Phone: _____ Fax: _____

____ Billing Only ____ Billing and Equipment ____ Billing Service

Imaging Site Demographics

What is your patient volume for diagnostic imaging per month? _____
What is your maximum patient volume for diagnostic imaging per month? _____
Office Manager: _____
Chief Technologist: _____
Document Prepared by: _____

Fig. 1.—Form shows second page of technology assessment questionnaire. This questionnaire requires provider to respond to questions regarding imaging equipment, personnel, and quality assurance programs in each office. D.B.A. = doing business as.

these 100 offices. The 100 offices selected for inspection were those at which the highest number of imaging studies were performed per month. They were inspected by registered radiology technologists who used a checklist to evaluate each specific facet of the inspection and were required to complete a questionnaire about each office. Evaluation of parameters such as quality of the imaging study, storage and handling of films, patient demographic information on the film (patient name, age, date of examination), and the presence of a report on each imaging study was part of the inspection performed by the technologist (Fig. 2).

Only outpatient radiologic examinations were studied in our research. This article addresses only radiography, essentially the only technique aside from sonography that nonradiologists perform in large volume. CT, MR imaging, sonography, and nuclear medicine studies were specifically excluded. We recognize the importance of these studies on radiology expenditures and their place in the changing patterns of imaging examinations used to work up specific disease entities; they are presently being studied and will be the subject of a separate analysis. Outpatient examinations were included in our study regardless of whether they were performed in a private office, imaging center, multispecialty clinic, or hospital. Data were gathered from billing statistics. Each procedure is identified by a specific *Current Procedural Terminology* code [12] and there had to be an appropriate *International Classification of Diseases indication* [13] for the study. Also, the name of the referring physician as well as that of the physician performing the study and both physicians' specialty were noted. Data were obtained from the HCFA-1500 (Health Care Financing Administration) claim form that was sent to our office for payment of the imaging study.

Our analysis was based on the number of examinations per 1000 enrollees. Because the health plan was growing and the number of enrollees rose during our study years, comparisons of simple counts would not be valid.

The health plan's data for the calendar year before we assumed responsibility for managing radiologic studies (1995) were compared with data for the calendar year after our program had been put into effect (1997). (We assumed responsibility for the health plan in 1996.) This gave us detailed data before our initiation of this program and a complete year's data following, thus avoiding start-up problems. Comparison of the enrollees on the basis of age and sex was undertaken. There was no significant change in the age or sex distribution of the patient population between study years. This was important to study because the number of enrollees rose from 125,000 to 162,000. A change in age or sex distribution of the population could affect radiology utilization. For 1993 and 1994, we had limited access to data that included only the total number of examinations performed and the number of examinations per 1000 enrollees. We used these 1993 and 1994 data to estimate the utilization trends that would have been expected to continue if our program had not been instituted.

RADIOLOGY INSPECTION CHECK LIST

PHYSICIAN NAME: _____ GROUP NAME: _____

ADDRESS: _____ COUNTY: _____

DATE: _____ SURVEYOR: _____

		YES	NO	N/A
1.	Radiology equipment inspected within the past twelve (12) months?			
	A. X-RAY EQUIPMENT:			
	a) Date: _____ By: _____ Physicist _____ Service Engineer _____ Other (please specify)			
	b) Deficiencies corrected within the past twelve (12) months?			
	B. ULTRASOUND EQUIPMENT			
	a) Date: _____ By: _____ Physicist _____ Service Engineer _____ Other (please specify)			
	b) Deficiencies corrected within the past twelve (12) months?			
	C. NUCLEAR IMAGING EQUIPMENT (Dose Calibrator)			
	a) Date: _____ By: _____ Physicist _____ Service Engineer _____ Other (please specify)			
	b) Deficiencies corrected within the past twelve (12) months?			
2.	Program for exposure of women of child-bearing age			
	A. Program/protocol in place to prevent x-ray exposure for women of child-bearing age?			
3.	Patient / Employee Safety			
	A. Office has current OSHA manual?			

Fig. 2.—Form shows page one of three-page inspection document. This document details inspectors' findings regarding equipment service records, patient safety, image quality, and reporting methods. N/A = not applicable, OSHA = Occupational Safety and Health Administration.

Results

Initially, there was considerable unhappiness created by the restriction of physician privileges. Many physician groups insisted that the guidelines would negatively impact their ability to care for patients. After the first several months, it became apparent that these guidelines had not caused significant hardship, and most complaints subsided. All quality-of-care measures charted by the health plan, including those mandated by accreditation from the National Committee for Quality Assurance and those required by the Health Care Financing Administration, were unchanged by the institution of our guidelines. Specifically, there was no significant change in the per enrollee number of hospital days, in emergency department visits, or in quality-of-care complaints by members. In areas such as maternity care management, diabetic care, asthma care management, and all other specific clinical care practices monitored by the health plan, no significant changes occurred.

In 1993, 22,350 radiographic examinations were performed, which is a rate of 226 examinations per 1000 enrollees. In 1994, 30,071 examinations were performed, which is a rate of 257 per 1000. In 1995, of 34,436 radiographic examinations were performed, for a rate of 269 per 1000. In that year, 20,906 examinations, or 163 per 1000, were performed by radiologists and 13,530 (39% of the total), or 105 per 1000, were performed by nonradiologists. In 1997, 38,912 radiographic examinations were performed, for a rate of 253 per 1000. Of the examinations in 1997, 32,970 or 214 per 1000 were performed by radiologists and only 5942 (15%) or 39 per 1000 were performed by nonradiologists. If we directly compare the

1995 data with the 1997 data, a 6% decrease in the number of radiologic examinations per 1000 examinations performed is revealed; a 31% increase in the number of examinations per 1000 enrollees performed by radiologists and a 63% decrease in those performed by nonradiologists are also revealed.

Another comparison reveals that in the years preceding the institution of this plan, radiology services per 1000 enrollees increased approximately 5–10% per year. In 1997, the number of radiographs per 1000 decreased by approximately 20–25% from the number expected if the trend had continued (Fig. 3).

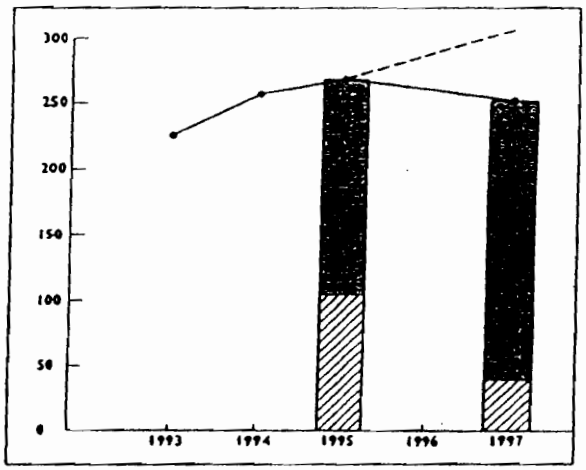

Fig. 3.—Graph shows radiographs per 1000 enrollees. Once plan was instituted, total (*solid line*) decreased 20–25% below previous trend (*dashed line*) and 6% in absolute terms below preplan year. Area with diagonal lines = radiographs obtained by nonradiologists, gray area = radiographs obtained by radiologists.

For each anatomic area, a marked increase in the percentage of imaging examinations performed by radiologists and a marked decrease in that of imaging examinations performed by nonradiologists were also revealed. For example, 96 per 1000 chest radiographs were obtained in 1995, 29% of which were obtained by nonradiologists. In 1997, 104 per 1000 chest radiographs were obtained, with 15% obtained by nonradiologists. These findings indicate a 29% increase in chest radiographs per 1000 obtained by radiologists and a 43% decrease in those obtained by nonradiologists. Even larger changes occurred in examinations of the lumbar spine. In 1995, 10.4 per 1000 examinations were performed, 35% of which were performed by nonradiologists. In 1997, 9.6 per 1000 examinations of the lumbar spine were performed with only 5% performed by nonradiologists. Overall, a decrease in spine examinations of 7% per 1000 was seen; a 35% increase in spine examinations performed by radiologists and an 86% decrease in those performed by nonradiologists occurred. Similarly, of extremity examinations, 11.1 per 1000 wrist examinations were performed in 1995. Of these, 46% were performed by nonradiologists. In 1997, 7.9 per 1000 were performed, only 9% of which were performed by nonradiologists. Overall, a 29% decrease in the number of wrist examinations performed per 1000, with a 20% increase in those performed by a radiologist and an 87% decrease in those performed by nonradiologists (Table 1).

Our technical assessment questionnaire and the follow-up inspection also revealed important findings. Although we examined only five radiology offices, no significant deficiencies were encountered in any of these offices. We then made the assumption that continuing to inspect radiology offices would not be beneficial because they routinely had their equipment inspected, issued a report on each imaging study, and had appropriate patient demographic information on each radiography report and on each image. They also routinely used technologists to perform the radiographic examinations, and all offices had a quality assurance program in place.

Of the 92 nonradiologist offices inspected, 10% had not had their equipment inspected within the previous 12 months. Nine percent of the offices that had deficiencies identified by either a physicist or service personnel had not corrected the deficiencies at the time of the survey. Sixteen percent of the offices did not have the images identified using right-sided or left-sided markers. Sixty-two percent of the offices inspected did not issue a formal radiology report of the imaging procedure performed; a note was made in the chart cryptically stating that a radiograph was either positive or negative, but no formal report was available. This seriously limited audit and quality assurance initiatives.

After tabulation of the deficiencies identified on our inspection, a certified letter was sent to each office requiring that the deficiencies be corrected within 90 days. We required that quality assurance programs be instituted if they were not in place and that all imaging studies have a formal report, either legibly handwritten or typed, and placed in the patient's chart. Of the 92 nonradiologist offices inspected, 72 offices, or 78%, had a significant deficiency identified. If the absence of a report is excluded as a criterion, 32% of the offices had serious deficiencies.

Discussion

There is an extensive literature showing that nonradiologist physicians who have a financial interest in the diagnostic imaging of their patients order more imaging than colleagues in the same specialty who do not have this type of financial interest [3, 5–7, 14–16]. This finding holds regardless of whether the nonradiologist has a financial interest in an outside imaging facility to which he or she refers patients or the financial interest consists of imaging that the nonradiologist performs in his or her own office. The finding also holds regardless of whether data are compared on the basis of the patient's presenting complaint or the data are an aggregate for all patients seen by a physician. Similar findings also hold for other ancillary services, such as physical therapy [17].

Given the ubiquity of this finding and the large differences in imaging frequency typically observed, the usual conclusion has been that financial self-interest is an important cause of the higher imaging utilization of self-referrers. However, because almost all studies are comparisons of two different sets of physicians, rather than comparisons of one set of physicians under two different financial incentives, other explanations are possible. For example, it is possible that physicians whose practice style includes much more imaging (perhaps because they are less inclined to rely on history and physical examination than colleagues) acquire imaging equipment because they naturally use it.

Our study is one of few that directly tests the role of financial incentives. Our plan halted reimbursement to nonradiologists for some forms of imaging but left them entirely free to refer their patients to radiologists if they believed the imaging they had been conducting on their patients was needed.

TABLE 1: Detailed Analysis of Radiographic Procedures: 1995 Compared with 1997

Current Procedural Terminology Codes	Description	1995						1997						Comparison of 1995 and 1997 Values (% per 1000)		
		Total Units	Per 1000	Performed by Radiologists	Per 1000	Performed by All Others	Per 1000	Total Units	Per 1000	Performed by Radiologists	Per 1000	Performed by All Others	Per 1000	Total Units	Performed by Radiologists	Performed by All Others
71010	Chest (one view)	3561	27.8	3209	25.1	352	2.7	4862	31.6	4800	31.2	62	0.4	14	24	−85
71020	Chest (two views)	12,327	96.2	8721	68.1	3606	28.2	16,027	104.1	13,543	88.0	2484	16.1	8	29	−43
73620	Foot (two views)	1712	13.4	74	0.6	1638	12.8	1760	11.4	292	1.9	1468	9.5	−14	228	−25
73630	Foot (complete)	2320	18.1	1128	8.8	1192	9.3	2781	18.1	1924	12.5	857	5.6	0	42	−40
73130	Hand (complete)	1369	10.7	994	7.8	375	2.9	1421	9.2	1285	8.3	136	0.9	−14	8	−70
73610	Ankle (complete)	1877	14.7	1118	8.7	759	5.9	1740	11.3	1641	10.7	99	0.6	−23	22	−89
73600	Ankle (two views)	278	2.2	40	0.3	238	1.9	184	1.2	150	1.0	31	0.2	−45	212	−89
72110	Spine (lumbarsacral)	1326	10.4	867	6.8	459	3.6	1485	9.6	1409	9.2	80	0.5	−7	35	−86
72050	Spine (cervical)	926	7.2	650	5.1	276	2.2	1166	7.6	1087	7.1	79	0.5	5	39	−76
73030	Shoulder	1417	11.1	617	4.8	800	6.2	1145	7.4	1024	6.7	121	0.8	−33	38	−87
73080	Elbow (complete)	471	3.7	294	2.3	177	1.4	571	3.7	538	3.5	33	0.2	1	52	−84
73090	Forearm (two views)	421	3.3	233	1.8	188	1.5	398	2.6	384	2.5	14	0.1	−21	37	−94
73100	Wrist (two views)	591	4.6	87	0.7	504	3.9	206	1.3	179	1.2	27	0.2	−71	71	−96
73110	Wrist (complete)	1417	11.1	767	6.0	650	5.1	1210	7.9	1107	7.2	103	0.7	−29	20	−87
73060	Humerus	188	1.5	104	0.8	84	0.7	203	1.3	198	1.3	5	0.0	−10	58	−95
73510	Hip (complete)	804	6.3	439	3.4	365	2.8	848	5.5	778	5.1	70	0.5	−12	47	−84
72170	Pelvis (anteroposterior only)	665	5.2	396	3.1	269	2.1	850	5.5	804	5.2	46	0.3	6	69	−86
73550	Femur	197	1.5	139	1.1	58	0.5	220	1.4	216	1.4	4	0.0	−7	29	−94
73560	Knee (two views)	1183	9.2	353	2.8	830	6.5	635	4.1	530	3.4	105	0.7	−55	25	−89
73562	Knee (three views)	821	6.4	397	3.1	424	3.3	650	4.2	559	3.6	91	0.6	−34	17	−82
73590	Tibia and fibula	565	4.4	279	2.2	286	2.2	550	3.6	522	3.4	27	0.2	−19	56	−92
Total		34,436	268.9	20,906	163.2	13,530	105.6	38,912	252.7	32,970	214.1	5942	38.6	−6	31	−63

Note.—Codes are from [12].

We found this change produced a decline in imaging of 20–25% from what would have been expected given the previous trend of imaging growth, and an absolute decline of 6%.

Before the institution of our plan, nonradiologists had been performing 39% of outpatient radiographs. The 20–25% decline from the trend that we observed was roughly half this 39% initial share. Thus, our research shows that approximately half the imaging performed by self-referrers disappeared when they lost their financial self-interest in it.

This estimate—that eliminating financial incentives decreases half the imaging self-referrers order—coincides remarkably well with the most relevant data comparing two different groups of physicians. An analysis of Medicare claims data from all nonradiologist physicians in Florida by the United States General Accounting Office reveals that nonradiologists who obtained radiographs of their own patients performed twice as many radiographic examinations per 1000 patient office visits as did physicians who referred their patients to outside offices for radiography [6].

However, results were generally different in the three published studies that, like our research, investigated how physician orders for radiologic studies changed when financial incentives changed. Hemenway et al. [18] reported that when the compensation of primary care physicians at a chain of for-profit ambulatory care clinics was changed from a flat hourly wage to include a bonus related to revenues generated, the number of radiographs per patient visit increased 16% and the number of laboratory tests per visit increased 23%. The authors note that these findings seem like relatively small changes and speculate that the relatively small response may reflect the structure of the bonus system, which provided only a relatively weak financial incentive. Hillman et al. [19] reported that a program somewhat like ours, which generally terminated payment to nonradiologists for the professional component of imaging services but left nonradiologists free to collect payment for the technical component, resulted in a 41% increase in the number of imaging claims payable and a 12% increase in imaging costs in localities in which the insurer instituting the program had a relatively large market share. In contrast, in areas in which the insurer had a small market share, no dramatic changes were seen. It seems possible that if payments from the insurer were a major source of revenues for physicians, physicians noted the new policy and were manipulating the system to maintain their incomes. Kangarloo [20] reported on the effect of a program somewhat like ours that was introduced into the employee health benefit coverage of a large Florida firm that had been experiencing 25% annual increases in total costs for diagnostic imaging. In the first year of the program, the number of radiographs per 1000 covered persons was 419, a 9% decline from the previous year's level. This seems roughly similar to our finding of a 20–25% decrease from the health plan's previous trend, given that there had been a rapid increase in total imaging costs. However, because Kangarloo did not quantify the previous trend in the number of radiographs, only a rough comparison is possible. Obviously, more data than those of the three previous studies plus our study are required to make generalized conclusions about nonradiologists' responses to changes in financial incentives for imaging.

The widely reported finding that self-referrers do more imaging than radiologist referrers casts doubt on the necessity and appropriateness of the large number of radiographs self-referrers obtain. Our finding that many of these radiographs are not obtained, rather than shift to radiologists, when financial incentives change is further evidence of their questionable necessity. To be fair, however, we should note that advocates of in-office self-referral argue that the inconvenience of sending patients outside the office for imaging and then waiting for results causes physicians to omit imaging examinations that would be useful for patient treatment.

However, we could not find any quality-of-care parameters required by accrediting agencies or monitored by the health plan that were altered by our program. There seems to be no measured adverse health effect when self-referral is terminated. The quality parameters monitored may not be particularly sensitive to minor changes in population health, but opponents to programs like ours tend to predict that these programs will produce widespread and severe deterioration in the quality of care. Even somewhat insensitive indicators should detect such changes.

The most dramatic effect of our program was the decline in the number of radiographs obtained by nonradiologists: it fell from 39% of the total before the program was instituted to 15% after it began.

The resulting shift of examinations to a radiologist's office means that more examinations are now performed using modern equipment with low-dose screens, resulting in a reduction in dose per examination and an overall decrease in radiation exposure for the patient. Quality, too, was enhanced; as noted, we found many quality deficiencies in nonradiologists' offices. Although some deficiencies, such as formal reports for each examination, may not have a direct impact on patient care, deficiencies such as failure to have equipment inspected, increased dose per examination, or failure to correct a deficiency that had been identified by a physicist are clinically serious. The lack of adequate labeling of a radiograph could also have serious and tragic consequences.

In addition, we believe our inspection program resulted in improvement in the performance of the imaging that still occurred in a nonradiologist's facility. The program set standards for equipment located in a clinician's office and also ensured that a technologist obtained the radiograph. Quality assurance programs were initiated and deficiencies were corrected. Many offices, faced with increased surveillance and costs, decided to abandon performing radiology examinations. We know that 132 offices have stopped billing the plan for imaging procedures; whether they continue to obtain radiographs and bill other carriers or have ceased imaging is something we do not know.

Like all research, our study has limitations. Data on 1993–1997 trends in the utilization of imaging among health plans not affected by our program would have been useful to show that the trends that were seen in 1993–1995 continued, as we have assumed. The long-term effects of our program can be shown only by data from 1998 and subsequent years, which are not yet available. Quite possibly, utilization may start rising again; historically, the use of health services has grown over time. However, if utilization does start rising, it will start from a level 20–25% below that had we not intervened. Also, effects of our program on other imaging techniques, such as sonography (for which we required accreditation), are presumably important, and there may be spillover effects between radiography and other imaging techniques. As far as we could determine, there was no significant out-of-network utilization of radiology services during the study. Because the health plan is a restrictive health maintenance organization, with a specific panel of providers, there is a small possibility that an occasional patient may have been referred to imaging facilities not associated with the health plan. These studies would not have been paid for by the health maintenance organization, a significant disincentive for this to occur.

In conclusion, our study shows that a program that limits imaging studies to appropriate physicians can decrease cost and improve quality. We reduced the number of radiographic examinations performed by 20–25% from the preceding trend without significantly interfering with the health care of subscribers. Before our study, approximately 40% of radiographs were obtained by nonradiologists; this decreased to 15%, representing a dramatic reduction. One can infer that many of the procedures previously performed in nonradiologists' offices were not necessary. Issues of radiography equipment maintenance, patient safety, and reporting were addressed by inspecting offices that performed imaging. Seventy-eight percent of the nonradiologists' offices had significant deficiencies that we required to be subsequently corrected. Our program decreased cost and radiation burden.

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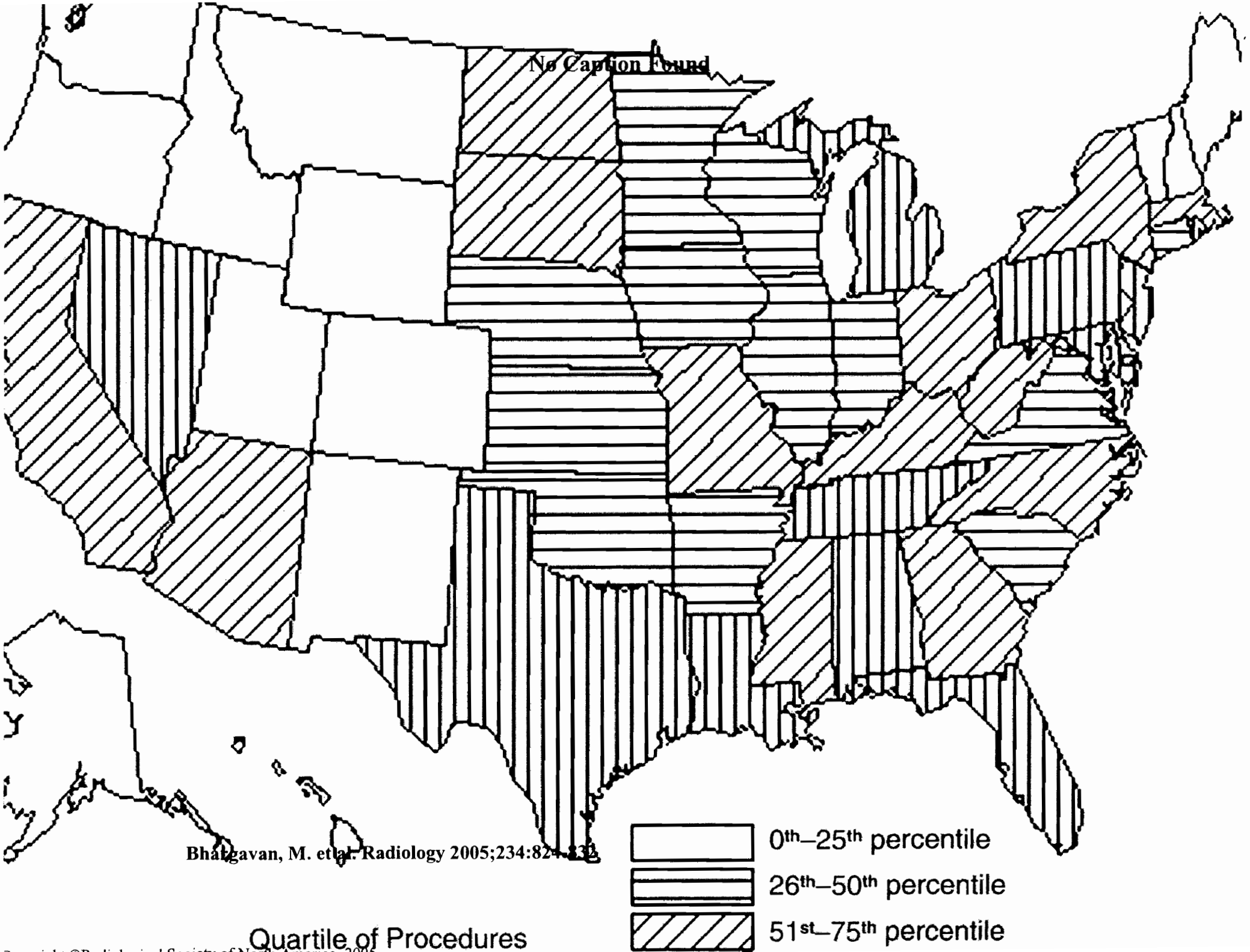

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March 15, 2005

Anthem.

Statement
Of
Anthem Blue Cross and Blue Shield
On
SB1298 An Act Concerning Health Insurance Coverage For Outpatient Imaging Services

Good morning Senator Crisco, Representative O'Connor and members of the Insurance Committee, my name is Christine Cappiello and I am the Director of Government Relations for Anthem Blue Cross and Blue Shield in Connecticut. I am here today to speak against **SB 1298 An Act Concerning Health Insurance Coverage For Outpatient Imaging Services.**

Anthem Blue Cross and Blue Shield oppose **SB 1298** because this legislation is unnecessary and potentially harmful to our members and your constituents. Since 2001, Anthem BCBS has seen a dramatic increase of 15% a year in the utilization around "Advanced Imaging", which are Computerized Tomography (CTScans), MRIs, Positron Emission Tomography (PETScans) and Nuclear Cardiology (Echo Cardiograms). In fact, "Advanced Imaging" costs us 58% of the total costs for imaging services in CT, but is less than 1% of all imaging in CT.

When we saw this trend, we became very alarmed. We were alarmed because we were fearful that this increase meant that our members are being given these imaging services needlessly and excessively. After researching this reason upward spike, we have attributed to specific reasons. The first reason that we discovered attributed to this spike is a result of physicians practicing defensive medicine. In today's world of medical malpractice, physicians are beginning to order unnecessary tests, for instance MRIs when X-rays would be sufficient, because they are concerned that they will be found negligent in the event that their patient files a claim of medial malpractice. Nationally, studies show that on average, that 4.8% of all the members of a health plan have had a one or more CT scans. That is an astounding number.

The second reason is one of supply and demand. General Electric, the largest supplier of MRI machines, expected all of the growth in MRI sales between 2001 and 2005 to occur out side the hospital. We have seen an increase in physicians who did previously have these machines in their office, now having them. Physicians are buying CTscans, PETscans and MRIs machines and driving their patients to these units. It is important to remember in CT, any licensed physician can have any of these machines in their offices and administer the tests, not just radiologists.

That supply and demand has also occurred on the hospital side. In CT, 60% or more of our hospitals have MRIs and 70% to 79% have CT scans. The bottom line is that hospitals need to

have people in those machines to cover the cost of having and maintaining those machines. And it has been our experience that it is not always done with the patient's medical need in mind.

For all these reasons, we believed it was important to put some clinical measures, like prior authorization, in place to fulfill our obligation to the member and the purchaser of health care. We believe it is essential to ensure access to diagnostic imaging when it is clinically indicated. At the same time, consumers need to understand that the newest, most expensive technology is not always necessary and in many cases will not improve the quality or results of their care. Further, we believe that physicians need to reaffirm their commitment to evidence-based medicine and evaluate whether an additional diagnostic test will change their treatment plans before ordering the test. Finally, hospitals and other providers should refrain from engaging in a "medical arms race," where every facility wants to have every technology even if doing so will create substantial excess capacity.

Anthem Blue Cross and Blue Shield also believes it is important that we leverage information on how and where costs and utilization are rising and share it in partnership with providers to ensure access to services while reducing unnecessary utilization.

Prior authorization on these services is an essential tool in ensuring that all these things occur. Therefore, Anthem Blue Cross and Blue Shield ***respectfully oppose*** this legislation and I would be happy to answer any questions that you might have.

I am also attaching a report from the Medicare Payment Advisory Commission's report to Congress which cites the increase new technology, including imaging services.

Quality is Our Bottom Line

The Connecticut Association of Health Plans
Testimony Before The
Insurance and Real Estate Committee
March 15, 2005

Regarding

SB 1298, AAC Health Insurance Coverage for Outpatient Imaging Services

The Connecticut Association of Health Plans strongly urges rejection of SB 1298, because it is, in all honesty, grossly out of touch with the current realities of health care economics. Outpatient imaging is one of the two fastest growing areas of medical expense for many health plans, due in large measure to the enormous investments made by institutions and physician entrepreneurs in imaging equipment. We have excellent data which show that there is a direct correlation between the availability of particular imaging techniques and their utilization – in other words, the high-tech imaging techniques listed in this bill, are consistently ordered when they're available, regardless of whether there is a less expensive imaging option available.

Unfortunately, in imaging, utilization follows the capital investment rather than medical necessity, and prohibiting requirements that members request approval for these services eliminates the only real tool that exists to manage imaging costs.

Please reject SB 1298. It would be very, very costly for members.

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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 Boulevard
Baltimore, MD 21244-1850

Ladies and Gentlemen,

I represent a group of seven urologists practicing in Lincoln, Nebraska and am writing to express our concerns regarding some CMS proposed changes evidenced on the 2008 Physician Professional Fee Schedule. We practice in a urological under served area of the state and striving to cover the needs of this population requires us to travel to 18 different communities in southeastern Nebraska. It is our goal to provide cost effective and up to date services for our patients. One area where we do this is through the lithotripsy services we provide and also one of the proposed changes that would directly impact us.

Per Click Fee Arrangements

Our primary concern at this time is the elimination of the Per Click Fee arrangement. We did research prior to purchasing the lithotripters housed in two Lincoln hospitals and determined a fair market value Per Click Fee arrangement. It is one agreed on by both hospitals to be fair. The hospitals will bill Medicare a facility charge for the procedure and will reimburse us a set amount each time the machine is used. They don't lose money and neither does the practice. How much more fair can you get? This arrangement distributes the risk so one party does not assume the entire risk. It would be impossible to determine a monthly lease rate that would be more equitable, as the number of patients with kidney stones varies greatly from month to month. Our original lithotripter was purchased for $395,000 and it does not make economic sense to provide service and potentially lose money. Therefore, we would insist on a fee arrangement preventing this scenario. In a month where the case numbers were limited, this could result in the hospital losing money. As long as the fair market value component is satisfied, why would CMS impose impossible restrictions? If arrangements exist violating the fair market value component, then target those physicians and facilities, without restricting those operating within the current provisions. As we have a unique lithotripter in each facility, the type of kidney stone and the availability of OR time at the facility, not any financial arrangement with the hospital, determines to which facility the patient presents.

Under Arrangements

The substance of the CMS proposal is to ban legitimate physician joint ventures from contracting with hospitals to provide therapeutic services that are designated health services, DHS, *only* because they are performed in a hospital setting. These therapeutic services include a variety of laser procedures for benign prostate disease and cryotherapy for cancer of the prostate. This technology is expensive and many hospitals, especially rural hospitals, many not have the resources or the volume of patients to justify purchases of this nature. By banning physician joint ventures from contracting with these hospitals, you are essentially denying patients access to this technology or requiring more out of pocket expense to travel to the nearest facility offering this technology.

Burden of Proof

CMS proposes, in any action involving Stark regulations it is the provider that would have to prove that referrals were not made in violation of Stark. Furthermore, Stark penalties extend to anyone who "causes a claim to be submitted in violation of the regulations." That could be interpreted to mean than any party to a contract that CMS believes is in violation could be subject to huge fines. Most Stark exceptions require payment 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 parties. How are providers and physicians going to prove the negative - that compensation does not reflect the volume or value of referral of other business generate between parties? Moreover, valuation experts often disagree on what is fair market value. Not only do we now take care of the health problems of the Medicare beneficiary at prices set arbitrarily by CMS, we now face the undeclared burden of a hidden tax in which we must prove our actions were legal, rather that the governmental agency which writes the law proving that our actions were illegal. What happened to the "innocent until proven guilty" principal?

In conclusion, we would ask 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 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.

Sincerely,

Christopher E. Larson, M.D.
President - Urology, P.C.

CEL/sls

ADULT PEDIATRIC UROLOGY

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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,

Stephanie Bolt MD

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August 30, 2007

Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-1385-P
Mail Stop C-4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: File Code CMS-1385-P
Comments on Proposed Changes to
Physician Self-Referral Regulations

To the Centers for Medicare & Medicaid Services:

We are writing to provide our comments on the proposed changes to the Stark Law contained in the proposed physician fee schedule regulations issued in July that would appear to prohibit the use of Under Arrangement agreements between hospital and physician practices.

We concur with CMS that abuses of the current system should not be tolerated. Our concern is that in its efforts to address these issues, CMS may in effect be throwing the baby out with the bath water.

Our national healthcare system faces unprecedented challenges with the escalating cost of care. Given the rate of advancement of new medical technology and the aging of our population, which brings with it an increasing demand for service, the best we can possibly hope for is to reduce the rate of annual increases in the cost of care to a "reasonable" level, however defined. Importantly, in order to be effective in moderating the future cost of care, while not unduly restricting access, the approach used must be based upon a legitimate economic model, and not through an artificially imposed regulatory mandate.

Research and experience in the private sector has demonstrated that the ability to reduce and effectively manage healthcare costs is maximized when the economic incentives are aligned between hospitals and physicians. Indeed, CMS itself is sponsoring demonstration projects that attempt to demonstrate this approach. It appears incongruous that CMS, on the one hand, appears to support this approach, and on the other hand, appears ready to prohibit economic models that use this approach.

It is unclear from the language used in the proposed changes to what extent Under Arrangement agreements would be affected. CMS' statement that "there appears to be no legitimate reason" for certain hospital / physician imaging joint ventures other than to allow referring physicians an opportunity to make money on referrals is a broad and ambiguous statement. It would be helpful for CMS to explain the specific types of arrangements and ventures that it has concerns with. Only through this level of specificity can providers know how to pursue collaborative cost reduction without running afoul of the law. Otherwise, by suggesting that any kind of joint venture might be suspect, providers will be reluctant to explore legitimate arrangements, and opportunities for successful integration will be lost.

Additionally, we would contend that there are legitimate reasons to pursue Under Arrangement agreements. Given the new focus on transparency, and recognizing that physicians are the core drivers of hospital outcomes, it is apparent that hospital and physician collaboration is an integral element to achieving and sustaining high quality care. In this same vein, hospital costs are largely driven by physician practice style. In order to achieve and sustain effective cost reduction and management, hospitals and physicians must collaborate in an integral manner.

Collaboration of this type and magnitude almost inevitably requires that physicians modify and standardize their clinical practice, and frequently requires that practices pursue infrastructure development that most practices are ill equipped to pursue, often times due to a lack of capital.

Allowing physician-hospital joint ventures to provide services under arrangement to hospitals will provide incentives for hospitals and physicians to collaborate to pursue high-end quality improvements and cost reductions, which benefit everyone.

Located in Wausau, Wisconsin, the Aspirus Heart & Vascular Institute, part of Aspirus Wausau Hospital, represents a cardiovascular program that has received repeated national recognitions for its quality outcomes, and boasts one of the lowest average charge per discharge rates for open heart surgery and percutaneous coronary interventions in the state of Wisconsin. These accomplishments have been achieved through collaboration between the hospital and physicians.

Despite these accomplishments, the hospital, in conjunction with its physician strategic partners, who represent independent cardiology and CV surgery practices, are committed to finding additional ways to further improve and sustain both quality and cost levels. The Under Arrangement model is a viable and effective model to align economic incentives between the hospital and physicians to continue to pursue quality and cost improvements.

It is our firm belief that the requirements of the "indirect compensation arrangements exception," found at §411.357(p), as amended in the so-called Phase III regulations that were released earlier this week, along with the anti-kickback statute and its safe harbor restrictions, already adequately protects against program abuse. Amending the definition of the term "entity" to include entities providing services under arrangements, as was proposed in the Physician Fee Schedule regulations proposed in July, is unnecessary, and will only

serve to prevent hospitals and physicians from achieving cost effective high quality care through innovative collaboration efforts. We therefore urge CMS to re-consider this proposal.

Thank you for this opportunity to provide comments on the proposed changes to the Stark law, and urge CMS to consider all aspects of the proposed changes.

Sincerely,

Rick L. Nevers
V.P. Cardiovascular Services

rek

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August 30, 2007

VIA FEDERAL EXPRESS
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Re: CMS-1385-P
Comments on Section II.I. - IDTF Issues

To Whom It May Concern:

Radiology Associates of Wausau, S.C. ("RAWSC") has been providing professional radiology services to Wausau, Wisconsin and surrounding communities for over thirty years. As is the case with many radiology groups, our practice has evolved over time from a primarily hospital-based practice to a multi-dimensional practice that provides radiology services not only to Aspirus Wausau Hospital (the "Hospital") but also for an independent diagnostic testing facility ("IDTF") owned by the hospital and an interventional radiology clinic operated by our group. RAWSC continually strives to ensure that the Wausau community has access to high-quality radiology services that are provided in a timely, efficient and cost-effective manner. Unfortunately, we are concerned that if CMS adopts the proposed revisions to the IDTF performance standards, RAWSC's efforts to provide efficient and timely services will be substantially impacted which, in turn, will negatively impact the IDTF, the Hospital and, most importantly, Medicare patients who receive services from all of these various entities.

For the reasons set forth below, we respectfully request that CMS consider abandoning the proposal to add a new performance standard at 410.33(g)(15) which would prohibit the IDTF from sharing space, equipment or staff or subleasing its operations to another individual or organization. As we understand it, CMS's intent for proposing this standard is to curb the use of questionable "lease" arrangements that have been proliferating between IDTFs and referring physicians. While we understand the laudable end CMS is trying to achieve, we believe the means of getting there may crush many other legitimate, if not necessary, arrangements in the process such as the one currently in place between RAWSC, the Hospital and the Hospital's IDTF.

RAWSC has been providing radiology services to the Hospital for many years. The Hospital then developed an IDTF for which RAWSC is the contracted provider of both the required physician supervision services as well as performing professional interpretation services for the IDTF. Pursuant to contract with the IDTF, RAWSC maintains one or more radiologists on-site at the IDTF in order to ensure the appropriate level of physician supervision is provided during the performance of procedures requiring direct supervision. Since only a portion of the services performed on any given day require direct supervision, the radiologists typically have time available to perform interpretation services both for studies performed at the IDTF as well as studies performed at the Hospital. In order to perform reading services for Hospital patients, RAWSC has leased office space from the building's owners that is within the IDTF suite and turned that office space into a radiology reading room. As a result, RAWSC is not only able to make efficient use of its radiologists' time but also to provide the Hospital and its patients with timely interpretation services.

In addition to leasing space for a reading room, RAWSC also leases an office in which one of the interventional radiology members of RAWSC performs spine and cervical injection procedures on patients using equipment owned by RAWSC. As there is only one front door to the IDTF suite, RAWSC's patients who report to RAWSC's office for interventional procedures use the same waiting room, changing rooms and bathrooms as the IDTF's patients. This arrangement is efficient, cost-effective and beneficial for the IDTF, the Hospital, RAWSC and patients because: 1) the location of the Spine Center in the IDTF is much easier for patients with limited mobility to access than if it was located within the Hospital campus; 2) the radiologist is on-site and able to provide direct supervision services for the IDTF when he/she is not performing interventional procedures; 3) the radiologist is able to perform reading services for the Hospital when he/she is not performing interventional procedures; and 4) this arrangement enables RAWSC to provide a wide range of services with a relatively small number of radiologists. As CMS is no doubt aware, the nationwide demand for radiology services currently exceeds the available supply and, as a result, it has become increasingly difficult for radiology groups to recruit new physicians and satisfy patient needs for their services.

If CMS were to adopt a prohibition on sharing office space, equipment and/or staff with an IDTF, RAWSC (and many other radiology groups around the country who provide supervision services to IDTFs and also perform reading services for hospitals while on-site at an IDTF) would be forced to relocate both its reading room and its Spine Center to another, unconnected office which would entirely eliminate the many efficiencies of the current arrangement from which patients benefit. Most importantly, RAWSC would be unable to utilize any of the radiologists on-site at the IDTF to perform reading services for Hospital patients or interventional procedures. As a result, RAWSC will either need to recruit additional radiologists to provide the on-site supervision services or RAWSC's radiologists (who are already more than busy enough) will need to take on additional supervision and reading responsibilities in order to ensure that both the IDTF and the Hospital continue to receive timely interpretation services. Therefore, on behalf of RAWSC, our patients and many other similarly situated radiology practices, we request that CMS

not adopt its proposal to prohibit an IDTF from sharing space, equipment and/or staff with any and all other individuals or entities.

In the event that CMS, nevertheless, adopts a sharing prohibition, we request that CMS clarify the extent to which an IDTF would be prohibited from sharing "staff." The preamble discussion on page 38171 of the Federal Register, states that the 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. Therefore, we are confused as to the statement that sharing of staff would extend to "supervising physicians." We request that, if CMS adopts a prohibition on sharing staff, the prohibition be limited to sharing of non-physician personnel.

Finally, although we implore CMS to consider abandoning a prohibition on IDTF sharing of space, equipment, and/or staff for the reasons set forth above, if CMS adopts such a provision we request that the implementation date be delayed for a least twelve months in order to provide IDTFs and physician practices with sufficient time to find new office space, recruit additional staff, notify their patients and generally restructure their existing relationships.

I appreciate this opportunity to comment on this significant proposed change to the IDTF performance standards. I can be reached by phone or email if a CMS staff member has any questions or wishes to discuss the above comments further.

Sincerely,

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August 29, 2007

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Attention: CMS-1385-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-1385-P.

Dear Sirs:

On behalf of the ten partners that practice at Southern Orthopaedic Surgeons, I appreciate the opportunity to address some of the proposed rule changes and Stark provisions to the calendar year 2008 physician fee schedule. While CMS does not make specific proposals with regard to some of these self-referral provisions, we would like to submit some comments and clarifications for your review.

The physical and ethical integrity of the Medicare program is a goal that is shared by all of those who have participated in it. We fully agree with CMS' decision to focus on the billing of diagnostic tests of one physician or group where the diagnostic test is performed by someone other than the full-time employee. Your approach to paying the less of the Medicare fee schedule amount, actual charges, or the charges of the physician performing the test is very reasonable. We would ask that you please keep in mind the administrative burden that is placed on a physician group in billing these services.

We would also ask that you please give careful consideration to proposed changes in the in-office ancillary exception practices. We feel that this service has provided exceptional care to our many patients, both through convenience and quality of care standpoint.

We strongly challenge some of the characterizations articulated in this section of the proposed rule. There are many advantages to physician owned physical and occupational therapy. There is a much closer working relationship between the doctor and the therapist when there is in-house services being provided. The patients feel very good about this arrangement from a quality of care standpoint. They know that their physician is actively involved in their therapy services.

We ask that CMS please keep in mind the underlying, financial motive that many of your free-standing centers have in promoting elimination of in-office ancillary services by physician practices. We totally support the appropriate use of Medicare resources in the area of physical therapy, but think that a categorical band on all physician owned physical therapy and occupational therapy would not be in the best interest of your patient population.

We appreciate your consideration of these issues, and would be more than happy to provide additional commentary if deemed necessary.

Sincerely,

Trice Nichols
Practice Administrator
Southern Orthopaedic Surgeons

602

Department of Anesthesiology

Robert M. Constantine, M.D.

St. Joseph's Hospital Health Center
301 Prospect Avenue
Syracuse, New York 13203
(315) 425-7721
(315) 448-5440

28 Aug 2007

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

RE: Relative Value Update and Anesthesia Conversion factor CMS - 1385-P

CMS Administrators:

The Specialty Society Relative Value Committee is recommending an increase in the Anesthesia Conversion factor of up to 32% to adjust for undervalued reimbursement for Medicare patient services. I strongly suggest CMS accept this recommendation in order to continue to provide quality care to your Medicare patients.

Medicare expenses are mushrooming as are medical expenses for all sectors of our population. Why should Medicare pay out more for Anesthesia services?

The specialty of Anesthesiology has been responsible for some of the most important improvements in patient safety and has significantly reduced risk of patient harm or death in the peri-operative period over the past several years, however, this accomplishment has never been significantly recognized in Medicare reimbursements.

Many improvements in anesthetics have significantly improved the efficiency of patient care such that many surgical procedures can be done as an outpatient procedure or as a markedly reduced hospital stay saving Medicare many billions of dollars.

The current reimbursement rate is insufficient to support the current market income of any anesthesia provider and is likely to reach the point soon to limiting access to anesthesia services are many of our Medicare patients. We should take a lesson from Primary Care Medicine. I previously practiced Primary Care Medicine, but, years ago I left Primary Care due to the low reimbursement rates. We should not allow this to happen in the specialty of Anesthesiology!

Remember, must of us are likely to be under the coverage of Medicare Services at some point in our lives. Lets preserve safety and access to care for Anesthesia Services when we are in need of them.

Sincerely,

Robert Constantine, MD

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WEST TENNESSEE
BONE
JOINT
Sports Medicine • Orthopedic Excellence

LOWELL F. STONECIPHER, M.D.
R. MICHAEL COBB, M.D.
L. DAVID JOHNSON, M.D.
KELLY D. PUCEK, M.D.
HAROLD M. ANTWINE, III, M.D.
JOHN E. EVERETT, M.D.
DAVID A. PEARCE, M.D.
JASON T. HUTCHISON, M.D.

DONNA W. KLUTTS
Practice Administrator

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–1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Physician Self-Referral Issue

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 with 20 years of direct patient care experience and a member of the American Physical Therapy Association. I worked 15 years with a non-for-profit hospital system. I have worked with a PT management company in an orthopedic physicians group for the last 5 years.

In the 5 years I have been with this orthopedic group, I have not experienced any of the "fraudulent and abusive environments" that my professional organization touts. I wonder if the "hundreds" of letters from concerned therapists received by CMS that warned of this work arrangement are employed in physicians clinics or for large outside rehab corporations that stand to financially benefit from the removal of the "in office ancillary service exception."

Physical therapy in the physician's office is an extremely convenient option for patients. Direct physician supervision is not required in therapy but I have found that patients take great comfort in being close to their referring M.D. They realize that any problems, small or life threatening, can be immediately addressed by the medical staff. Our patients are given an option on where they wish to receive their therapy. Patients are not mandated to receive rehab at our facility; in fact over half of therapy referrals go out of this clinic.

As a practicing therapist, I would certainly appreciate your office closely reviewing this perceived problem before making any decisions. I appreciate your time and attention to this matter.

Sincerely,

Tom Johnson
P.T. Director
W. TN Bone and Joint Clinic

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SOMERTON PHYSICAL THERAPY AND REHABILITATION
MARK J. ROSEN, P.T., P.C.

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12000 Bustleton Avenue
Philadelphia, PA 19116
215-677-8870
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Mark J. Rosen, P.T.
Larry Bruno, M.P.T.

August 27, 2007

Mr. Kerry 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, Maryland 21244-8018

SUBJECT – MEDICARE PROGRAM: Proposed Revisions to Payment Policies Under the Physician Fee Schedule and Other Part Payment Policies for CY 2008: Proposed Rule

PHYSICIAN SELF-REFERRAL ISSUES

Dear Mr. Weems:

The purpose of this letter is to provide input and personal experiences relative to the issues surrounding physicians' self-referral and the "in-office ancillary services" exception. I hope the following comments will further highlight the abusive nature of physician-owned physical therapy services, and demonstrate the support needed for physical therapy services' removal from permitted services under the in-office ancillary exception.

As a background, I have been in private practice as a licensed physical therapist in Philadelphia, Pennsylvania for the past 33 years. I am a member of the American Physical Therapy Association and have been an independent practitioner during this time period. Over these many years, I have developed relationships with a variety of medical providers, who have trusted in me the rehabilitative care of many of their patients. Obviously, in a free enterprise system, patients had the opportunity to seek services in a variety of settings, including: private practices, hospitals and rehabilitation centers. With the present "loop hole," physicians presently influence their patients to stay at their own facility to benefit themselves economically, often at the cost of potential outcomes.

After listening to a large majority of my referring physicians' complaints about reimbursement issues causing difficulty in economic survival of their practice, many have said they have no alternative but to include physical therapy services within their practice as an opportunity to enhance their income. As you can imagine, this has caused an ongoing hardship for practitioners like me and others in similar circumstances. We have dedicated our professional lives and built reputations to enhance the well-being of people in our demographic regions. Indeed, it is more than ironic that we find ourselves in direct

August 27, 2007

competition with the aforementioned referring physicians – who previously entrusted **our** care - now keeping those patients within their own practices for economic gain. There is certainly a conflict of interests and professionalism with this situation.

My own personal experience has identified many offices with inadequate staffing and treatment options that could not compare to those provided in most independent private practitioner facilities. Most physician-owned facilities target new graduate physical therapists that are willing to work for just slightly above "normal" entry level payment; thereby allowing the physicians to reap large profits for services they, themselves, do not personally provide. Obviously, there is incentivisation to continue treating these patients as long as possible, with the referring physician reaping the economic benefits. Physicians have often felt insulated with these arrangements; as the physical therapists are responsible for the patients' care, as well as signing the charts…yet often aides and assistants provide the majority of services.

I certainly hope that CMS will take the appropriate steps to close this "loop hole," which in my opinion will not just improve the quality of care for Medicare and Medicaid patient populations, but also will reduce spending with the elimination of self-referral.

Sincerely,

Mark J. Rosen, P.T.
MJR/cr

Ralph E. Hopkins, M.D., F.A.C.S.

Diplomate American Board of Urology

August 28, 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 a urologist, in solo practice, in West Central Wyoming and I have been in solo practice for almost 30 years. I have been trying to get a partner for a least fifteen to twenty years and I have been unable to do so. I offer state of the art urology service to patients within a 150-250 radius. Many of my patients live in a Health Professional Shortage Area (HPSA)

A few years ago Lithotripsy was offered to urologists of Wyoming on a mobile service basis, I was ecstatic because the patients were having to travel four and half hours to Billings, five and half hours to Salt Lake City, or six and half hours to Denver, to get treatment. The Wyoming urologists entered into joint venture partnership with Sun Medical, which is now Healthtronics Medical, and the benefits have been numerous for patients. Under the present partnership the patient's have been able to stay close to home and not be out the enormous expense of traveling to a larger city, having to stay in hotels. This is not to mention the gas and food expense. They have had the quality and state of the art medical care here that they could get at any of the big cities.

The physician partnership provides patients access to the latest technology in a rural setting. The hospital couldn't even afford the rent or lease on laser equipment which I wanted last fall on a full time status. The arrangement for payment is left up to Healthtronics and I have no idea what those arrangements are. This mobile Lithotripsy has also provided lower hospital costs by sharing the expensive equipment among the hospitals in the entire state

All I do is practice what I consider state of the art medicine. This can be backed up by going to my web site which is www.jacksonholeseminars.com.

705 E. Washington Ave. • Riverton, Wyoming 82501 • Email: jhurology@wyoming.com
Tel. (307) 856-5758 • 1-877-859-5758 • Fax (307) 856-5759

I would also like to ask the CMS to clarify the American Lithotripsy Society versus Thompson case. Our partnership cannot be deemed to form a DHS or causing a claim to be submitted for a DHS at the present time. There is no way that this physician partially owned lithotripter could really result in over utilization of higher cost of the Medicare program because we are basically treating stones and BPH. All of these have to be confirmed and they are confirmed by both Prostatic Ultra Sound and CT of the kidneys. If this were a diagnostic service I could see where that could be of concern.

I think over utilization of this is absolutely an excuse by the government to cause difficulty for patients to get care as it is not a diagnostic test as pointed out as above.

The Stark legislative history shows that congress clearly intended to only require compensation to the exception and not an ownership exception when their law was passed initially. The ability of the mobile lithotripter allows superior technology. As a matter of fact we are getting ready to try brand new lithotripter since ours is twelve years old.

The hospitals in my area could not possibly afford to purchase or rent a lithotripter, laser or microwave machine (for treatment of enlarged prostate) on my volume, but by spreading it out over eight to twelve hospitals in the state it makes a lot of sense. Congress clearly planned to preserve the Per Procedure fees in the Stark history and therefore I don't think CMS can out and out contradict congressional intent by prohibiting these arrangements. It makes sense the reimbursement rates may increase or decrease and hospitals are better off by the present arrangements than trying to rent or purchase one of these technology treatments.

I am not a member of an ambulatory surgical center so I will not comment to this, but it also appears that the present proposal will prohibit the ability of surgeons to belong to these. I think that would be very detrimental since these have been shown to reduce Medicare spending.

In summary I cannot stress strongly enough that this is a service provided to patients in my rural area. If I were not practicing here patients would have to travel a minimum of four to five hours for treatment and some of them are just not capable of doing this.

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. If you have any further questions please contact me at your earliest convenience.

Sincerely,

Ralph E Hopkins, M. D.

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LB. PHYSICAL THERAPY, INC.

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142 Badt Drive Coloma, MI 49038 Phone: (269) 468-7720 Fax: (269) 468-7703
333 N. 2nd Street Niles, MI 49120 Phone: (269) 687-9110 Fax: (269) 687-9120

[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: P. Luyckx, 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 30 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. Pierre Luyckx, DPT